PROGRAMME GRANTS FOR APPLIED RESEARCH

VOLUME 4 ISSUE 14 SEPTEMBER 2016
ISSN 2050-4322

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National Institute for Health Research

DOI 10.3310/pgfar04140

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Declared competing interests of authors: Martin R Underwood is a member of the National Institute for Health Research Journals Library Editorial Group.

Published September 2016
DOI: 10.3310/pgfar04140

This report should be referenced as follows:

Taylor SJC, Carnes D, Homer K, Pincus T, Kahan BC, Hounsome N, *et al*. Improving the self-management of chronic pain: COping with persistent Pain, Effectiveness Research in Self-management (COPERS). *Programme Grants Appl Res* 2016;**4**(14).

Programme Grants for Applied Research

ISSN 2050-4322 (Print)

ISSN 2050-4330 (Online)

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: nihredit@southampton.ac.uk

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This report

The research reported in this issue of the journal was funded by PGfAR as project number RP-PG-0707-10189. The contractual start date was in January 2009. The final report began editorial review in April 2014 and was accepted for publication in August 2015. As the funder, the PGfAR programme agreed the research questions and study designs in advance with the investigators. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The PGfAR editors and production house have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the final report document. However, they do not accept liability for damages or losses arising from material published in this report.

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Abstract

Improving the self-management of chronic pain: COping with persistent Pain, Effectiveness Research in Self-management (COPERS)

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Background: Chronic musculoskeletal pain is a common problem that is difficult to treat. Self-management support interventions may help people to manage this condition better; however, there is limited evidence showing that they improve clinical outcomes. Our overarching research question was 'Does a self-management support programme improve outcomes for people living with chronic musculoskeletal pain?'.

Aim: To develop, evaluate and test the clinical effectiveness and cost-effectiveness of a theoretically grounded self-management support intervention for people living with chronic musculoskeletal pain.

Methods: In phase 1 we carried out two systematic reviews to synthesise the evidence base for self-management course content and delivery styles likely to help those with chronic pain. We also considered the psychological theories that might underpin behaviour change and pain management principles. Informed by these data we developed the Coping with persistent Pain, Evaluation Research in Self-management (COPERS) intervention, a group intervention delivered over 3 days with a top-up session after 2 weeks. It was led by two trained facilitators: a health-care professional and a layperson with experience of chronic pain. To ensure that we measured the most appropriate outcomes we reviewed the literature on potential outcome domains and measures and consulted widely with patients, tutors and experts. In a feasibility study we demonstrated that we could deliver the COPERS intervention in English and, to increase the generalisability of our findings, also in Sylheti for the Bangladeshi community.
In phase 2 we ran a randomised controlled trial to test the clinical effectiveness and cost-effectiveness of adding the COPERS intervention to a best usual care package (usual care plus a relaxation CD and a pain toolkit leaflet). We recruited adults with chronic musculoskeletal pain largely from primary care and musculoskeletal physiotherapy services in two localities: east London and Coventry/Warwickshire.
We collected follow-up data at 12 weeks (self-efficacy only) and 6 and 12 months. Our primary outcome

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was pain-related disability (Chronic Pain Grade disability subscale) at 12 months. We also measured costs, health utility (European Quality of Life-5 Dimensions), anxiety, depression [Hospital Anxiety and Depression Scale (HADS)], coping, pain acceptance and social integration. Data on the use of NHS services by participants were extracted from NHS electronic records.

Results: We recruited 703 participants with a mean age of 60 years (range 19–94 years); 81% were white and 67% were female. Depression and anxiety symptoms were common, with mean HADS depression and anxiety scores of 7.4 [standard deviation (SD) 4.1] and 9.2 (SD 4.6), respectively. Intervention participants received 85% of the course content. At 12 months there was no difference between treatment groups in our primary outcome of pain-related disability [difference –1.0 intervention vs. control, 95% confidence interval (CI) –4.9 to 3.0]. However, self-efficacy, anxiety, depression, pain acceptance and social integration all improved more in the intervention group at 6 months. At 1 year these differences remained for depression (–0.7, 95% CI –1.2 to –0.2) and social integration (0.8, 95% CI, 0.4 to 1.2). The COPERS intervention had a high probability (87%) of being cost-effective compared with usual care at a threshold of £30,000 per quality-adjusted life-year.

Conclusions: Although the COPERS intervention did not affect our primary outcome of pain-related disability, it improved psychological well-being and is likely to be cost-effective according to current National Institute for Health and Care Excellence criteria. The COPERS intervention could be used as a substitute for less well-evidenced (and more expensive) pain self-management programmes. Effective interventions to improve hard outcomes in chronic pain patients, such as disability, are still needed.

Trial registration: Current Controlled Trials ISRCTN22714229.

Funding: The project was funded by the National Institute for Health Research Programme Grants for Applied Research programme and will be published in full in *Programme Grants for Applied Research*; Vol. 4, No. 14. See the NIHR Journals Library website for further project information.

Contents

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List of tables

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List of figures

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List of boxes

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List of abbreviations

A&E	accident and emergency
ASES	Arthritis Self-Efficacy Scale
BDI	Beck Depression Inventory
BNF	*British National Formulary*
CACE	complier average causal effect
CBT	cognitive–behavioural therapy
CDSES-33	Chronic Disease Self-Efficacy Scale-33
CES-D	Center for Epidemiologic Studies Depression
CI	confidence interval
CIRS	Chronic Illness Resources Survey
COPERS	Coping with persistent Pain, Effectiveness Research into Self-management
CPAQ	Chronic Pain Acceptance Questionnaire
CPG	Chronic Pain Grade
DDD	defined daily dose
DVD	digital versatile disk
EQ-5D	European Quality of Life-5 Dimensions
FABQ	Fear Avoidance Beliefs Questionnaire
GLM	generalised linear model
GP	general practitioner
HADS	Hospital Anxiety and Depression Scale
HCP	health-care professional
heiQ	Health Education Impact Questionnaire
HRG	Healthcare Resource Group
IAPT	Improving Access to Psychological Therapies
IASP	International Association for the Study of Pain
ICC	intracluster correlation coefficient
ICER	incremental cost-effectiveness ratio
IMMPACT	Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials
INB	incremental net benefit
IQR	interquartile range
ITT	intention to treat
MI	multiple imputation
MLM	multilevel model
MMICS	Multinational Musculoskeletal Inception Cohort Study
MRC	Medical Research Council
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NMB	net monetary benefit
NSAID	non-steroidal anti-inflammatory drug
OA	osteoarthritis
PCA	Prescription Cost Analysis
PCTU	Pragmatic Clinical Trials Unit
PHQ	Patient Health Questionnaire for Depression and Anxiety
PSEQ	Pain Self-Efficacy Questionnaire
QALY	quality-adjusted life-year
RCT	randomised controlled trial
SD	standard deviation
SF-36	Short Form questionnaire-36 items
SMD	standardised mean difference
SUR	seemingly unrelated regression
SUS	Secondary Uses Service
TSC	Trial Steering Committee
WHO	World Health Organization
WTP	willingness to pay

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Plain English summary

Many people live with long-term pain in joints and muscles (chronic musculoskeletal pain). Drug treatments may have problems or be ineffective and so other strategies, including supporting people to cope better with the different aspects of the problem ('self-management'), are appealing. In this research programme we sought to answer the question 'Does a self-management support programme improve outcomes for people living with long-term musculoskeletal pain?'.

First we needed to develop the best possible support programme. We started by looking at what is already known about best practice for such programmes, including how to make such programmes accessible. Based on this we developed the COPERS course, a group course spread over 3 days in 1 week with a follow-up session 2 weeks later. The groups were run jointly by a health professional and a person with experience of living with chronic pain. We tested the acceptability of the COPERS course by delivering it to both English- and Sylheti-speaking (Bangladeshi) groups.

We then tested adding the COPERS course to best usual care for people living with chronic musculoskeletal pain. We recruited 703 people from east London and Coventry/Warwickshire with an average age of 60 years. We found that the COPERS course did not improve how pain affected people's function, the outcome that we were most interested in. It did, however, provide a worthwhile reduction in depression in participants with symptoms of depression. This may be important as many people with long-term pain also have depression. The COPERS course also appeared to be cost-effective. Overall, the COPERS course is highly likely to represent good value for the NHS.

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Scientific summary

Introduction

Chronic pain (pain persisting beyond 3 months) is a common and increasing problem – one estimate suggests that 7.8 million people in the UK suffer moderate to severe pain lasting for > 6 months. Musculoskeletal disorders are costly to the UK, accounting for around 10% of the secondary health-care budget (around £5.16B in 2011) and resulting in around 21 million primary care consultations per year. In common with other health services worldwide, attempts to optimise patients' own management of their condition (so called 'self-management') have been one of the UK Department of Health's key responses to the increasing burden of long-term conditions among the population. However, despite better understanding of the causes of chronic musculoskeletal pain, the best way to promote self-management among those with chronic musculoskeletal pain is unclear.

Original aims and objectives of the programme

Our overall aim was to develop a method to improve the quality of life and clinical and social outcomes, and reduce the health-care resource use of people living with chronic, non-malignant pain, specifically via a self-management programme derived from a modified, condition-specific version of the Expert Patients Programme. Following an extensive examination of the research evidence we departed from basing the programme on the Expert Patients Programme to develop what we hoped might be a more effective intervention.

The objectives were to develop a new self-management programme and evaluate its clinical effectiveness and cost-effectiveness.

The report is divided into two parts: the first part describes the development work and the feasibility testing of the new intervention; the second part describes a large randomised controlled trial (RCT) including a cost-effectiveness study.

Part I: development

Identifying effective components and characteristics of self-management programmes for chronic musculoskeletal pain and who is likely to respond such programmes

We conducted a systematic review of RCTs of self-management courses for chronic musculoskeletal pain to identify the most successful course content and the optimal delivery characteristics. We searched 10 databases for RCTs comparing self-management with usual care or a waiting list control for papers published between January 1994 and April 2009, including MEDLINE, EMBASE, PsycINFO and The Cochrane Library. Outcomes of interest included global health, pain intensity, functional capability, quality of life, self-efficacy, anxiety, depression and social function. Interventions were categorised according to the presence of psychological, mind–body therapy, physical, lifestyle and educational components; group or individual delivery; tutor; setting; and duration. Data were extracted and meta-analysed (random-effects models) as standardised mean differences (SMDs) when possible. We compared subgroups of studies with and without particular features to explore their potential influence.

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We included 46 RCTs in the original review ($n = 8539$), covering a wide variety of chronic musculoskeletal conditions. In summary, the findings suggested that these interventions resulted in small beneficial effects across most outcomes in the short and medium term but that these positive effects were reduced in the longer term. Self-efficacy showed small improvements in the short, medium and longer term. There was most evidence to support group-delivered courses and health-care professional-delivered courses or mixed professional-/lay-delivered courses. Results were inconclusive for course setting and duration. Most interventions included a psychological component and there was little evidence in favour of those that did not. There appeared to be evidence in favour of interventions with a physical activity component, inconclusive positive evidence for educational and mind–body therapy components and no evidence that interventions that included a lifestyle component were superior to those that did not or that interventions with many different components were superior to those that had fewer components. These subgroup analyses involved multiple testing and so our findings should be viewed as exploratory and tentative. Using the same searches we reviewed the evidence for predictors, moderators and mediators of patient outcomes. We also conducted a meta-regression of the studies looking for evidence of moderators. We defined 'predictors' of treatment outcome as baseline variables that affect outcome but do not interact with treatment. 'Moderators' are variables measured at baseline that interact with treatment to change outcomes. 'Mediators' are variables measured during treatment that impact on outcome, with or without interaction with treatment. There was evidence that self-efficacy and depression at baseline predict outcome and evidence that pain catastrophising and physical activity can mediate outcome from self-management. There was no clear evidence on moderators.

Exploring experiences of self-management courses for chronic musculoskeletal pain

We conducted a qualitative study to understand how the different components and characteristics of self-management courses are perceived by people with chronic musculoskeletal pain, tutors and experts, with the aim of exploring the reasons why they might be associated with different outcomes and to inform the new intervention. We interviewed 16 previous self-management course participants, including four who had completed less than half a course, and conducted two focus groups, one with experts in self-management and the other with course tutors.

We observed differences between patients whose lives revolved around their pain and patients who had managed to achieve and sustain positive change in their lives. When asked what would be an important outcome from a self-management course, although patients always mentioned a reduction in their pain, other important outcomes related to personal confidence in their ability around functional, emotional and social activities. Barriers to course uptake were explored. Good facilitation and the social aspects of group courses appeared to be important for successful course delivery.

Selecting outcome measures for evaluating self-management programmes for patients with painful musculoskeletal conditions

We reviewed relevant consensus statements and the literature to develop a preferred list of patient-centred outcome measures for evaluating self-management programmes for patients with chronic painful musculoskeletal conditions. Outcome domains were informed by the findings of the first two projects (the systematic review and the qualitative project). We reviewed papers published between 2004 (i.e. subsequent to the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials consensus statement) and 2009 (when we conducted the work) that had reported or reviewed clinimetric data on outcome measures in three domains: pain and disability, depression and fear avoidance. For our two other domains of interest, self-efficacy and social support, we carried out a systematic literature search and reviewed the clinimetrics of the measures. The most validated and reliable measures were presented to a panel of eight people and consensus was sought on the most appropriate instruments. Data from our pilot study also informed our final choice of outcome measures for the main trial.

Development and feasibility testing of the new intervention

Based on evidence from our previous work we designed and manualised a psychologically orientated group course based on principles of cognitive–behavioural therapy with elements covering acceptance, education about chronic pain, distraction, relaxation, visualisation, posture, social time, encouragement to buddy up and an introduction to new hobbies and activities. We called the new course COPERS (Coping with persistent Pain, Effectiveness Research into Self-management) after our study. The COPERS course was underpinned by social learning theory and the theory of planned behaviour/reasoned action. Twenty-four individual course components (sessions) were delivered over 3 days with a single 2-hour follow-up session 2 weeks later. Teaching and learning modalities were varied and included a digital versatile disk featuring a medical expert addressing frequently asked questions, group discussion, role play and exercises. The course, for groups of up to 14 participants, was designed to be highly interactive and included experiential learning. Courses were facilitated by two trained facilitators – a lay individual with previous experience of facilitation of chronic pain and a health professional with experience of treating chronic pain (general practitioner, psychologist, physiotherapist, chiropractor or osteopath). We designed a 2-day training programme for potential facilitators.

To test the feasibility of the intervention and inform a future definitive trial we planned a pilot RCT of 100 participants randomised to the COPERS intervention or usual general practice care plus a patient advice leaflet on a 3 : 1 basis, favouring the active intervention. In addition, we planned a non-randomised arm in which we delivered a version of the course translated into Sylheti to a cohort of Bangladeshi patients not fluent in English. We used a mixed-methods approach with qualitative feedback from course participants, facilitators and observers, and quantitative information obtained from self-report questionnaires and activity data.

Systematically identifying eligible participants from general practice medical records proved difficult and spurred us to develop better search strategies for the main trial. Very uneven initial randomisation allocation led us to abandon the randomised design and offer everyone the intervention. A total of 167 (32%) of 526 potential participants expressed an interest in participating, 70 (42%) of whom were recruited to the English-speaking courses and 40 (24%) of whom were recruited to the Sylheti-speaking course. We ran nine COPERS courses, six in English and three in Sylheti. Forty-two people attended an English-speaking course and 26 attended a Sylheti-speaking course. Nine facilitators were trained and seven facilitated a course. A facilitator focus group was convened and 13 interviews were conducted with participants, which indicated that the COPERS course was regarded as beneficial by most participants. The influence of the group experience was important. Key recommended changes included:

- better facilitator training
- audio recording of each course to check quality and ‘treatment drift’
- shortening the outcome questionnaire
- adopting the pain-related disability subscale of the Chronic Pain Grade (CPG) as the primary outcome
- providing a more credible control
- conducting the trial in English only.

Part II: the main trial

Trial aims

To establish the clinical effectiveness and cost-effectiveness (expressed as the cost–utility) of the COPERS self-management intervention for patients with chronic musculoskeletal pain added to usual care plus a relaxation CD.

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Methods

We conducted a pragmatic, multicentre, individual patient RCT. Participants aged > 18 years with at least a 3-month history of musculoskeletal pain were recruited from primary care or physiotherapy services in east London and the Midlands. Patients were randomised to the intervention or the control (allocation ratio 1.33 : 1) using varied permuted blocks and strict allocation concealment.

We collected follow-up data at 12 weeks (self-efficacy only) and 6 and 12 months. Our primary outcome was pain-related disability (CPG subscale) at 12 months. We also measured NHS resource use and costs (Secondary Uses Service data and general practice records), health utility [European Quality of Life-5 Dimensions (EQ-5D)], anxiety and depression [Hospital Anxiety and Depression Scale (HADS)], pain acceptance (Chronic Pain Acceptance Questionnaire), social engagement and integration in populations exposed to self-management interventions (Health Education Impact Questionnaire social integration subscale), self-efficacy (Pain Self-Efficacy Questionnaire) and pain intensity (CPG subscale) and calculated defined daily doses (DDDs) of prescribed analgesics and weak and strong opioids.

To determine the fidelity with which the intervention was delivered we audio-recorded each COPERS course and two researchers systematically assessed facilitator adherence to the course content and competence in delivering the course material.

We sought to randomise 685 participants (391 intervention participants and 294 control participants) to detect a SMD of 0.3 in CPG disability between the intervention group and the control group, with 80% power at the 5% significance level. All main analyses followed intention-to-treat principles and accounted for clustering by course in the intervention arm. We used multiple imputation for missing, or incomplete, primary outcome data.

The EQ-5D scores were used to estimate the total quality-adjusted life-years (QALYs) for each participant over the 12 months of follow-up. Missing data for costs and QALYs were imputed. We calculated the incremental cost-effectiveness ratio (ICER) and examined the probability of the intervention being cost-effective.

Results

We identified 5878 potentially eligible primary care patients in our electronic searches. These patients were invited by post to participate and 531 (9%) joined the study. Including patients from secondary care we recruited 703 participants in total, with a mean age of 60 years. In total, 81% were white, 67% were female, 23% were in employment, 85% had pain for at least 3 years and 23% were on strong opioids. Symptoms of depression and anxiety were common, with baseline mean HADS scores of 7.4 [standard deviation (SD) 4.1] and 9.2 (SD 4.6), respectively.

We delivered 31 COPERS courses, 14 in London and 17 in the Midlands. Intervention integrity was assessed as high, particularly for adherence. Overall, 282 (70%) intervention participants achieved our predefined adherence criterion (≥ 17 sessions attended) and we considered 95 (24%) to be non-adherent (attending ≤ 8 sessions), including 67 (17%) who did not attend any sessions.

At 12 months there was no significant difference between treatment groups in CPG disability [difference –1.0 intervention vs. control, 95% confidence interval (CI) –4.9 to 3.0]. However, self-efficacy, anxiety, depression, pain acceptance and social integration were significantly better in the intervention group at 6 months. At 12 months' follow-up the differences favouring the intervention were sustained for depression (–0.7, 95% CI –1.2 to –0.2) and social integration (0.8, 95% CI 0.4 to 1.2), with the results for self-efficacy (1.4, 95% CI –0.2 to 3.1) and anxiety (–0.4, 95% CI –0.9 to 0.1) tending to favour the intervention.

Intervention patients received considerably more analgesics than control patients in the 12 months after randomisation (mean difference in DDD 98, 95% CI 17 to 178). There was no evidence of any difference in the prescription of strong opioids between study arms (mean difference in DDD –1, 95% CI –12 to 11) nor in the proportions of those receiving strong opioids at 12 months.

Post hoc moderator analysis showed that the improvement in depressive symptoms seen in the intervention arm at 12 months was concentrated in those who were depressed at baseline (SMD –0.50, 95% CI –0.74 to –0.25), with those who were not depressed at baseline experiencing no overall change in depression (*p*-value for interaction = 0.004).

The total cost of the course per participant across the two centres was £145.24, including the cost of facilitator training. Total costs were higher in the intervention group than in the control group (£2955 vs. £2767). The difference in mean costs was £188 (95% CI –£125 to £501). Total QALYs were higher in the intervention group (0.4475) than in the control group (0.4150). The difference in mean QALYs was 0.0325, which is equivalent to approximately 12 quality-adjusted days (95% CI –0.0074 to 0.0724). The ICER point estimate was £5786 per QALY. The COPERS intervention had a high probability (87%) of being cost-effective compared with usual care at the National Institute for Health and Care Excellence threshold of £30,000 per QALY.

All reported results proved robust in extensive sensitivity analyses and with different analytical approaches.

Conclusions

The COPERS intervention had marked psychological effects that were concentrated in those who were depressed at baseline, but did not appear to affect health-care resource use or disability. We are not in a position to say with certainty what the active elements of the intervention were but it seems likely that these were the psychologically orientated components and the effect of being in a group of peers. In the absence of more effective group self-management interventions, the COPERS intervention could be used as a substitute for less well-evidenced (and more expensive) pain self-management programmes. However, effective interventions to improve harder outcomes in chronic pain patients, such as disability, are still required.

Trial registration

This trial is registered as ISRCTN22714229.

Funding

Funding for this study was provided by the Programme Grants for Applied Research programme of the National Institute for Health Research.

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Chapter 1 Introduction

Background to the study

Chronic conditions, especially musculoskeletal conditions, impose an increasing burden on society and the NHS.[1] Despite increased understanding of the factors contributing to the development of chronic pain, the population burden of chronic pain is rising, with more cases now than 40 years ago.[2]

A key component of the UK Department of Health's response to the perceived growing burden of chronic disease[3] was to promote self-management[4] and the most tangible aspect of this was the introduction and promotion of its flagship, lay-led (i.e. peer-led), self-management training course, the Expert Patients Programme.[5] This decision was made based on a belief and some limited evidence, mainly from the USA, that such self-management programmes for long-term conditions improve health status, slow disease progression and reduce health-care use.[6] The Expert Patients Programme was rolled out and implemented within the NHS from 2005 onwards.[3] By 2007 the Department of Health had invested £18M in the programme.[7] In 2008 the then prime minister, Gordon Brown, announced further expansion of the programme.[8]

The Expert Patients Programme is a complex intervention. It is an anglicised version of the Stanford Chronic Disease Self-Management Program developed in the 1980s.[9] It is based on Bandura's social cognitive theory of behaviour,[10] which suggests that positive behaviour changes are more likely to occur if a person is confident of making the change and expects a good outcome. The Expert Patients Programme consists of a structured, 6-week course (2.5 hours per week) covering education, coping strategies such as relaxation, visualisation, positive thinking, action planning and goal-setting. It includes strategies to deal with anger, fear and frustration, and aims to promote better communication with health-care professionals (HCPs) and physical activity. The courses are led by trained and accredited laypeople who themselves have a chronic condition. The objectives of self-management programmes are to encourage participants to take responsibility for their own health, increase their knowledge about their health condition, identify positive or dysfunctional coping strategies, teach more effective management strategies, create networks for support and reduce isolation.[11] The UK Department of Health's aims were to increase quality of life, reduce the demand for consultations and drugs and avoid unnecessary investigatory tests, thus generating longer-term cost savings and increasing patient satisfaction.[5] Despite a reduced emphasis on the Expert Patients Programme in recent years, the concept of supporting better self-management among people with chronic conditions remains central to the UK Department of Health agenda.[12]

The optimal way to support people with chronic musculoskeletal pain to manage their condition is unclear. Systematic reviews report, at best, only modest benefits for lay-led self-management programmes compared with usual care for long-term musculoskeletal conditions such as low back pain and osteoarthritis (OA).[13,14] For OA self-management there is moderate-quality evidence (11 studies including 1706 participants) that indicates small benefits up to 21 months in terms of self-management skills, pain, OA symptoms and function, although the magnitudes of the effect sizes are of doubtful clinical importance.[13] The authors of this review found no improvement in positive and active engagement in life or quality of life. Similar findings were reported from lay-led self-management courses for low back pain.[14] Despite these modest effects there is still considerable popular support for these types of programmes. Some authorities argue that a small average benefit for many patients may still be worthwhile compared with a larger benefit for smaller numbers of patients with less common disorders.[15] Nevertheless, the Expert Patients Programme and other programmes of this nature need further research and validation. Squire and Hill[16] have argued that a clear policy based on good research and evidence is required to guide clinicians, service delivery organisations and researchers in the content and delivery of self-management programmes for chronic pain patients.

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A note on terminology

Although it is obvious that only the affected individual can 'self-manage' his or her condition, courses to promote better self-management are commonly referred to as 'self-management courses', whereas a more accurate term might be 'self-management *support* courses'. For brevity we have used the term 'self-management course' throughout this report but it should be understood that by this we really mean 'self-management support course'.

Chronic musculoskeletal pain

The focus of this research programme is on chronic, non-malignant musculoskeletal pain. The International Association for the Study of Pain (IASP) defines chronic pain as that which has persisted beyond normal tissue healing time, usually interpreted as 3 months.[17] Estimates of the prevalence of chronic pain vary, but one estimate is that 7.8 million people in the UK suffer moderate to severe pain that has lasted for > 6 months.[2]

Musculoskeletal health care is costly. In 2011 in the UK, NHS trusts (secondary care services) spent around 10% of their patient care expenditure on musculoskeletal disorders (around £5.16B), and in 2009/10 there were around 21 million primary care consultations for musculoskeletal conditions in the UK.[6,18] Musculoskeletal pain is more commonly reported by women and those from socially or financially disadvantaged groups.[19] Chronic pain can cause considerable disruption to people's lives. Around one-quarter of those who have chronic pain report severe disruption (> 2 weeks in the last 3 months) to their usual activities and chronic pain was associated with poorer mental health and well-being and lower levels of happiness and higher levels of anxiety and depression.

Psychology and chronic pain

The presence of chronic pain is strongly associated with adverse psychological factors.[20] European guidelines on the management and prevention of low back pain[21] include psychological criteria to identify those at risk of poor outcomes, known as 'psychosocial yellow flags'. These were developed to determine whether or not patients required more detailed assessment and to identify those for whom physical intervention could be less appropriate because of the dominance of psychological problems that would affect a successful outcome of the treatment. Psychological factors that consistently predict poor outcome include:

- beliefs that back pain is harmful and potentially disabling
- fear-avoidant behaviour and reduced activity levels
- low mood and reduced social interaction
- expectation that passive rather than active participation in treatment will help.

These factors can be identified during a consultation or with screening questionnaires.[22,23]

Treatment approaches for people living with chronic low back pain that address some of the psychological issues include cognitive–behavioural therapy (CBT) and reactivation and reassurance strategies.[24] These encourage new behaviours and activity to overcome and change the psychological constructs limiting recovery and activity. Self-management courses incorporate some of the same strategies but more work is needed to maximise and quantify the clinical effectiveness and cost-effectiveness of these programmes. Redirecting resources to develop appropriate psychological interventions, with potentially more sustained benefits and fewer side effects than drug treatment, may have long-term clinical and economic advantages.

The biomedical model as opposed to the biopsychosocial model might be of limited benefit, especially for patients with high levels of health anxiety.[25] Linton *et al.*[24] suggest that a key component in establishing reassurance in patients is empathy and emotional support from the clinician. Emotional support outweighs the need for information and explanations in patients with unexplained pain.[26] A systematic review, however, found that cognitive reassurance was more effective in sustaining long-term improvements in patient outcomes than affective reassurance.[27] Cognitive reassurance includes objective information giving with clear explanations, whereas affective reassurance includes concepts such as empathy and warmth.

The components of an effective self-management intervention should be designed in the knowledge that individual factors will determine different responses by patients to different components. Conceptually, the identification of groups of people for whom the same components will prove effective must be considered before implementing interventions. Indeed, the failure to adapt specific components that target the needs of different subgroups may explain the negative findings in some recent trials of behavioural interventions.[28]

Self-management and evidence

We use the following broad definition of self-management throughout:

> *Self-management education programmes are distinct from simple patient education or skills training, in that they are designed to allow people with chronic conditions to take an active part in the management of their own conditions.*
>
> *Foster* et al.[14]

The UK national evaluation of the original Expert Patients Programme for the self-management of chronic conditions reported a statistically significant increase in patients' self-efficacy (which can be interpreted as self-confidence in relation to a specific context) and self-reported energy levels but no reduction in health-care utilisation.[15] Others found that the beneficial effects of lay-led self-management programmes for chronic conditions were modest in the short term and demonstrated a paucity of evidence on long-term benefit.[14] Two subsequent systematic reviews[13,29] have reported improvements in patients' confidence to manage their symptoms and small effects on pain and disability; both studies concluded that the benefits were too small to have any meaningful effect. Possible explanations for these findings included:

1. Suboptimal content of interventions.
2. Suboptimal delivery of interventions.
3. Programmes are effective only for some patients.
4. Measuring outcomes that may not be relevant to the intervention – the majority of studies measured change in pain symptoms, which are unlikely to change in chronic conditions. Self-management interventions may have a greater effect on confidence, positive outlook and coping methods than pain.
5. Poor targeting of the interventions (i.e. to those least likely to benefit).
6. Supporting self-management is an inherently ineffective approach.

Measuring outcomes

The fourth point above illustrates one of the key methodological challenges in measuring outcomes in populations experiencing persistent symptoms resulting from long-term conditions: selecting suitable outcomes. Typically, these will depend on the aim of the study. Measuring patient-centred outcomes, that is, those that are meaningful, relevant and important to patients, has already been recognised in both the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT)[30] and Multinational Musculoskeletal Inception Cohort Study (MMICS)[31] recommendations. IMMPACT and MMICS were international consensus studies that recommended a list of outcome measures for research in chronic pain and back pain populations, respectively. Both made recommendations with regard to measures for pain, psychological states, patient satisfaction, disability, global health/well-being, health-care use, symptoms and adverse events, physical functioning, work-related outcomes, tests and examinations, financial issues, lifestyle, weight and social/demographic factors.

Predictors, moderators and mediators

In many areas of health-related research, attention has started to focus on better matching of subgroups of patients to interventions. This aims to improve the effectiveness of treatment by targeting those most likely to benefit and avoiding offering treatment to groups for whom treatment is neither acceptable nor beneficial.

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For example, in research in the musculoskeletal pain and mental health population, identification of subgroups is considered a priority.[22] The terminology around subgroup effects can be confusing. We have adopted the distinctions between predictors, moderators and mediators to describe how participant factors affect outcomes in randomised controlled trials (RCTs) suggested by Kraemer *et al*.:[32]

- Predictors are baseline variables that affect outcome (significant main effect only) but do not interact with treatment. Such factors significantly predict outcome equally for target interventions and control conditions.
- Moderators are baseline variables (such as patient baseline characteristics) that interact with treatment to change outcome for each subgroup. These specify for whom and under what conditions treatment works.
- Mediators are variables measured during treatment (factors that change during the intervention) that impact on outcome, with or without interaction with treatment, for example mood might be a mediator for a different outcome such as employment status. Mediators help inform the process and potential mechanisms (including causal mechanisms) through which treatment might work and therefore can be used to improve subsequent interventions through strengthening the components that best influence the identified mediators.

There is evidence from prospective cohort studies reporting predictors of outcomes for people with chronic musculoskeletal pain, but far less from RCTs reporting moderators and mediators.[20,33–35] Most of what is published, at least for low back pain, is of poor quality.[36] RCTs are the best study design to explore moderators and mediators but those that include planned subgroup analysis require very large samples.[37,38] Such subgroup analyses must also be based on good theoretical reasoning and previous evidence to support the hypothesis that the correct subgroups have been identified a priori.[39] In practice, these analyses are usually undertaken as secondary analyses and, consequently, are statistically underpowered, leading to a lack of robust data for mediators and moderators in self-management interventions.

Components of courses

Self-management involves undertaking tasks that enable a person to live with their chronic condition(s). Component tasks may include addressing the medical, social or role and emotional management of their condition(s).[40] This suggests that interventions aimed at improving self-management may require several different components. There are several meta-analyses of different treatments for those with chronic musculoskeletal pain. Psychological approaches (such as CBT),[41–43] exercise and activity[21] are beneficial, whereas patient education on its own has little or no effect.[44,45] The evidence for mind–body therapies (such as relaxation) is equivocal.[46–48] Self-management education courses or programmes for chronic musculoskeletal pain combine some or all of these approaches, but the evidence to date suggests that the overall effects of such courses are modest.[13,14]

As the content and characteristics of interventions promoting self-management for chronic pain vary considerably, there is a need to determine which components and course characteristics of these complex interventions are most likely to be beneficial to participants. To date, there have been few attempts to dissect the functional details of multicomponent, self-management programmes for chronic pain.

Adherence and dose

Attendance rates are a barrier to the effectiveness of self-management programmes. A national evaluation of the Expert Patients Programme evaluated courses at different case study sites, with participation rates at each site (participants attending at least four out of six sessions) ranging from 62% to 88%.[49] The number of sessions attended at group self-management courses may impact on outcomes, with many factors influencing continued attendance or if participants attend at all. Participants' physical and mental health,

their confidence within a group environment and their expectations about the learning experience may affect whether or not they attend the first session. Expectations can be influenced to some extent by the recruitment process in terms of information giving beforehand, and appropriate screening may identify any serious physical or mental impediments to attendance. However, after attending the first session, other factors come into play. On an individual level, relevance of content and perceived difficulty of the material are important, as well as whether or not the participant's own diagnosis and disease experience chimes with those of the rest of the group. One qualitative study sampling 'completers' of group CBT or group education for chronic pain found that motivation to attend was influenced by group cohesion and the actions of the facilitators for one group.[50] Facilitator competency during the delivery of courses is something that can be influenced by adequate training and preparation.

Reach and uptake

Identifying potential study participants with chronic pain from general practice is challenging. There are no universally acknowledged Read codes to identify chronic musculoskeletal pain and each general practice may have a different coding practice. Some UK-based studies have tackled this problem by sending out a blanket screening questionnaire to all registered patients over a certain age, excluding any major physical or psychiatric comorbidity.[51,52] Eligibility was then assessed from the screening questionnaires returned and suitable participants formally invited into the study. Enrolment rates for eligible patients were high at 53%[51] and 50%,[52] respectively, but the numbers of screening questionnaires sent out in the initial blanket mail-out were 12,448[51] and 45,994,[52] respectively. Another approach is to directly query the general practice patient record systems looking for indicator Read codes, prescriptions for analgesics and frequency of consultations and to send out invitations to potentially eligible patients, excluding any major physical or psychiatric comorbidity[53–56] Once a potential participant has expressed an interest in the study, actual conversion to enrolment into the study can be influenced by a number of factors, for example some potential participants may not enrol because they think that the control arm is not a credible option or some may not be able to attend courses on weekdays because of other commitments such as work or child care.

Summary of evidence gaps: the need for research in this area

Treatment for chronic musculoskeletal conditions such as low back pain has done little to reduce their prevalence and health impact over the last two decades.[57,58] Chronic pain frequently coexists with other pain syndromes[59] and traditional treatment approaches focus on conditions separately, which is unlikely to have a substantial impact on the population, or individual, burden of chronic pain.[59] There has been a shift towards a more biopsychosocial approach.[60] Two increasingly used psychosocial interventions are cognitive–behavioural approaches and self-management support programmes. Both approaches are rapidly expanding. However, the evidence has not been sufficient to justify such widespread and rapid introduction.

Some investigators have used RCTs to evaluate the effectiveness of self-management programmes but few have explored the effectiveness of different components of these programmes or courses. RCTs have found that self-management interventions may change attitudes but produce only modest improvements in clinical outcome. Overall, these data do not indicate whether specific aspects of the courses are effective or ineffective; it may be, for example, that social networking or the approach of the tutors is the most important factor.

We proposed to explore the components or elements of chronic pain self-management programmes that may be more effective than others and determine the most appropriate outcomes to measure. Without this work there are the twin hazards of continuing to spend NHS resources on ineffective interventions or failing to invest adequately in delivering an effective and cheap intervention. Even quite modest overall effects may be worth identifying because of the enormous personal, social and economic costs of chronic painful disorders.

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Aims and objectives

The overall aim of this programme of research was to develop and test a self-management intervention for people living with chronic musculoskeletal pain.

The objectives were to develop a new self-management approach and provide evidence for, or against, its clinical effectiveness and cost-effectiveness. We proposed developing an intervention to promote individual independence, improve quality of life and reduce the level of need for health-care resources, thus lessening a proportion of the economic, personal and social burden of chronic pain conditions.

To achieve this we first needed to identify what was already known about good-quality self-management programmes for chronic pain by examining the existing scientific literature and evidence in a systematic manner. We also wanted to consult experts and patients to identify and explore best practice, theoretical underpinnings for self-management and ways to measure patient outcomes. Once this preliminary work was completed we devised and evaluated our new programme/intervention in a feasibility study to ensure that we had the best possible intervention and systems for measuring the effect of the intervention on patients.

Finally, we tested the new intervention in a pragmatic RCT. We collected information on both the clinical effectiveness and the cost-effectiveness of our intervention. The findings provide the information needed to decide whether or not the NHS should invest in such services in the future.

Overview of the study and the report

There are two parts to this report: the development of the intervention and testing the clinical effectiveness and cost-effectiveness of the intervention. *Figure 1* illustrates the overall design of the study.

Part I: development, design and feasibility testing of the intervention

The development phase consisted of two systematic reviews, a qualitative study, modelling, the design of the intervention and a feasibility study. *Chapter 8* summarises the findings from part I and is not shown as part of the study design illustrated in *Figure 1*.

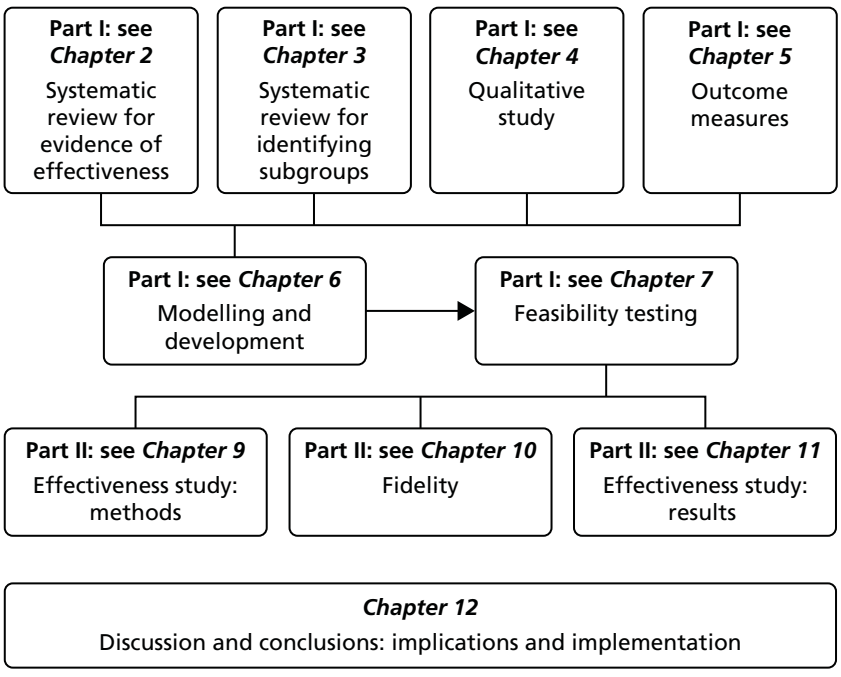

FIGURE 1 The structure of the study and report.

Part II: clinical effectiveness and cost-effectiveness of the intervention

The testing phase consisted of a RCT and a cost-effectiveness analysis and study of the fidelity of the delivery of the intervention in the RCT.

At the end of part II we bring together the findings and discuss these in relation to current thinking in the field of chronic pain and self-management.

Patient and public involvement

We included patients and the public in phases 1 and 2 of the research. In phase 1 we recruited four people (one male and three females) with a chronic condition to a patient advisory group. These people gave advice and made comments on all of our patient-related documentation, resulting in substantial improvements to the documentation. In addition, they played a role in the outcomes study (see *Chapter 5*) by reviewing outcome measurement tools and commenting on their acceptability, brevity, comprehension and ease of completion (in retrospect we feel that we could have included more patient advisors in this phase of the study). People with experience of chronic pain were heavily involved in the development and refinement of the intervention, particularly in terms of their collaboration during the feasibility study when we collected data from all participants and from the lay facilitators on their experiences of every session (using a questionnaire) and at focus groups and interviews following the completion of the courses. The free and frank discussions at the focus groups enabled us to refine the intervention and the training to deliver the intervention. We also consulted extensively with the Bangladeshi community through interviews during the feasibility study of the intervention delivered in Sylheti. Two professional bilingual Bangladeshi advocates also provided extensive advice on patient-related material, running the courses in Sylheti and outcome measures in the Sylheti-speaking community.

In phase 2 we included two patient representatives with a chronic condition on the Trial Steering Committee (TSC), one female and one male. Both were experienced representatives who had previously sat on National Institute for Health Research (NIHR) research priorities panels. These people gave valuable advice to the TSC and the excellent recruitment rates and low attrition seen in the study are, in part, a reflection of their contribution.

In addition, Social Action for Health [see www.safh.org.uk (accessed 11 April 2016)] was a coapplicant in the study. Social Action for Health is a community interest company providing socially orientated services to the local community. Members of Social Action for Health were part of the trial study team and represented the patient perspective for decisions made throughout the progress of the study.

Finally, and perhaps most importantly, patients were integral to the design and delivery of the intervention as we recruited patients with experience of chronic pain to deliver our intervention for the feasibility study and the main trial.

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Chapter 2 Systematic review: evidence for the effectiveness of components and characteristics of pain and self-management programmes

Abstract

Introduction: Evidence for self-management courses and course components that are beneficial for participants has not been established.

Aims: To systematically re-examine the overall effectiveness and determine the most successful course content and optimal delivery methods of self-management courses.

Methods: We searched 10 relevant electronic databases for RCTs and systematic reviews. RCTs were categorised according to the presence of psychological, mind–body therapy, physical, lifestyle and educational components; group or individual delivery; tutor; setting; and duration of the interventions studied. Outcomes analysed were pain intensity, global health, quality of life, physical function, self-efficacy, depression, anxiety and social function in the short term (< 4 months), medium term (4–8 months) and long term (> 8 months). Data were extracted comparing self-management with usual care or a waiting list control. Data were combined as a standardised mean difference (SMD) meta-analysis (random effects) with subgrouping. When statistical pooling was not possible we carried out a narrative synthesis.

Results: Forty-six RCTs published from 1994 to 2009 were included in the original meta-analyses and a further 18 RCTs were included in updated analyses to 2013. Heterogeneity between studies was generally high. Overall, the number of components or duration of the interventions did not influence effectiveness, but courses with a psychological component, courses delivered in groups and courses delivered by a HCP appeared to work well, showing significant effect sizes on several outcomes during post-course follow-up (short, medium and long term). Data were sparse on subgroup comparisons and on the detail of the components of individual interventions.

Conclusions: Our analysis provided useful information to inform the design of our intervention.

Introduction

The evidence for the effectiveness of self-management support courses[61] (commonly known as 'self-management courses' and sometimes referred to as 'pain management programmes') for chronic musculoskeletal pain is limited. There is even less information on the effectiveness of specific components or on the content of courses and the way that they are delivered.

Aim

The aim of this review was to identify the types of courses (content and characteristics) that are most likely to be effective in helping those with chronic pain.

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We sought to identify the evidence on:

- the overall effectiveness of self-management courses
- the key components and characteristics of potentially effective self-management programmes (including self-management education strategies) for people with chronic musculoskeletal pain.

We did this by comparing research on delivery characteristics (including setting) and components of self-management programmes for chronic musculoskeletal disorders that appear to have been successful or unsuccessful.

Method

We conducted a systematic review of RCTs examining the effectiveness of different types of self-management interventions (with and without individual components).

In addition, we systematically searched for systematic reviews to see if any other researchers had performed this type of work and used citation tracking from relevant reviews to supplement our searches.

We completed the initial systematic review of articles published between January 1994 and April 2009 to inform the design of the intervention study. At the end of the study we updated the review for selected outcomes [those measured in the COPERS (Coping with persistent Pain, Effectiveness Research into Self-management) study] to September 2013 to allow us to put our final results into context (see *Chapter 12*). The inclusion and exclusion criteria for the reviews are shown in *Table 1*.

Outcome measures

The outcomes that we were interested in were extracted and grouped into the following categories:

- global health measures
- pain intensity
- physical/functional capability
- quality of life
- self-efficacy
- anxiety
- depression
- social role/function
- Short Form questionnaire-36 items (SF-36)[62] general mental health (excluded in update review)
- number of visits to HCPs (excluded in update review)
- fatigue (excluded in update review).

The mean and standard deviation (SD) of the final value and/or change scores for each group at each follow-up interval were extracted.

Search method

Electronic literature searches

The initial searches were conducted between January 1994 and April 2009 as self-management courses and the understanding of chronic pain have advanced considerably during this period. The following electronic databases were searched to identify all relevant studies: MEDLINE and MEDLINE In-Process & Other Non-Indexed Citations (Ovid), EMBASE (Ovid), PsycINFO (Ovid), Cumulative Index to Nursing and Allied Health Literature (CINAHL), Allied and Complementary Medicine Database (AMED) using the Health Information Resources [see www.library.nhs.uk (accessed 11 April 2016)], Web of Science Social Sciences

TABLE 1 Inclusion and exclusion criteria for systematic reviews

Definitions	Inclusion criteria	Exclusion criteria
Type of study	• Systematic reviews and RCTs evaluating self-management interventions • RCTs with at least 20 people in each trial arm at the end of the study/trial (to exclude studies that were underpowered to detect a SMD of < 0.8) • Published between January 1994 and April 2009	• Non-English-language studies • Studies without reported outcomes • Conference abstracts
Types of participants	• Patients with non-specific musculoskeletal pain, degenerative joint disease, chronic widespread pain, arthritis, OA, fibromyalgia and unexplained, non-pathological neuropathic painful musculoskeletal conditions • For studies including individuals with different long-term conditions, at least 50% of participants had to have chronic musculoskeletal pain (e.g. arthritis) • If mixed groups of pain patients were included at least 80% had to be chronic and at least 80% had to have musculoskeletal pain • The IASP definition of chronic pain was used.[17] Only studies with patients having pain lasting beyond the normal expected healing time (a minimum of 3 months) were included	• Migraine, headache, facial pain, eye pain, irritable bowel syndrome, angina, chronic obstructive pulmonary disease, non-cardiac chest pain, inflammatory joint conditions such as rheumatoid arthritis, ankylosing spondylitis or chronic fatigue/myalgic encephalopathy • Patients with chronic pain arising from malignant disease were excluded as they require specific management • Studies involving people aged < 18 years
Types of self-management interventions	• Self-management programmes that had the broad goal of improving participants' health status or quality of life • Aimed at (and delivered to) patients. Carers or tutors may have been involved but the programmes were principally directed at patients • Structured programmes with individual elements that were organised and delivered in a consistent way • Taught or self-taught components that aimed to increase participants' skills and knowledge and enabled participants to deploy these enhanced skills in aspects of their lives beyond the intervention • Psychological elements had to be behavioural and/or cognitive and/or structured (i.e. not psychotherapy)	• Interventions with only one component such as those involving exercise training alone did not constitute self-management programmes • Studies without a clear description of programmes/interventions

Citation Index (SSCI) and The Cochrane Library [Cochrane Database of Systematic Reviews (CDSR), Database of Abstracts of Reviews of Effects (DARE), Cochrane Central Register of Controlled Trials].

Other sources

We also checked the citation lists of relevant systematic reviews and guidelines identified in our electronic database searches for any additional relevant studies.

Study selection

Two reviewers conducted the searches and independently screened all titles and abstracts for potentially eligible studies. Full texts of all potentially relevant articles were obtained. Inter-rater reliability for screening titles and abstracts was checked on a sample of the studies (approximately 10%). The full texts of all retrieved articles were scrutinised by both reviewers to determine whether or not to proceed to full data extraction. Disputed articles went to a third reviewer for arbitration.

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Assessment of study bias

Two review authors independently assessed trial quality according to the following criteria modelled on The Cochrane Collaboration methods.[39] We asked:

1. Did the study have an adequate randomisation sequence?
2. Was allocation concealment carried out?
3. Was there a description (i.e. numbers provided) of withdrawals and dropouts?
4. Was outcome assessment blinded?
5. Was there an intention-to-treat (ITT) analysis?

Each question was rated as yes/no or unclear (see *Table 3*).

Data extraction

The two reviewers working independently each extracted data about country of origin, number randomised to each arm, who delivered the course (HCP or lay tutor or a combination), whether the course was delivered to groups or individuals or was self-delivered, setting [community, medical, occupational, remote (telephone/internet) or mixed], total number of sessions and contact hours, course duration, course components (see *Table 2*), description of control group and the description and results of any moderator analyses. Data were extracted, when possible, at four time points: baseline, short-term follow-up (< 4 months), medium-term follow-up (4–8 months), long-term follow-up (> 8 months) or a mixture of follow-up points.

Description of self-management components

To handle the vast number of data arising from the studies, we categorised self-management interventions into psychological, mind–body therapy, physical, lifestyle or medical education components, as described in *Table 2*. Each study was coded so that the intervention arm was described using two or more components from the list. We accept that these categorisations represent our interpretation of the published reports of studies and that some components may well have overlapped between our broad categories.

Final study selection

Following data extraction, the RCTs were further selected to include only comparisons of the self-management intervention(s) with waiting list controls or usual care.

TABLE 2 Framework for organising aspects of interventions into components

Psychological	Mind–body therapies	Physical	Lifestyle management	Medical management
• CBT • Operant conditioning • Fear avoidance • Coping skills • Goal-setting/action planning • Modelling by others • GEXP (graded exposure in vivo) • Problem-solving • Pain reconceptualisation • Attention distraction (diversion)	• Guided imagery • Visualisation • Biofeedback (electromyographic) • Relaxation • Meditation • Self-hypnosis • Prayer • Alexander technique • Mindfulness training	• Exercise (any) • Yoga • T'ai chi • Qigong • Posture	• Pacing (activity) • Diet • Stress management • Relationships • Sleep management • Financial management • Healthy lifestyle advice • Ergonomics • Peer support	• Education about condition • Drug control • Drug side effects • Communication with HCPs

Meta-analysis methods

The meta-analyses were carried out using Review Manager v5 (The Cochrane Collaboration, The Nordic Cochrane Centre, Copenhagen, Denmark). Calculations were based on final values as these were the most commonly reported data. Change score data were also collected when possible. When studies reported *p*-values for change from baseline for each group, this enabled a SD for the change score to be calculated.[39] Change scores were analysed in the same way as the final value data for the outcomes when there were sufficient data and compared with the final value results for the same outcomes as a sensitivity analysis. We used a random-effects model because of the heterogeneity in study populations and interventions.

When there was more than one measurement tool for an outcome we combined data across studies using a SMD meta-analytical approach (see section 9.2.3.2 of the *Cochrane Handbook for Systematic Reviews of Interventions*[39]), where

$$\text{SMD} = \text{difference in mean outcome between two groups} \div \text{SD of outcome among participants.} \quad (1)$$

For those instruments for which an increase in score indicates improvement we reversed the sign on the mean score to enable us to combine these as a pooled SMD with measures from instruments for which a decrease in score is beneficial.

The resulting SMDs were interpreted using Cohen's *d*[63,64] (where *d* is derived from the difference between two independent means divided by the within-population SD as above). The effect sizes were conventionally defined as follows: 'minor' < 0.2, 'small' ≥ 0.2, 'moderate' ≥ 0.5 and 'large' ≥ 0.8.

Meta-analysis comparisons

We tested:

1. *Overall effectiveness*. Total effect size or SMD for self-management interventions with regard to our prespecified outcome categories compared with the control.
2. *The effect of course delivery mode*. We grouped the studies at each follow-up interval into different course delivery modes [group, individual, mixed (group and individual) or remote (internet, mail, telephone)] and compared the pooled SMDs for each subgroup.
3. *The effect of course leader*. We grouped the studies and outcomes at each follow-up interval into those that were delivered by a HCP, those that were delivered by a lay tutor and those using a mix of delivery methods and compared the pooled SMDs for each subgroup.
4. *The effect of course setting*. We grouped the studies at each follow-up interval into those delivered in the community, those delivered in a medical setting (primary care or hospital) and those delivered in an occupational setting and compared the pooled SMDs for each subgroup.
5. *The effect of course duration*. We grouped the studies at each follow-up interval into those with courses of ≤ 8 weeks and those with courses of > 8 weeks and compared the pooled SMDs for each subgroup.
6. *The effect of contributing self-management components*. We tested whether or not the presence of a particular self-management component improved the effectiveness of the interventions. We compared the pooled SMDs of studies with psychological, mind–body therapy, physical, lifestyle and medical education components with the pooled SMDs of studies without these components.
7. *The effect of number of components*. We tested whether or not the number of components (two, three, four or five) influenced the effect size, comparing the pooled SMDs at short-, medium- and long-term follow-up intervals.

We produced forest plots of final value data for each comparison showing the pooled SMD for each subgroup.

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Assessment of publication bias

Funnel plots were generated using Review Manager v5 for the outcomes with the most studies. The funnel plots were visually examined for symmetry about the *y*-axis and resemblance to an inverted funnel to denote absence of bias.

We present data from the original review meta-analysis and the updated review data.

Results

The results of the review of the effectiveness of self-management interventions are shown first followed by the effectiveness review of self-management courses with and without the different components and characteristics.

Literature search

The initial search produced 4676 results and of these we included 46 RCTs. When we updated the search to September 2013 we included a further 18 trials in the meta-analyses for the overall effectiveness of self-management interventions.

Figure 2 shows the flow chart for the initial search and *Figure 3* shows the flow chart for the updated search.

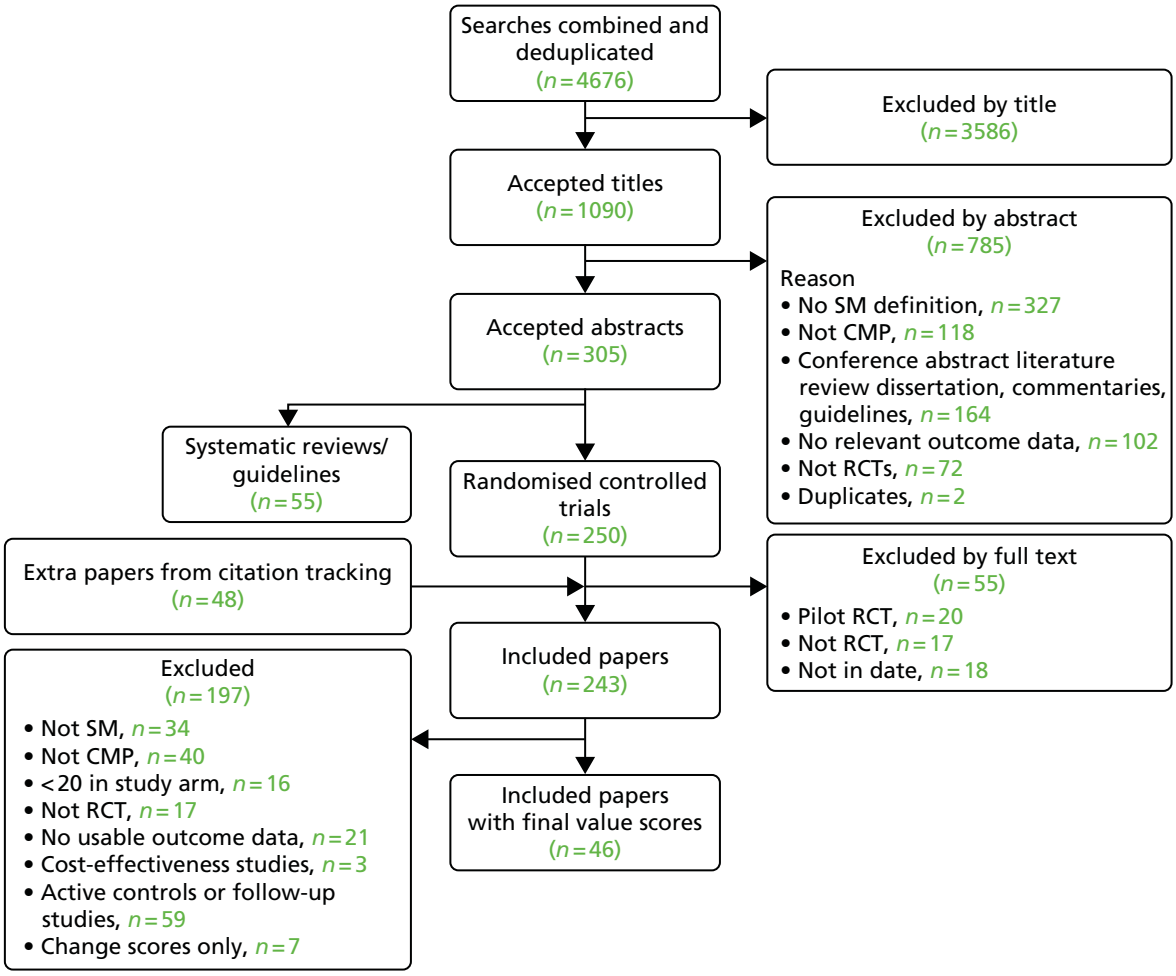

FIGURE 2 Searches for the systematic review 1994–2009. CMP, chronic musculoskeletal pain; SM, self-management.

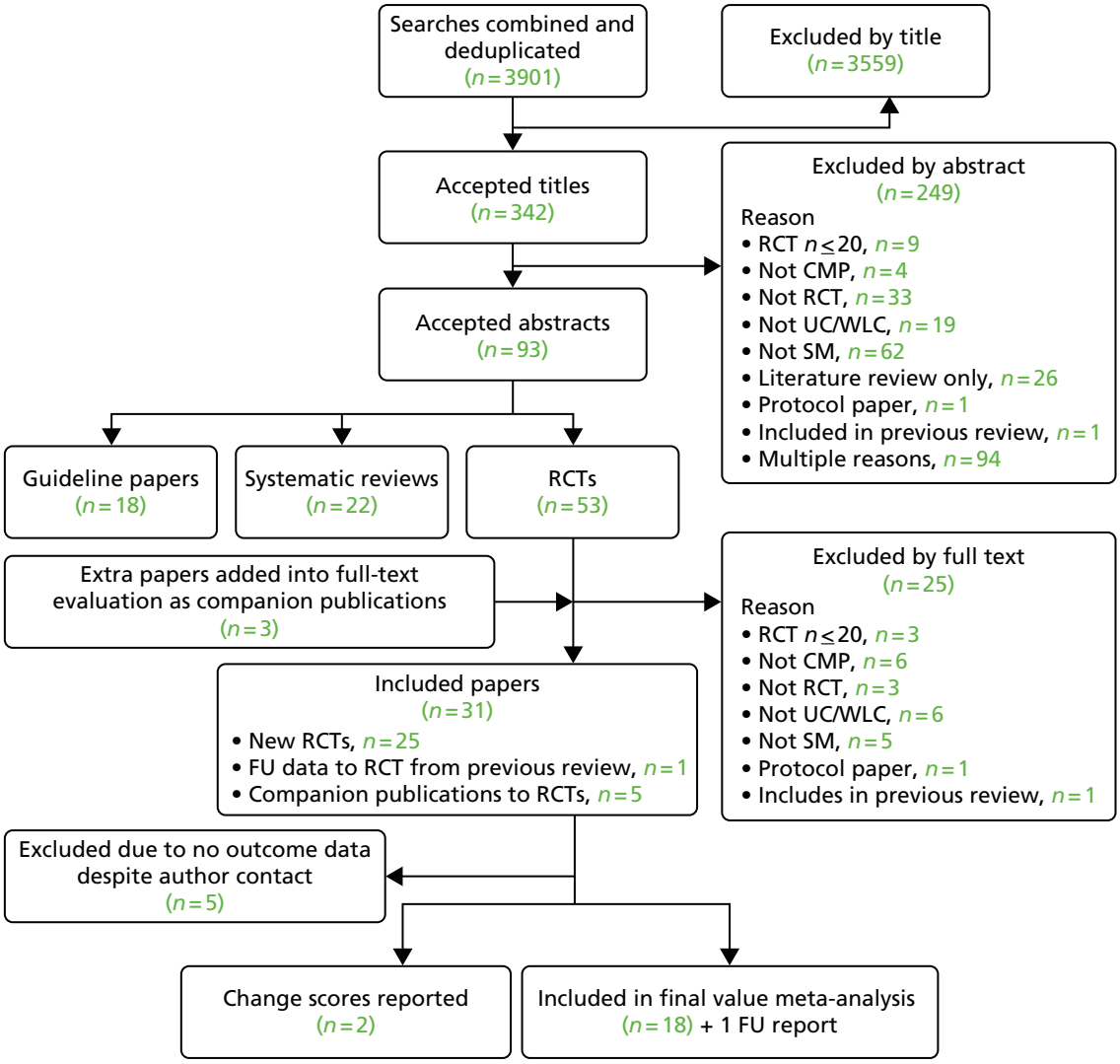

FIGURE 3 Systematic review update June 2009–September 2013. CMP, chronic musculoskeletal pain; FU, follow-up; SM, self-management; UC, usual care; WLC, waiting list control.

Effectiveness analyses

For our original meta-analyses we included 46 RCTs[54,65–111] with final-value data comparing self-management programmes with usual care or waiting list controls ($n = 8539$) (*Table 3*). Thirteen RCTs were conducted in the USA,[72,74,77,83,85,86,91–93,95,104,106,108] seven in the Netherlands,[69,81,94,96,98,102,110] five in the UK,[54,67,70,88,97,103] five in Canada,[68,76,80,87,107] three each in Sweden,[82,89,99] Norway[75,78,79,84] and China,[100,105,111] two in Germany[71,73] and one each in Turkey,[65] Iran,[66] Switzerland,[90] Spain[101] and Brazil.[109] Of these studies, 13 (28%) were on OA (hip or knee),[74,81,88,91,92,94–97,101,104,105,111] 12 (26%) were on low back pain,[54,66,71,73,77–79,83,89,93,102,109,110] nine (20%) were on mixed pain,[68,70,75,76,80,84,99,100,106] five (11%) were on fibromyalgia,[69,82,85,87,90] three (7%) were on mixed arthritis (OA and rheumatoid arthritis)[72,107,108] and one (2%) each was on temporomandibular joint disorder,[86] osteoporosis,[65] upper limb pain[98] and knee pain.[67,103] The mean age of participants for the 44 studies reporting age was 55 years (range 38–82 years). In the 41 studies reporting gender breakdown, 72% were female participants, with two studies having exclusively female patients. Thirty-six studies were health care professionally led, six were mixed health care and lay led and four were lay led. Twenty-seven studies were conducted in a medical setting, sixteen in the community and three in occupational settings. Twenty-seven were delivered in groups, five were delivered remotely via the internet and five were delivered individually; nine used mixed group and individual delivery.

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TABLE 3 Characteristics of included papers

Study	Country	Population	*n*	Self-management component details	Control arm	Course characteristics				Follow-up	Quality assessment[a]				
						Delivery	Leader	Setting	Duration		QA1	QA2	QA3	QA4	QA5
Corey 1996[68]	Canada	Mixed pain	200	P + MBT + PA + LS + ED	UC	Group	HCP	Medical	4 weeks	L	U	U	Y	Y	N
Vlaeyen 1996[69]	The Netherlands	Fibromyalgia	131	P + MBT + PA + LS	WLC	Group	HCP	Medical	6 weeks	S	U	U	Y	U	N
				MBT + PA + LS	WLC	Group	HCP	Medical	6 weeks	S	U	U	Y	U	N
Williams 1996[70]	UK	Mixed pain	78	P + MBT + PA + LS + ED	WLC	Group	HCP	Medical	8 weeks	S	Y	U	Y	Y	N
Basler 1997[71]	Germany	Low back pain	94	P + MBT + PA + LS + ED	UC	Group	HCP	Medical	12 weeks	M	U	U	Y	U	N
Fries 1997[72]	USA	OA + RA	809	MBT + PA + LS + ED	WLC	Remote	HCP	Community	52 weeks	M, L	Y	U	N	U	Y
Keller 1997[73]	Germany	Low back pain	65	P + MBT + PA + ED	WLC	Group + individual	HCP	Medical	6 weeks	S	U	U	Y	U	N
Mazzuca 1997[74]	USA	OA	211	P + PA + LS + ED	UC	Individual	HCP	Medical	6 weeks	M, L	U	Y	Y	U	N
Haldorsen 1998[75]	Norway	Mixed pain	469	P + MBT + PA + LS + ED	UC	Group + individual	HCP	Medical	4 weeks	L	U	Y	Y	Y	N
LeFort 1998[76]	Canada	Mixed pain	110	P + MBT + PA + LS + ED	WLC	Group	HCP	Community	6 weeks	S	U	Y	Y	U	Y
Von Korff 1998[77]	USA	Low back pain	255	P + PA + LS + ED	UC	Group	Lay	Medical	4 weeks	S, M, L	U	U	Y	Y	Y
Glomsrod 2001,[78] Lonn 1999[79]	Norway	Low back pain	81	PA + LS + ED	UC	Group	HCP	Medical	13 weeks	L	Y	U	Y	U	Y
Currie 2000[80]	Canada	Mixed pain	60	P + MBT + LS	WLC	Group	HCP	Medical	7 weeks	S	Y	U	Y	U	Y
Hopman-Rock 2000[81]	The Netherlands	OA	120	P + MBT + PA + LS + ED	UC	Group	HCP	Medical	6 weeks	S, M	U	U	Y	Y	N
Mannerkorpi 2000[82]	Sweden	Fibromyalgia	69	P + MBT + PA + LS + ED	UC	Group	HCP	Community	24 weeks	M	U	U	Y	Y	N
Moore 2000[83]	USA	Low back pain	266	P + PA + LS + ED	UC	Group + individual	HCP	Medical	3 weeks	S, M, L	U	U	Y	U	Y
Haugli 2001[84]	Norway	Mixed pain	174	P + MBT + PA + ED	UC	Group	HCP	Occupational	45 weeks	S, L	U	U	Y	Y	N
Oliver 2001[85]	USA	Fibromyalgia	400	P + MBT + PA + LS + ED	UC	Group	HCP + lay	Community	52 weeks	L	U	U	Y	U	N

Study	Country	Population	*n*	Self-management component details	Control arm	Course characteristics				Follow-up	Quality assessment[a]				
						Delivery	Leader	Setting	Duration		QA1	QA2	QA3	QA4	QA5
Dworkin 2002[86]	USA	TMD	124	P + MBT + LS + ED	UC	Individual	HCP	Medical	6 weeks	S, M, L	U	U	Y	U	Y
King 2002[87]	Canada	Fibromyalgia	124	P + PA + LS + ED	WLC	Group	HCP	Community	12 weeks	S	Y	U	Y	Y	Y
				P + LS + ED	WLC	Group	HCP	Community	12 weeks	S	Y	U	Y	Y	Y
Quilty 2003[88]	UK	OA	87	PA + LS	UC	Individual	HCP	Community	10 weeks	M, L	Y	Y	Y	U	Y
Buhrman 2004[89]	Sweden	Low back pain	56	P + MBT + PA + LS	WLC	Remote	HCP	Community	8 weeks	S	Y	U	Y	U	N
Cedraschi 2004[90]	Switzerland	Fibromyalgia	164	P + MBT + PA + LS	WLC	Group	HCP	Medical	6 weeks	M	Y	Y	Y	U	N
Hughes 2004[91]	USA	OA	150	P + PA	UC	Group	HCP + lay	Community	8 weeks	S, M, L	Y	U	Y	U	N
Mazzuca 2004[92]	USA	OA	186	PA + LS + ED	WLC	Individual	HCP	Medical	4 weeks	S, M, L	U	U	Y	U	N
Haas 2005[93]	USA	Low back pain	109	P + MBT + PA + LS + ED	WLC	Group	Lay	Community	6 weeks	M	Y	Y	Y	U	Y
Heuts 2005[94]	The Netherlands	OA	273	P + MBT + PA + LS + ED	UC	Group	HCP	Medical	6 weeks	S, L	Y	U	Y	Y	Y
Pariser 2005[95]	USA	OA	92	P + MBT + PA + LS + ED	UC	Remote	HCP	Community	6 weeks	S	U	U	N	U	N
Tak 2005[96]	The Netherlands	OA	109	PA + LS	UC	Group + individual	HCP	Medical	8 weeks	S	Y	U	Y	Y	Y
Victor 2005[97]	UK	OA	193	P + MBT + PA + LS + ED	WLC	Group + individual	HCP	Medical	4 weeks	S, L	U	U	Y	Y	N
Bernaards 2006[98]	The Netherlands	Upper limb pain	314	P + PA + LS	UC	Group	HCP	Occupational	24 weeks	M, L	Y	N	U	Y	N
Brattberg 2006[99]	Sweden	Mixed pain	60	P + LS	WLC	Remote	HCP + lay	Community	20 weeks	S, L	U	U	Y	U	N
Li 2006[100]	China	Mixed pain	64	P + LS + ED	WLC	Group + individual	HCP	Occupational	3 weeks	S	Y	U	Y	U	Y
Núñez 2006[101]	Spain	OA	100	P + PA + LS	UC	Group + individual	HCP	Medical	12 weeks	L	Y	U	Y	U	N

continued

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TABLE 3 Characteristics of included papers (*continued*)

Study	Country	Population	*n*	Self-management component details	Control arm	Course characteristics				Follow-up	Quality assessment[a]				
						Delivery	Leader	Setting	Duration		QA1	QA2	QA3	QA4	QA5
Smeets 2006[102]	The Netherlands	Low back pain	111	P + PA	WLC	Group + individual	HCP	Medical	10 weeks	S	Y	Y	Y	Y	Y
Alp 2007[65]	Turkey	Osteoporosis	50	P + PA + LS + ED	UC	Group	HCP + lay	Medical	5 weeks	S, M	Y	U	U	Y	N
Hurley 2007,[67] Hurley 2012[103]	UK	Knee pain	418	P + MBT + PA + LS + ED	UC	Group + individual	HCP	Medical	6 weeks	M	Y	U	Y	Y	Y
Johnson 2007[54]	UK	Low back pain	234	P + MBT + PA + LS + ED	UC	Group	HCP	Community	6 weeks	S, L	Y	U	Y	N	Y
Martire 2007[104]	USA	OA	143	P + PA + ED	UC	Group	Lay	Community	6 weeks	S, M	U	U	Y	U	Y
Tavafian 2007[66]	Iran	Low back pain	102	P + MBT + PA + LS + ED	UC	Group	HCP	Medical	4 days	S	U	N	Y	U	Y
Yip 2007[105]	China	OA	182	PA + LS + ED	UC	Group	HCP + lay	Medical	6 weeks	S, M	Y	U	Y	Y	Y
Ersek 2008[106]	USA	Mixed pain	256	P + MBT + PA + LS + ED	UC	Group	HCP	Community	7 weeks	S, M, L	Y	U	Y	U	N
Laforest 2008[107]	Canada	OA + RA	113	P + MBT + LS + ED	WLC	Individual	HCP	Community	6 weeks	S	Y	U	Y	Y	N
Lorig 2008[108]	USA	OA + RA	866	P + MBT + PA + LS + ED	UC	Remote	Lay	Community	6 weeks	M, L	U	U	Y	U	Y
Ribeiro 2008[109]	Brazil	Low back pain	60	PA + ED	UC	Group	HCP	Medical	5 weeks	S, M	Y	Y	Y	Y	N
van der Hulst 2008[110]	The Netherlands	Low back pain	163	P + PA	WLC	Group	HCP	Medical	7 weeks	S, M	Y	U	Y	U	Y
Yip 2008[111]	China	OA	95	PA + LS + ED	UC	Group	HCP + lay	Medical	6 weeks	S, M, L	Y	U	Y	Y	Y
Studies included in the update															
Crotty 2009[112]	Australia	OA hip or knee	152	P + MBT + PA + LS + ED	UC	Group + individual	HCP + lay	Medical	6 weeks	M	Y	Y	U	Y	Y
Jenkinson 2009[51]	UK	Knee pain	389	PA + LS	UC	Individual	HCP	Community	104 weeks	L	Y	Y	Y	Y	Y

Study	Country	Population	*n*	Self-management component details	Control arm	Course characteristics				Follow-up	Quality assessment[a]				
						Delivery	Leader	Setting	Duration		QA1	QA2	QA3	QA4	QA5
Kroenke 2009[113]	USA	Mixed pain	250	P + MBT + PA + LS + ED	UC	Individual	HCP	Community	52 weeks	M, L	Y	Y	U	Y	Y
Chiauzzi 2010[114]	USA	Low back pain	209	P + PA + LS + ED	UC	Remote	Self	Community	4 weeks	S, M	Y	U	Y	Y	Y
Glombiewski 2010[115]	Germany	Low back pain	128	P + MBT + LS	WLC	Individual	HCP	Medical	32 weeks	M	Y	U	U	U	Y
Hamnes 2012[116]	Norway	Fibromyalgia	150	P + MBT + PA + LS + ED	WLC	Group	HCP	Medical	1 week	S	Y	Y	U	U	U
Hansson 2010[117]	Sweden	OA hip/knee/hand	114	PA + LS + ED	UC	Group	HCP	Medical	5 weeks	M	Y	U	Y	Y	U
Hsu 2010[118]	USA	Fibromyalgia	45	P + MBT + PA + LS + ED	WLC	Group	HCP	Medical	3 weeks	S, M	Y	U	Y	Y	Y
Lamb 2010[53]	UK	Low back pain	701	P + MBT + PA + ED	UC	Group	HCP	Mixed	6 weeks	S, M, L	Y	Y	Y	Y	Y
Williams 2010[119]	USA	Fibromyalgia	118	P + MBT + PA + LS + ED	WLC	Remote	Self	Community	24 weeks	M	Y	Y	Y	Y	Y
Luciano 2011[120]	Spain	Fibromyalgia	216	P + MBT + PA + ED	UC	Group	HCP	Medical	9 weeks	S	Y	U	U	Y	Y
Morone 2011[121]	Italy	Low back pain	73	P + MBT + PA + LS + ED	UC	Group	HCP	Medical	4 weeks	S, M	U	U	Y	Y	N
Brosseau 2012[122]	Canada	OA knee	222	P + PA	UC	Group	HCP	Community	52 weeks	L	Y	Y	U	Y	Y
Carpenter 2012[123]	USA	Low back pain	141	P + MBT + PA + LS + ED	WLC	Remote	Self	Community	3 weeks	S	Y	U	U	Y	U
Coleman 2012[124]	Australia	OA knee	146	P + MBT + PA + LS + ED	WLC	Group	HCP	Community	6 weeks	S, M	Y	Y	Y	Y	Y
Kao 2012[125]	Taiwan	OA knee	259	P + PA + LS + ED	UC	Group	HCP	Medical	4 weeks	S	Y	U	Y	U	N
Martin 2012[126]	Spain	Fibromyalgia	180	P + MBT + PA + ED	WLC	Group	HCP	Medical	6 weeks	M	Y	U	U	U	N
McBeth 2012[52]	UK	Mixed pain	442	P + PA + LS	UC	Remote	HCP	Community	24 weeks	M, L	Y	Y	Y	Y	Y
				P + LS	UC	Remote	HCP	Community	24 weeks	M, L	Y	Y	Y	Y	Y

ED, medical Education; L, long term; LS, lifestyle; M, medium term; MBT, mind–body therapy; N, no; P, psychological; PA, physical activity; RA, rheumatoid arthritis; S, short term; TMD, temporomandibular joint disorder; U, unclear; UC, usual care; WLC, waiting list control; Y, yes.

a QA1 = adequate randomisation sequence; QA2 = allocation concealment; QA3 = clear description of withdrawals; QA4 = masked outcome assessment; QA5 = ITT analysis.

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For the update review we included an additional 19 sets of data; one trial[67] was included in the original meta-analyses but published longer-term follow-up data after our 2009 cut-off[103] and we included this study in the update analyses. Of the 18 new studies, five were from the USA,[113,114,118,119,123] three from the UK,[51–53] two each from Australia[112,124] and Spain[120,126] and one each from Italy,[121] Germany,[115] Sweden,[117] Norway,[116] Taiwan[125] and Canada[122] ($n = 3745$). Five focused on low back pain,[53,114,115,121,123] five on OA,[112,117,122,124,125] five on fibromyalgia,[116,118–120,126] two on mixed pain[52,113] and one on knee pain only.[51] Fourteen were health care professionally led,[51–53,113,115–118,120–122,124–126] one was mixed health care and lay led[112] and three were self-led.[114,119,123] Nine were conducted in a medical setting,[112,115–118,120,121,125,126] eight in the community[51,52,113,114,119,122–124] and one in a mixed setting.[53] Ten were delivered in groups,[53,116–118,120–122,124–126] four were delivered remotely via the internet[52,114,119,123] and three were delivered individually;[51,113,115] one used a mixed method of delivery.[112] The mean age of participants for 17 of the 18 studies reporting age was 54 years (range when specified 25–84 years) and 2509 (67%) of the 3745 participants were female (see *Table 3*).

Quality assessment

Around half of the original 46 studies (54%) reported an adequate randomisation sequence, and in the remainder of the studies this was unclear. Allocation concealment was present in nine studies (20%), absent in two (4%) and unclear in 35 (78%). Masked outcome assessment was reported in 19 studies (41%), with the remainder unclear. Nearly all studies (91%) reported reasons for dropping out of the study and, in the 44 studies reporting this, the mean attrition rate across all study arms was 18% (range 6–47%). One study reported a 100% completion rate and 11 studies had an attrition rate of > 20%. Only 22 studies (48%) reported that they had analysed their data on an ITT basis, using last observation carried forward or imputation methods to fill in missing data (see *Table 3*). Quality assessment in the updated articles showed that 17 out of 18 studies reported adequate randomisation procedures, 9 out of 18 used concealed allocation, 10 out of 18 reported withdrawals, in 14 out of 18 researchers were masked to outcomes and in 15 out of 18 ITT analyses were conducted (see *Table 3*).

Overall effectiveness of self-management programmes

We used the data from the original review (up to 2009) to inform our intervention design (*Table 4*). The final column of this table includes the updated meta-analyses. The addition of studies from the updated search made little difference to these findings with the exception that there are more studies reporting depression and those reporting medium- and longer-term results show small effects on most outcomes. The differences in results between 2009 and 2013 showed changes in effect sizes for anxiety (small significant medium effect size in the long term) and social function (in the medium term) (see *Appendix 1* for forest plots).
In summary, these data suggest that the interventions studied have small beneficial effects on global health, pain intensity, physical function, quality of life, anxiety and social function in the short term and sometimes the medium term but that these effects are much reduced in studies reporting longer-term follow-up (beyond 8 months). For quality of life and anxiety, the effects in studies reporting longer-term follow-up remain small rather than 'minor', but closer examination reveals that in each case there was only one small study supplying longer-term follow-up data, raising the possibility of publication bias. For depression the beneficial effects are 'minor' in the short term but small in the medium term; however, there are far fewer studies reporting medium-term (or long-term) effects. Unlike the other outcomes, there appears to be a small beneficial effect on self-efficacy in studies reporting short-, medium- and long-term follow-up.

Effectiveness of the different characteristics of self-management programmes

The data for these analyses come from the studies identified in the original search (1994–2009).

For ease of reading we present the statistically significant SMD effect sizes [with 95% confidence intervals (CIs)] only for data favouring self-management over waiting list control or usual care for each outcome subgroup comparison except for fatigue, SF-36 general mental health and visits to HCPs. Tables showing all of the results are available from the corresponding author.

TABLE 4 Summary of total effect sizes by outcome and follow-up interval for the original systematic review and including the studies from the updated search

Outcome	Follow-up (months)	January 1994–April 2009		January 1994–September 2013	
		Number of participants (number of studies)	Effect size (95% CI)	Number of participants (number of studies)	Effect size (95% CI)
Global health					
Short term	< 4	632 (8)	–0.34 (–0.59 to –0.08)	976 (10)	–0.33 (–0.52 to –0.13)
Medium term	4–8	1082 (7)	–0.46 (–0.73 to –0.19)	1575 (10)[a]	–0.33 (–0.51 to –0.15)
Long term	> 8	1101 (5)	–0.05 (–0.18 to 0.08)	1818 (9)[a]	–0.10 (–0.23 to 0.03)
Pain intensity					
Short term	< 4	2810 (26)	–0.27 (–0.37 to –0.16)	4723 (35)	–0.35 (–0.47 to –0.24)
Medium term	4–8	3911 (20)	–0.25 (–0.38 to –0.12)	6038 (32)[a]	–0.29 (–0.38 to –0.20)
Long term	> 8	3332 (18)	–0.18 (–0.28 to –0.07)	5104 (25)[a]	–0.18 (–0.26 to –0.10)
Physical function					
Short term	< 4	2453 (19)	–0.26 (–0.40 to –0.12)	4093 (26)	–0.31 (–0.44 to –0.18)
Medium term	4–8	3759 (18)	–0.15 (–0.23 to –0.07)	5546 (28)[a]	–0.19 (–0.25 to –0.13)
Long term	> 8	2482 (13)	–0.12 (–0.20 to –0.04)	3980 (19)[a]	–0.14 (–0.22 to –0.06)
Quality of life					
Short term	< 4	258 (2)	–0.40 (–0.65 to –0.15)	258 (2)	–0.40 (–0.65 to –0.15)
Medium term	4–8	399 (2)	–0.11 (–1.05 to 0.82)	665 (4)	–0.14 (–0.55 to 0.27)
Long term	> 8	170 (1)	–0.50 (–0.80 to –0.19)	170 (1)	–0.50 (–0.80 to –0.19)
Self-efficacy					
Short term	< 4	1275 (12)[a]	–0.37 (–0.50 to –0.24)	1173 (15)[a]	–0.38 (–0.52 to –0.25)
Medium term	4–8	1214 (7)	–0.29 (–0.44 to –0.14)	2030 (10)	–0.25 (–0.34 to –0.17)
Long term	> 8	1701 (7)	–0.25 (–0.35 to –0.15)	2173 (8)	–0.23 (–0.31 to –0.14)
Depression					
Short term	< 4	1162 (13)[a]	–0.15 (–0.28 to –0.03)	1743 (15)[a]	–0.15 (–0.24 to –0.05)
Medium term	4–8	597 (4)	–0.25 (–0.47 to –0.03)	1899 (12)[a]	–0.26 (–0.38 to –0.13)
Long term	> 8	641 (3)	–0.04 (–0.26 to 0.18)	1516 (7)[a]	–0.20 (–0.44 to 0.03)

continued

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TABLE 4 Summary of total effect sizes by outcome and follow-up interval for the original systematic review and including the studies from the updated search (*continued*)

Outcome	Follow-up (months)	January 1994–April 2009		January 1994–September 2013	
		Number of participants (number of studies)	Effect size (95% CI)	Number of participants (number of studies)	Effect size (95% CI)
Anxiety					
Short term	< 4	282 (5)	–0.23 (–0.54 to 0.08)	863 (7)	–0.16 (–0.33 to 0.01)
Medium term	4–8	451 (3)	–0.28 (–0.56 to 0.00)	878 (6)	–0.14 (–0.31 to 0.03)
Long term	> 8	50 (1)	–0.28 (–0.84 to 0.27)	553 (3)	–0.41 (–0.58 to –0.24)
Social function					
Short term	< 4	555 (7)	–0.31 (–0.57 to –0.04)	899 (9)	–0.33 (–0.53 to –0.12)
Medium term	4–8	286 (4)	–0.19 (–0.61 to 0.22)	931 (8)[a]	–0.24 (–0.40 to –0.09)
Long term	> 8	205 (2)	0.19 (–0.09 to 0.47)	922 (6)[a]	–0.11 (–0.26 to 0.05)

CI, confidence interval.

a Includes studies with two intervention arms viable for the comparison. Therefore, the number of studies shown contributing to the plot is inflated by $n + 1$ and the total number of participants shown contributing to the plot is inflated by double counting of the control arm. A sensitivity analysis in the original systematic review showed that removing these multiarm studies made no difference to the results and so they have been kept in.

In *Tables 5–7* we present small (≥ 0.2), moderate (≥ 0.5) and large (≥ 0.8) effect sizes for different outcomes at different follow-up intervals. Results that favoured the control arm, favoured neither subgroup, were non-estimable or resulted in minor effect sizes are presented in the accompanying text for each outcome.

Effect sizes for course delivery mode (see *Tables 5–7*)

Of the 46 studies, 27 (59%) involved group interventions, five (11%) remote interventions and five (11%) individually delivered interventions; the remaining nine (20%) used a mixture of both group delivery and individual delivery (see *Table 3*). We assessed the four types of delivery methods against eight outcomes over three time periods, giving a potential of 96 subgroup effect sizes. Twenty-three small to large beneficial effects favouring self-management were found. Only one effect size comparison favoured the control (mixed led, medium term, quality of life: –0.33, 95% CI –0.11 to –0.56). Forty of the subgroup effect sizes showed no difference between self-management interventions and the waiting list control/usual care, seven showed minor (< 0.2) benefits favouring self-management and 48 were non-estimable because of a lack of data. Courses delivered to groups appeared to have the most statistically significant beneficial effects compared with control groups in the short, medium and long term. Data on outcomes for courses delivered to individuals were very sparse. Mixed and remotely delivered interventions may be beneficial but not as much as courses delivered to groups.

Effect sizes for type of course leader (see *Tables 5–7*)

The majority of courses [36/46 (78%)] were delivered by HCPs, with six courses (13%) delivered by a combination of HCPs and laypeople and four courses (9%) delivered by laypeople only (see *Table 3*). Effect sizes were calculated for these three different types of leader combinations. A total of 90 comparisons were made. Small to large beneficial effects sizes were shown favouring self-management in 12 instances and minor benefits (< 0.2) were shown in nine. Thirty-nine subgroup comparisons showed no significant benefit in either study arm and 28 comparisons were non-estimable because of a lack of data. No comparisons favoured the control arm.

TABLE 5 Effect of course delivery methods over short-term follow-up (< 4 months)

	Course delivery mode (95% CI)				Course leader (95% CI)			Course setting (95% CI)			Course duration (95% CI)	
Outcome	Group	Individual	Mixed	Remote	HCP led	Lay led	Mixed	Medical	Community	Occupational	≤ 8 weeks	> 8 weeks
Global health	0.45 (0.17 to 0.73)			0.61[a] (0.07 to 1.15)			0.56 (0.26 to 0.86)	0.42 (0.05 to 0.80)			0.30 (0.03 to 0.58)	0.61[a] (0.07 to 1.15)
Pain intensity	0.24 (0.12 to 0.35)		0.59 (0.03 to 1.15)		0.27 (0.14 to 0.39)			0.28 (0.11 to 0.45)		0.46 (0.11 to 0.81)	0.24 (0.12 to 0.36)	0.22 (0.03 to 0.42)
Physical function	0.25 (0.09 to 0.40)				0.28 (0.10 to 0.47)			0.24 (0.03 to 0.45)	0.21 (0.07 to 0.34)	0.78[a] (0.27 to 1.29)	0.26 (0.10 to 0.41)	
Quality of life	0.40[a] (0.10 to 0.69)				0.40 (0.15 to 0.65)				0.40[a] (0.10 to 0.69)		0.40 (0.15 to 0.65)	
Self-efficacy	0.37 (0.25 to 0.50)				0.38 (0.23 to 0.52)	0.37[a] (0.03 to 0.71)		0.37 (0.07 to 0.66)	0.41 (0.26 to 0.57)		0.39 (0.25 to 0.54)	
Anxiety			0.67[a] (0.17 to 1.18)							0.67[a] (0.17 to 1.18)		
Depression								0.25 (0.04 to 0.46)				
SF-36 social function	0.38 (0.09 to 0.68)						0.51 (0.11 to 0.91)			0.54[a] (0.04 to 1.04)		

a Data from one study only.

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TABLE 6 Effect of course delivery methods over medium-term follow-up (4–8 months)

	Course delivery mode (95% CI)				Course leader (95% CI)			Course setting (95% CI)			Course duration (95% CI)	
Outcome	Group	Individual	Mixed	Remote	HCP led	Lay led	Mixed	Medical	Community	Occupational	≤ 8 weeks	> 8 weeks
Global health	0.54 (0.21 to 0.88)				0.67 (0.20 to 1.15)			0.54 (0.22 to 0.87)			0.36 (0.12 to 0.6)	1.08[a] (0.52 to 1.64)
Pain intensity	0.25 (0.02 to 0.47)	0.20 (0.02 to 0.37)	0.29[a] (0.06 to 0.51)	0.22 (0.12 to 0.32)				0.24 (0.01 to 0.47)			0.25 (0.08 to 0.42)	
Physical function			0.26 (0.09 to 0.44)									
Quality of life	0.62[a] (0.09 to 1.15)								0.62[a] (0.09 to 1.15)			0.62[a] (0.09 to 1.15)
Self-efficacy	0.29 (0.08 to 0.50)			0.29[a] (0.13 to 0.44)	0.37 (0.16 to 0.59)				0.30 (0.09 to 0.52)		0.27 (0.11 to 0.43)	
Anxiety			0.25[a] (0.02 to 0.48)						0.65[a] (0.12 to 1.19)			0.65[a] (0.12 to 1.19)
Depression												0.76[a] (0.22 to 1.30)
SF-36 social function												

a Data from one study only.

TABLE 7 Effect of course delivery methods over long-term follow-up (≥ 8 months)

	Course delivery mode (95% CI)				Course leader (95% CI)			Course setting (95% CI)			Course duration (95% CI)	
Outcome	Group	Individual	Mixed	Remote	HCP led	Lay led	Mixed	Medical	Community	Occupational	≤ 8 weeks	> 8 weeks
Global health												
Pain intensity	0.20 (0.04 to 0.36)							0.26 (0.15 to 0.36)				0.23 (0.03 to 0.42)
Physical function												
Quality of life	0.50[a] (0.19 to 0.80)				0.50[a] (0.19 to 0.80)				0.50[a] (0.19 to 0.80)		0.50[a] (0.19 to 0.80)	
Self-efficacy	0.23 (0.10 to 0.35)			0.29[a] (0.13 to 0.44)	0.25 (0.10 to 0.40)	0.29[a] (0.13 to 0.44)		0.26 (0.01 to 0.52)	0.23 (0.11 to 0.36)	0.39[a] (0.02 to 0.76)	0.26 (0.14 to 0.37)	0.23 (0.04 to 0.42)
Anxiety												
Depression												
SF-36 social function												

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Health-care professional-led self-management courses showed beneficial effects in the short, medium and long term over a range of outcomes. Lay-led courses had a small, statistically significant beneficial effect on self-efficacy only. Mixed HCP- and lay-delivered courses showed moderate to large benefits for SF-36 social function scores and global health status, but data for several comparisons were sparse with some effect sizes obtained from only one study.

Effect sizes for course setting (see *Tables 5–7*)

Twenty-seven (59%) studies were conducted in medical settings, 16 (35%) in community settings and three (7%) in occupational settings. A total of 90 comparisons were made. Small to large beneficial effects favouring self-management were shown for 22 subgroup analyses, with one comparison favouring the control (medical setting, medium term, quality of life: –0.33, 95% CI –0.11 to –0.56). In 31 comparisons there was no difference between the study arms, five comparisons showed minor benefits (< 0.2) for self-management and 28 comparisons were non-estimable because of a lack of data.

Pain intensity was significantly improved at all three follow-up time points in the studies conducted in medical settings but not in the studies in community settings.

Self-efficacy showed small to moderate statistically significant improvements favouring self-management in medical and community settings at most time intervals. Data for self-efficacy for self-management courses in an occupational setting were sparse. Physical function appeared to show statistically significant effect sizes favouring self-management in medical, community and occupational settings in the short term. Overall, medical and community settings had better outcomes than occupational or remote settings but there were too few studies in occupational settings to draw firm conclusions.

Effect sizes for course duration (see *Tables 5–7*)

Two course duration periods were assessed: ≤ 8 weeks and > 8 weeks. A total of 60 comparisons were made. Around one-third of the comparisons (18/48) showed small to large beneficial effects favouring self-management. However, one comparison favoured the control (< 8 weeks, medium term, quality of life: –0.33, 95% CI –0.11 to –0.56). All other subgroup analyses showed no benefit for either arm or minor benefits for self-management (25/48), or were non-estimable because of a lack of data (5/48).

Small to moderate statistically significant beneficial effect sizes were shown for a mix of outcomes for both short and longer durations of self-management courses at all time intervals. Statistically significant effect sizes did not appear to be enhanced by increased duration of courses.

Effectiveness of the different components of self-management programmes

In *Tables 8–13* we present small (≥ 0.2), moderate (≥ 0.5) and large (≥ 0.8) effect sizes for different outcomes at different follow-up intervals. Results that favoured the control arm, favoured neither subgroup, were non-estimable or resulted in minor effect sizes are presented in the accompanying text.

Effectiveness of self-management courses that include a psychological component (see *Tables 8–10*)

Only eight (17%) of the interventions in the included studies did not have a psychological component. A total of 48 comparisons were made, 21 of which showed no differences or minor effect sizes of < 0.2 between self-management and control. Eleven of the comparisons were non-estimable because of a lack of data. For interventions that included a psychological component we found small statistically significant effect sizes favouring self-management for pain intensity, physical/functional capability, SF-36 social function and self-efficacy for both short- and medium-term follow-up and there was evidence of benefit in the long term for self-efficacy but not for the other outcomes. There was no evidence that depression improved significantly for interventions with a psychological component although at medium-term follow-up anxiety was improved compared with the control groups. There was little evidence to support self-management interventions without a psychological component but most comparisons, except for pain, physical/functional capability and self-efficacy, had only one study or none at all examining this subgroup.

TABLE 8 Effect of inclusion of different types of components over short-term follow-up (< 4 months)

	Psychological (95% CI)		Lifestyle (95% CI)		Medical education (95% CI)		Physical activity (95% CI)		Mind–body therapies (95% CI)	
Outcome	With	Without	With	Without	With	Without	With	Without	With	Without
Global health		0.53 (0.18 to 0.88)	0.29 (0.02 to 0.56)	0.69[a] (0.15 to 1.24)	0.30 (0.03 to 0.58)	0.61[a] (0.07 to 1.15)	0.34 (0.02 to 0.66)			0.48 (0.24 to 0.72)
Pain intensity	0.28 (0.16 to 0.41)		0.20 (0.09 to 0.32)	0.36 (0.10 to 0.62)	0.21 (0.09 to 0.33)	0.38 (0.17 to 0.59)	0.23 (0.11 to 0.35)	0.28 (0.04 to 0.51)	0.21 (0.06 to 0.36)	0.28 (0.12 to 0.44)
Physical function	0.34 (0.18 to 0.50)		0.22 (0.04 to 0.39)	0.36 (0.17 to 0.55)		0.24 (0.10 to 0.38)	0.22 (0.08 to 0.36)	0.65 (0.28 to 1.02)		0.24 (0.10 to 0.38)
Quality of life	0.40[a] (0.10 to 0.69)		0.40 (0.15 to 0.65)		0.40[a] (0.10 to 0.69)		0.40 (0.15 to 0.65)		0.40[a] (0.10 to 0.69)	
Self-efficacy	0.41 (0.25 to 0.56)		0.41 (0.24 to 0.57)	0.31 (0.09 to 0.52)	0.35 (0.21 to 0.48)	0.56 (0.18 to 0.94)	0.39 (0.25 to 0.52)		0.42 (0.17 to 0.67)	0.35 (0.19 to 0.51)
Anxiety					0.36 (0.04 to 0.67)			0.51 (0.14 to 0.88)		0.39 (0.09 to 0.70)
Depression										
SF-36 social function	0.35 (0.05 to 0.65)		0.35 (0.05 to 0.65)					0.48 (0.11 to 0.84)		0.39 (0.12 to 0.66)

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TABLE 9 Effect of inclusion of different types of components over medium-term follow-up (4–8 months)

	Psychological (95% CI)		Lifestyle (95% CI)		Medical education (95% CI)		Physical activity (95% CI)		Mind–body therapies (95% CI)	
Outcome	With	Without	With	Without	With	Without	With	Without	With	Without
Global health	0.45 (0.10 to 0.79)	0.52 (0.10 to 0.95)	0.42 (0.13 to 0.70)	0.77[a] (0.22 to 1.32)	0.51 (0.17 to 0.85)		0.46 (0.19 to 0.73)		0.33 (0.01 to 0.65)	0.67 (0.26 to 1.09)
Pain intensity	0.29 (0.11 to 0.48)	0.22 (0.11 to 0.33)	0.22 (0.09 to 0.35)		0.22 (0.09 to 0.35)		0.20 (0.08 to 0.33)			0.30 (0.05 to 0.55)
Physical function	0.21 (0.12 to 0.30)			0.25 (0.06 to 0.44)						
Quality of life										
Self-efficacy	0.30 (0.09 to 0.52)		0.23 (0.06 to 0.40)	0.46 (0.20 to 0.73)	0.26 (0.12 to 0.40)	0.58[a] (0.16 to 1.00)	0.29 (0.14 to 0.44)			0.36 (0.17 to 0.55)
Anxiety	0.38 (0.01 to 0.74)		0.31 (0.11 to 0.50)						0.38 (0.01 to 0.74)	
Depression					0.25 (0.03 to 0.47)		0.25 (0.03 to 0.47)			
SF-36 social function	0.38 (0.09 to 0.67)		0.38 (0.09 to 0.67)						0.38 (0.09 to 0.67)	

a Data from one study only.

TABLE 10 Effect of inclusion of different types of components over long-term follow-up (≥ 8 months)

	Psychological (95% CI)		Lifestyle (95% CI)		Medical education (95% CI)		Physical activity (95% CI)		Mind–body therapies (95% CI)	
Outcome	With	Without	With	Without	With	Without	With	Without	With	Without
Global health										
Pain intensity										0.20 (0.07 to 0.34)
Physical function										
Quality of life	0.50[a] (0.19 to 0.80)		0.50[a] (0.19 to 0.80)		0.50[a] (0.19 to 0.80)		0.50[a] (0.19 to 0.80)		0.50[a] (0.19 to 0.80)	
Self-efficacy	0.25 (0.15 to 0.34)		0.22 (0.12 to 0.33)	0.45 (0.16 to 0.73)	0.24 (0.14 to 0.33)	0.52[a] (0.09 to 0.96)	0.25 (0.15 to 0.35)		0.23 (0.13 to 0.33)	0.47 (0.13 to 0.81)
Anxiety										
Depression										
SF-36 social function										

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Effectiveness of self-management courses that include a lifestyle component (see *Tables 8–10*)

We included a variety of elements for the lifestyle component such as sleep management, relationship advice, diet advice, ergonomic guidance for return to work and stress management. Seven (15%) of the included studies involved an intervention that did not include a lifestyle component. A total of 48 comparisons were made, 17 of which showed no differences or minor effect sizes of < 0.2 between self-management and control. Ten of the comparisons were not estimable because of a lack of data. Overall, there was no discernible difference in the effect on self-efficacy, physical/functional capability, depression or global health status between interventions with and those without a lifestyle component.

Effectiveness of self-management courses that include a medical education component (see *Tables 8–10*)

Thirty-five (76%) of the interventions included a medical education component. A total of 48 comparisons were made, 21 of which showed no differences or minor effect sizes of < 0.2 between self-management and control. Ten of the comparisons were not estimable because of a lack of data. There was some evidence in favour of a medical education component with regard to anxiety in the short term and pain intensity and depression in the medium to long term. Significant moderate benefits in terms of self-efficacy were noted compared with control groups in interventions *without* an educational component in the short term and in medium- and long-term single studies. Data for many comparisons were very sparse.

Effectiveness of self-management courses that include a physical activity component (see *Tables 8–10*)

A total of 48 comparisons were made, 18 of which showed no differences or minor effect sizes of < 0.2 between self-management and control. Twenty of the comparisons were not estimable because of a lack of data. Only six (13%) of the included studies involved an intervention that did not include a physical activity component. Interventions that included a physical activity component showed some small statistically significant effect sizes favouring self-management for the following outcomes: pain intensity (medium term), self-efficacy (short term), SF-36 general mental health (short term) and global health status (short term).

Most comparisons were limited by having only one study or no studies without a physical activity component.

Effectiveness of self-management courses that include a mind–body therapy component (see *Tables 8–10*)

Twenty-six (57%) of the included studies involved a mind–body therapy component. A total of 48 comparisons were made, 23 of which showed no differences or minor effect sizes of < 0.2 between self-management and control. Six of the comparisons were not estimable because of a lack of data. We found no discernible patterns with regard to the effect of including mind–body therapy in self-management interventions. In the short term, interventions that did not include mind–body therapy showed small significant benefits over a wide range of outcomes compared with control groups. In the medium term the picture was mixed, with small benefits over control groups seen for different outcomes both for interventions with a mind–body therapy component and those without. Depression consistently failed to improve with self-management, irrespective of whether or not the course included mind–body therapy.

Effect of the number of components included in self-management courses (see *Tables 11–13*)

We could potentially have estimated a total of 96 effects. No studies were available to estimate nine of these effects. Sixty-one of these comparisons showed no differences or minor effect sizes of < 0.2 between self-management and control. When the effect estimates were > 0.2, increasing the number of components present in self-management courses from two through to five did not appear to have an overall beneficial effect on any outcome measure.

TABLE 11 Effect of number of components over short-term follow-up (< 4 months)

Outcome	Two components (95% CI)	Three components (95% CI)	Four components (95% CI)	Five components (95% CI)
Global health	0.65 (0.27 to 1.04)		0.77[a] (0.16 to 1.38)	
Pain intensity	0.37 (0.15 to 0.59)	0.23 (0.03 to 0.42)		
Physical function	0.37 (0.19 to 0.55)		0.37 (0.07 to 0.67)	
Quality of life				0.40[a] (0.10 to 0.69)
Self-efficacy	0.42[a] (0.03 to 0.81)	0.28 (0.10 to 0.47)	0.50 (0.04 to 0.96)	0.43 (0.15 to 0.72)
Anxiety		0.67[a] (0.17 to 1.18)		
Depression				
SF-36 social function		0.54[a] (0.04 to 1.04)	0.63[a] (0.03 to 1.23)	

a Data from one study only.

TABLE 12 Effect of number of components over medium-term follow-up (4–8 months)

Outcome	Two components (95% CI)	Three components (95% CI)	Four components (95% CI)	Five components (95% CI)
Global health	0.77[a] (0.22 to 1.32)			
Pain intensity	0.32 (0.06 to 0.59)		0.63 (0.11 to 1.16)	
Physical function	0.21 (0.01 to 0.42)			
Quality of life				
Self-efficacy	0.58[a] (0.16 to 1.00)	0.30 (0.08 to 0.52)		
Anxiety				0.38 (0.01 to 0.74)
Depression				
SF-36 social function				

a Data from one study only.

TABLE 13 Effect of number of components over long-term follow-up (> 8 months)

Outcome	Two components (95% CI)	Three components (95% CI)	Four components (95% CI)	Five components (95% CI)
Global health				
Pain intensity			0.36 (0.20 to 0.52)	
Physical function				
Quality of life				0.5[a] (0.19 to 0.80)
Self efficacy	0.52[a] (0.09 to 0.96)		0.39[a] (0.02 to 0.76)	0.22 (0.11 to 0.32)
Anxiety				
Depression				
SF-36 social function				

a Data from one study only.

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Discussion

Effectiveness of self-management programmes

This review identified 64 studies (65 papers) providing usable final-value outcome data for meta-analysis. Overall, it showed 'small' statistically significant effect sizes in the short term (< 4 months) for pain intensity, physical/functional capability, self-efficacy, SF-36 general mental health, global health status and SF-36 social role. These effect sizes became 'minor' (SMD < 0.2) and/or statistically insignificant in the medium term (4–8 months) and long term (≥ 8 months) for all outcomes except for self-efficacy (small statistically significant effect size for all time intervals) and global health status (small statistically significant effect size for medium-term follow-up).

Course content and components

We examined the effect of individual course components by comparing effect sizes for interventions with certain components and interventions without these components. This approach was hampered by few interventions *not* having the component of interest, in particular psychological and physical components.

Overall, the evidence suggested that:

- Increasing the number of components does not necessarily equate to improved effectiveness.
- There is strong evidence for beneficial effects of psychological components but the content and mode of delivery to optimise effect is unknown.
- Any exercise can be recommended as long as the exercise is carried out regularly and is within the capability of the individual. Initial exercise advice should be given on an individual basis but physical activity can then be conducted in a group and/or supervised setting to encourage adherence.
- Education and mind–body therapies are better placed as adjunct rather than stand-alone therapies. Education should inform patients about their condition, managing their medication and self-management strategies that can have positive effects on lifestyle.
- Of the mind–body therapies, the strongest positive evidence appears to be for relaxation.

Course delivery

The evidence suggested that group delivery was effective. Some cognitive–behavioural elements or personalised exercise plans may be more effectively deployed on an individual basis but should perhaps be discussed or practised as part of a group session.

Other reviews have found that individual classes[127] were best or that individual, group and home-based exercises were all equally effective.[128] Guidelines on exercise[129] recommend both individual structured and group approaches to exercise. In addition, another study suggested that a group lecture format was most effective for delivering education.[130]

Course leader

The evidence suggested that HCP-led courses were most effective, although there was also some evidence for lay-led or mixed courses. We found limited evidence (three studies) to suggest that lay leaders are as effective as HCPs.

Our subgroup comparison between HCP-, lay- and mixed-led courses showed that HCP-led content produced small but significant effect sizes mainly in the short term There was some evidence for the effectiveness of lay-led courses for pain, physical/functional capability and self-efficacy but the effect sizes were either < 0.2 or the data were obtained from one study only.

Two other reviews[52,127] have found that HCP-supervised or -monitored programmes were most effective.

Course setting

The evidence suggested that the effects of setting were varied. Our subgroup analysis showed that the medical setting and community settings were favoured compared with occupational and remote settings.

One review[113] suggested that a 'back school' in an occupational setting was effective, whereas another review[131] felt that programmes should be conducted in primary care (UK). One review examining web-based CBT[132] found that 'live' internet sessions had the lowest dropout rate and that internet-delivered self-management material showed promise, especially for people with limited mobility. Self-management material available online may help to support participants during and after courses and provide a virtual forum to complement any friendships formed during the group sessions.

Course duration

The evidence suggested that shorter courses were as effective as longer ones (and were likely to be more cost-effective).

Other evidence from studies reviewing course duration is equivocal, with one review finding increased effectiveness for courses > 100 hours[133] and another suggesting that longer courses (3–6 months) are too costly and impractical to implement[134] and that, in a subgroup analysis, there is no evidence of a difference in effectiveness between courses of $\geq$ 30 hours and courses of < 30 hours.

In summary, therefore, we found that shorter courses were as effective as longer ones and that multicomponent courses were not necessarily more effective than those with two or three components; however, we found weak or no evidence that self-management courses reduce the number of health-care visits. Solely HCP-led courses were more beneficial for pain outcomes but would be more expensive to run than lay courses. A mixed-led approach is probably more viable. Using a digital versatile disk (DVD) of a pain consultant delivering an education component instead of being there in person, or perhaps having some psychological material delivered by a student psychologist rather than a consultant, may be a worthwhile alternative. Group and individual sessions were found to be effective, although individual sessions are more labour intensive and are therefore more likely to be expensive. Self-management courses delivered in a community setting may be less expensive than those delivered in a primary care venue. If any remotely delivered online material for use as a supporting or follow-up aid is included then the costs of website design and maintenance, website hosting and forum moderation would need to be considered.

Study limitations

Internal validity: study bias

Unfortunately, because of time constraints, it was not possible to write to the study authors to clarify their methods or seek more data.

Although the funnel plot and metabias test suggested that there was no publication bias, the low number of studies ($n = 26$) and uncertainty about the appropriateness of the metabias test for SMDs of continuous outcomes make these conclusions tentative. We also found very few studies that showed negative effects of self-management programmes and we did not consider literature in any other language than English and so there is a possibility of publication bias.

Treatment of the control groups

We acknowledge that 'usual care' (the control condition in most of the studies included in this review) can vary markedly from setting to setting and is often very poorly described in publications. Thus, there is likely to have been considerable heterogeneity in the treatment received across the control groups.

Multiple testing

We made no adjustment for multiple testing. We are aware that some of the positive associations that we report may have arisen by chance as a result of the large number of tests conducted.

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Component analysis framework

We employed a subjective approach to categorising studies into component categories for our subgroup meta-analysis. It was sometimes difficult to distinguish the component elements from the intervention descriptions and so there is an amount of subjectivity involved. We found that descriptions for CBT or psychological interventions included elements from our psychological component framework and our mind–body therapies component framework. It may have been more meaningful to group psychological and mind–body therapies together.

We used the SMD to combine the results from different outcome measurement tools, using Cohen's *d*[63,64] as a measure of effect size. We are cognisant of the difficulties with interpretation of Cohen's scale in a clinical setting.

We expected a high degree of heterogeneity because of the variation in self-management courses and particularly the variation between subgroups, with studies being subjectively grouped according to number and type of components. We found moderate to substantial heterogeneity for most outcomes, with a small statistically significant effect size, except for self-efficacy, which had < 25% heterogeneity across all time intervals.

Our subgroup analyses did not completely resolve heterogeneity for all subgroups. Although some subgroups showed an I^2 value of 0%, some comparator subgroups had very few studies and so it was difficult to draw any conclusions from these patterns.

Overall conclusions

Our meta-analysis echoed the findings from previous systematic reviews, showing that self-management courses produce small statistically significant beneficial effects in the short term for outcomes such as pain intensity and physical/functional capability, but that these effects are not maintained into the longer term.

We found that increasing the number of self-management components and number of sessions did not necessarily result in increased effectiveness, which has implications for costs. We found strong evidence of effectiveness for courses including a psychological course component and encouraging evidence for courses delivered to groups. There was some limited evidence of beneficial effects for mind–body techniques and medical education, and these are best provided as an adjunct.

The ways in which the findings of the systematic review influenced the design of the intervention are described fully in *Chapter 6*.

Chapter 3 Identifying who is likely to respond to self-management programmes for chronic musculoskeletal pain

Abstract

Introduction: Establishing the characteristics of groups of people who are likely to gain the most benefit from self-management interventions is important but, as yet, this has not been accomplished.

Aim: The aim of this systematic review was to examine the evidence for predictors, moderators and mediators of patient outcomes, as reported in RCTs of self-management support for people with chronic musculoskeletal pain.

Methods: We searched relevant electronic databases for RCTs and systematic reviews that measured and reported baseline measures and analysed them in relation to interventions and outcomes. We assessed the evidence according to the methodological strengths of the studies. We carried out meta-regression analyses for age and gender, as potential moderators.

Results: Most of the studies were compromised by lack of power for moderator and mediator analyses. There was evidence that self-efficacy and depression at baseline predict outcome and evidence that pain catastrophising and physical activity can mediate outcome from self-management. There was no clear evidence on moderators.

Conclusions: Although the current evidence is scarce, it suggests that the development of interventions should include careful consideration of self-efficacy, depression, physical activity and catastrophising.

Introduction

In this chapter we review the available evidence indicating which type, or types, of people may benefit most from self-management courses for chronic pain. Specifically, we reviewed the literature identifying predictors, moderators and mediators of the effects of self-management interventions.

We used a systematic review approach to identify:

- RCTs of self-management for chronic musculoskeletal pain that reported subgroup analyses looking at predictors, moderators and mediators in different subgroups of patients
- RCTs of self-management for chronic musculoskeletal pain that included data on treatment moderation suitable for a meta-regression.

Definitions

The definitions of predictors, moderators and mediators have been refined in recent years. We adopted the approach of Kraemer *et al.*[32] in which three types of subgroups are described and clearly defined:

Predictors of treatment outcome are defined as baseline variables that affect outcome (significant main effect only) but do not interact with treatment. Such factors significantly predict outcome equally for target interventions and control conditions.

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Effect moderators (or *moderators*) are variables measured at baseline (such as patient baseline characteristics) that interact with treatment to change outcomes. The interaction should be related to outcome in the linear model with or without a main effect. These specify for whom and under what conditions treatment works and can improve power in subsequent trials by better selection of target groups for stratification.

Mediators are variables measured during treatment (such as change-in-process factors) that impact on outcome, with or without interaction with treatment. Mediators help inform the process and potential mechanisms (including causal mechanisms) through which treatment might work. They can be used to improve subsequent interventions through strengthening the components that best influence the identified mediators. Mediators should not be a component of the treatment or outcome. There should be a clear distinction between the constructs measured by the proposed mediators and treatment outcome.

Predictors and moderators may include:[31,32,42]

- demographic status [age, gender, education, marital status, lifestyle (alcohol consumption, exercise, smoking)]
- clinical status (e.g. disability, duration of pain, pain intensity)
- psychological status (e.g. catastrophising, depression, fear avoidance and beliefs)
- work-related factors [e.g. employment status, type of work, reasons for not working, number of sick days taken over previous year, financial factors (pending compensation, sickness benefit, insurance and duration on current benefits), job satisfaction, social support at work, a sense of control at work]
- medication history.

Methods

Studies were identified as an eligible subset of those identified in *Chapter 2*.

Quality assessment of included studies

For the overall quality of the papers we used the assessment carried out for the review of main effects. Early in the project we sought established methodological criteria for the assessment of subgroup analyses within RCTs. We were unable to identify any such criteria suitable for our purpose. Consequentially, as part of this programme of work we carried out a literature review and Delphi study to determine a consensus on methodological criteria for the evaluation of studies reporting moderator analyses within RCTs. We used these assessment criteria to assess the quality of our moderator studies and grade the evidence for moderators.[135]

We applied the following criteria to included papers:

1. Was there an a priori specification of the subgroup?
2. Was there a theoretical or an evidence-based rationale for the selection of subgroup factors?
3. For moderator and predictor analyses only: was the measurement of subgroup factors carried out prior to randomisation?
4. Was the measurement of subgroup factors adequate (reliable and valid) and appropriate for the target population?
5. For moderator and mediator analyses only: does the analysis contain an explicit test of the interaction between subgroups and treatment?

Papers were classified as providing either confirmatory findings or exploratory findings. Confirmatory findings refer to studies that include a priori hypotheses in relation to subgroups, for which support was obtained through adequate statistical testing. Exploratory findings inform future research (hypothesis generating) and are the product of post hoc testing. Only studies that satisfied all of the above five criteria

relevant to the analysis were regarded as providing confirmatory evidence. Papers satisfying criteria 3–5 were categorised as exploratory findings. Studies that did not satisfy these criteria were regarded as having insufficient findings. For this review we applied these same criteria to predictor and mediator analyses as appropriate.

We included any RCTs identified in the searches in *Chapter 2* that reported predictor, moderator or mediator analyses. For selected RCTs that did not report any subgroup analyses but which had ≥ 80% completion rates for their primary analysis and > 200 participants in each arm, the authors were contacted and asked if they had carried out, or were now able to carry out, such analyses. We also contacted authors when any aspects of their reported subgroup analyses were unclear.

Data extraction

We extracted the following data from each RCT:

- country and setting
- population: brief description of participants, including size of eligible population identified and actual uptake
- intervention/control
- baseline factors measured
- outcomes measured
- description of predictor, moderator and mediator analyses
- results of predictor, moderator and mediator analyses.

Finally, an independent statistician scrutinised the included studies to determine whether or not there were appropriate data to include in the meta-regression and whether any moderator or mediator analyses were carried out appropriately. The statistician checked for the presence of a reported power calculation; whether there were any statistician authors or whether the authors described seeking statistical advice; and the statistical methods used and the quality of reporting, paying particular attention to moderator and mediator analyses. We also conducted a meta-regression to identify potential moderators. We included any RCTs identified in our original search (see *Chapter 2*) whose final-value data were suitable for inclusion in a meta-regression. For all potential moderators reported in ≥ 10 studies we performed a random-effects meta-regression.[39] We collapsed outcomes into the following domains: pain intensity, physical/functional capability, self-efficacy, depression and global health status. When a variety of measurement tools had been reported for a domain, we calculated SMDs (difference in mean outcome between groups/SD of outcome among participants).[39] To make the best use of the available data, and reduce the possibility of making a type 1 error, we collapsed the different follow-up time points (early and late) to obtain one average effect size per outcome. We considered results from the meta-regression to be statistically significant if $p < 0.10$. We used this criterion because of a potential type II error as a result of the limited number of studies in these effect size calculations.[42,136] We used an I^2 statistic to estimate the percentage of residual variation attributable to between-study heterogeneity and an adjusted R^2 statistic to estimate the proportion of between-study variance explained by the covariate. We produced scatter diagrams using circles as plotting symbols in which the areas of the circles indicated the value of a third variable.[137] We fitted values and predicted random effects against age and gender separately, with 95% confidence.

Results

Of the 126 RCTs that looked at self-management programmes, a total of 20 articles[67,75,93,104,107,110,138–151] covering 16 studies ($n = 4047$) met our inclusion criteria and included appropriate analyses of predictors, moderators or mediators. In addition, 46 of 126 studies met our criteria for meta-regression to identify potential treatment moderators.

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Of the 16 studies, five were from the USA,[93,104,138–140] four were from the Netherlands,[93,141–143] two each were from Canada,[107,144] Norway[75,145] and Sweden[146,147] and one was from the UK.[67]

Methodological quality

In the first instance we applied quality assessment criteria to the trial methodology, using criteria adapted from The Cochrane Collaboration methods[39] and described in *Chapter 2*. We independently analysed and coded each publication separately, even though some studies were further analyses of previously published RCTs; hence, in *Table 14* we present the quality appraisal for 20 reports covering 16 studies.[67,75,93,104,107,110,138–151] Nine RCTs were of high quality, six were of medium quality[104,110,138,139,145,148] and one was of low quality.[146] Eight of the subgroup studies provided confirmatory evidence, one study provided exploratory evidence[93] and seven studies provided insufficient evidence. For subgroup analyses we applied the criteria described in *Quality assessment of included studies*. Only three studies[67,107,142] used high-quality trial methodology and carried out preplanned theoretically driven subgroup analysis, using correct statistical analysis. However, there were no two trials in this category (for any predictors, moderators and mediators) that examined the same subgroup.

We did not find any high-quality studies appropriately reporting moderator analyses.

Predictors

Hurley *et al.*[67] found that higher levels of depression at baseline predicted poorer physical functioning at 6 months in people with chronic knee pain (effect size 0.48; $p = 0.011$), whereas higher levels of self-efficacy at baseline, measured by positive exercise beliefs (effect size –0.24; $p = 0.001$) and confidence in the ability to exercise (effect size –0.62; $p = 0.001$), predicted better physical functioning at 6 months, regardless of intervention arm.

Mediators

Smeets *et al.*[142] found that reduced levels of pain catastrophising during treatment led to a post-treatment decrease in patient-specific complaints, disability and pain in people with chronic low back pain. Patients in the intervention group scored, on average, 1.3 points lower for disability (out of 24) than patients in the control arm, after adjusting for pain catastrophising. For current pain, the difference was 4.7 units on a visual analogue scale (out of 100). For patient complaints, the difference was 6.7 (out of 100).

Laforest *et al.*[107] reported that increases in physical activity mediated greater decreases in helplessness in people with arthritis; however, the data were not available to quantify this effect. This effect was defined by Laforest *et al.*[107] as a moderator, although from the authors' description it is a mediator. Because of these limitations, we recommend that the findings for the mediating effects of physical activity be reviewed with caution.

Meta-regression to identify potential moderators

All RCTs identified from the original search that supplied full data on age and gender at baseline against at least one of our selected outcomes were included ($n = 46/126$).

We used bivariable meta-regression to determine whether or not the baseline characteristics (age and gender) explained the variation in treatment outcomes. Age and gender were selected because they are the most frequently reported demographic characteristics.[39] They were the only variables reported in at least 10 studies.

For one outcome, general mental health, a single measurement tool had been used, the SF-36.[62] We intended to combine the data as a weighted mean difference but because of anomalies in score values between studies we judged that SMD analyses would be more robust. A variety of measurement tools was reported for each domain; for these we also calculated SMDs.

TABLE 14 Quality assessment of the included studies: predictors, moderators and mediators

Study	1. Was the analysis a priori?	2. Was selection of factors for analysis theory/evidence driven?	3. Were subgroups measured prior to randomisation?	4. Adequate quality of measurement of baseline factors?	5. Contains an explicit test of the interaction between subgroup and treatment (e.g. regression)?	Strength of evidence[a]	Quality of underlying trial
Gallagher 1997[138]	Yes	Yes	NA, gender as moderator	Yes	Yes	Confirmatory	Medium
Haas 2005[93]	No	No	Yes	Yes	Yes	Exploratory	High
Haldorsen 1998[75]	No	No	Yes	Yes	Unclear	Insufficient	High
Haugli 2000[145]	Yes	Yes	Unclear	Yes	Yes	Confirmatory	Medium
Haugli 2003[148]	Yes	Yes	Unclear	Yes	Yes	Confirmatory	Medium
Heapy 2005[140]	Yes	Yes	Yes	Yes	No	Insufficient	High
Hurley 2007[67]	Yes	Yes	NA, cluster randomisation	Yes	Yes	Confirmatory	High
Jensen 2001[147]	Yes	Yes	NA, gender as moderator	Yes	No	Insufficient	High
Jensen 2005[149]	Yes	Yes	NA, gender as moderator	Yes	No	Insufficient	High
Kole-Snijders 1999[141]	Yes	No	No	Yes	Yes	Insufficient	High
Laforest 2008[107]	Yes[b]	Yes	Yes	Yes	Yes	Confirmatory	High
Lemstra 2005[144]	No	No	Unclear	Yes	No	Insufficient	High
Lindh 1997[146]	Yes	Yes	NA, demographic moderators	Yes	No	Insufficient	Low
Lorig 2002[139]	Yes	Yes	Yes	Yes	No	Insufficient	Medium

continued

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TABLE 14 Quality assessment of the included studies: predictors, moderators and mediators (*continued*)

Study	1. Was the analysis a priori?	2. Was selection of factors for analysis theory/evidence driven?	3. Were subgroups measured prior to randomisation?	4. Adequate quality of measurement of baseline factors?	5. Contains an explicit test of the interaction between subgroup and treatment (e.g. regression)?	Strength of evidence[a]	Quality of underlying trial
Martire 2007[104]	Yes	Yes	NA, demographic moderators	Yes	Yes	Confirmatory	Medium
Nour 2006[150]	Yes	Yes	Yes	Yes	Unclear	Insufficient	High
Smeets 2006[142]	Yes	Yes	Yes	Yes	Yes	Confirmatory	High
Spinhoven 2004[151]	Yes	Yes	No	Yes	Yes	Insufficient	High
van der Hulst 2008[110]	Yes	Yes	Yes	Yes	Yes	Confirmatory	Medium
Veenhof 2007[143]	Yes[b]	Yes	NA, cluster randomisation	Yes	Yes[c]	Confirmatory	High

NA, criterion could not be applied either because the subgroups of interest were not modifiable (e.g. age or sex) or because of cluster randomisation.

a 'Confirmatory' findings come from studies that report an a priori specified analysis plan based on statistical theory/evidence. 'Explanatory' findings are those findings that are used to inform trials and future research; these are often post hoc analyses and/or hypotheses generating.

b Analysis is weak because of multiple testing.

c The significant findings were from the exploratory analysis only.

Forty-six studies were included in the meta-regression and eight in the 16 subgroup meta-regressions. Gender was significantly associated with effect size for SF-36 general mental health and global health status, indicating that self-management interventions were more effective for groups with a higher proportion of females (all $p < 0.10$ and $p \geq 0.05$) (*Table 15*). Inspection of bubble graphs (see *Appendix 2, Meta-regression*) suggested a positive association between studies with an increasing proportion of males (note that a fall in measures indicated improvement in our analyses). Gender was not statistically significantly associated with effect size for pain intensity, physical/functional capability, self-efficacy or depression. Age was associated with effect size for physical/functional capability and self-efficacy (all $p < 0.10$ and $p > 0.05$). The bubble graphs (see *Appendix 2, Meta-regression*) suggested a positive association between effect size and these outcomes, indicating that self-management interventions might be more effective in younger samples. Age was not associated with effect sizes for the other outcomes.

Discussion

Summary of findings for predictors, moderators and mediators

There were only three studies with sufficient methodological rigour, including a priori planned subgroup analysis, to inform on predictors and mediators. The findings from these studies suggest that high levels of depression at baseline are associated with lower function and that self-efficacy, especially about the ability to exercise, is associated with improved function 6 months later, regardless of any intervention.[67] There was also evidence that reduction in catastrophic thinking directly after the intervention was associated with improved function 6 months later.[142] Finally, engaging in exercise during the intervention was associated with better function at outcome.[107]

TABLE 15 Meta-regression results for age and proportion of male participants as moderators[a]

Measure	Studies (sample size), *n*	Moderator	I^2 (%)	Regression coefficient	95% CI for regression coefficient	*p*-value
Pain intensity	39 (6067)	Proportion male	47.7	–0.0006	–0.0062 to 0.0051	0.840
Functional capability	27 (4790)	Proportion male	51.8	–0.0019	–0.0084 to 0.0047	0.560
Self-efficacy	17 (2576)	Proportion male	32.4	–0.0017	–0.0115 to 0.0082	0.732
Depression	16 (1902)	Proportion male	24.2	–0.0025	–0.0108 to 0.0058	0.533
SF-36 general mental health	11 (1117)	Proportion male	51.6	0.0097	–0.0021 to 0.0214	0.095[b]
Global health status	14 (1801)	Proportion male	59.1	0.0114	–0.0003 to 0.0230	0.055[b]
Pain intensity	39 (6012)	Age	43.1	0.0004	–0.0114 to 0.0121	0.116
Functional capability	28 (4873)	Age	45.8	0.0078	–0.0008 to 0.0164	0.074[b]
Self-efficacy	17 (2576)	Age	17.3	0.0081	–0.0004 to 0.0165	0.060[b]
Depression	16 (1902)	Age	13.3	0.0060	–0.0025 to 0.0144	0.156
SF-36 general mental health	11 (1117)	Age	53.2	0.0118	–0.0082 to 0.0317	0.176
Global health status	14 (1801)	Age	61.2	0.0159	–0.0085 to 0.0402	0.223

a Positive regression coefficients imply worsening outcome.
b Significant effect ($p < 0.10$).

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Findings from the meta-regression looking at age and gender in relation to outcomes showed no significant associations with pain intensity, physical/functional capability, self-efficacy, depression, SF-36 general mental health or global health status. As mentioned in the methods section, because of the small number of studies for each outcome, marginally significant associations ($p < 0.10$), were considered as hypothesis generating for future studies to explore possible relationships.[42]

Recommendations

Based on the above findings we can make the following recommendations:

- Findings for the predictive effect of self-efficacy on outcomes and the mediating effects of pain catastrophising on function indicate that interventions should incorporate strategies to improve self-efficacy and coping techniques.
- Based on the currently available evidence, we do not recommend targeting the intervention to a particular age group or gender.
- There is currently no evidence to support an association between duration of pain/complaint, pain intensity, work status, disability level or diagnosis of depression at baseline and outcome. Therefore, access to current interventions should not be limited based on these factors.
- We recommend that study authors use the criteria that we identified for assessing the quality of moderator studies to guide their methodology.

Limitations/considerations of this review

Because of the small numbers of studies carrying out appropriate analyses, we were unable to quantitatively assess predictors, moderators and mediators of self-management programme outcome success, other than age and gender. Overall, the evidence is insufficient to inform on moderators, mediators and predictors of intervention success, other than for self-efficacy as a predictor and catastrophic thinking as a mediator. We have only considered RCT data here rather than including observational data. This is because we were specifically interested in factors to consider in the context of a RCT rather than an observational cohort study.

Because of the lack of consistent reporting of potential predictors, moderators and mediators in research, the meta-regression featured only two potential moderators, age and gender. These were selected as they are the most commonly reported characteristics in studies and data were readily available. Only when researchers report potential moderating variables as a standard can meta-analytical techniques be used to calculate a more accurate estimate of the variance between studies.

Studies reporting significant predictor, moderator or mediator effects of self-management interventions are more likely to be published than those studies that do not report significant effects. We did not include unpublished studies or dissertations in this review and therefore the studies identified for this review are likely to reflect those that escaped the 'file drawer' problem,[152] which might be a result of publication bias.

An additional limitation, which most meta-analytical studies face, involves combining scores from different tests. For example, several different tests measuring self-efficacy were combined and it was unclear whether or not they were suitable for merging until an item analysis had been carried out on the measures. It could be argued that only constructs that are measured using the same instrument should be merged, to avoid this problem.

The analysis showed heterogeneity of findings for some outcomes. For example, a mild to moderate level of heterogeneity of findings across studies was reported in the meta-regression. Heterogeneity may result from the small number of studies available for each test. Other factors that have not yet been identified, or not yet included in moderator research, might also explain some of this heterogeneity. It would be premature to conclude that intervention effects do not vary by patient or study characteristics. We were unable to examine several moderator effects because of insufficient data (i.e. education, self-efficacy, pain duration, ethnicity, disability and depression).

We aimed to identify moderators, predictors and mediators of efficacy of self-management programmes for those with musculoskeletal pain. We believe that this systematic summary of the literature identifying moderators, predictors and mediators, and meta-analysis to examine influences of moderating factors provides useful recommendations based on evidence and we have also provided a checklist of methodological criteria for assessing moderator studies.

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Chapter 4 Qualitative study

Abstract

Introduction: Our knowledge about the impact of self-management courses on individuals is limited. This study aimed to understand how different components and characteristics of self-management courses are perceived by people living with long-term conditions, course tutors and experts, to explore reasons why they might lead to different outcomes and to consider the implications for the content of a new intervention.

Methods: We used a qualitative approach with purposive sampling to maximise sample diversity. Face-to-face interviews were conducted with people with chronic musculoskeletal pain who had attended self-management courses. We then ran two focus groups, one with experts in the field of self-management for long-term conditions and one with self-management course lay tutors, to explore our interview findings. Topics discussed included referral, attendance, course content and character and outcomes.

Results: Sixteen previous course participants from Warwick and London were interviewed; in addition, six experts attended one focus group and five tutors attended the other. We identified two types of chronic pain behaviour: fixated and distracted. Promoters of positive change included support, motivation, engagement in the process, high-quality tutoring and identifying with the learning process. Sustainers of change included implementation of coping strategies, networking and socialising, distraction, support from others and new identity creation. Those who responded well to self-management courses moved away from absorption in their 'pain world' towards integrating into their social and/or work communities. We grouped outcomes into six domains: functional, physical, emotional, social, economic and medical.

Conclusions: Courses should involve good-quality facilitation, cognitive–behavioural approaches to promote change, medical education, a group/social setting and exposure to information about local activities to encourage long-term lifestyle behaviour change. Flexibility in course structure is required to accommodate social interaction and self-discovery to promote self-acceptance and the development of a new identity other than that of a 'pain patient'.

Background

In this study we explored participant experiences of self-management programmes for chronic pain to identify and understand why some aspects of different courses may be more beneficial than others; the uptake, retention in and acceptability of self-management courses; and why some participants feel that they might do well on self-management courses, whereas others do not.

The findings are interpreted in the light of existing theory around concordance and living with chronic conditions and, when necessary, we propose new explanations for the findings. This study provided information for the development of the new self-management intervention. By exploring what people's perceptions were of important components of self-management courses we were able to emphasise these components in our new course.

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Method

We adopted qualitative methods, using an iterative approach (each stage informed the next). We used both in-depth interviews with participants and focus groups with experts in self-management of long-term conditions and lay tutors to explore the findings from the interviews. Interviews were conducted with participants in Tower Hamlets (inner-city London) and Warwick (a mix of urban and rural living in the Midlands). These represent two very socially and economically different areas, chosen to increase the range of views and opinions encountered. In Tower Hamlets there is a large Bengali population. First-generation Bengali migrants in Tower Hamlets have a particularly high prevalence of chronic pain.[153] As part of this overall programme of work we wanted to ensure that our intervention was suitable for this population.

First, we conducted face-to-face in-depth interviews with participants who had attended self-management programmes; the information from the interviews informed the questions and topic guide for the focus groups. We convened focus groups with experts from the field of self-management and lay tutors. Additionally, we used the focus groups to triangulate findings from the interviews.

Recruitment and sampling: individual interviews

We aimed for a diverse sample, with a total anticipated sample size of 20 (or fewer if data saturation was reached earlier). We recruited people living with persistent pain who had attended self-management courses. Two Expert Patients Programme community interest companies, one in London and one in Warwick, and Social Action for Health in London approached participants who had attended their self-management programmes and invited them to be interviewed by the study team. The invitation letter contained a consent to contact form and a reply-paid envelope so that the researchers could approach those willing to participate. We also invited people to participate via an internet chat forum for people who had attended self-management courses.

Participant inclusion and exclusion criteria are shown in *Table 16*.

We used a purposive, diversity sampling method to obtain a good representation of different genders, age groups, socioeconomic areas (by postcode) and self-management course attendance record. Further data about the participants were collected after they had consented to participate in the study.

Conducting the interviews

Face-to-face interviews were arranged by the researchers at a time and place convenient to the participants. With permission, interviews were audio-recorded, transcribed and anonymised, with each interview lasting approximately 1 hour. The content of the topic guide was informed by knowledge of the literature, the specific needs of this study and the study team's past experience of issues in other trials and evaluations of self-management programmes. The topic guide covered referral processes, motivation to attend courses, memorable aspects of courses, most effective and least effective components, positive and negative aspects of support/networking, follow-up, strategies for coping and long-term effects/outcomes of courses. Most interviews were conducted by a medical anthropologist; as a substantial proportion of

TABLE 16 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
• Adults aged ≥ 18 years • Presence of chronic musculoskeletal pain (pain lasting > 3 months) • Experience of attending a self-management course • Willing to participate and can understand English or has appropriate advocacy support to enable participation	• Associated comorbidities that may affect their ability to communicate and/or participate in an interview process • The presence of a terminal illness

first-generation Bangladeshi residents who live in Tower Hamlets are not fluent in English some interviews were carried out by a health researcher fluent in Bengali/Sylheti and English.

The focus groups

We convened two focus groups (maximum six participants in each), one with UK-based self-management academic researchers and opinion leaders in this field (the study team identified key personnel to approach based on their own knowledge of researchers and policy-makers in this field) and one with self-management course lay tutors and providers (a mix of programme leaders and tutors was approached). The focus groups were facilitated by a health researcher familiar with self-management research and a musculoskeletal clinician. We fed the findings from the individual interviews into the focus groups to test the 'acceptability' of our findings and to generate discussion about participant receipt of self-management courses and the issues raised by participants who attended courses.

Analysis

All focus group conversations and individual interviews were audio-recorded and transcribed. NVivo software version 9 (QSR International, Warrington, UK) was used to manage the analysis of the data. We carried out thematic analysis using the framework method; this involves familiarisation with the literature and the development of a framework based on emergent themes and subthemes.[154] A third experienced qualitative researcher was involved as an independent reviewer; to promote study validity, he commented on the framework of themes and subthemes based on a sample of interviews and independently coded a transcript. Three researchers coded the same three transcripts to test the framework and to compare the inter-rater reliability of our coding. We used this as a training exercise to improve the consistency and reliability of coding. The results from the focus groups with experts and lay tutors were also compared and contrasted with the findings from the interview study.

Ethical approval was granted by the East London and the City Research Ethics Committee Alpha (reference number 09/H0704/24).

Results

Sample

Twenty-six people participated in this study. We conducted 16 one-to-one interviews, at which point we felt that we had reached data saturation. Twelve interviews were conducted with English-speaking participants and four were conducted in Bengali/Sylheti. Four interviews were conducted in Warwickshire and the remainder were conducted in East London. *Table 17* shows the characteristics of the interview sample.

We ran two focus groups. The tutor focus group included five self-management course tutors or facilitators active in east London, south London and Essex (FG1.1–1.5). The expert focus group also consisted of five participants (one primary care trust service commissioner, three academic researchers and one self-management course service provider) (FG2.1–2.5). When the focus group discussion reflected the thoughts and beliefs of the interviewees we have added this into the text. We also report dissonant data from the focus group discussion when applicable.

Themes and subthemes from the interviews

We initially derived eight main themes (*Table 18*, first column). When we initially tested this framework we found a lot of duplication of data in themes 3 and 8. There were many references to social aspects of life (theme 3) but these were nearly always in the context of barriers to and/or promoters of change (theme 8); these themes were therefore merged. Additionally, the original themes 1 and 4 were collapsed to behaviour and thoughts, including empowerment and 'negative' behaviours, including self-absorption, anger and frustration. We also identified a new theme about outcome expectations. The last two columns in *Table 18* show the final framework used for the analysis of the interviews.

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TABLE 17 Interview sample ($n = 16$)

Participant	Male/female	Pain duration (years)	Age (years)	Previous self-management course attendance	Location rural/urban	Language fluency English/Bengali
P1	M	4	> 45	< 50%	U	E
P2	F	23	> 45	< 50%	U	E
P3	F	10	≤ 45	50%	R	E
P4	M	15	> 45	50%	U	E
P5	M	7	≤ 45	50%	U	E
P6	F	20	> 45	50%	R	E
P7	F	16	> 45	50%	R	E
P8	F	6	≤ 45	50%	R	E
P9	F	18	≤ 45	Unsure	U	E
P10	F	23	> 45	50%	U	E
P11	F	20	≤ 45	50%	U	B and E
P12	M	16	> 45	50%	U	B and E
P13	F	13	≤ 45	< 50%	U	B
P14	M	17	> 45	< 50%	U	B
P15	F	10	≤ 45	Unsure	U	B
P16	F	5	≤ 45	≥50%	U	B

TABLE 18 Framework: original and evolved themes and subthemes

Original framework		Reasons for evolving framework	New framework	
Theme	Subtheme		Theme	Subtheme
Theme 1: personal attitude and behaviour	(a) Self-responsibility/ empowerment (b) Lack of self responsibility/ empowerment	Overlap with theme 4. Merged 1(a) with 4(b) and 1(b) with 4(a) and 4(c) to create theme II		
Theme 2: identity	(a) Self (past, current and future) (b) Social (context of self with others, family and friends)	This theme is robust: remains as theme I	Theme I: identity	(a) Self (past, current and future) (b) Social (context of self with others, family and friends)
Theme 3: social support/sharing/ networking		Overlap with theme 8. Merged 3 and 8(a) and 8(b) to create theme VI		

TABLE 18 Framework: original and evolved themes and subthemes (*continued*)

Original framework		Reasons for evolving framework	New framework	
Theme	**Subtheme**		**Theme**	**Subtheme**
Theme 4: psychological aspects of living with constant pain	(a) Self-absorption (with condition, self-justification, legitimisation, reinforcement, visual 'badges', carers and caring)	See theme 1	Theme II: pain-related behaviours and thoughts	
	(b) Positive emotions (distraction, looking beyond illness)			
	(c) Negative emotions (anger, frustration, depression, boredom)			
Theme 5: knowledge and information		This theme is robust: remains as theme II	Theme III: knowledge and information	(a) Marketing, referrals and recruitment
Theme 6: course-specific details	(a) Referrals	Renamed to more accurately represent data; expanded to create theme IV(a)	Theme IV: course characteristics	(a) Marketing, referrals and recruitment
	(b) Relationship of course with general practitioner and treatment plans	Merged with theme IV(a)		
	(c) Expectations/long-term effects/outcomes, application of learning	A theme in itself and therefore classified accordingly as theme VII		
	(d) Tutor impact/ behaviour/delivery	Expanded to include aspects of delivery. Renamed and now theme IV(b)		(b) Course delivery and impact of tutor
	(e) Attendance	Unaltered		(c) Attendance
	(f) Mix and character of attendees	Unaltered		(d) Mix and character of attendees
Theme 7: course components	(a) Pacing	Themes 7(a) and 7(b) inseparable and treated as one factor. Combined to form theme V(a)	Theme V: course components	(a) Pacing, action planning and goal-setting
	(b) Goal-setting			
	(c) Medication advice	Themes 7(c) and 7(d) combined to form theme V(b)		(b) Medical education
	(d) Treatments			
	(e) Other	Unaltered		(c) Other
Theme 8: change	(a) Promoters of change	Combined with theme 3 to form theme VI	Theme VI: change	(a) Promoters of change
	(b) Barriers to change			(b) Barriers to change
		Newly created theme VII from theme 6(c)	Theme VII: expectations and outcomes post course	

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Findings

Theme I: identity

We noted a 'persistent pain' identity in some participants, some of whom had visual cues to help others identify their condition, such as bandages, walking aides or strapping. These participants' lives were busy with being in pain, for example centring their days or weeks around medical appointments and/or personal health regimes. Referring back to one's previous self, that is, before pain, was common. Views expressing boredom, social isolation, frustration and loneliness, predominantly caused by a lack of understanding from others, were not unusual. Examples of reframing one's self-identity were evident in those who had adjusted well to their condition and who related positive stories about their quality of life. References to past selves were present in those who did not appear to be coping as well, whereas those with more positive attitudes to life described ways of adapting previous skills and experiences:

> *I was not like this before you know, they look at me and feel sorry for me, they say why is your health like this?*
>
> *P11*

> *I was very fit and active up until about 4 years ago, I started to get really bad pains in my joints, well I would say really chronic pains, it actually felt like my joints were being ripped apart.*
>
> *P1*

> *Because it's like you revert back to like the young kid stage again; you have got to rely on your parents to do everything for you, you know, and that's how I feel sometimes*
>
> *P8*

> *I feel defeated, because basically it brings a lot of failure and it can actually let you sit down and feel sorry for yourself, and because I was never that sort of person.*
>
> *P4*

> *So no wonder why I feel so bitter, absolutely bitter about all this, really – not a finger of help, nothing! The help had to come from outside and my daughter had to really . . .*
>
> *P15*

> *I do art now, it's really helped me . . . I feel I've achieved something.*
>
> *P1*

> *I volunteer at the HIV [human immunodeficiency virus] centre, it gets me out and stops me thinking about myself and it's good to go there.*
>
> *P3*

> *I've accepted I just have to do it [housework] differently now.*
>
> *P16*

Theme II: pain-related behaviours and thoughts

The behaviours and commentaries described by participants could be grouped into two areas: broadly 'positive' and broadly 'negative'. Positive or adaptive behaviours were characterised by descriptions of engaging in social activities and evolvement of new concepts of living within the current capabilities of the individuals and not past ones; these participants did not overly dwell on their pain and described active lives, hobbies and social interactions, and had realistic expectations. We grouped self-absorption, pain fixation, dependency, isolation, frustration, anger, boredom and low mood and self-esteem into negative or pessimistic behaviours. These participants tended not to identify with the self-management concepts and not to incorporate self-management terminology in their speech. Some participants thought that they were coping already and that the course made them more confident about their coping skills and so

reaffirmed their behaviour, others found it difficult to apply the techniques learned on the course to everyday life and some highly motivated participants continued their learning and had taken up new activities and adapted their lifestyles:

> *When I'm bad, I just sit and stare at the vase on the mantel piece, I feel really low, I do nothing.*
>
> *P10*

> *Some days I cannot get off the couch, I just watch TV [television].*
>
> *P11*

> *I pray, my pain it does not go but my mind is on my praying, it gives me strength.*
>
> *P12*

> *If I get really involved in it [painting] I can forget about the pain, but most of the time it's too painful.*
>
> *P1*

> *The relaxation helps, yeah, really helps, and the breathing – it sounds stupid breathing – but it does.*
>
> *P10*

Theme III: knowledge and information

Most self-management courses involve giving participants a course manual or handbook. These manuals were generally well received and were used as reference tools and memory joggers and to supplement knowledge from missed sessions. They were also used as 'proof' for 'significant others' to justify behaviour and explain learning and new behaviours.

There was a strong suggestion from the interviews that a system of building up information and material related to the course gradually was preferable to receiving information all at once, as this could be overwhelming. Some participants took the manual at the first session and did not return to the course as they thought that they had all the information that they needed. It was also mentioned that the internet was underused. Some participants were computer literate; however, others were not and this form of communication would have been inappropriate, unfamiliar and impossible because of a lack of equipment.

> *Someone actually called it [a course handbook] their bible. I can still remember on the course, someone called it, it's my bible.*
>
> *FG 1.2*

> *they take it, they take the handbook and then they do not come back!*
>
> *FG 1.5*

> *You cannot say, 'right, I've got this terrible pain, now let me refer to the book and see how I can get rid of this pain!'*
>
> *P6*

> *I'm not going to say I've read it! [laughter] But, no, I just browse through it and bits and pieces. And certain things, I often turn round to the governor, and say, 'You see look – told you! That's what you should be doing!!'*
>
> *P7*

> *we do not give them [course handbooks] because people just do not read them!*
>
> *FG 1.3*

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But I think also to give them those in separate little . . . in stages [murmur of agreement] rather than give them a big manual at the end.

FG1.5

Theme IV: course characteristics

In theme IV, we separated the data into four categories: marketing, referrals and recruitment; course delivery and impact of tutor; attendance; and mix and character of attendees.

Theme IVa: marketing, referrals and recruitment

Two schools of thought emerged about recruitment and marketing. The participants did not want to be told or coerced to go on a course, but they did want legitimisation of the course through recommendation by their general practitioner (GP). They also felt that there was a need for a self-referral route, coupled with increased marketing and information for the public, as many GPs were not aware of the different courses. The tutors, however, were keen for recruitment to take place through GP registers and GPs themselves, as this allowed for better targeting of those with greater need and gave access to a ready source of potential participants.

Encouragement from those involved with the course from the initial point of contact was important. Building rapport with potential participants helped manage expectations and encouraged engagement with learning and the process. The presence of the recruiter at the first session was welcomed. The tutors thought that the recruitment process was very important for managing expectations. Both unrealistically high and very low expectations were seen by tutors:

And I think that's a gap where some health care professionals will not understand what it is.

FG1.4

we are getting access to the GPs' register, i.e. we have got a standard letter saying: a self management course is coming to the area, and so on, and we have asked the GP practice would they use that letter, you know, put their letterhead on it and also sign it and so on . . . And we are getting a really, really good response that way.

FG1.6

Mile End itself phoned up: a new unit's opened up dealing with persistent pain, we wondered if you'd like to attend. So I thought, I'll go anywhere where . . . there's always ways of learning things.

P2

I must be honest, if that physiotherapist had not have put me forward, I would not have known about it.

P4

you cannot lose anything but you might gain. I can tell her, but that's me telling her; if somebody else tells her, it's totally different. It comes over different, you know what I mean?

P7

But I do think doctors need to know, because I do not think many doctors know that EPPs [Expert Patients Programmes] exist!

P8

I think you have to be ready to be open-minded about helping yourself, and if you have gone there because you have been referred, not because you want to go, I think that would be a bad reason.

P3

> *When they are sort of at the stage where they are asking: I really want to do something. I want to . . . I'm fed up of waiting for everything and I'd like to help. I think that would be when doctors should refer them to EPP [Expert Patients Programme].*
>
> *P4*

> *They are professional people, they would think and say whether you're doing it wrong or right and advise you how else it would be good. We would comply with them.*
>
> *P5*

> *Because of the fact that some participants tend to be isolated in their everyday life, they do kind of look for somebody to kind of latch on to, you get me?*
>
> *FG1.5*

Theme IVb: course delivery and impact of tutor

Both professional and lay leadership was valued. The tutor was generally perceived as a strong role model, often with 'more right' to give advice and guidance than their GP:

> *Yeah, and the fact that the tutors themselves has an action plan as well. Yeah, the role modelling is important.*
>
> *FG1.3*

> *Well, by relating, they were more or less relating to . . . they definitely knew about pain themselves, that's the main thing.*
>
> *P1*

> *The reason why because they know, they could understand the highs and lows.*
>
> *P7*

Participants generally had a need to feel 'listened to' and to be taken seriously. Some would have preferred more time to tell 'their story', whereas others felt that this would incur too much competition. The tutors felt that it was an important part of their job to contain comparisons between people. There were lengthy discussions about mixed-disease courses and disease-specific courses. There were pros and cons of both, with no clear conclusions possible.

Effective course tutors were described as friendly, open, honest and non-judgemental; they respected others' opinions, made people laugh, enjoyed the sessions and were relaxed; they listened and were flexible, informal and engaging; they controlled the input of those who were very negative or those who were overdominant and curtailed those who talked too much about themselves; they related to the group culturally; and they had experience of chronic pain.

Conversely, the descriptions of poor tutoring involved reading from a crib sheet; rigidly sticking to timescales at the expense of learning; not having experience of chronic pain; and not managing disruptive, negative or self-absorbed people.

Theme IVc: attendance

A number of factors were mentioned with regard to attendance and non-attendance on courses. Attendance was influenced by personal motivation to attend the course, the quality of the tutors and receptiveness to information and participation in group activity and social bonding. When all or some of these were mentioned the participants demonstrated good attendance. Those with poor attendance were those with a low or depressed mood, a negative attitude to the course, lack of positive support and demanding friends and family. Other factors that affected attendance were medical appointments, sickness and holidays – these were common to those with both low and high rates of attendance

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(*Figure 4*). The interviewees and the tutors in the focus group indicated that people with low self-esteem and those who felt intimidated about talking in front of others were unlikely to fare well on courses:

> *They'd be negative against everything and would not give things a try, but it could be they are actually chronically, clinically depressed, but they actually left.*
>
> *P9*

> *but they have not got that something to help them, to drive, to push probably.*
>
> *P9*

> *It was nice to share ideas with other people and get ideas, get new ideas, fresh ideas, some of which I have taken on board and some I have not! I wanted it to stop my illnesses, to be beneficial for my body, that's what I thought, it would be enough.*
>
> *P10*

> *There are seven of us in this house including my husband and I, it's a two-bedroom house, and we are living in such difficulties [she goes on to describe the problems encountered getting to the course] . . . It was quiet a distance for me. I just went the one day.*
>
> *P3*

> *They do not get me to do exercise nor do they do it themselves. You have to do things yourself.*
>
> *P4*

Theme IVd: mix and character of attendees

Attending a course that was delivered to a group appeared to have an impact on several factors. It gave participants motivation to achieve goals as they had to feed back progress to the group and it reduced levels of isolation – some were inspired by others and some made friends and all appeared to learn from each other or the course itself. Conversely, some participants felt that the action planning and feedback could be false, that is, an exercise in creative storytelling, and others insinuated that the goal-setting could potentially set them up for failure if they consistently did not achieve in front of the group and indeed this was suggested as a reason for people not attending. 'Eureka' moments were described, such as the

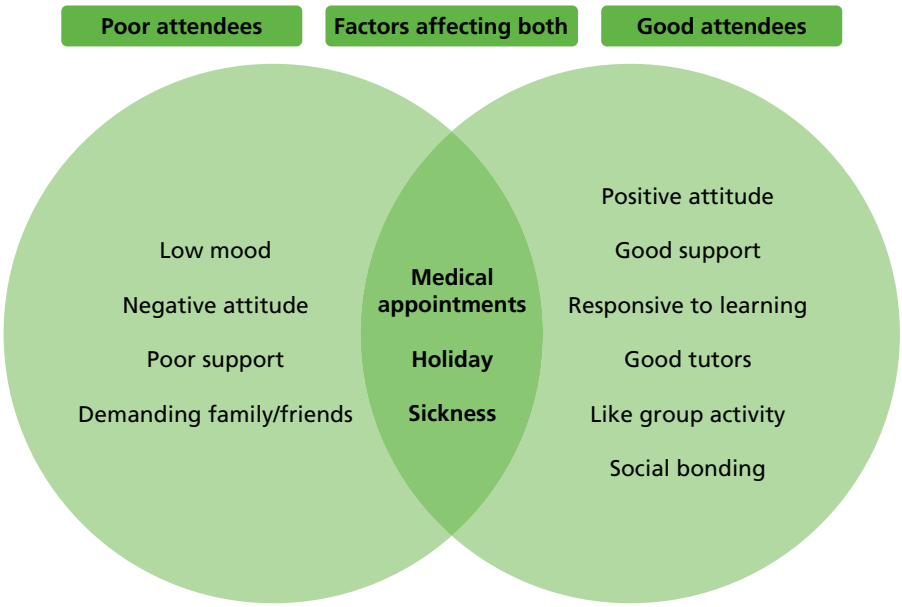

FIGURE 4 Factors influencing attendance.

realisation that others felt the same and had the same issues to deal with, and some found this inspiring and motivating:

> *It is that proper group work and I think that might be where the gap is where . . . maybe more emphasis on forming as a group, like group activities, before just throwing at them the information, might help in that process.*
>
> *P4*

> *You get ideas when they ask you questions but now I can't say, you get it when talking, you can learn things too. If you say your idea then that's one way and I'll think another way.*
>
> *P8*

Theme V: course components

There was a danger that self-management courses legitimised 'the sick role', especially pacing, as it justified resting and not doing things under the guise of 'I'm pacing myself'. With pacing, patients are advised to schedule their activity evenly over a period of time; this may involve resting at points so that the person does 'not overdo it'. Sometimes this was described as being used constructively to explain behaviour and at other times it was felt that pacing was used to manipulate circumstances to justify not doing some things:

> *I just tell her [his wife] 'I'm pacing myself' and watch telly.*
>
> *P4*

> *I can go back to the computer or I'll just sit and chill out for the rest of the hour, that's entirely up to me, but it's pacing myself during the day.*
>
> *P1*

Encouragement of new activity and establishing contacts and generating new relationships were very helpful. Participants did want more information about local resources and even more courses. Additionally, participants liked being able to talk about their condition; however, the tutors actively discouraged this to avoid competition and self-absorption. Narratives of conditions were 'permitted' within the context of personal goal-setting, action planning and pacing:

> *The free-thinks [small amount of allocated time for discussion] I think there needs to be a little bit built in where discussion can take place.*
>
> *FG1.4*

> *Mmm. People are itching to talk, are not they?*
>
> *FG1.3*

> *One woman, to get into the bath, she needed a handrail. They said, 'Well, have you been in touch with . . . some sort of organisation?' 'No!' 'Oh, get in touch with them and ask that . . .'. She came in, I think it was a week or two later, and she said, 'They have put one in for me!'*
>
> *FG3.1*

> *I've learnt to cope with it on my own; it's like it's all right people saying, 'Oh, do this, do that!', but they are not with you all the time, they are not seeing you how you are.*
>
> *P7*

> *I'm really bitter about because no one helped me, no one advised me and I never got nothing.*
>
> *P2*

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The main components of courses that participants liked were breathing techniques, relaxation, visualisation and social networking. They disliked the lack of involvement of 'significant' others and that feedback from the goal-setting could be daunting. Here, both tutors and participants admitted that there was scope for 'stretching the truth'. The content of the courses was seen as useful, but its sustained application was considered difficult. The social networking and 'doing something different' was commented on and expanded on more than any other component of the courses.

Theme VI: change

From the data we identified three main explanations/models of behaviour about change: behaviours of those who remain fixated and absorbed in pain (*Figure 5*), factors that appear to promote and sustain beneficial change (*Figure 6*) and the process of change as lifestyles expand, broaden and evolve to include more things.

Figure 5 shows the behaviours associated with those who appeared to be fixated on their condition; their lives and their identity revolved around being in pain, with few non-pain-related activities. As a result, 'sickness'-related activity and behaviours were maintained. These participants were generally isolated, bored and frustrated and they had a low mood and were dependent on family and friends. Conversely, those who were not fixated on their pain used distraction techniques to broaden their activity and life experience, often creating new activities and hobbies, leading to new social networks and a self-identity associated with the activity rather than with their pain.

Figure 6 shows the factors that we found to be associated with participants who had managed to change and sustain the changes that enhanced their quality of life. Those participants who had adapted and coped well were motivated, were engaged in the process, had support and reported having good, inspiring tutors.

Each figure illustrates the potential impact that group-related activities may have.

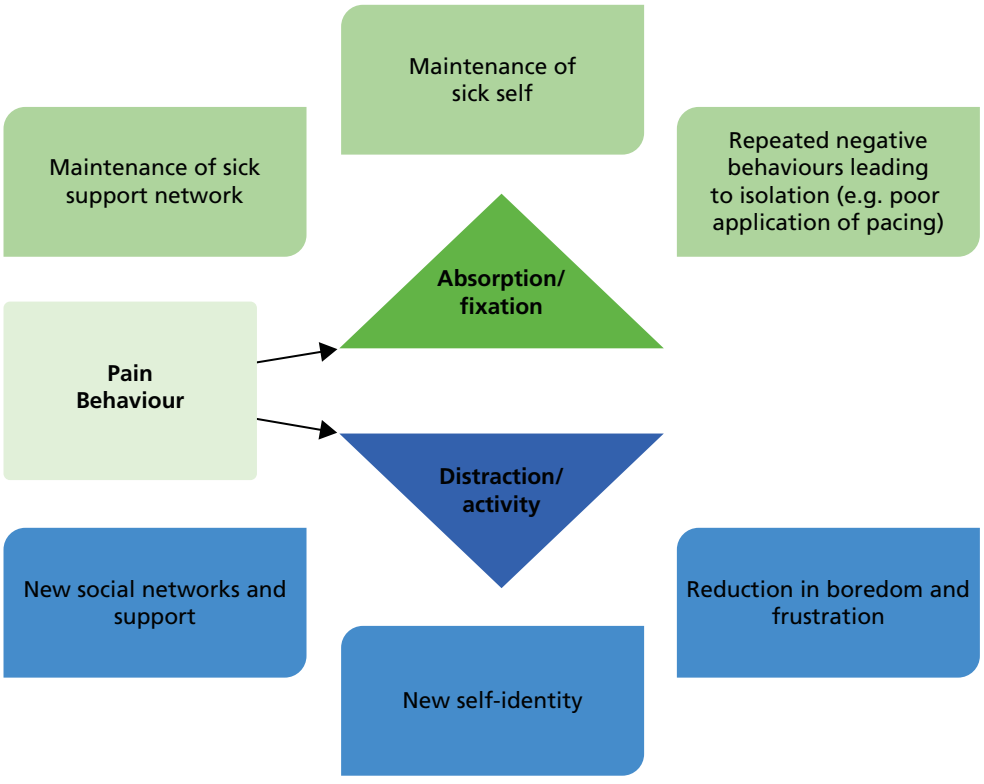

FIGURE 5 Observed behaviours and attitudes towards pain.

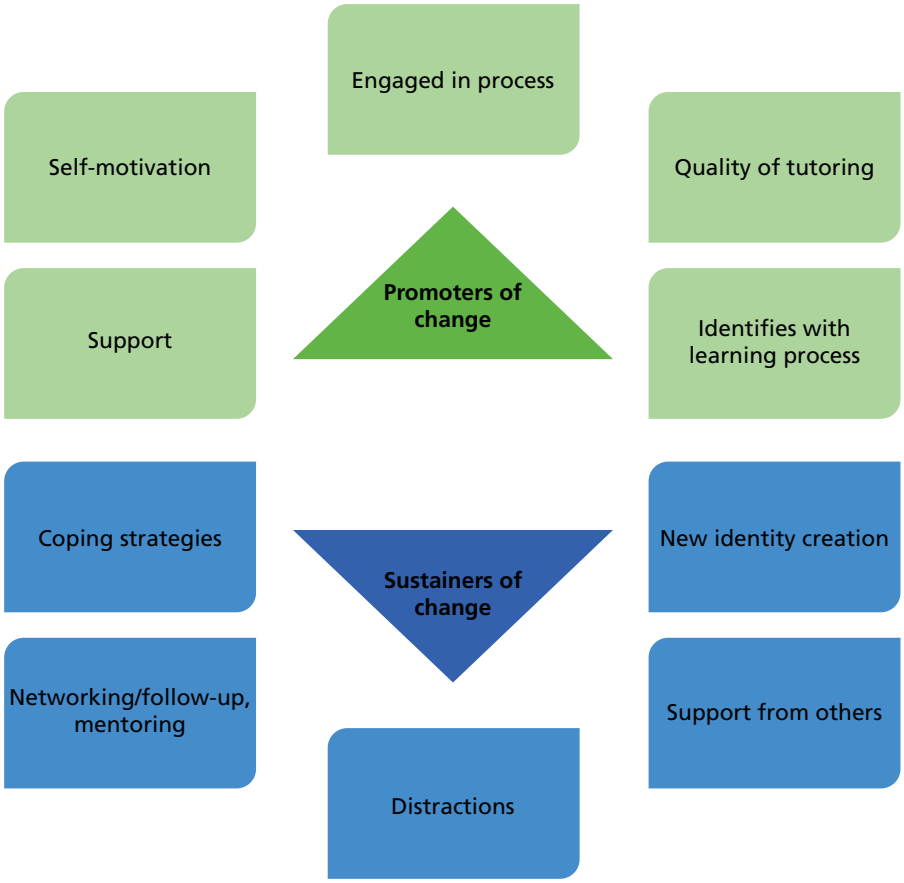

FIGURE 6 Factors promoting and sustaining change behaviour.

Barriers to change included depression, lack of motivation, physical capability/disability, change in benefit payments, change in family dynamics, stress/pressure/confusion and change in behaviour conflicting with a 'sick role'.

Theme VII: expectations and outcomes post course

Those who were really engaged with the course enjoyed the social release it gave them and were inspired; they felt that there was a void at the end of the course. These participants were very vocal about continuing contact. Views expressed included a preference for ad hoc contact, such as top-up classes, and 'buddying' to maintain the social network and a need for local information about services, for example walking groups:

> *because after the six weeks, they kind of say, 'Well what can we do now?'*
>
> *P2*

> *Some of us decided to meet up and carry on the goal-setting and action planning.*
>
> *P3*

> *There are course junkies, other courses to combine with are the healthy moves and healthy guides.*
>
> *FG1.3*

> *it was not between the tutor and the course people, but the people themselves, so they did a buddying up, mentoring thing.*
>
> *P3*

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Outcomes

Outcomes that were seen as important to participants are summarised in *Box 1*. These are grouped into the following categories: functional, physical, emotional, social, economic and medical; examples of each are provided in parentheses in *Box 1*. Participants were rarely able to definitively outline success criteria unless they were based on a pain outcome, that is, no more pain, less pain, functional ability to start doing tasks that they used to be able to do. However, when asked what they wanted from the course the outcomes mentioned related to personal confidence in their ability to do things and these were not necessarily functional but also emotional and social. Confidence was inherent but rarely explicitly stated, for example 'I want to be able to . . .', 'I am going to try and do . . .', 'I have learned to do "x", which is great' and 'I feel more able to . . .'. Quotations were given in a positive context or the converse negative context: 'I can't . . .', 'I wish I could . . .', 'I'm just hopeless . . .', 'others could but not me'. Self-efficacy was not really an outcome but a means to achieving a better outcome.

Additional findings from the expert focus group

A key consideration for the expert focus group was the legitimacy and credibility of findings from some studies and the transferability of some concepts in the Stanford self-management model[9] to a UK audience:

> *It makes me wonder why people go on doing it [Expert Patients Programme] when there are better things available.*
>
> *FG2.8*

> *if we had a drug which on balance produced no effect, would we be working so hard to get GPs to put people on it?*
>
> *FG2.5*

Identifying those who do well and those who do not was discussed extensively but no firm conclusions were made about subgroups and screening. Selecting a 'choose all' strategy to include those with varying degrees of severity was, however, seen as a good way of recruiting:

> *Some people do benefit enormously . . ., it doesn't make it unique to EPP [Expert Patients Programme] . . . a good regime of analgesics leaves some people self managing.*
>
> *FG2.5*

> *Rather than working hard to try and understand who does benefit and how we can target them better . . . what can we do about those who didn't [benefit].*
>
> *FG2.1*

BOX 1 Domains that were seen as important to participants, which underpinned self-confidence

Functional (practical daily living requirements).

Physical (equipment aides, support and practical help).

Emotional (dealing with frustration, anger, boredom, isolation, depression).

Social (social networking, relationships with partners, family and friends).

Economic (financial support, benefits, etc., work-related issues).

Medical (pain and drug-management related).

Cognitive reframing and linking pain and mood were flagged as lacking in current approaches to self-management. The group postulated that without personal identity reframing and acknowledgement of negative behaviours and cognitions no change would be made.

The involvement of GPs and other HCPs in referrals and recruitment lent credibility to the courses and was seen as integral to the success of any programme; additionally, medical staff involvement encouraged and motivated participants. However, the counter-argument that many chronic pain patients were disillusioned with their GP was not seen as detrimental to the self-management courses as GPs themselves were not running them.

> *the GP has assigned it, so it does make a difference.*
>
> *FG2.5*

All agreed that there was a need for aftercare or support. The Alcoholics Anonymous model was discussed, as were approaches to smoking cessation. Buddying and mentoring concepts were discussed and were thought to be helpful, but it was also thought that such schemes would be difficult to organise and maintain and that it would be difficult to provide support for the 'buddies/mentors'. Longer-term thinking and support groups were discussed:

> *Education is an incredibly weak way to change behaviour . . . otherwise, you know, who would smoke?*
>
> *FG2.4*

> *Distraction is such a short-term thing . . . but developing interests and involvement which really compete for space in someone's life.*
>
> *FG2.1*

> *it took about a year to get them to own it [the support group], it's a very different dynamic with a key core of people.*
>
> *FG2.5*

Additional findings from the tutor/facilitator focus group

The tutor/facilitator focus group was characterised by the strength of the participants' beliefs in the concept and process of the Expert Patients Programme. The terminology used and the phrases used from the Expert Patients Programme literature were common to all participants in this group:

> *We do not want cloned tutors . . . where you expand too big and you have got tutors for tutors sake, and the empathy is not there.*
>
> *FG1.3*

Tutors relayed stories relating to very practical considerations, such as not being able to access rooms because they were locked or centres were closed or had no disabled facilities. Participants had few criticisms of the Expert Patients Programme courses; however, they did suggest that providing more time for general discussion would be beneficial.

Discussion

Statement of principal findings

Our data indicate that those who got the most out of the courses were those who were motivated to change at the outset and who became engaged in the process. The quality of the tutoring influenced participants' perceptions of the courses. Factors that helped people were social support (family, new and old friends) and undertaking new activities that extended beyond the course; conversely, factors that did not help were a low, depressed or negative mood at the outset and a reluctance to alter behaviour, activities or lifestyle.

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Strengths and weaknesses of the study

Our study focused on participants with chronic pain who had untaken self-management courses as well as tutors and experts. Each group's perspectives were 'triangulated' with the perspectives of the other groups to assess responses and reactions. Discordant data were mainly obtained from the 'experts', who questioned the overall evidence for effectiveness for lay-led self-management in general, and, conversely, the tutors, who provided very positive narratives about the effectiveness of the courses that they had run.

One-third of our sample was Bangladeshi, reflecting our London population. We were able to identify some cultural issues, for example running gender-specific courses and not organising sessions that coincided with Friday afternoon prayers for men, but we were not able to draw any conclusions about cognitive ethnic differences from this study as it was not designed for this purpose. A further limitation was that we were not able to interview those who were invited to attend a self-management course but who chose not to go. Our sampling strategy generated a range of views that enabled us to consider issues relevant to the design and delivery of self-management programmes and some speculative data about the traits of people who seem to respond or not to self-management courses. The model adds to the existing literature by consolidating common findings about social interaction and activity and depression and behaviour change.

Strengths and weaknesses in relation to other studies

Social interaction

Group cohesion was reported by those who had integrated self-management concepts and approaches into their everyday lives. The loss of 'the group' at the end of the course was felt by all those we interviewed. The development of support groups could provide a sort of continuity for participants. However, support groups can provide both positive and negative effects, such as reinforcing and maintaining dysfunctional pain behaviours.[155] The quality of support groups can be enhanced by training core members to facilitate groups, having a structure to support group meetings, having good facilitation and appreciating that this type of service will not suit all those with chronic pain.[156]

Activity

New activities promoted self-esteem, distracted thoughts from pain and created a positive outlook. Guidelines for the management of chronic low back pain recommend activity and the focus of this activity is on exercise.[21] However, research does not recommend any one particular form of exercise over another, as any exercise would appear to have a benefit. We would argue from our findings that activity should include the uptake of hobbies and non-exercise-related activities. These tasks will normally involve mobilising the body and, although they would not typically be described as exercise for many people, for those with chronic pain these types of activity constitute a form of exercise that they would not necessarily consider doing. Activities and hobbies are more than a distraction or short-term solution; they normally engage people in the longer term, which potentially encourages a lifestyle change.[157] The mention of exercise was problematic with this group of people as the idea of undertaking an 'exercise programme' was beyond their capability and capacity.

Recruitment and attrition

Low uptake, recruitment and retention in group self-management programmes remains an issue.[158,159] The main barriers to attending self-management programmes were comorbidities, poor physical functioning, lack of finance, depression and health-care use (coinciding appointments). In addition to these factors we postulate that poor uptake may also result from the lack of credibility surrounding the courses, which could be enhanced by medical professional endorsement, and the fact that many chronic pain patients are isolated and find it difficult to make the transition to helping themselves and lack confidence to become social and group orientated.

Self-efficacy

Cognitive–behavioural therapy is a technique that is used to help enhance self-efficacy in the area of chronic pain treatment.[48,160] We too infer that cognitions are important for enhancing self-efficacy, but that they can be affected by levels of literacy and comprehension, cultural norms and past educational experience. These may unduly influence people's perceptions of 'educational'-type courses. Strong suggestions were expressed about the need for informality, lots of discussion and socialising. Conversely, our participants reported that some people did not cope well with the discussion part of the sessions on the Expert Patients Programme courses as they found them intimidating, especially when required to feed back on their goal-setting exercises. However, less formal teaching and learning techniques do involve reflection, discussion and investigation to embed learning, such as 'problem-based learning'[161] and 'reflective learning'.[162]

Social, cultural and ethnic grouping

Six of our sample were Bangladeshi. We were able to identify some culturally important issues but we are not able to say whether or not these are representative of particular ethnic communities, which is why we have not undertaken different cultural comparisons. The concept of somatisation (absorption and hypervigilance of pain) is ubiquitous,[163] but in the south-east Asian populations physical symptoms are more legitimate than depressive feelings for visiting a physician.[164] Explanations or disease theories can differ between cultures and background and explanations of disease, healing and diagnoses will vary in their acceptability. Examples include shamanism, in which illness is explained by spirits and magic, chiropractic, in which it is explained by misalignment of the spine, psychotherapy, in which it is explained by conflict in the mind, and 'new age' rationale, which is about energy imbalances.[165] Understanding different explanations of disease and accommodating cultural traditions is an important part of self-management, especially if the culture of care rests within the family. Other more recent qualitative work in Tower Hamlets, focusing on the pain experience of the first-generation Bangladeshi immigrants, has, however, found remarkable similarities between this group's experiences of pain and those found in studies focusing on white British populations.[152] There is a paradox of care in these circumstances between offending those who want and need to be seen to be caring and thus to be perceived, for example, as a good Christian or Muslim and the individual need to be dependent and self-sufficient. It is difficult for chronic pain patients to self-manage if others around them continue to care and provide for them.[166]

Conclusion

From our study the most important factor that appeared to be associated with better coping and improved quality of life was shifting individual focus away from pain to other activities. However, this was not easy as chronic pain patients were often very occupied with their pain, which superseded other activities. Acceptance and self-efficacy appeared to be important factors in the process of positive change and enhanced quality of life.

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Chapter 5 Outcome measures

Abstract

Aim: To develop a preferred list of patient-centred outcome measures for evaluating self-management programmes for chronic pain patients with musculoskeletal conditions.

Objectives: To review the literature for valid, reliable and appropriate outcome measures for evaluating the effects of self-management interventions that match the most important domains emerging from the work presented in *Chapters 2–4* and discuss these with laypeople and pain sufferers to recommend a basket of appropriate and acceptable measurement tools.

Methods: We selected outcomes by using the data from the previously described systematic reviews to generate a draft preferred list of outcomes for which to identify patient-centred outcome measures. By 'patient-centred' outcome measures we mean those outcome measures that are the most meaningful, relevant and important to patients. We carried out a literature review to identify the most commonly used outcome measures for evaluating self-management interventions for chronic musculoskeletal pain and consulted patients, laypeople and experts. In the first instance we used the published IMMPACT and MMICS recommendations. To identify any relevant studies published after these consensus statements were published we reviewed papers published between 2004 (because the IMMPACT consensus review was published in January 2005, before the MMICS recommendations) and 2009 (the year the search was conducted) that had reported or reviewed clinimetric data on outcome measures in our list. We used these to inform three domains: pain and disability, depression and fear avoidance. When no recent review was identified (self-efficacy and social support), we carried out a systematic literature search and reviewed the measures' clinimetrics. The clinimetric criteria applied to the questionnaires were based on published recommendations. Validated and reliable measures were presented to a panel of eight people (two laypeople, three study team members, one outcome measure expert, one GP and one psychologist). Data from our pilot study were also used to inform our decision-making. Consensus was sought for the most appropriate and valid methods.

Results: Seventy-eight questionnaires were considered and tools were chosen to evaluate responses to self-management interventions. We used these data to inform our final selection of outcome measures. The primary outcome selected was pain-related disability [subscale of the Chronic Pain Grade (CPG)]. Secondary outcomes were pain intensity (subscale of the CPG), quality of Life [European Quality of Life-5 Dimensions (EQ-5D)], perception of social support [social integration and support domain from the Health Education Impact Questionnaire (heiQ)], self-efficacy [Pain Self-Efficacy Questionnaire (PSEQ)], pain acceptance [Chronic Pain Acceptance Questionnaire (CPAQ)], depression and anxiety [Hospital Anxiety and Depression Scale (HADS)] and the general health question in the 2011 census.

Conclusions: A preferred battery of measures to evaluate responses to self-management courses was agreed, representing the most important domains to assess relevant outcomes.

Background

The importance of the selection of patient-based outcome measures when designing a clinical trial is well established.[167] Our aim was to develop a preferred list of patient-centred outcome measures for evaluating self-management programmes for chronic pain in patients with musculoskeletal pain for consideration for adoption in our pilot study and trial. By 'patient-centred' outcome measures we meant those outcome measures that are the most meaningful, relevant and important to patients. This project was directly informed by findings and data from *Chapters 2–4*.

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At the time that we developed this study two international consensus studies had recommended a list of outcome measures that we considered to be the most informative in selecting our outcome measures.

The MMICS project aimed to improve the quality and completeness of measurement in prospective cohort studies of the transition from acute to persistent disabling low back pain.[31] It involved a collaboration of teams of back pain experts from 11 countries who had expertise in clinical practice, prospective cohorts, epidemiology, social sciences and health services. MMICS methodology included identifying preferred factors predicting back pain progression (using experts) followed by a systematic appraisal of published reviews and empirical studies of appropriate measurement instruments. Measurement instruments were assessed for clinimetric properties such as reliability, validity and responsiveness, and for practical considerations such as length and complexity of language.

The IMMPACT study aimed to develop consensus recommendations for specific measures of each of the core outcome domains in chronic pain trials.[30] The 35 participants were selected on the basis of their research, clinical or administrative expertise relevant to the design and evaluation of chronic pain treatment outcomes. Literature reviews of measures of the IMMPACT core outcome domains were carried out to identify measures that could be used across all chronic pain conditions and that were not specific to certain types of chronic pain. Again, the measurement tools were clinimetrically assessed and a list of outcome measures recommended. Although this project drew heavily on these two sources, it was also designed to address the use of measures that did not appear in these two sets of recommendations.

Objective

The objective of this study was to develop a preferred list of patient-centred outcome measures for evaluating self-management programmes for chronic pain patients with musculoskeletal conditions.

Methods

We reviewed the literature for valid, reliable and appropriate outcome measures for evaluating the effect of self-management interventions that matched the most important domains emerging from the systematic reviews and discussed these with laypeople and pain sufferers to recommend a basket of appropriate and acceptable measurement tools (costs of instruments and/or copyright issues were not among the practical aspects considered).

The project progressed through five stages (*Figure 7*).

In the first instance we consulted two consensus statements on outcomes measures (MMICS[31] and IMMPACT[30] recommendations). We then examined reviews published in the previous 5 years of measures in each specific domain to identify reports of clinimetric quality. In one instance (depression) there were many candidate measures, all with strong clinimetric properties and a strong evidence base. For this domain alone, therefore, we conducted a Delphi study.[135] A list of 11 measures developed from the MMICS and IMMPACT recommendations and published reviews was presented to five international experts in the measurement of depression in pain populations. Experts selected the top two measures from the preprepared list during an interview (see *Appendix 3*) and gave their reasons for selection.

When no recent review of instruments to measure a domain had been carried out, original systematic literature searches were performed to:

(a) ascertain which measures have been previously used in chronic pain research
(b) seek out the psychometric and clinimetric data for the most commonly used measures.

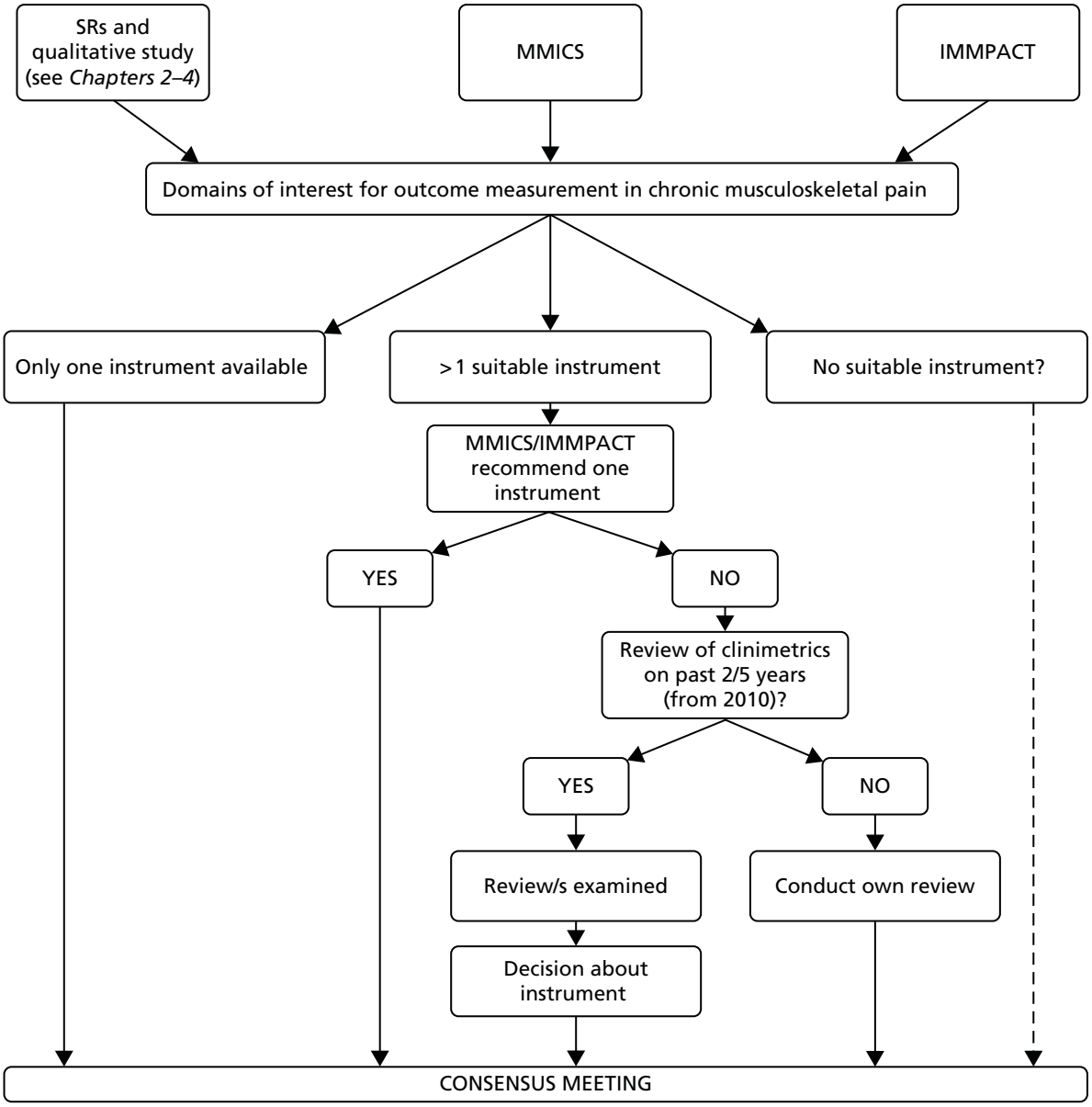

FIGURE 7 Stages of the study. SR, systematic review.

For the domain of social integration and support we extracted common measures of social support, with good clinimetric properties, but the research team felt that these failed to capture the main components described by patients in our qualitative work. We therefore also searched for new, less well-established measures that seemed to have a better fit with the description of the domain. These, accompanied by published evidence on clinimetric properties, were presented to the user group.

Finally, all of the candidate instruments were presented at a meeting of experts, including members of the research team, and external clinicians, experts in outcomes research and patients. As well as clinimetric quality, ease of use, brevity, acceptability to patients and patient preference were also considered, with a final preferred list of outcome measures being identified.

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Results

Selection of domains

The following measurement domains were included after brainstorming and consideration of the IMMPACT and MMICS recommendations:

- pain and pain-related disability
- pain intensity, interference
- pain catastrophising
- recovery
- depression and anxiety
- health-related quality of life
- perception of social support/social integration
- self-efficacy
- fear avoidance
- coping and acceptance
- patient satisfaction at follow-up
- health-care resource use.

Selection of candidate instruments

We were able to immediately select candidate measurement tools based on the IMMPACT and MMIC recommendations for the following domains (the tool chosen is given in brackets):

- pain intensity (numerical rating scale)
- pain interference (Brief Pain Inventory[168])
- health-related quality of life (either SF-36[42] or EQ-5D[169])
- recovery (numerical rating scale)
- pain catastrophising (Pain Catastrophising Questionnaire[170])
- patient satisfaction at follow-up (the Patient Global Impression of Change[171]).

For the domain of fear avoidance, the only systematic review in this area looked at fear avoidance and prognosis in back pain.[34] The two main contenders for measuring fear avoidance from this review were the Tampa Scale of Kinesiophobia[172] and the Fear Avoidance Beliefs Questionnaire (FABQ).[173] The MMICS study[31] reported a slight advantage for the FABQ if work-related fear is considered important. These two measures were presented at the expert consensus meeting.

Another immediate selection was based on the fact that there was only one suitable measure for the domain of pain acceptance: the CPAQ.[174]

For disability, the MMICS recommendations included only instruments specific to low back pain. The IMMPACT recommendations included the Brief Pain Inventory. The Brief Pain Inventory, however, measures both pain and pain-related disability. Furthermore, it is a measure principally designed for measuring acute pain. For this study we were interested in making a difference to long-term outcomes and so a measure that measures pain and its impact on just 1 day was not appropriate for our current purpose. For this reason we carried out a further search to identify measures of chronic pain and chronic pain-related disability. We identified the CPG as a well-established measure with good clinimetric properties when used to measure chronic pain and chronic pain-related disability.[175] We added this measure to our potential pool of measures to assess in the pilot study.

For depression, the Delphi study produced conflicting opinions from experts (see *Appendix 3*). The main reasons given for endorsing measures were absence of confounding somatic items, brevity and clarity, and widespread use in research. The consensus was around the use of four depression measures. The HADS[176] was thought to be a good candidate, although there was some concern about responsiveness. Reasons for

using the Beck Depression Inventory (BDI)[177] were around compatibility with other studies in our population. The Center for Epidemiologic Studies Depression (CES-D) scale[178] allows international comparisons and would be a useful measure. Finally, the Patient Health Questionnaire for Depression and Anxiety (PHQ)-4[179] was thought to be a useful screening tool. The overall recommendation based on the Delphi study was to use the HADS as both a baseline descriptor and an outcome measure as the simplest option. The HADS, CES-D scale and PHQ-4 were presented to the expert consensus meeting for selection of a single measure.

For self-efficacy it was not possible to make a selection of outcome measures based on the MMICS and IMMPACT guidelines, and we could not identify a recent relevant systematic review. We conducted an original systematic review for self-efficacy and identified 37 different self-efficacy questionnaires (see *Appendix 3* for methodological details and a description of the results). We selected the two most commonly used measures (where > 10 articles had used these measures): (1) the Arthritis Self-Efficacy Scale (ASES)[180] with its four variants (for chronic disease and shorter versions) and (2) the PSEQ.[181] We searched for further information on the clinimetric and psychometric properties of these instruments. We reviewed the clinimetric properties of the questionnaires (full details are provided in *Appendix 3*). Construct validity was evident for most measures. There was evidence for content validity for the ASES-20,[180] ASES-11[183] and PSEQ[181] questionnaires. There was some evidence of test–retest reliability for the ASES-20,[180] Chronic Disease Self-Efficacy Scale-33 (CDSES-33)[182] and PSEQ. There was (limited) evidence for responsiveness for the ASES-20, CDSES-33 and PSEQ.

For perceived social support there were no recommendations from the MMICS or IMMPACT guidelines, nor were we able to identify a systematic review comparing measures. We carried out a literature search to identify candidate instruments (see *Appendix 3* for the methods and results). There were 30 social support questionnaires identified in the first broad search and a further nine additional social support measures identified from specialist text books (see *Appendix 3*). At this stage we created a reduced list of six measures that focused on our target population and which included items representing the domains that we had previously identified, with special emphasis on social (re)integration, while considering the psychometric properties of the questionnaires (see *Appendix 3*). Two of these six questionnaires were most closely aligned with our aims of tapping into use of both health resources and social relationships for social support. However, we decided to delay a full clinimetric assessment of the questionnaires because we felt that they did not quite capture our remit in reference to social (re)engagement. It was decided to present these two measures to the focus group meeting prior to clinimetric assessment.

Consensus meeting

The consensus meeting included five members from the project team (TP, ST, DC, CM and KH) and four other participants: two clinical psychologists (one from Mile End Persistent Pain Service and one from Whitechapel Health Centre), one researcher from Patient Reported Outcomes Measurement Group at Oxford University and one chronic pain patient and lay representative.

The measurement domains discussed and the decisions made with regard to recommending tools are described in the following sections.

Self-efficacy

The ASES (and its variants)[180] and the PSEQ[181] were presented. The PSEQ was the final measure selected because it had the most consistent evidence for reliability, validity and test–retest reliability. It was relevant for our population and the questions were comprehensive and comprehensible. It was also quick to administer, with 10 items, and was judged as easy to read, complete and score.

Depression

Findings and comments from the Delphi study were presented to the group, along with the shortlist of depression measures. The final selected measure was the HADS.[176] This was recommended because it has good clinimetric properties, is widely used and covers depression and anxiety in 14 items. The PHQ-4[179] was rejected as it is a screening tool and more detail was needed. The Depression, Anxiety and Positive

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Outlook Scale,[184] although good and covering positive outlook, was not widely used. In addition, the group felt that the HADS also covered positive outlook.

Quality of life

The EQ-5D[169] and SF-36[62] were potential candidates for this domain. The EQ-5D was chosen because it is shorter and simpler than the SF-36 and widely recognised and used in economic analysis. However, when this work was reported to the TSC, we were advised to use both measures in the pilot study.

Coping and fear

The only acceptable tool measuring catastrophic thinking was the Pain Catastrophising Questionnaire.[170] However, the group felt that the questions were quite disturbing and our patient representative expressed concern that some people might find it quite upsetting to complete. The discussion focused on prioritising the important domains for our target population while reducing the burden by not including too many measures. On reflection the group decided to exclude the domain of coping and fear, which is partially covered by the HADS.

Acceptance

The CPAQ[174] was selected as it covered two domains independently in one questionnaire: activity engagement and pain and willingness, that is, engagement and avoidance. There were no other competing contenders for this domain.

Social support

Two measures were presented to the group members: the Chronic Illness Resources Survey (CIRS)[185] and the Social Support Survey.[186] Discussion centred on eliciting the aspects of social (re)engagement. After a brainstorming session it was decided that the presented social support questionnaires failed to measure social integration and confidence to socially integrate adequately. We decided to seek guidance from others by exploring different questionnaires in the wider arena for non-pain health populations that might measure the construct that we had identified, that is, social integration. After a second search we found a relatively new measure, the heiQ,[187] which included a domain called social integration and support that measured exactly our area of interest, that is, social engagement and integration in populations exposed to self-management interventions. Despite it being in the early stages of evaluation, there were no competing measures and we therefore decided that we would use this domain from the heiQ.

We also asked the group to consider which domain should be used for our primary outcome. An overall measure of health-related quality of life was deemed to be the most appropriate choice. Such a measure would synthesise the anticipated effects of our intervention on a wider range of aspects of participants' lives. The EQ-5D[169] was the consensus group's preferred measure for the primary outcome. The five-level version of the EQ-5D was developed after our study was designed. When we refer to the EQ-5D we are referring to what might now be better identified as the EQ-5D-3L. We have, however, used the nomenclature current at the time that the study was developed.

Conclusion

The measures included in the feasibility study are provided in *Table 19*. Following the pilot study we reviewed the performance of the measures before making our final selection (see *Chapter 8*).

TABLE 19 Chosen basket of outcome measures

Outcome measure	Description	Calculation	Score range
CPG overall[175]	The CPG overall score is a composite of the CPG disability score, the CPG pain intensity score and the score for another question assessing the number of days off usual activities because of pain	The question assessing the number of days off usual activities because of pain has four categories: 0–6 days, 7–14 days, 15–30 days and ≥ 31 days. Categories are assigned 0 points for 0–6 days through to 3 points for ≥ 31 days. CPG pain intensity is categorised as < 50 vs. ≥ 50 and CPG disability is categorised as 0 (0–29 points), 1 (30–49 points), 2 (50–69 points) or 3 (70–100 points). An overall disability score is then formed by adding the points from the grouped CPG disability score (range 0–3) to the points assigned for the number of days off work (range 0–3), giving an overall range of 0–6	Grade 0 – pain free: no pain problems in the last 6 months; grade I – low pain disability and low pain intensity: characteristic pain intensity < 50 and < 3 disability points; grade II – low pain disability and high pain intensity: pain intensity of ≥ 50 and < 3 disability points; grade III – high pain disability, moderately limiting: 3–4 disability points, regardless of pain intensity; grade IV – high disability, severely limiting: 5–6 disability points
CPG – pain-related disability[175]	This is a composite of three questions that assess the participant's pain-related disability at present and the maximum and average intensity over the past 6 months	Each question is scored on a scale of 0–10. The final score is the mean of the three questions, multiplied by 10	Range 0–100, with higher scores indicating worse pain-related disability
CPG – pain intensity[175]	This is a composite of three questions that assess the participant's pain intensity at present and the maximum and average intensity over the past 6 months	Each question is scored on a scale of 0–10. The final score is the mean of the three questions, multiplied by 10	Range 0–100, with higher scores indicating worse pain intensity
EQ-5D[169]	Quality-of-life measure. This is a composite of five questions that ascertain whether the participant has any problems with mobility, self-care, performing their usual activities, pain or discomfort, or anxiety or depression	Each question has three answers ranging from 'no problems' (scored as 1) to the worst category (scored as 3)	Perfect health = 1.0. UK norms for healthy males/females: 40–49 years – 0.89/0.87; 50–59 years – 0.80/0.82[188]
heiQ[187]	This is a composite of five questions that ascertain the extent to which the participant is able to enjoy life	Each question has four answers ranging from 'strongly agree' (scored as 4) to 'strongly disagree' (scored as 1). The final score is the sum of the score for each question	Range 5–20, with higher scores indicating more enjoyment in life
CPAQ[174]	This is a composite of 20 questions that ascertain the participant's ability to cope with his or her pain	Each question is scored on a scale of 0–6, with 0 indicating that the statement is never true and 6 indicating that the statement is always true. There are two subscales: pain willingness and activities engagement. The statements in the pain willingness subscale are reverse scored so that an answer of 'always true' gives a score of 0 and an answer of 'never true' gives a score of 6. The statements in the activities	Range 0–120, with higher scores indicating a better ability to cope

continued

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TABLE 19 Chosen basket of outcome measures (*continued*)

Outcome measure	Description	Calculation	Score range
		engagement subscale are scored on a scale of 0–6, with 0 indicating that the statement is never true and 6 indicating that the statement is always true. The final score is the sum of the score for each question	
HADS depression score[176]	This is a composite of seven questions that ascertain the extent of the participant's depression (these are the even number questions of the HADS questionnaire)	Each question has four answers ranging from not experiencing a symptom at all, scored as 0, to experiencing a symptom nearly all of the time, scored as 3. The final score is the sum of the score for each question	Range 0–21, with higher scores indicating more severe depression
HADS anxiety score[176]	This is a composite of seven questions that ascertain the extent of the participant's anxiety (these are the odd number questions of the HADS questionnaire)	Each question has four answers ranging from not experiencing a symptom at all, scored as 0, to experiencing a symptom nearly all of the time, scored as 3. The final score is the sum of the score for each question	Range 0–21, with higher scores indicating more severe anxiety
PSEQ[181]	This is a composite of 10 questions that ascertain the participant's level of confidence to live a normal life despite his or her pain	Each question is scored on a scale of 0–6. The final score is the sum of the scores for all 10 questions	Range 0–60, with higher scores indicating higher levels of confidence

Note: across all of our analyses in phase 2 a decrease in score indicates improvement; this involved us changing the signs of the scores for those instruments for which an increase in score indicates improvement.

Chapter 6 Development of the new self-management intervention

Abstract

Based on evidence from our previous work (see *Chapters 2–5*) we designed and manualised a psychologically orientated group course based on principles of CBT with elements covering acceptance, education about chronic pain, distraction, relaxation, visualisation, posture, social time, encouragement to buddy up and an introduction to new hobbies and activities. The course was underpinned by social learning theory and the theory of planned behaviour/reasoned action. The 24 different individual course components/sessions were delivered over 3 short days (10.00–14.45) with a single 2-hour follow-up session 2 weeks later. Teaching and learning modalities were varied and included a DVD featuring a medical expert addressing frequently asked questions, group discussion, role play and exercises. The course, for groups of up to 14 participants, was designed to be highly interactive and included experiential learning. Courses were facilitated by two trained facilitators: a lay individual with previous experience of small group facilitation and personal experience of chronic pain and a health professional with experience of treating people with chronic pain (chiropractor, GP, osteopath, psychologist or physiotherapist). We also designed a 2-day training programme for potential facilitators.

Introduction

The Medical Research Council (MRC)[28] framework for developing and evaluating complex interventions describes three areas of activity involved in the actual design of an intervention:

1. identifying the evidence base
2. identifying or developing theory
3. modelling processes and outcomes.

We identified the relevant evidence through the systematic reviews reported in *Chapters 2* and *3* and the qualitative study reported in *Chapter 4*. In this chapter we describe how the findings of these projects, together with relevant behaviour change theory, influenced the design of the COPERS intervention and our resulting conceptual model of the intervention. We then describe the intervention to be tested in the pilot and feasibility studies in detail and conclude by mapping the components of the intervention onto the behaviour change techniques taxonomy developed by Abraham and Michie and published in 2008[189] (the taxonomy has since been further refined but this was the version available when we designed the intervention). Finally, we describe the training programme we developed to train facilitators to deliver the intervention in the pilot and feasibility studies.

Summary of the evidence base

The evidence identified from our reviews (see *Chapters 2* and *3*) indicated that group-based courses including psychological approaches with education about pain, undertaking activities and developing new interests were associated with better coping and improved quality of life. We also found that both lay- and HCP-led courses had some beneficial outcomes. From our qualitative work (see *Chapter 4*) we found that participants on courses enjoyed the social element and relaxation training. They had negative reactions to traditional exercise regimens. Good trainers with good facilitation skills made a difference to participants' perceptions of courses and were associated with better course attendance. The ideal setting for courses was somewhere convenient and accessible and, if possible, familiar to participants. *Table 20* explains in more detail how the evidence from *Chapters 2–4* informed our course design.

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TABLE 20 Key findings and their influence on course design

Key findings from *Chapters 2–4*	How these findings influenced course design[a]
Group delivery appears to be effective (see *Chapter 2*); networking with others popular feature of self-management courses (see *Chapter 4*)	Group intervention
Most evidence to support professional tutors (see *Chapter 2*); mixed professional- and lay-led courses also effective (see *Chapter 2*)	Groups to be led by a combination of a lay tutor and a professional tutor
Medical and community settings both associated with effective courses (see *Chapter 2*); convenience of courses important to participants (see *Chapter 4*)	Courses to be held in convenient community or health centre setting
Courses > 8 weeks no more effective than courses < 8 weeks (see *Chapter 2*)	Short-duration course
Psychological components commonly used in self-management interventions for musculoskeletal pain evaluated in RCTs (see *Chapter 2*); self-management interventions with psychological components appear to be more effective than usual care (see *Chapter 2*); larger number of different components not associated with bigger effect sizes compared with usual care (see *Chapter 2*)	Principal component of new intervention to be psychological
Limited evidence to support mind–body therapy components (see *Chapter 2*) but relaxation popular with participants (see *Chapter 4*)	(Relaxation to be control intervention in the main trial)
Increasing self-efficacy may mediate intervention (see *Chapter 3*)	Course should aim to promote self-efficacy
There was evidence that pain catastrophising and physical activity can mediate outcome from self-management (see *Chapter 3*)	We decided to address this in the intervention
Increasing physical activity may mediate the intervention (see *Chapter 3*); patient resistance to concept of exercise but not general activity (see *Chapter 4*)	We decided against a large physical activity component in the course but instead to include taster activities (possible hobbies)
Depression at baseline may be a predictor for poorer outcomes (see *Chapter 3*)	Course covers depression and encourages people who feel that they may be depressed to discuss this with their GP. We considered screening people for depression at baseline and treating depression before enrolling people on the course but rejected this as we could not determine a suitable cut-off and many potential participants had depression
Few other predictors have been identified and no moderators (see *Chapter 3*)	Not possible to identify a subpopulation of chronic musculoskeletal pain patients who might particularly benefit from the intervention. Course to be offered to all eligible adult patients
Concerns of attendees about what happens after the course is completed (see *Chapter 4*)	Follow-up session at 2 weeks
Loss of activities common in chronic musculoskeletal pain patients; distraction from pain may be useful (see *Chapter 4*)	Inclusion of 'taster' sessions in the course
Isolation may arise in chronic musculoskeletal pain patients (see *Chapter 4*)	Introduction of 'buddy' system during the course

a Influences on the main trial are shown in parentheses.

The aim of the new programme was to facilitate and train people to acquire lifelong skills. We decided to use psychological, social and physical techniques to change perceptions and feelings about issues that influence behaviours and to promote accepting, adapting to and coping with life with chronic pain.

Identifying appropriate theories to underpin course design

At the same time as conducting the systematic reviews we searched the literature and spoke to experts about behaviour change theory and models of persisting pain. We considered psychological theoretical models and learning and behaviour modification techniques. We drew on social learning theory[190] and cognitive–behavioural theory,[191] including psychological flexibility (acceptance and commitment therapy), that is, the acceptance of internal experiences or things that cannot be changed countered by behaviour change techniques that are designed to reorientate people towards meaningful activity.[192] We reviewed the theory of planned behaviour and reasoned action[193,194] (including emotional rationalisation) and health belief models.[195] Additionally, we looked at attention control techniques[160] and techniques to promote posture and balance[196] to underpin and inform our intervention. The theories that we considered were mapped onto the broad components of the intervention arising from the evidence base.

Social learning theory

Bandura's[10] model of social learning suggests that behaviour is learned through the process of observation of the environment and the social world to which we are exposed. Bandura identified the importance of learning from role models and peers. He suggested that imitation and social reactions to those imitations (positive and negative reinforcement) can influence future behaviour. Our systematic reviews and our qualitative research also reflected this, with group courses having better outcomes than individual and remote (web-based) courses and participants recalling other participants who coped well with their pain (and, conversely, those who coped particularly poorly). We decided that a group approach, in which participants could learn from each other and try techniques in the company of and with the support of others, was appropriate.

Theory of planned behaviour/reasoned action

The theory of planned behaviour and reasoned action suggests that a person's behaviour is determined by an intention to perform the behaviour, which is based on an individual's attitude towards the behaviour, his or her subjective norms and his or her readiness to perform the behaviour (i.e. whether or not the individual feels that he or she has control and the ability to perform the behaviour).[197]

Typically, the more favourable the attitude and the subjective norm, and the greater the perceived control, the stronger the person's intention to perform the behaviour in question should be. There are many coping behaviours that those with chronic pain adopt, and these behaviours may be beneficial or detrimental. Other behaviours that could be advantageous to pain management are not adopted at all. Raising an individual's awareness of his or her own behaviour may change attitudes towards existing behaviours if he or she is exposed to, or becomes aware of, alternative behaviours that may be beneficial.

We wanted our self-management course to provide an environment that could promote positive attitudes, challenge and or change inappropriate subjective norms and empower and motivate people to realise that they have the ability to change.

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Cognitive–behavioural concepts and acceptance

Cognitive–behavioural therapy evolved out of behaviour therapy and cognitive psychology research. Cognitive therapy has the premise that some behaviours are not simply influenced by rational thoughts but are also controlled by automatic thoughts.[191] In rational emotive therapy, developed by Ellis,[198] it was proposed that once people are made aware of their thoughts and behaviours they can rationalise their emotions towards them and modify their behaviour accordingly. These two therapies informed the basis of CBT.

Cognitive–behavioural treatment focuses on individuals' thoughts, images, beliefs and attitudes (cognitions) and how these impact on behaviour and emotions. The therapeutic process facilitates individual reflection on negative patterns of thinking or behaviour that may cause difficulties in living. Once these behaviours are addressed, this, in turn, is expected to change the way that individuals feel about their issues. In our study the focus was on pain-related behaviours, thoughts and emotions.

We used the fundamentals of modern CBT, which incorporates problem-solving (identifying problem behaviours), goal-setting and action planning, to underpin our approach to help individuals raise their consciousness about how they feel, think and behave towards their pain. Within the action planning stage we also considered ideas surrounding graded exposure used to overcome fear-avoidant behaviour.[173] Modern CBT also encompasses relaxation training, acceptance and commitment therapy, and mindfulness.[192] These are known as third-generation behavioural therapies, with the first- and second-generation therapies being traditional behaviour therapy and CBT. These third-generation therapies focus more on thoughts and feelings rather than behaviour.[199]

Acceptance and commitment therapy has six core principles designed to help develop psychological flexibility:

1. cognitive defusion – learning methods to reduce the tendency to reify thoughts, images, emotions and memories (in other words when people 'overvalue/prioritise' thoughts and images and/or fit and fix them into misleading mental models)
2. acceptance – allowing thoughts to come and go without struggling with them
3. contact with the present moment – awareness of the here and now, experienced with openness, interest and receptiveness
4. observing the self – accessing a transcendent sense of self, a continuity of consciousness that is unchanging
5. values – discovering what is most important to one's true self
6. committed action – setting goals according to values and carrying them out responsibly.[200]

Pain catastrophising theory

Pain catastrophising describes a maladaptive thinking/cognitive style often seen in patients with chronic pain who have associated anxiety and depressive disorders.[201,202] It is characterised by the tendency to magnify the future threat of a predicted pain stimulus, regardless of whether or not it will occur. Chronic pain patients who catastrophise lose their ability to inhibit pain-related thoughts in anticipation of, during or following a painful encounter.

Figure 8 illustrates the relationships between the theories that we considered and our desired outcomes.

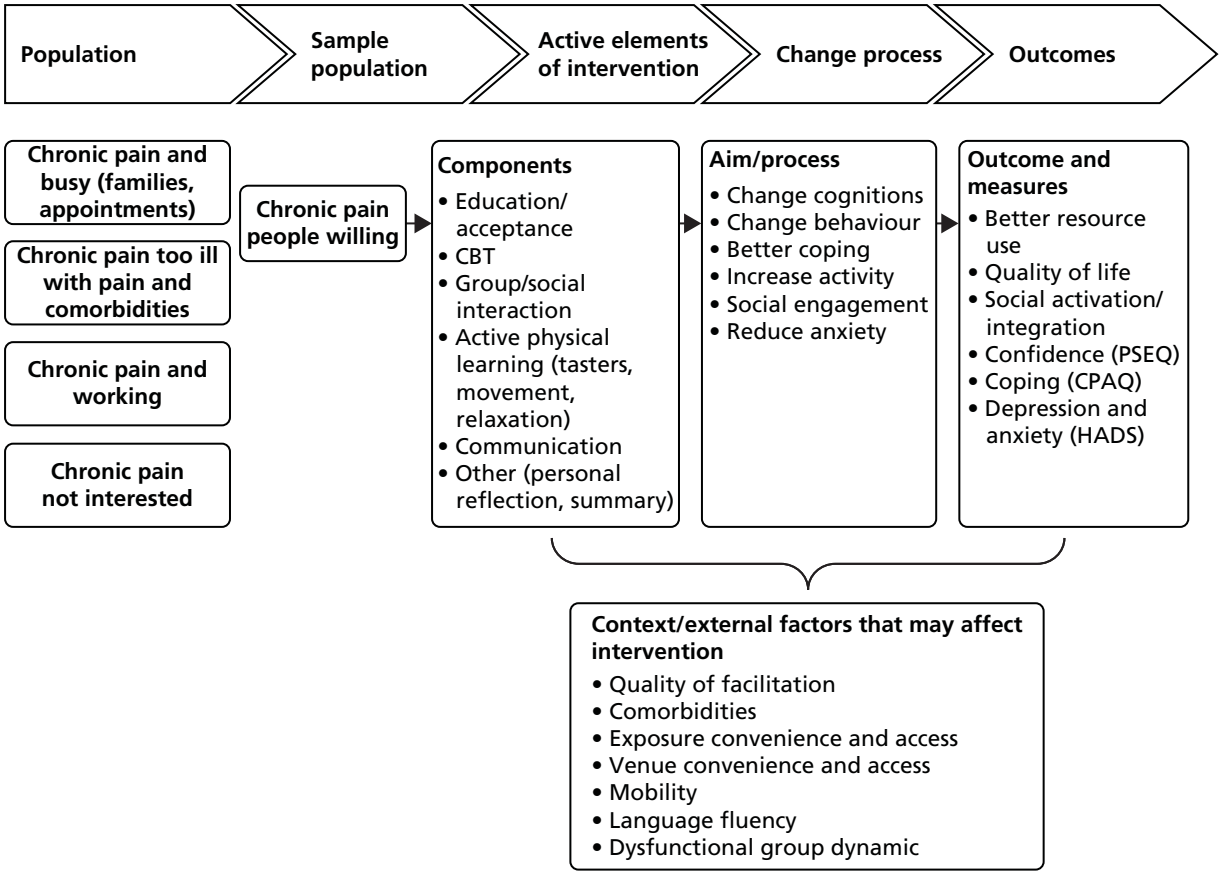

FIGURE 8 Conceptual model.

Modelling the potential course structure and function

As recommended by the MRC guidelines[28] we considered patient pathways through the self-management programme and the likely action and interaction of the different components with regard to outcomes in an attempt to model the impact and effect of our intervention.

The first stage of modelling was to consider recruitment. We know that only a proportion of those with chronic pain will be interested in participating in the study and/or a self-management course (regardless of research). Once recruited, each participant will be exposed to various components of the intervention with the aim of affecting thoughts and behaviours to produce the desired outcomes.

Our conceptual model in *Figure 8* diagrammatically represents the patients, the components of the intervention, the factors that may affect the intervention positively and negatively and the outcomes that we hope to affect. The first column in the model shows the chronic pain population and its potential to be involved in the study and the potential barriers that may affect uptake.

The model shows the patient pathways through the proposed self-management programme. We considered the likely action and interaction of the different components (e.g. sessions, materials, suggested behaviour changes) with regard to outcomes. This involved us elaborating the behaviour change theories relevant to the new intervention. However, it was not possible to develop any appropriate statistical models of the action of the intervention because of a lack of published data.

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Mapping behaviour change techniques to course design

The outcomes that we decided that we might affect with our intervention were function despite pain, health-care resource use, social engagement, depression, anxiety, self-confidence in managing pain and coping. After assessing the relevant behaviour change theories we identified individual behaviour change techniques that might affect our chosen outcomes. We used Abraham and Michie's[189] taxonomy of behaviour change techniques to describe the techniques that we adopted to promote positive behaviour change in self-management groups.

Table 21 shows our rationale for mapping and modelling theory to behaviour change techniques and the methods used by facilitators throughout the courses. Some sessions required facilitators to employ techniques focusing on providing feedback; other sessions provided instruction to promote behaviour change; and some sessions allowed participants to try out techniques within the 'safety' of the learning

TABLE 21 Theories, therapies and cognitive and behavioural techniques influencing the design of the course

Underlying theories and therapies	Influence on course design	Cognitive and behaviour change techniques used throughout the course
Biopsychosocial model of medicine: physiology, psychology and the social environment and society play a part in health	Whole course	• Plan social support/social change • Facilitate social comparison • Barrier identification/problem-solving • Devise behavioural goals • Action planning • Model/demonstrate the behaviour • Provide information on where and when to perform behaviour • Provide instruction on how to perform the behaviour • Provide opportunities to devise ways of performing the behaviour • Learn where and when to perform the behaviour • Learn how to perform the behaviour • Prompt generalisation of a target behaviour • Provide information on the consequences of the behaviour • Reflect on the consequences of the behaviour • Reflect on where and when to perform the behaviour • Prompt self-monitoring of the behaviour • Prompt self-monitoring of the behaviour outcome • Review of behavioural goals and outcomes • Stress management • Prompt self-talk • Prompt use of imagery • Prompt practice • Emotional control training • Environmental restructuring • Communication skills • Provide feedback • Prompt focus on past success • Environmental restructuring • Teach to use prompts/cues • Repetition • Use of follow-up prompts • Prompt anticipated regrets and setbacks • Relapse prevention/coping and planning
Acceptance and commitment therapy: accepting the here and now and living with it	Pain information; acceptance: the uninvited guest; relaxation and mindfulness	
Fear avoidance and catastrophising: pain and fear lead to avoidance behaviour, which is not always beneficial	The pain cycle, goal-setting and action planning	
Attention management: keeping the brain occupied on things other than pain reduces pain perception	Attention control and distraction; relaxation, breathing, visualisation and imagery; taster sessions (e.g. art)	
Social cognitive theory: behaviour may be influenced by interaction between personal factors, environmental factors and own and others' behaviour	Group work/discussion, reflection, listening skills	
Cognitive therapy: recognising the link between thoughts, emotions and behaviour; theory of planned behaviour: based on beliefs about the likely consequences of behaviour; rational emotive principles: logical unemotional rationalisation of events, thoughts, emotions	Identifying problems, goal-setting and action planning; barriers to change – unhelpful thinking; barriers to change – reframing negatives to positives; communicating with your GP; anger, irritability and frustration: managing emotion; follow-up – managing setbacks	
Mind–body therapies: muscle relaxation, biofeedback, visualisation and mindfulness techniques	Relaxation and breathing; relaxation and visualisation; relaxation and mindfulness of thoughts	
Physical theory and therapies: Alexander technique for posture and physical therapy practice of balancing and stretching	Posture, balance and stretch	

environment and the group. The techniques employed by facilitators were dependent on the needs of the participants and the groups and therefore were utilised as required in each individual session. No negative or coercive behaviour change techniques were recommended or used as part of the course.

Overall course design

We appreciated that we would have to consider adult learning theory and a variety of modes of delivery. Our qualitative research indicated that an informal 'non-lecture style' was preferred, with plenty of opportunities for discussion and socialising. Cognitive and social approaches to behaviour change are often challenging as they require participants to reflect about themselves and confront issues that they may or may not be already aware of. Facilitating this process of change and learning requires skill. Facilitators needed training to motivate participants, actively listen, be non-judgemental, empathise and be patient.

A variety of educational, role-playing and discussion sessions that facilitate the learning and practice of behavioural change techniques, such as those used in CBT, have been shown to be effective within the group learning environment in other studies on chronic pain.[48,53] A short, intense group intervention has also been shown to be effective for depression.[203]

There were two very important messages that we had to convey from the outset: (1) we promised no cure (to temper expectation and begin the process of acceptance) and (2) self-responsibility and personal action are important.

Social learning theory takes into account individual ability to learn by experience, either directly or indirectly through others. This was fundamental to the programme; it was the facilitator's role to encourage learning through discussion and self-exploration, and to motivate participants to practise implementing techniques and use those that they felt might help them.

The theory of planned behaviour and emotional rationalisation are based on feedback from promoting, praising and practising positive behaviours, thoughts and feelings, to help generate confidence in personal ability and promote self-confidence. The facilitators and group participants were expected to contribute to this process.

Figure 9 shows how the course content was constructed and linked to aspects of chronic pain that were considered important by the people who we interviewed for the study, the theories that we assessed and the components that showed evidence of benefit.

Figure 10 shows the learning sequence that we adopted; this was informed from our interviews and by consulting educationalists in the School of Medicine and Dentistry at Queen Mary University of London. Our interviewees were relatively uninformed about their condition, knowledge about the persisting nature of pain was unclear and many had not accepted their condition or that there might not be a cure for it. We proposed to tackle these issues first and then build on the learning to encompass key behavioural change strategies and coping techniques. The educationalists recommended using a variety of different teaching techniques and we therefore used videos, didactic education (very little), brainstorming, role play and practice. We were also keen to make the setting as informal as possible and provide as much social time as possible.

Key considerations from the evidence influencing course design have already been described; other key considerations are summarised in *Table 22*.

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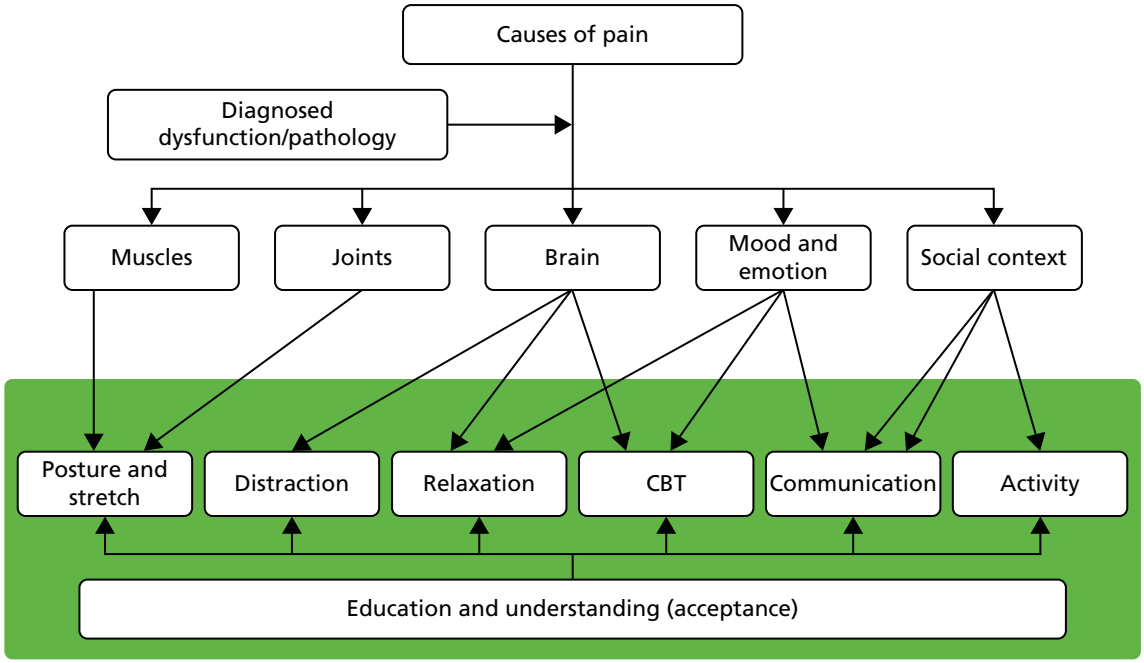

FIGURE 9 Mapping pain factors to the course content. Shaded box indicates course content.

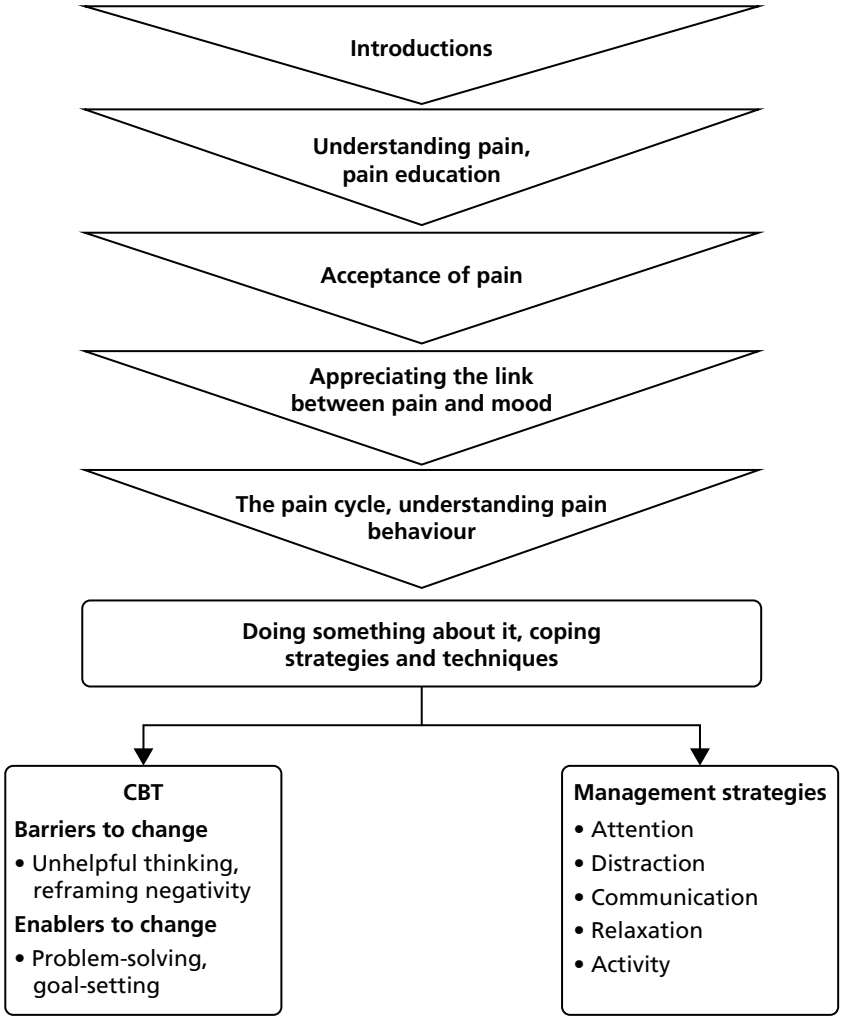

FIGURE 10 Learning sequence.

TABLE 22 Other key considerations influencing course design

Consideration	How this influenced course design
Adult educationalists advised that to be interesting and effective the course should employ a variety of media and modalities, be delivered in 20-minute bites and encourage experiential learning	Inclusion of role play, filmed material, small group exercises, exercises for pairs, active listening exercises, brain storming, etc.
Attrition from self-management courses running over 6–8 weeks known to be a problem	Course was run over 3 days in a single week
Expert professional input may be useful or appealing to participants	Expert professional input delivered by DVD for economy
Reproducibility and fidelity of the intervention	Development of a course manual and training package

The course

We designed a group course to be facilitated by a lay person with chronic pain who had experience in small group facilitation (e.g. experience as a tutor on the Expert Patients Programme) and a HCP (GP, psychologist, physiotherapist, chiropractor or osteopath) to be delivered over 3 short days (10.00–14.45) with a 2-hour follow-up session 2 weeks later. We also designed a 2-day training programme for all potential facilitators. All courses were to be held in a convenient accessible location for the target population. A 'buddying system' was incorporated into the model.

The components of the course included psychological concepts using cognitive–behavioural approaches to managing chronic pain (these covered acceptance, attention control, goal-setting and action planning, recognising unhelpful thinking and behaviours). The course also covered communication skills, relationships, intimacy, promoting better sleep, education about chronic pain, social time, hobbies and activities, posture and movement, breathing, relaxation, and visualisation and guided imagery. The course included a bespoke educational DVD of a pain consultant answering common questions from patients with chronic pain; this was produced in both English and Bengali (which the Sylheti-speaking Bangladeshi community also understand).

A summary of the course aims, learning outcomes, rationale and teaching methods is provided in the following sections and *Box 2* (in the box the numbers 1–24 are used to describe the individual sessions or components of the course).

Day 1: Living with and dealing with pain

- Aims: introduce aims of the course and concept of group work, and increase understanding of pain and reasons for it; introduce concept of acceptance and no cure; introduce the idea of recognising different moods and their effects on pain.
- Learning outcomes: know where pain comes from and why we have it and, in chronic pain, why it persists; the participants should be able to be able to describe why they have persistent pain to somebody else and be able to identify some of their own beliefs about their pain and identify some negative thoughts and behaviours, for example when is pain OK/manageable and, when it is at its worst, how this can relate to mood.
- Teaching methods: group introductions/presentation, facilitated discussion, watching a DVD of frequently asked questions, pain/mood exercise.

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BOX 2 Course schedule

Day 1 sessions

1. Introductions

   - Aim: to introduce self succinctly and effectively.
   - Rationale: social awareness.

2. DVD on pain education

   - Aim: to increase understanding about chronic pain.
   - Rationale: introduce idea of acceptance.

Break

3. Acceptance

   - Aim: to relate the scenario about the unwanted guest to chronic pain.
   - Rationale: introduce idea of acceptance.

Taster activity (pain perception when thoughts not focused on pain).

Lunch break

4. Pain, bearable or not?

   - Aim: to start introducing the concept that pain and mood are linked.
   - Rationale: pain is not only physiological but also psychological, social and emotional.

5. The pain cycle

   - Aim: to explain the pain cycle and understand the process and the unhelpful things that we do that keep us in that cycle.
   - Rationale: behaviour theory and fear avoidance.

Break

6. Posture

   - Aim: to promote body awareness, posture and muscle weakness.
   - Rationale: evidence for exercise, physical therapy principles, Alexander technique.

7. Relaxation and breathing

   - Aim: to reduce muscle tension and introduce breathing as a relaxation technique.
   - Rationale: principles of third-generation CBT, mind–body therapies and biofeedback.

Summary of the day

- Aim: reflection and embedding learning.

BOX 2 Course schedule (*continued*)

Day 2 sessions

8. Reflections from day 1

   - Aim: to understand and empathise with the group.
   - Rationale: improve bonding and group cohesion, social cognitive theory.

9. Goal-setting and action planning

   - Aim: to help participants logically and systematically to identify problems, brainstorm solutions, set goals and devise action plans as a means of escaping the pain cycle.
   - Rationale: based on cognitive–behavioural techniques, change management principles, theory of reasoned action and theory of planned behaviour.

Break

10. Barriers: unhelpful thinking

    - Aim: to introduce ideas about unhelpful thoughts, automatic thoughts and errors in thinking.
    - Rationale: recognising errors in thinking can help with realistic assessment and more constructive/rational views of the world; based on the fundamentals of rational emotive therapy and cognitive–behavioural principles.

Taster activity.

Lunch break

11. Barriers: reframing 'cons' to 'cans'

    - Aim: to identify reasons why people stay in the pain cycle and barriers to change.
    - Rationale: based on cognitive–behavioural techniques.

12. Attention control and distraction

    - Aim: to learn how to focus the mind away from pain thoughts.
    - Rationale: based on attention control and distraction techniques.

13. Making pain more manageable

    - Aim: to summarise the techniques learnt so far to manage pain.
    - Rationale: embedding learning from the day.

Break

14. Balance and stretch (as day 1).

15. Relaxation and visualisation (as day 1).

Summary of the day (as day 1).

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BOX 2 Course schedule (*continued*)

Day 3 sessions

16. Reflections from day 2

    - Aim: to understand and empathise with the group and ascertain current thoughts.
    - Rationale: improve bonding, group cohesion and understanding of learning, social cognitive theory.

17. Communicating with health professionals

    - Aim: to reflect on consulting behaviour, promote effective communication and constructive consultations.
    - Rationale: promote effective health-care utilisation; based on theories of reasoned action and planned behaviour.

Break

18. Listening skills

    - Aim: to improve listening and communication skills.
    - Rationale: to help with social integration, based on social cognitive theory.

19. Anger, irritability and frustration

    - Aim: to identify reasons for negative emotions and implement goal-setting and action planning.
    - Rationale: cognitive–behavioural principles.

Taster activity.

Lunch break

20. Stretch

    - Aim: to learn how to stretch muscles gently with low risk of injury and pain.
    - Rationale: manual therapy.

21. Relaxation and mindfulness of thoughts

    - Aim: to learn to apply guided imagery and detach emotion from reality to appreciate 'the now'.
    - Rationale: evidence for focusing attention and separating emotion from sensation: mindfulness.

Break

22. Summary of the course

    - Aim: to clarify learning from the past 3 days and introduce the idea of buddying.
    - Rationale: embedding learning.

BOX 2 Course schedule (*continued*)

Follow-up sessions

23. Reflections and narratives

    - Aim: to understand and empathise with the group and ascertain current thoughts.
    - Rationale: improve bonding, group cohesion and understanding of learning.

Break

24. Managing setbacks

    - Aim: to know what to do when experiencing a setback or a flare-up.
    - Rationale: cognitive–behavioural principles, attention control and re-embedding learning.

Day 2: Doing something about life with pain

- Aim: identify opportunities to change and understand when change is possible and when it is not.
- Learning outcomes: be able to break down issues into manageable chunks and set simple, measurable, achievable, realistic goals within a suitable time frame; be able to identify negative behaviours and thoughts and spot errors in thinking.
- Teaching methods: group discussion, self-reflection and practice.

Day 3: Communication and relationships

- Aim: promote effective utilisation of health-care services and improve communication skills.
- Learning outcomes: moderate expectations; communicate effectively.
- Teaching methods: group discussion and role play.

Follow-up at 2 weeks

- Aim: managing setbacks: knowing what to do when experiencing a setback or a flare-up.
- Learning outcomes: improve bonding, group cohesion and understanding of learning; embedding learning.

Facilitator recruitment and training

The recruitment criteria and training needs for facilitators were obtained from the qualitative study.

We were aware that courses facilitators who were highly regarded were those who managed difficult participants, included participants to the extent that they were comfortable with, were flexible and knew the course content well so that they could deviate when necessary and return to issues as appropriate. Facilitators who had good listening skills, who did not talk too much themselves and who made people laugh and relax were valued.

We recruited HCPs and laypeople. We recruited HCPs who had a specific interest in and understanding of chronic pain and we recruited laypeople who had experience of chronic pain and who had previous tutoring experience.

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The course was designed to deliver:

- facilitation skills training
- trial procedures and protocol training
- course content familiarisation and delivery
- adverse event handling.

The course was spread over 2 days (Saturday and Sunday) and involved didactic education, role play and practice. Trainees were observed and evaluated throughout the course to assess their understanding, strengths and weaknesses (the training course structure is provided in *Appendix 4*).

Chapter 7 Feasibility study

Abstract

Introduction: In 2010 we conducted a feasibility study to inform us about the COPERS self-management course, in particular its delivery and content plus the trial procedures, in preparation for a definitive trial.

Method: We designed a pilot RCT with 100 chronic musculoskeletal pain patients randomised 3 : 1 to the intervention or usual GP care plus an advice leaflet. We included a non-randomised arm in which we delivered a version of the course translated into Sylheti to Bangladeshi patients not fluent in English. We used a mixed-methods evaluation including quantitative process information; qualitative feedback from course participants, facilitators and observers on their experience of the course; and quantitative data from participant self-report questionnaires at baseline and 3 months' follow-up.

Results: Systematically identifying eligible participants from GP medical records proved difficult and spurred us to develop better search strategies for the main trial. Very uneven initial randomisation allocation led us to abandon the randomised design and offer all participants the intervention. In total, 167 (32%) of 526 potential participants, of whom 343 (65%) were female, expressed an initial interest in participating; 56 of these (34%) were recruited to the English-speaking courses and 41 (25%) to the Sylheti-speaking courses. We ran nine courses, six in English and three in Sylheti. Forty-two people attended the English-speaking courses and 26 attended the Sylheti-speaking courses. Nine facilitators were trained and seven facilitated a course. We sought written feedback from facilitators and participants and we also carried out 13 in-depth participant interviews. The course was regarded as beneficial by most participants, with the group experience being important. Key recommended changes before a definitive trial included:

- better facilitator training
- the provision of clear aims and summaries for each session of the course as well as links between sessions
- audio-recording of each course to check quality and 'treatment drift'
- making the outcome questionnaires user friendly and shorter
- adopting the pain-related disability subscale of the CPG as a future primary outcome
- the provision of a more credible control arm
- conducting the main trial only in English.

Conclusion: The feasibility study provided important information on the intervention and its delivery and on the design and conduct of a definitive trial of the intervention.

Introduction

Having designed the self-management support intervention for chronic musculoskeletal pain (see *Chapter 6*) we conducted a feasibility study to test the design of the new intervention and to inform a future definitive trial of the intervention. We called the intervention COPERS after the name of the study (COping with persistent Pain, Effectiveness Research into Self-management). The COPERS course aimed to improve the overall quality of life for people living with chronic pain.

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Objectives

The objectives of the feasibility study were to evaluate the quality and appropriateness of the COPERS course and the trial processes, including the participant recruitment process, facilitator training, delivery of the course content and collection of outcome measures, in preparation for the main RCT.

Methods

We proposed a pilot RCT of 100 participants randomised to the intervention or usual GP care plus best practice patient advice on a 3 : 1 basis favouring the active intervention. In addition to this pilot RCT, to test the practicality of including participants from a wider range of backgrounds in our main study, we delivered the intervention separately in both English for the general population and in Sylheti for members of the Bengali community living in Tower Hamlets (*Figure 11*).

We used a mixed-methods approach including both qualitative feedback from course participants, facilitators and observers, and quantitative information from self-report questionnaires and activity data.

We chose randomisation on a 3 : 1 basis to enable us to run at least six to eight courses while testing the randomisation process and the acceptability of the control arm. This study was not designed to show an effect of the intervention but to test the feasibility of the intervention and the trial protocols. It was conducted in Tower Hamlets, London, from January to April 2010.

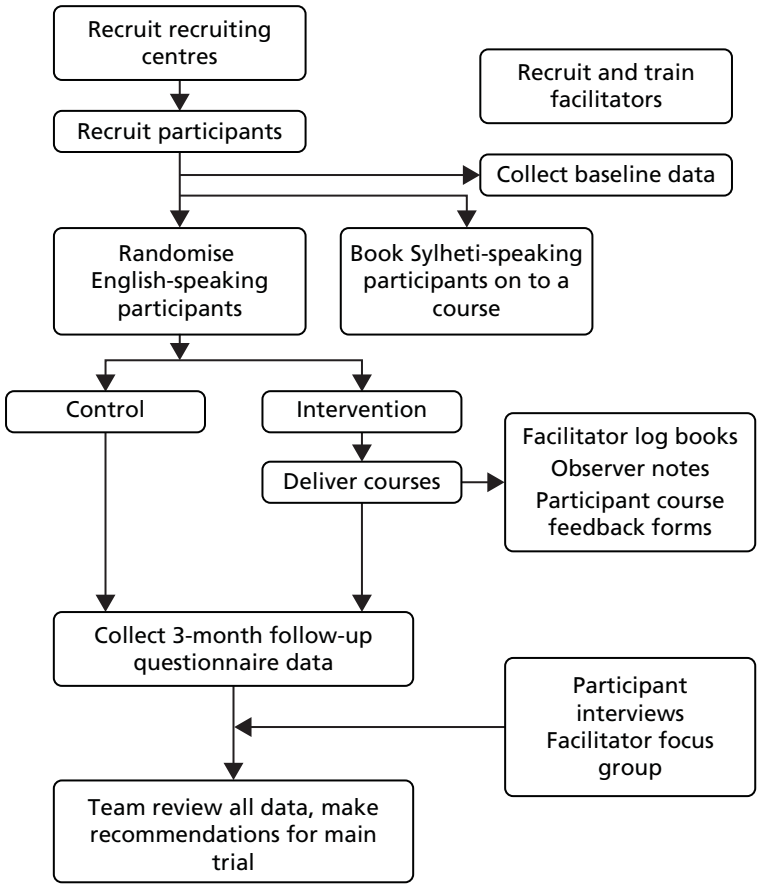

FIGURE 11 Design of the feasibility study.

Recruitment

We aimed to recruit participants to the English-speaking courses by targeting patients with chronic pain who were registered with the local persistent pain service, physiotherapy department or two local general practices. We selected the community-based pain and physiotherapy services as they reported in excess of 1000 new chronic pain patients per year. We also involved general practices as clinicians estimated that around 10% of GP consultations in Tower Hamlets were for chronic pain.[204] One of the general practices was chosen because around 90% of patients were Sylheti speaking (in other local practices the equivalent figure was around 50%).

Recruitment of participants

Participant recruitment is key to any successful trial. We reviewed six studies that had also recruited participants to trials of group interventions for musculoskeletal pain (*Table 23*). Their mean uptake rate from invitations was 8.8%; we aimed for an uptake of around 10%.

Participant identification and participant recruitment materials

We anticipated inviting approximately 600 patients with chronic pain to participate in the feasibility study. We estimated a 60% response rate (around 360 people) based on previous studies that we have conducted and expected that around one-third of these would accept the invitation to participate, resulting in around 120 potential participants. Of these, we anticipated that about 10% would not be able to commit to the study or would not meet our inclusion criteria.

We asked the clinical staff at recruiting centres to search their computerised medical records to identify eligible patients. At this point we realised that there was no easy way to identify people with chronic pain from the patient electronic records in general practice using condition terms and/or Read codes, such as low back pain and OA combined with recent consultations for pain. This led to a separate study to explore the best way of identifying patients relevant to our trial.[206] We also encouraged face-to-face invitations at all recruitment sites as we anticipated that the personal interaction and authentication of the course by a HCP/patient adviser would increase interest (see *Chapter 4*). Potential participants were identified and reviewed by their clinician according to the inclusion and exclusion criteria described later in this chapter. Those deemed likely to be eligible were invited to participate in the trial by their clinic or general practice by letter. With the letter they also received a participant information leaflet and a consent to approach form to complete and return to the study team if they were interested in joining the study (the final versions of these documents as used in the main trial are contained in *Appendix 6*). We translated participant recruitment materials into Bengali script for the Bangladeshi participants (see *Appendix 5*). In addition, one of the recruiting general practices employed a bilingual patient advisor advocate who was able to translate and explain the information to any less literate Bangladeshi patients living with chronic pain identified for the study. Reminder invitation letters were sent after 10 days.

TABLE 23 Trial uptake data

Study	Country	Pain condition	Setting	Duration of course (weeks)	Number invited	Number recruited	Uptake rate (%)
Bernaards 2006[98]	The Netherlands	Upper limb	Occupational	24	8000	466	5.8
Johnson 2007[54]	UK	Lower back	Community	6	2068	234	11.3
Lamb 2010[53]	UK	Lower back	Community	6	9744	701	7.2
Moore 2000[83]	USA	Lower back	Medical	3	2582	226	8.8
UK BEAM Trial Team 2004[205]	UK	Lower back	Community	6	11,341	1334	11.8
Von Korff 1998[77]	USA	Lower back	Medical	4	3292	255	7.7

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Sylheti-speaking groups

In addition to the English-speaking courses (proposed pilot RCT), we proposed three additional courses conducted in the Sylheti language for Bangladeshi participants. We ran separate Sylheti courses for male and female participants. The Bangladeshi community has a written language, Bengali, and a spoken language, Sylheti. Depending on the level of education potential participants may or may not have been able to read and understand the Bengali script but all could understand and speak Sylheti. Participants recruited to the Sylheti-speaking courses were not included in the randomisation process but were enrolled directly onto the courses. We were particularly keen to explore how this course could be made available to the Bangladeshi community of Tower Hamlets (where many of the study team were based), who, in common with other South Asian groups living in the UK, have a high prevalence of chronic musculoskeletal pain.[153] Delivering the course in a language other than English provided the specific experience needed to inform a decision for the main trial on whether to present all courses in English or to also offer the programme in minority languages.

Consent

The study team telephoned interested patients and spoke to them about the study to check that they were eligible and ensure that they had enough information. We were also able to establish language fluency during this initial telephone contact. If potential participants were still interested in the study, we attained informed verbal consent to participate and assigned them a study number. We then asked them to complete the baseline questionnaire and sign the study consent form and return both documents to the study team in the Freepost envelope provided. Another member of the COPERS team, fluent in Sylheti, made the initial contact telephone calls to interested Bangladeshi participants and sent out the consent form and questionnaire (Sylheti-speaking participants were given both a Bengali script and an English version of the questionnaire).

Participant inclusion criteria

- Adults (aged > 18 years) with a diagnosis of chronic non-specific musculoskeletal pain.

Participant exclusion criteria

- Not fluent in spoken English (except for Bangladeshi participants eligible for the Sylheti-speaking course).
- Serious comorbidity such as cancer and not in remission.
- Poorly controlled major psychological illness.
- Terminal illness.
- Unaddressed or poorly controlled addiction to drugs or alcohol or other substance misuse.
- Inability to give valid consent.

Randomisation

On receipt of the signed study consent form the English-speaking participants were randomised to either the intervention or the control group. An independent statistician based at the Pragmatic Clinical Trials Unit (PCTU) at Queen Mary University of London performed the randomisation using minimisation, with gender as a minimisation factor, in a ratio of 3 : 1 favouring the intervention. Participants were then telephoned by the study team and informed of their allocation. Those randomised to the intervention group were enrolled on the earliest available convenient course and asked to complete a baseline questionnaire prior to the course. The Bangladeshi participants were not randomised but booked on to courses directly.

The intervention

The structure of the course and the rationale for its design are described in *Chapter 6*.

We aimed to book courses on alternating days when possible, for example Monday, Wednesday and Friday, in easily accessible, familiar and local places, with a large room, kitchen and toilet facilities. The course content was modified to be culturally appropriate for the local Bangladeshi population but remained as similar in design and structure as possible to test whether or not our approach was directly transferable to this particular ethnic group. The modifications included single-sex courses and avoiding a clash with Friday prayers.

Training facilitators to deliver the intervention

We recruited HCPs (chiropractors, GPs, osteopaths, psychologists and physiotherapists) and laypeople with chronic pain and experience of facilitating and/or teaching to deliver the intervention. Training took place over 2 days and consisted of familiarisation with the course content and structure, facilitation skills and trial procedures.

Control arm

Participants randomised to the control arm of the study received usual GP care plus best practice advice in the form of a 20-page booklet called *The Pain Toolkit*, developed by Frances Cole and Pete Moore.[207] We asked the control participants to refrain from attending any self-management courses for the duration of the study but encouraged them to contact their local Expert Patients Programme after the COPERS follow-up period had elapsed.

Data collection

We collected both quantitative and qualitative data as part of the feasibility study. Quantitative data included questionnaire-based self-reported outcomes and participant feedback. Qualitative data included observational field notes from the courses, free response questions from participant feedback forms, a focus group with team members and COPERS facilitators, and in-depth interviews with some of the participants.

Questionnaire for self-reported outcomes

Questionnaire-based self-reported outcomes were collected at baseline (just prior to randomisation) and 3 months after randomisation. We collected data from the Bangladeshi participants before the beginning of each course and 3 months after the course. The questionnaires were returned to the study team using reply-paid envelopes. Reminder letters and telephone calls were used to contact those who failed to respond.

We used the basket of outcome measures identified in *Chapter 5*. These were:

- pain intensity using a 0–10 numerical rating scale
- pain extent using a pain manikin drawing
- heath-related quality of life using the EQ-5D[169]
- self-efficacy using the PSEQ[181]
- anxiety and depression using the HADS[176]
- coping and acceptance using the CPAQ[174]
- in addition, following a TSC meeting decision we used the SF-36.[208]

At baseline we also collected self-reported demographic data: date of birth, gender, living arrangements (alone or with others), language fluency, ethnicity,[209] employment status and education level, duration of pain and location of pain (the final questionnaires used in the main trial are in *Appendix 6*).

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Facilitator log books

Each facilitator (two per course) was required to complete a structured log book. Facilitators were asked to reflect and comment on the following for each session/component of the course:

- engagement of participants in the process
- level of understanding shown by participants
- types of questions asked
- displays of discordance/expressed difficulties/dysfunctional elements
- group dynamics
- personal reflections and suggestions for improvements.

The facilitators returned their completed log books to the study team after each course was finished.

Observer field notes

Each course was observed by a member of the study team and notes were taken and prepared in a structured format for each session on:

- the facilitation process
- the content generated
- the types of questions asked
- displays of discordance/expressed difficulties/dysfunctional elements
- the level of understanding shown
- group dynamics/engagement of trainees in the process
- personal reflections and suggestions for improvements.

Participant feedback questionnaires

Participants on the English-speaking courses were asked how satisfied they were, on a 5-point scale, with aspects of the course, together with some free-response questions (*Box 3*).

Questionnaires were handed out to participants by the course observers at the end of each course and questionnaire completion was optional and anonymous.

Participant interviews

Purposive sampling was used to identify participants to approach for interview. We invited a mix of genders and ages (≤ 40 years or > 40 years) and those who had good or poor attendance or who had chosen not to attend the course at all. The topic guide for the in-depth interviews was generated by the study team and aimed to cover:

- the invitation process (recruitment and marketing)
- randomisation (reasons for attending)
- the baseline questionnaire
- course content
- course duration and facilities
- the group process ('buddying' and mix of participants)
- facilitation
- post-course changes and activities.

All interviews were recorded and written up but were not transcribed verbatim.

BOX 3 Participant feedback questionnaires

Quantitative questions

On a scale of 0–5, with 0 indicating least satisfied and 5 indicating most satisfied, how satisfied were you with the following:

- the course today?
- the teaching methods used?
- the handouts?
- the facilitators?
- the group discussions process?
- the amount of time for socialising?
- the amount of time spent on each topic?
- the taster session?
- the facilities?
- the amount of information given?

Qualitative questions

- Name three things that you learned were important to you.
- What parts of the course did you enjoy the most and why?
- What parts of the course did you least enjoy and why?
- How relevant was the course content to you?
- Comments about facilitation.
- Suggestions for improvements.

Data analysis

Questionnaire for self-reported outcomes

The output from the baseline questionnaire was used to produce summary statistics on demographics and outcome measures for both the randomised participants and the Bangladeshi participants.

Facilitator feedback and observer data

Data collected from the observer notes, the facilitator focus group and facilitator log books were combined. Two members of the study team familiarised themselves with the data to identify themes and subthemes.

Participant data

Response rates and mean scores were calculated for the participant feedback questionnaire items. The qualitative data from the participant feedback questionnaire and the participant interviews were analysed using a framework approach.[154] Two researchers reviewed the data independently to derive a framework of themes and subthemes.

These data were used to inform the facilitator focus group and modifications to the course and the trial processes.

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Results

Recruitment sources and participant identification

Recruitment and delivery of the intervention took place over 9 months (February to October 2010). We identified 526 potential participants, of whom 32% ($n = 167$) expressed an initial interest in participating. Of these, 42% ($n = 70$) were allocated a study ID number and sent a questionnaire and consent form to participate in the English-speaking study, and 24% ($n = 40$) were enrolled into the Sylheti-speaking feasibility study, representing an overall 21% recruitment rate (*Table 24*).

Reasons for declining to take part were:

- a preference for 'physical' treatment such as physiotherapy or injections
- inability to get time off work, especially for teachers
- inability to attend because of childcare issues
- language barriers (English fluency not sufficient to take part in a group process).

Consenting participants were randomised using minimisation with a 60 : 40 female/male split expected and a 3 : 1 ratio in favour of the intervention. However, we abandoned allocation to the control arm as the initial randomisation sequence was top heavy with control participants and did not yield sufficient participants in the intervention arm to fill the first prebooked course. We continued to run the randomisation sequence and eventually the randomisation sequence was as expected overall. We modified our randomisation strategy for the main study to include randomly permuted blocks to ensure that a steady flow of participants was randomised to the active intervention.

We ran nine courses in total starting in the last week of March 2010 and continuing to mid-July 2010, with around seven participants on each course. There were six mixed-gender English-speaking courses, one Sylheti-speaking male course and three Sylheti-speaking female courses. Fifty-six participants [$n = 30/56$ (54%) female participants] were booked onto the English-speaking courses. Fourteen participants (25%) did not attend any sessions. Four participants attended day 1 only and 38 attended ≥ 2 days (*Table 25*).

TABLE 24 Source of participants

Recruitment source	Number of invitations (letter or face to face)	Reminder letters	Initial interest	Enrolled	
				Allocated study ID number	Booked onto Sylheti course
Pain service	423	342	124	59	26
GP 1	68	5	24	0	12
GP 2	23	19	12	7	2
Physiotherapy	12	0	7	4	1
Total	526	366	167	70	41

TABLE 25 Recruitment and attendance day 1

Participants	Number contacted	Total number booked on a course (% of those contacted)	Attendance at day 1 (% of those approached/booked)
English-speaking females	228	30 (13)	23 (77)
English-speaking males	134	26 (19)	19 (73)
Sylheti-speaking females	115	34 (30)	22 (65)
Sylheti-speaking males	46	7 (15)	4 (57)

Four male participants attended the Sylheti-speaking course, with three attending ≥ 3 days. The first Sylheti-speaking female course had 20 participants booked but four (20%) did not attend any sessions. Of the remaining 16 participants all attended at least 2 days. The second Sylheti-speaking female course had 14 participants booked but eight (57%) did not attend any sessions.

There were 10 participants on the English-speaking courses who were not from a white British/Irish ethnic group and who spoke English with varied fluency. They coped with the course but those who were not very fluent did struggle to maintain full involvement with the discussions, often preferring to listen rather than talk.

There were more female than male participants interested in being part of the study (75 females vs. 34 males), particularly for the Sylheti-speaking group (33 females vs. 7 males) (*Table 26*). The mean number of participants attending each English-speaking course was seven and the mean number of participants attending each Sylheti-speaking courses was nine. The median age range of participants was 41–50 years (see *Table 26*).

Questionnaire for self-reported outcomes

Of 56 potential participants allocated a study ID number and booked on a course, 48 (86%) returned usable baseline questionnaire and study consent forms. The response rate at 3 months was 52% ($n = 25$). Of 41 Bangladeshi participants booked onto courses, 18 (44%) returned their baseline questionnaire and three (7%) retuned their follow-up questionnaire.

The participants found the questionnaire extremely difficult to complete because it was long and repetitive; this was particularly so for the Bangladeshi group. We provided assistance and extra time prior to the courses being run to help participants complete the questionnaire but participants and the assistants found the task arduous and slow. *Table 27* shows that, despite providing the questionnaire in both English and standard Bengali to the Bangladeshi group, more English questionnaires were returned. Our qualitative work explained that help to complete the questionnaire was often given by participants' children who were fluent in English and but who did not read Bengali.

There was a high proportion of missing data in the participant questionnaires, meaning that the data should be interpreted with caution (*Table 28*). At baseline, differences in employment were seen between the groups, with few of the Bangladeshi group being employed and the majority of responders being

TABLE 26 Age and gender of those allocated study IDs

	Sylheti speaking		English speaking	
Age (years)	Male	Female	Male	Female
≤ 20	0	0	0	0
21–30	0	1	0	2
31–40	2	9	7	5
41–50	3	8	6	17
51–60	0	13	7	12
61–70	0	2	3	4
71–80	2	0	3	0
≥ 81	0	0	1	2
Total	7	33	27	42

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TABLE 27 Questionnaire completion: Sylheti-speaking courses

Course	Questionnaires sent	Questionnaires returned (response rate, %)	Returned in English	Returned in Bengali	Fully completed (completion rate, %)	Partially completed (completion rate, %)
Baseline						
B1	4	3 (75)	0	3	0	3
B2	16	6 (38)	5	1	3	3
B3	6	6 (100)	5	1	1	5
Total	26	15 (58)	10	5	4 (27)	11 (73)
Follow-up						
B1	4	0 (0)	0	0	0	0
B2	16	2 (13)	2	0	2	0
B3	6	0 (0)	0	0	0	0
Total	26	2 (8)	2	0	2 (100)	0 (0)

TABLE 28 Participant characteristics at baseline

Characteristic	Sylheti speaking ($N = 26$), *n* (%)	English speaking ($N = 48$), *n* (%)
Employment		
Employed	1 (4)	13 (27)
Family/home keeper	8 (31)	5 (10)
Retired	1 (4)	8 (17)
Unable to work because of ill health	4 (15)	17 (35)
Unemployed	3 (12)	5 (10)
Missing	9 (35)	0 (0)
Education		
None	3 (12)	1 (2)
Until < 12 years	4 (15)	0 (0)
Until 13–16 years	4 (15)	18 (38)
Until 17–19 years	1 (4)	9 (19)
Until ≥ 20 years	2 (8)	18 (38)
Still a student	0 (0)	2 (4)
Missing	12 (46)	0 (0)
Support		
Living alone	0 (0)	17 (35)
Living with others	6 (23)	27 (56)
Missing	20 (77)	4 (8)

TABLE 28 Participant characteristics at baseline (*continued*)

Characteristic	Sylheti speaking ($N = 26$), *n* (%)	English speaking ($N = 48$), *n* (%)
Pain		
Duration > 4 years	13 (50)	36 (75)
Duration < 4 years	4 (15)	11 (23)
Missing	9 (35)	1 (2)
Mean extent (out of 13 sites)	5 sites ($n = 18$)	5 sites ($n = 47$)
Mean intensity (out of 10)	7.7 ($n = 18$)	7.0 ($n = 44$)

female home/family carers. The other between-group difference related to education: 7/14 (50%) of the Bangladeshi participants who supplied data on age completing education had either no formal education or were educated only to the age of 11 years, compared with 2% of the English-speaking group.

The mean scores for pain extent, intensity, depression and social integration were similar between the groups at baseline (*Table 29*). EQ-5D, anxiety, self-efficacy and coping showed differences between the groups, indicating worse states in the Bangladeshi group. This is consistent with other evidence from Tower Hamlets.[153]

At follow-up, overall, almost all mean outcomes showed a tendency towards improvement but, when confined to those for whom we had longitudinal data, as anticipated, no statistically significant changes in scores were seen in these pilot data (see *Table 29*).

Recruitment and related issues are summarised in *Table 30*. These issues were identified from feedback from the facilitators and from observations by the study team. Detailed feedback data are provided in *Appendix 5*.

TABLE 29 Summary baseline and follow-up questionnaire data

Outcome	Baseline English speaking ($n = 43$), mean score (SD)	Baseline Sylheti speaking ($n = 26$), mean score	Follow-up English speaking ($n = 22$), mean score (SD)
CPG pain intensity (scale 0–10)[a]	6.7 (2.1)	7.7	6.3 (2.2)
CPG pain extent (scale 0–13)[b]	4.6 (2.4)	5	–
EQ-5D score[c]	0.23 (0.4)	0.12	0.31 (0.4)
PSEQ score (scale 0–60)[d]	22.5 (12.7)	25.4	30.2 (13.1)
HADS anxiety score (scale 1–21)[e]	11.3 (4.1)	12.7	10.2 (3.8)
HADS depression score (scale 1–21)[e]	9.4 (3.8)	9.3	8.8 (4.1)
CPAQ score (scale 0–120)[f]	46.7 (17.3)	41.9	54.1 (18.02)
heiQ score (scale 5–20)[g]	12.8 (3.1)	12.4	13.1 (3.5)

a 10 = worst pain imaginable.
b 13 = all over pain.
c Perfect health = 1.0; UK norms for healthy males/females: age 40–49 years = 0.89/0.87; age 50–59 years = 0.80/0.82.[188]
d 60 = completely confident.
e 0–7 'normal', 8–10 borderline, 11–21 'abnormal'.
f 0 = not coping at all.
g Higher scores indicate a better social life.

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TABLE 30 Recruitment and outcome data collection issues

Process	Issues identified	Potential solutions
Recruitment sources and patient identification	Time-consuming to secure collaborations with recruitment sources allowing for approvals	Allow time for recruitment of recruitment sources
	Recruitment sources did not yield enough participants	Do not target all recruitment sources at the same time – phased recruitment; try to estimate number of participants expected compared with actual and flag up deficits early – allow for exclusions; boost recruitment by advertising in non-GP sites (e.g. local adverts in waiting rooms, pharmacy posters)
	More potential participants yielded from medical record searches than expected	Construct more specific search strategies for medical record systems to target the most appropriate participants
	Fewer participants yielded from secondary care registers than expected	
	GPs/clinicians too busy to screen lists of potential participants generated from medical record searches	Ensure participating GPs/clinicians are given enough time to check patient lists against exclusion criteria
	GP/clinic staff did not have dedicated resources to perform the searches of their record systems or have time to produce the mail-merge invitation letters and post the packs	Recruit a research assistant and allocate time to perform the initial searches of patient records to identify suitable participants and also to prepare the invitation packs and reminder letters
	Difficulty in finding a patient advocate who had time to assist in the recruitment of non-English-speaking participants	Provide specific funding for a patient advisor/ advocate to help in face-to-face or over the telephone recruitment for non-English-speaking participants
Randomisation and course booking	Freepost envelopes were sometimes delayed compared with stamped envelopes	Allow time for post office processing of the Freepost service
	Need time to receive baseline questionnaire back prior to course dates	Allow at least 4 weeks for participants to return their baseline questionnaire and consent form; allow 2 months between the participant invitation mail-out and course booking
Control group	It was difficult to 'sell' the control arm of usual care and an educational leaflet to potential participants	Provide a more credible control arm to motivate people to take part
Randomisation	Individual randomisation by minimisation yielded an unpredictable sequence of allocations	Use the block randomisation method to ensure that enough participants are allocated to the intervention to run a course
Cultural adaptation	Courses running on a Friday precluded the male Muslim population because they were attending prayer	Choose alternative day to Friday
Data collection	Questionnaire fatigue an issue	Shorten questionnaire
	Response rate from non-English-speaking participants particularly poor	Use English-speaking population to test effectiveness to optimise the amount of data collected
	Low questionnaire response rate generally	Incentivise return with vouchers

Table 31 shows the number of respondents recording each satisfaction score for each question. Overall, the average response rate was 72%.The mean overall satisfaction score was high (4.3). There was little variation in overall scores; however, the ranges indicate that there was less satisfaction with time allocated for discussion, socialising and each topic. At least four people found the 'taster' unsatisfactory.

Participant interviews and feedback

The emergent themes and subthemes arising from the free response questions in the course feedback questionnaires related to knowledge and learning, course content, relevance to self, facilities and course structure and duration. These issues were also summarised and repeated in the participant interviews.

Sample

We approached 18 course participants who were potentially exposed to the intervention for interview; five declined [reasons included work commitments ($n = 2$); having an operation; bereavement; and 'no time'] and we therefore interviewed 13 participants, including four males. Three interviews were conducted in Sylheti and the remainder were conducted in English. Four researchers conducted the interviews; all were members of the study team.

Themes

We organised the data into 12 themes: clarity of aims, motivation, positive aspects, negative aspects, learning, social interaction, effect of others, repercussions/outcomes post course, suggested changes, facilitation, 'buddying', course material; these themes are detailed in *Appendix 6*. There was no need to conduct second-order analysis to interpret the data in greater depth as the aim of the evaluation was to find out what modifications needed to be carried out to the intervention programme.

In summary, participants wanted not only the aims of course made clearer but also the rationale for each session. Participants greatly valued the social interaction and wanted more time for informal interaction. They valued good facilitation, which was seen as good group control, that is, managing

TABLE 31 Satisfaction scores for each question

How satisfied were you with the . . .?	Level of satisfaction from least to most (0–5)						Number of questionnaires received[a]	Mean score
	0	1	2	3	4	5		
Course today	–	–	3	7	30	46	86	4.4
Teaching methods	–	–	–	12	26	46	84	4.4
Handouts	–	–	1	14	33	38	86	4.3
Facilitators	–	–	1	4	21	61	87	4.6
Group discussions	–	1	–	6	26	52	85	4.5
Time for socialising	1	2	5	13	26	36	83	4.0
Time on each topic	–	2	7	13	26	37	85	4.0
Taster session	–	1	3	11	22	42	79	4.3
Facilities	–	–	2	10	24	50	86	4.4
Information given	–	–	2	6	27	50	85	4.5
Mean score								4.3

a Course participants were asked to complete a questionnaire on each of the 3 main days of the course, but often did not do this.

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difficult people and situations; this had implications for facilitator training. Different participants preferred different sessions but they really liked the relaxation sessions and requested audio-recordings of the scripts used. 'Buddying' was wanted by some and not others and those interviewed strongly recommended that it be left up to individuals in the groups to identify other participants to 'buddy up' with if they so wished.

Study team meeting for modifications and changes

Two study team meeting sessions were conducted because of the number of data, one for facilitator/observer feedback and one for participant feedback. The recommendations from the study team meetings are provided in *Table 32*.

Overall summary of the results of the feasibility study

The process evaluation of the feasibility study gave clear indications of areas for improvement for the main RCT. The key areas are summarised as follows:

- The feasibility study demonstrated that it is feasible and acceptable to translate and deliver the intervention in another language; however, it also demonstrated that it was not feasible to collect sufficient outcome data from the non-English-speaking Bangladeshi population. The main trial should be conducted only among people fluent in English (but the results could probably be extrapolated to non-English-speaking people).
- A credible control is required to encourage participants to enter into a definitive trial. Usual care and a pain education booklet were not sufficient to attract participants.
- More time was required to secure recruitment sites. A phased approach would assist in the planning of recruitment to courses, along with recruitment monitoring against an expected rate per source to flag up problems early in the study.
- A more specific search strategy needed to be developed for general practice medical record systems to find suitable participants. GPs do not have time to look through lists of hundreds of patients. General practices may need assistance from the study team in performing the searches and preparing invitation packs and reminder letters.

TABLE 32 Recommendations from the study team meetings

Facilitator/observer feedback	Participant feedback
Course content: • introduce variation in learning methods • reorder pain cycle content so positive at the end • simplify cognitive behavioural sessions • use participant examples more • remove sleep management session and incorporate as a problem-solving example • provide handouts • CD for relaxation • keep tasters (change photography) • remove buddying, keep informal Facilitation: • make aims clearer • summarise each session • use links • more training on dealing with difficult people • pair inexperienced with experienced	Trial process: • make trial more user friendly • make control more credible • change Freepost address label • provide weekend courses Course content: • refer to diagnosed pain conditions more • include cortical and descending pathway information • link rationale for each session to pain experience and causes • course duration appropriate • withdraw intimacy session • more discussion time Facilitation: • more facilitation skills training

- At least 8 weeks should be allowed between posting out participant invitation letters and the start of a local course to allow time for potential participants to complete and return the baseline questionnaire and complete the enrolment process.
- A block system for randomisation would ensure that groups of participants are randomised in sufficient numbers to provide enough participants for a course.
- The questionnaire was too long.
- Good facilitators, and hence good facilitator training, were absolutely key to the successful delivery of the intervention and the retention and satisfaction of course participants.

Consideration of our outcome measures and choice of a primary outcome measure for the main trial

It is usual in trials of treatment for chronic painful disorders to see a substantial improvement between baseline and follow-up in the control arm.[210,211] This is because of a combination of two factors. First, the natural history of the disease is to improve as people will be more likely to be motivated to join a trial if they are in a period of relatively more severe pain; chronic musculoskeletal pain tends to wax and wane over time. Second, one would expect to see some regression to the mean in the results for any outcome measure, irrespective of any change in the underlying disorder. That the EQ-5D[169] did not identify this expected change in our pilot study gave the study team serious concerns that it would not be sufficiently responsive to any change in participants' underlying disorder. The team therefore considered that an alternative primary outcome was needed. The closest measure in the portfolio that we had evaluated (see *Chapter 5*) was the pain-related disability component of the CPG. This is a disorder-specific outcome that is directly related to overall quality of life. It has much greater disorder-specific clinical relevance than other measures in our portfolio. For this reason the study team chose to use the pain-related disability subscale of the CPG as the primary outcome in the main trial.

Results in the context of other research

Past research on self-management courses has shown that self-management can have small effects on self-efficacy[14] and that group approaches can benefit participants. The group process encourages active involvement, cheering successes and offering and receiving advice and support.[49] Our findings support the 'power' of the group process as an active part of learning and behaviour change. Self-efficacy seems to enable and contribute to and/or evolve out of the group process. Participants could be empowered either by those who were seemingly worse off than themselves or by those who appeared to be proactive and/or worthy role models. We also found in our systematic review (see *Chapter 2*) that group-based self-management programmes provided more beneficial effects for participants than remote or individually delivered programmes.

Providing a meaning for learning about the complex interactions between the body, pain, mind and emotions, be it internal (via self) or external (via others), was observed in participants who went on to illustrate examples of better coping strategies. Heightened self-awareness potentially could lead to hypervigilance or, conversely, self-awareness could promote coping strategies that related to personal life situations and were therefore more meaningful to the participant.

Cognitive–behavioural approaches for pain management have been systematically reviewed[48] and found to be effective for short-term pain relief. However, it is still unclear which types of cognitive approaches or which elements of the cognitive approaches are more effective than others. Based on our interview data we postulate that self-reflection on unhelpful behaviours and goal-setting have most impact on change. These elements of CBT are often linked with plans to carry out activities in the future; if these plans are carried out they can have an impact on physical and mental health. Other systematic reviews conclude that exercise (any type) is beneficial for persistent non-specific pain.[33] In the COPERS programme we encouraged activity as opposed to exercise to avoid raising existing negative cognitions about exercise, but ironically the posture and stretch sessions were very well received despite us trying to avoid the concept of exercise as much as we could.

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Strengths and limitations

We specifically sought to deliver the intervention in a language other than English to a minority ethnic group. This research had its origins in a collaboration with Social Action for Health, a Tower Hamlets-based community organisation that seeks to promote health and well-being in the Bengali community of Tower Hamlets. Social Action for Health had identified the management of chronic musculoskeletal pain as a community priority. We had also demonstrated the higher prevalence of chronic musculoskeletal pain in first-generation Bengali migrants living in Tower Hamlets[153] and were aware of the issues through our clinical work. Developing a programme to help this group was therefore a priority for both us and our patient partners.

The large Bengali community in Tower Hamlets meant that it was plausible to develop and a deliver an intervention tailored to this group. This information is locally important. However, we cannot necessarily extrapolate from these findings to other minority ethnic groups or establish how practical it might be to deliver such a programme in areas that do not have the same dominant minority ethnic group. Nevertheless, we have for the first time demonstrated that such an intervention is deliverable to such groups. We had no a priori expectation that this experience would not be transferable to other ethnic groups living in the UK.

Our evaluation was designed to gather information about the COPERS course and its content to determine whether or not any improvements needed to be made and how to improve delivery. We systematically collected data from participants, observers and facilitators. The data were gathered and analysed by different team members to try and avoid bias in interpretation; however, some bias may have occurred. We demonstrated that it was feasible to deliver the COPERS course in Sylheti, that the courses were acceptable to participants and that there was a relatively low rate of attrition. However, this pilot showed that it would be very difficult to determine the effectiveness of the Sylheti language course in a definitive effectiveness trial because most participants were unwilling or unable to complete questionnaires administered by post. An alternative would be to formally evaluate English-language courses for those fluent in English of all ethnicities and extrapolate the data to non-English-language courses. Delivering courses in multiple languages poses an issue in ethnically diverse areas because there is no one dominant language group; however, it is feasible in areas with predominantly one ethnic group, as we have shown. There is also the additional problem that some of our outcome measures have not been validated in other languages.

Recommended changes

The changes required to the COPERS course were not major changes. The suggestions for change could be categorised into three main areas: changes to the course content, changes to processes and changes to facilitator training. We believed that many of the issues that the participants flagged would be avoided by better facilitator training. The facilitator training course was therefore modified and run closer to the start of the courses; when this was not possible we decided to provide ‘top-up’ training to refamiliarise facilitators with the techniques and course material. Facilitators who wanted top-up training would be able to observe other courses and receive individual coaching on a one-to-one basis from the study team (in practice, two facilitators out of 39 (5%) requested additional training and observed a course). Additionally, we would endeavour to always pair a new facilitator with an experienced COPERS facilitator. We also needed to provide a more credible control. Relaxation does not have medium- to long-term effects on pain severity[48] but our participants really enjoyed this element of the course. Relaxation can be carried out in groups or alone and so we decided to use this as part of our control as it has limited clinical effects and does not involve any interaction with others.

The use of observer notes for each course was useful to check for ‘treatment drift’ and fidelity. The observers also helped to debrief the facilitators after each day. An audio-recording of each course was used to check quality and ‘treatment drift’ in the main trial.

Conclusions

We demonstrated that it was feasible to deliver the COPERS course in a non-English-speaking population. However, because of the difficulties experienced with filling courses in multiple languages and collecting outcome data, there was an argument for conducting the main trial in English first and, if effective, then either simply extrapolating the results directly to non-English-speaking groups or perhaps evaluating the intervention in a true implementation study in these groups.

The qualitative evaluation of the feasibility study illustrated that the COPERS course was regarded as beneficial by most participants; however, ways to improve the course were suggested. As a result the course content was modified, the aims were made clearer and summarising and linking between sessions were incorporated as essential deliverables for each session. High-quality facilitation appeared to be the key to a successful course and therefore effective training for facilitators was prioritised.

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Chapter 8 Phase 1: development of the intervention – discussion

Principal findings from phase 1

In phase 1 of this programme of work we carried out the substantial background work required to prepare for delivering a definitive trial of a self-management approach to managing chronic musculoskeletal pain. Following this we developed:

- systems for recruiting our population of interest
- an active intervention grounded in the best available evidence that was acceptable to participants, manualised and deliverable to a wide range of people living with chronic pain
- an acceptable, manualised training programme to train facilitators to deliver the intervention
- a credible and acceptable control treatment
- a carefully selected package of outcome measures.

This put us in the best possible position to answer our original research question: 'Does a self-management support programme improve outcomes for people living with chronic musculoskeletal pain?'.

The evidence

Group-delivered courses that had HCP input had better outcomes than other types of courses and longer courses did not appear to provide additional benefits over shorter courses. We found mixed evidence for the effectiveness of different proposed components of the intervention package. Courses with a psychological component, however, had more evidence of beneficial effects than those without psychological components and increasing the number of components did not appear to improve course effectiveness. We proposed that this indicated that other factors related to the group process, such as socialisation, may be as important as the content in the success of self-management courses.

Our qualitative work with chronic pain patients who had participated in courses also indicated that they gained benefit from the social aspects of courses and learning from others, as well as the need to focus their attention on things other than pain. People who had accepted their pain and had personal coping strategies that enabled them to lead fulfilling lives were most positive about their experience of pain management courses.

The psychological theories that we reviewed supported our qualitative study findings and underpinned the structure and content of the course. The theory underpinning the decisions to include a variety of sessions and behavioural change techniques worked well within the group learning environment; this has also shown to be effective in other studies of chronic pain.[48,53]

Informed by the available theoretical and empirical evidence we developed a brief group intervention to be delivered jointly by a HCP and a lay expert.

The course

The course ran over 3 days in 1 week with a top-up session 2 weeks later. The target attendance was 10–12 participants.

The learning sequence that we adopted enabled each session to build on the previous session and in many cases the participants were able to predict the next phase of learning in advance. The learning and flow of information was pitched at a level at which participants could follow the structure and understand the

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content. This was shown in the daily feedback sheets that asked participants what they had learned: their learning mapped well onto the learning objectives.

In our feasibility study we demonstrated that the course was feasible, acceptable to participants and deliverable in a NHS context. Participants were positive about the course and the content appeared to be meaningful to them. Attrition was very low over the 3 main days: participants attended on average 85% of the course. Attrition has been reported as an issue in other trials. In one such trial of an Expert Patients Programme run over a 6-week period (intervention arm $n = 313$), one-quarter of participants failed to attend any session, only 60% were considered to have completed the course (attending at least four of the six sessions) and only one-third attended all six sessions.[15]

We tested the feasibility of the intervention in a non-English-speaking Bangladeshi population. In Tower Hamlets in east London 32% of the community are of Bangladeshi origin,[212] with some not speaking English or not speaking English well. The prevalence of chronic pain in the Bangladeshi population (arrived in UK after the age of 14 years) is higher than that in the white British and British Bangladeshi population living in Tower Hamlets, at around 75% compared with around 50%.[153] We demonstrated that the intervention can be delivered in Sylheti to a group who may find services hard to access. Although we could not collect validated participant-reported outcomes, our evidence from interviews and feedback from the courses indicated that the participants valued the courses and appreciated the effort made to accommodate their needs, for example running single-sex courses. From a national perspective the ethnic distribution varies, supporting our decision to run the trial in two areas. The non-white population in London makes up about 40% of the total population, whereas in the West Midlands it is around 17%.[212] In the census 8% report that English is not their main language and of these 21% do not speak English well (this equates to 1.7% of the total English and Welsh population).[213] Our experience running the non-English speaking courses was that they were feasible and well received but it was hard to recruit sufficient people onto the courses to make them viable and hard to collect outcome data, which may affect the analysis and sample size required for the main trial (attrition and incomplete data).

The facilitation and group process may have optimised the learning process as discussion embedded participant thinking. All of the course evaluation material suggested that good facilitation skills were crucial for positive participant perception. Comprehensive facilitator training was essential for courses to run effectively. We found that it was possible to train both laypeople and non-psychologists to facilitate the courses and deliver the cognitive–behavioural approach that we had developed. The facilitator training included four components: facilitation skills training, course content familiarisation and practice, trial management protocols and evaluation.

Delivery styles varied, indicating a need to embed fidelity assessment from the outset to measure both adherence and the competence of those delivering the intervention. Measuring whether or not an intervention has been delivered as efficiently and effectively as possible has been advocated by others;[214,215] however, published reports of fidelity assessment, or the methods used to perform it, are sparse.

We found that the course withstood the inexperience of our facilitators in delivering an entirely new course; the content in terms of the discussions, information and handouts was robust enough to make an impression regardless of delivery style. We recommended that inexperienced personnel be partnered with experienced personnel in the main trial.

Recruitment and participants

Recruitment to the feasibility study was challenging; the conversion rate from invitation to course attendance was lower than we had hoped (approximately 13% of those invited) but was in line with other studies of this nature recruiting patients from primary care with chronic conditions.[53,83,98] Nevertheless, we had sufficient interest from patients to run nine courses and this demonstrated a demand for learning about non-pharmacological approaches to managing pain. Procedures for future recruitment need to be enhanced by increasing the number of invitations sent and devising and testing a comprehensive and

inclusive electronic search strategy for patients with chronic pain. To address this need we developed and tested an electronic patient record search strategy using repeat prescription data for chronic pain-related medication, musculoskeletal Read codes and contact within the last 3 months.[206]

In our feasibility study participants reported poor quality of life, low self-efficacy to manage their chronic pain, relatively high levels of social isolation, poor coping skills and a tendency towards anxiety and depression. This is consistent with the findings of a European survey carried out in 2005[216] that asked respondents about the impact that pain had on their daily lives. In total, 32% reported that they were no longer able to work outside the home or attend social activities and 21% reported having a diagnosis of depression as a result of having chronic pain (24% in the UK); thus, our secondary outcome measures need to reflect these health and social states.

We noted the levels of depression and considered whether depression should be addressed with patients prior to, or in conjunction with, attending these types of courses.

The control

The pilot study indicated that the control arm needed to have more credibility; there was little motivation for people to join the trial if they perceived that they would receive no added benefit, that is, usual care. Our systematic review illustrated that mind–body approaches (mostly relaxation) may have some short-term beneficial outcomes but did not produce medium- or long-term benefits and this has also been shown by other reviews of relaxation.[217,218] Our qualitative work indicated that participants really enjoyed this part of the course that they attended and so we decided that if there was little evidence for effectiveness but positive appeal for relaxation this may be an incentive for recruiting people into the trial who might otherwise decline.

Strengths and weaknesses

We designed a novel approach to analyse the effectiveness of courses by content and characteristics by looking at interventions with and without prespecified components and characteristics. Although many studies were available, some subgroups had few data available and the conclusions drawn were tentative. However, looking at all of the studies, and the data indicating beneficial outcomes, we were able to identify characteristics and components that seemed to elicit better effects than others. This allowed us to translate the findings directly into our intervention design, enabling us to put together an evidence-based intervention at a level of detail that included content and delivery style.

A byproduct of our predictor, mediator and moderator study was that we found that there was no consensus about methodological standards for mediator studies. We carried out an additional expert consensus study that informed and enhanced our systematic review.[135] Additionally, we also tested and piloted an electronic search strategy for identifying chronic pain patients.[206] The strategy that we devised is applicable to other conditions but would need further testing. We involved patients in the selection of outcome measures but, in retrospect, as was pointed out by one of our reviewers at the end of the entire programme, we would have liked more patient involvement in this process. Following the recommendations in MRC guidance,[28] as part of the feasibility phase of the project we started to design and develop a methodology for rigorously and systematically assessing and measuring the fidelity of our intervention delivery from the outset,[207] so that the assessment was embedded into the training, delivery and implementation of the intervention. Importantly, we were able to demonstrate that we could deliver the course in Sylheti for the Bangladeshi community of Tower Hamlets. We were not able to include this group in the main trial; nevertheless, showing that the course can be simply translated and delivered to another ethnic group indicates that our findings are likely to be generalisable to other non-English-speaking groups in the UK. We suggest that running a parallel non-randomised arm of the study for groups who may find services hard to access may be a sustainable and credible option for researchers to demonstrate the generalisability of an intervention for groups who cannot be included in a randomised comparison.

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Findings in relation to other studies

Optimal self-management of chronic pain can be achieved by addressing the reasons surrounding acceptance, negative cognitions and behaviour change to enhance quality of life. The course that we proposed is theoretically driven by behavioural approaches and techniques to address the emotional, psychological and social aspects of living with chronic pain. The Expert Patients Programme and the Chronic Disease Self-Management Programme are two interventions that have gone partway towards addressing the issues of living with chronic pain. In these programmes weekly sessions are held over 6 weeks, which has implications for attendance.[15] Our short intensive intervention appeared to overcome this problem because there was less scope for 'life' events to occur over the duration of a week, preventing attendance.

Our framework had a strong emphasis on utilising specific behaviour change techniques such as goal-setting and tailored education to address health beliefs. Our model is delivered to groups and addresses issues surrounding social integration. Our approach creates the opportunity for social support and integration shown to be important to this population and is likely to be more cost-effective than individually delivered programmes. We structured some group sessions to formally address and facilitate behaviour change through the application of well-established psychological theories, principally social cognitive theory.

Cognitive–behavioural therapy and the Expert Patients Programme have shown some evidence of effectiveness for improving function and pain and quality of life and self-efficacy.[13,14,53] Cognitive–behavioural approaches are typically delivered by HCPs and the Expert Patients Programme by laypeople. Our research shows that courses delivered by HCPs have a more beneficial impact on pain-related outcomes, whereas lay-led courses have a more beneficial impact on self-efficacy. Using both may optimise the potential for effectiveness but perhaps reduce cost–utility; this will need testing in the trial.

Conclusions

The MRC guidance for developing complex interventions[28] enabled us to develop and test an evidence-based and theory-informed pain self-management course.[219] The process enhanced the intervention and gave the study team confidence in the modified intervention and trial procedures and processes necessary to run efficiently a full effectiveness and cost-effectiveness RCT.

The development phase of this study was comprehensive and thorough. Funding external feasibility or pilot studies has many 'hidden' benefits that may help ensure the success of large expensive trials. The feasibility study gave the team knowledge and experience and on-the-job training to deliver the intervention and run the trial. In addition, we were able to use existing contacts and peer networks and create new contacts and networks to help recruit general practices and use our already-trained facilitators to deliver the courses at the standard that we wanted.

Chapter 9 Randomised controlled trial of the clinical effectiveness and cost-effectiveness of the COPERS intervention: methods

Abstract

In part II of this report we describe how we tested the clinical effectiveness and cost-effectiveness of our self-management programme in a large RCT.

Aim

To establish the effectiveness and cost-effectiveness (expressed as the cost–utility) of the new self-management intervention (COPERS) for patients with chronic musculoskeletal pain when added to usual care plus a relaxation CD of simple relaxation exercises.

Study objective

To test the clinical effectiveness of a self-management course for chronic pain and usual care compared with usual care plus an education leaflet and a CD of simple relaxation exercises with respect to (1) the primary clinical outcome of pain-related disability and (2) the secondary outcomes: anxiety, depression, coping skills, chronic pain acceptance, social integration, self-efficacy, being prescribed analgesics and being prescribed weak and strong opioid drugs.

Methods: effectiveness study

Figure 12 illustrates the recruitment process and the different stages of the trial. This was a two-arm RCT with a follow-up period of 12 months to assess participant outcomes.

Ethical approval

The study was approved by the Cambridgeshire Ethics Committee on 18 March 2011 (reference no. 11/EE/046). Additional ethical approval was obtained to give participants unconditional £5 high-street shop vouchers with the 6- and 12-month questionnaires and, on the advice of the TSC, to add questions about non-NHS, pain-related personal costs at 12 months (7 October 2011). We sought further approval for additional questions at 12 months enquiring about attendance at other similar or pain-related courses, new hobbies or activities undertaken and any psychological help participants may have sought during the trial period (August 2011–July 2012).

Recruitment

Recruitment of recruiting centres

The study was conducted in two areas: inner east London (Tower Hamlets, City and Hackney and Newham Primary Care Trusts, which were coterminus with their respective London boroughs) and the Midlands (Warwickshire and Coventry Primary Care Trusts). Thus, the COPERS study population included residents of deprived inner-city areas and those living in affluent urban, suburban and rural settings.

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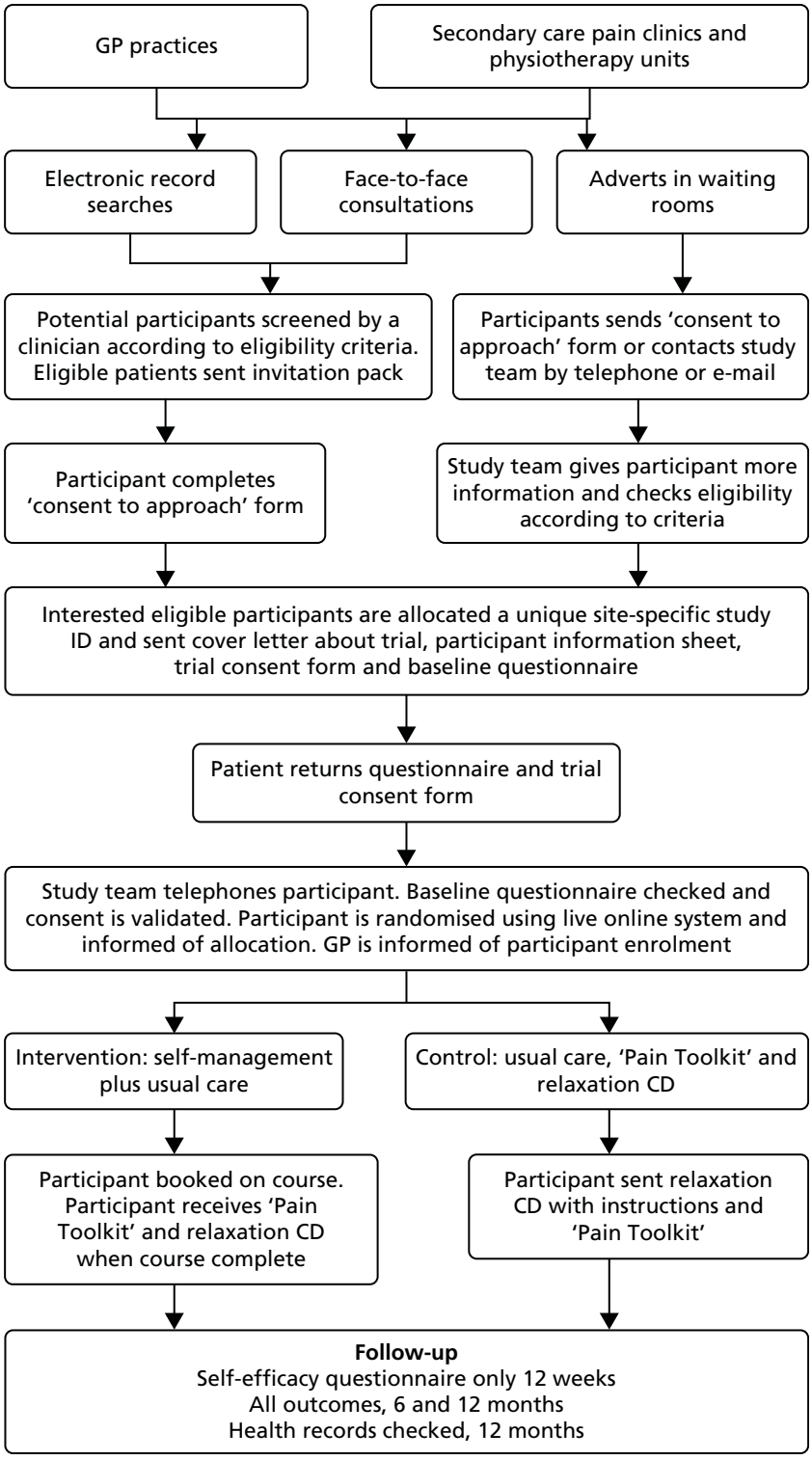

FIGURE 12 Recruitment process and different stages of the trial.

Assisted by the primary care research networks in London and the Midlands we invited all general practices in both areas to recruit participants. We also invited intermediate and secondary care pain clinics, rheumatology services and musculoskeletal physiotherapy services to recruit participants. Interested practices and services signed a study agreement form and were reimbursed for all costs associated with recruiting patients.

Recruitment of participants

Participants were recruited in three ways:

- searches of general practice/service electronic patient records
- clinician referrals during face-to-face consultations (GPs, pain physicians, rheumatologists or physiotherapists)
- through posters displayed in clinics advertising the study.

Recruitment of participants from general practice

Each practice designated a key contact to liaise with the study team. The contact was given a standard operating procedures booklet for the study and was responsible for maintaining the master list of those approached securely within the practice. The electronic searches were conducted by practice staff with the support of the study team. No single computer code for a diagnosis of chronic musculoskeletal pain is routinely used in primary care and so we developed a new search strategy to identify potential study participants. Full details of the development of our general practice search strategy and its rationale are described elsewhere.[206] In summary, during extensive consultation and piloting of searches we noted the different coding and prescribing 'cultures' in individual practices. Therefore, there was no definitive final search and each search was tailored to the individual practice but constructed using the same principles. Whenever possible searches followed three stages:

- *Stage 1*. We selected patients who were aged ≥ 18 years and who were registered with the general practice and had consulted within the previous 6 months.
- *Stage 2*. Within the population identified in stage 1 we searched for repeat prescribing information for a variety of drugs associated with chronic pain including low-dose tricyclic antidepressants, strong and weak opioids, non-steroidal anti-inflammatory drugs (NSAIDs), pregabalin and gabapentin. We chose the drugs most commonly prescribed within each individual practice and excluded opiates more commonly used in palliative care (e.g. slow-release morphine).
- *Stage 3*. We searched the population identified in the first two stages by high-order Read (classification) codes for low back pain, back pain, OA and fibromyalgia and/or other codes commonly used by the practice staff for musculoskeletal conditions.[220]

This strategy generated a list of potential participants, who were screened by their GP for suitability to ensure that no vulnerable people were approached (see inclusion and exclusion criteria). From previous searches and test runs we estimated that this search would yield around 5% of the registered patients, which is consistent with the National Pain Audit finding that 6.4% of the population have chronic pain (the exact figure varies by definition of chronic pain).[221]

General practices sent all screened potential participants an invitation letter to the trial from each patient's own GP. These were placed in preprepared envelopes that contained a consent to approach form, a patient information leaflet and a Freepost envelope for returning the consent to approach form to the study team. The general practices sent a postal reminder letter 10–14 days later if the study team had not received a response. The general practices provided us with an anonymised list of all of the patients invited into the study, which described only gender, age and ethnicity (if available).

General practitioners were also able to recruit patients directly into the study by offering an information pack or the study contact telephone number during a consultation. In addition, we placed posters about the study in practice waiting areas. This served as both a prenotification for participants approached by post or during a consultation and an opportunity for people to self-refer into the study. Those who wanted to refer themselves into the study could obtain information packs from the practice reception or by telephoning the study team.

We recruited from general practices in three waves, within sublocalities, to ensure that we had a sufficient flow of randomised participants living near enough to attend the intervention courses. At the time of the

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initial telephone contact with the study team potential participants were informed of the date and location of the course that they would attend if randomised to the active intervention. Completion of the baseline questionnaire and consent form could be deferred if a potential participant was unable to attend the next available course.

Recruitment of participants from other services

Recruitment processes in other services followed a similar general approach to that in general practices but we did not design a specific computer search for these services. When a service had a suitable electronic record identifying patients consulting for chronic musculoskeletal pain invitation packs were posted by the service with a covering letter signed by the treating clinician. Otherwise patients were recruited directly by the treating clinician or through self-referral.

Consent and withdrawal

We obtained participant consent in two stages. First, we sought consent for the study team to receive contact details to allow an approach (the consent to approach form). Second, on enrolment to the trial participants provided informed consent, including consent to access routine NHS records. Full details of the study procedures around consent are available in *Appendix 6*.

Participants were free to withdraw from the study at any time and without explanation; on formal withdrawal from the study we ceased to collect further questionnaire data but, when possible, we asked participants if we could still collect patient record data at 12 months. If we could not contact participants we assumed that this permission was withdrawn as well.

Inclusion criteria

- People aged ≥ 18 years with musculoskeletal pain of > 3 months' duration.
- Available to participate in an intervention course if randomised to the intervention arm.
- The IASP[17] defines chronic pain as that which has persisted beyond normal tissue healing time, usually interpreted as 3 months. Causes/types of pain included, but were not restricted to, OA, back pain, chronic widespread pain and fibromyalgia.

Exclusion criteria

- Unable to give informed consent.
- Not fluent in English.
- Life expectancy of < 6 months.
- Presence of chronic pain arising from active malignant disease.
- Presence of inflammatory arthritis such as rheumatoid arthritis.
- Presence of a serious comorbidity that was more disabling than chronic pain.
- Poorly controlled serious mental health illness that would make it difficult to participate in the intervention.
- Misusing substances to an extent that would make it difficult to participate in the intervention.

We excluded people living with chronic pain arising from malignant disease because this requires specific management. However, chronic pain in people living with or beyond cancer may arise from non-malignant causes and such patients were eligible for our study.

We restricted the study to those who were fluent in spoken English for practical reasons:

- The interactive, participatory nature of the intervention meant that it was unsuitable for delivery through an interpreter or advocate.
- Our systematic review (see *Chapter 3*) identified that lack of fluency in the language of the programme was associated with lack of clinical effect.

- The only language other than English that was sufficiently common to consider running courses in the study recruitment areas was Sylheti. We piloted delivering the intervention in Sylheti and found that it was not feasible to include a Sylheti language stream in the evaluation of the intervention (see *Chapter 7*).
- The validity and reliability of the outcome measures translated into languages other than English have not always been established.

People with serious mental health problems or substance abuse problems were able to join the study. They were excluded only if their GP, or other screening clinician, judged that their current problems were so severe that they were likely to cause difficulties within the group sessions or if patients themselves felt that this might be the case.

Randomisation

The randomisation ratio between the intervention and control arms was 1.33 : 1 (see *Sample size* for an explanation). Randomisation was overseen and implemented by the PCTU at Queen Mary University of London. Participants were randomised after the study team had received signed informed consent and the completed baseline questionnaire. Strict allocation concealment was maintained through the use of Sheffield University's Clinical Trials Research Unit's web-based, real-time, randomisation programme,[222] which was accessed by the study team while on the telephone to participants to avoid having to call them again. Randomisation was performed using random permuted blocks stratified by site of recruitment, with randomly varying block lengths of seven and 14. All randomisations were logged using an online audit trail of use according to each user ID.

Interventions

The active intervention

The intervention was a group-based facilitated learning course about chronic pain. The course had 24 distinct components (also called sessions) covering various aspects of pain education and pain management. At the end of the 3-day course participants received the same relaxation CD and self-help booklet as those in the control arm.

We aimed to include around 12 participants per course. The minimum number of participants required for a course to take place was eight and the maximum was 16. When a course was undersubscribed prior to the course running those registered were offered alternative courses. Our target was that all participants randomised to a course should start the course within 8 weeks of randomisation; whenever possible participants were recruited onto the next available course. This was not always possible when participants were booked on a course but were subsequently unable to attend; we gave participants a choice of up to three dates or venues.

Recruiting and training intervention course facilitators

Courses were led by two facilitators, a HCP and a lay person. We recruited facilitators from a variety of sources:

- *HCPs.* Relevant HCPs included chiropractors, GPs, occupational therapists, osteopaths, physiotherapists and psychologists. Press releases were issued to professional magazines explaining that we were seeking people who might be interested in becoming study facilitators. We also used our own peer networks to recruit facilitators. Interested people submitted their curriculum vitae to the study team and were interviewed by telephone. The recruitment criteria were experience with chronic pain patients, articulate, empathic, having an interest in the psychological aspects of health care and available to run at least two courses.
- *Lay facilitators.* Lay facilitators were recruited through an internet self-management news site [www.self-management.org.uk (accessed 2010)] and community interest companies providing expert patient self-management programmes. Interested people sent their curriculum vitae to the study team.

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The recruitment criteria for lay facilitators were interest and experience in facilitating self-management or self-help groups, current or past personal experience of chronic pain and available to run at least two courses.

Applicants meeting the recruitment criteria were invited to a local joint 2-day training course for lay and professional facilitators. We invited the trained and experienced facilitators from the pilot study to participate and paired these more experienced facilitators with the newly trained facilitators to optimise delivery of the intervention.

The training course covered the course content, how to facilitate, dealing with difficult situations and what to do if an adverse event occurred. During the course facilitators were required to demonstrate that they were good listeners, empathic, flexible, able to encourage equal participation, able to encourage laughter, able to manage difficult people and able to summarise sessions and put the course content into a chronic pain context. Those who were evaluated by the study team as competent by structured observation throughout the course and after a brief written 'test' at the end of the training were asked to facilitate future intervention courses.

The control intervention

Those in the control arm received usual care and a copy of *The Pain Toolkit* booklet,[207] a relaxation CD and instructions for relaxation. During the study period 2011–12 *The Pain Toolkit* booklet was a free resource for people with chronic pain distributed by the Department of Health; from 2009 to 2012, 250,000 copies of the toolkit were distributed to health services. Because of its wide availability it can be viewed as a component of good usual care. Control participants also received a simple relaxation pack in the form of an audio CD with instructions for use and the rationale for the benefits of relaxation (see *Appendix 6*). Participants were asked to practise the techniques on the CD every day for at least 3 weeks (the same duration as the intervention) and as much as they liked thereafter. Both *The Pain Toolkit* booklet and the relaxation pack were posted to control patients following randomisation.

Quality control and fidelity of intervention delivery

To promote fidelity of intervention delivery the first day of each course was observed by a member of the study team experienced in delivering the intervention. In the case of first-time facilitators or facilitators who expressed a lack of confidence the course was observed in its entirety. When necessary, immediate feedback was given to facilitators during breaks in the course and at the end of each day, enabling them to modify and improve their performance.

Our assessment of the actual fidelity of delivery of the intervention is described in detail elsewhere[223] and in *Chapter 10*. In summary, every course was audio-recorded. After all the courses had been delivered a random selection of audio-taped sessions was chosen for formal evaluation of fidelity. The evaluators used a checklist to record adherence to structure and content and facilitator competence.

Outcome measures

The rationale for our final choice of outcome measures is described in detail in *Chapters 5* and *7*. All selected outcome measures were used with approval and licence when required.

Primary outcome measure

Our primary outcome was pain-related disability as measured using the pain-related function subscale of the CPG[175] at 12 months post randomisation. This measure has three items, each scored from 0 to 10, that assess the extent to which the participants' pain has, in the previous 6 months: (1) interfered with their ability to perform their daily activities; (2) changed their ability to take part in recreational, social and family activities; and (3) changed their ability to work. The pain-related disability score is the mean score for these three items multiplied by 10 and is recorded on a scale from 0 to 100, with higher scores indicating worse pain-related disability.

Secondary outcome measures

- CPG pain-related disability subscale[175] at 6 months post randomisation.
- CPG pain intensity subscale[175] at 6 and 12 months post randomisation.
- HADS depression subscale[176] at 6 and 12 months post randomisation.
- HADS anxiety subscale[176] at 6 and 12 months post randomisation.
- EQ-5D[169] at 6 and 12 months post randomisation.
- PSEQ[181] at 12 weeks and 6 and 12 months post randomisation.
- CPAQ[174] at 6 and 12 months post randomisation.
- heiQ social integration subscale[187] at 6 and 12 months post randomisation.
- Census global health question[209] at 6 and 12 months post randomisation.
- Total defined daily dose (DDD) consumed of psychotropic drugs up to 12 months post randomisation.
- Total DDD consumed of analgesics (including all opioids and other central nervous system drugs) for pain up to 12 months post randomisation.
- Total DDD consumed of weak opioids up to 12 months post randomisation.
- Total DDD consumed of strong opioids up to 12 months post randomisation.
- Proportion of participants using weak opioids at 12 months post randomisation (defined as having received a prescription for a weak opioid up to 12 weeks before the 12-month follow-up date).
- Proportion of participants using strong opioids at 12 months post randomisation (defined as having received a prescription for a strong opioid up to 12 weeks before the 12-month follow-up date).

Additional baseline data collected

In addition, at baseline we collected:

- demographic data from participants, that is, age, gender, ethnicity
- pain duration
- living arrangements
- language fluency
- age at completion of education
- employment status.

Additional data collected at 6 and 12 months

Private health-care use was collected at 6 and 12 months:

- number of and money spent on non-NHS consultations (including complementary and alternative consultations)
- type and number of and money spent on tests and investigations
- type of and money spent on medicines
- type of and money spent on devices and aids
- overnight admissions/stays in private hospitals
- money spent on support and help at home as a result of pain.

Additional data collected at 12 months

We also collected data about other activities and interests undertaken in the last year to test whether or not participants were inspired to undertake other similar courses to help and/or manage their pain better.

We asked about:

- attendance on other similar courses
- psychological services accessed
- hobbies and interests undertaken on a regular basis
- regular relaxation undertaken.

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At 12 months the study team also collected data from participants' general practice records for the 12 months post randomisation on:

- number and type of comorbidities
- number of consultations (doctor and nurse consultations and other face-to-face, telephone and home visits)
- hospital admissions
- referrals to outpatient services
- tests and investigations
- all medications prescribed (in addition we collected data on all medications prescribed in the 3 months prior to randomisation).

We also collected secondary care information from the Secondary Uses Service (SUS) database.[224]

Schedule of data collection

Participants received follow-up questionnaires by post at 12 weeks and 6 and 12 months post randomisation. Based on our systematic review[225] (see *Chapter 3*), we hypothesised that improving self-efficacy was the principal mediator of the expected benefits from a self-management intervention. Improving self-efficacy was a key aim for the COPERS intervention. To ensure that we had evidence for any effect that our intervention had on this hypothesised mediator we sent participants the PSEQ at 12 weeks.

At baseline and 6 and 12 months we collected all of our primary and secondary outcomes from participants. We sent a postal reminder after 2 weeks if no response was received. If there was still no response we collected the primary clinical outcome and the EQ-5D data needed for the health economic analysis by telephone. We sent participants a £5 high-street shop voucher that was redeemable in multiple stores with their 6- and 12-month questionnaires to encourage a response. The vouchers were given on a non-conditional basis. This expression of appreciation has been shown to improve questionnaire return rates, with a systematic review reporting that 'the odds of response were more than doubled when a monetary incentive was used (odds ratio 2.02; 95% confidence interval 1.79 to 2.27) and almost doubled when incentives were not conditional on response (1.71; 1.29 to 2.26)'.[226]

At 12 months we collected health-care activity data from participants' medical records for the 12 months post randomisation and the 3 months prior to randomisation for our health economic analyses.

Figure 13 illustrates the data collected at each time point and how the data were collected.

Analysis of drug data

Medications used over a 15-month period were collected from participants' medical records. We extracted drug names and strength used plus quantity and dates prescribed. We used the Prescription Cost Analysis (PCA) database[227] to attach a cost to each individual preparation used. Using the World Health Organization (WHO) DDD[228] for each drug we generated the number of days of each medication used organised by *British National Formulary* (BNF) chapter and subchapter.[229] The WHO does not provide DDDs for topical NSAIDs or rubefaciants and so we used a previously published report to define these.[56]

The total DDD consumed for each drug was defined as:

$$\text{Total DDD}_{\text{DrugA}} = (\text{strength}_{\text{MedA}} \times \text{quantity}_{\text{MedA}})/\text{DDD}_{\text{MedA}}. \quad (2)$$

The total DDD for a group of medications (e.g. the total DDD for opioids) was the sum of the total DDD for each drug within that medication group (e.g. each drug that was considered an opioid). For example, if there were three opioid drugs (drugs A, B and C), the total $\text{DDD}_{\text{opioid}}$ was defined as:

$$\text{Total DDD}_{\text{opioid}} = \text{total DDD}_{\text{DrugA}} + \text{total DDD}_{\text{DrugB}} + \text{total DDD}_{\text{DrugC}}. \quad (3)$$

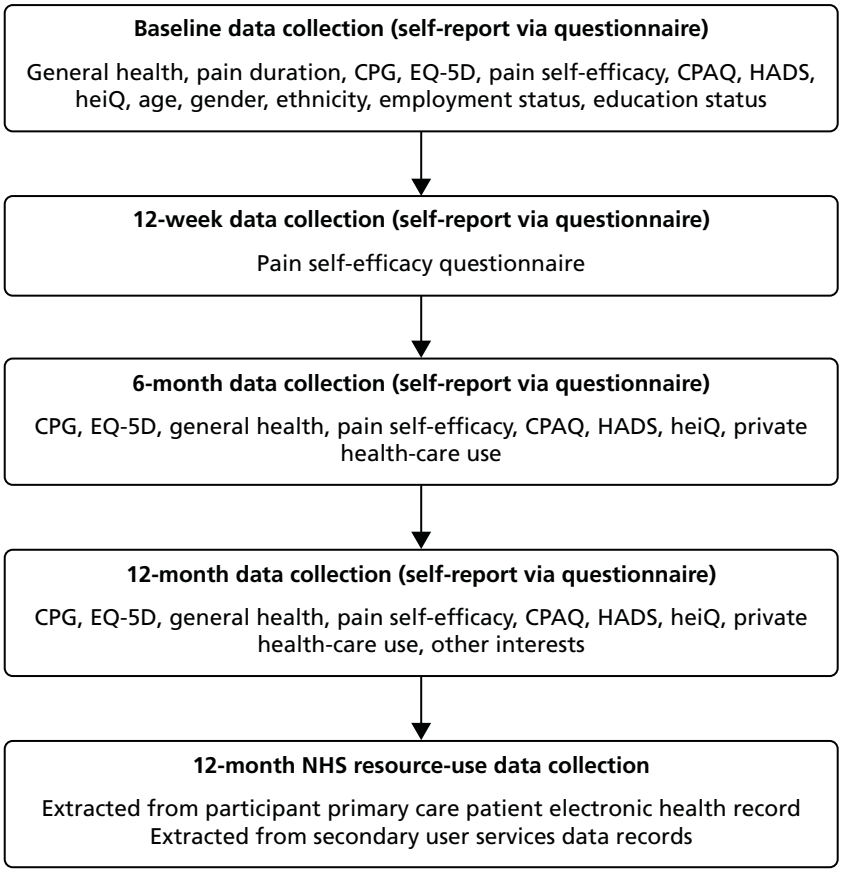

FIGURE 13 Follow-up data collection.

The DDD (used in the denominator of the calculation for the total DDD) was determined in the first instance using the WHO register, then by precedent in other trials[56,230] and then by clinician consensus. For compound drugs, for example co-codamol, we separated out the components (paracetamol and codeine) and worked out the DDD for each component drug.

Medication outcomes

We considered the following outcomes:

- Total DDD consumed of psychotropic drugs up to 12 months post randomisation.
- Total DDD consumed of all analgesics up to 12 months post randomisation.
- Total DDD consumed of weak opioids up to 12 months post randomisation (codeine, dihydrocodeine and meptazinol, as defined by BNF paragraph 4.7.2[229]).
- Total DDD consumed of all NSAIDs (oral and topical combined) up to 12 months post randomisation.
- Total DDD consumed of all central nervous system drugs for neuropathic pain up to 12 months post randomisation.
- Total DDD consumed of strong opioids up to 12 months post randomisation (all opioids prescribed other than the ones listed above as weak, as defined by BNF paragraph 4.7.2[229]).

Calculations were based on BNF subchapters 4.1 and 4.3 for psychotropic drugs, BNF paragraph 4.7.2 for opioids and BNF paragraphs 4.7.1, 4.7.2 and 4.7.3 and paragraphs 10.1.1, 10.2.2 and 10.3.2 for analgesics including opioids[229] (*Table 33*). These are drugs used for treating chronic pain. We excluded all drugs administered as injections but included topical preparations, patches and liquids.

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TABLE 33 Pain-related drugs

Drugs	BNF			Comments
	Chapter	Subchapter	Paragraph	
Psychotropic	4. Central nervous system	4.1 Hypnotics and anxiolytics	4.1.1 Hypnotics	Not chloral and derivatives, clomethiazole or antihistamines
			4.1.2 Anxiolytics	
		4.3 Antidepressant drugs	4.3.2 Monoamine oxidase inhibitors	
			4.3.3 Selective serotonin reuptake inhibitors	
			4.3.4 Other antidepressant drugs	
Analgesic		4.7 Analgesics	4.7.1 Non-opioid analgesics	4.8.1 Gabapentin and pregabalin feature as antiepileptics but also feature in 4.7.3 Neuropathic and functional pain. For this analysis 4.3.1 Tricyclic antidepressants are included in paragraph 4.7.3
			4.7.2. Opioid analgesics	
			4.7.3 Neuropathic and functional pain	
	10. Musculoskeletal and joint diseases (exclude steroids, DMARDs)	10.1 Drugs used in rheumatic diseases and gout	10.1.1 NSAIDs	Exclude aspirin; no steroids
		10.2 Drugs used in neuromuscular disorders	10.2.2 Skeletal muscle relaxants	
		10.3 Drugs for the relief of soft tissue inflammation	10.3.2 Rubefacients and other topical antirheumatics	Not enzymes

DMARD, disease-modifying antirheumatic drug.

Adverse event reporting

An adverse event was defined as any untoward physiological or psychological occurrence in a subject to whom the intervention or control intervention was administered.

We defined serious adverse events as:

- death
- life-threatening events
- events necessitating hospitalisation
- events resulting in persistent or significant disability or incapacity
- events otherwise considered medically significant by the chief investigators.

Minor adverse incidents, for example a participant being tearful and distressed during a session, were logged and fed back to the study team by the end of the course.

If a course participant experienced an adverse event the facilitators were required to notify the study manager and, if necessary, the chief investigators immediately. The study team would then inform the Research Ethics Committee and the sponsor if, in the opinion of the chief investigators, the event was serious and (1) related to the COPERS intervention or (2) unexpected and possibly related to the COPERS intervention.

Details of any adverse events were recorded and stored in the trial master file.

Sample size

The sample size calculation was based on detecting a SMD of 0.3 in pain-related disability between the intervention group and the control group, with 80% power and at a 5% significance level. This effect size was commensurate with the largest change seen in a systematic review of Expert Patients Programmes[14] and also with the sort of change effected by interventions for other chronic pain syndromes, such as low back pain, on any continuous outcome measure. An initial sample size calculation indicated that we would require data on 350 subjects (175 in each group). We inflated the sample size because of the possibility of a 'clustering' effect in the group intervention arm and chose a ratio between intervention participants and control participants to maximise statistical efficiency.[231] Using an intracluster correlation coefficient (ICC) of 0.1 and assuming an average of nine individuals in each group (from an average of 13 individuals recruited to each group, with a 30% loss to follow-up) meant that 480 individuals were needed, with 275 in the intervention group and 205 in control the control group (ratio of 1.33 : 1 between the intervention group and the control group). Allowing for this very conservative estimated 30% loss to follow-up we originally sought to randomise 685 participants (391 intervention participants and 294 control participants).

Previous research[221] and electronic record searches in the pilot study indicated that around 5% of adults on GP registers consult with chronic musculoskeletal pain. Based on our pilot study we estimated that 10% of these may be interested in participating in the trial and around half of these would be recruited into the trial.

Around 80% of the population consists of adults aged > 18 years [www.statistics.gov.uk (accessed 19 April 2016)]. This meant that to recruit 685 participants we needed a population base of around 342,000 registered patients, assuming that 80% (approximately 274,000) would be adults. Of these, 5% would be identified from searches as having chronic pain ($n = 13,700$), of whom around 10% might express an interest in participating in the study ($n = 1370$). Half of these might be recruited and enrolled ($n = 685$). Using an average total practice list size of 7000, this equates to around 49 practices. We estimated that we would recruit between 12 and 14 patients per practice.

Blinding and protection from bias

All baseline data were collected by self-completed questionnaire prior to randomisation. After allocation, however, it was impossible to blind participants to treatment allocation because of the nature of the intervention. General practices and clinicians were informed of their patients' enrolment into the trial but not their treatment allocation, although participants were free to divulge this information to their clinicians. We felt that this information in itself would have little impact on their care. Outcome data were collected using a participant-completed postal questionnaire. Complete blinding of the research team was not possible because of the need to manage course attendance and the unbalanced randomisation. Whenever possible we blinded the research team to treatment allocation during outcome data collection, for example, for those who did not return their questionnaire after the second reminder, primary outcome data and the EQ-5D instrument were collected over the telephone by research personnel blind to treatment allocation using a set script, asking participants not to divulge their allocation prior to collecting their data. To achieve this blinding London staff contacted Midlands patients and vice versa. Patient record data, such as GP consultations, hospital admissions and drug usage, were extracted by personnel blind to treatment allocation. All data were coded according to participants' study ID and notes were anonymised as much as possible by clinical staff at the practices.

Data management

All data were managed in line with Queen Mary University of London's PCTU standard operating procedures and were subject to review by PCTU staff audit and the Data Monitoring and Ethics Committee. All electronic participant data were stored in encrypted and/or password-protected files in a secure environment. A database was designed to manage the data input to ensure consistency of practice and coding, with a built-in audit trail that enabled us to track all entries and changes. Regular audit and double-checking of all primary outcome data was conducted to ensure the accuracy of data entry and a further random 10% of all data were double entered.

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Statistical analysis

Our statistical analysis plan has been published elsewhere.[232] We briefly summarise the analytical approach used here.

The main analysis for each outcome followed ITT principles, meaning that all participants with a recorded outcome were included in the analysis[233] and were analysed according to the treatment group to which they were randomised.

All analyses accounted for clustering by course in the intervention arm,[234,235] Participants in the control arm (who did not attend courses) acted as their own cluster (i.e. we analysed the data as if each participant in the control arm belonged to a 'course' in which he or she was the only member).

Site of recruitment (London or Midlands), age, gender and HADS depression score at baseline were included as covariates in each analysis.[236–239] Additionally, for continuous outcomes (CPG pain-related disability, CPG pain intensity, PSEQ, HADS anxiety, HADS depression, CPAQ, heiQ and EQ-5D), the outcome measured at baseline was included in the analysis. Continuous covariates (age, HADS depression score at baseline) were assumed to have a linear relationship with the outcome.

Analysis of the primary outcome

The primary outcome (CPG pain-related disability at 12 months) was analysed using a mixed-effects linear regression model with 'course' as a random effect. Restricted maximum likelihood was used. The model included site of recruitment, age, gender, HADS depression score at baseline and CPG pain-related disability at baseline as covariates.

All participants who completed at least one of the three questions that form the CPG pain-related disability score at either 6 or 12 months were included in the analysis. Participants who did not fill out any portion of the CPG pain-related disability score at either 6 or 12 months were excluded from the analysis.

Multiple imputation (MI)[240] was used to account for participants who had an observed outcome at 6 months but who were missing the outcome at 12 months, as well as participants who completed some but not all of the questions on the CPG pain-related disability scale at 12 months. Imputation was performed using REALCOM-IMPUTE version 1.0.20 (University of Bristol, Centre for Multilevel Modelling; www.bristol.ac.uk/cmm/software/realcom/).[241]

Twenty imputations were performed and the results were combined using Rubin's rules.[240] Only participants who were to be included in the analysis were included in the imputation model. Imputation was performed separately within each study arm. The imputation model included the three questions that form the CPG pain-related disability score at baseline and 6 and 12 months as well as site of recruitment, age, gender, the HADS depression score at baseline and employment status (employed or in full-time education vs. not employed or in full-time education) (14 variables in total). In the intervention arm, multilevel imputation was performed, with 'course' included in the imputation model as a random effect.

Missing data in any of the covariates to be adjusted for in the analysis (site of recruitment, age, gender, HADS depression score at baseline, CPG pain-related disability at baseline) were accounted for using the same MI model as above.

Sensitivity analyses for the primary outcome

We performed three sensitivity analyses[242] for the primary outcome to assess the robustness of the results to other methods of accounting for missing data. The first sensitivity analysis involved specifying a different imputation model than that used in the primary analysis and the last two sensitivity analyses involved reanalysing the primary outcome using two approaches that are not based on MI.

Sensitivity analysis 1

We determined which baseline covariates are associated with loss to follow-up and included them in the imputation model. The analysis model was the same as above except for the inclusion of additional covariates in the imputation model.

Sensitivity analysis 2

We performed a complete case analysis in which all participants who did not complete all components of the CPG pain-related disability scale at 12 months were excluded from the analysis. The analysis model was the same as above except that missing baseline covariates were replaced using mean imputation.

Sensitivity analysis 3

We analysed the three components that form the CPG pain-related disability score at 12 months rather than the CPG pain-related disability score itself. This was carried out by performing a multivariate analysis in which each of the three components of the 12-month score was included in the model as an outcome (i.e. each participant had three outcomes). A three-level mixed-effects model was used, with random effects for 'course' and participant. Treatment–question interactions were included, allowing the treatment effect to vary for each of the three components. An overall treatment effect for CPG pain-related disability at 12 months was estimated using the lincom function in Stata version 14 (StataCorp LP, College Station, TX, USA) to combine the treatment estimates from the three separate components. As above, missing baseline covariates were replaced using mean imputation.

Participants with no completed follow-up data

The primary analysis assumed that the excluded participants (those not completing any questions on the CPG pain-related disability questionnaire at both 6 and 12 months) were missing at random (i.e. they were missing based on the covariates included in the analysis model). To assess the robustness to departures from this assumption, the primary outcome was assessed under a range of missing not at random scenarios. This was carried out using the formula $\Delta\Delta = \Delta_{primary} + Y_1P_1 - Y_2P_2$, where Δ is the treatment effect under the missing not at random scenario, $\Delta_{primary}$ is the treatment effect from the primary analysis, Y_1 and Y_2 are the assumed mean responses for participants with missing data in treatment groups 1 and 2, respectively, and P_1 and P_2 are the proportion of participants who were excluded from the analysis in groups 1 and 2, respectively. The standard error for Δ was assumed to be approximately equal to the standard error for $\Delta_{primary}$. Y_2 varied between 10, 25, 50, 75 and 90 and, for each value of Y_2, Y_1 was set to $Y_2 - 10$, Y_2 and $Y_2 + 10$. For example, for $Y_2 = 25$, Y_1 varied between 15, 25 and 35.

Redefinition of the primary end point

The primary outcome was a composite of three questions. The first question (Q1) assessed to what extent the participant's pain had interfered with daily activities in the previous 6 months. This was assessed on a scale of 0–10, with higher scores indicating more interference. The last two questions assessed to what extent the participant's pain had changed their ability to take part in (1) recreational, social and family activities (Q2) and (2) work (Q3). Both of these questions were measured on a scale from 0 to 10, with higher scores indicating more extreme change.

For the last two questions, higher change scores are meant to represent a higher *negative* change; however, it is possible that some participants might have misinterpreted this and recorded a high score to indicate a large positive change. We therefore performed a sensitivity analysis by redefining the outcome for participants whose scores indicated that they might have misinterpreted the intended direction of the questions relating to change.

For participants with a score of ≤ 2 for Q1 (indicating very little interference in daily activities) *and* a score of ≥ 8 for either Q2 or Q3 (intending to indicate an extreme negative change in their ability to take part in social activities or to work), we assumed that the participant had misinterpreted the intended direction of the scale for Q2 or Q3 (as it is inconsistent for the pain to have had very little interference in daily activities and for there to have been an extreme negative change in the participant's ability to take part in activities or work). We

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therefore rescored Q2 or Q3 based on a reverse scale (i.e. a score of 10 was rescored as 0, 9 was rescored as 1, 8 was rescored as 2, etc.). We reanalysed the outcome using the same method as for the main analysis.

Subgroup analyses for the primary outcome

Subgroup analyses were performed for the primary outcome (CPG pain-related disability at 12 months). All subgroup analyses were performed using the same analysis model as for the primary outcome but also included the subgroup of interest and a treatment–subgroup interaction. Interaction tests were considered significant at the 5% level. No correction was made for multiple tests.

The following a priori subgroups were assessed:

- non-pain related:
  - comorbidities: three or fewer compared with more than three comorbidities, including musculoskeletal comorbidities
  - living arrangements: living alone compared with living with others
  - baseline self-efficacy: PSEQ score of 0–20 (not likely to be confident) compared with 21–39 (more likely to be confident and to self-manage) compared with ≥ 40 (confident)
  - socioeconomic status (based on the Index of Multiple Deprivation 2010[243]), calculated from participant postcodes via a geographical information system: lower social class (less than observed median in data) compared with higher social class (equal to or greater than observed median in data)
- pain related
  - pain duration: 0–12 months compared with 13 months to 4 years compared with ≥ 5 years
  - baseline pain intensity: CPG intensity score of 0–3 (low) compared with 4–7 (medium) compared with 8–10 (high)
  - baseline pain-related disability: CPG disability score of 0–3 (low) compared with 4–7 (medium) compared with 8–10 (high)
  - baseline depression: HADS depression score of < 11 compared with ≥ 11.

Analysis of secondary outcomes

Chronic Pain Grade pain-related disability at 6 months

This outcome was analysed using the same methods as for CPG pain-related disability at 12 months.

Chronic Pain Grade pain intensity, Hospital Anxiety and Depression Scale anxiety and depression and Health Education Impact Questionnaire at 6 and 12 months

These outcomes were analysed using the same methods as for CPG pain-related disability at 6 and 12 months.

Pain Self-Efficacy Questionnaire at 6 and 12 months

We had prespecified in the statistical analysis plan that this outcome would be analysed using the same methods as for CPG pain-related disability at 6 and 12 months, except that the individual components of the PSEQ score at 12 weeks were also included in the imputation model. However, we were unable to perform the imputations because too many variables with missing data were included in the imputation model.

Therefore, rather than including the individual components of the PSEQ at baseline, we tried to include the overall score at baseline in the imputation model (setting scores to missing if participants had any missing components). However, there were still too many variables with missing data in the imputation model and the imputations did not work.

We therefore tried using mean imputation to replace missing baseline scores with the overall mean PSEQ score at baseline. This allowed us to include the baseline PSEQ score in the imputation model as an auxiliary variable (as it contained no missing data) rather than as a variable with missing data that needed to be imputed. This method allowed the imputations to proceed and so was the basis for the analyses of the PSEQ at 6 and 12 months.

Chronic Pain Acceptance Questionnaire at 6 and 12 months

We prespecified in the statistical analysis plan that this outcome would be analysed using the same methods as for CPG pain-related disability at 6 and 12 months, with the exception that we would include only the individual questions for CPAQ at 6 and 12 months in the imputation model and include the full CPAQ score at baseline (leading to 41 variables rather than 60). For participants who were missing the CPAQ score at baseline, we used mean imputation. However, we were unable to perform the imputations because too many variables with missing data were included in the imputation model.

To reduce the total number of variables, we combined the individual components into pairs, leading to 10 pairs of two components at each time point. For example, if Q1, Q2, . . ., Q20 are the 20 individual questions that form the overall CPAQ score at any time point, we generated 10 pairs as:

$$P1 = Q1 + Q2,\ P2 = Q3 + Q4,\ \ldots, P10 = Q19 + Q20. \quad (4)$$

We set P to missing if either of the Qs involved was missing. We then included the Ps in the imputation model at 6 and 12 months, reducing the total number of variables from 40 to 20. This method allowed the imputations to proceed and so was the basis for the analyses of the CPAQ at 6 and 12 months.

European Quality of Life-5 Dimensions at 6 and 12 months

The EQ-5D was analysed using the same analysis model as for the primary outcome (i.e. mixed-effects linear regression model with 'course' as a random effect, adjusted for site of recruitment, age, gender, HADS depression score at baseline and EQ-5D at baseline).

All participants who fully completed the EQ-5D at either 6 or 12 months were included in the analysis. EQ-5D scores with missing components were regarded as completely missing.

Multiple imputation was used to account for participants who were missing the outcome at either 6 or 12 months. The MI strategy was the same as that for the primary and other secondary outcomes, except that, instead of imputing the individual components of the EQ-5D score, we imputed the whole score.

Census global health question at 6 and 12 months

This outcome was analysed using a mixed-effects ordered logistic regression model with 'course' as a random effect. Site of recruitment, age, gender, HADS depression score at baseline and the outcome at baseline were included as fixed covariates.

All participants who completed the census global health question at either 6 or 12 months were included in the analysis.

Multiple imputation was used to account for participants who were missing the outcome at either 6 or 12 months. The MI strategy was the same as that for the primary and other secondary outcomes, except that we imputed the whole score (as there are no individual components).

Total defined daily doses up to 12 months post randomisation for psychotropic drugs, drugs for pain, weak opioids and strong opioids

These outcomes were analysed using a mixed-effects linear regression model with 'course' as a random effect. Restricted maximum likelihood was used. The model included site of recruitment, age, gender,

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HADS depression score at baseline and total DDD in the 3 months before randomisation as covariates. All participants who had data on total DDD up to 12 months post randomisation were included in the analysis. Mean imputation was used for missing baseline covariates.

Proportion of participants using weak opioids and strong opioids at 12 months post randomisation

These outcomes were analysed using a mixed-effects logistic regression model with 'course' as a random effect. The model included site of recruitment, age, gender, HADS depression score at baseline and weak or strong (depending on outcome) opioid use at baseline (defined as a prescription for weak or strong opioids in the 12 weeks before randomisation) as covariates. All participants who had data on whether or not they had had a weak/strong opioid prescription at 12 months were included in the analysis.

Adherence-adjusted analyses

The primary complier average causal effect (CACE) analysis for each outcome was adjusted for all of the baseline covariates included in the primary analysis models, namely site of recruitment, age, gender and HADS depression score at baseline and the corresponding outcome at baseline. As a sensitivity analysis we also conducted CACE unadjusted analyses. We assumed:

- that randomisation was a valid instrument for treatment received
- that the intervention was not available outside the trial
- the stable unit treatment value assumption
- monotonicity
- that exclusion restriction assumptions hold.

We used two-stage least-squares estimation on the multiply imputed data.

We predefined four levels of adherence (or exposure) to the intervention: none; low adherence – less than seven sessions ($\leq$ 1 day); medium adherence – eight to 16 sessions; and adherent – $\geq$ 17 sessions attended. Day 1 included seven sessions, day 2 included eight sessions, day 3 included seven sessions and the follow-up included two sessions. We defined 'compliers' as those who attended at least half of the course (i.e. those present for at least 12 of the 24 course components).

Ethical considerations

There were few ethical concerns with this study. To maintain patient confidentiality only the clinical staff and primary care research network were able to search clinical records and invite suitable patients to participate. Research staff provided guidance and advice when needed and when confidentiality could be maintained. Only potential participants who had provided their contact details to the research team were approached. Patients received one reminder letter if they did not respond.

The risks to the participants in this study were low; however, the study team was aware that the course could trigger emotional reactions. We therefore ensured that the facilitator training course trained facilitators in distress management. Each course had two facilitators so if any participant became unduly distressed he or she was helped by a facilitator who, if necessary, and with the participant's agreement, withdrew the participant from the group and helped him or her until he or she was ready to return to the group, go home or seek further help from a more suitable HCP. Under no circumstances was a participant left alone while distressed. If the facilitators felt that a participant was a danger to him- or herself or others, they sought permission to contact the participant's GP or take him or her to an emergency department.

We ensured that another member of the study team was always available by mobile phone for the duration of any course should any emergency advice be needed.

Methods: health economic analysis

For the economic analysis we adopted a NHS perspective spanning primary, secondary and intermediate health-care sectors, given that the poor reporting of out-of-pocket expenses made it difficult to reflect a wider societal perspective. Economic evaluation followed the National Institute for Health and Care Excellence (NICE) *Guide to the Methods of Technology Appraisal 2013*.[244]

Microcosting of the intervention

A microcosting of the self-management course for primary care patients with chronic musculoskeletal pain included a bottom-up construction of the costs associated with setting up and delivering the programme. The course running costs included salaries, room rental, course materials, facilitators' travel expenses and administration costs. The cost of training facilitators included salaries and travel expenses (for both trainers and facilitators), room rental, course materials and administration costs. Courses were run in multiuse settings and the same daily rate was used for all venues. Trainers and facilitators were paid a fixed fee per session. Assumptions used in the microcosting are summarised in *Appendix 6*. The costs of the intervention were estimated as a cost per course and a cost per participant. Costs associated with usual care included the costs of the pain education booklet and the relaxation CD.

Cost of the intervention per participant

The estimated cost of the intervention per participant was based on the number of participants enrolled on the courses. The average cost per participant was estimated with and without the costs of staff training. The average cost of the intervention for each region (London and the Midlands) is reported without training, given that the two centres shared training costs. Sensitivity analyses were conducted using the minimum and maximum number of participants who could be enrolled on each course.

Use of health-care resources by participants

Service use data (all providers) were collected for each participant from GP electronic records at the 12-month follow-up. In addition, information about prescribed medication over the 3-month pre-randomisation period was requested to account for possible differences in baseline prescribing between the intervention group and the control group. To obtain these data, practices produced a printout of all prescriptions issued over a 15-month period for each participant. These data were then manually entered into a master database for analysis by product name and strength. This allowed both allocation of costs and the calculation of the number of days each medication was prescribed. Data relating to secondary care use over the 12 months since randomisation were downloaded from the SUS database[224] after 15 months. This allowed for a 3-month 'lag' in the availability of SUS data. The primary care data included consultations, prescriptions, tests and investigations, and referrals to community care. Consultations included contacts with GPs, nurses, health-care assistants and other health professionals such as specialist nurses, physiotherapists, psychologists, counsellors, pharmacists, phlebotomists, dietitians, etc. Contacts with GPs and nurses also included telephone consultations, out-of-hours services and home visits. Referrals to community care included rehabilitation programmes, exercise programmes, community mental health teams, community diabetes teams and other health professionals. Secondary care services included inpatient stays, outpatient appointments and accident and emergency (A&E) admissions.

Cost of health-care services

Individual-level resource use data were combined with unit costs to calculate the total cost of health service use for each participant. Primary care consultations and referrals to community care were costed using the *Unit Costs of Health and Social Care 2012*.[245] Unit costs that were not available in this source were supplemented with costs from the *National Schedule of Reference Costs 2011–2012*.[246] Tests and investigations were costed using the *National Schedule of Reference Costs 2011–2012*, direct access diagnostic and pathology services.[246] The unit costs and assumptions used for costing primary health-care services is shown in *Appendix 6*.

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Prescriptions were analysed using the PCA database 2011–12.[227] Some items, however, were missing in this database, whereas others had no cost per item. Costs missing in the PCA database were supplemented with costs from other sources, including the BNF,[229,247] the *NHS Drug Tariff*,[248] the *Monthly Index of Medical Specialities*[249] and UK retailers' price lists.[250–252] The flow chart depicting the costing process is shown in *Appendix 6*. Briefly, prescription items that were not found in the PCA database were first checked for spelling. If costs were not identified after the spelling check, they were taken from the BNF edition 62 published in 2011[229] or from the BNF website in September 2013.[247] If costs were missing in the BNF, they were sourced from the NHS Drug Tariff, the *Monthly Index of Medical Specialties* or retailers' price lists (for items other than drugs). Items missing in all of the above sources were substituted with alternative items from the PCA database that contained the same active ingredients/strengths. Generic products were selected when possible. Pack size was considered when indicated. When pack size was not indicated, the smallest pack size was assumed. For items that were included in the PCA database but for which there were no costs, the cost per item was taken from the BNF edition 62.[229] Costs missing in the BNF edition 62[229] were supplemented with costs from the BNF 2013.[247] Costs obtained from UK retailers were used without value-added tax.

The costs of secondary health-care services used by participants were downloaded as part of the SUS database, and were used to cost the services received by participants due to the difficulties encountered in matching the SUS data set to unit cost databases. When costs were not provided, the *National Schedule of Reference Costs 2011–2012*[246] was used. Outpatient costs were matched by specialty code. The average unit costs (all NHS trusts) were used given insufficient information about the type of outpatient appointment (consultant led/non-consultant led, face to face/non-face to face) provided by SUS. Inpatient and A&E department costs were matched by the Healthcare Resource Group (HRG) code. The average HRG costs (all NHS trusts) were used because of a lack of information about inpatient stay (elective/non-elective, short stay/long stay) provided by the SUS. A&E department costs were assumed to be 'not leading to admitted'.

Health-related quality of life

Health-related quality of life was measured using the EQ-5D at baseline and 6 and 12 months' follow-up. The EQ-5D is recommended by NICE[244] and aims to measure the extent of problems across the domains of mobility, self-care, usual activities, pain/discomfort and anxiety/depression using three levels of severity (no problems, moderate problems and severe problems). The EQ-5D domain scores were converted to a preference-based score using a tariff derived from members of the general public.[253] EQ-5D scores at the three time points (baseline, 6 months and 12 months) were then aggregated to estimate the total quality-adjusted life-years (QALYs) for each participant over the 12-month period. More information about QALY calculation is provided in the following section.

Data analysis

Data analyses were conducted using Microsoft Excel® 2012 (Microsoft Corporation, Redmond, WA, USA) and Stata 12.1.[254] The base-case cost-effectiveness analysis was conducted for the ITT population on the imputed data set using a multilevel model (MLM). Sensitivity analyses were conducted using a generalised linear model (GLM) and a seemingly unrelated regression (SUR) model. The secondary analyses were performed on the non-imputed data set using a GLM, SUR and MLM. Per-protocol analysis was conducted on the imputed data set using a MLM. Subgroup analyses included participants with different levels of compliance and exposure to treatment. Additional subgroup analysis excluded participants with high service use costs (top 5%). All subgroup analyses were conducted on the imputed data set using a MLM. The intervention and follow-up period lasted for 12 months only so a discount factor of 1 was applied to the costs and benefits following standard discounting practice.[255]

Missing data

The number of missing items in the health economics data set was analysed at baseline and 6 and 12 months' follow-up. The proportion of missing data was reported for consultations, prescriptions, investigations, referrals to community care, secondary care service use data and the EQ-5D. Baseline data

were collected for prescriptions (3 months pre-randomisation) and the EQ-5D. There were two types of missing data within the EQ-5D data set: missing items within a measure and missing measures at a particular time point (baseline or 6 or 12 months' follow-up). EQ-5D data were considered missing if there were no data for at least one descriptive domain as this precludes calculation of total QALYs. Only data missing at a particular time point were imputed for the EQ-5D. Within GP records and the SUS database there was only one type of missing data, that is, when data were missing at a particular time point for all items. The aggregate costs were therefore imputed for primary and secondary care services.

Use of health-care resources by participants

The use of health-care services by participants from the intervention and control groups was analysed in quarters and over the entire duration of the trial. The number of contacts for each participant was extracted from the GP and SUS databases and arranged into quarters starting from the randomisation date.
The following categories together accounted for approximately 95% of all primary care consultations: contacts with GPs (surgery and telephone), nurses (surgery and telephone) and health-care assistants (surgery). The category 'other specialists' included contacts with specialist nurses, physiotherapists, psychologists, counsellors, pharmacists, phlebotomists, dietitians and other health professionals, which together accounted for < 5% of all primary care contacts. It had been anticipated that the intervention would predominantly affect the use of primary care services, such as GP and nurse consultations. Other categories included in the resource use analysis were investigations, referrals to community care, inpatient stays, outpatient appointments and A&E admissions.

Cost of health-care services

The use of health-care services by participants from the intervention and control groups was analysed in quarters and over the entire duration of trial. Unit costs were assigned to each service category and multiplied by the number of contacts. Differences in costs between the intervention group and the control group, with 95% CIs, were estimated for consultations, investigations, prescriptions, referrals to community care, outpatient attendances, inpatient stays and A&E admissions.

Quality-adjusted life-years

The total QALYs over the 12-month period were estimated using the area-under-the-curve method.
Two formulae for the area-under-the-curve calculation were compared: trapezoidal and Simpson's rules.[256]
The trapezoidal rule assumes that data for different time points (baseline and 6 and 12 months' follow-up) are connected by a straight line, whereas Simpson's rule applies a quadratic polynomial function (i.e. a parabola). Depending on the direction of QALY changes over time in the intervention and control groups, these methods may produce different incremental QALYs. The trapezoidal method was chosen as the more conservative method as Simpson's method would potentially overestimate the difference in QALYs between the intervention group and the control group.

Imputations

Missing data for costs and QALYs were imputed using a MI procedure in Stata 12.1. Missing data were assumed to be missing at random. Patterns of missing data were not found to be related to patient characteristics. Imputed data included total primary care costs, total secondary care costs, baseline prescription costs and EQ-5D scores at baseline and 6 and 12 months' follow-up. For each missing category five data sets were imputed.[257] Participants were excluded from imputations if they had more than one missing time point for the EQ-5D. We used a single-level imputation procedure as ICCs for both costs and QALYs were very low (< 0.001, 5–17 participants per cluster). Single-level imputations were carried out using the Stata chained imputation procedure.[258] Given the skewed distributions of cost and QALY data we used the predictive mean matching imputation method, which has been recommended for skewed distributions.[259] Covariates included in the imputation were age, gender, site of recruitment (London or Midlands), course and HADS depression score at baseline. Participants in the control arm were considered in the analysis as their own cluster (course).

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Cost-effectiveness analysis

In the cost-effective analysis we assessed the incremental changes in costs and QALYs in the intervention group compared with the control group (a cost–utility analysis). In the base-case analysis, costs and QALYs were analysed using a mixed-effects linear regression model with 'course' as a random effect. Covariates included in the model as fixed effects were age, gender, site of recruitment, treatment group, EQ-5D score at baseline, prescription cost at baseline and HADs depression score at baseline. Sensitivity analyses were conducted using a GLM and a SUR model. SUR assumes that costs and QALYs are drawn from a bivariate normal distribution.[260] Covariates included in the GLM were age, gender, site of recruitment, course, treatment group, EQ-5D score at baseline, prescription cost at baseline and HADS depression score at baseline. The SUR model included regression equations for costs and QALYs, each regressed on the above variables.

The outcomes of the cost–utility analyses were an incremental cost-effectiveness ratio (ICER) and the probability of the intervention being cost-effective at the NICE threshold of £30,000 per QALY gained. The ICER was estimated as the difference in mean total costs between the intervention group and the control group divided by the difference in mean QALYs between the intervention group and the control group. A parametric approach was then used to address the uncertainty around ICER point estimates for the imputed data set.[261] Briefly, this method involved calculating the net monetary benefit (NMB) for each participant at different willingness-to-pay (WTP) thresholds,[245] having first controlled for covariates using a MLM, GLM or SUR model. We then used Rubin's rule[240] to estimate the mean and standard error of the NMB for the intervention and control groups. The incremental net benefit (INB) was estimated for each WTP threshold (i.e. mean INB = mean NMB control – mean NMB intervention) and a normal distribution was assigned to the INB based on patient-level data. The probability of the intervention being cost-effective was estimated using 10,000 random samples from the above distribution.

Sensitivity analyses were conducted using the non-imputed data set (complete case analysis). Only participants with a complete health economics data set were included in this analysis. The 'complete' data set included EQ-5D data at baseline and 6 and 12 months' follow-up, and resource use costs for primary and secondary care over 12 months. Total costs and QALYs were analysed using a mixed-effects linear model. Sensitivity analyses were conducted using a GLM and a SUR model. The non-parametric bootstrap method was used to address the uncertainty around the ICER point estimates. The probabilities of the intervention being cost-effective were estimated using both bootstrap and INB approaches.

The primary cost-effectiveness analysis was conducted on an ITT basis. Subgroup analyses were conducted using the per-protocol population. Additional subgroup analyses included participants with different rates of compliance and exposure to the intervention. Compliers were defined as individuals who attended 12–17 sessions and non-compliers were defined as those who attended ≤ 11 sessions. Full exposure to the intervention assumed 17 sessions, moderate exposure 9–16 sessions and no exposure eight sessions or fewer. The moderate-exposure subgroup was excluded from the cost-effectiveness analysis because of the small number of participants ($n = 23$).

Chapter 10 Fidelity

Abstract

Introduction: The fidelity of intervention delivery is crucial in any consideration of the results of the intervention. Fidelity has many components but this study was concerned with the fidelity of intervention delivery (intervention integrity), which was influenced by both the adherence of facilitators to the course content and their competence (or skill) in delivering the intervention.

Aim: To assess how well the COPERS intervention was delivered during the trial by measuring the adherence and competence of the facilitators delivering the intervention.

Methods: We identified seven of the 24 course components (or sessions) that we considered to be the most important in terms of effecting participant behaviour change. All of the courses were audio-recorded and intervention integrity was assessed by examination of the recordings of these seven components. Checklists to capture adherence and competence systematically were designed. Researchers also gave an overall impression rating for intervention delivery. We randomly selected four of the seven components on each of the 31 courses. Using the appropriate checklist one evaluator listened to each recorded component in its entirety and rated adherence, competence and overall impression. We checked the intra- and inter-rater reliability.

Results: Intra- and inter-rater reliability were excellent for adherence, very good for competence and less good for overall impression. Adherence was very good or excellent across the courses with competence being more variable across the courses, being excellent for some sessions and less good for others. The overall impression measure proved to be challenging to use and the data were difficult to interpret.

Conclusions: Overall, the results suggested that the COPERS course was delivered competently and as intended.

Background

Complex interventions such as the COPERS intervention are recognised in MRC guidance[28] as having varied and challenging issues in terms of their design, evaluation and implementation. This guidance recognises that intervention fidelity is underevaluated. Intervention fidelity is defined as the use of methodological strategies to monitor and enhance the reliability and validity of behavioural programmes.[214]

The construct of 'intervention fidelity' originated from concerns about the 'treatment integrity' of psychotherapeutic interventions expressed in the 1980s and 1990s.[262–264] The monitoring, measurement and assessment of intervention fidelity is important as it has been demonstrated that fidelity is a mediator of study outcomes.[265–268] For example, when interventions lack impact, this may reflect implementation failure rather than genuine ineffectiveness. One of the potential explanations for the small effect sizes generally seen in studies of self-management support[14] may be the lack of intervention fidelity, but this is rarely reported.

In the last 20 years the notion of intervention fidelity has become increasingly differentiated and multilayered.[269–271] There is an ongoing debate about how core elements of fidelity should be defined and measured[264,272] and a recognition of the need for reliable fidelity measurement instruments.[273] There is

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little consensus about the key elements that contribute to intervention fidelity, possibly because it is a multidimensional construct.[268] Some authorities have identified five domains of fidelity:

1. study design
2. training
3. intervention delivery, defined as the monitoring and assessment of behaviours at the point of intervention delivery
4. intervention receipt by participants
5. intervention enactment, defined as the extent to which participants apply the skills learned in their daily lives.[215,269]

However, intervention enactment may be considered an outcome measure rather than an indicator of fidelity. Here we focus on the domain of intervention delivery or integrity.

The effectiveness of complex interventions may also be dependent on the 'skills' of those delivering them. 'Skills' can be characterised by the separate, but related, constructs of adherence and competence:[214]

- adherence – the extent to which the intervention is delivered in the way that it was intended to be delivered (as per protocol and/or design)
- competence – the level of 'skill' demonstrated by those delivering an intervention; this may include the ability to respond appropriately to a wide variety of contextual cues.

Competence is less likely to be assessed than adherence. This may be a reflection of the debate surrounding the definition of competence and 'skill',[263] the methodological difficulties surrounding the monitoring and measurement of competence[274] and the significant expenditure of time and resources required to collect and analyse competence data.[263]

Aim

The overall aim of the fidelity study was to assess how well the COPERS intervention was delivered by measuring the adherence and competence of the facilitators delivering the intervention.

Methods

Setting and data collection

The research team identified seven of the 24 course components (or sessions) that they considered to be the most important in terms of effecting participant behaviour change (*Table 34*). These components focused on participant education and theoretically driven behaviour change techniques and strategies in contrast to other components, which encouraged social interaction, relaxation and postural awareness. All of the courses were audio-recorded and intervention integrity was assessed by examination of the recordings of the components listed in *Table 35*.

Developing the intervention integrity measures

We used the monitoring and assessment tools from three previously published trials to inform the development of the COPERS measures.[53,275,276] The learning outcomes outlined in the COPERS facilitator training course manual helped to design a provisional set of criteria to measure adherence and competence. To develop the measures we used a two-stage pilot testing process.

Our adherence measure was designed to assess the delivery of key elements of each component as described in the facilitators' manual. The generic competence measure was designed to determine the extent to which the facilitators created an environment in which participants could share their experiences

TABLE 34 Components evaluated for fidelity of intervention delivery

Component	Component description
Component 2 (day 1): pain information	Participants watched a DVD aimed at educating them about chronic pain and introducing them, through facilitated discussion, to the notion of acceptance of their pain
Component 3 (day 1): acceptance	Participants were asked to consider a scenario about an uninvited/unwanted guest as a metaphor for their pain
Component 5 (day 1): the pain cycle	Groups were introduced to the pain cycle and the varied and individual emotions and behaviours that may perpetuate that cycle
Component 9 (day 2): identifying problems, goal-setting and action planning	Groups were introduced to strategies to enable them to systematically identify problems, brainstorm creative solutions, set goals and devise strategies to escape the pain cycle
Component 10 (day 2): barriers to change – unhelpful thinking	Groups were encouraged to consider that reflexive, automatic thinking patterns may prevent individuals from achieving their goals
Component 11 (day 2): barriers to change – reframing negatives to positives	Participants were asked to consider what they were able to do rather than what they were unable to do
Component 12 (day 2): attention control and distraction	Participants were introduced to techniques that might enable them to focus their minds away from thoughts about pain

and learn new skills. An overall impression score was designed to reflect the extent to which the aims and objectives of the component were achieved and how the material was received by the group.

We tested a variety of scoring systems for adherence, competence and the overall impression score. We found that each method of assessment had its own strengths and weaknesses. Numerical scales and Likert scales seemed, intuitively, to be more suitable for measuring degrees of competence but they had low levels of intra- and inter-rater reliability. Frequency methods of assessment were resource intensive and time-consuming, had low levels of intra- and inter-rater reliability and were challenging to verify from audio recordings only. Dichotomous response categories (such as yes/no, present/absent or occurred/did not occur), when used to evaluate adherence items, were time efficient and had high intra- and inter-rater reliability.

The research team revised and amended the evaluation forms. The final agreed measures consisted of component-specific adherence forms, a generic competence form and an 'overall impression' scoring sheet (see *Appendix 7*).

The option to transcribe the audio recordings was unrealistic because of the volume involved and potential cost; evaluators were therefore asked to provide supportive quotations and or comments to justify their ratings.

Data analysis and presentation

Adherence measurement

The adherence form consisted of items that reflected the occurrence or non-occurrence of an event. Component-specific items, relating to the key elements prescribed in the COPERS facilitators' manual, formed the basis of the assessments. The team added a third response of 'unsure' for cases when an item was unclear. The evaluation forms allowed the assessors to add explanatory notes if necessary to justify the categories chosen [these categories were 'yes', element occurred/was delivered (2 points); 'no', element did not occur/was not delivered (0 points); and 'unsure' (1 point)].

The number of adherence items evaluated for each component varied (*Table 35*). To ensure that all scores from the components were standardised to a consistent scale we summed the 'raw scores' for each component and divided them by the total number of items for that component. For example, component

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TABLE 35 Number of items scored for each component and number of components evaluated

Component	Number of components (sessions delivered) evaluated	Adherence: items evaluated	Adherence: maximum score	Competence: items evaluated	Competence: maximum score	Overall impression: items evaluated	Overall impression: maximum score
2: Pain information	16	6	12	4	8	1	4
3: Acceptance	17	3	6	4	8	1	4
5: The pain cycle	20	6	12	4	8	1	4
9: Identifying problems, goal-setting and action planning	19	8	16	4	8	1	4
10: Barriers to change – unhelpful thinking	18	6	12	4	8	1	4
11: Barriers to change – reframing negatives to positives	18	5	10	4	8	1	4
12: Attention control and distraction	14	6	12	4	8	1	4

2 (pain information) had six adherence items with a maximum 'raw' score of 12 (6 × 2). The total aggregate six-item score for this component was divided by 6. Thus, a maximum (100%) score was 2 and a minimum score was zero.

Competence measurement

A competence evaluation form was designed to evaluate all of the course components. This generic measure consisted of items related to the extent to which the facilitators introduced the aims/rationale of each component, the success or failure of the facilitators to generate group discussion and individual disclosure, whether or not the facilitators consolidated and summarised the participant learning at the conclusion of each component and whether or not the facilitators linked that learning to other components in the course. Assessment was scored as 'yes'/demonstrated (2 points), 'no'/not demonstrated (0 points) and 'unsure' (1 point). The scores were also standardised by dividing the maximum 'raw' score of eight by the number of items (i.e. four); thus, the maximum score was 2 and the minimum score was zero.

Overall impression rating

We used an overall general impression rating scale ranging from 1 to 4, anchored at 1, 'did not go well', and 4, 'excellent'.

As the scores were not normally distributed, the median and 25th and 75th percentiles are presented.

Selection and assessment of components

We used a random sampling grid to select four of the seven selected components from each course. Using the appropriate evaluation form one evaluator listened to each recorded component in its entirety and rated adherence, competence and overall impression. A number of components could not be analysed because of equipment failure, facilitator error, incomplete recording or poor sound quality; evaluators were instructed to substitute that component with the next available selected component from that course.

Three members of the COPERS research team (DE, TM, KH) evaluated/assessed the audio recordings.

Intra-/inter-rater reliability

A total of 10% of the assessed component recordings were tested for intra- and inter-rater reliability. Of this sample, a purposive sample of 10% of the evaluations that reflected a range of scores was used to assess both intra- and inter-rater reliability. For inter-rater reliability each reviewer was asked to code a session that had already been coded (they were blinded to the initial reviewer's scores). For intrarater reliability a period of at least 2 weeks between the first and the second evaluations was adopted. We calculated the percentage agreement for each item rated on the evaluation forms.

Results

In total, 31 COPERS courses were delivered, 14 in London and 17 in Warwick. A total of 122 individual COPERS components were assessed (see *Table 35*) amounting to approximately 71 hours of intervention. Because of missing recordings two London courses were assessed on three rather than four components; all Warwick courses were assessed on four components.

Intra-/inter-rater reliability

Intrarater reliability was measured using assessments from 16 COPERS components consisting of 94 adherence item scores, 64 competence item scores and 16 overall impression scores. Intra-rater reliability was 91% for adherence items, 76% for competence items and 69% for overall impression scores.

Fifteen COPERS components were used to measure inter-rater reliability, consisting of 95 adherence item scores, 71 competence item scores and 15 overall impression scores. Inter-rater agreement was 80% for adherence items, 67% for competence items and 54% for overall impression scores.

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Adherence

Both COPERS study centres achieved the maximum overall course delivery adherence score (median 2.00); however, there were some component score variations (*Table 36*). The lowest levels of adherence were observed for component 10 (unhelpful thinking) [median 1.67, interquartile range (IQR) 1.67–2.00] and component 2 (pain information) (median 1.75, IQR 1.42–2.00).

Competence

Competence scores exhibited higher levels of variability than adherence scores (*Table 37*). The overall median course delivery competence score for both COPERS centres was 1.50 (IQR 1.25–2.00). In Warwick the highest level of competence was for component 11 (reframing negatives to positives) (median 1.75, IQR 1.25–2.00) and the lowest for component 12 (attention control and distraction) (median 1.13, IQR

TABLE 36 Overall adherence scores for London and Warwick

Component	Warwick median	25th–75th percentile	London median	25th–75th percentile	Warwick/London median	25th–75th percentile
2: Pain information	1.67	1.50–2.00	1.83	1.33–2.00	1.75	1.42–2.00
3: Acceptance	2.00	1.92–2.00	2.00	1.67–2.00	2.00	1.83–2.00
5: The pain cycle	2.00	1.75–2.00	2.00	2.00–2.00	2.00	2.00–2.00
9: Identifying problems, goal-setting and action planning	2.00	2.00–2.00	2.00	1.91–2.00	2.00	2.00–2.00
10: Barriers to change – unhelpful thinking	1.67	1.67–1.67	1.92	1.62–2.00	1.67	1.67–2.00
11: Barriers to change – reframing negatives to positives	1.70	1.60–2.00	2.00	2.00–2.00	2.00	1.60–2.00
12: Attention control and distraction	2.00	1.67–2.00	2.00	1.83–2.00	2.00	1.67–2.00
Overall course adherence score	2.00	1.67–2.00	2.00	1.83–2.00	2.00	1.67–2.00

TABLE 37 Overall competence scores for London and Warwick

Component	Warwick median	25th–75th percentile	London median	25th–75th percentile	Warwick/London median	25th–75th percentile
2: Pain information	1.50	1.13–2.00	2.00	1.25–2.00	1.75	1.25–2.00
3: Acceptance	1.50	1.38–2.00	1.25	1.00–2.00	1.50	1.00–2.00
5: The pain cycle	1.63	1.50–2.00	2.00	1.56–2.00	1.88	1.50–2.00
9: Identifying problems, goal-setting and action planning	1.50	1.00–2.00	1.25	1.06–1.88	1.50	1.00–2.00
10: Barriers to change – unhelpful thinking	1.50	1.50–2.00	1.38	1.00–1.56	1.50	1.00–1.81
11: Barriers to change – reframing negatives to positives	1.75	1.25–2.00	1.50	1.06–2.00	1.63	1.25–2.00
12: Attention control and distraction	1.13	1.00–1.88	1.25	1.00–1.63	1.13	1.00–1.63
Overall course competence score	1.50	1.31–2.00	1.50	1.00–2.00	1.50	1.25–2.00

1.00–1.88). In London the highest level of competence was observed for component 5 (the pain cycle) (median 2.00, IQR 1.56–2.00) and the lowest also for component 12 (attention control and distraction) (median 1.25, IQR 1.00–1.63).

Overall impression scores

The median overall impression score for all courses was 3.00 (IQR 2.00–3.00). There was some component score variability (*Table 38*). Component 12 (attention control and distraction) had an overall median impression score of 2.00, reflecting the low facilitator competence scores for this component. Component 11 (reframing negatives to positives) had a similarly low overall median impression score of 2 (IQR 2.00–3.25), although this component was delivered with the maximum score for adherence (median 2.00, IQR 1.60–2.00) and with good levels of competence (median 1.63, IQR 1.25–2.00).

Discussion

The aim of this study was to develop a methodology and assess the level of intervention integrity achieved during the delivery of the COPERS self-management course in a RCT setting. Overall, the results suggested that the COPERS course was delivered competently and as intended. We were satisfied that intervention fidelity was acceptable and therefore that the results of the intervention are a reflection of an intervention that was delivered well.

As has been pointed out by others, this work suggests that effective adherence in complex interventions may involve not only the delivery of prescribed 'surface' content but also adherence to essential but non-content-related 'core' theoretical/structural elements.[270] Component 10 (unhelpful thinking) in the COPERS programme illustrates the challenges in defining adherence in complex interventions. This component was intended to help participants recognise and change patterns of automatic negative and self-limiting thoughts. The COPERS manual outlined the informational content of this component and the structure, sequence, timing and mode of delivery of the various elements to be used by the facilitators. To deliver this component as prescribed, a high level of adherence to both 'surface' content *and* 'core' elements was required. Component 10 had a relatively low adherence score, which was primarily caused by the facilitators' difficulty in maintaining the complex structure of the component rather than a failure to deliver the prescribed content.

TABLE 38 Overall impression scores for London and Warwick

Component	Warwick median	25th–75th percentile	London median	25th–75th percentile	Warwick/London median	25th–75th percentile
2: Pain information	3.00	2.00–3.00	3.00	3.00–4.00	3.00	3.00–3.00
3: Acceptance	3.00	2.00–3.00	3.00	3.00–4.00	3.00	2.50–3.00
5: The pain cycle	3.00	3.00–4.00	3.00	2.25–4.00	3.00	3.00–4.00
9: Identifying problems, goal-setting and action planning	3.00	2.00–3.00	2.50	2.00–3.75	3.00	2.00–3.00
10: Barriers to change – unhelpful thinking	2.50	2.00–3.00	3.00	2.75–3.25	3.00	2.00–3.00
11: Barriers to change – reframing negatives to positives	2.00	2.00–3.25	2.50	2.00–3.75	2.00	2.00–3.25
12: Attention control and distraction	2.50	2.00–3.00	2.00	1.00–3.00	2.00	1.75–3.00
Overall course impressionistic score	3.00	2.00–3.00	3.00	2.00–4.00	3.00	2.00–3.00

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Component 10 also demonstrated that the constructs of adherence and competence are complex and may be seen to overlap. Competence, defined as the skilful delivery of content, implies some level of adherence. However, adherence, defined as the extent to which content is or is not delivered, does not imply any degree of skill or competence. High levels of content adherence may be associated with a mechanistic, inflexible or unresponsive delivery style and therefore with low levels of competence.[263] However, within component 10, facilitator 'failure' to order the component content as prescribed, that is, low structural adherence, was directly related to low levels of competence. Component content designed to promote group participation, if poorly sequenced or timed, resulted in a didactic/mechanistic delivery style that inhibited rather than encouraged group disclosure and discussion.

Seemingly low levels of adherence may not necessarily be associated with poor intervention delivery. In component 2 (pain information), some facilitators deviated from the prescribed content of the manual (and were by definition non-adherent) but these deviations could be reinterpreted positively as the facilitators had responded to individual or group need or intervention receipt. Some of the facilitators reframed questions and subtly changed delivery from the prescribed content in the manual but they still achieved the component's overall aims and objectives. This may be a demonstration of high levels of facilitator competence despite them being rated as non-adherent.[270] There is, as yet, little empirical work that demonstrates the conditions that may influence adaptation or reinvention or whether, and in what circumstances, these deviations from prescribed protocol may enhance outcomes or decrease effectiveness.

The monitoring and assessment of competence within the COPERS study illustrated the difficulties associated with its measurement. Competence can be considered as a complex construct that includes the ability to establish collaborative relationships and form alliances with participants[277] through the use of responsive tailoring of programme content,[276] the pacing of delivery[278] and the use of positive verbal and non-verbal behaviours.[279]

The findings from the COPERS study support the view that competence is considered to be more contextually and/or externally or environmentally dependent than adherence. The greater variability in the competence scores than in the adherence scores reflects, in part, the diversity of facilitator skills required to deliver the COPERS programme and the recognised practical and methodological difficulties in measuring what may seem to be a subjective concept.[215,263]

For example, facilitators were required to encourage participant reactions, elicit individual narratives and generate group discussion and debate. They were also required to deliver complex component structures, introduce their groups to new knowledge and skills and make the components individually relevant to 'real-world' situations, often while managing difficult situations, people and emotions. The COPERS study demonstrated how competence and effective course delivery may be influenced and moderated by many factors such as positive or negative individuals and/or groups, component content, facilitator and cofacilitator teamwork and skill, issues related to the use of computer hardware and software, the venue, the distribution of handouts, the use of flip charts, the co-ordination and organisation of group activities, feedback and time management. Experience also influences competence; we noted that our facilitators improved with each course that they conducted. Our ratings might also reflect the inexperience of the facilitators who were delivering a new initiative.

The overall impression measure was, in part, designed to reflect some of the 'non-facilitator-determined' factors not evaluated by the adherence and competence measures. This subjective measure assessed the extent to which the delivery of each component achieved its specific aims and was consistent with the goals of the wider programme. The overall impression measure proved to be challenging to use and the data difficult to interpret. Evaluators found it relatively straightforward to assess a component as either 'excellent' or 'did not go well' but the consistent use of the intermediate scores was problematic. The relationship between the level of adherence and competence, and the overall impression score was difficult to determine but generally low overall impression scores seemed to be associated with deficiencies in assessed competence rather than low levels of adherence.

Limitations

We tested only 10% of samples for both intra- and inter-rater reliability; although this sample size may be considered relatively small by some, it was felt to be reasonable and feasible, and indeed represented a higher degree of feasibility checking than has been reported in many other studies.

We used audio recordings to evaluate the components but it is doubtful if sound recordings alone can capture the subtleties of facilitator competence involving non-verbal behaviours and the dynamics of both facilitators and individual and group interactions. The component-specific adherence measures were designed to assess the fundamental requirements of course delivery; however, the use of a generic competence measure may not have reflected the range of skills required to deliver the various components. The absence of standardised definitions and the lack of valid and reliable measures of adherence and competence made assessments of the impact of either on outcomes difficult. There is a need for more empirical work to clarify how the findings from psychotherapeutic research may be applied to other similar interventions and populations free of mental health issues.[278]

Conclusions

Complex interventions pose significant challenges for developing practical methods for assessing 'treatment integrity'. Generic adherence and competence criteria seem inadequate to encompass the full complexity of interacting elements that occur in behaviour change interventions. The robust monitoring and assessment of treatment integrity requires the systematic collection of appropriate data, the formulation of programme- and component-specific measures and the comprehensive training of assessors. The explicit manualisation of programmes and their component competencies is necessary to ensure robust evaluation. We have proposed one model of assessing adherence and competence and demonstrated its use in a large pragmatic RCT. We recognise, however, that more work is necessary to develop valid, resource-efficient methods of evaluating intervention integrity. We are confident that the COPERS intervention was delivered with high levels of adherence and good levels of competence and that the programme aims were largely achieved. We therefore anticipate that our outcome data will not be influenced by poor intervention delivery.

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Chapter 11 Randomised controlled trial of the clinical effectiveness and cost-effectiveness of the COPERS intervention: results

Recruitment

Recruitment of recruiting centres

We invited all of the general practices in our study areas ($n = 282$) to participate in the trial. We approached practices using the NIHR primary care research networks; we also used our own peer networks. Practices were paid service support costs to compensate them for the time spent on the study. We recruited 12 out of 141 (9%) practices in east London and 13 out of 141 (9%) practices in Warwick. Reasons given by general practices for not participating in the trial included lack of time or resources and/or that many of their registered patients with chronic pain did not speak fluent English. The practices that we recruited were based in areas with a wide range of deprivation (from the lowest to the second highest decile for deprivation) but generally all had very high Quality and Outcomes Framework scores (which might be a marker of good clinical care or organisation). We also recruited two secondary care pain services (one in London and one in Warwick) and one community musculoskeletal service in London to identify patients for the trial.

Recruitment of participants

Recruitment took place between August 2011 and July 2012. The total number of patients registered at the 25 recruited general practices was 223,425, of whom 8138 (3.6%) were identified by our searches. Screening by practice clinical staff led to 2278 (28.0%) of these patients being excluded. The remaining 5878 patients were invited by post to participate and 531 (9.0%) of these joined the study (recruitment rate 2.4/1000 registered patients). This represents a conversion rate from those identified by our searches of 6.5% (*Table 39* and *Figure 14*). Although our approach was identical in both areas the proportion of potential participants approached by general practices who joined the study was higher in the Midlands (11%) than in London (7%). This may reflect the differences in socioeconomic and demographic factors between the two areas.

We recruited an additional 167 participants from secondary and intermediate care services. The Warwick centre was unable to provide the number of patients approached. A total of 2865 people attending the pain service or the musculoskeletal physiotherapy service in east London were identified from the service databases. Clinical staff excluded just 31 (1.1%) of these and 2834 (98.9%) were invited by their clinicians to join the study. In total, 150, or 5.2% of those originally identified, agreed to participate in the study. Five people in Warwick (and none in London) referred themselves to the trial giving a final total of 703 participants, with 383 participants recruited from Warwick and 320 recruited from London (see *Figure 14*).

To ensure that all of our intervention participants received the group intervention as intended it was important that every intervention patient was recruited to a group with at least eight participants. This meant that we had to recruit 18 participants more than our target of 685 participants. This necessary 'over-recruitment' was approved in advance by the TSC and the Research Ethics Committee.

As part of recruitment, general practices and secondary/intermediate services sent a total of 8712 letters inviting patients to join the trial. In response the trial offices received around 1500 informal telephone enquiries about the trial. Those callers who dropped out at this point could not meet the requirements to join the study, for example they could not take time off work to complete the course, they were no longer interested once the study had been explained to them or they did not meet our inclusion criteria; in London, this was principally because of a lack of fluency in English.

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TABLE 39 Recruitment to the study from general practices

General practice	Practice characteristics			Identified, *n*	Excluded by practice, *n*	Invited, *n*	Enrolled, *n*
	List size, *n*	Deprivation decile[a] (1 = most deprived)	QOF score[a] (out of 1000)				
1	16,927	4	997.2	599	376	223	9
2	14,984	6	990.4	1058	211	847	60
3	14,147	5	984.9	390	30	360	36
4	14,000	1	962.1	546	34	512	6
5	12,600	8	961.9	568	285	283	50
6	12,500	9	997	218	83	135	21
7	12,190	2	990.1	602	439	163	12
8	12,181	1	995.7	312	74	238	22
9	12,051	4	986.4	309	87	222	11
10	10,878	8	988.7	372	104	268	38
11	10,500	5	917.6	428	254	174	33
12	10,000	8	983.9	375	44	331	40
13	9200	4	997.3	404	37	367	28
14	8300	1	962.7	350	10	340	26
15	8107	3	991	281	41	240	26
16	7300	1	982.4	166	6	160	7
17	7059	5	959.3	143	36	107	14
18	5700	1	961.9	300	37	263	24
19	5500	5	985.3	291	11	280	36
20	4300	2	889.5	38	0	38	6
21	3496	2	997.3	143	36	107	8
22[b]	3093	5	988.6	0	0	0	3
23	3000	3	995.9	51	0	51	7
24	2900	2	951.7	175	25	150	8
25	2512	4	982.6	19	0	19	0
Total London	97,584	–	–	3365 (3.4%)	825 (24.5%)	2540 (75.5%)	170 (6.7%)
Total Midlands	125,841	–	–	4773 (3.8%)	1453 (30.4%)	3338 (69.9%)	361 (10.8%)
Overall total	223,425	–	–	8138 (3.6%)	2260 (27.8%)	5878 (72.2%)	531 (9.0%)

QOF, Quality Outcomes Framework.
a Source: http://fingertips.phe.org.uk/profile/general-practice/ (accessed 20 April 2016).
b Practice resource changes meant that the site did not complete the full recruitment process.

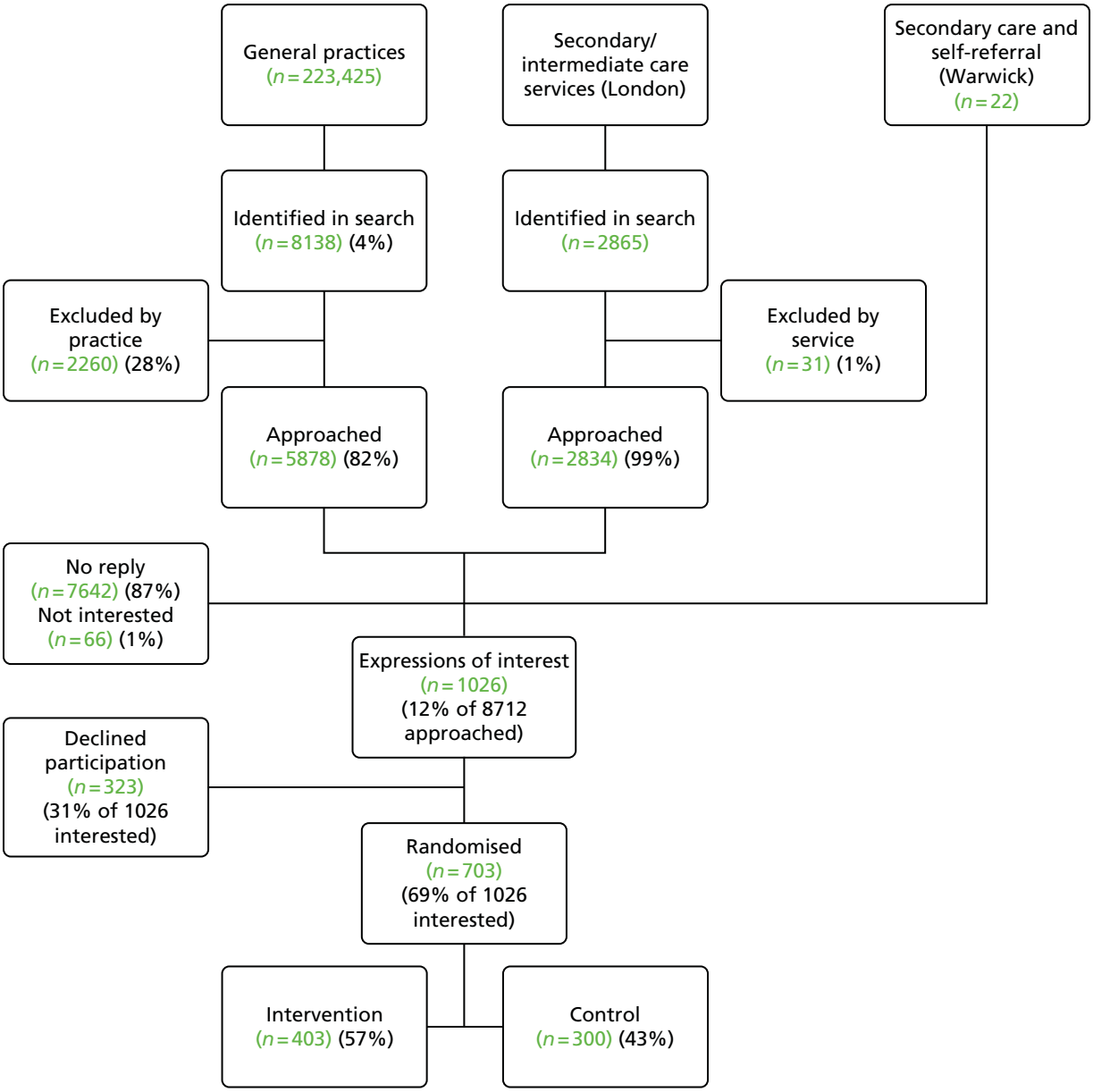

FIGURE 14 Recruitment flow chart.

A total of 1026 people returned a consent to approach form or contacted us directly and met our inclusion criteria. These people were then sent a baseline questionnaire and a trial consent form. Of these, 323 people declined to join the study (*Figure 15*). Reasons for this included:

i. They could not commit or no longer wanted to commit to the course or the relaxation programme (unavailable because of holiday, work or family commitments; did not like being in groups or with strangers; too difficult to get to venues; did not think that they would benefit from being in the trial; had done other similar things in the past; or were no longer interested).
ii. They had other more serious comorbidities and/or scheduled hospital visits.
iii. They were not fluent in English.

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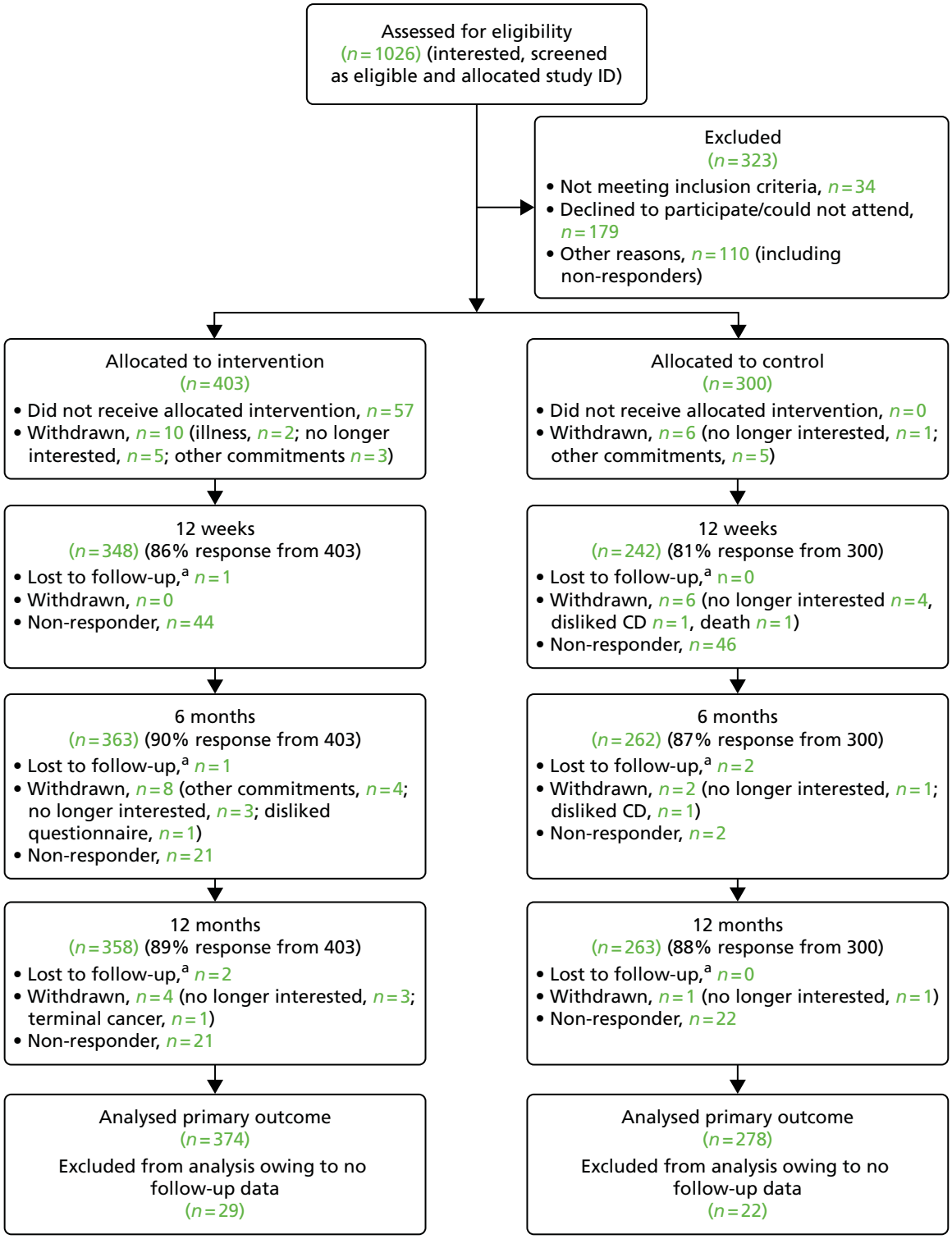

FIGURE 15 Consolidated Standards of Reporting Trials flow diagram. Total analysed is for primary outcome only. a, Loss to follow-up (moved or changed telephone number).

Description of invitees

Practices provided anonymous demographic data on 6182 (71%) of the 8712 people whom they invited to participate in the trial (not all practices were able to supply these data). The proportion of women invited was the same in each site (64%). The overall mean age was 59 years (range 18–101 years), but the mean age in Warwick (67 years) was higher than that in London (52 years). Describing the ethnicity of those invited was hampered by a lack of data. Of the 3151 invitees for whom ethnicity was recorded, 2122 (67%) were white British or European and 1029 (33%) were Asian or African (*Table 40*). The difference in ethnicity recording and reporting between east London and the Midlands might represent an underestimation of the proportion of white British/European invitees.

Baseline characteristics of study participants

Of those recruited, 67% were female; the mean age was 60 years (range 19–94 years) and 81% were white British. Age and gender were similar between those recruited and those invited (with available data). *Table 41* provides baseline characteristics of all participants.

There were no important differences in baseline characteristics between the intervention arm and the control arm (*Table 42*). Just over half of the participants [381/703 (54%)] had completed formal education

TABLE 40 Characteristics of patients invited into the trial ($n = 6182$, 71% of invitees)

Site	Female, *n* (%)	Age (years), mean (range)	Ethnicity, *n* (%)		
			White British, mixed or European	Asian or African or mixed	Unknown
London ($N = 3187$)	2025 (64)	52 (18–95)	1029 (32)	971 (30)	1187 (37)
Warwick ($N = 2995$)	1911 (64)	67 (19–101)	821 (27)	83 (3)	2091 (70)
Total ($N = 6182$)	3936 (64)	59 (18–101)	1850 (30)	1054 (17)	3278 (53)

TABLE 41 Baseline characteristics: all participants

Characteristics	All participants ($n = 703$)
Age (years), mean (range)	59.9 (19.3–94.4)
CPG pain-related disability score, mean (SD)	63.3 (25.1)
CPG pain intensity score, mean (SD)	71.3 (16.3)
PSEQ score, mean (SD)	31.0 (13.9)
CPAQ score, mean (SD)	56.6 (20.1)
HADS depression score, mean (SD)	7.4 (4.1)
HADS anxiety score, mean (SD)	9.2 (4.6)
hEIQ score, mean (SD)	13.9 (3.5)
EQ-5D score, mean (SD)	0.40 (0.34)
Comorbidities, median (range)	2 (0–8)

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TABLE 42 Baseline characteristics in the intervention arm and the control arm

Characteristics	Control ($N = 300$), *n* (%)	Intervention ($N = 403$), *n* (%)	Number of participants with missing data (control, intervention)
Age (years), mean (SD)	59.4 (13.8)	60.3 (13.5)	0, 0
Male	98 (33)	132 (33)	0, 0
Lives alone	101 (34)	143 (36)	4, 6
Ethnicity			
White	239 (80)	325 (81)	0, 0
Black	36 (12)	53 (13)	
Asian	20 (7)	13 (3)	
Mixed	5 (2)	9 (2)	
Other	0 (0)	3 (1)	
Self-rated English language fluency			
Fluent	259 (86)	341 (85)	0, 0
Good	36 (12)	56 (14)	
Below average	3 (1)	6 (1)	
Poor[a]	2 (1)	0 (0)	
Age at which formal education ended			
No formal education received	4 (1)	1 (< 1)	0, 0
≤ 12 years	0 (0)	1 (< 1)	
13–16 years	153 (51)	222 (55)	
17–19 years	66 (22)	68 (17)	
≥ 20 years	66 (22)	102 (25)	
Still in full-time education	3 (1)	3 (1)	
Other	8 (3)	6 (1)	
Employment status			
Employed, including self-employed (full- or part-time)	78 (26)	91 (23)	0, 0
Unemployed and looking for work	10 (3)	20 (5)	
Still in full-time education	3 (1)	1 (< 1)	
Unable to work because of long-term sickness	62 (21)	86 (21)	
Looking after home/family	14 (5)	23 (6)	
Retired from paid work	132 (44)	175 (43)	
Other	1 (< 1)	7 (2)	
Time kept from usual activities because of pain in the past 6 months			
0–6 days	84 (28)	136 (34)	3, 3
7–14 days	49 (16)	72 (18)	
15–30 days	57 (19)	71 (18)	
≥ 31 days	107 (36)	121 (30)	

TABLE 42 Baseline characteristics in the intervention arm and the control arm (*continued*)

Characteristics	Control ($N = 300$), *n* (%)	Intervention ($N = 403$), *n* (%)	Number of participants with missing data (control, intervention)
State of health			
Very good	17 (6)	27 (7)	0, 0
Good	100 (33)	138 (34)	
Fair	130 (43)	159 (39)	
Bad	45 (15)	63 (16)	
Very bad	8 (3)	16 (4)	
Duration of pain			
0–3 months	4 (1)	1 (< 1)	0, 0
4–12 months	10 (3)	15 (4)	
13 months–2 years	43 (14)	45 (11)	
3–4 years	45 (15)	55 (14)	
5–6 years	40 (13)	49 (12)	
7–10 years	50 (17)	81 (20)	
> 10 years	108 (36)	157 (39)	
CPG overall			
0	0 (0)	0 (0)	3, 5
1	18 (6)	30 (8)	
2	66 (22)	99 (25)	
3	81 (27)	123 (31)	
4	132 (44)	146 (37)	
CPG pan-related disability score, mean (SD)	63.8 (24.4)	62.9 (25.7)	0, 1
CPG pain intensity score, mean (SD)	70.9 (15.3)	71.5 (17.0)	1, 1
PSEQ score, mean (SD)	30.6 (14.1)	31.2 (13.8)	0, 5
CPAQ score, mean (SD)	55.3 (19.1)	57.5 (20.7)	7, 15
HADS depression score, mean (SD)	7.5 (4.0)	7.4 (4.2)	3, 2
HADS anxiety score, mean (SD)	9.3 (4.7)	9.2 (4.6)	3, 3
HADS depression score			
0–7	159 (54)	217 (54)	3, 2
8–10	74 (25)	95 (24)	
11–21	64 (22)	89 (22)	
heiQ score, mean (SD)	13.8 (3.4)	14.0 (3.6)	5, 3
EQ-5D score, mean (SD)	0.39 (0.34)	0.41 (0.34)	1, 1
Number of comorbidities, median (IQR)	3 (2–4)	2 (2–3)	21, 32

continued

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TABLE 42 Baseline characteristics in the intervention arm and the control arm (*continued*)

Characteristics	Control ($N = 300$), *n* (%)	Intervention ($N = 403$), *n* (%)	Number of participants with missing data (control, intervention)
Total amount of drugs taken above the DDD in 3 months prior to randomisation, expressed in units of DDD			
Psychotropic, median (IQR)	0 (0–0)	0 (0–0)	4, 3
Weak opioids, median (IQR)	0 (0–7)	0 (0–8)	4, 3
Strong opioids, median (IQR)	0 (0–0)	0 (0–0)	4, 3
Analgesics (including opioids, non-opioids, NSAIDs and other CNS drugs and oral and topical preparations), median (IQR)	44 (0–136)	49 (0–140)	4, 3
Drugs taken orally for neuropathic pain, median (IQR)	0 (0–7)	0 (0–0)	4, 3
NSAID analgesics (both oral and topical), median (IQR)	0 (0 –44)	0 (0–56)	4, 3
Proportion of participants prescribed weak opioids	76 (26)	107 (27)	4, 3
Proportion of participants prescribed strong opioids	72 (24)	90 (23)	4, 3

CNS, central nervous system.
a When we spoke to people on the telephone their language skills were suitable; however; they rated themselves as poor on the baseline questionnaire.

at or below the age of 16 years and only 169 out of 703 (24%) were in any form of employment, with 148 out of 703 (21%) unable to work because of long-term sickness and another 307 out of 703 (44%) being retired from work. In the previous 6 months nearly half of the participants [341/703 (49%)] had been prevented from engaging in their usual activities for ≤ 14 days because of their pain and 356 of 703 (51%) had been prevented from engaging in their usual activities ≥ 15 days because of their pain. In total, 40% (282/703) described their current health as good or very good at baseline (this compares with 83% of adults in Tower Hamlets, 83% in Hackney, 83% in Newham, 85% in Warwickshire and 81% in Coventry in the 2011 census[280]). Most of the participants had had pain for at least 3 years (85%), with 38% reporting pain for > 10 years.

Mean (SD) anxiety and depression scores on the HADS instrument at baseline were 9.2 (4.6) and 7.4 (4.1), respectively. The mean value exceeded the usual cut-off for caseness for anxiety (≥ 8) and was close to that for depression (≥ 8).[176] Overall, health utility as assessed by the EQ-5D instrument (commonly interpreted as quality of life) was very low, with a mean (SD) score of 0.4 (0.34). The median number of comorbidities (determined from primary care records) was two (range 0–8).

Overall, this was a group of with a high rate of medication use. Many individuals were taking multiple analgesic medications, meaning that a substantial minority were taking more than one DDD of analgesic medication per day. Similarly, it is notable that a substantial minority were prescribed no analgesic medication in the 3 months prior to randomisation. It is noteworthy that just under one-quarter (23%) were being prescribed strong opioids at baseline.

Overall attendance on the course was excellent, with little evidence of attrition; on average, participants attended 85% of the course.

Retention and follow-up rates

We obtained primary outcome data from 621 (88%) participants at 12 months. At 6 and 12 months' follow-up 6% and 5% of responders, respectively, provided only primary outcome and quality of life (EQ-5D) data (*Table 43*).

A comparison of the characteristics of those retained in the study and the characteristics of those not included in the primary analysis is provided in *Table 44*. In general, the two groups were remarkably similar, the one exception being that people living alone were over-represented among those lost to follow-up (51% vs. 33%).

Delivery of the intervention

Recruitment and training of facilitators

We identified 30 potential facilitators, 14 HCPs and 16 laypeople, who attended one of three 2-day training courses. Twenty-four (80%) of these were both available to deliver the course and assessed as being competent to deliver it. Eleven HCPs and 13 laypeople delivered courses; this included two members of the study team who delivered sessions on 10 courses when no other experienced qualified HCP was available.

The mean age of the HCPs delivering the intervention was 44.3 years (range 34–59 years), seven (64%) were female and the mean duration of practice was 13 years (range 3–29 years). They included one chiropractor, three osteopaths, four physiotherapists and three psychologists. All courses were facilitated by at least one experienced facilitator who had delivered the intervention before.

The mean age of the lay facilitators was 55 years (range 33–71 years), 10 (77%) were female and all had personal experience of living with chronic pain. The mean number of years of small group facilitation experience was 4 years (range 0–10 years); two had a background in teaching but considered that they had no previous facilitation experience of this nature. The characteristics of the facilitators are provided in *Table 45*. Overall, the median number of courses delivered was one (range 1–6) for the lay facilitators and three (range 1–5) for the HCPs.

TABLE 43 Response rates by site and follow-up period

Site	Enrolled, *n*	Sent 6-month questionnaire, *n*	All responders, *n*	Telephone responders (CPG and EQ-5D only), *n* (%)	Response rate[a] (%)	Response rate[b] (%)
6 months						
London	320	307	275	30 (11)	90	86
Warwick	383	364	350	6 (2)	96	91
Total	703	671	625	36 (6)	93	89
12 months						
London	320	303	271	22 (8)	89	85
Warwick	383	363	350	7 (2)	96	91
Total	703	666	621	29 (5)	93	88

a Denominator = number sent the 6-month questionnaire.
b Denominator = number enrolled.

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TABLE 44 Characteristics of responders and participants lost to follow-up

Characteristics	Responder (*N* = 652), *n* (%)	Lost to follow-up[a] (*N* = 51), *n* (%)
Age (years), mean (SD)	60.2 (13.4)	56.8 (16.0)
Male	215 (33)	15 (29)
Living alone	218 (33)	26 (51)
Ethnicity		
White	523 (80)	41 (80)
Black	83 (13)	6 (12)
Asian	30 (5)	3 (6)
Mixed or other	16 (2)	1 (2)
Fluent in or good at English	642 (98)	50 (98)
Age at which formal education ended		
≤ 12 years	6 (1)	0 (0)
13–19 years	472 (72)	37 (73)
≥ 20 years or still in full-time education or other	174 (27)	14 (27)
Employment or in full-time education	157 (24)	16 (31)
Time kept from usual activities because of pain in past 6 months		
0–14 days	318 (49)	23 (45)
≥ 14 days	328 (51)	28 (55)
State of health		
Very good, good or fair	530 (81)	41 (80)
Bad or very bad	122 (19)	10 (20)
Duration of pain		
0–2 years	106 (16)	12 (24)
3–6 years	171 (26)	18 (35)
≥ 7 years	375 (58)	21 (41)
CPG pain-related disability score, mean (SD)	63 (25)	69 (26)
CPG pain intensity score, mean (SD)	71 (16)	76 (16)
PSEQ score, mean (SD)	31 (14)	26 (13)
HADS depression score, mean (SD)	7.4 (4.0)	8.6 (4.6)
HADS anxiety score, mean (SD)	9.2 (4.6)	9.9 (5.1)
CPAQ score, mean (SD)	57 (20)	51 (19)
heiQ score, mean (SD)	14.0 (3.5)	12.8 (3.6)
EQ-5D score, mean (SD)	0.41 (0.34)	0.34 (0.37)
Number of comorbidities, mean (SD)	2.7 (1.4)	2.6 (1.3)

a Lost to follow-up refers to participants who were excluded from the primary analysis for CPG pain-related disability at 12 months because they did not complete any CPG pain-related disability questions at either 6 or 12 months.

TABLE 45 Characteristics of the course facilitators

Facilitator	Site	Age (years)	Gender	Ethnicity	Type	HCP profession/ experience	Years of professional experience (HCP) or facilitation (lay)	Number of courses facilitated
1[a]	London	60	M	White British	HCP	Osteopath	5	5
2[a]	London	48	F	White British	HCP	Osteopath	14	5
3[a]	London	50	M	White British	Lay	EPP accreditation	4	3
4[a]	London	34	M	Bangladeshi	Lay	EPP accreditation	3	3
5	London	35	F	British Pakistani	HCP	Psychologist (BABCP)	9	2
6[a]	London	36	M	White British	HCP	Osteopath	9	2
7	London	41	F	Indian	Lay	EPP accreditation	7	2
8[a]	London	49	M	White British	HCP	Chiropractor	25	1
9	London	37	F	White British	HCP	Clinical psychologist	14	1
10	London	36	M	White British	HCP	Clinical psychology assistant	3	1
11	London	64	F	British Pakistani	Lay	EPP accreditation	4	1
12	London	55	F	White British	Lay	EPP accreditation	7	1
13	London	53	F	White British	Lay	EPP accreditation	0	1
14[a]	London	69	F	White British	Lay	Ex-nursing tutor	30	1
15	London	42	F	Black Caribbean	Lay	EPP accreditation	9	1
16	Warwick	53	F	Other white	Lay	EPP accreditation	4	6
17	Warwick	53	F	White British	HCP	Physiotherapist	29	5
18	Warwick	61	F	White British	Lay	EPP accreditation	7	5
19	Warwick	37	F	White British	HCP	Physiotherapist	9	4
20	Warwick	51	F	White British	HCP	Physiotherapist	20	4
21	Warwick	72	M	White British	Lay	EPP accreditation	5	4
22	Warwick	53	F	White British	HCP	Physiotherapist	7	2
23	Warwick	69	F	White British	Lay	Ex-teacher	0	1
24	Warwick	57	F	British Bangladeshi	Lay	CDSMP certification	1	1

BABCP, British Association for Behavioural & Cognitive Psychotherapies; CDSMP, Chronic Disease Self-Management Programme; EPP, Expert Patients Programme; F, female; M, male.
a Took part in the pilot study.

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Courses run and attendance

Thirty-one courses were held in total, 14 in London and 17 in Warwick. The average number of participants booked on each course was 14 (London, $n = 15$; Warwick, $n = 13$) and the average number who attended on day 1 was 11 (London, $n = 11$; Warwick, $n = 11$) (*Tables 46–49*). Courses were delivered in accessible venues near the recruitment sites including community centres, hospitals, university premises and a hospice. The mean duration from randomisation to attending a course was 42 days (range 1–168 days).

TABLE 46 Phase I, September 2011–December 2011: course venues, facilitators and participants

Course	Venue	Facilitator	Number enrolled (target 16)	Attended day 1 (% of enrolled)	Attendance rate (average number of sessions/24 × 100) (%)
L01	University	Osteopath and lay person	13	9 (69)	82
L03	Community hospital	Osteopath and lay person	12	7 (58)	71
L04	Hospice community centre	Osteopath and lay person	14	10 (71)	88
L05	General practice	Osteopath and lay person	14	11 (79)	90
L06	Hospice community centre	Psychologist and lay person	17	13 (76)	87
L07	University	Chiropractor and lay person	14	13 (93)	83
W04	Community centre	Physiotherapist and lay person	10	10 (100)	95
W06	Community centre	Physiotherapist and lay person	12	12 (100)	91
W07	Community centre	Physiotherapist and lay person	10	9 (90)	93
Overall			116	94 (81)	86
London			84	63 (75)	84
Warwick			32	31 (97)	92

TABLE 47 Phase II, January 2012–March 2012: course venues, facilitators and participants

Course	Venue	Facilitator	Number enrolled (target 16)	Attended day 1 (% of enrolled)	Attendance rate (average number of sessions/24 × 100) (%)
L08	Hospice community centre	Psychologist and lay person	16	8 (50)	70
L09	Community hospital	Osteopath and lay person	16	12 (75)	65
L10	Community hospital	Osteopath and lay person	17	11 (65)	84
L11	Community hospital	Psychologist and lay person	16	10 (63)	91
L12	University	Osteopath and lay person	14	10 (71)	98
W08	Community centre	Physiotherapist and lay person	16	11 (69)	99
W09	Community centre	Physiotherapist and lay person	16	13 (81)	90
W10	Community centre	Physiotherapist and lay person	15	11 (73)	89
W13	Community centre	Physiotherapist and lay person	15	11 (73)	96
W14	Community centre	Physiotherapist and lay person	16	16 (100)	70
W15	Community centre	Physiotherapist and lay person	16	14 (88)	65
W16	Hotel conference centre	Osteopath and lay person	16	13 (81)	84
Overall			189	140 (74)	91
London			79	51 (65)	98
Warwick			110	89 (81)	99

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TABLE 48 Phase III, April 2012– July 2012: course venues, facilitators and participants

Course	Venue	Facilitator	Number enrolled (target 16)	Attended day 1 (% of enrolled)	Attendance rate (average number of sessions/24 × 100) (%)
L13	Hospice community centre	Osteopath and lay person	17	10 (59)	93
L14	Community hospital	Osteopath and lay person	16	12 (75)	80
L15	University	Osteopath and psychologist and lay person	17	14 (82)	74
W18	Community centre	Osteopath and lay person	16	16 (100)	93
W19	Community centre	Physiotherapist and lay person	14	8 (57)	55
W20	Community centre	Physiotherapist and lay person	9	6 (67)	69
W21	Community centre	Physiotherapist and lay person	11	10 (91)	60
W23	Community centre	Physiotherapist and lay person	12	11 (92)	85
W24	Community centre	Physiotherapist and lay person	5	5 (100)	98
W25	Community centre	Physiotherapist and lay person	11	10 (91)	84
Overall			128	102 (80)	80
London			50	36 (72)	82
Warwick			78	66 (85)	78

TABLE 49 Phases I–III: course venues, facilitators and participants

Course	Number enrolled	Attended day 1 (% of enrolled)	Attendance rate (average number of sessions/24 × 100) (%)
Overall	433	336 (78)	86
London	213	150 (70)	83
Warwick	220	186 (85)	88

Adverse events

No serious adverse events occurred as a result of the study. Twenty-one incidents resulted in emotional upset, which was dealt with at the scene by the facilitators or later after follow-up contact with one of the study managers. One person in the control arm of the study died but the death was not related to the study.

Course adherence

Fifty-seven initial course non-attendees were booked onto a further course/courses, but most of these failed to attend any subsequent courses. Overall, 67 (17%) of those randomised to the intervention did not attend any course. The reasons given for not attending any course were that participants felt too unwell, had a preference for the control arm, had work commitments, had family issues, had been bereaved or considered the venues or times of courses offered unsuitable. *Tables 46–49* show the number of courses that were run, the number of participants booked on the courses, the number attending on day 1 and the mean number of sessions attended per course per participant. There were 24 sessions/components on the course and overall the mean attendance broken down by sessions attended was 86% (20–21 sessions).

Overall, 282 (70%) intervention participants achieved our predefined criterion of adherence (≥ 17 sessions attended), whereas we considered 95 (24%) non-adherent to the intervention as they attended eight sessions or fewer. If we dichotomise participants into compliers and non-compliers based on our predefined criterion of attendance at more than half the course (at least 12 sessions), 76% were compliant. Attendance was consistently better in Warwick than in London (*Table 50*).

Primary outcome analyses

We included 652 participants in the analysis of the primary outcome of pain-related disability as determined by the CPG [278/300 (93%) control, 374/403 (93%) intervention]. Pain-related disability did not differ between groups at 12 months [intervention mean (SD) 52.9 (28.0) vs. control mean (SD) 53.3 (28.8); difference (intervention vs. control) –1.0, 95% CI –4.9 to 3.0] (*Table 51*). The results were similar at 6 months. This effectively excludes any possibility of a worthwhile effect on our primary outcome; the limit of the 95% CI is 0.22 SDs of its baseline value, well within our prespecified clinically importance benefit of 0.3 SDs.

All sensitivity analyses for the primary outcome showed similar results.

Secondary outcomes: questionnaire items

The results for the secondary outcomes (except for the census global health question and the drug data) at 6 and 12 months' follow-up are shown in *Table 51*. Self-efficacy (PSEQ score: difference 2.3, 95% CI 0.6 to 4.1), anxiety (HADS anxiety score: difference –0.7, 95% CI –1.3 to –0.2), depression (HADS depression score: difference –0.7, 95% CI –1.2 to –0.2), pain acceptance (CPAQ score: difference 3.4, 95% CI 1.3 to 5.5) and

TABLE 50 Compliance and levels of adherence to the intervention by site

Exposure	London, *n* (%)	Warwick, *n* (%)	Both, *n* (%)
Adherent (≥ 17 sessions)	115 (63)	167 (76)	282 (70)
Moderate adherence (9–16 sessions)	16 (9)	10 (5)	26 (6)
Non-adherent (≤ 8 sessions)	52 (28)	43 (20)	95 (24)
Total	183 (100)	220 (100)	403 (100)
Complier (≥ 12 sessions)	130 (71)	175 (80)	305 (76)
Non-complier (≤ 11 sessions)	53 (29)	45 (20)	98 (24)
Total	183 (100)	220 (100)	403 (100)

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TABLE 51 Main results for primary and secondary outcomes

Outcome	Control ($n = 300$), mean (SD)	Intervention ($n = 403$), mean (SD)	Treatment effect[a] (95% CI)
CPG pain-related disability[b]			
6 months	54.3 (26.7)	53.2 (25.7)	–1.2 (–4.8 to 2.4)
12 months	53.3 (28.8)	52.9 (28.0)	–1.0 (–4.9 to 3.0)
CPG pain intensity[c]			
6 months	64.3 (19.4)	65.0 (18.8)	1.0 (–1.5 to 3.6)
12 months	64.4 (20.1)	63.5 (20.3)	–0.9 (–3.7 to 1.9)
PSEQ score[d]			
6 months	32.7 (15.0)	35.5 (14.0)	2.3 (0.6 to 4.1)
12 months	33.4 (15.1)	35.4 (14.1)	1.4 (–0.2 to 3.1)
HADS anxiety score[e]			
6 months	9.1 (4.8)	8.2 (4.7)	–0.7 (–1.3 to –0.2)
12 months	8.4 (4.5)	8.1 (4.5)	–0.4 (–0.9 to 0.1)
HADS depression score[e]			
6 months	7.0 (4.4)	6.3 (4.1)	–0.7 (–1.2 to –0.2)
12 months	6.9 (4.6)	6.2 (4.3)	–0.7 (–1.2 to –0.2)
CPAQ score[f]			
6 months	59.2 (19.7)	64.4 (20.0)	3.4 (1.3 to 5.5)
12 months	74.0 (14.4)	73.1 (15.1)	–0.8 (–3.0 to 1.4)
heiQ score[g]			
6 months	14.3 (3.6)	14.9 (3.3)	0.6 (0.1 to 1.0)
12 months	14.1 (3.6)	14.9 (3.5)	0.8 (0.4 to 1.2)
EQ-5D score[h]			
6 months	0.41 (0.35)	0.46 (0.34)	0.03 (–0.01 to 0.08)
12 months	0.45 (0.35)	0.46 (0.34)	0.00 (–0.04 to 0.04)

a Treatment effects are defined as a difference in means (Intervention vs. control) for all outcomes.
b 10 = worst pain imaginable.
c 13 = all over pain.
d 60 = completely confident.
e 0–7 'normal', 8–10 borderline, 11–21 'abnormal'.
f 0 = not coping at all.
g Higher scores indicate a better social life.
h Perfect health = 1.0; UK norms for healthy males/females: age 40–49 years = 0.89/0.87; age 50–59 years = 0.80/0.82.[188]

social integration (heiQ score: difference 0.6, 95% CI 0.1 to 1.0) were all significantly better in the intervention group than in the control group at 6 months' follow-up.

At 12 months' follow-up the differences favouring the intervention were sustained for depression (difference –0.7, 95% CI –1.2 to –0.2) and social integration (difference 0.8, 95% CI 0.4 to 1.2) and, although no longer statistically significant, the results for self-efficacy (difference 1.4, 95% CI –0.2 to 3.1) and anxiety (difference –0.4, 95% CI –0.9 to 0.1) tended to favour the intervention. The improvement in pain acceptance seen in the intervention group at 6 months was no longer present by 12 months (difference –0.8, 95% CI –3.0 to 1.4). Of the questionnaire items, only pain intensity (CPG pain intensity score at 6 months: difference

1.0, 95% CI –1.5 to 3.6) and EQ-5D score (at 6 months: difference 0.03, 95% CI –0.01 to 0.08) were not significantly better in the intervention group at either 6 or 12 months.

Table 52 shows the treatment effect sizes expressed as SMDs at 6 and 12 months using the adjusted SDs for centre, age, gender, baseline depression score and baseline value of the outcome.

Responses to the census global health question are summarised in *Table 53*. This table presents the results based on available data; those who did not provide data are not included. There was no difference between groups at either 6 or 12 months (odds ratio for being in a higher category at 6 months 1.09, 95% CI 0.77 to 1.54; odds ratio at 12 months 1.07, 95% CI 0.77 to 1.51).

TABLE 52 Treatment effects expressed as adjusted SMDs

Outcome	Treatment effect (95% CI)[a]
CPG pain-related disability score	
6 months	–0.06 (–0.24 to 0.12)
12 months	–0.04 (–0.22 to 0.13)
CPG pain intensity score	
6 months	0.07 (–0.10 to 0.24)
12 months	–0.06 (–0.23 to 0.12)
PSEQ score	
6 months	0.25 (0.07 to 0.43)
12 months	0.15 (–0.02 to 0.32)
HADS anxiety score	
6 months	–0.24 (–0.41 to –0.06)
12 months	–0.13 (–0.30 to 0.03)
HADS depression score	
6 months	–0.25 (–0.44 to –0.06)
12 months	–0.22 (–0.39 to –0.06)
CPAQ score	
6 months	0.27 (0.08 to 0.45)
12 months	–0.03 (–0.20 to 0.13)
heiQ score	
6 months	0.25 (0.06 to 0.43)
12 months	0.32 (0.16 to 0.49)
EQ-5D score	
6 months	0.13 (–0.03 to 0.29)
12 months	0.01 (–0.16 to 0.17)

a Effect sizes were calculated by dividing the treatment effect and the confidence limits by the estimated residual SD from the analysis model adjusted for centre, age, gender, baseline HADS depression score and baseline value of the outcome.

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TABLE 53 Responses to the census global health question at baseline and 6 and 12 months' follow-up

	Baseline, *n* (%)		6 months, *n* (%)		12 months, *n* (%)	
Response	Control	Intervention	Control	Intervention	Control	Intervention
Very good	17 (6)	27 (7)	11 (5)	20 (6)	8 (3)	14 (4)
Good	100 (33)	138 (34)	81 (34)	121 (35)	84 (34)	130 (38)
Fair	130 (43)	159 (39)	100 (42)	144 (42)	115 (47)	144 (42)
Bad	45 (15)	63 (16)	39 (16)	46 (13)	32 (13)	40 (12)
Very bad	8 (3)	16 (4)	7 (3)	11 (3)	6 (2)	14 (4)
Total	300 (100)	403 (100)	238 (100)	342 (100)	245 (100)	342 (100)

Secondary outcomes: prescribed medicines

Differences in prescribed medicines between the groups at 12 months' follow-up, expressed as DDD, are presented in *Table 54*. Intervention arm patients were prescribed significantly more DDDs of weak opioids in the 12 months following randomisation than those in the control arm, amounting to a difference of 18 days of medication at WHO standard dosing (95% CI 5 to 32 days). The proportion of intervention arm participants taking weak opioids at 12 months also tended to be higher than that in the control group, although the difference was not statistically significant (the odds of taking weak opioids was increased by 39% in the intervention arm, 95% CI 10% fewer to 114% more).

Overall, intervention patients received considerably more analgesics than control arm patients in the 12 months after randomisation (98 DDDs, 95% CI 17 to 178 DDDs). However, there was no evidence of any difference in the prescription of strong opioids between study arms (–1 DDD, 95% CI –12 to 11 DDDs) nor in the proportions of those receiving strong opioids at 12 months (the odds of taking strong opioids was increased by 4% in intervention arm, 95% CI 41% fewer to 85% more).

TABLE 54 Total amount of drugs prescribed as DDD in the 12 months post randomisation and proportion of participants using opioids at 12 months post randomisation

Type of drug	Control ($n = 258$[a])	Intervention ($n = 350$[a])	Treatment effect[b] (95% CI)
DDD in 12 months post randomisation, median (IQR)			
Psychotropics	0 (0–21)	0 (0–28)	–12 (–30 to 6)
Weak opioids	0 (0–36)	0 (0–64)	18 (5 to 32)
Strong opioids	0 (0–22)	0 (0–24)	–1 (–12 to 11)
Analgesics (including opioids and other CNS drugs)	232 (45–551)	295 (57–648)	98 (17 to 178)
Proportion of participants using opioids at 12 months post randomisation, *n* (%)			
Weak opioids	59 (23)	103 (29)	1.39 (0.90 to 2.14)
Strong opioids	64 (25)	82 (23)	1.04 (0.59 to 1.85)

CNS, central nervous system.
a A total of 258 participants (86%) in the control arm and 350 (87%) participants in the intervention arm had drug prescription data available and were included in the analysis.
b Treatment effect represents a difference in means for DDD outcomes at 12 months and an odds ratio for opioid use outcomes at 12 months.

Mediator analysis

The mediation analysis examining the potential role of self-efficacy at 12 weeks as a mediator is not presented because of the lack of effect seen on our primary outcome.

Preplanned subgroup analyses for the primary outcome

The results of our preplanned subgroup analyses for the primary outcome of CPG pain-related disability at 12 months are presented in *Table 55*. There is no evidence to support the intervention being more effective in those who live alone, who have four or more comorbidities or who have a lower socioeconomic status.

There was a suggestion of a non-significant tendency for those with a shorter pain duration to show more benefit in terms of the primary outcome; however, interpretation is difficult as this subgroup analysis is hampered by the small number of participants as the vast majority of participants had long-standing pain. There was no evidence that treatment effects differed across subgroups.

No trend was seen in the association between pain-related self-efficacy and the primary outcome; however, there was an (inconclusive) suggestion that the effect size might be greatest in the group with an intermediate level of baseline self-efficacy.

Finally, there was a suggestion that those with a HADS depression score highly indicative of the likelihood of depression (scores of ≥ 11) may have shown a much greater improvement in pain-related disability at 12 months but, again, the numbers are relatively small and this finding is not statistically significant.

Compliers average causal effects

As a secondary analysis, the CPG pain-related disability, CPG pain intensity, PSEQ, HADS anxiety, HADS depression, CPAQ, heiQ and EQ-5D scores at 12 months were reanalysed to obtain a CACE of treatment, using our prespecified definition of 'compliers' (those who attended at least half of the course).

These analyses were performed on the same participants as the corresponding ITT analyses, so, for example, the CACE of the primary outcome excluded all participants who did not complete any CPG pain-related disability questions at 12 months and we assumed that the excluded participants were missing at random.

The CACE for the primary outcome of pain-related disability as determined by the CPG did not differ between treatment groups at 12 months (difference –1.0 intervention vs. control, 95% CI –5.9 to 3.9). This again excludes our prespecified worthwhile benefit of 0.3 SDs of the baseline score.

Only depression (HADS depression score –0.9, 95% CI –1.5 to –0.3) and social integration (heiQ score 1, 95% CI 0.5 to 1.5) were significantly better in the intervention group than in the control group at 12 months' follow-up among the compliers.

Treatment effects on primary and secondary outcomes estimated from CACE adjusted and unadjusted analyses at 12 months' follow-up are shown in *Table 56*.

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TABLE 55 Results of the preplanned subgroup analyses for the primary outcome (CPG pain-related disability at 12 months)

Subgroup	Control, number included in analysis	Intervention, number included in analysis	Control, mean (SD)	Intervention, mean (SD)	Treatment effect (95% CI)	*p*-value for interaction
Non-pain related						
Comorbidity						
0–3	192	269	50.2 (29.2)	50.6 (27.7)	–0.6 (–5.1 to 4.0)	0.72
≥ 4	76	90	59.8 (26.8)	57.8 (28.0)	–2.1 (–9.4 to 5.3)	
Living arrangements						
Living with others	185	239	52.4 (28.1)	50.9 (28.0)	–0.1 (–4.9 to 4.8)	0.60
Living alone	89	129	54.5 (30.8)	56.9 (27.4)	–2.2 (–8.9 to 4.5)	
PSEQ score						
0–20	72	83	71.7 (22.5)	72.8 (23.6)	0.5 (–7.0 to 7.9)	0.78
21–39	121	184	56.5 (23.2)	54.6 (24.2)	–2.2 (–7.6 to 3.3)	
40–60	85	103	34.0 (29.1)	34.6 (25.9)	0.4 (–6.4 to 7.1)	
Socioeconomic status						
Lower	136	197	52.0 (29.3)	48.5 (27.3)	–2.4 (–7.8 to 3.0)	0.42
Higher	142	177	54.6 (28.4)	57.9 (28.1)	0.8 (–4.7 to 6.2)	
Pain related						
Pain duration						
0–12 months	13	13	40.0 (30.3)	31.8 (29.4)	–5.5 (–23.5 to 12.6)	0.88
13 months to 4 years	80	93	51.7 (29.2)	51.3 (26.6)	–1.7 (–8.9 to 5.4)	
≥ 5 years	185	268	54.9 (28.5)	54.5 (28.1)	–0.8 (–5.5 to 3.8)	
CPG pain intensity score						
0–3	4	17	45.0 (42.6)	21.6 (20.1)	–22.5 (–47.9 to 2.8)	0.24
4–7	186	219	47.1 (28.1)	46.1 (25.8)	–1.0 (–5.8 to 3.8)	
8–10	87	138	66.7 (25.3)	67.4 (25.1)	–0.2 (–6.6 to 6.3)	
CPG pain-related disability score						
0–3	51	70	31.7 (27.6)	33.3 (27.4)	0.5 (–8.1 to 9.1)	0.60
4–7	138	187	51.1 (26.1)	48.4 (23.7)	–2.8 (–8.2 to 2.5)	
8–10	89	117	69.8 (23.8)	71.5 (23.6)	1.1 (–5.6 to 7.8)	
HADS depression score						
0–10	222	291	49.0 (28.7)	49.0 (27.4)	–0.2 (–4.6 to 4.2)	0.44
11–21	56	83	70.6 (22.5)	67.1 (25.7)	–3.8 (–12.0 to 4.4)	

Notes: Participants with missing baseline values of the subgroup were excluded from the analysis for all subgroup analyses apart from those for CPG pain-related disability and HADS depression. The numbers included in each subgroup are approximate for CPG pain-related disability and HADS depression as these variables were included in the MI model. Therefore, participants with a missing baseline value for CPG pain-related disability or HADS depression were included in the analysis; however, it is unclear which of the subgroups they belong to.

TABLE 56 Results from adjusted and unadjusted CACE analyses at 12 months

Outcome	Adjusted treatment effect (95% CI)	Unadjusted treatment effect (95% CI)
CPG pain-related disability score	–1.0 (–5.9 to 3.9)	–0.6 (–6.8 to 5.5)
CPG pain intensity score	–1.0 (–4.4 to 2.4)	–0.6 (–5.0 to 3.7)
PSEQ score	1.7 (–0.3 to 3.7)	2.7 (–0.4 to 5.9)
HADS anxiety score	–0.5 (–1.1 to 0.1)	–0.4 (–1.4 to 0.5)
HADS depression score	–0.9 (–1.5 to –0.3)	–0.8 (–1.7 to 0.2)
CPAQ score	–1.0 (–5.3 to 3.3)	–0.7 (–5.4 to 4.0)
heiQ score	1.0 (0.5 to 1.5)	1.1 (0.3 to 1.8)
EQ-5D score	0.00 (–0.05 to 0.05)	0.01 (–0.07 to 0.09)

Participant exposure to other similar non-trial interventions

To make some assessment of performance bias, we collected data on participation in courses and activities other than the COPERS course during the 12-month follow-up period (*Table 57*). There were a considerable number of missing data, making interpretation of the data difficult. Overall, few respondents had attended any other courses and there appeared to be no differences in the proportions attending these courses between the groups. Reported practice of regular relaxation appeared to be somewhat higher in the control arm than in the intervention arm, with 32% of respondents in the control arm saying that they practised daily relaxation, compared with 21% in the intervention arm, and 26% of respondents in the control arm saying that they practised relaxation every week, compared with 18% in the intervention arm.

TABLE 57 Participation in courses and activities other than the COPERS course during the follow-up period

Other activity/courses	Control ($N = 300$), *n* (%)	Intervention ($N = 403$), *n* (%)	Number of participants with missing data (control, intervention)
Courses or activities attended during the follow-up period outside of the COPERS trial			
Pain management	20 (9)	26 (9)	86, 109
Expert Patient Programme/ self-management course	9 (4)	11 (4)	96, 118
Other wellness or well-being courses	15 (7)	15 (5)	96, 114
Return to work courses	7 (4)	9 (3)	101, 116
Frequency of practising relaxation and/or meditation during the follow-up period			
Daily	75 (32)	66 (21)	69, 82
Weekly	59 (26)	59 (18)	
Monthly	14 (6)	21 (7)	
Rarely	56 (24)	93 (29)	
Never	27 (12)	82 (26)	

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Changes from baseline

Our primary outcome decreased (i.e. improved) within both the control arm and the intervention arm between baseline and 6 months' follow-up [mean (SD) difference between baseline and 6 months: control –8.8 (23.0), intervention –9.3 (23.3)] and these decreases were sustained at 12 months' follow-up (*Figure 16*). CPG pain intensity followed a similar pattern. Indeed, all of the questionnaire variables improved to some extent between baseline and 6 months in both arms of the study and these improvements were sustained, but not generally increased, at 12 months. The one exception to this was the improvement in pain acceptance as measured by the CPAQ. In both study arms this appears to have improved a great deal in the second half of the follow-up period [mean (SD) difference between baseline and 6 months: control 3.0 (12.1), intervention 5.4 (14.6); between baseline and 12 months: control 17.2 (20.7), intervention 14.3 (22.7)] (*Table 58*).

Post hoc analyses

As a result of the finding that mean levels of depressive symptoms were high at baseline we looked at the proportion of participants who might be depressed at each time point. We examined two cut-off points: a HADS depression score of ≥ 8, which is the most sensitive and specific cut-off for possible depression, and a HADS depression score of ≥ 11, which is often considered to be a cut-off for probable depression.[281] In total, 169 out of 698 (24%) participants scored 8–10 and 153 out of 698 (22%) participants scored ≥ 11 on the HADS depression subscale.

The statistically significant sustained reduction in depressive symptoms seen in the intervention group prompted us to conduct an exploratory post hoc subgroup analysis to assess whether or not the treatment differed between those who were depressed at baseline and those who were not depressed at baseline (HADS depression score 0–7 vs. 8–21). We hypothesised that the reduction in depressive symptoms had arisen in those who were likely to have been depressed at baseline and we also wanted to ascertain that people who were not depressed at baseline did not suffer psychologically through exposure to the intervention. This post hoc analysis revealed that the improvement in depressive symptoms seen in the intervention arm was indeed concentrated in those who were depressed at baseline, whereas those who were not depressed at baseline experienced no overall change in HADS depression score at 12 months (*p*-value for interaction = 0.004) (*Table 59*). Moreover, the SMD among those depressed at baseline was –0.50 (95% CI –0.74 to –0.25), which is highly likely to be clinically relevant.[282]

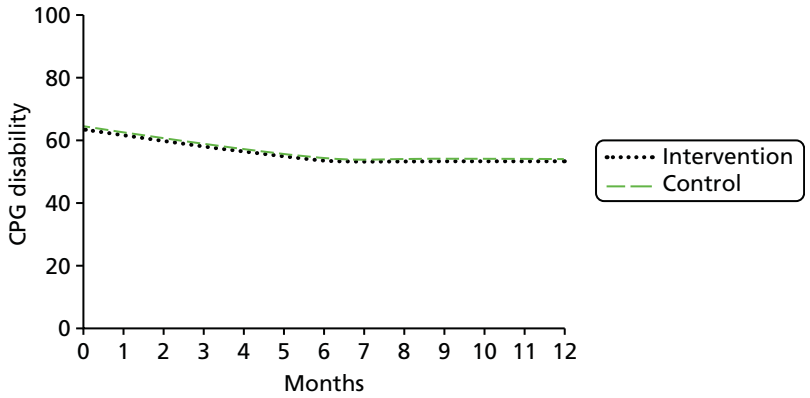

FIGURE 16 Reduction in pain-related disability over the 12-month trial period.

TABLE 58 Mean (SD) change from baseline within each study arm at 6 and 12 months' follow-up

Outcome	Control	Intervention	Number of participants (control, intervention)
CPG pain-related disability score			
6 months	–8.8 (23.0)	–9.3 (23.3)	261, 356
12 months	–9.1 (26.4)	–9.5 (26.1)	261, 355
CPG pain intensity score			
6 months	–6.5 (16.2)	–5.4 (15.8)	241, 337
12 months	–6.1 (17.2)	–7.2 (17.7)	245, 341
PSEQ score			
6 months	1.9 (10.6)	3.2 (11.0)	240, 338
12 months	2.2 (10.7)	3.3 (10.6)	244, 334
HADS anxiety score			
6 months	–0.1 (3.2)	–0.7 (3.4)	234, 333
12 months	–0.5 (3.2)	–0.9 (3.5)	242, 338
HADS depression score			
6 months	–0.3 (2.9)	–0.9 (3.0)	238, 339
12 months	–0.3 (3.1)	–1.0 (3.4)	242, 339
CPAQ score			
6 months	3.0 (12.1)	5.4 (14.6)	228, 321
12 months	17.2 (20.7)	14.3 (22.7)	227, 323
heiQ score			
6 months	0.3 (2.5)	0.7 (2.7)	238, 337
12 months	0.1 (2.7)	0.7 (2.8)	234, 340
EQ-5D			
6 months	0.02 (0.29)	0.04 (0.28)	255, 359
12 months	0.04 (0.29)	0.04 (0.28)	258, 353

TABLE 59 Subgroup analysis of HADS depression score at 12 months by HADS depression score at baseline (0–7 vs. 8–21)[a]

HADS depression score at baseline	HADS depression score at 12 months, mean (SD)		Treatment effect (95% CI)	*p*-value for interaction
	Control	Intervention		
Original scale				
0–7	4.2 (3.0)	4.0 (3.0)	0.0 (–0.7 to 0.6)	0.004
8–21	9.4 (4.8)	8.2 (4.7)	–1.5 (–2.3 to –0.8)	
SMD				
0–7	–	–	–0.01 (–0.23 to 0.21)	–
8–21	–	–	–0.50 (–0.74 to –0.25)	

a A total of 625 participants were included in the subgroup analysis: 348 patients with a HADS depression score of 0–7 ($n = 148$ usual care, $n = 200$ intervention) and 277 patients with a HADS depression score of 8–21 ($n = 113$ usual care, $n = 164$ intervention).

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Sensitivity analyses

All of the sensitivity analyses produced similar results to those of the primary analysis and demonstrated that the primary outcome results were robust (*Table 60* and *Figure 17*).

The *y*-axis in *Figure 17* shows the treatment effect for the CPG pain-related disability score at 12 months (e.g. a value of –2 indicates that the mean CPG disability score was 2 points less in the intervention group than in the control group). The *x*-axis shows the assumed CPG disability score in participants in the control group who were lost to follow-up (e.g. a value of 10 indicates that we set the average CPG disability score for participants in the control arm who were lost to follow-up to 10). In sensitivity analysis 1 we set the CPG disability score for participants in the intervention arm who were lost to follow-up to 10 points less than the score for participants in the control arm (e.g. if the value on the *x*-axis was 10, this would indicate that participants in the control arm who were lost to follow-up had a CPG disability score of 10 and participants in the intervention arm who were lost to follow-up had a CPG disability score of 0). In sensitivity analysis 2 we set the CPG disability score for participants in the intervention arm who were lost to follow-up to 10 points more than the score for participants in the control arm (e.g. if the value on the *x*-axis was 10, this would indicate that participants in the control arm who were lost to follow-up had a CPG disability score of 10 and participants in the intervention arm who were lost to follow-up had a CPG disability score of 20).

TABLE 60 Sensitivity analyses for CPG pain-related disability at 12 months

Analysis	Treatment effect (95% CI)
Main analysis	–1.0 (–4.9 to 3.0)
Complete case analysis	–0.9 (–4.9 to 3.1)
Multivariate analysis	–0.1 (–5.5 to 5.2)
Different imputation model	–1.1 (–5.1 to 2.9)
Redefinition of primary outcome	–1.1 (–5.0 to 2.9)

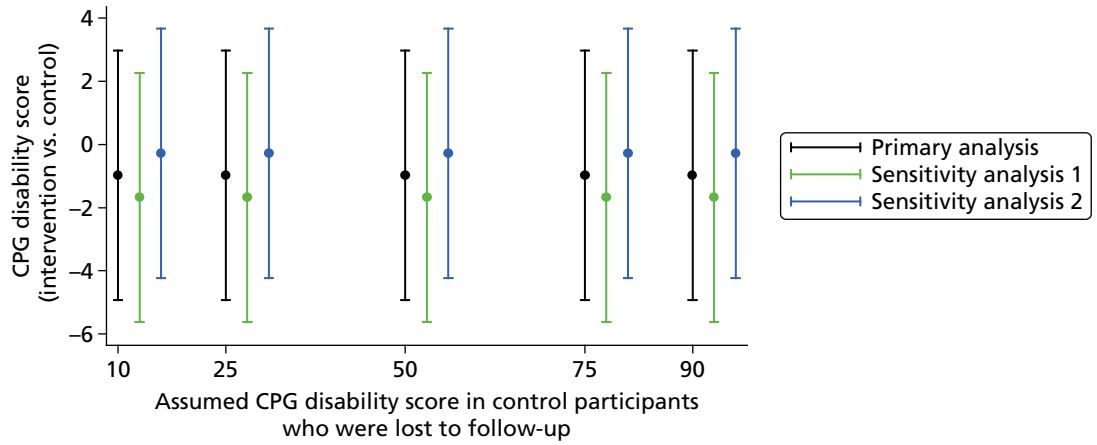

FIGURE 17 Sensitivity analysis for CPG pain-related disability at 12 months (assuming that missing data are missing not at random).

The primary analysis excluded all participants who did not complete any CPG pain-related disability questions at either 6 or 12 months. This analysis assumed that the excluded participants were missing at random, that is, the reason that these participants' data were missing was based on variables that were included in the analysis (e.g. that older participants with a high baseline CPG pain-related disability score were more likely to be excluded from the analysis).

In the sensitivity analyses in *Figure 17* we have made different assumptions regarding participants who were excluded from the analysis to assess how robust the primary analysis results are to departures from the missing at random assumption. Specifically, the analyses have assumed that the excluded participants were missing not at random, that is, the reason that these participants' data were missing was actually based on their CPG pain-related disability scores at 6 and 12 months (e.g. participants with a higher CPG disability score at 6 and 12 months were more likely to be excluded from the analysis).

Figure 17 indicates that the results of the primary analysis for CPG pain-related disability are robust to departures from the missing at random assumption (i.e. even if the missing data from participants who were lost to follow-up were missing not at random, this would not alter the conclusions from our main analysis).

Health economics

Microcosting of the COPERS intervention

In total, 31 courses were delivered across two centres over the duration of the trial (14 in London and 17 in the Midlands). Each course consisted of three 1-day sessions delivered during 1 week and a 2-hour follow-up session delivered 2 weeks later. Each course was conducted by two specially trained facilitators. Facilitators were recruited from NHS staff (off-duty time) and self-employed health-care specialists. Facilitator costs included a daily fee of £100 plus £40 travel costs per person. Administrator costs associated with booking the venue, allocating facilitators and arranging the sessions were £20 per hour (14 hours per course). Courses were run in community, primary care, hospital and university premises. Meeting rooms were hired at £100 per day for 3.5 days (3-day course and half-day follow-up session). Each participant was supplied with an educational DVD (£1.20 each), a relax pack including an education booklet and a CD (£1.17 each), and printed handouts (£1.21 each). Facilitators were recruited by team members who were paid £20 per hour (2 hours per recruit). On recruitment, facilitators attended a 2-day training course run by two members of the research team. Trainers were paid £200 per day plus £20 travel expenses. Facilitators were paid £100 per day for attending the training course and £10 per day towards travel expenses. Facilitators were provided with DVDs, relax packs (including a pain education booklet and a CD) and training manuals. In total, 35 facilitators (divided into two groups) were trained.

Table 61 summarises the direct costs of delivering the 31 courses. The total cost of the intervention was £62,888, of which £48,184 was the cost of running the course and £14,704 was the cost of training the facilitators.

More than two-thirds of the total running cost was accounted for by staff-related costs, which included salaries (£32,463) and travel expenses (£2480). The majority of facilitators were freelancers paid a fixed fee (£100) to run a session. The salary cost for this group does not include any additional employment costs. The salary cost of the course administrator (university employee) included a fixed fee of £20 per hour plus 24% salary on-costs (employer's pension and National Insurance contributions). Organisation overheads were not included and London multipliers were not used.

The second highest category of costs was venue costs. Rooms were hired at a flat rate of £100 per day (£350 per course). The total cost of venues over the duration of the programme, including hospitality costs, was £11,470.

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TABLE 61 Course costs

Component	Cost per course (£)	Total cost (£)
Course running costs		
Salary		
Facilitators	700.00	21,700.00
Administrator	347.20	10,763.20
Subtotal (salary)	1047.20	32,463.20
Facilitators' travel	80.00	2480.00
Course materials		
DVD	16.80	520.80
Relax packs (including CD)	16.38	507.78
Handouts	16.94	525.14
Facility	350.00	10,850.00
Hospitality	20.00	620.00
Consumables	7.00	217.00
Subtotal (course)	1554.32	48,183.92
Training costs		
Salary		
Trainers	992.00	1984.00
Facilitators	3600.00	7200.00
Administrator (recruitment of facilitators)	1562.40	3124.80
Subtotal (salary)	6154.40	12,308.80
Trainers' travel	80.00	160.00
Facilitators' travel	360.00	720.00
Course materials		
DVD	24.00	48.00
Relax packs (including CD)	23.40	46.80
Manuals	180.00	360.00
Facility	200.00	400.00
Hospitality	320.00	640.00
Consumables	10.00	20.00
Subtotal (training)	7351.80	14,703.60
Total cost of intervention	62,887.52	
Cost per participant (including training)	145.24	
Cost per participant (excluding training)	111.28	

Course materials and other consumables (e.g. letters and stamps) accounted for only a small proportion of the total running costs (£1771). Costs presented in this category reflect the direct costs incurred by the programme. Training costs were shared between the two centres and included all costing items described above: salaries (trainers, facilitators and administrator), travel, venue, course materials, etc. (see *Table 61*).

Given that trainers were university employees, 24% salary on-costs were added to a fixed pay rate of £200 per day. The total cost of training was £420 per facilitator and £14,704 per whole programme.

Costs associated with providing usual care for primary care patients with chronic musculoskeletal pain included the costs of a pain education booklet and a relaxation CD (£1.17 each).

Cost of the intervention per participant

Our base-case estimations of the cost of the intervention per participant were based on the following assumptions:

- The cost of the intervention per participant was calculated by dividing the total cost of the intervention by the total number of participants enrolled on the courses across the two centres. Sensitivity analysis considered the maximum and minimum number of participants per course, observed in the trial.
- The quantity of training materials was based on the average number of participants per course. Sensitivity analysis considered no wastage of course materials.
- Training was included in the calculation of the average cost per participant across the two centres. The cost per participant for each centre was presented without training costs, given that centres shared training courses.

Different costing scenarios for the cost of the intervention per participant are shown in *Table 62*. The average number of participants per course across the two centres was 14 (London $n = 15$, Warwick $n = 13$). The minimum number of participants enrolled on a course was five and the maximum was 17.

The total cost of the course per participant across the two centres was £145.24 with training and £111.28 without training. The cost without training was £102 for London and £120 for Warwick. In the cost-effectiveness analyses we used a conservative estimate of £145.24 per participant.

Two costing scenarios were considered to address the uncertainty around the number of participants enrolled on the course and the use of course materials. Given the maximum ($n = 17$) and the minimum ($n = 5$) number of participants enrolled on the courses, the minimum cost per participant including training was £120 and the maximum cost including training was £389. Based on the actual number of participants

TABLE 62 Cost of the intervention per participant

Costing scenario	Number of participants per course	Cost per participant (£)
All centres, including training	14	145.24
All centres, excluding training	14	111.28
London, excluding training	14	102.16
Warwick, excluding training	14	120.11
London, excluding training, no wastage	15	102.43
Warwick, excluding training, no wastage	13	119.79
Minimum number of participants, all centres, including training	5	389.38
Maximum number of participants, all centres, including training	17	120.05

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at each centre (in contrast to the average number across the two centres), we estimated that the recycling of course materials had only a very small impact on the total cost per participant (< £1) because of the low cost of the course materials (see *Tables 61* and *62*).

Use of health-care resources by participants

The use of health-care resources by participants was analysed at 12 months post randomisation. The analyses of contacts with primary and secondary health-care services by participants in the intervention and control groups are summarised in *Table 63*. To assess any changes in resource use over time we looked at the use of health-care services in 3-month periods, which is summarised in *Table 64*. Given that the intervention may affect the use of primary care resources by participants, in particular consultations with GPs or practice nurses; these categories are shown separately from other service use data in *Table 64*.

Over 12 months, participants in both the intervention group and the control group had, on average, 12 consultations with primary care, three investigations/tests, four outpatient appointments and less than one referral to community care, inpatient stay or A&E admission. The average number of prescriptions over 12 months was 50 and 52 per participant for the intervention and control groups, respectively. There were no significant differences between the groups in the use of health-care resources for any category (see *Table 63*).

Quarterly analyses of resource use did not find any statistically significant changes in the number of health-care contacts in either group over the duration of the trial (see *Table 64*). Consultations with GPs and nurses (both surgery and telephone) and health-care assistants (surgery) accounted for almost 95% of all primary care contacts, with consultations with all other specialists accounting for < 5%. The numbers of contacts were not significantly different between the groups at any time period.

We also collected information about the use of private care including:

- number of and money spent on non-NHS consultations (including complementary and alternative consultations)
- type and number of and money spent on tests and investigations
- type of and money spent on medicines
- type of and money spent on devices and aids
- overnight admissions/stays in private hospital
- money spent on support and help at home as a result of pain.

TABLE 63 Use of health-care services by participants (average number of contacts)

Service	Intervention, mean (SD)	Control, mean (SD)	Difference in means	95% CI
Primary care sector (intervention, $n = 370$; control, $n = 276$)				
Consultations	12.32 (11.12)	12.80 (12.50)	–0.48	–2.31 to 1.35
Investigation	3.35 (3.09)	3.43 (3.32)	–0.07	–0.58 to 0.43
Prescriptions	49.62 (48.77)	51.71 (55.01)	–2.09	–10.19 to 6.01
Referrals to community care	0.40 (0.71)	0.38 (0.72)	0.02	–0.09 to 0.13
Secondary care sector (intervention, $n = 383$; control, $n = 291$)				
Outpatient	4.08 (5.12)	4.32 (6.52)	–0.24	–1.15 to 0.67
Inpatient	0.65 (1.43)	0.55 (1.04)	0.11	–0.08 to 0.29
A&E	0.57 (1.21)	0.57 (1.29)	0.01	–0.19 to 0.20

TABLE 64 Health-care service use per participant

Service	Number of contacts, mean (SD)							
	Intervention group				Control group			
	3 months	6 months	9 months	12 months	3 months	6 months	9 months	12 months
Primary care								
GP surgery	1.87 (1.94)	1.84 (1.84)	1.94 (2.05)	1.76 (2.22)	1.81 (1.79)	1.84 (1.91)	1.95 (1.98)	1.83 (1.80)
GP telephone	0.32 (0.83)	0.40 (0.99)	0.41 (1.30)	0.35 (0.98)	0.31 (0.72)	0.38 (1.03)	0.36 (0.99)	0.42 (1.13)
Nurse surgery	0.45 (1.06)	0.48 (1.02)	0.52 (1.57)	0.66 (1.59)	0.68 (2.29)	0.46 (0.92)	0.60 (1.51)	0.67 (1.64)
Nurse telephone	0.06 (0.29)	0.04 (0.26)	0.04 (0.27)	0.04 (0.19)	0.08 (0.56)	0.09 (0.72)	0.08 (0.86)	0.07 (0.49)
Health-care assistant	0.13 (0.41)	0.11 (0.39)	0.14 (0.60)	0.13 (0.42)	0.15 (0.51)	0.11 (0.47)	0.14 (0.52)	0.12 (0.40)
Other specialists[a]	0.15 (0.55)	0.14 (0.54)	0.18 (0.65)	0.15 (0.67)	0.18 (0.70)	0.17 (0.62)	0.17 (0.58)	0.16 (0.65)
Investigations	0.79 (1.24)	0.82 (1.20)	0.84 (1.23)	0.91 (1.33)	0.86 (1.32)	0.79 (1.19)	0.82 (1.31)	0.95 (1.45)
Prescriptions	13.43 (12.50)	12.86 (12.18)	14.32 (13.50)	14.03 (13.26)	14.39 (13.61)	14.55 (14.05)	15.34 (14.65)	15.93 (16.24)
Referrals to community care	0.10 (0.33)	0.11 (0.34)	0.09 (0.30)	0.10 (0.36)	0.09 (0.30)	0.08 (0.33)	0.11 (0.35)	0.09 (0.32)
Secondary care								
Inpatient	0.12 (0.35)	0.16 (0.56)	0.21 (0.68)	0.16 (0.50)	0.13 (0.45)	0.15 (0.44)	0.11 (0.38)	0.15 (0.51)
Outpatient	0.98 (1.66)	1.00 (1.58)	1.06 (1.75)	1.04 (1.67)	1.06 (2.06)	1.09 (2.30)	1.16 (2.13)	1.01 (1.77)
A&E	0.13 (0.50)	0.16 (0.48)	0.18 (0.53)	0.10 (0.38)	0.13 (0.42)	0.17 (0.61)	0.12 (0.37)	0.14 (0.51)

a GP out of hours, NHS walk-in service, home visits, specialist nurse, physiotherapist, psychologist, counsellor, pharmacist, phlebotomist, dietitian, etc.

However, the private care costs were not well reported given that participants preferred not to answer questions about their personal expenses. Therefore we did not use these data in the health economics analysis.

Cost of health-care services

Resource use data were combined with unit costs to calculate the cost of health-care services for each quarter and over 12 months. The total costs of the health-care services used by participants are summarised in *Table 65*. The largest proportion of costs was associated with inpatient stay (approximately £1000 per participant). The next highest cost categories were prescriptions (approximately £580), followed by consultations (approximately £540) and outpatient appointments (approximately £480 per participant). There were no differences in the number of referrals to community care between the intervention group and the control group (see *Table 63*), although the participants from the intervention group were referred to more costly community rehabilitation programmes. Consequently, the mean referral costs for community care were higher for the intervention group (mean costs of £117 and £75, respectively), although this difference was not statistically significant. The breakdown of the costs of service use by

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TABLE 65 Summary of health-care costs for the intervention and control groups

Service	Intervention, mean (SD) (£)	Control, mean (SD) (£)	Difference in means (£)	95% CI (£)
Primary care sector (intervention, $n = 370$; control, $n = 276$)				
Consultations	539 (462)	541 (428)	–2	–70 to 66
Prescriptions	576 (873)	585 (878)	–9	–143 to 126
Investigation	56 (85)	52 (92)	4	–10 to 17
Referrals to community care	117 (607)	75 (383)	42	–34 to 118
Secondary care sector (intervention, $n = 383$; control, $n = 291$)				
Outpatient	484 (587)	476 (750)	8	–96 to 113
Inpatient	1044 (2701)	1000 (3021)	45	–395 to 484
A&E	61 (129)	64 (166)	–3	–26 to 20

quarters is shown in *Table 66*. There was no significant difference in the cost of health-care services between the intervention group and the control group for any category of primary or secondary care or any time period.

Missing data and multiple imputations

The complete health economics data set was obtained for 540 participants (intervention, $n = 319$; control, $n = 221$), 77% of all trial participants. Information about the completeness of the health economics data set is summarised in *Table 67*. The proportion of missing data varied from 3% to 24% for different data categories. The highest proportion of missing data was for baseline prescriptions, followed by the EQ-5D and primary care contacts.

The baseline characteristics of participants with complete and incomplete data are summarised in *Table 68*. This table demonstrates that participants with missing data had lower health-related quality of life and higher depression scores at baseline than participants with complete data. Among participants with complete data, those in the intervention group had a higher mean baseline EQ-5D score, whereas among participants with incomplete data those in the control group had a higher mean baseline EQ-5D score. Among participants with complete data, those in the intervention group had a lower mean baseline HADS depression score, whereas among participants with incomplete data those in the control group had a lower mean baseline HADS depression score. However, none of these reported differences was statistically significant.

To address bias associated with missing data, MIs were conducted for 107 participants (intervention, $n = 53$; control, $n = 54$). MIs were conducted for primary and secondary care costs (12 months post randomisation), baseline prescriptions (3 months pre randomisation) and EQ-5D score (baseline and 6 and 12 months post randomisation). The 3-month pre-randomisation data were used for baseline adjustment in the sensitivity analyses. The complete baseline prescription data were obtained for 561 participants (intervention, $n = 332$; control, $n = 229$). MIs were conducted for 86 participants (intervention, $n = 40$; control, $n = 46$). The final number of participants in the imputed data set was 647 (intervention, $n = 372$; control, $n = 275$). This corresponds to 92% of the total number of participants in the trial and 99% of the trial population included in the statistical analyses of the primary outcome. The comparison of the imputed and complete data sets is shown in *Table 69*. *Figure 18* shows the cost-effectiveness planes for the complete case and imputed data sets, generated using a non-parametric bootstrap.

TABLE 66 Cost of health-care service use per participant

	Cost, mean (SD) (£)							
	Intervention group				Control group			
Service	3 months	6 months	9 months	12 months	3 months	6 months	9 months	12 months
Primary care								
GP surgery	108.63 (112.53)	106.59 (106.68)	112.71 (118.71)	102.21 (128.85)	105.07 (103.77)	106.54 (110.80)	112.85 (114.74)	105.91 (104.44)
GP telephone	7.72 (19.94)	9.54 (23.86)	9.79 (31.29)	8.37 (23.44)	7.39 (17.30)	9.04 (24.68)	8.52 (23.83)	10.00 (27.19)
Nurse surgery	10.03 (23.44)	10.56 (22.54)	11.52 (34.61)	14.62 (35.11)	15.12 (50.60)	10.16 (20.22)	13.28 (33.48)	14.72 (36.16)
Nurse telephone	0.61 (2.95)	0.39 (2.69)	0.44 (2.79)	0.39 (1.96)	0.78 (5.71)	0.90 (7.41)	0.78 (8.82)	0.71 (5.01)
Health-care assistant	1.32 (4.31)	1.13 (4.05)	1.46 (6.25)	1.38 (4.42)	1.59 (5.32)	1.17 (4.85)	1.43 (5.43)	1.21 (4.18)
Other specialists[a]	3.79 (17.09)	4.01 (19.56)	6.78 (33.13)	5.01 (32.83)	3.89 (17.98)	3.40 (15.56)	3.83 (19.59)	2.63 (11.66)
Investigations	13.10 (34.53)	13.15 (42.69)	12.97 (36.34)	16.67 (40.48)	12.06 (37.94)	13.05 (38.97)	13.50 (38.52)	13.74 (48.25)
Prescriptions	153.53 (243.66)	149.70 (231.06)	162.78 (240.24)	168.23 (254.68)	159.25 (229.74)	164.80 (240.45)	174.82 (268.06)	181.87 (251.09)
Referrals to community care	37.03 (288.00)	29.38 (253.48)	13.26 (144.30)	36.94 (285.43)	15.12 (153.40)	6.68 (31.20)	28.18 (237.88)	24.61 (235.31)
Secondary care								
Inpatient	206.79 (1006.36)	199.35 (935.18)	320.43 (1193.87)	318.12 (1523.05)	244.97 (1584.35)	331.96 (1663.91)	213.61 (951.03)	209.65 (1022.30)
Outpatient	109.68 (178.62)	123.71 (207.27)	126.20 (206.14)	124.44 (200.35)	121.02 (255.63)	119.62 (229.96)	127.45 (255.25)	107.51 (192.15)
A&E	13.76 (49.62)	16.37 (53.19)	18.02 (53.98)	12.68 (47.02)	15.93 (56.15)	19.54 (74.05)	13.42 (42.21)	15.11 (59.96)

a GP out of hours, NHS walk-in service, home visits, specialist nurse, physiotherapist, psychologist, counsellor, pharmacist, phlebotomist, dietitian, etc.

TABLE 67 Completeness of the health economics data set

	Baseline, *n* (%)		6-month follow-up, *n* (%)		12-month follow-up, *n* (%)	
Service	Intervention	Control	Intervention	Control	Intervention	Control
Consultations	NA	NA	370 (92)	276 (92)	370 (92)	276 (92)
Prescriptions	332 (82)	229 (76)	350 (87)	258 (86)	350 (87)	258 (86)
Investigations	NA	NA	370 (92)	276 (92)	370 (92)	276 (92)
Referrals	NA	NA	370 (92)	276 (92)	370 (92)	276 (92)
SUS data	NA	NA	383 (95)	291 (97)	383 (95)	291 (97)
EQ-5D	402 (100)	299 (100)	360 (89)	256 (85)	354 (88)	259 (86)

NA, not applicable.

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TABLE 68 Baseline characteristics of participants with complete and incomplete data

Parameter	Complete data (intervention $n = 319$, control $n = 221$)		Incomplete data (intervention $n = 84$, control $n = 79$)	
	Intervention, mean (SD)	Control, mean (SD)	Intervention, mean (SD)	Control, mean (SD)
Baseline EQ-5D score	0.4301 (0.3298)	0.4014 (0.3321)	0.3164 (0.3733)	0.3617 (0.3546)
HADS depression score	7.24 (4.05)	7.31 (3.92)	8.11 (4.49)	8.02 (4.13)
Age (years)	61 (13)	61 (12)	57 (14)	54 (17)
Gender (%)	Male 33, female 67	Male 30, female 70	Male 32, female 68	Male 41, female 59
Site of recruitment (%)	London 41, Warwick 59	London 39, Warwick 61	London 61, Warwick 39	London 63, Warwick 37%

TABLE 69 Comparison of complete and imputed data sets

Parameter	Complete data set		Imputed data set	
	Intervention, mean (SD)	Control, mean (SD)	Intervention, mean (SD)	Control, mean (SD)
Baseline prescription cost (£)	154 (252)	176 (253)	148 (273)	161 (257)
Baseline EQ-5D score	0.4313 (0.3298)	0.4014 (0.3321)	0.4132 (0.3380)	0.3970 (0.3381)
6-month follow-up EQ-5D score	0.4678 (0.3353)	0.4096 (0.3461)	0.4511 (0.3452)	0.4102 (0.3542)
12-month follow-up EQ-5D score	0.4700 (0.3354)	0.4491 (0.3423)	0.4529 (0.3492)	0.4445 (0.3551)
Primary care cost (£)	1267 (1343)	1317 (1232)	1286 (1407)	1285 (1271)
Secondary care cost (£)	1453 (2545)	1605 (3449)	1614 (3126)	1469 (3213)

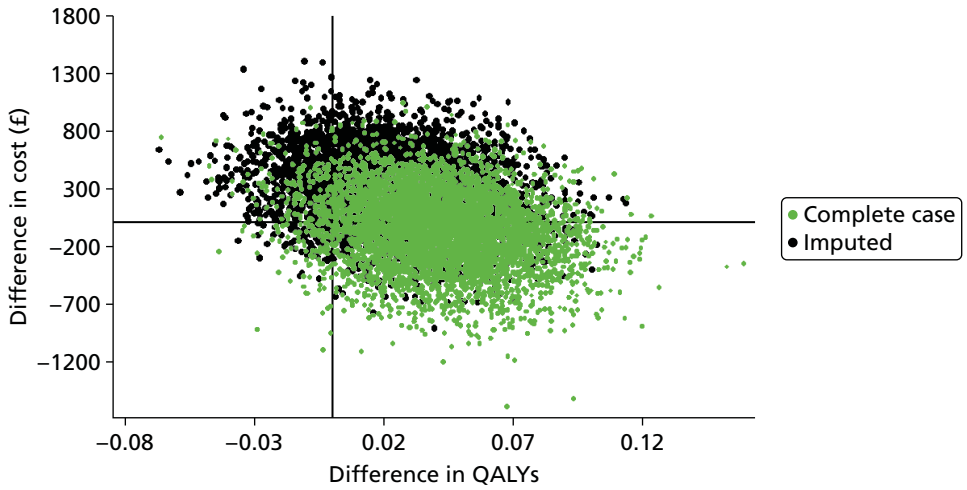

FIGURE 18 Cost-effectiveness planes depicting 5000 bootstrapped estimates generated from complete case data and one imputed data set.

Health-related quality of life

Complete EQ-5D data (baseline and 6 and 12 months' follow-up) were obtained for 298 participants in the intervention group and 205 participants in the control group. Health-related quality of life was low in the studied population compared with the UK national norms for the EQ-5D.[188] At baseline, the mean total EQ-5D scores were 0.41 for the intervention group and 0.40 for the control group. The difference between the two groups was not statistically significant (*Table 70*). Over the duration of the trial there was an increase in health-related quality of life in both groups. However, at 6 months the increase in the mean EQ-5D score in the intervention group was greater than that for the control group. Consequently, participants in the intervention group spent, on average, more time in a higher health state than participants in the control group. This resulted in higher mean total QALYs for the intervention group (0.44) than the control group (0.42) (see *Table 70*).

Cost-effectiveness analysis

The results of the primary cost-effectiveness analysis for the imputed and complete case data sets are shown in *Tables 71* and *72*, respectively. The base-case cost-effectiveness analysis was conducted for the ITT population on the imputed data set using a multilevel mixed-effects model (see *Table 71*). The mean total cost was higher in the intervention group than in the control group (£2955 and £2767, respectively). The difference in mean costs was £188 (95% CI –£125 to £501). Total QALYs were higher in the intervention group (0.4475) than in the control group (0.4150). The difference in mean QALYs was 0.0325, which is equivalent to approximately 12 quality-adjusted days. This difference was not statistically significant because of the wide CIs (95% CI –0.0074 to 0.0724). The ICER point estimate was £5786 per QALY. The probability of the intervention being cost-effective at the NICE threshold of £30,000 per QALY was 87%. *Figures 19* and *20* show the cost-effectiveness planes generated using bootstrapping of one imputed data set and the cost-effectiveness acceptability curve derived from five imputed data sets using a parametric approach to represent uncertainty, respectively (see the methods section). Sensitivity analyses conducted using the SUR model and GLM generated higher ICERs (£8995 and £9582, respectively), and lower probabilities of being cost-effective (80% and 79%, respectively) than the MLM (see *Table 71*).

TABLE 70 Mean EQ-5D scores in the intervention and control groups over 12 months

Assessment	Intervention, mean (SD)	Control, mean (SD)	Difference in means	95% CI
Non-imputed				
Baseline (intervention $n = 371$, control $n = 274$)	0.4139 (0.3368)	0.3976 (0.3376)	0.0163	–0.0364 to 0.0691
6-month follow-up (intervention $n = 360$, control $n = 256$)	0.4572 (0.3391)	0.4067 (0.3493)	0.0505	–0.0046 to 0.1057
12-month follow-up (intervention $n = 354$, control $n = 259$)	0.4590 (0.3448)	0.4506 (0.3459)	0.0083	–0.0471 to 0.0638
Imputed (intervention* n = *372, control* n = *275)				
Baseline	0.4132 (0.3380)	0.3970 (0.3381)	0.0162	–0.0366 to 0.0690
6-month follow-up	0.4511 (0.3452)	0.4102 (0.3542)	0.0409	–0.0133 to 0.0952
12-month follow-up	0.4529 (0.3492)	0.4445 (0.3551)	0.0084	–0.0470 to 0.0638
Total QALYs	0.4421 (0.3058)	0.4155 (0.3083)	0.0266	–0.0213 to 0.0745

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TABLE 71 Summary of the cost-effectiveness analyses for the imputed data set (intervention $n = 372$, control $n = 275$)

Group	Mean cost (95% CI) (£)	Mean QALYs (95% CI)	Difference in cost (95% CI) (£)	Difference in QALYs (95% CI)	ICER (£)	Probability of being cost-effective (%)[a]
Imputed MLM						
Intervention	2955 (2752 to 3159)	0.4475 (0.4217 to 0.4733)	188 (–125 to 501)	0.0325 (–0.0074 to 0.0724)	5786	87
Control	2767 (2539 to 2996)	0.4150 (0.3844 to 0.4456)				
Imputed SUR						
Intervention	3041 (2847 to 3236)	0.4417 (0.4157 to 0.4678)	250 (–48 to 550)	0.0279 (–0.0122 to 0.0680)	8995	80
Control	2791 (2573 to 3008)	0.4138 (0.3832 to 0.4446)				
Imputed GLM						
Intervention	3052 (2857 to 3247)	0.4417 (0.4157 to 0.4678)	267 (–32 to 566)	0.0279 (–0.0122 to 0.0680)	9582	79
Control	2785 (2568 to 3002)	0.4139 (0.3832 to 0.4446)				
Imputed data set unadjusted						
Intervention	3045 (2657 to 3433)	0.4421 (0.4109 to 0.4733)	290 (–302 to 882)	0.0266 (–0.0213 to 0.0745)	10,891	72
Control	2755 (2308 to 3202)	0.4155 (0.3789 to 0.4521)				

a At £30,000 per QALY gained.

TABLE 72 Summary of the cost-effectiveness analyses for the complete case data sets (intervention $n = 319$, control $n = 221$)

Group	Mean (SD) cost (£)	Mean (SD) QALYs	Difference in cost (95% CI) (£)	Difference in QALYs (95% CI)	ICER (£)	Probability of being cost-effective (%)[a]
Complete case MLM						
Intervention	2859 (771)	0.4593 (0.2450)	–65 (–197 to 68)	0.0418 (–0.0008 to 0.0844)	Dominant (–5160 to 6398)	96
Control	2923 (772)	0.4174 (0.2499)				
Complete case SUR						
Intervention	2865 (768)	0.4593 (0.2452)	–57 (–189 to 74)	0.0418 (–0.0003 to 0.0839)	Dominant (–5841 to 6367)	97
Control	2923 (768)	0.4174 (0.2497)				
Complete case GLM						
Intervention	2866 (768)	0.4593 (0.2452)	–58 (–189 to 74)	0.0418 (–0.0003 to 0.0839)	Dominant (–5841 to 6367)	97
Control	2923 (768)	0.4174 (0.2497)				
Complete case unadjusted						
Intervention	2866 (3290)	0.4593 (0.2949)	–58 (–694 to 578)	0.0418 (–0.0085 to 0.0922)	Dominant (–44,672 to 46,233)	92
Control	2923 (3925)	0.4174 (0.3010)				

a At £30,000 per QALY gained.

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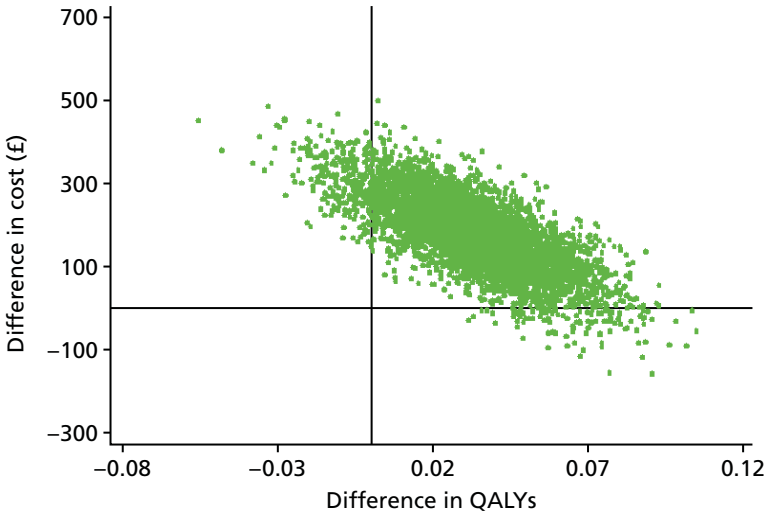

FIGURE 19 Cost-effectiveness plane showing 5000 bootstrapped estimates generated from one imputed data set adjusted using the mixed-effects linear model.

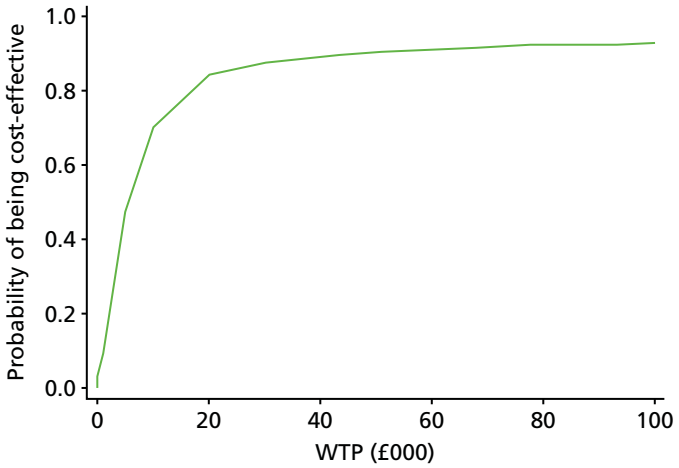

FIGURE 20 Cost-effectiveness acceptability curve estimated using the INB method from five imputed data sets adjusted using the mixed-effects linear model.

Complete case analyses were conducted for reference purposes only (see *Table 72*). The mean total costs for complete case were lower in the intervention group than in the control group; however, these differences were not statistically significant. The differences in mean QALYs between the intervention group and the control group were higher in the complete case analysis than in the imputed data analysis. The complete case analysis produced dominant ICERs as the intervention was less costly and more effective than the control. The probability of the intervention being cost-effective varied from 92% for unadjusted data to 97% for adjusted data. The results of the complete case analysis should be interpreted with caution because of potential bias associated with excluding non-responders from the analysis.

A secondary cost–utility analysis was conducted using the per-protocol population (*Table 73*). We excluded from the analysis 51 participants from the intervention group who, although randomised to the intervention group, did not receive any intervention. MIs were performed for this data set. Imputed data were analysed using the mixed-effects linear model. The difference in mean costs between the intervention group and the control group was £141, the difference in mean QALYs was 0.0351 and the ICER point estimate was £4033 per QALY. The probability of the intervention being cost-effective at £30,000 per QALY was 91%.

TABLE 73 Summary of the cost-effectiveness analyses

Group	Mean cost (95% CI) (£)	Mean QALYs (95% CI)	Difference in cost (95% CI) (£)	Difference in QALYs (95% CI)	ICER (£)	Probability of being cost-effective (%)[a]
Per protocol						
Intervention ($n = 321$)	2887 (2814 to 2960)	0.4523 (0.4254 to 0.4793)	141 (30 to 253)	0.0351 (–0.0048 to 0.0749)	4033	91
Control ($n = 275$)	2745 (2661 to 2830)	0.4173 (0.3878 to 0.4467)				
Compliance ≥ 12 sessions						
Intervention ($n = 295$)	2898 (2817 to 2980)	0.4578 (0.4290 to 0.4867)	143 (23 to 265)	0.0412 (–0.0009 to 0.0833)	3493	94
Control ($n = 275$)	2754 (2664 to 2845)	0.4166 (0.3858 to 0.4474)				
Compliance < 12 sessions						
Intervention ($n = 77$)	3480 (3156 to 3804)	0.4460 (0.3414 to 0.5106)	729 (397 to 1063)	0.0293 (–0.0402 to 0.0988)	24,896	54
Control ($n = 275$)	2750 (2599 to 2901)	0.4167 (0.3847 to 0.4486)				
Exposure 17 sessions (full)						
Intervention ($n = 275$)	2884 (2788 to 2981)	0.4744 (0.4453 to 0.5035)	141 (–2 to 284)	0.0588 (0.0168 to 0.1008	2396	99
Control ($n = 275$)	2743 (2638 to 2849)	0.4156 (0.3853 to 0.4460)				
Exposure ≤ 8 sessions (non-exposed)						
Intervention ($n = 74$)	3526 (3157 to 3896)	0.4416 (0.3734 to 0.5099)	767 (387 to 1147)	0.0259 (–0.0466 to 0.0983)	29,631	50
Control ($n = 275$)	2759 (2589 to 2930)	0.4158 (0.3830 to 0.4485)				
Excluding high-cost participants (top 5%)						
Intervention ($n = 353$)	2293 (2217 to 2368)	0.4560 (0.4295 to 0.4826)	159 (42 to 277)	0.0369 (–0.0414 to 0.0779)	4326	92
Control ($n = 262$)	2133 (2042 to 2255)	0.4191 (0.3876 to 0.4507)				

a At £30,000 per QALY gained.

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Table 73 also summarises the results of the cost-effectiveness analyses for subgroups of participants with different levels of compliance and exposure to treatment. Analyses were conducted using the mixed-effects model. Between-group differences in cost were lower, and between-group differences in QALYs higher, among participants with high levels of compliance (≥ 12 sessions) than among those with low compliance (< 12 sessions). The ICER point estimate was £3493 for the high compliance subgroup and £24,896 for the low compliance subgroup. The probabilities of being cost-effective were 94% and 54%, respectively.

Similar analyses were conducted for subgroups with different levels of exposure to treatment (see *Table 73*). Participants who attended 17 sessions (full exposure) had a lower mean total cost and higher mean total QALYs than participants who attended eight or fewer sessions. A small number of participants attended 9–16 sessions ($n = 23$). Cost–utility analyses were not conducted because of the small size of this subgroup. The ICER point estimates were £2396 for participants with high exposure and £29,631 for those with an exposure of eight or fewer sessions. The probabilities of the intervention being cost-effective in these subgroups of participants were 99% and 50%, respectively.

We also conducted a subgroup analysis excluding the 'high-cost' participants. The top 5% of participants with total costs > £12,000 were excluded (intervention group, $n = 19$; control group, $n = 13$). Removing high-cost participants did not significantly affect the results of the cost-effectiveness analysis compared with the base case. The ICER was £4326 per QALY and the probability of the intervention being cost-effective was 92%.

In summary, our cost–utility analyses demonstrated that the intervention was more costly and more effective than the control. However, the differences in costs and QALYs were small and not statistically significant. The results of the analyses were robust to different analytical models. The mixed-effects linear model (accounting for clustering effects) produced better cost-effectiveness results than a SUR model and GLM. The results of the probabilistic analysis indicated that the intervention has a high probability (> 79%) of being cost-effective compared with usual care for patients with chronic pain. Subgroup analysis suggested that the intervention is more likely to be cost-effective in participants with a high compliance rate.

Chapter 12 Phase 2: evaluating the COPERS intervention – discussion

Summary and discussion of the principal findings

Our carefully designed evidence-informed chronic pain self-management intervention (COPERS) was relatively cheap to deliver at £111.28 per participant (excluding facilitator training costs), had a good uptake (336/403, 83%) with little attrition (85% of sessions attended) and was delivered as intended. The intervention had no impact on our primary outcome of pain-related disability at 12 months or on pain-related disability at 6 months. However, at 6 months' follow-up the intervention led to improved psychological well-being compared with the control with regard to *all* of our psychological measures: anxiety, depression, chronic pain acceptance and pain-related self-efficacy. Across all of these outcomes the effect sizes were modest and their *individual* clinical importance is unclear. These beneficial effects appeared to be attenuated at 12 months except for depressive symptoms, which remained lower in the intervention group than in the control group. Social integration, as measured by the heiQ, was also significantly improved in the intervention group compared with the control group at both 6 and 12 months. Again, the effect size appeared to be modest but, as with depressive symptoms, there was no evidence of any attenuation at 12 months.

Pain intensity, as measured by the CPG pain intensity subscale, was not influenced by the intervention and nor was the overall response to the census global health question. The treatment group received significantly more analgesic medication and more weak opioids than the control group in the 12 months following the intervention but there was no difference in the prescription of strong opioids or psychotropic medication between the two groups. The intervention did not have any consistent pattern of effect on health service use: those in the intervention group had slightly few primary care and outpatient consultations and investigations; however, they had slightly more inpatient admissions. None of these differences approached conventional statistical significance. This resulted in an overall increase in base-case health-care costs in the intervention group of £188, that is, £76.72 more than the acquisition cost of the intervention. This does not support the notion that improved self-management reduces health-care costs.[283] These results proved robust in extensive sensitivity analyses and using different analytical approaches.

Both the intervention group and the control group improved between baseline and follow-up; the observation that there are improvements in both intervention and control groups over time is well recognised in intervention studies for chronic musculoskeletal pain.[210,211] This probably reflects the fluctuating course of chronic musculoskeletal pain, with people joining studies during periods of worsening symptoms.[210]

We cannot exclude the possibility that, in this population, our control intervention may have had a beneficial effect or that those randomised to the control group consequentially sought additional care. However, the key component of our control intervention (relaxation) was selected because it had not been shown to be effective and *The Pain Toolkit* booklet is already a standard part of care. Our health service activity data do not support the notion that we have underestimated any treatment effects because of changed care-seeking behaviour. Any such effects are very unlikely to be of sufficient magnitude to change our overall conclusions.

There was a small gain in health utility of approximately 0.033 QALYs (12 quality-adjusted days) in the intervention group compared with the control group in our study. By way of comparison, the national evaluation of the Expert Patients Programme estimated that the programme generated 0.02 QALYs (approximately 7 quality-adjusted days) compared with usual care.[15] An evaluation of the Improving Access to Psychological Therapies (IAPT) demonstration sites, which compared the IAPT programme with usual care, found that the IAPT programme was associated with a gain of 0.013–0.014 QALYs (approximately

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5 quality-adjusted days).[284] Thus, the QALY gain from the COPERS intervention is at least as good as that of comparable interventions already in common use.

Our cost–utility analyses demonstrated that the COPERS intervention is more costly and more effective than usual care. Our base-case analysis generated an ICER of £5786 per QALY with an 87% probability of the intervention being cost-effective at a threshold of £30,000 per QALY (see *Table 71*). The probability of the intervention being cost-effective was higher in the per-protocol population (91%) and in subgroups with high rates of compliance and exposure to the intervention (92–99%; see *Table 73*). This demonstrates that the COPERS programme is highly likely to be cost-effective compared with current care for people living with chronic musculoskeletal pain, with a cost per QALY that falls well within the usual NICE threshold range of £20,000–30,000 per QALY. Although the health gain observed in the COPERS study is typical of that of many patient self-management programmes, it is an extremely cost-effective intervention.[15,285–288]

The findings of a long-term effect on depression are striking. Our exploratory post hoc analyses examined this further. Nearly half of our participants [322/703 (46%)] met criteria for possible depression at baseline. There was a clinically important sustained improvement in depressive symptoms at 12 months among these participants. The SMD in this group (–0.50, 95% CI –0.74 to –0.25) was of a similar size to that reported in Cochrane reviews of exercise for depression (–0.62, 95% CI –0.81 to –0.42)[289] and tricyclic antidepressants in primary care (–0.49, 95% CI –0.67 to –0.32).[290] Our observed effect size exceeds that found in an individual patient data meta-analysis of selective serotonin reuptake inhibitors for mild/moderate depression (0.11, 95% CI –0.18 to 0.41) or severe depression (0.17, 95% CI –0.08 to 0.43).[291] Other reviews have found similar modest effect sizes from selective serotonin reuptake inhibitors; for example, Kirsch *et al.*[292] quote 2004 NICE guidance defining a SMD of 0.50 or a drug/placebo difference of 3 points on the scale as a threshold for clinical significance. However, it should be noted that studies focusing primarily on depression usually adopt different outcome measures from the one used in this study, (typically the 21-item Hamilton Rating Scale for Depression,[293] which is completed by the researcher following a clinical interview and observation of the patient, or the 21-item participant-completed BDI[177]).

The commonly intractable nature of chronic pain was evident by the duration of pain experienced by COPERS participants. Our participants were predominantly older (mean age 60 years, range 19–94 years) women (67%). Our study population had a high level of morbidity and disability at baseline: EQ-5D scores were low compared with UK national norms[188] and below those reported in studies of patients with other serious chronic conditions.[294] Participants' mean HADS depression and anxiety symptom scores were high compared with norms for the general UK population [3.68 (SD 3.07) and 6.14 (SD 3.76), respectively[281]]. Compared with clinical populations with life-threatening illnesses, mean HADS depression and anxiety scores were similar to those found in patients with non-operable lung cancer [7.22 (SD 5.16) and 7.20 (SD 5.25), respectively] but better than those found in patients with end-stage chronic obstructive pulmonary disease [10.18 (SD 3.95) and 11.44 (SD 4.76), respectively].[295] In total, 46% of the COPERS study population met criteria for possible depression on the HADS and nearly half of these (22% of the overall study population) were above the higher HADS threshold for probable depression; the equivalent UK norm figures are 7.8% and 2.9%, respectively.[281]

General practice consultation rates (including doctor, nurse and any other health professional face-to-face or telephone contact in general practice) among the COPERS study population were very high, with the intervention and control group participants having a mean (SD) of 12.32 (11.2) and 12.80 (12.50) consultations in the 12-month follow-up period, respectively. This compares with 2008 data showing an average of around three general practice consultations per year for registered male patients aged 45–64 years and an average of four consultations per year for similarly aged women.[296] That one-quarter of our participants were using strong opioids gives some measure of the difficulties faced in managing their pain. This is a particularly striking observation because the COPERS study was run in localities with low opioid use compared with the rest of England; all participating primary care trust's opioid prescribing rates were below regional and national median rates (Knaggs R, University of Nottingham, personal communication).

None of our prespecified moderator analyses achieved, or even approached, conventional statistical significance. This is to be expected in a trial powered on main effects rather than on interactions. Indeed, for a study of this nature in which there was no main effect, identifying a subgroup in which there was a large positive effect would inevitably mean commensurate harm in the rump of the trial population. It might be that these middle groups are worth targeting as key variables are more susceptible to meaningful change.

As we achieved a positive long-term effect on depression, the effect of the intervention in just those with depression at baseline is of greater interest post hoc than it was a priori. One would not expect a substantial improvement in depressive symptoms in those who were not depressed at baseline. It is reassuring that our post hoc analyses confirmed this and that we have not harmed those who were not depressed (see *Table 59*). The apparent effect size in the depressed group and the *p*-value for interaction are impressive. However, one cannot apply these findings in practice. There remains the possibility that this apparently statistically significant interaction may be no more than a chance finding because of multiple comparisons. Furthermore, it would not be possible to implement the COPERS intervention 'as is' because half of the participants were not depressed. The group dynamic might be radically different if only those with depression at baseline joined the group and the whole ethos of the intervention would change to a treatment for depression, in which case there are established psychological treatments for depression. Implementing the COPERS intervention just to help those with depression and including the whole population of those living with chronic pain, many of whom would not themselves gain any benefit, might be questionable.

Results in context

Once the COPERS analysis was completed we updated our original systematic review for the effectiveness of self-management interventions for chronic musculoskeletal pain. We reran our original searches to identify all studies published up to September 2013. When appropriate, we extracted outcome data and added these to our original meta-analyses. Finally, we added in the COPERS trial results (*Table 74*).

TABLE 74 Summary of total effect sizes by outcome and follow-up interval including the studies from the updated review

		Review January 1994–April 2009		Review January 1994–September 2013		
Outcome	Follow-up (months)	Total *n* participants (number of studies)	Effect size (95% CI)	Total *n* participants (number of studies)	Effect size (95% CI)	Including COPERS results
Pain intensity	4–8	3911 (20)	–0.25 (–0.38 to –0.12)	6038 (32)[a]	–0.29 (–0.38 to 0.20)	–0.28 (–0.37 to 0.19)
	> 8	3332 (18)	–0.18 (–0.28 to 0.07)	5104 (25)[a]	–0.18 (–0.26 to 0.10)	–0.17 (–0.25 to 0.10)
Physical function	< 4	2453 (19)	–0.26 (–0.40 to 0.12)	4093 (26)	–0.31 (–0.44 to 0.18)	
	4–8	3759 (18)	–0.15 (–0.23 to 0.07)	5546 (28)[a]	–0.19 (–0.25 to 0.13)	–0.18 (–0.23 to 0.12)
	> 8	2482 (13)	–0.12 (–0.20 to 0.04)	3980 (19)[a]	–0.14 (–0.22 to 0.06)	–0.13 (–0.21 to 0.05)
Quality of life	4–8	399 (2)	–0.11 (–1.05 to 0.82)	665 (4)	–0.14 (–0.55 to 0.27)	–0.13 (–0.40 to 0.15)
	> 8	170 (1)	–0.50 (–0.80 to 0.19)	170 (1)	–0.50 (–0.80 to 0.19)	–0.24 (–0.70 to 0.21)

continued

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TABLE 74 Summary of total effect sizes by outcome and follow-up interval including the studies from the updated review (*continued*)

Outcome	Follow-up (months)	Review January 1994–April 2009		Review January 1994–September 2013		
		Total *n* participants (number of studies)	Effect size (95% CI)	Total *n* participants (number of studies)	Effect size (95% CI)	Including COPERS results
Self-efficacy	4–8	1214 (7)	–0.29 (–0.44 to 0.14)	2030 (10)	–0.25 (–0.34 to 0.17)	–0.24 (–0.32 to 0.16)
	> 8	1701 (7)	–0.25 (–0.35 to 0.15)	2173 (8)	–0.23 (–0.31 to 0.14)	–0.20 (–0.28 to 0.13)
Depression	4–8	597 (4)	–0.25 (–0.47 to 0.03)	1899 (12)[a]	–0.26 (–0.38 to 0.13)	–0.24 (–0.35 to 0.13)
	> 8	641 (3)	–0.04 (–0.26 to 0.18)	1516 (7)[a]	–0.20 (–0.44 to 0.03)	–0.20 (–0.38 to 0.01)
Anxiety	4–8	451 (3)	–0.28 (–0.56 to 0.00)	878 (6)	–0.14 (–0.31 to 0.03)	–0.16 (–0.28 to 0.04)
	> 8	50 (1)	–0.28 (–0.84 to 0.27)	553 (3)	–0.41 (–0.58 to 0.24)	–0.28 (–0.51 to 0.06)
Social function	4–8	286 (4)	–0.19 (–0.61 to 0.22)	931 (8)[a]	–0.24 (–0.40 to 0.09)	–0.22 (–0.34 to 0.11)
	> 8	205 (2)	0.19 (–0.09 to 0.47)	922 (6)[a]	–0.11 (–0.26 to 0.05)	–0.15 (–0.27 to 0.02)

a Includes studies with two intervention arms viable for the comparison. Therefore, the number of studies shown contributing to the plot is inflated by $n + 1$ and the total number of participants shown contributing to the plot is inflated by double counting of the control arm. A sensitivity analysis in the previous systematic review showed that removing these multiarm studies made no difference to the results and so they have been kept in.

Overall, despite our efforts to develop and test a more effective intervention, the effect sizes found with the COPERS intervention across a range of domains were broadly similar to those found in previous research. That in a large well-conducted study with a low risk of bias we found similar results to those found in multiple smaller studies lends credence to the notion that these are 'true' estimates of effect sizes.

Strengths of the study

A key strength of this study is that its pragmatic design means that our results directly relate to the real-world setting.[297] Another of its principal strengths lies in the robustness of the results. The study was adequately powered and recruited to target and attrition of follow-up data was very low. The statistical analysis plan was written and published before data were unblinded or any analysis was undertaken. We used MI to reduce bias, conducted extensive sensitivity analyses and adopted different analytical approaches to test the robustness of our statistical and economic analyses.

The study was designed and conducted to minimise bias: strict allocation concealment was maintained and usual health-care providers were aware that participants had joined the study but were not informed of their allocation arm. The intervention was delivered by trained facilitators who in the main were completely uninvolved in the collection or evaluation of study data; however, throughout the delivery of the intervention experienced members of the study team codelivered 10 of the 31 courses with new inexperienced facilitators. All outcome data collected by telephone were collected by researchers unaware of the allocation arm of the participants and a script was used asking respondents not to reveal their allocated treatment. Primary care patient record data were extracted by trained personnel blind to the

allocation arm of participants. All questionnaire data, secondary care service use data and primary care record data were entered, checked and cleaned before any unblinding. All primary outcome data were double entered and checked and a further 10% random selection of other data were double entered and checked; accuracy was high, aided by sophisticated database construction limiting errors. Study participants were ethnically diverse (indeed our participants were more ethnically diverse than the UK overall) and lived in localities ranging from those characterised as very affluent to those characterised as very deprived. Our feasibility study indicated that the intervention could be successfully delivered in languages other than English and was acceptable to a non-English-speaking ethnic group. The study successfully identified the right patients – those significantly disabled by their chronic pain – as evidenced by their high levels of disability and morbidity at baseline. This population also consumed a considerable amount of health-care resources, including strong opioids. Thus, this is a highly appropriate group in which to study complex, non-pharmacological interventions such as the COPERS intervention, directed at improving health outcomes and potentially reducing health-care resource use.

The intervention tested was evidence informed and underpinned by behaviour change theory – the strengths in the design and nature of the intervention are described in the discussion to *Chapter 8*. In addition, the COPERS intervention was relatively cheap and, if successful, could plausibly be implemented within the NHS. Both the feasibility study and the main trail suggest that it was highly acceptable to participants.

The fidelity of intervention delivery in trials of complex interventions has not been routinely considered until recently[14] but its importance has recently been underlined by the WISE (Whole System Informing Self-management Engagement) study, in which the failure of a complex, whole-system self-management support intervention may have arisen from a failure to implement the intervention as intended.[298] Our study included a detailed and comprehensive assessment of the fidelity of intervention delivery[223] (see *Chapter 10*) and so we can be confident that the intervention tested here was delivered as intended. We intended the COPERS groups to include around 14 participants and we achieved this with the exception of just one course.

We were able to show a sustained effect of the intervention on our key target mediator, self-efficacy, indicating that the intervention worked as intended. That these changes failed to result in the desired effect on our primary outcome suggests that this is not, on its own, a sufficient change to result in changes in pain-related disability, but there may be other important unmeasured mediators that we were unable to investigate.

Limitations of the study

Our choice of primary outcome might be considered a limitation. Although we had identified pain-related disability as determined by the CPG as one of our preferred potential outcome measures (see *Chapter 5*), we did not use this as the primary outcome in the feasibility study (see *Chapter 7*). In designing the study we wished to move beyond the existing evidence that consistently showed benefits for intermediate outcomes such as self-efficacy without showing improvements in clinically relevant outcomes. In our development work we considered different candidate measures for our clinically relevant primary outcome. The mixture of disorders included in the trial meant that a generic outcome measure was needed. We had originally considered using the EQ-5D. In the feasibility study, however, it was clear that this was not sufficiently responsive to change from baseline for it to be a suitable outcome. For this reason we chose a measure with a narrower focus on pain-related disability (the main trial data confirmed that the EQ-5D was unresponsive to the intervention). Our choice of which pain-related disability outcome measure to use was constrained by the necessity of choosing an instrument suitable for pain at different musculoskeletal sites. The CPD pain-related disability subscale had been used with positive results in other studies of chronic pain populations, suggesting that it was an appropriate choice and sensitive to change.[53,83] Indeed, as anticipated from previous studies,[208,210] CPG scores fell by more than one-third of a SD between baseline and 6 months (and then remained at similar levels at 12 months) in both the intervention arm and the control arm, suggesting that it is sensitive to change.

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Another potential limitation of our study might have been our inclusion of a relaxation CD and leaflet along with usual care in the control arm. Our pilot study had demonstrated that recruiting people to trials in which one arm is usual care might be difficult and other researchers have described the possibility of 'resentful demoralisation', when patients with a strong preference for one arm of a study are assigned to the other arm.[299] To maximise recruitment and, perhaps, reduce the risk of resentful demoralisation we chose to add a very simple relaxation package to our control intervention (this package was also given to treatment arm patients at the end of the COPERS course). We chose the relaxation package because our systematic review (see *Chapter 2*) had suggested that, although relaxation was popular, it was unlikely to have an effect on our primary outcome of pain-related disability. A 2006 systematic review found that progressive muscle relaxation (the technique provided in our control arm) reduced chronic pain but in the two studies that reported longer-term follow-up the effect on pain was not sustained at 3 or 6 months.[300] However, one of the most important effects of our intervention was on the secondary outcome of depression and there is systematic review evidence that relaxation may improve participant-reported depression.[301] Moreover, there is a suggestion from the 12-month questionnaire that control arm patients might have practised regular relaxation more frequently than intervention arm patients, although the data are difficult to interpret because of poor response rates to the questions. (The questions were at the end of the questionnaire and we assumed that most missing responses meant that people did not practise any relaxation.) Thus, there is the possibility that the control arm intervention diminished the apparent effect of our intervention on depression and, by extension, potentially on our other secondary psychological outcomes. It might be argued in favour of our choice of control that, even if the relaxation CD had some efficacy, we would want to be able to demonstrate that our intervention was superior to such a simple (and very slightly effective) intervention. Control and intervention arm participants also received a copy of *The Pain ToolKit* booklet but we have already explained that we consider this to be good usual care (see *Chapter 9*).

The ethnic mix of our participants was not nationally representative (COPERS trial: 80% white, 13% black, 5% Asian; England and Wales: 86% white, 3.4% black, 7.5% Asian[302]). Unusually, we achieved an over-representation of minority ethnic groups compared with national norms. This reflects our decision to recruit in a very ethnically diverse locality. Nevertheless, our recruited population might still not have been representative of the ethnic mix of the communities from which we were recruiting. The overall uptake of the offer to join the study by patients recruited from primary care was low and differed between east London (6.7%) and the Midlands (10.8%), leading to concerns about the generalisability of the study and the feasibility of implementing the intervention (if it were successful). However, because of the nature of our electronic search many of the people identified for invitation from primary care records may not have been eligible. Even if invitees were eligible, it is not clear how inviting participants to participate in a research project, in which they are not guaranteed to receive an intervention and have to initiate contact with researchers themselves (data protection necessitated that they were invited by their GP, not the research team), relates to offering patients an intervention outside a research setting as part of usual care. Uptake (when reported) is generally low in studies of self-management. Overall, the low uptake seen in our study suggests that, although we can be confident that our results apply to the group included, we are less confident about extrapolating these results to the wider chronic pain population. These uptake rates are, however, comparable with those in other studies recruiting from primary care.[53,56,83] That the clinical course of low back pain is similar in RCTs and cohort studies provides some reassurance that the results from a trial of this nature do reflect real life.[210] The high levels of depressive symptoms seen in the COPERS study population are interesting in this context because there is evidence from other chronic conditions that depressed patients are less likely to participate in group self-management support and more likely to drop out.[303] If this is also true for chronic pain it suggests that levels of depressive symptoms could be even higher in eligible patients who did not participate in our study.

In common with other studies of self-management[14] the majority of participants in our study were female (67%). A 2014 Cochrane review of self-management in OA included 29 studies and reported that overall 68% of participants were female[13] [our chronic pain patients were younger (mean age 60 years) than those in the OA review (mean age 65 years)]. It is not clear why women are more attracted to self-management interventions than men although, in general, more women than men report chronic pain. In a previous study we found that the relative risk of women having chronic widespread pain was 1.3 (95% CI 1.2 to 1.4).[59]

We originally wanted to identify subgroups who were most likely to benefit from a pain self-management intervention. In our systematic review (see *Chapter 3*) we failed to identify any groups who might benefit more than others and so we directed the intervention at all adult chronic musculoskeletal pain patients who met our inclusion criteria. Prespecified subgroup analyses (see *Chapter 11*) failed to identify any group in whom our primary outcome was significantly improved (although there was a suggestion that those with less intense pain and a shorter duration of pain and those with neither high nor low self-efficacy at baseline might benefit the most) but these analyses lacked statistical power. Thus, the issue of subgrouping remains unaddressed.

Strengths and limitations in relation to other studies

Measuring a primary outcome at 12 months' follow-up is a strength of our study; most other studies of self-management in general, and of chronic pain self-management in particular, consider shorter follow-up periods.[13,14] Including self-efficacy among our choice of outcome measures is another strength. Although we regard increasing self-efficacy as a process outcome, it has been advocated as an important outcome that often goes unmeasured in studies of chronic pain self-management.[13]

Our intervention was successful compared with other self-management support interventions. A recent RCT of the Arthritis Self-Management Programme in Australia, which also aimed to look at a real-world setting, was terminated because of a lack of enthusiasm from potential referrers and patients.[297] In contrast to our study, which principally recruited patients with very longstanding musculoskeletal pain from primary care, the Australian study recruited patients with knee and hip OA from secondary care, including private hospitals.

The results of the economic evaluation demonstrate that the COPERS self-management course is a relatively inexpensive intervention, with an average acquisition cost of approximately £145 per person, including staff training (see *Chapter 11*). This is a little over half of the cost of a year's supply of duloxetine at a dose of 60 mg per day (£268.80),[304] which is recommended for use for either fibromyalgia or knee OA.[305,306] It also compares favourably to the cost of the Expert Patients Programme, which is estimated to cost £250 per patient.[15] The estimated cost per participant for the COPERS course is also much lower than the average cost of £599 per patient for the IAPT programme[283] (another study estimated that the cost of the IAPT programme per patient varied from £493 for low-intensity therapy to £1416 for high-intensity therapy[307]). Several factors suggest that the cost per person would be lower should the COPERS intervention become widely available. The first factor relates to training: although the training of facilitators in the trial was conducted by university staff, wider adoption of the intervention would be likely to reduce costs through using experienced facilitators in a training role. The second factor relates to venue costs: the COPERS team had to hire premises but courses could be delivered in NHS/primary care settings if the intervention were more widely adopted. Therefore, our cost estimate of £145 per participant per course may be regarded as conservative.

The COPERS intervention is not a true CBT intervention. However, it was never our intention to deliver CBT as such; we intended only to deliver an intervention informed by some of the principles of a cognitive–behavioural approach.

Meaning of the study: possible mechanisms and implications for clinicians or policy-makers

Our original conceptual model, adapted to include our revised primary outcome (*Figure 21*), suggested that we would influence a variety of outcomes. In fact, we influenced only the psychological outcomes and social integration and support, and a sustained effect at 12 months was seen only for depression and social integration and support. In other words, our psychologically based group intervention had marked

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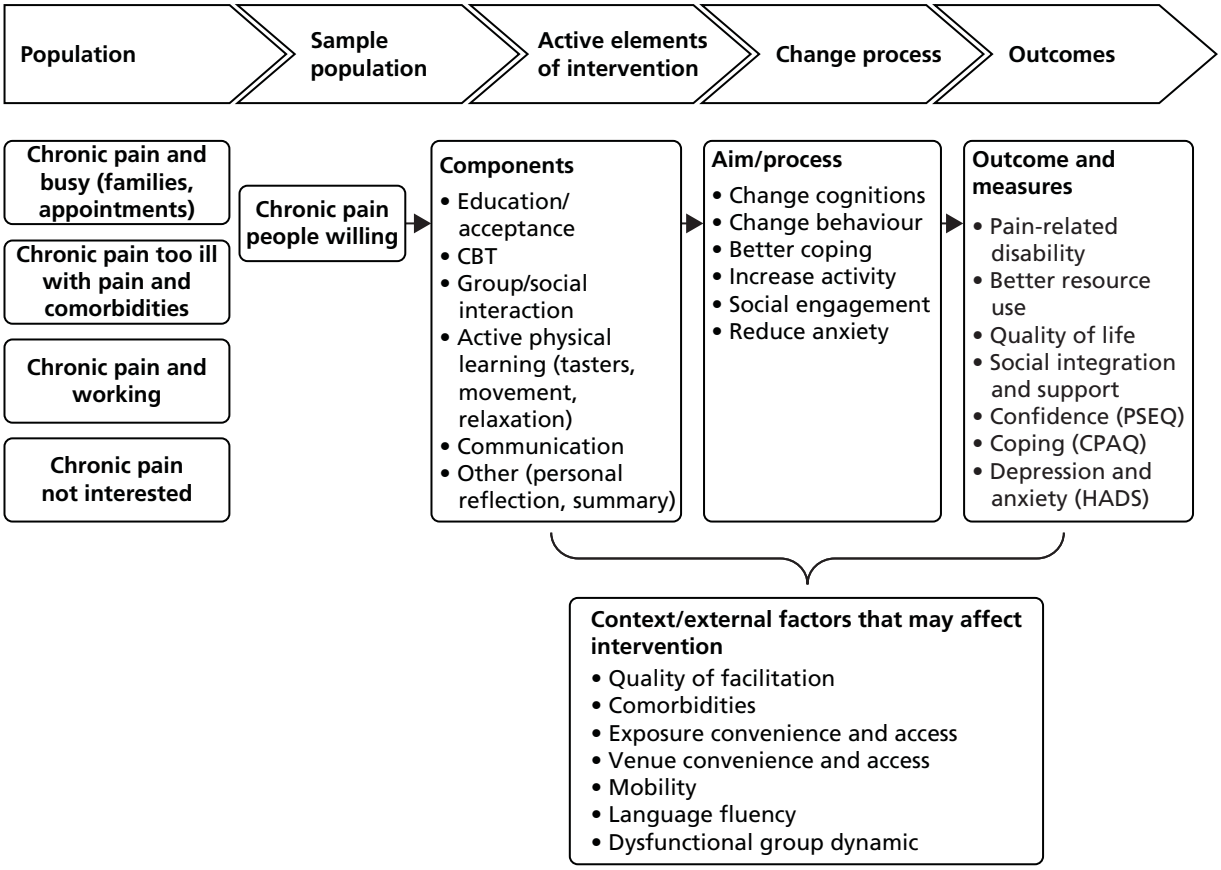

FIGURE 21 The COPERS contextual model.

psychological effects that were concentrated in those who were depressed at baseline, but did not appear to affect health-care resource use or disability. We are not in a position to say with certainty what the active elements of the intervention were for certain but it seems likely that these were the psychologically orientated components and the effect of being in a group of peers.

Implications

Overall, for patients with chronic pain, this rigorous, well-designed and well-conducted study suggests that we now know the *limitations* of self-management support interventions for chronic musculoskeletal pain.

First, the study demonstrates that research studies of these interventions appeal to a limited number of a particular type of chronic pain patient: those who are older, those who are likely to be retired or not working and predominantly female patients. Even if they are not representative of chronic pain patients as a whole, there may be merits in targeting this group as we also know that these patients are likely to be significantly disabled by their pain and have high levels of anxiety and depression, may well be on strong opioids, will be taking a lot of prescribed medications, attend their GP very frequently and have a long history of pain. Moreover, the feasibility study for the COPERS intervention showed that the intervention can actually be applied to a lot of other groups, for example the Sylheti-speaking group in Tower Hamlets could complete the intervention with the Bengali DVD, even though it was not feasible to include them in the main trial because of difficulties with collecting outcome data.

Second, the outcomes of these interventions appear to be modest and predominantly psychological. Such interventions do not appear to have a marked, if any, effect on health-care resource use, at least within

the first 12 months. However, there is a strong suggestion in our post hoc analyses that this type of intervention may be very effective in the subgroup of chronic pain patients with depression with no deleterious effects on those who were not depressed at baseline.

Although some commissioners may interpret the modest effects of the COPERS intervention as justification not to fund this type of self-management support for chronic pain patients, the COPERS intervention is feasible and safe, can be delivered to large numbers of people, is evidence based and leads to levels of improvement that are at least as good as those seen with other similar interventions and meets NICE criteria for cost–utility. We suggest that the COPERS intervention could be a substitute for other less well-evidenced and more expensive chronic pain management programmes. Its potential role in the management of depression in chronic pain patients merits further research.

Research recommendations

Our work suggests that there is a need to address the following research questions (presented in order of importance).

Research questions related to chronic musculoskeletal pain

1. What can be done to improve the disability experienced by patients with chronic musculoskeletal pain?
2. Does the COPERS intervention have a role in the management of chronic pain patients with mild to moderate depression? Is it more effective and acceptable than alternative non-pharmacological treatments for depression in this population? Our post hoc analyses strongly suggest that this is an effective treatment for depression in this population. Nevertheless, this is based on a mixed clientele joining the groups. As the group dynamic may be different if only people with depression join the groups, it cannot be promoted as an intervention for this population. A new trial is needed to target this population and focus on depression. It may be appropriate to use a depression outcome that is more responsive to change than the HADS.
3. Could self-management interventions delivered before chronic musculoskeletal pain has become very longstanding be more effective than those delivered after the individual has experienced years of chronic pain? Would they be acceptable to patients? Would they have the potential to alter the disease trajectory and long-term outcomes?

Research questions related to methodology

1. Should complex interventions have single outcome measures? Work is needed to explore the interpretation of the results of trials of complex interventions in which multiple outcomes are reported. In common with many complex interventions, the COPERS intervention had multiple facets that might affect different outcomes in different ways. The traditional model whereby paramount importance is given to the primary outcome is well established. In this model any apparently important benefits in secondary outcomes are no more than hypothesis generating. A further full trial with these as the primary outcome would be needed to confirm the findings. This approach leads to a hazard that important beneficial effects, in our case a reduction in depressive symptoms, might be discarded as a chance finding when, in fact, it may be an important positive result. Research in this area may consider how such findings should be considered within the trial and also when data pooling.
2. Are large RCTs the best way to evaluate novel, complex, non-pharmacological interventions? There is a large opportunity cost in developing and testing interventions of this nature. The risk of harm from such interventions is small and a negative trial is unlikely to dissuade others from implementing similar intervention packages. Once we put the results of the COPERS trial into context they made little difference to the estimates of effects of such interventions on a wide range of outcomes and so our

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study has, arguably, not added to the evidence base commensurately with its size. Although a positive trial would support implementation it would strictly support the implementation only of the package tested. In reality, it is variants of the proven intervention that are delivered. For example, few physiotherapy departments offer more than six sessions for people with low back pain, whereas NICE guidance,[129] based on the available evidence, suggests up to 12 sessions. This is in contrast to trials of pharmacological interventions in which fully understanding the benefits and harms of a particular preparation is critical. It may be worthwhile for the research community to explore whether or not other approaches might generate 'good enough' data to inform policy and practice across a wider range of topic areas for the same research cost.

Acknowledgements

This project was funded by the NIHR under its Programme Grants for Applied Research scheme (RP-PG-0707–10189). It also benefited from facilities funded through the Birmingham Science City Translational Medicine Clinical Research and Infrastructure Trials Platform, with support from Advantage West Midlands.

Other acknowledgements

Other researchers involved in the project

- Naheedah Choudhury (project administrator).
- Maria Ramirez (trial co-ordinator, Warwick).
- Clare Miles (systematic reviewer).
- David Ellard (senior research fellow) contributed to the design of the fidelity methods and fidelity assessment.
- Anna Volkmann (researcher) conducted the English qualitative interviews for *Chapter 4*.
- Yasmin Choudhury (researcher) conducted the Sylheti qualitative interviews for *Chapter 4*.
- Geoff Harding (medical sociologist) contributed to the analysis of the qualitative data for *Chapter 4*.

Clinical Trials Units

- Queen Mary University of London PCTU for the support given for the feasibility study and feasibility randomisation and for data management for the main trial and the quality audit: Stephen Bremner, Sandy Smith, Mike Waring and Amy Hoon.
- Warwick Medical School Clinical Trials Unit: Sarah Duggan, Clare Daffern and Cheryl Ritchie.
- Sheffield University Clinical Trials Unit for the use of the online randomisation service.

Clinical research networks

- North and East London: Local Clinical Research Network.
- London Primary Care Research Network: Jo Burns and Selina Gann.
- North Central London Research Consortium: Lynis Lewis.
- Warwick and Coventry: Local Clinical Research Network.
- Warwick and Coventry Primary Care Research Network: Sue Ellwell.

Coapplicants

Coapplicants who have contributed to various aspects of the study: Jayne Gallagher (pain anaesthetist, Barts Health NHS Trust), Sally Hearne (primary care trust commissioner), Elizabeth Bayliss (Social Action for Health, Tower Hamlets) and Qasim Aziz (gastroenterologist, Queen Mary University of London).

Oversight committees

- Trial Steering Committee: Mike Hurley (chairperson), Nadine Foster, Bart Koes, Lance McCracken, Jim Reece and Obi Ukoumunne.
- Data Monitoring and Ethics Committee: Gene Feder (chairperson), Blair Smith and Rebecca Turner.

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Patient advisors

We would like to thank our four patient advisors for their invaluable contribution to the project.

Secondary care user services data

- North East London Commissioning Support Unit for the London secondary care user service data.
- Arden Commissioning Support Unit for the Warwick and Coventry secondary care user service data.

Recruiting clinics

- Dylan Morrisey and colleagues at Mile End Hospital Physiotherapy Department for recruiting patients for the feasibility study.
- Angie Alamgir and colleagues at the Persistent Pain Service, Mile End Hospital, for involvement in both the feasibility study and the main trial.
- Ingrid Bergson and colleagues at City and Hackney Locomotor Service.
- Susie Crome from Social Action for Health for help with the recruitment facilitators.

General practices in London

Blithehale Health Centre, Chrisp Street Health Centre, Dr Gadhvi-Fountayne Road Health Centre, Elsdale Street Surgery, Elm-Fountayne Road Health Centre, Island Health, St Stephens Health Centre, Statham Grove Surgery, Shah Jalal Surgery, the Wapping Group Practice, Tredegar Health Centre and the Nightingale Practice.

General practices in Warwick and Coventry

Atherstone Surgery, Chancery Lane Surgery, Clarendon Lodge Medical Practice, Croft Medical Centre, Dr Chaudhuri Surgery, Manor Court Surgery, Old Mill Surgery, Rother House Medical Centre, Sherbourne Medical Centre, Sky Blue Medical Group, Stockingford Medical Centre and the Forum Health Centre.

Facilitators in London

Mohammad Anwar, Julie Atkins, Ingrid Bergson, Jonathan Field, Christine Hunter, Alex Irving, Zahida Kahn, Jonathan Liptich, Paul Montague, Samina Rashid, Sam Shakes and Angela Usher.

Facilitators in Warwick and Coventry

Malcolm Benny, Sarah Bridgewater, Sally Brown, Susanne Finnegan, Karen Keats, Jill Nussbaum, Cheryl Ritchie and Yvonne Rolston.

Participants

We would like to thank those who participated in the interviews and focus groups for the qualitative study and the outcome measures discussion group; those who participated in the feasibility study, including those at Whitechapel Health Centre who supported the recruitment of participants for the feasibility study for Sylheti-speaking participants; and the 703 study participants who took part in the main trial and gave their time to complete the questionnaires.

Film production

Chris Payne.

Report production

Antoinette Connelly.

Contributions of authors

Stephanie JC Taylor (Professor of Primary Care and Public Health, applicant, principal investigator) was primarily responsible for developing the proposal for funding and had overall responsibility for the conduct of the programme of work. She made major contributions to all aspects of the programme. She oversaw drafting of the final report and has reviewed it for crucial intellectual content.

Dawn Carnes (Senior Research Fellow, health services research, coapplicant) made substantial contributions to the design, organisation and conduct of the programme of work and was also responsible for collecting, analysing and interpreting data. She had primary responsibility for drafting of the final report and critiquing it for crucial intellectual content.

Kate Homer (Research Fellow and Systematic Reviewer, health services research) contributed substantially to the conduct of the study including the analysis and interpretation of data at each stage of the programme of work. She made a substantial contribution to the drafting of the report and critiqued it for crucial intellectual content.

Tamar Pincus (Professor in Psychology, coapplicant) contributed substantially to the design, conduct, analysis and interpretation of the moderator, mediator and predictor systematic review and the review that helped determine the outcome measures, contributed to the development of the intervention, drafted *Chapters 3* and *5* and critiqued the whole report for crucial intellectual content.

Brennan C Kahan (Senior Statistician) made substantial contributions to the design of the statistical analysis plan, carried out the clinical effectiveness analyses and contributed to the interpretation of the findings. He helped draft the methods and results chapters for the main trial (see *Chapters 9* and *11*, respectively) and commented on these chapters, critiquing them for crucial intellectual content.

Natalia Hounsome (Senior Health Economist) made a substantial contribution to the design of the health economic analysis plan, carried out the cost-effectiveness analyses and contributed to the interpretation of the findings. She drafted the relevant text for the health economics methods, results and conclusions sections, critiquing them for crucial intellectual content.

Sandra Eldridge (Professor of Biostatistics, coapplicant) made a substantial contribution to the development of the intervention and the design, the statistical analysis and interpretation of the data and critiqued the whole report for intellectual content.

Anne Spencer (Professor of Health Economics, coapplicant) made a substantial contribution to the design of the health economic analysis plan, oversaw the cost-effectiveness analyses and contributed to the interpretation of the findings. She helped draft the relevant text for the health economics methods, results and conclusions sections, critiquing them for crucial intellectual content.

Karla Diaz-Ordaz (Statistician) made significant contributions to the design of the statistical analysis plan, carried out the case analyses and contributed to the interpretation of findings and helped draft the methods and results chapters (see *Chapters 9* and *11*, respectively) and commented on these chapters, critiquing them for crucial intellectual content.

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Anisur Rahman (Professor of Rheumatology, coapplicant) contributed to the overall study design and made a major contribution to the conduct of the feasibility study, contributed to the development of the intervention and conduct of the main trial and critiqued the final report for crucial intellectual content.

Tom S Mars (Research Assistant, health services research) contributed substantially to the delivery of the intervention and the design of the methodology for the assessment and analyses of fidelity and drafted *Chapter 10*.

Jens Foell (General Practitioner) helped develop and tested the search strategy for identifying primary care chronic pain patients and helped with health economic data collection and extraction.

Chris J Griffiths (Professor of Primary Care, coapplicant) contributed to the development of the proposal and critiqued the report for intellectual content.

Martin R Underwood (Director, Warwick Clinical Trials Unit, coprincipal investigator) was the second principal investigator responsible for the Midlands recruiting site. He had major input into developing the proposal for funding and had overall responsibility for the conduct of the programme of work. He made substantial contribution to all aspects of the programme. He had major involvement in the drafting of the final report and has reviewed it for crucial intellectual content.

Publications

Miles CL, Pincus T, Carnes D, Homer KE, Taylor SJC, Bremner SA, *et al.* Can we identify how programmes aimed at promoting self-management in musculoskeletal pain work and who benefits? A systematic review of subgroup analysis within RCTs. *Eur J Pain* 2011;**15**:775e1–11.

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Carnes D, Underwood M, Homer K, Bremner S, Eldridge S, Pincus T, *et al.* Effectiveness and cost-effectiveness of a novel, group self-management course for adults with chronic musculoskeletal pain: study protocol for a multi-centre, randomised controlled trial (COPERS). *BMJ Open* 2013;**3**:e002492.

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Data sharing statement

Please apply to our Data Access Committee via Dr Arouna Woukeu, Clinical Trials Information Systems (CTIS) manager at the PCTU.

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Appendix 1 Systematic review (April 2009–September 2013): final value data by outcome and follow-up – forest plots

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Global health

Study or subgroup	Intervention Mean	SD	Total	Control Mean	SD	Total	Weight	SMD Random, 95% CI	Year
LeFort 1998[76]	−48.7	20.3	52	−48.7	21.9	50	11.0%	0.00 (−0.39 to 0.39)	1998
Victor 2005[97]	−66	19	87	−69	19	56	12.3%	0.16 (−0.18 to 0.49)	2005
Li 2006[100]	−15.5	3.2	34	−15.2	3.4	30	8.6%	−0.09 (−0.58 to 0.40)	2006
Brattberg 2006[99]	−58.6	22.5	27	−45.9	18.2	28	7.7%	−0.61 (−1.15 to −0.07)	2006
Alp 2007[65]	−66.3	10.7	22	−56.2	14.7	23	6.7%	−0.77 (−1.38 to −0.16)	2007
Tavafian 2007[66]	−61.6	22.7	44	−47.3	26.1	47	10.2%	−0.58 (−1.00 to −0.16)	2007
Yip 2008[111]	−3.1	1	40	−2.7	0.9	37	9.5%	−0.42 (−0.87 to 0.04)	2008
Ribeiro 2008[109]	−73.3	20.7	26	−57	25.2	29	7.6%	−0.69 (−1.24 to −0.15)	2008
Kao 2012[125]	−59.2	18.6	114	−50.8	18.5	91	14.0%	−0.45 (−0.73 to −0.17)	2012
Coleman 2012[124]	−69.2	10.8	69	−67.1	10.88	70	12.4%	−0.19 (−0.53 to 0.14)	2012
Total (95% CI)			**515**			**461**	**100.0%**	**−0.33 (−0.52 to −0.13)**	

Heterogeneity: $\tau^2 = 0.05$; $\chi^2 = 19.11$, df = 9 ($p = 0.02$); $I^2 = 53\%$
Test for overall effect: $z = 3.31$ ($p = 0.0009$)

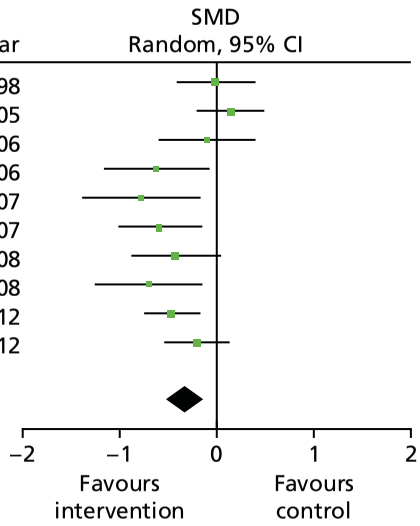

FIGURE 22 Short-term follow-up (< 4 months).

Study or subgroup	Intervention Mean	SD	Total	Control Mean	SD	Total	Weight	SMD Random, 95% CI	Year
Mannerkorpi 2000[82]	−45.6	19	28	−26.3	16.3	29	6.7%	−1.08 (−1.64 to −0.52)	2000
Cedraschi 2004[90]	−34.3	17.3	61	−28.8	18.9	68	11.0%	−0.30 (−0.65 to 0.05)	2004
Haas 2005[93]	−56.5	22.8	42	−56.4	19.6	39	8.9%	0.00 (−0.44 to 0.43)	2005
Alp 2007[65]	−70	15.2	22	−54.3	14.4	23	5.8%	−1.04 (−1.67 to −0.42)	2007
Lorig 2008[108]	−3.5	1.1	310	−3.3	1.1	331	16.2%	−0.18 (−0.34 to −0.03)	2008
Ribeiro 2008[109]	−69.7	20.7	26	−52.5	23.2	29	6.8%	−0.77 (−1.32 to −0.22)	2008
Yip 2008[111]	−3.1	0.9	39	−2.8	0.9	35	8.4%	−0.33 (−0.79 to 0.13)	2008
Coleman 2012[124]	−69.6	14.02	68	−66	14.02	68	11.2%	−0.26 (−0.59 to 0.08)	2012
McBeth 2012[52]	−61	22	87	−61	21	88	12.4%	0.00 (−0.30 to 0.30)	2012
McBeth 2012[52]	−64.6	18.9	94	−61	21	88	12.5%	−0.18 (−0.47 to 0.11)	2012
Total (95% CI)			**777**			**798**	**100.0%**	**−0.33 (−0.51 to −0.15)**	

Heterogeneity: $\tau^2 = 0.05$; $\chi^2 = 23.10$, df = 9 ($p = 0.006$); $I^2 = 61\%$
Test for overall effect: $z = 3.53$ ($p = 0.0004$)

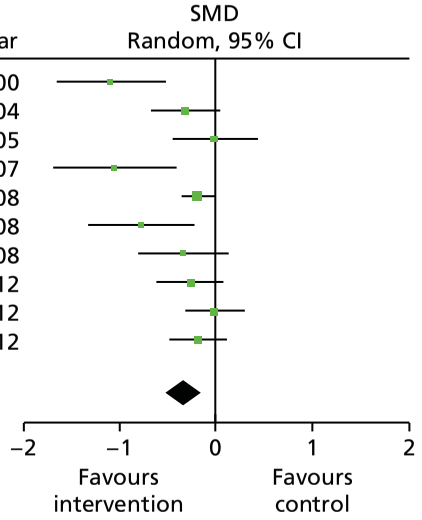

FIGURE 23 Medium-term follow-up (4–8 months).

Study or subgroup	Intervention Mean	SD	Total	Control Mean	SD	Total	Weight	SMD Random, 95% CI	Year
Victor 2005[97]	−64	20	72	−66	20	53	9.3%	0.10 (−0.26 to 0.45)	2005
Heuts 2005[94]	−62	17.8	87	−58.3	20.1	105	12.3%	−0.19 (−0.48 to 0.09)	2005
Núñez 2006[101]	−50.1	22.5	43	−56.4	20.9	37	6.8%	0.29 (−0.16 to 0.73)	2006
Yip 2008[111]	−3.2	1	29	−3	1	24	4.9%	−0.20 (−0.74 to 0.35)	2008
Lorig 2008[108]	−3.2	6.9	307	−2.8	5	344	20.9%	−0.07 (−0.22 to 0.09)	2008
Kroenke 2009[113]	−35.2	29.7	123	−24.2	25.5	127	14.2%	−0.40 (−0.65 to −0.15)	2009
Brosseau 2012[122]	−66.14	20.48	42	−69.92	18.24	36	6.7%	0.19 (−0.25 to 0.64)	2012
McBeth 2012[52]	−63.9	20.1	102	−58.4	20.9	98	12.6%	−0.27 (−0.55 to 0.01)	2012
McBeth 2012[52]	−58.9	20.4	91	−58.4	20.9	98	12.3%	−0.02 (−0.31 to 0.26)	2012
Total (95% CI)			**896**			**922**	**100.0%**	**−0.10 (−0.23 to 0.03)**	

Heterogeneity: $\tau^2 = 0.02$; $\chi^2 = 13.53$, df = 8 ($p = 0.09$); $I^2 = 41\%$
Test for overall effect: $z = 1.48$ ($p = 0.14$)

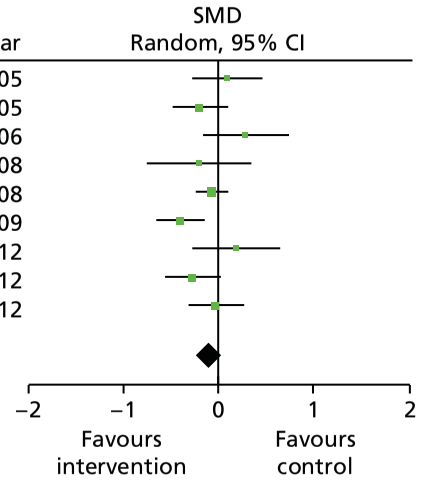

FIGURE 24 Long-term follow up (> 8 months).

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Pain intensity

Study or subgroup	Intervention Mean	SD	Total	Control Mean	SD	Total	Weight	SMD Random, 95% CI	Year
Williams 1996[70]	63.4	19.6	30	68.1	20.7	31	2.4%	−0.23 (−0.73 to 0.27)	1996
Keller 1997[73]	3.1	2.1	29	5.6	2.1	23	2.0%	−1.17 (−1.77 to −0.58)	1997
Von Korff 1998[77]	3.9	2.2	124	4	2.1	121	3.6%	−0.05 (−0.30 to 0.20)	1998
LeFort 1998[76]	−35	18.7	52	−27.6	17.9	50	2.9%	−0.40 (−0.79 to −0.01)	1998
Currie 2000[80]	10.2	3.5	31	12	3.6	26	2.2%	−0.50 (−1.03 to 0.03)	2000
Hopman-Rock 2000[81]	2.7	2.1	55	2.5	2.4	44	2.8%	0.09 (−0.31 to 0.49)	2000
Haugli 2001[84]	4.6	2.3	61	5.3	2.2	39	2.8%	−0.31 (−0.71 to 0.10)	2000
Dworkin 2002[86]	2.8	1.9	48	3	2	51	2.9%	−0.10 (−0.50 to 0.29)	2002
Buhrman 2004[89]	36.2	20.4	22	32.6	21.6	25	2.1%	0.17 (−0.41 to 0.74)	2004
Mazzuca 2004[92]	12.4	4.1	104	12.5	4.2	71	3.3%	−0.02 (−0.33 to 0.28)	2004
Hughes 2004[91]	4.9	3.4	68	6.2	4.3	43	2.9%	−0.34 (−0.73 to 0.04)	2004
Tak 2005[96]	3.5	2.1	35	5.1	2.3	39	2.5%	−0.72 (−1.19 to −0.25)	2005
Pariser 2005[95]	5.2	3.1	40	5.5	3	45	2.7%	−0.10 (−0.52 to 0.33)	2005
Victor 2005[97]	−54	22	87	−56	26	56	3.2%	0.08 (−0.25 to 0.42)	2005
Smeets 2006[102]	4.2	2.6	55	5.3	2.3	50	2.9%	−0.44 (−0.83 to −0.06)	2006
Brattberg 2006[99]	−50	30.1	27	−42.1	27.1	28	2.2%	−0.27 (−0.80 to 0.26)	2006
Li 2006[100]	−6.1	1.9	34	−4.9	1.6	30	2.3%	−0.67 (−1.18 to −0.17)	2006
Johnson 2007[54]	2.9	2.5	110	3.5	2.7	113	3.5%	−0.23 (−0.49 to 0.03)	2007
Martire 2007[104]	8.1	3.3	89	8.6	3.3	54	3.1%	−0.15 (−0.49 to 0.19)	2007
Alp 2007[65]	2.1	2	22	4.3	2.4	23	1.9%	−0.98 (−1.60 to −0.35)	2007
Yip 2007[105]	3.7	2.1	79	4.4	2.3	70	3.2%	−0.32 (−0.64 to 0.01)	2007
Tavafian 2007[66]	−71.5	16.2	44	−56.6	30	47	2.7%	−0.61 (−1.03 to −0.19)	2007
Yip 2008[111]	3.9	2	40	3.8	2.2	37	2.6%	0.05 (−0.40 to 0.49)	2008
Ribeiro 2008[109]	3.5	2.9	26	3.4	2.9	29	2.2%	0.03 (−0.50 to 0.56)	2008
Ersek 2008[106]	4	2.1	133	5	2.1	123	3.6%	−0.47 (−0.72 to −0.23)	2008
Laforest 2008[107]	6.5	2.5	59	6.6	2.5	38	2.8%	−0.04 (−0.45 to 0.37)	2008
Lamb 2010[53]	46.76	23.13	354	52.9	22.74	189	3.9%	−0.27 (−0.44 to −0.09)	2010
Hsu 2010[118]	4.43	2.69	24	5.01	1.8	21	2.0%	−0.25 (−0.83 to 0.34)	2010
Chiauzzi 2010[114]	5.04	2.05	95	5.44	1.94	104	3.4%	−0.20 (−0.48 to 0.08)	2010
Luciano 2011[120]	6.34	2.35	108	7.7	2.03	108	3.5%	−0.62 (−0.89 to −0.34)	2011
Morone 2011[121]	4.5	2.3	41	7.6	2.1	29	2.2%	−1.38 (−1.91 to −0.85)	2011
Kao 2012[125]	−70	16.7	114	−60.5	18.5	91	3.4%	−0.54 (−0.82 to −0.26)	2012
Hurley 2012[103]	5.2	1.7	237	7.1	1.8	128	3.7%	−1.09 (−1.32 to −0.86)	2012
Coleman 2012[124]	−51.2	15.78	69	−44	15.9	70	3.2%	−0.45 (−0.79 to −0.12)	2012
Carpenter 2012[123]	5.2	1.5	63	5.7	1.7	68	3.1%	−0.31 (−0.65 to 0.04)	2012
Total (95% CI)			**2609**			**2114**	**100.0%**	**−0.35 (−0.47 to −0.24)**	

Heterogeneity: $\tau^2 = 0.08$; $\chi^2 = 117.83$, df = 34 ($p < 0.00001$); $I^2 = 71\%$

Test for overall effect: $z = 6.07$ ($p < 0.00001$)

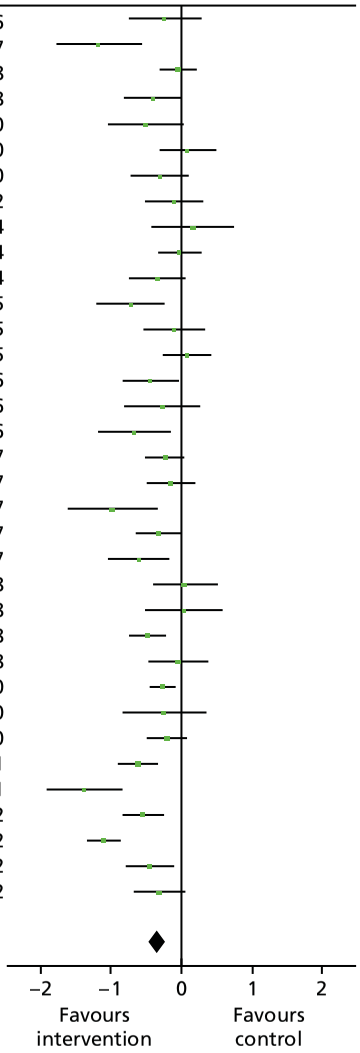

FIGURE 25 Short-term follow-up (< 4 months).

Study or subgroup	Intervention Mean	SD	Total	Control Mean	SD	Total	Weight	SMD Random, 95% CI	Year
Fries 1997[72]	4.4	2.3	375	5	2.3	434	5.1%	−0.26 (−0.40 to −0.12)	1997
Mazzuca 1997[74]	4.5	3.5	82	4.8	3.2	83	3.5%	−0.09 (−0.39 to 0.22)	1997
Basler 1997[71]	4.1	2.1	24	4.2	1.4	40	2.0%	−0.06 (−0.56 to 0.45)	1997
Von Korff 1998[77]	3.4	0.8	119	4	0.9	109	3.8%	−0.70 (−0.97 to −0.44)	1998
Hopman-Rock 2000[81]	3.5	2.1	55	3.8	2	44	2.7%	−0.14 (−0.54 to 0.25)	2000
Mannerkorpi 2000[82]	−32.9	20.2	28	−24	19.1	29	1.9%	−0.45 (−0.97 to 0.08)	2000
Dworkin 2002[86]	2.1	1.5	48	2.8	2	51	2.7%	−0.39 (−0.79 to 0.01)	2002
Quilty 2003[88]	4.3	2.5	40	5.1	2.6	43	2.5%	−0.31 (−0.74 to 0.12)	2003
Mazzuca 2004[92]	12.3	4.1	104	12.9	5.1	71	3.5%	−0.13 (−0.43 to 0.17)	2004
Hughes 2004[91]	5.1	3.7	60	6.7	3.9	36	2.6%	−0.42 (−0.84 to 0.00)	2004
Haas 2005[93]	41.4	28.9	54	42.3	29.3	47	2.8%	−0.03 (−0.42 to 0.36)	2005
Bernaards 2006[98]	3.5	2.4	126	3.3	2.3	133	4.0%	0.08 (−0.16 to 0.33)	2006
Yip 2007[105]	3.9	2.2	67	4.3	2.4	53	3.0%	−0.17 (−0.53 to 0.19)	2007
Hurley 2007[67]	5.7	3.5	229	6.7	3.5	113	4.2%	−0.29 (−0.51 to −0.06)	2007
Alp 2007[65]	1.4	1.1	22	5.1	1.8	23	1.1%	−2.42 (−3.21 to −1.64)	2007
Martire 2007[104]	7.2	3.5	89	8.3	3.5	54	3.2%	−0.31 (−0.65 to 0.03)	2007
Lorig 2008[108]	5.9	2.4	310	6.3	2.3	331	4.9%	−0.17 (−0.33 to −0.01)	2008
Ribeiro 2008[109]	3.3	3.1	26	3.9	3.1	29	1.9%	−0.19 (−0.72 to 0.34)	2008
Ersek 2008[106]	4.8	2.2	133	4.6	2	123	4.0%	0.09 (−0.15 to 0.34)	2008
Yip 2008[111]	3.5	2.2	39	3.5	2.4	35	2.3%	0.00 (−0.46 to 0.46)	2008
Kroenke 2009[113]	5.24	2.51	123	5.86	2.2	127	4.0%	−0.26 (−0.51 to −0.01)	2009
Crotty 2009[112]	15.9	8.26	75	16.3	7.93	77	3.3%	−0.05 (−0.37 to 0.27)	2009
Lamb 2010[53]	44.5	25.16	387	53	23.29	187	4.7%	−0.35 (−0.52 to −0.17)	2010
Chiauzzi 2010[114]	4.78	2.44	95	5.18	2.24	104	3.7%	−0.17 (−0.45 to 0.11)	2010
Williams 2010[119]	4.3	1.6	59	4.9	1.5	59	3.0%	−0.38 (−0.75 to −0.02)	2010
Hsu 2010[118]	4.38	2.16	24	5.43	1.31	21	1.6%	−0.57 (−1.17 to 0.03)	2010
Glombiewski 2010[115]	4.6	1.9	65	5.73	1.7	51	2.9%	−0.62 (−0.99 to −0.24)	2010
Morone 2011[121]	4.4	2.5	41	6.5	1.9	29	2.1%	−0.91 (−1.41 to −0.41)	2011
McBeth 2012[52]	−60.4	19.1	94	−53.5	21.3	88	3.6%	−0.34 (−0.63 to −0.05)	2012
Martin 2012[126]	7.24	2.17	54	8.22	1.62	56	2.8%	−0.51 (−0.89 to −0.13)	2012
McBeth 2012[52]	−61.3	23.6	87	−53.5	21.3	88	3.5%	−0.35 (−0.64 to −0.05)	2012
Coleman 2012[124]	−50.8	17.32	68	−44.8	18.14	68	3.2%	−0.34 (−0.67 to 0.00)	2012
Total (95% CI)			**3202**			**2836**	**100.0%**	**−0.29 (−0.38 to −0.20)**	

Heterogeneity: $\tau^2 = 0.04$; $\chi^2 = 81.07$, df = 31 ($p < 0.00001$); $I^2 = 62\%$
Test for overall effect: $z = 6.33$ ($p < 0.00001$)

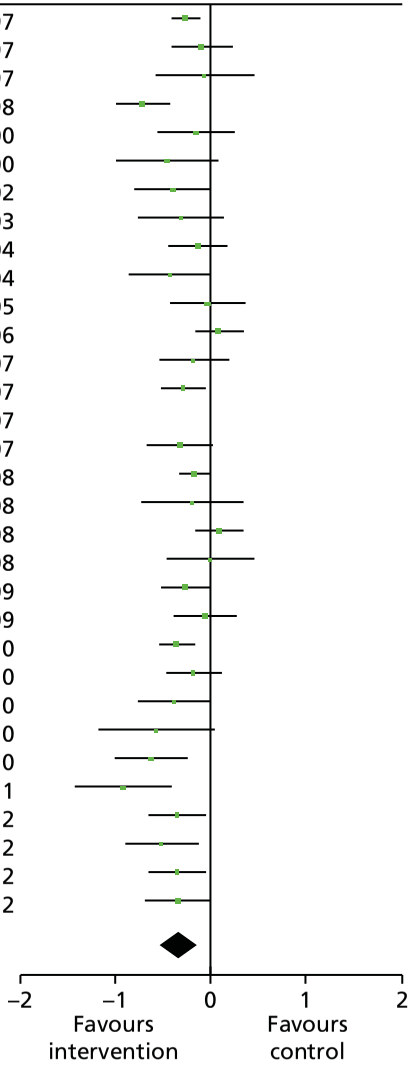

FIGURE 26 Medium-term follow-up (4–8 months).

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Study or subgroup	Intervention Mean	SD	Total	Control Mean	SD	Total	Weight	SMD Random, 95% CI	Year
Corey 1996[68]	5.3	2.9	74	6.5	2.2	64	3.5%	−0.46 (−0.80 to −0.12)	1996
Mazzuca 1997[74]	3.8	3.4	82	5.4	3.4	83	4.0%	−0.47 (−0.78 to −0.16)	1997
Haldorsen 1998[75]	4.8	2.7	293	5.2	2.9	94	5.3%	−0.15 (−0.38 to 0.09)	1998
Von Korff 1998[77]	3.2	2	112	3.8	3.1	106	4.7%	−0.23 (−0.50 to 0.04)	1998
Lonn 1999[79]	2.2	1.9	38	3.3	2.1	35	2.2%	−0.54 (−1.01 to −0.08)	1999
Haugli 2000[145]	4.4	2.3	77	5.5	2.4	44	3.1%	−0.47 (−0.84 to −0.09)	2000
Dworkin 2002[86]	2.2	1.5	48	2.9	2.4	51	2.9%	−0.34 (−0.74 to 0.05)	2002
Quilty 2003[88]	4.8	2.6	40	5.4	2.3	43	2.5%	−0.24 (−0.67 to 0.19)	2003
Hughes 2004[91]	5.4	3.7	58	5.3	4.4	32	2.5%	0.03 (−0.41 to 0.46)	2004
Mazzuca 2004[92]	12.9	4.1	104	12.7	5.1	71	4.1%	0.04 (−0.26 to 0.35)	2004
Victor 2005[97]	−51	28	72	−58	26	53	3.3%	0.26 (−0.10 to 0.61)	2005
Heuts 2005[94]	3.35	2.75	96	3.85	2.7	117	4.6%	−0.18 (−0.45 to 0.09)	2005
Núñez 2006[101]	−38.6	21.9	43	−30.3	24.6	37	2.4%	−0.35 (−0.80 to 0.09)	2006
Bernaards 2006[98]	3.1	2.2	108	3.2	2.4	101	4.6%	−0.04 (−0.31 to 0.23)	2006
Johnson 2007[54]	2.8	2.6	102	3.6	2.7	94	4.4%	−0.30 (−0.58 to −0.02)	2007
Ersek 2008[106]	5	2.1	133	4.5	2.1	123	5.0%	0.24 (−0.01 to 0.48)	2008
Lorig 2008[108]	5.8	2.5	307	6.1	2.4	344	7.1%	−0.12 (−0.28 to 0.03)	2008
Yip 2008[111]	2.2	2.2	29	2.7	2.3	24	1.8%	−0.22 (−0.76 to 0.32)	2008
Jenkinson 2009[51]	6.39	4.15	109	7.04	4.21	76	4.2%	−0.16 (−0.45 to 0.14)	2009
Kroenke 2009[113]	5.08	2.5	123	6.03	2.1	127	5.0%	−0.41 (−0.66 to −0.16)	2009
Lamb 2010[53]	44.5	26.04	392	51	23.93	195	6.6%	−0.26 (−0.43 to −0.08)	2010
Hurley 2012[103]	5.9	2.6	189	6.4	2	94	5.0%	−0.21 (−0.45 to 0.04)	2012
McBeth 2012[52]	−59.8	21.4	102	−56.2	19.9	98	4.5%	−0.17 (−0.45 to 0.10)	2012
Brosseau 2012[122]	−61.17	18.32	42	−67.44	18.32	36	2.4%	0.34 (−0.11 to 0.79)	2012
McBeth 2012[52]	−62.1	22.3	91	−56.2	19.9	98	4.3%	−0.28 (−0.57 to 0.01)	2012
Total (95% CI)			**2864**			**2240**	**100.0%**	**−0.18 (−0.26 to −0.10)**	

Heterogeneity: $\tau^2 = 0.02$; $\chi^2 = 43.80$, df = 24 ($p = 0.008$); $I^2 = 45\%$
Test for overall effect: $z = 4.49$ ($p < 0.00001$)

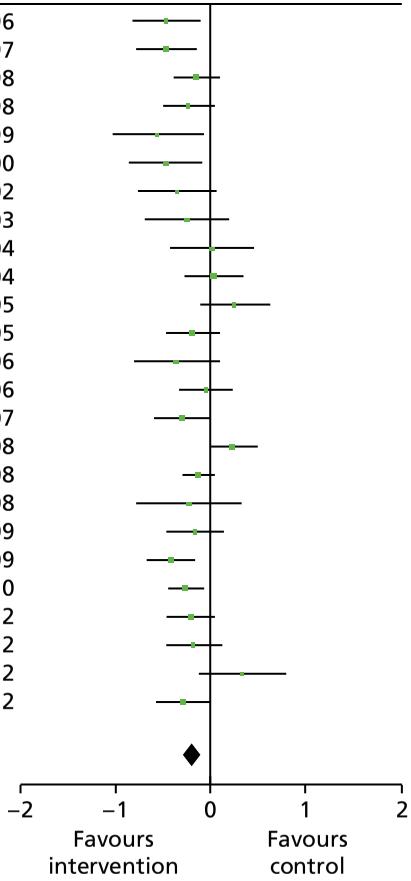

FIGURE 27 Long-term follow-up (> 8 months).

Physical function

Study or subgroup	Intervention Mean	SD	Total	Control Mean	SD	Total	Weight	SMD Random, 95% CI	Year
Keller 1997[73]	2.2	1.7	29	3.6	1.7	21	2.6%	−0.81 (−1.40 to −0.23)	1997
LeFort 1998[76]	−44.6	25.1	52	−38.3	21.6	50	3.7%	−0.27 (−0.66 to 0.12)	1998
Von Korff 1998[77]	6.6	5.6	124	7.4	6.3	121	4.6%	−0.13 (−0.38 to 0.12)	1998
Moore 2000[83]	5.4	5.8	108	6.6	6.2	105	4.4%	−0.20 (−0.47 to 0.07)	2000
Mazzuca 2004[92]	42.1	13.3	104	40.9	14.3	71	4.2%	0.09 (−0.21 to 0.39)	2004
Hughes 2004[91]	17.3	12.6	68	22.3	12.8	43	3.7%	−0.39 (−0.78 to −0.01)	2004
Victor 2005[97]	−48	25	87	−56	26	56	4.0%	0.31 (−0.02 to 0.65)	2005
Smeets 2006[102]	11.4	5.3	55	13.9	4.8	50	3.7%	−0.49 (−0.88 to −0.10)	2006
Li 2006[100]	−21.7	4.3	34	−18.3	4.3	30	3.0%	−0.78 (−1.29 to −0.27)	2006
Brattberg 2006[99]	−70.9	21.2	27	−59.3	23.3	28	2.9%	−0.51 (−1.05 to 0.03)	2006
Tavafian 2007[66]	−79.3	18.6	44	−54.4	27	47	3.4%	−1.06 (−1.50 to −0.62)	2007
Yip 2007[105]	4.6	3.8	79	4.5	3.6	70	4.1%	0.03 (−0.29 to 0.35)	2007
Alp 2007[65]	−78.6	14.2	22	−63.4	22.6	23	2.5%	−0.79 (−1.40 to −0.18)	2007
Martire 2007[104]	24.7	10.9	89	27.2	10.9	54	4.0%	−0.23 (−0.57 to 0.11)	2007
Johnson 2007[54]	7.4	5.3	110	8	5.3	113	4.5%	−0.11 (−0.38 to 0.15)	2007
Ersek 2008[106]	11.8	4.9	133	12.4	5.4	123	4.6%	−0.12 (−0.36 to 0.13)	2008
Ribeiro 2008[109]	−69.1	35.6	26	−73.3	38.9	29	2.9%	0.11 (−0.42 to 0.64)	2008
van der Hulst 2008[110]	11	5	72	13	5	79	4.1%	−0.40 (−0.72 to 0.08)	2008
Yip 2008[111]	4.5	3.7	40	4.2	4.3	37	3.4%	0.07 (−0.37 to 0.52)	2008
Lamb 2010[53]	6.5	5.27	335	7.3	5.28	179	4.9%	−0.15 (−0.33 to 0.03)	2010
Luciano 2011[120]	2.44	2.51	108	3.22	2.79	108	4.5%	−0.29 (−0.56 to −0.02)	2011
Morone 2011[121]	18	12.9	41	25.8	14.1	29	3.1%	−0.58 (−1.06 to −0.09)	2011
Kao 2012[125]	−65.1	10	114	−65.3	10	91	4.4%	0.02 (−0.26 to 0.30)	2012
Coleman 2012[124]	−54.1	11.63	69	−48.5	11.71	70	4.0%	−0.48 (−0.81 to −0.14)	2012
Carpenter 2012[123]	13.5	5.8	63	16.3	5.2	68	4.0%	−0.51 (−0.85 to −0.16)	2012
Hurley 2012[103]	20	5.9	237	25.9	6.3	128	4.7%	−0.97 (−1.20 to −0.75)	2012
Total (95% CI)			**2270**			**1823**	**100.0%**	**−0.31 (−0.44 to −0.18)**	

Heterogeneity: $\tau^2 = 0.08$; $\chi^2 = 101.71$, df = 25 ($p < 0.00001$); $I^2 = 75\%$
Test for overall effect: $z = 4.57$ ($p < 0.00001$)

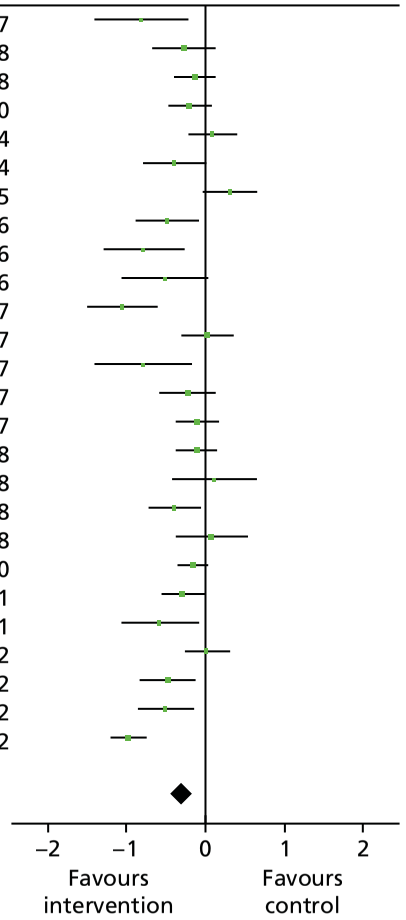

FIGURE 28 Short-term follow-up (< 4 months).

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Study or subgroup	Intervention Mean	SD	Total	Control Mean	SD	Total	Weight	SMD Random, 95% CI	Year
Fries 1997[72]	−74.9	17.4	375	−73.1	18.8	434	11.8%	−0.10 (−0.24 to 0.04)	1997
Mazzuca 1997[74]	1.2	0.6	82	1.3	0.7	83	3.3%	−0.15 (−0.46 to 0.15)	1997
Von Korff 1998[77]	5.8	5.9	119	7.2	6.5	109	4.4%	−0.23 (−0.49 to 0.04)	1998
Moore 2000[83]	5.2	6	100	6.4	6	101	4.0%	−0.20 (−0.48 to 0.08)	2000
Mannerkorpi 2000[82]	−51.9	19.5	28	−47.3	18.3	29	1.2%	−0.24 (−0.76 to 0.28)	2000
Quilty 2003[88]	26.5	13.2	40	27.5	10.7	43	1.8%	−0.08 (−0.51 to 0.35)	2003
Hughes 2004[91]	18.3	12.6	60	24.1	14.6	36	1.9%	−0.43 (−0.85 to −0.01)	2004
Cedraschi 2004[90]	−42.2	19.8	61	−43.9	19.6	68	2.7%	0.09 (−0.26 to 0.43)	2004
Mazzuca 2004[92]	43.9	14.3	104	43	16	71	3.4%	0.06 (−0.24 to 0.36)	2004
Martire 2007[104]	23.1	11.4	89	26	11.4	54	2.8%	−0.25 (−0.59 to 0.09)	2007
Alp 2007[65]	−83.8	14.5	22	−63.4	20.9	23	0.8%	−1.11 (−1.74 to −0.48)	2007
Hurley 2007[67]	21.6	11.1	229	25	11.3	113	5.6%	−0.30 (−0.53 to −0.08)	2007
Yip 2007[105]	4.7	3.7	67	4.4	3.3	53	2.5%	0.08 (−0.28 to 0.44)	2007
van der Hulst 2008[110]	10	5	68	11	5	72	2.9%	−0.20 (−0.53 to 0.13)	2008
Lorig 2008[108]	2	1.3	310	2.2	1.1	331	10.1%	−0.17 (−0.32 to −0.01)	2008
Ribeiro 2008[109]	−68.3	42.8	26	−63.8	44.1	29	1.2%	−0.10 (−0.63 to 0.43)	2008
Yip 2008[111]	4.3	3.7	39	3.6	2.8	35	1.6%	0.21 (−0.25 to 0.67)	2008
Ersek 2008[106]	11.4	5.3	133	12	5.1	123	4.9%	−0.11 (−0.36 to 0.13)	2008
Crotty 2009[112]	53.9	29.56	75	57.4	29.96	77	3.1%	−0.12 (−0.44 to 0.20)	2009
Chiauzzi 2010[114]	4.78	2.44	95	5.18	2.24	104	3.9%	−0.17 (−0.45 to 0.11)	2010
Lamb 2010[53]	6.1	5.44	352	7.4	5.34	177	8.0%	−0.24 (−0.42 to −0.06)	2010
Williams 2010[119]	−41.1	8.7	59	−38.9	8.6	59	2.4%	−0.25 (−0.62 to 0.11)	2010
Glombiewski 2010[115]	3.9	2.2	65	4.4	2	51	2.4%	−0.23 (−0.60 to 0.13)	2010
Morone 2011[121]	16.8	14.2	41	26	16.1	29	1.4%	−0.61 (−1.09 to −0.12)	2011
Coleman 2012[124]	−54.2	15.57	68	−48.5	15.57	68	2.8%	−0.36 (−0.70 to −0.03)	2012
McBeth 2012[52]	−66.6	27.4	87	−61.1	30.1	88	3.5%	−0.19 (−0.49 to 0.11)	2012
Martin 2012[126]	5.19	1.83	54	5.92	1.84	56	2.3%	−0.40 (−0.77 to −0.02)	2012
McBeth 2012[52]	−71.2	24.8	94	−61.1	30.1	88	3.6%	−0.37 (−0.66 to −0.07)	2012
Total (95% CI)			**2942**			**2604**	**100.0%**	**−0.19 (−0.25 to −0.13)**	

Heterogeneity: $\tau^2 = 0.00$; $\chi^2 = 30.35$, df = 27 ($p = 0.30$); $I^2 = 11\%$

Test for overall effect: $z = 6.29$ ($p < 0.00001$)

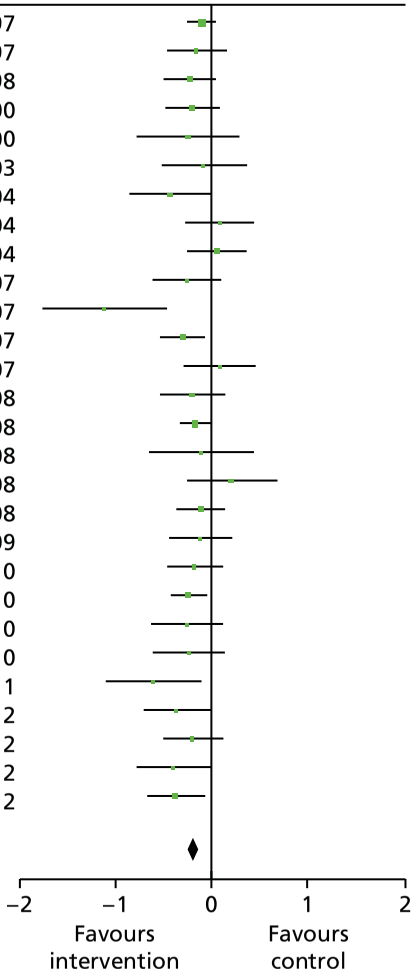

FIGURE 29 Medium-term follow-up (4–8 months).

Study or subgroup	Intervention Mean	SD	Total	Control Mean	SD	Total	Weight	SMD Random, 95% CI	Year
Mazzuca 1997[74]	1.3	0.7	82	1.3	0.7	83	5.0%	0.00 (–0.31 to 0.31)	1997
Von Korff 1998[77]	5.8	6.3	112	6.8	6.4	106	6.0%	–0.16 (–0.42 to 0.11)	1998
Moore 2000[83]	4.8	6	97	5.6	5.8	95	5.5%	–0.14 (–0.42 to 0.15)	2000
Quilty 2003[88]	29.7	11.2	40	28.3	11.3	43	2.9%	0.12 (–0.31 to 0.55)	2003
Mazzuca 2004[92]	43.7	12.2	104	44	12.6	71	5.0%	–0.02 (–0.33 to 0.28)	2004
Hughes 2004[91]	17.8	11.2	58	20.2	14.7	32	2.9%	–0.19 (–0.62 to 0.24)	2004
Heuts 2005[94]	–61.5	21.3	91	–55.4	22.8	108	5.6%	–0.27 (–0.55 to 0.01)	2005
Victor 2005[97]	–50	25	72	–52	24	53	4.0%	0.08 (–0.27 to 0.44)	2005
Núñez 2006[101]	–27.2	15.5	43	–23.5	19	37	2.8%	–0.21 (–0.65 to 0.23)	2006
Johnson 2007[54]	6.7	5.6	101	8	5.5	94	5.5%	–0.23 (–0.52 to 0.05)	2007
Ersek 2008[106]	11.6	5.7	133	11.9	5.6	123	6.6%	–0.05 (–0.30 to 0.19)	2008
Lorig 2008[108]	1.9	1.2	307	2.1	1	344	10.6%	–0.18 (–0.34 to –0.03)	2008
Yip 2008[111]	4	3.7	29	3.5	3.1	24	2.0%	0.14 (–0.40 to 0.68)	2008
Kroenke 2009[113]	14	6.5	123	17.2	5.3	127	6.4%	–0.54 (–0.79 to –0.29)	2009
Lamb 2010[53]	6.1	5.62	339	6.9	5.12	159	8.9%	–0.15 (–0.33 to 0.04)	2010
McBeth 2012[52]	–59.8	21.4	102	–56.2	19.9	98	5.7%	–0.17 (–0.45 to 0.10)	2012
McBeth 2012[52]	–62.1	22.3	91	–56.2	19.9	98	5.4%	–0.28 (–0.57 to 0.01)	2012
Brosseau 2012[122]	–63.25	25.71	42	–75.69	19.65	36	2.7%	0.53 (0.08 to 0.90)	2012
Hurley 2012[103]	22.3	8.7	189	23.8	6.3	94	6.6%	–0.19 (–0.44 to 0.06)	2012
Total (95% CI)			**2155**			**1825**	**100.0%**	**–0.14 (–0.22 to –0.06)**	

Heterogeneity: $\tau^2 = 0.01$; $\chi^2 = 26.58$, df = 18 ($p = 0.09$); $I^2 = 32\%$
Test for overall effect: $z = 3.45$ ($p = 0.0006$)

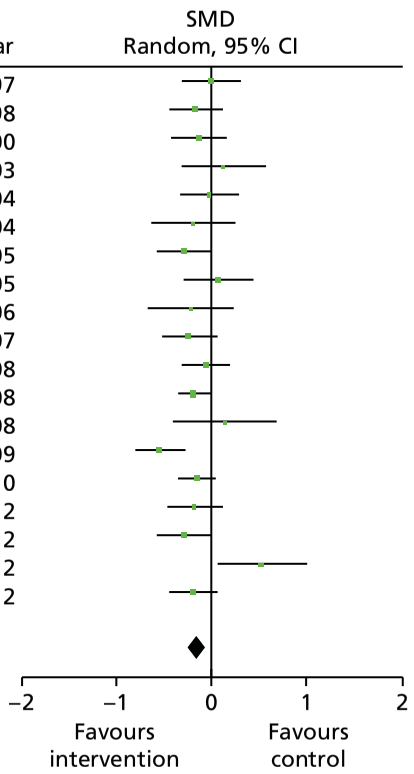

FIGURE 30 Long-term follow-up (> 8 months).

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Quality of life

Study or subgroup	Intervention Mean	SD	Total	Control Mean	SD	Total	Weight	SMD Random, 95% CI	Year
Tak 2005[96]	−28.6	3.6	35	−27.3	2.7	38	28.3%	−0.41 (−0.87 to 0.06)	2005
Johnson 2007[54]	−0.8	0.2	98	−0.7	0.3	87	71.7%	−0.40 (−0.69 to 0.10)	2007
Total (95% CI)			**133**			**125**	**100.0%**	**−0.40 (−0.65 to −0.15)**	

Heterogeneity: $\tau^2 = 0.00$; $\chi^2 = 0.00$, df = 1 ($p = 0.97$); $I^2 = 0\%$
Test for overall effect: $z = 3.16$ ($p = 0.002$)

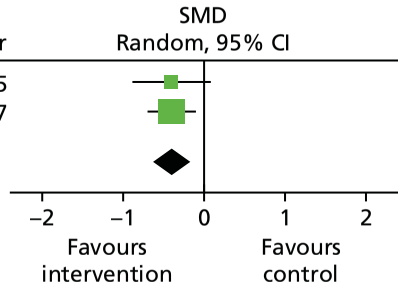

FIGURE 31 Short-term follow-up (< 4 months).

Study or subgroup	Intervention Mean	SD	Total	Control Mean	SD	Total	Weight	SMD Random, 95% CI	Year
Mannerkorpi 2000[82]	−4.8	0.9	28	−4.2	1	29	20.4%	−0.62 (−1.15 to −0.09)	2000
Hurley 2007[67]	−0.6	0.3	229	−0.7	0.3	113	28.5%	0.33 (0.11 to 0.56)	2007
Crotty 2009[112]	−0.42	0.48	75	−0.38	0.48	77	26.3%	−0.08 (−0.40 to 0.24)	2009
Hansson 2010[117]	−0.65	0.23	61	−0.55	0.32	53	24.8%	−0.36 (−0.73 to 0.01)	2010
Total (95% CI)			**393**			**272**	**100.0%**	**−0.14 (−0.55 to 0.27)**	

Heterogeneity: $\tau^2 = 0.14$; $\chi^2 = 17.32$, df = 3 ($p = 0.0006$); $I^2 = 83\%$
Test for overall effect: $z = 0.69$ ($p = 0.49$)

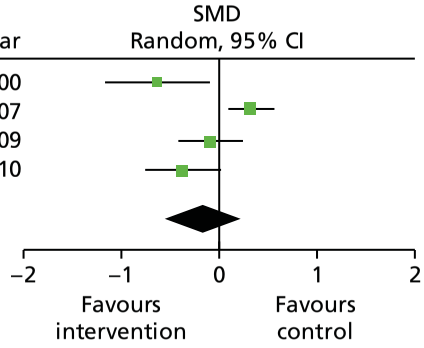

FIGURE 32 Medium-term follow-up (4–8 months).

Study or subgroup	Intervention Mean	SD	Total	Control Mean	SD	Total	Weight	SMD Random, 95% CI	Year
Johnson 2007[54]	−0.8	0.2	89	−0.7	0.2	81	100.0%	−0.50 (−0.80 to −0.19)	2007
Total (95% CI)			**89**			**81**	**100.0%**	**−0.50 (−0.80 to −0.19)**	

Heterogeneity: Not applicable
Test for overall effect: $z = 3.19$ ($p = 0.001$)

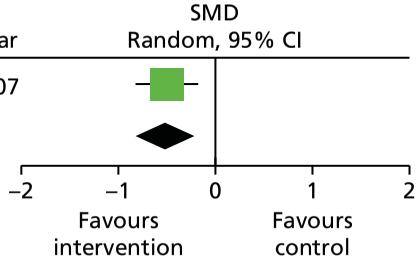

FIGURE 33 Long-term follow-up (> 8 months).

Self-efficacy

Study or subgroup	Intervention Mean	SD	Total	Control Mean	SD	Total	Weight	SMD Random, 95% CI	Year
Williams 1996[70]	−33.7	9.4	30	−26.7	9.2	31	4.5%	−0.74 (−1.26 to −0.22)	1996
LeFort 1998[76]	−59.7	18.1	52	−46.9	17.2	50	6.2%	−0.72 (−1.12 to −0.32)	1998
Haugli 2000[145]	−6.2	2	61	−6	2.1	39	6.2%	−0.10 (−0.50 to 0.30)	2000
King 2002[87]	−61.7	24.5	35	−46.1	21.3	34	4.9%	−0.67 (−1.16 to −0.19)	2002
King 2002[87]	−51.1	22	41	−46.1	21.3	34	5.4%	−0.23 (−0.68 to 0.23)	2002
Buhrman 2004[89]	−3.9	1	22	−3.1	0.9	25	3.7%	−0.83 (−1.43 to −0.23)	2004
Hughes 2004[91]	−74.7	20.6	68	−66.1	19.9	43	6.5%	−0.42 (−0.81 to −0.03)	2004
Pariser 2005[95]	−253.4	58.9	40	−248.2	59.2	45	5.8%	−0.09 (−0.51 to 0.34)	2005
Martire 2007[104]	−148.8	28	89	−138.3	28.1	54	7.4%	−0.37 (−0.71 to −0.03)	2007
Yip 2007[105]	−34.9	6.3	79	−32.8	78	70	7.7%	−0.30 (−0.62 to 0.03)	2007
Yip 2008[111]	−35.2	6.2	40	−34.1	7	37	5.5%	−0.17 (−0.61 to 0.28)	2008
Ersek 2008[106]	−6.3	2	133	−5.7	2	123	9.5%	−0.30 (−0.55 to −0.05)	2008
Lamb 2010[53]	−4.3	13.31	325	−40.6	13.51	173	11.0%	−0.18 (−0.36 to 0.01)	2010
Chiauzzi 2010[114]	5.04	2.05	95	5.44	1.94	104	8.7%	−0.20 (−0.48 to 0.08)	2010
Carpenter 2012[123]	−7	1.8	63	−5	2.3	68	6.9%	−0.96 (−1.32 to −0.60)	2012
Total (95% CI)			**1173**			**930**	**100.0%**	**−0.38 (−0.52 to −0.25)**	

Heterogeneity: $\tau^2 = 0.03$; $\chi^2 = 29.10$, df = 14 ($p = 0.01$); $I^2 = 52\%$
Test for overall effect: $z = 5.59$ ($p < 0.00001$)

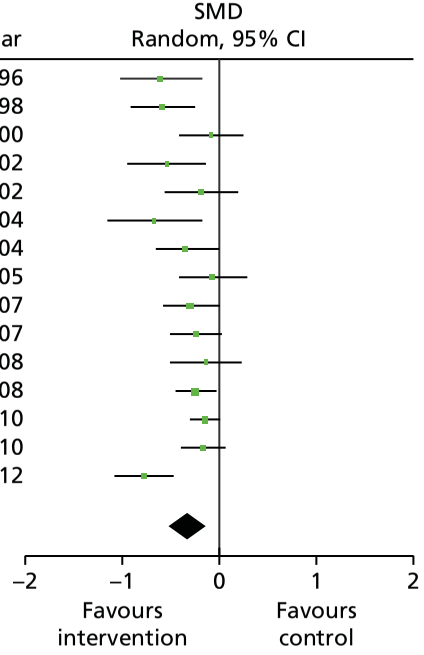

FIGURE 34 Short-term follow-up (< 4 months).

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Study or subgroup	Intervention Mean	SD	Total	Control Mean	SD	Total	Weight	SMD Random, 95% CI	Year
Mannerkorpi 2000[82]	−45.6	20.7	28	−35.5	18.7	29	2.8%	−0.51 (−1.03 to 0.02)	2000
Hughes 2004[91]	−73.5	22.6	60	−60.2	23.1	36	4.5%	−0.58 (−1.00 to −0.16)	2004
Haas 2005[93]	−60.7	24.2	44	−65.4	22.7	39	4.2%	0.20 (−0.23 to 0.63)	2005
Martire 2007[104]	−150.2	27.5	89	−139.5	27.4	54	6.8%	−0.39 (−0.73 to −0.05)	2007
Yip 2007[105]	−36.1	13.1	67	−33.3	8	53	6.1%	−0.25 (−0.61 to 0.11)	2007
Lorig 2008[108]	−5.7	2.1	310	−5.1	2.1	331	32.7%	−0.29 (−0.44 to −0.13)	2008
Yip 2008[111]	−36.8	6.2	39	−35.2	7.7	35	3.8%	−0.23 (−0.69 to −0.23)	2008
Hansson 2010[117]	−62.44	19.06	61	−58.02	21.6	53	5.8%	−0.22 (−0.59 to 0.15)	2010
Chiauzzi 2010[114]	4.78	2.44	95	5.18	2.24	104	10.2%	−0.17 (−0.45 to 0.11)	2010
Lamb 2010[53]	−43.3	13.54	333	−40.4	13.38	170	23.1%	−0.21 (−0.40 to −0.03)	2010
Total (95% CI)			**1126**			**904**	**100.0%**	**−0.25 (−0.34 to −0.17)**	

Heterogeneity: $\tau^2 = 0.00$; $\chi^2 = 8.67$, df = 9 ($p = 0.47$); $I^2 = 0\%$
Test for overall effect: $z = 5.61$ ($p < 0.00001$)

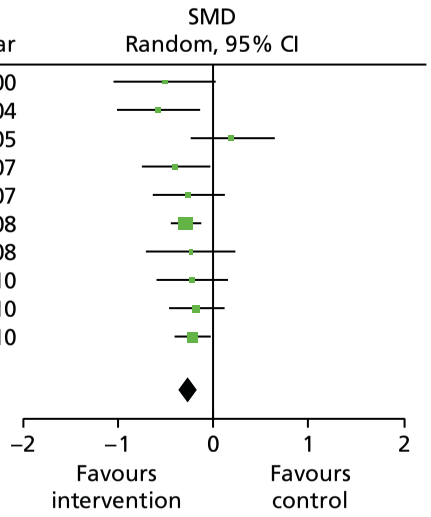

FIGURE 35 Medium term follow-up (4–8 months).

Study or subgroup	Intervention Mean	SD	Total	Control Mean	SD	Total	Weight	SMD Random, 95% CI	Year
Haugli 2000[145]	−6.6	2	77	−5.8	2.1	44	5.3%	−0.39 (−0.76 to −0.02)	2000
Oliver 2001[85]	−55.4	18.7	165	−52	19.6	170	16.0%	−0.18 (−0.39 to 0.04)	2001
Hughes 2004[91]	−74.5	19.6	58	−64	20.3	32	3.8%	−0.52 (−0.96 to −0.09)	2004
Heuts 2005[94]	−3.9	0.8	89	−3.7	0.9	106	9.2%	−0.23 (−0.52 to 0.05)	2005
Yip 2008[111]	−38.3	7	29	−35.5	7.5	24	2.5%	−0.38 (−0.93 to 0.16)	2008
Ersek 2008[106]	−6.2	2.2	133	−6	2	123	12.3%	−0.09 (−0.34 to 0.15)	2008
Lorig 2008[108]	−5.9	2.1	307	−5.3	2.1	344	30.9%	−0.29 (−0.44 to −0.13)	2008
Lamb 2010[53]	−43.2	14.08	317	−41.3	13.28	155	20.0%	−0.14 (−0.33 to −0.06)	2010
Total (95% CI)			**1175**			**998**	**100.0%**	**−0.23 (−0.31 to −0.14)**	

Heterogeneity: $\tau^2 = 0.00$; $\chi^2 = 5.52$, df = 7 ($p = 0.60$); $I^2 = 0\%$
Test for overall effect: $z = 5.18$ ($p < 0.00001$)

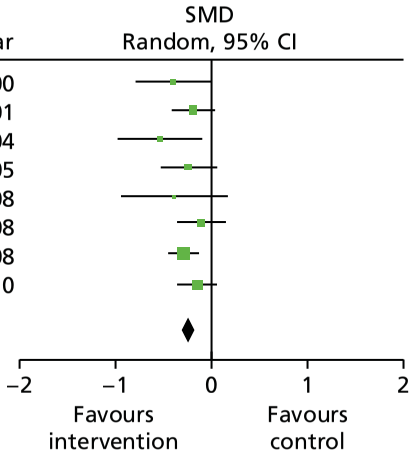

FIGURE 36 Long-term follow-up (> 8 months).

Depression

Study or subgroup	Intervention Mean	SD	Total	Control Mean	SD	Total	Weight	SMD Random, 95% CI	Year
Vlaeyen 1996[69]	13.4	5.8	42	13.2	5.8	39	4.8%	0.03 (–0.40 to 0.47)	1996
Vlaeyen 1996[69]	11.9	5.8	31	13.2	5.8	39	4.1%	–0.22 (–0.69 to 0.25)	1996
Williams 1996[70]	12.2	6.3	30	17.3	7	31	3.4%	–0.76 (–1.28 to –0.23)	1996
Keller 1997[73]	12.5	10.4	27	18.4	8.8	22	2.8%	–0.60 (–1.17 to –0.02)	1997
LeFort 1998[76]	6.8	5.6	52	7.7	4..8	50	6.1%	–0.17 (–0.56 to 0.22)	1998
Currie 2000[80]	10.3	8	28	12.3	3.4	25	3.1%	–0.31 (–0.86 to 0.23)	2000
Buhrman 2004[89]	6	4.7	22	5.4	4	25	2.8%	0.14 (–0.44 to 0.71)	2004
Pariser 2005[95]	3.5	3.7	40	4.1	3.9	45	5.0%	–0.16 (–0.58 to 0.27)	2005
Brattberg 2006[99]	6.7	4.6	27	8.7	5	28	3.2%	–0.41 (–0.94 to 0.12)	2006
Smeets 2006[102]	9.1	6.5	55	9.4	7.8	50	6.2%	–0.04 (–0.42 to 0.34)	2006
Martire 2007[104]	5.7	5.6	89	6.6	5.4	54	8.0%	–0.16 (–0.50 to 0.18)	2007
Ribeiro 2008[109]	8.4	3.8	26	8.9	5	29	3.3%	–0.11 (–0.64 to 0.42)	2008
Ersek 2008[106]	11.1	2.9	133	10.9	3.3	123	15.2%	0.06 (–0.18 to 0.31)	2008
Chiauzzi 2010[114]	10.07	11.01	95	11.72	10.4	104	11.8%	–0.15 (–0.43 to 0.12)	2010
Hurley 2012[103]	4.13	3.24	255	4.67	3.57	127	20.2%	–0.16 (–0.37 to 0.05)	2012
Total (95% CI)			**952**			**791**	**100.0%**	**–0.15 (–0.24 to –0.05)**	

Heterogeneity: $\tau^2 = 0.00$; $\chi^2 = 13.78$, df = 14 ($p = 0.47$); $I^2 = 0\%$
Test for overall effect: $z = 3.00$ ($p = 0.003$)

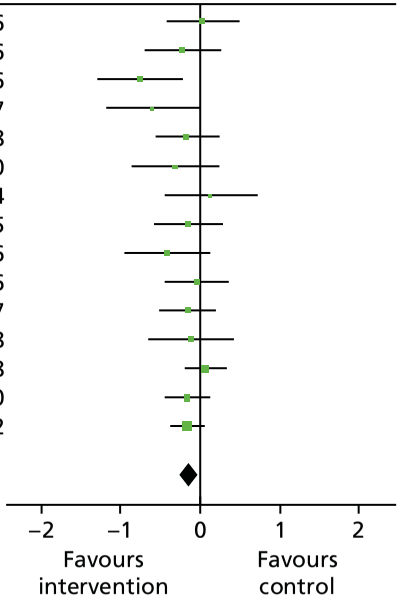

FIGURE 37 Short-term follow-up (< 4 months).

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Study or subgroup	Intervention Mean	SD	Total	Control Mean	SD	Total	Weight	SMD Random, 95% CI	Year
Mannerkorpi 2000[82]	3.2	2	28	4.9	2.4	29	4.2%	−0.76 (−1.30 to −0.22)	2000
Martire 2007[104]	5.3	5.6	89	6	5.5	54	8.2%	−0.13 (−0.46 to 0.21)	2007
Hurley 2007[67]	3.9	2.2	229	4.3	2.2	113	12.2%	−0.18 (−0.41 to 0.04)	2007
Ribeiro 2008[109]	7.4	4.7	26	8.4	4.3	29	4.3%	−0.22 (−0.75 to 0.31)	2008
Crotty 2009[112]	15.7	17.82	75	15.2	17.18	77	8.8%	0.03 (−0.29 to 0.35)	2009
Kroenke 2009[113]	1.16	0.77	123	1.64	0.7	127	11.0%	−0.65 (−0.91 to −0.40)	2009
Williams 2010[119]	16.4	11.9	59	17.5	11.5	59	7.5%	−0.09 (−0.45 to 0.27)	2010
Glombiewski 2010[115]	13.3	10	65	15.1	7.5	51	7.4%	−0.20 (−0.57 to 0.17)	2010
Chiauzzi 2010[114]	10.55	12.09	95	12.65	11.47	104	10.1%	−0.18 (−0.46 to 0.10)	2010
McBeth 2012[52]	1.7	2.9	87	2.8	3.5	88	9.4%	−0.34 (−0.64 to −0.04)	2012
McBeth 2012[52]	1.7	2.8	94	2.8	3.5	88	9.6%	−0.35 (−0.64 to −0.05)	2012
Martin 2012[126]	9.77	4.09	54	10.2	4.22	56	7.2%	−0.10 (−0.48 to 0.27)	2012
Total (95% CI)			**1024**			**875**	**100.0%**	**−0.26 (−0.38 to −0.13)**	

Heterogeneity: $\tau^2 = 0.02$; $\chi^2 = 19.15$, df = 11 ($p = 0.06$); $I^2 = 43\%$
Test for overall effect: $z = 4.02$ ($p < 0.0001$)

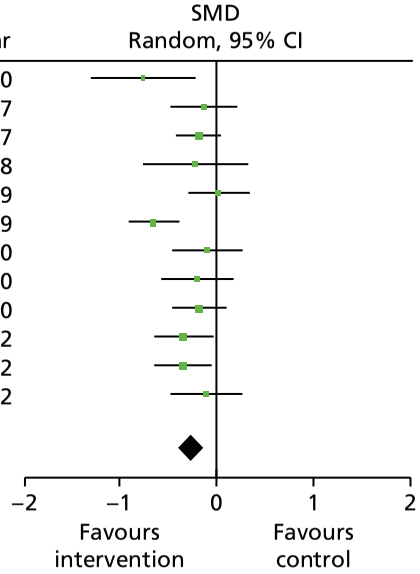

FIGURE 38 Medium-term follow-up (4–8 months).

Study or subgroup	Intervention Mean	SD	Total	Control Mean	SD	Total	Weight	SMD Random, 95% CI	Year
Oliver 2001[85]	14.2	8.9	165	15.5	10	170	16.1%	−0.14 (−0.35 to 0.08)	2001
Brattberg 2006[99]	6.7	3.8	25	7.8	4.8	25	9.0%	−0.25 (−0.81 to 0.31)	2006
Ersek 2008[106]	11.2	3.1	133	10.8	2.7	123	15.5%	0.14 (−0.11 to 0.38)	2008
Kroenke 2009[113]	1.14	0.69	123	1.69	0.74	127	15.2%	−0.77 (−1.02 to −0.51)	2009
McBeth 2012[52]	−62.1	22.3	91	−56.2	19.9	98	14.5%	−0.28 (−0.57 to 0.01)	2012
Hurley 2012[103]	3.89	3.36	159	3.86	3.22	77	14.9%	0.01 (−0.26 to 0.28)	2012
McBeth 2012[52]	−59.8	21.4	102	−56.2	19.9	98	14.8%	−0.17 (−0.45 to 0.10)	2012
Total (95% CI)			**798**			**718**	**100.0%**	**−0.20 (−0.44 to 0.03)**	

Heterogeneity: $\tau^2 = 0.07$; $\chi^2 = 28.81$, df = 6 ($p < 0.0001$); $I^2 = 79\%$
Test for overall effect: $z = 1.73$ ($p = 0.08$)

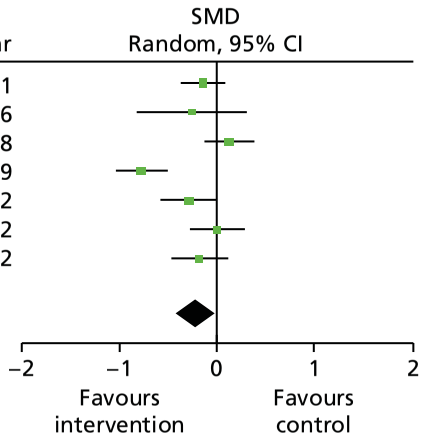

FIGURE 39 Long-term follow-up (> 8 months).

Anxiety

Study or subgroup	Intervention Mean	SD	Total	Control Mean	SD	Total	Weight	SMD Random, 95% CI	Year
Williams 1996[70]	42.3	10.6	30	45	11.7	31	9.5%	−0.24 (−0.74 to 0.27)	1996
Buhrman 2004[89]	7.2	4	22	6	3.3	25	7.5%	0.32 (−0.25 to 0.90)	2004
Li 2006[100]	51.9	10.4	34	58.2	7.8	30	9.5%	−0.67 (−1.18 to −0.17)	2006
Brattberg 2006[99]	6.6	4.6	27	8.1	4.3	28	8.6%	−0.33 (−0.86 to 0.20)	2006
Ribeiro 2008[109]	32.9	10.5	26	34.5	10.1	29	8.7%	−0.15 (−0.68 to 0.38)	2008
Chiauzzi 2010[114]	7.24	8.38	95	7.87	7.95	104	23.7%	−0.08 (−0.36 to 0.20)	2010
Hurley 2012[103]	5.58	4.17	255	6.08	4.54	127	32.5%	−0.12 (−0.33 to 0.10)	2012
Total (95% CI)			**489**			**374**	**100.0%**	**−0.16 (−0.33 to 0.01)**	

Heterogeneity: $\tau^2 = 0.01$; $\chi^2 = 7.60$, df = 6 ($p = 0.27$); $I^2 = 21\%$
Test for overall effect: $z = 1.87$ ($p = 0.06$)

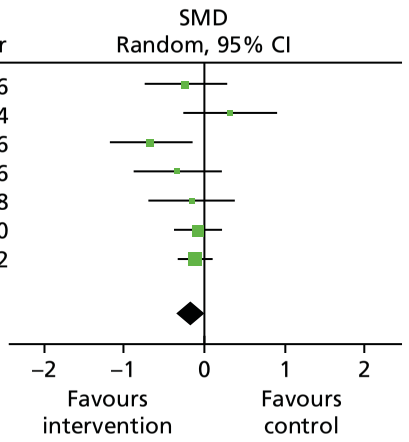

FIGURE 40 Short-term follow-up (< 4 months).

Study or subgroup	Intervention Mean	SD	Total	Control Mean	SD	Total	Weight	SMD Random, 95% CI	Year
Mannerkorpi 2000[82]	5.1	2	28	6.6	2.5	29	8.8%	−0.65 (−1.19 to −0.12)	2000
Hurley 2007[67]	5.3	2.8	229	6	2.8	113	28.4%	−0.25 (−0.48 to −0.02)	2007
Ribeiro 2008[109]	34.4	11.5	26	34.4	11.5	26	8.5%	0.00 (−0.54 to 0.54)	2008
Williams 2010[119]	18.1	7.1	59	18.4	5.9	59	16.2%	−0.05 (−0.41 to 0.32)	2010
Chiauzzi 2010[114]	7.22	8.97	95	8.32	8.57	104	22.7%	−0.13 (−0.40 to 0.15)	2010
Martin 2012[126]	13.41	4.31	54	12.75	4.55	56	15.4%	0.15 (−0.23 to 0.52)	2012
Total (95% CI)			**491**			**387**	**100.0%**	**−0.14 (−0.31 to 0.03)**	

Heterogeneity: $\tau^2 = 0.01$; $\chi^2 = 7.22$, df = 5 ($p = 0.20$); $I^2 = 31\%$
Test for overall effect: $z = 1.61$ ($p = 0.11$)

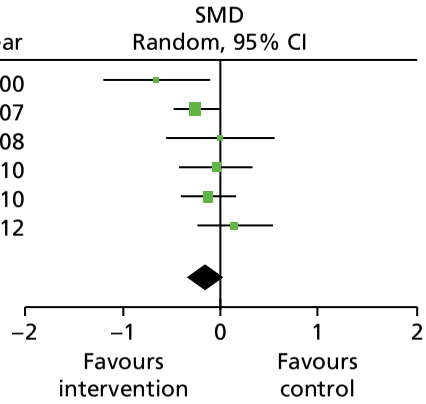

FIGURE 41 Medium-term follow up (4–8 months).

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Study or subgroup	Intervention Mean	SD	Total	Control Mean	SD	Total	Weight	SMD Random, 95% CI	Year
Brattberg 2006[99]	6.5	4.4	25	7.8	4.6	25	9.4%	−0.28 (−0.84 to 0.27)	2006
Kroenke 2009[113]	5.8	5	123	8	5.1	127	46.5%	−0.43 (−0.69 to −0.18)	2009
Hurley 2012[103]	5.06	3.84	159	6.4	2	94	44.1%	−0.41 (−0.66 to −0.15)	2012
Total (95% CI)			**307**			**246**	**100.0%**	**−0.41 (−0.58 to −0.24)**	

Heterogeneity: $\tau^2 = 0.00$; $\chi^2 = 0.23$, df = 2 ($p = 0.89$); $I^2 = 0\%$
Test for overall effect: $z = 4.68$ ($p < 0.00001$)

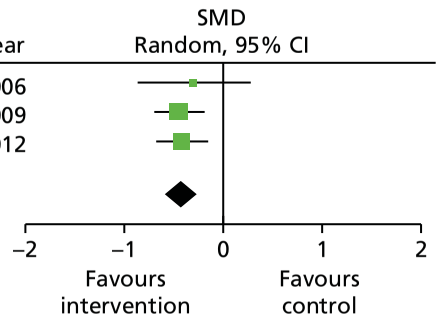

FIGURE 42 Long-term follow-up (> 8 months).

Social function

Study or subgroup	Intervention Mean	SD	Total	Control Mean	SD	Total	Weight	SMD Random, 95% CI	Year
LeFort 1998[76]	−55.1	27.5	52	−48.5	24.8	50	12.0%	−0.25 (−0.64 to 0.14)	1998
Victor 2005[97]	−74	27	87	−79	26	56	13.5%	0.19 (−0.15 to 0.52)	2005
Li 2006[100]	−6.2	2	34	−5.2	1.6	30	9.4%	−0.54 (−1.04 to −0.04)	2006
Brattberg 2006[99]	−59.3	31.3	27	−47.3	26.9	28	8.7%	−0.41 (−0.94 to 0.13)	2006
Tavafian 2007[66]	−87.7	21.6	44	−69.1	32.7	47	11.2%	−0.66 (−1.08 to −0.24)	2007
Alp 2007[65]	−98.4	6.8	22	−88.1	21.3	23	7.5%	−0.63 (−1.23 to −0.03)	2007
Ribeiro 2008[109]	−88.9	18.8	26	−88.8	21.7	29	8.8%	0.00 (−0.53 to 0.52)	2008
Kao 2012[125]	−77.7	16	114	−73.6	21.1	91	15.4%	−0.22 (−0.50 to 0.05)	2012
Coleman 2012[124]	−83	18.27	69	−72.3	17.57	70	13.4%	−0.59 (−0.93 to −0.25)	2012
Total (95% CI)			**475**			**424**	**100.0%**	**−0.33 (−0.53 to −0.12)**	

Heterogeneity: $\tau^2 = 0.05$; $\chi^2 = 17.52$, df = 8 ($p = 0.03$); $I^2 = 54\%$
Test for overall effect: $z = 3.13$ ($p = 0.002$)

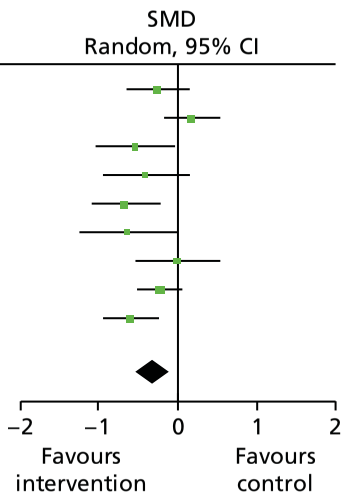

FIGURE 43 Short-term follow-up (< 4 months).

Study or subgroup	Intervention Mean	SD	Total	Control Mean	SD	Total	Weight	SMD Random, 95% CI	Year
Mannerkorpi 2000[82]	−56.7	29.2	28	−43.1	25.6	29	7.5%	−0.49 (−1.02 to 0.04)	2000
Cedraschi 2004[90]	−41.2	21.6	61	−34.2	21	68	14.9%	−0.33 (−0.67 to 0.02)	2004
Alp 2007[65]	−100	0	22	−84.2	22.9	23		Not estimable	2007
Ribeiro 2008[109]	−81.7	24	26	−87.9	18.7	29	7.4%	0.29 (−0.25 to 0.82)	2008
Crotty 2009[112]	−4.32	1.91	75	−4.25	1.89	77	17.0%	−0.04 (−0.35 to 0.28)	2009
McBeth 2012[52]	−77.2	25.1	87	−68.5	25.7	88	18.6%	−0.34 (−0.64 to −0.04)	2012
McBeth 2012[52]	−78.2	24.4	94	−68.5	25.7	88	19.1%	−0.39 (−0.68 to 0.09)	2012
Coleman 2012[124]	−77.8	21.44	68	−72.7	21.44	68	15.6%	−0.24 (−0.57 to −0.10)	2012
Total (95% CI)			**461**			**470**	**100.0%**	**−0.24 (−0.40 to −0.09)**	

Heterogeneity: $\tau^2 = 0.01$; $\chi^2 = 7.79$, df = 6 ($p = 0.25$); $I^2 = 23\%$
Test for overall effect: $z = 3.12$ ($p = 0.002$)

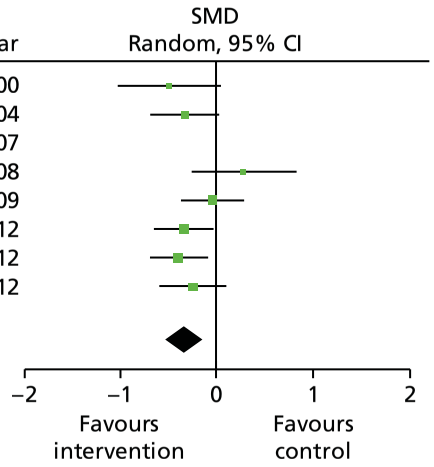

FIGURE 44 Medium-term follow-up (4–8 months).

Study or subgroup	Intervention Mean	SD	Total	Control Mean	SD	Total	Weight	SMD Random, 95% CI	Year
Victor 2005[97]	−71	29	72	−79	26	53	14.5%	0.29 (−0.07 to 0.64)	2005
Núñez 2006[101]	−61.2	30.8	43	−62.5	32.2	37	10.4%	0.04 (−0.40 to 0.48)	2006
Kroenke 2009[113]	−53.1	30.9	123	−47	28.5	127	24.1%	−0.20 (−0.45 to 0.04)	2009
McBeth 2012[52]	−77.6	25.1	102	−72.1	27.5	98	20.8%	−0.21 (−0.49 to 0.07)	2012
Brosseau 2012[122]	−84.23	19.53	42	−79.17	21.55	36	10.1%	−0.24 (−0.69 to 0.20)	2012
McBeth 2012[52]	−76.8	24.5	91	−72.1	27.5	98	20.1%	−0.18 (−0.47 to 0.11)	2012
Total (95% CI)			**473**			**449**	**100.0%**	**−0.11 (−0.26 to 0.05)**	

Heterogeneity: $\tau^2 = 0.01$; $\chi^2 = 6.80$, df = 5 ($p = 0.24$); $I^2 = 26\%$
Test for overall effect: $z = 1.36$ ($p = 0.17$)

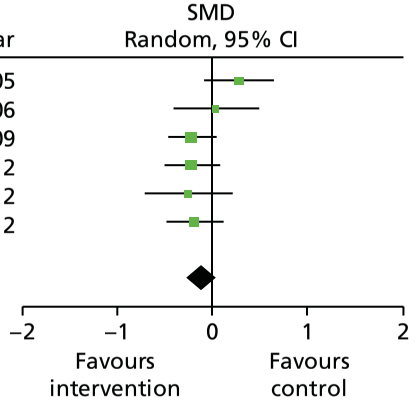

FIGURE 45 Long-term follow-up (> 8 months).

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Appendix 2 Systematic review of predictors, mediators and moderators

Search strategies for the review

MEDLINE and MEDLINE In-Process & Other Non-Indexed Citations (via Ovid)

1. PATIENT EDUCATION AS TOPIC/
2. (patient$ adj (educat$ or train$ or teach$ or instruct$ or skill$ or participat$ or involv$)).ti,ab.
3. (expert adj patient).ti,ab.
4. SELF CARE/
5. SELF EFFICACY/
6. (self adj (manage$ or care or improve$ or develop$ or help or monitor$)).ti,ab.
7. (support adj group).ti,ab.
8. ((computer or internet or web or telephone or online) adj base$).ti,ab.
9. ((group or clinician or lay or volunteer or professional or expert or advisor or consultant or peer or tutor or educator) adj (led or run)).ti,ab.
10. or/1-9
11. CHRONIC DISEASE/ and PAIN/
12. MUSCULOSKELETAL DISEASES/ and PAIN/
13. LOW BACK PAIN/ or FIBROMYALGIA/ or NECK PAIN/ or SHOULDER PAIN/ or OSTEOARTHRITIS/
14. ((chronic or persistent or long-term or wide-spread or recurrent or non-specific or musculoskeletal) adj pain).ti,ab.
15. ((lower back or knee or neck or shoulder or hip or thoracic) adj pain).ti,ab.
16. osteoarthriti$.mp. or (osteo$ adj2 pain).ti,ab.
17. (osteoarthriti$ or (osteo$ adj2 pain)).ti,ab.
18. or/11-17
19. 10 and 18

EMBASE (via Ovid)

1. PATIENT EDUCATION/
2. (patient$ adj (educat$ or train$ or teach$ or instruct$ or skill$ or participat$ or involv$)).ti,ab.
3. (expert adj patient).ti,ab.
4. SELF CARE/
5. SELF CONCEPT/
6. (self adj (manage$ or care or improve$ or develop$ or help or monitor$)).ti,ab.
7. (support adj group).ti,ab.
8. ((computer or internet or web or telephone or online) adj base$).ti,ab.
9. ((group or clinician or lay or volunteer or professional or expert or advisor or consultant or peer or tutor or educator) adj (led or run)).ti,ab.
10. or/1-9
11. CHRONIC PAIN/ and MUSCULOSKELETAL DISEASE/
12. MUSCULOSKELETAL PAIN/
13. SPINAL PAIN/ or LIMB PAIN/ or FIBROMYALGIA/ or NECK PAIN/ or SHOULDER PAIN/ or OSTEOARTHRITIS/
14. ((chronic or persistent or long-term or wide-spread or recurrent or non-specific or musculoskeletal) adj pain).ti,ab.

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15. ((lower back or knee or neck or shoulder or hip or thoracic) adj pain).ti,ab.
16. osteoarthriti$.mp. or (osteo$ adj2 pain).ti,ab. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
17. (osteoarthriti$ or (osteo$ adj2 pain)).ti,ab.
18. or/11-17
19. 10 and 18

PsycINFO (via Ovid)

1. CLIENT EDUCATION/
2. (patient$ adj (educat$ or train$ or teach$ or instruct$ or skill$ or participat$ or involv$)).ti,ab.
3. (expert adj patient).ti,ab.
4. SELF MANAGEMENT/
5. SELF EFFICACY/
6. (self adj (manage$ or care or improve$ or develop$ or help or monitor$)).ti,ab.
7. (support adj group).ti,ab.
8. ((computer or internet or web or telephone or online) adj base$).ti,ab.
9. ((group or clinician or lay or volunteer or professional or expert or advisor or consultant or peer or tutor or educator) adj (led or run)).ti,ab.
10. or/1-9
11. MUSCULOSKELETAL DISORDERS/ and CHRONIC PAIN/
12. BACK PAIN/ or FIBROMYALGIA/
13. ((chronic or persistent or long-term or wide-spread or recurrent or non-specific or musculoskeletal) adj pain).ti,ab.
14. ((lower back or neck or knee or thoracic or shoulder or hip) adj pain).ti,ab.
15. (osteoarthriti$ or (osteo$ adj2 pain)).ti,ab.
16. or/11-15
17. 10 and 16

Health Information Resources (www.nlh.nhs.uk) (Cumulative Index to Nursing and Allied Health Literature, Allied and Complementary Medicine Database)

1. (self AND (manage* OR help OR improve* OR care OR monitor* OR develop*)).ti,ab
2. (support group).ti,ab
3. (patient* AND (educat* OR train* OR teach* OR instruct* OR skill* OR participat* OR involv*)).ti,ab
4. (expert patient).ti,ab
5. ((computer OR internet OR web OR telephone OR online) AND base*).ti.ab
6. ((group OR clinician OR lay OR volunteer OR professional OR expert OR advisor OR consultant OR peer OR tutor OR educator) AND (led OR run)).ti,ab
7. OR (1-6)
8. (((chronic OR persistent OR long-term OR wide-spread OR recurrent OR non-specific OR musculoskeletal OR thoracic) AND pain)).ti,ab
9. ((lower back OR neck OR knee OR shoulder OR spinal OR shoulder OR hip) AND pain).ti,ab
10. (osteoarthriti* OR (osteo* AND pain)).ti,ab
11. OR (8-10)
12. 7 AND 11

The Cochrane Library (Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects and Cochrane Central Register of Controlled Trials)

(self NEAR/1 (manage* OR help OR improve* OR care OR monitor* OR develop*)) OR support group OR (patient* NEAR/1 (educat* OR train* OR teach* OR instruct* OR skill* OR participat* OR involv*)) OR expert patient* (computer OR internet OR web OR telephone OR online) OR ((group OR clinician OR lay OR volunteer OR professional OR expert OR advisor OR consultant OR peer OR tutor OR educator) NEAR/1 (led OR run)) in Title, Abstract or Keywords

AND

(((chronic OR persistent OR long-term OR wide-spread OR recurrent OR non-specific OR musculoskeletal OR thoracic) NEAR/1 pain)) OR ((lower back OR neck OR knee OR shoulder OR spinal OR shoulder OR hip) NEAR/1 pain) OR osteoarthrit* in Title, Abstract or Keywords

Web of Science (Social Sciences Citation Index)

((self SAME (manage* OR help OR care)) OR "support group" OR (patient* SAME (educat* OR train* OR teach* OR instruct* OR skill*)) OR "expert patient" OR ((group OR clinician OR lay OR volunteer OR professional OR expert OR peer OR tutor OR educator) SAME (led OR run))) in Topic

AND

(((chronic OR persistent OR long-term OR wide-spread OR recurrent OR non-specific OR musculoskeletal OR thoracic) SAME pain) OR ((lower back OR neck OR knee OR shoulder OR spinal OR shoulder OR hip) SAME pain) OR osteoarthri*) in Topic

Meta-regression

To examine the impact of moderator variables, we used meta-regression analyses for the outcomes listed in *Table 75*. Age and gender were chosen as the moderators to assess as these are the most frequently reported demographics and we included at least six studies that reported these moderators for each outcome. All calculations were performed using Stata 11.

TABLE 75 Number of studies for each outcome by each follow-up period

Outcome	Short term (< 4 months), *n*	Medium term (4–8 months), *n*	Long term (> 8 months), *n*
Pain intensity	26	20	18
Physical/functional capability	19	18	13
Self-efficacy	12	7	7
Depression	13	4	3
SF-36 general mental health	9	5	4
Global health status	8	7	5

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There were few observations for some outcomes when considering only one time point. In addition, modelling each time point separately gave rise to multiplicity, increasing the type 1 error substantially. Therefore, the different time points were collapsed giving one average effect size to represent the different time points per outcome. Results from the meta-regression were considered statistically significant if $p < 0.05$, marginally significant if $p < 0.10$ and non-significant if $p > 0.10$. p-values between 0.05 and 0.10 were noted in light of potential type 2 errors as a result of the limited number of effect sizes in some of our pooled effect size calculations.[32]

Table 76 presents the results for the meta-regression analyses with age and gender as moderators. Gender was not associated with effect sizes for pain intensity, physical/functional capability, self-efficacy and depression. Gender was marginally significantly associated with effect sizes for SF-36 general mental health and global health status (all $p < 0.10$), suggesting a positive association between effect sizes for these outcomes, that is, that self-management interventions favoured samples that included a lower percentage of males. Age was also marginally significantly associated with effect sizes for physical/functional capability and self-efficacy (all $p < 0.10$), suggesting a positive association between effect sizes for these outcomes, that is, that self-management interventions favoured younger samples.

Heterogeneity

Study heterogeneity was generally in the mild to moderate range ($I^2 = 13.27$–61.16%). Of the 12 comparisons, none exceeded 65%; five exceeded 50%, suggesting moderate to high levels of heterogeneity; four fell between 25% and 50%, suggesting low to moderate levels of heterogeneity; and three fell below 25%, suggesting low levels of heterogeneity and a high concordance between studies.

TABLE 76 Meta-regression analyses with age and gender as moderators

Measure	Studies, *n*	Moderator	Adjusted R^2 (%)	I^2	*t*	*p*-value	95% CI
Pain intensity	39	Gender	–12.17	47.66	–0.20	0.840	–0.0062 to 0.0051
Physical/functional capability	27	Gender	–3.57	51.84	–0.58	0.560	–0.0084 to 0.0047
Self-efficacy	17	Gender	–20.19	32.36	–0.44	0.732	–0.0115 to 0.0082
Depression	16	Gender	–18.67	24.23	–0.64	0.533	–0.0108 to 0.0058
SF-36 general mental health	11	Gender	35.48	51.60	1.86	0.095	–0.0021 to 0.0214
Global health status	14	Gender	13.50	59.06	2.12	0.065	–0.0003 to 0.0230
Pain intensity	39	Age	20.70	43.09	–1.61	0.116	–0.0114 to 0.0121
Functional capability	28	Age	28.27	45.84	1.86	0.074	–0.0008 to 0.0164
Self-efficacy	17	Age	46.56	17.32	1.98	0.060	–0.0004 to 0.0165
Depression	16	Age	42.30	13.27	1.62	0.156	–0.0025 to 0.0144
SF-36 general mental health	11	Age	35.35	53.17	1.47	0.176	–0.0082 to 0.0317
Global health status	14	Age	12.72	61.16	1.29	0.223	–0.0085 to 0.0402

Meta-regression results

```
Meta-regression                                          Number of obs  =
39
REML estimate of between-study variance                  tau2           =
.01926
% residual variation due to heterogeneity                I-squared_res  =
47.66%
Proportion of between-study variance explained           Adj R-squared  = -
12.17%
With Knapp-Hartung modification
------------------------------------------------------------------------------
   SummaryES |      Coef.   Std. Err.      t    P>|t|     [95% Conf.
Interval]
-------------+----------------------------------------------------------------
 PerCentMale |  -.0005626   .0027746    -0.20   0.840    -.0061845
.0050593
       _cons |   -.234762   .0820146    -2.86   0.007    -.4009394   -
.0685847
------------------------------------------------------------------------------
```

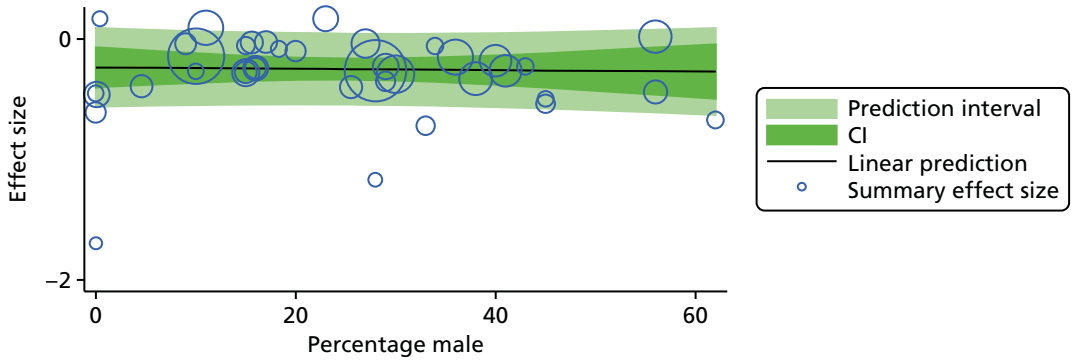

FIGURE 46 Pain intensity, sex and effect size.

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```
Meta-regression                                         Number of obs   =
39
REML estimate of between-study variance                 tau2            =
.01184
% residual variation due to heterogeneity               I-squared_res   =
43.09%
Proportion of between-study variance explained          Adj R-squared   =
20.70%
With Knapp-Hartung modification
------------------------------------------------------------------------------
--
   SummaryES |      Coef.   Std. Err.      t    P>|t|     [95% Conf.
Interval]
-------------+----------------------------------------------------------------
--
     Ave_Age |   .0053627   .0033299     1.61   0.116    -.0013842
.0121097
       _cons |  -.5428533   .1938214    -2.80   0.008    -.9355727    -
.150134
------------------------------------------------------------------------------
--
```

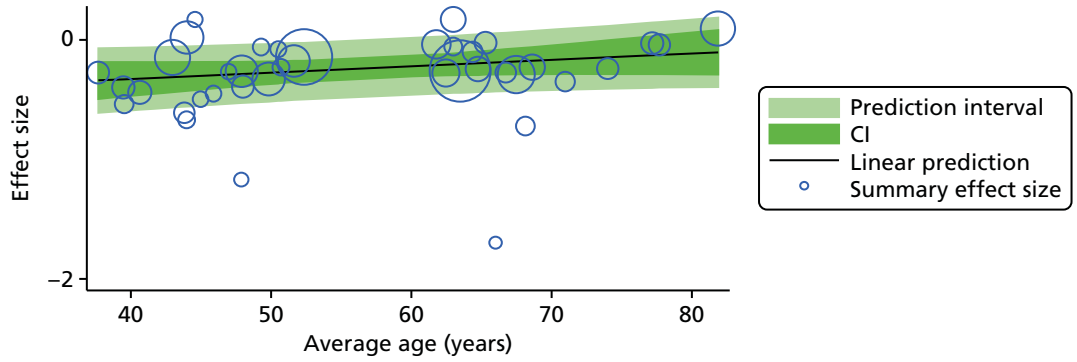

FIGURE 47 Pain intensity, age and effect size.

```
Meta-regression                                          Number of obs  =
27
REML estimate of between-study variance                  tau2           =
.02572
% residual variation due to heterogeneity                I-squared_res  =
51.84%
Proportion of between-study variance explained           Adj R-squared  =  -
3.57%
With Knapp-Hartung modification
------------------------------------------------------------------------------
--
   SummaryES |      Coef.   Std. Err.      t    P>|t|     [95% Conf.
Interval]
-------------+----------------------------------------------------------------
--
 PerCentMale |  -.0018458   .0031869    -0.58   0.568    -.0084092
.0047177
       _cons |  -.1692657   .0984468    -1.72   0.098    -.3720207
.0334894
------------------------------------------------------------------------------
--
```

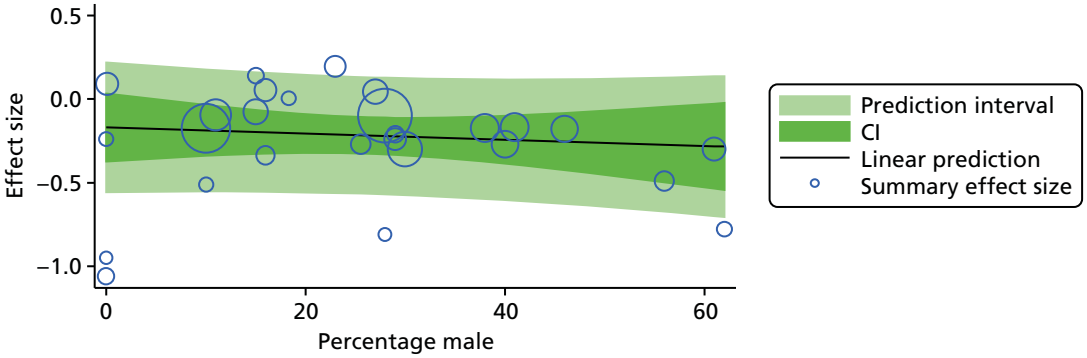

FIGURE 48 Physical/functional capability, sex and effect size.

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```
Meta-regression                                          Number of obs   =
28
REML estimate of between-study variance                  tau2            =
.01661
% residual variation due to heterogeneity                I-squared_res   =
45.84%
Proportion of between-study variance explained           Adj R-squared   =
28.27%
With Knapp-Hartung modification
------------------------------------------------------------------------------
   SummaryES |      Coef.   Std. Err.      t    P>|t|     [95% Conf.
Interval]
-------------+----------------------------------------------------------------
     Ave_Age |   .0077655   .0041768     1.86   0.074    -.0008202
.0163511
       _cons |  -.6485839   .2433096    -2.67   0.013    -1.148714   -
.1484539
------------------------------------------------------------------------------
```

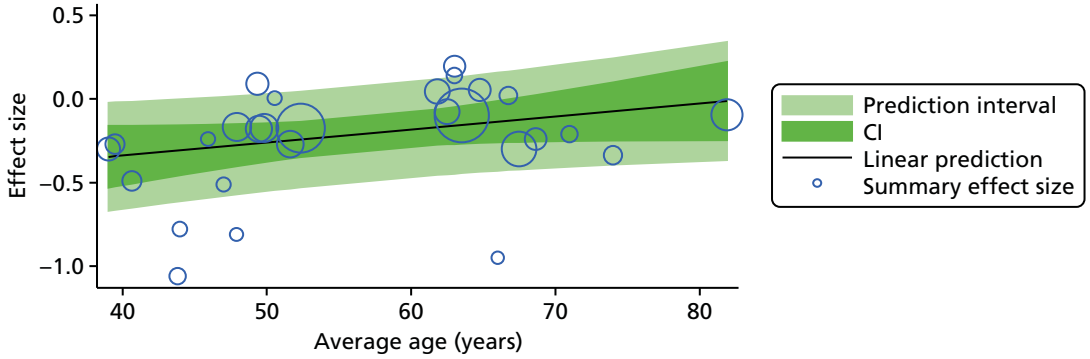

FIGURE 49 Functional capability, age and effect size.

```
metareg SummaryES PerCentM, wsse(SummarySE_ES) mm

Meta-regression                                          Number of obs   =
17
Method of moments estimate of between-study variance     tau2            =
.01428
% residual variation due to heterogeneity                I-squared_res   =
32.36%
Proportion of between-study variance explained           Adj R-squared   = -
20.19%
With Knapp-Hartung modification
------------------------------------------------------------------------------
--
   SummaryES |      Coef.   Std. Err.      t    P>|t|     [95% Conf.
Interval]
-------------+----------------------------------------------------------------
--
 PerCentMale |  -.0016184   .0046446    -0.35   0.732    -.0115181
.0082813
       _cons |  -.2908392   .0900272    -3.23   0.006    -.4827277   -
.0989507
```

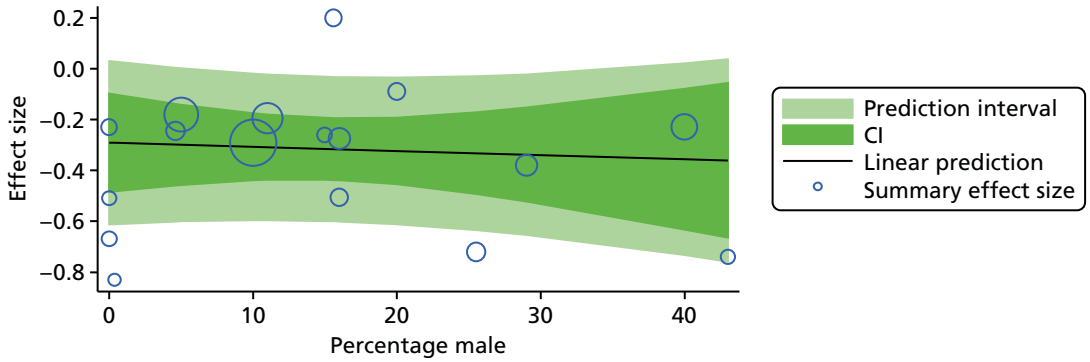

FIGURE 50 Self-efficacy, sex and effect size.

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```
metareg SummaryES Ave_Age, wsse(SummarySE_ES) mm

Meta-regression                                          Number of obs  =
17
Method of moments estimate of between-study variance     tau2           =
.006351
% residual variation due to heterogeneity                I-squared_res  =
17.32%
Proportion of between-study variance explained           Adj R-squared  =
46.56%
With Knapp-Hartung modification
------------------------------------------------------------------------------
--
   SummaryES |      Coef.   Std. Err.      t    P>|t|     [95% Conf.
Interval]
-------------+----------------------------------------------------------------
--
     Ave_Age |   .0080561   .0039525     2.04   0.060    -.0003684
.0164806
       _cons |  -.7776062   .2358272    -3.30   0.005     -1.28026   -
.2749525
------------------------------------------------------------------------------
--
```

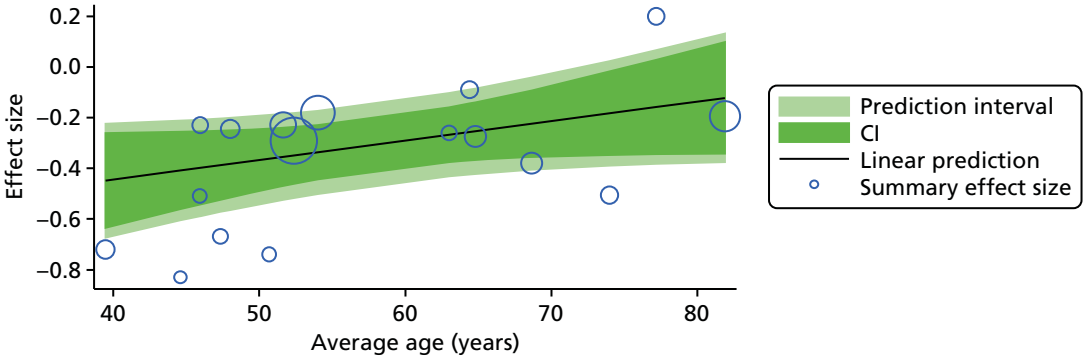

FIGURE 51 Self-efficacy, age and effect size.

```
Meta-regression                                          Number of obs   =
16
Method of moments estimate of between-study variance     tau2            =
.01211
% residual variation due to heterogeneity                I-squared_res   =
24.23%
Proportion of between-study variance explained           Adj R-squared   = -
18.67%
With Knapp-Hartung modification
------------------------------------------------------------------------------
   SummaryES |      Coef.   Std. Err.      t    P>|t|     [95% Conf.
Interval]
-------------+----------------------------------------------------------------
 PerCentMale |  -.0024756   .0038725    -0.64   0.533    -.0107813
.0058302
       _cons |   -.123099   .1006789    -1.22   0.242    -.3390337
.0928357
------------------------------------------------------------------------------
```

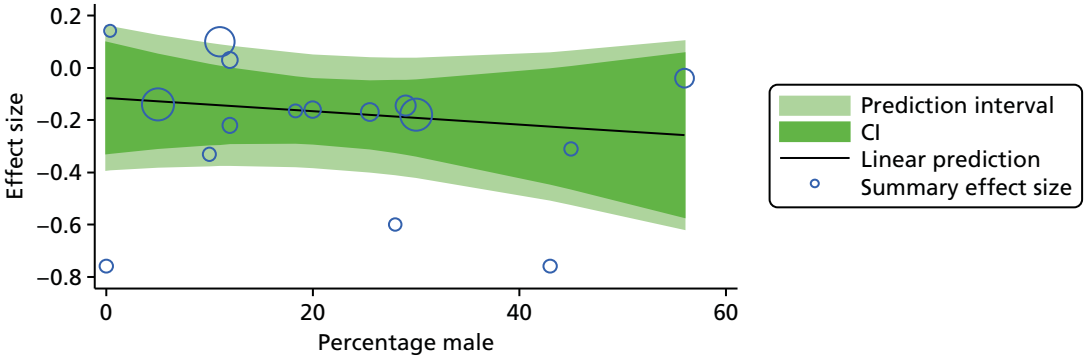

FIGURE 52 Depression, sex and effect size.

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```
Metareg SummaryES Ave_Age, wsse(SummarySE_ES) mm

Meta-regression                                          Number of obs  =
16
Method of moments estimate of between-study variance     tau2           =
.00589
% residual variation due to heterogeneity                I-squared_res  =
13.27%
Proportion of between-study variance explained           Adj R-squared  =
42.30%
With Knapp-Hartung modification
------------------------------------------------------------------------------
--
   SummaryES |      Coef.   Std. Err.      t    P>|t|     [95% Conf.
Interval]
-------------+----------------------------------------------------------------
--
Ave_Age |    .0059301   .0039536     1.50   0.156    -.0025494    .0144097
       cons |  -.5070137   .2324535    -2.18   0.047    -1.005577   -.0084506
------------------------------------------------------------------------------
```

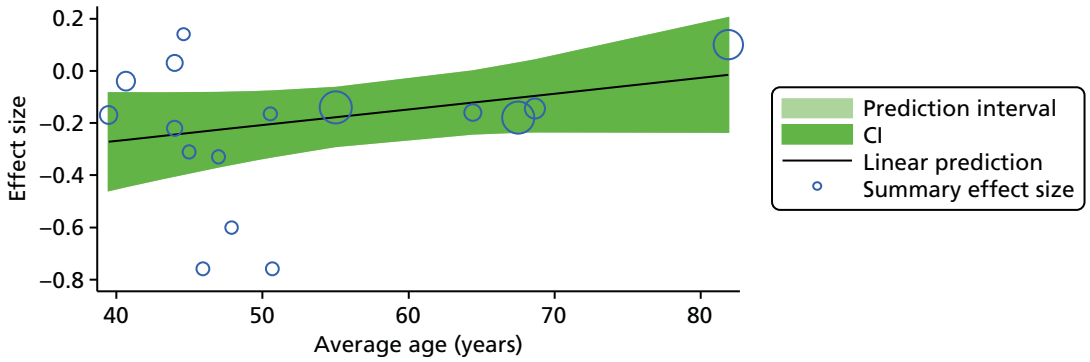

FIGURE 53 Depression, age and effect size.

```
Meta-regression                                          Number of obs   =
14
Method of moments estimate of between-study variance     tau2            =
.05279
% residual variation due to heterogeneity                I-squared_res   =
59.06%
Proportion of between-study variance explained           Adj R-squared   =
13.50%
With Knapp-Hartung modification
------------------------------------------------------------------------------
   SummaryES |      Coef.   Std. Err.      t    P>|t|     [95% Conf.
Interval]
-------------+----------------------------------------------------------------
 PerCentMale |   .0113429   .0053389     2.12   0.055    -.0002895
.0229753
       _cons |  -.4725985   .1315918    -3.59   0.004    -.7593125   -
.1858845
------------------------------------------------------------------------------
```

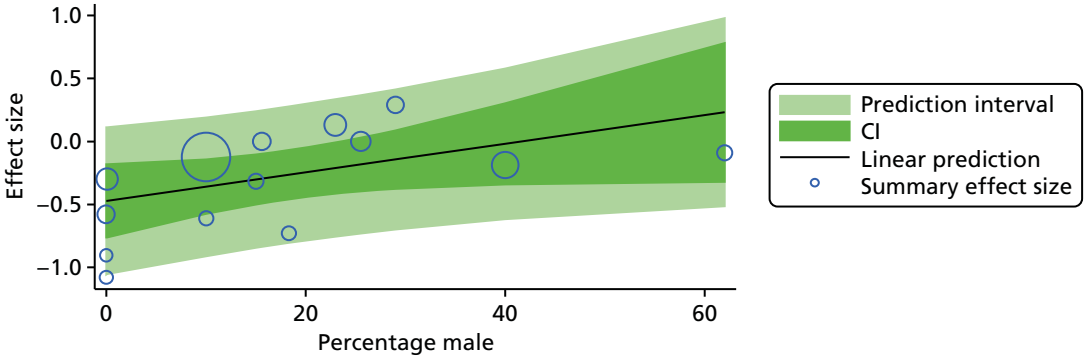

FIGURE 54 General health score, sex and effect size.

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```
Meta-regression                                         Number of obs   =
14
REML estimate of between-study variance                 tau2            =
.07286
% residual variation due to heterogeneity               I-squared_res   =
61.16%
Proportion of between-study variance explained          Adj R-squared   =
12.72%
With Knapp-Hartung modification
------------------------------------------------------------------------------
   SummaryES |      Coef.   Std. Err.      t    P>|t|     [95% Conf.
Interval]
-------------+----------------------------------------------------------------
     Ave_Age |   .0117597   .0091412     1.29   0.223    -.0081573
.0316767
       _cons |  -.9141217   .5073514    -1.80   0.097    -2.019545
.191302
------------------------------------------------------------------------------
```

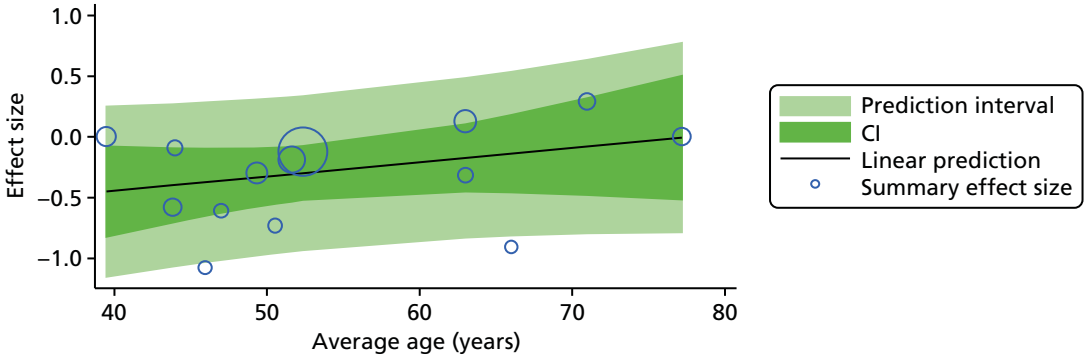

FIGURE 55 General health score, age and effect size.

```
Meta-regression                                          Number of obs  =
11
REML estimate of between-study variance                  tau2           =
.04834
% residual variation due to heterogeneity                I-squared_res  =
51.60%
Proportion of between-study variance explained           Adj R-squared  =
35.48%
With Knapp-Hartung modification
------------------------------------------------------------------------------
--
   SummaryES |      Coef.   Std. Err.      t    P>|t|     [95% Conf.
Interval]
-------------+----------------------------------------------------------------
--
 PerCentMale |   .0096764   .0051961     1.86   0.095    -.0020781
.0214309
       _cons |   -.501659   .1634463    -3.07   0.013    -.8714002   -
.1319179
------------------------------------------------------------------------------
--
```

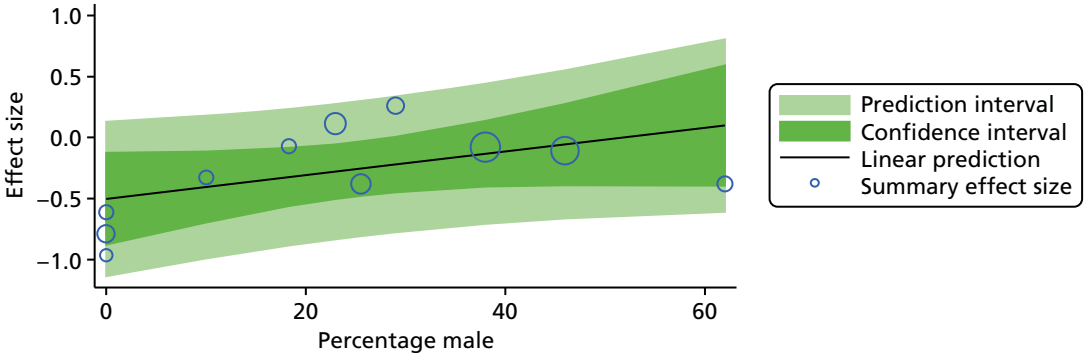

FIGURE 56 General mental health, sex and effect size.

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```
Meta-regression                                         Number of obs   =
11
REML estimate of between-study variance                 tau2            =
.04844
% residual variation due to heterogeneity               I-squared_res   =
53.17%
Proportion of between-study variance explained          Adj R-squared   =
35.35%
With Knapp-Hartung modification
------------------------------------------------------------------------------
   SummaryES |      Coef.   Std. Err.      t    P>|t|     [95% Conf.
Interval]
-------------+----------------------------------------------------------------
     Ave_Age |   .0158437   .0107781     1.47   0.176    -.0085381
.0402255
       _cons |  -1.073206   .5653125    -1.90   0.090    -2.352032
.2056193
------------------------------------------------------------------------------
```

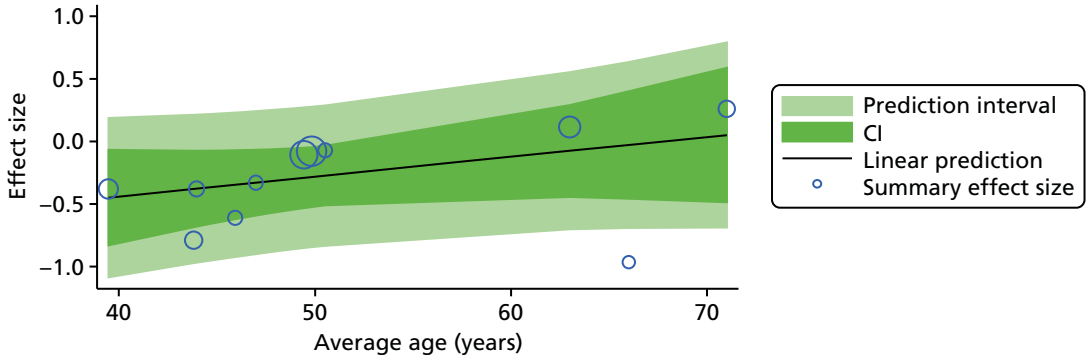

FIGURE 57 General mental health, age and effect size.

Appendix 3 Clinimetric study of outcome measures

Measures of depression in pain populations

Measure	Description	Advantages	Limitations
HADS[176]	14 items, seven for depression and seven for anxiety	Designed for people with physical problems, commonly used, short, good psychometrics, responsive in our population, cut-points exist	One item (feeling slowed down) may reflect pain
DAPOS[184]	11 items, five for depression, three for anxiety and three for positive outlook	No somatic items, designed and validated in a chronic pain population, positive outlook dimension, a potentially useful subgroup, short, psychometrics OK, responsive in our population	No cut-points, not commonly used
BDI[177]	24 items, subgrouped into affect, cognitive and somatic items	Very commonly used	Contaminated by somatic items, quite depressing, developed for psychiatric population so may lack sensitivity in less depressed groups
Zung Depression Inventory[308]	24 items, similar to the BDI	Used in pain populations, designed and validated in back pain	Contaminated by somatic items
CES-D[178]	20 items, similar to BDI in structure	Very commonly used, good psychometrics	Contaminated items
SF-36 mental health[309]	Five-item subscale, mixture of anxiety and depression items	Very common, good psychometrics, short if only those five items used	
GHQ-12[310] (psychological)	12 items, a mixed bag representing distress	Very common, properties OK, has been used in our population	Cut-points exist but they are very low: our entire population would become a case
PHQ-4[179] (depression and anxiety)	Two items on each	Short	More screening than evaluation of mood
PHQ-9[179]	Nine items	Commonly used in our population, cut-points exist	Some items may reflect pain: 'Moving or speaking so slowly that other people could have noticed or being so fidgety or restless that you've been moving around a lot more than usual'
HSCL-20[311]	20 items		Overeating, poor appetite and sexual interest items may reflect pain
EQ-5D depression and anxiety subscale[312]	Three items, simple self-classification as 'very', 'moderate' or 'not'	Essential for health economic analysis	Not sensitive, does not distinguish between depression and anxiety

DAPOS, Depression, Anxiety and Positive Outlook Scale; GHQ-12, General Health Questionnaire 12; HSCL-20, Hopkins Symptom Checklist-20.

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Self-efficacy systematic review methodology and results

Inclusion criteria

- Studies were included if they were a published in a peer-reviewed journal and included adults with pain as a result of either chronic musculoskeletal disorders or chronic disease.
- Studies that included some clinimetric or psychometric evaluation of the most commonly used self-efficacy and social support measures identified in the first search.

Search strategy for self-efficacy

1. Self-efficacy adj4 (scale or inventory or instrument or measure* or assess* or outcome).ti.ab
2. Self-efficacy.ti.ab
3. QUESTIONNAIRES/.ti.ab
4. OUTCOME ASSESSMENT (HEALTH CARE)/ti.ab
5. PSYCHOMETRICS/.ti.ab
6. 3 OR 4 OR 5
7. 2 AND 6
8. 1 OR 7
9. CHRONIC DISEASE/ and PAIN/
10. MUSCULOSKELETAL DISEASES/ and PAIN/
11. LOW BACK PAIN/ or FIBROMYALGIA/ or NECK PAIN/ or SHOULDER PAIN/ or OSTEOARTHRITIS/
12. ((chronic or persistent or long-term or wide-spread or recurrent or non-specific or ongoing or musculoskeletal) adj pain).ti,ab.
13. ((lower back or knee or neck or shoulder or hip or thoracic) adj pain).ti,ab.
14. Osteoarthriti* or (osteo* adj2 pain).ti,ab.
15. 9 OR 10 OR 11 OR 12 OR 13
16. 8 AND 14

The most commonly used measures (ASES[180] plus variants and PSEQ[313]) from the first search were selected for clinimetric evaluation. The names of these measures were used in the second search:

1. Arthritis self-efficacy or Chronic Disease self-efficacy or Stanford self-efficacy or Pain self-efficacy or PSEQ
2. Test Reliability/ or exp Psychometrics/ or exp Test Validity/ or exp Test Interpretation/
3. Validity or reliability or development or consistency or responsiveness or interpretability or psychometrics or clinimetrics
4. 1 AND (2 or 3)

Clinimetric assessment

Clinimetric assessment was planned for the most commonly used measures obtained from both of the searches. To evaluate the clinimetrics of the questionnaires a checklist was used based on criteria developed in a former study.[314] The following information was extracted: name of the questionnaire, target population, domains measured, number of scales, number of questionnaire items; number of response options, range of scores, time to administer, ease of scoring and study population used in the clinimetric study.

Validity

Content validity here refers to the degree to which the items within a research instrument represent the domain of measurement. If a positive rating for readability and comprehension of the items was given by the studied population and/or experts, content validity was achieved.

The internal consistency of a questionnaire was rated as satisfactory when the Cronbach's alpha was between 0.70 and 0.90 for each subscale (if more than one)[315] and when the dimensional structure of the questionnaire was assessed by factor analysis or principal components analysis.

Construct validity refers to when a questionnaire demonstrates its ability to identify or measure the variables or constructs that it proposes to identify or measure. Construct validity is adequate when studies show correlations of the evaluated measure with other measures that the tool is hypothesised to be related to.

For floor and ceiling effects to be judged as adequate, authors were required to provide sufficient information regarding the distribution of scores.

Reproducibility (test–retest reliability)

This was evaluated as adequate if the interclass correlation coefficient was calculated and was > 0.70. The use of Pearson correlation coefficients to estimate test–retest reliability was viewed as doubtful.

An adequate assessment of the agreement of the questionnaire was the calculation of the 95% limits of agreement (the kappa coefficient or the standard error of measurement was viewed as an adequate measure of agreement).

Responsiveness

The aim here was to measure whether or not the questionnaire can measure change in the measurement domain in association with an intervention of some kind. If change scores were calculated and these were associated with changes in a reference measure that was based on predefined hypotheses then the measurement tool was given adequate responsiveness status.

Interpretability is when information is given that describes or explains a quantitative score obtained on a test. This information could be presented in various ways: (1) the authors had presented a minimal clinically important difference (MCID); (2) a report of means and SDs of patients scores before and after treatment; (3) comparative data on the distribution of scores in relevant subgroups; (4) information on the relationship of scores to well-known functional measures or to clinical diagnosis; or (5) relating changes in disability score to patients' global ratings of the magnitude of change they have experienced. At least two of these types of information were needed for a positive rating of interpretability to be assigned.

Results

The electronic searches identified 1520 references, which were downloaded to an EndNote bibliographic database (version X2, Thomson Reuters, CA, USA). A search through the references within the EndNote database for the term 'self-efficacy' in either the title or the abstract resulted in 224 references being retained. Thirty-eight dissertations were then removed and 21 studies were excluded as they did not fit the inclusion criteria (chronic pain population including musculoskeletal conditions); in addition, three references were books and so these were removed. Of the 162 references remaining, five were discussion/review articles (data were extracted from three of these) (*Table 77*).

We identified the two most commonly used measures (> 10 articles had used these measures): (1) ASES-11 with its four variants (for chronic disease and shorter versions)[180] and (2) PSEQ-5.[313] We searched for further information on the clinimetric and psychometric properties of these instruments.

The second search identified a further 21 articles for the ASES and its variants. The authors of this test were contacted for unpublished data and we were referred to the following website for psychometric data, where a further three references were retrieved [http://patienteducation.stanford.edu/research/ (25 April 2016)]. For the PSEQ-specific search, a further 20 articles were located. Three of these articles were relevant plus an additional eight studies identified from the reference lists of these papers. A description of these questionnaires and their properties is presented in *Table 78*.

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TABLE 77 Studies that featured psychometric evaluation of self-efficacy scales

Study	Measure	Description of psychometric evaluation
Baheiraei 2005[316]	Osteoporosis Self-Efficacy Scale[317]	Psychometric properties of the Persian version of the scale
Horan 1998[317]	Osteoporosis Self-Efficacy scale[317]	Development and evaluation
Barlow 1997[183]	ASES[180]	Reliability and validity of the scale in British people with arthritis
Lomi 1992[318]	ASES, Swedish version	Evaluation of a Swedish version of the ASES with respect to factor structure and reliability on rheumatology and chronic pain patients
Mueller 2003[319]	ASES,[180,320]	Validation of the ASES short-form scale
Nicholas 2007[181]	PSEQ[313]	Reliability and validity in a low back pain population
Sarda 2007[321]	PSEQ[313]	The translation of the PSEQ into Portuguese. The Brazilian version of the PSEQ had a high concordance with the original version
Lim 2007[322]	PSEQ[313] Chinese version[322]	Reliability and construct validity
Shin 2001[323]	Exercise Self-Efficacy Scale[190]	Reliability, face validity and factor analysis of the scale in a Korean population with chronic diseases
Anderson 1995[324]	Chronic Pain Self-Efficacy Scale (CPSS)[324]	Development and initial validation in chronic pain patients
Barlow 2000[325]	Parent's Arthritis Self-Efficacy (PASE)[325] scale	Development and validation
Bursch 2006[326]	Child Self-Efficacy Scale – parent and child version[326]	Reliability and validity tested
Gard 2005[327]	Motivation for Change questionnaire[327]	Development and reliability
Gibson 1996[328]	Spinal Function Sort Measure[329]	Reliability and validity tested
Sandborgh 2008[330]	Pain Belief Screening Instrument (PBSI)[331]	Reliability and validity tested
Vlaeyen 1990[332]	Liste des Cognitions de la Douleur[332]	Development of the scale

TABLE 78 Description of the self-efficacy questionnaires

Questionnaire	Target population	Domains	Number of scales	Number of items	Number of response options	Range of scores	Time to administer	Ease of scoring	Study population(s) used in clinimetric studies
ASES-20[180]	Arthritis patients	Self-efficacy pain, self-efficacy function, self-efficacy other symptoms	Three	20	10	20–200	?	Easy	Arthritis patients
ASES-11[180]	Arthritis patients	Self-efficacy pain, self-efficacy other symptoms	Two	11	10	Self-efficacy pain 5–50; self-efficacy other 6–60	< 10 minutes	Easy	UK arthritis patients
ASES-8[180]	Arthritis patients (short version)	Self-efficacy pain, self-efficacy other symptoms	Two	8	10	8–80	< 10 minutes	Easy	Arthritis patients
CDSES-33[182]	Chronic disease patients	Self-efficacy to perform self-management behaviours, general self-efficacy, self-efficacy to achieve outcomes	10	33	10	33–330	?	Easy	Chronic disease patients
CDSES-6[333]	Chronic disease patients (short version)	Symptom control, role function, emotional functioning and communicating with physicians		6	10	6–60	< 10 minutes	Easy	Chronic disease patients
PSEQ[313]	Chronic pain?	Measures the strength and generality of patients' beliefs about how confident they are that they can do each of the 10 activities or tasks at present despite the pain that they experience		10	7	0–60	10 minutes	Easy	Chronic low back pain and heterogeneous chronic pain[181]

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Content validity

Information regarding the content validity of the questionnaires is summarised in *Table 79*.

For perceived social support there were no recommendations from the MMICS[31] or IMMPACT[30] guidelines, nor were we able to identify a systematic review comparing measures. We carried out a literature search to identify candidate instruments. Items were selected by experts and patients for four of the questionnaires (PSEQ, ASES-20, CDSES-33 and ASES-11). Readability and comprehensibility were assessed in two questionnaires (PSEQ and ASES-11). Factor analysis and principal components analysis demonstrated the presence of factors for the ASES-20 (two factors), ASES-11 (two factors) and PSEQ (one factor). Internal consistency was studied in all of the questionnaires and Cronbach's alpha ranged from 0.76 to 0.94 and was given a positive rating if it was > 0.70.[315] Therefore, content validity was most explored for the ASES-20, ASES-11 and PSEQ questionnaires. Item reduction and confirmatory factor analysis were carried out only for the ASES-20.

Construct validity

Construct validity was demonstrated for all measures except for the CDSES-6 through correlations of the self-efficacy measures with various outcomes. Hypotheses were given regarding expected relationships, although these were not always directional. Outcomes were depression, psychological well-being, reported pain and fatigue, positive effect, pain-related disability and pain coping strategies among the ASES scales. PSEQ scores were correlated with depression, anxiety, unhelpful coping strategies, pain ratings, somatic focusing and perceived capacity for work-related tasks (*Table 80*).

Information regarding floor/ceiling effects was available only for the ASES-8 and CDSES-33. Both questionnaires were free from floor effects, although minimal ceiling effects were reported for the CDSES-33. Such information was missing for the ASES-20, ASES-11, CDSES-6 and PSEQ.

Reproducibility

Test–retest reliability was assessed for three out of the six questionnaires (ASES-20, CDSES-33 and PSEQ) (*Table 81*). Time intervals between test administrations were between 9.4 days and 16.3 weeks. Test–retest correlations ranged from 0.68 to 0.88 across the three questionnaires. Pearson's product correlations were used to assess test–retest reliability; however, the ICC is thought to be a more appropriate test of retest–reliability.

TABLE 79 Content validity of the self-efficacy questionnaires

	Content validity					
Questionnaire	Item selection	Reading level examined	Item reduction	Dimensionality studied	Internal consistency	Confirmatory factor analysis
ASES-20[180]	Experts and patients[182]		Items were removed that were not related to the total score[180]	Yes, factor analysis revealed two factors (function and other symptoms)[180]	Cronbach's alpha coefficient: 0.76, 0.89 and 0.87 for pain, physical functioning and other symptoms, respectively;[180] 0.82, 0.91 and 0.92 for pain, physical functioning and other symptoms, respectively.[334] Coefficients were 0.90 for FSE, 0.87 for OSE and 0.75 for PSE,[180] McKay 1999[335]	Confirmatory factor analysis revealed three subscales. Item loadings ranged from 0.59 to 0.90 for OSE, from 0.45 to 0.82 for PSE and from 0.59 to 0.75 for FSE[180]
ASES-11[180]	Experts and patients[183]	Comprehensibility was examined among 53 people with arthritis[183]		Yes, factor analysis attempted and two factors resulted (pain and other symptoms)[325]	Cronbach's alpha coefficient: pain 0.84, 0.85 and 0.82; other symptoms 0.91, 0.90 and 0.89 for studies 2, 3 and 4, respectively.[183] A high degree of consistency was demonstrated for both subscales across all three studies through interitem correlations (range 0.26–0.86, all correlations were significant) and corrected item total correlations (range 0.48–0.84, all significant)[183]	
ASES-8[180]					Cronbach's alpha coefficient: 0.89	
CDSES-33[182]	Experts and patients[182]				Cronbach's alpha coefficient: between 0.82 and 0.89 for eight out of 10 scales[182]	
CDSES-6[333]					Cronbach's alpha coefficient: 0.91	
PSEQ[313]	Expert and patients[181]	Readability and comprehension of the scale were assessed by patients[181]		Yes, principal components analysis attempted and one factor resulted (Westmead and tertiary referral pain centre RNSH samples)[181]	Cronbach's alpha coefficient: 0.92 (Westmead sample),[336] 0.93 (RNSH sample),[181] 0.94[328] and 0.92[337]	

FCE, floor/ceiling effect; FSE, self-efficacy for phyicsal function; OSE, self-efficacy for other symptoms ; PSE, self-efficacy for pain management; RNSH, Royal North Shore Hospital.

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TABLE 80 Construct validity of the self-efficacy questionnaires

	Construct validity			
Questionnaire	Hypothesis	(Main) results	FCE	Study size, *n*
ASES-20[180]	Yes – self-efficacy will be related to present health status and future health status (non-directional)[180]	Pearson's correlations were used. Baseline FSE with baseline pain ($r = -0.29$), disability ($r = -0.76$) and depression ($r = -0.16$). Baseline OSE with baseline pain ($r = -0.27$), disability ($r = -0.25$) and depression ($r = -0.44$). Baseline PSE with baseline pain ($r = -0.29$), disability ($r = -0.21$) and depression ($r = -0.33$).[180] Predictive and concurrent validity also presented		97[180]
ASES-11[180]	Concurrent validity was examined through Pearson product–moment correlations of the ASES scores with demographic variables, physical status, psychological status and social well-being (no directional hypotheses). Congruence between specific arthritis self-efficacy and generalised self-efficacy beliefs was predicted, although the strength was expected to be modest (hypotheses). The predictive abilities of the two subscales of the ASES were examined using hierarchical regression analyses with psychological well-being (depression and positive affect) as the dependent variable (no directional hypotheses)	Greater self-efficacy results were associated with decreased physical functioning (in study 2 only). Greater self-efficacy beliefs tended to be associated with less reported pain and less fatigue. The strongest patterns of associations were in the expected directions, with correlation coefficients ranging from 0.30 to 0.61 for depression and from 0.25 to 0.63 for positive affect. Greater self-efficacy beliefs were associated with more positive psychological well-being.[183] A consistent pattern of positive association was found between the ASES other symptoms subscale and the Generalised Self-Efficacy Scale.[183] The ASES other symptoms subscale was influential in predicting depression (CES-D) and positive affect ($B = -0.31$, $p = 0.024$ and $B = -0.34$, $p = 0.006$, respectively). The ASES pain subscale was less predictive of depression or positive affect[183]		Study 1 53, study 2 145, study 3 66, study 4 80[183]

TABLE 80 Construct validity of the self-efficacy questionnaires (*continued*)

	Construct validity			
Questionnaire	Hypothesis	(Main) results	FCE	Study size, *n*
ASES-8[180]	Yes – self-efficacy will be associated negatively with pain, disability and depression (clear hypotheses)	Controlling for age, gender and pain intensity, self-efficacy was associated significantly and negatively with pain-related disability ($r = -0.29$, $p < 0.001$), pain ($r = -0.34$, $p < 0.001$) and depressive symptoms ($r = -0.49$, $p \leq 0.001$) and positively with use of pain coping strategies (particularly task persistence, $r = 0.48$, $p < 0.001$)[338]	The scale showed no floor effects (no one had the lowest possible score) and minimal (1.4%) ceiling effects in the sample[338]	140 chronic pain patients[338]
CDSES-33[182]	In addition to the item convergence and discriminant validity tests conducted as part of the multitrait scaling analyses, construct validity was examined by evaluating correlations among self-efficacy measures and their corresponding behaviour or outcome to ensure that self-efficacy was not highly correlated with the corresponding measure[180]	The absolute magnitude of the correlations between self-management behaviours and self-efficacy to perform the behaviours ranged from 0.01 to 0.41. Therefore, the scales were sufficiently independent of the actual behaviours that they can be viewed as distinct scales. The absolute magnitude of the correlations between health outcomes and self-efficacy to achieve the outcomes ranged from 0.14 to 0.75. The largest correlation was between self-efficacy for managing depression and three of the psychological scales: depressive symptoms (–0.75), CES-D depression (–0.68) and psychological well-being/distress (0.72). However, multitrait scaling analysis in which these items were included showed that the items in these scales were discriminating sufficiently well to be used as distinct measures. The remaining correlations were of less concern, falling below 0.65[182]	No floor or ceiling effects were observed[182]	1130[182]

continued

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TABLE 80 Construct validity of the self-efficacy questionnaires (*continued*)

Questionnaire	Construct validity			
	Hypothesis	(Main) results	FCE	Study size, *n*
CDSES-6[333]				
PSEQ[313]	Validity was assessed by examination of the relationships between the PSEQ and validated measures of constructs that would be expected to have different types of relationship with self-efficacy.[181] Self-efficacy theory would predict a strong relationship between the PSEQ and measures of activity[181] (expected negative correlations with higher medication usage, pain coping strategies, pain-related activities and pain beliefs). Positive correlations would be expected with coping strategies (for active approaches) and negative correlations with passive approaches (these authors had hypotheses)	Pearson product–moment correlations between the PSEQ and the other assessment measures were examined. Because of the large number of intercorrelations, only correlations of $r > 0.40$ and $p < 0.001$ were considered significant. As expected, significant negative correlations were obtained between the PSEQ and total number of medications used, impact of pain on daily life (SIP-self-rated and SIP-significant-other-rated), mood (BDI, STAI) and unhelpful coping strategies and beliefs (catastrophising subscale of the CSQ, the PBQ) (between $r = –0.45$ and $r = –0.60$). Also as expected, significant positive correlations were obtained between the PSEQ and active coping strategies measured (ignoring pain, coping self-statements and increasing activity) (between $r = –0.45$ and $r = –0.60$). In contrast, no significant correlations were found between the PSEQ and measures of pain and somatic focusing (average pain ratings, MPQ subscales or MSPQ), but all were in the negative direction, as expected[181] (all $r > 0.40$, $p > 0.001$).[311] In a study with CLBP patients there were high correlations between PSEQ scores and perceived capacity for work-related tasks, as well as another self-efficacy measure ($r = 0.78$ and 0.63, respectively)[328]		Westmead sample 103; tertiary referral pain centre (RNSH) sample 1306

CLBP, chronic low back pain; CSQ, Coping Style Questionnaire; FCE, floor/ceiling effect; FSE, self-efficacy for physical function; MPQ, McGill Pain Questionnaire; MSPQ, Modified Somatic Perception Questionnaire; OSE, self-efficacy for other symtoms; PBQ, Pain Beliefs Questionnaire; PSE, self-efficacy for pain management; RNSH, Royal North Shore Hospital; SIP, Sickness Impact Scale; STAI, State Trait Anxiety Index.

TABLE 81 Reproducibility of the self-efficacy questionnaires

Questionnaire	Test–retest reliability	Time interval between tests	Study size, *n*
ASES-20[180]	The test–retest correlations (*r*) were 0.75 for pain self-efficacy, 0.84 for functional self-efficacy, 0.68 for other self-efficacy and 0.88 for the total score[334]	16.3 weeks[334]	CLBP 59[180]
ASES-11[180]			
ASES-8[180]			
CDSES-33[182]	Test–retest reliability coefficients (*r*) ranged from 0.82 to 0.89 (method not specified)[182]	10 days[182]	
CDSES-6[333]			
PSEQ[313]	Carried out with Pearson correlations and analysis of chance. The test–retest correlation (*r*) from baseline to 3 months was 0.73 ($p < 0.001$). The mean scores for the two occasions were 26.7 (SD 12.5) and 26.9 (SD 12.6), respectively (i.e. no significant change). Interestingly, similar findings were reported by Williams 1996[70] with a waiting-list control group of mixed chronic pain patients ($n = 31$) tested 12 weeks apart. In that study, in which patients [mean age 51.1 (SD 10.7) years; mean pain duration 7.2 (SD 6.6) years; mean BDI 16.6 (SD 6.5); mean pain severity (0–100) 67.9 (SD 22.3)] continued with whatever treatments their doctors had prescribed, the mean (SD) PSEQ score at baseline was 26.3 (10.8) and at 12 weeks was 26.7 (6.2); again, no significant change was found (as well as no change in pain or disability)[313]	3 months	245 chronic pain patients

Responsiveness

The responsiveness of three of the questionnaires (ASES-20, CDSES-33 and PSEQ) was evaluated in five studies (*Table 82*). Hypotheses were provided in all of the studies except for that by Burckhardt *et al.*[339] regarding specific changes in self-efficacy in association with the intervention (note that a change was explored in Nicholas *et al.*,[313] not predicted). No data on responsiveness were found for the other three questionnaires (ASES-11, ASES-8, CDSES-6). The best way to analyse responsiveness is through receiver operating characteristic curve analysis and no study used this technique.

Interpretability

Interpretability data were provided for three of the questionnaires (ASES-20, CDSES-33 and PSEQ) across seven studies (see *Table 82*). Baseline and post means were given for all three questionnaires; however, scores for relevant subgroups were described only for the PSEQ. MCIDs were not reported for any of the self-efficacy measures and there were no interpretability data available for the other three questionnaires (ASES-11, ASES-8 and CDSES-6).

Systematic review of social support measures in chronic pain populations with clinimetric properties

Search strategy for social support measures

The main aspects of social support that we wanted to measure were (1) friends and family and (2) health-care resources.

The studies in *Table 83* either refer to psychometric evaluation of social support scales or are the actual psychometric studies.

Table 84 provides a description of additional measures of social support extracted from specialist texts. Finally, *Table 85* provides a list of measures that fitted most closely to our aims.

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TABLE 82 Responsiveness and interpretability of the self-efficacy questionnaires

	Responsiveness					Interpretability			
Questionnaire	Treatment	Time to follow-up	Hypothesis	(Main) results	Study size, *n*	Interpretability	Baseline and follow-up scores	Scores of relevant subgroups	MCID
ASES-20[180]	Patient education, Burckhardt 1994,[339]	4- to 8-month follow-up and 1 week after treatment, Burckhardt 1994,[339]	Not specifically about self-efficacy. Burckhardt 1994 programme would improve psychological functioning[339]	There were significant improvements on all three subscales of the ASES[339]	99 Burckhardt 1994[339]	? Burckhardt 1994,[339]	Pre and post-treatment means for all measures, including self-efficacy. Burckhardt 1994 baseline mean, post-treatment means and change scores[339]	?	?
ASES-11[180]									
ASES-8[180]									
CDSES-33[182]	Self-management programme[333]	12 months[333]	Programme improve self-efficacy[333]	Participation in the Chronic Disease Self-Management Programme was associated with improvements in all health behaviours (exercise, cognitive symptom management, improved communication with physician and self-efficacy)[333]	613[333]	?[333]	Baseline mean and change scores[333]	?	?
CDSES-6[333]									

	Responsiveness					Interpretability			
Questionnaire	Treatment	Time to follow-up	Hypothesis	(Main) results	Study size, *n*	Interpretability	Baseline and follow-up scores	Scores of relevant subgroups	MCID
PSEQ[313]	Cognitive–behavioural programme;[340] cognitive–behavioural programme and physiotherapy[313]	1- and 6-month follow-ups[313,340]	Yes[313,340]	There were significant improvements in all measures (physical and psychological), including self-efficacy	243;[340] 181[313]	?[313,340]	Mean and SDs provided for all measures including PSEQ	High PSEQ scores were highly associated with clinically significant functional levels and provide a useful gauge for evaluating outcomes in chronic pain patients.[181] Scores of around 40, as found in injured workers who had returned to work[341,342] were associated with return to work and maintenance of functional gains whereas lower scores after treatment (e.g. 30) tended to predict less-sustainable gains[343]	?

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TABLE 83 Psychometric studies for social support questionnaires

Study	Measure	Description of psychometric evaluation
Ahlstrom 2002[344]	Swedish version of the Ways of Coping Questionnaire; 6/66 items focus on 'seeking social support'	Some psychometrics presented
Bell 1982[345]	Social Support Index	Reliability and validity reported in Orth-Gomer and Unden[346]
Bennett 2001[347]	Social Support Survey[186]	Reliability and validity has been established in previous research
Berkman 1979[348]	Social Network Index	Reliability and validity reported in Orth-Gomer and Unden[346]
Blazer 1982[349]	Social support scale	Reliability and validity reported in Orth-Gomer and Unden[346]
Broadhead 1982[350]	Broadhead questionnaire	Reliability and validity reported in Orth-Gomer and Unden[346]
Cohen 1985[351]	Interpersonal Support Evaluation List (ISEL)	Reliability and validity reported in Orth-Gomer and Unden[346]
Da Costa 2000[352]	Short version of the Social Support Questionnaire (SSQ-6)	The SSQ-6 is psychometrically sound
Da Costa 2006[353]	Social Support Questionnaire (SSQ) Sarason 1987[354] was used to assess perceived satisfaction with social support	The SSQ is psychometrically sound and includes six items measuring satisfaction with social support, Sarason 1987[354]
Dean 1981[355]	The Instrumental-Expressive Social Support Scale	Reliability and validity reported in Orth-Gomer and Unden[346]
Doeglas 1996[356]	The Social Support Questionnaire (SSQ) consists of two parts: the Social Support Questionnaire for Transactions (SSQT) and the Social Support Questionnaire for Satisfaction with the supportive transactions (SSQS)[374]	Yes
Eakin 2007[357]	Spanish version of the CIRS[357]	Validation
Edwards 2009[358]	Social Support Survey[186]	Reliability and validity has been established in other studies. Designed for chronically ill patients
Esteve 2005[359]	The Vanderbilt Pain Management Inventory (VPMI) has a seeking social support scale (identified through confirmatory FA)	Some psychometrics presented (reliability)
Evers 2002[360]	Social functioning in the past 6 months was measured with the IRGL social functioning scales	Good reliability and validity demonstrated elsewhere
Franks 2004[361]	The Norbeck Social Support Questionnaire (NSSQ)[362]	Reliability and validity demonstrated elsewhere
Funch 1986[363]	Social support scale	Yes, reliability and validity
Garcia-Campayo 2007[364]	The Norbeck Social Support Questionnaire (NSSQ)[362]	Reliability and validity demonstrated elsewhere
Gard 2005[327]	Social support is one of the scales in the Motivation for Change Questionnaire[327]	Development and reliability
Glasgow 2005[365]	CIRS[185]	Cross validation and sensitivity to intervention data
Glasgow 2000[185]	CIRS[185]	Psychometrics presented

TABLE 83 Psychometric studies for social support questionnaires (*continued*)

Study	Measure	Description of psychometric evaluation
Henderson 1980[366]	Interview Schedule for Social Interaction (ISSI)	Reliability and validity reported earlier, in this review
Hesselink 2004[367]	Perceived social support was measured using a standardised 12-item questionnaire, the Social Support List – Interactions (SSL12-I), measuring 'everyday social support', 'social support in problem situations' and 'esteem support'[368]	Cronbach's alpha given for the present study
Marhold 2002[369]	Obstacles to Return-to-Work Questionnaire (ORQ). One scale identified by Confirmatory Factor Analysis as 'social support at work'	Development and validation
McCormack 2008[370]	Resources and Support for Self-Management (RSSM) questionnaire	Development and validation
McFarlane 1981[371]	Social relationship scale	Reliability and validity reported earlier, in this review
Raleigh 1994[372]	A scale in the Multidimensional Hope Scale measures social support	Development and evaluation; reliability and validity
Savelkoul 2001[373]	Action-directed coping and coping by seeking social support were measured with two subscales of a short version of the Utrecht Coping Questionnaire	Reliability and validity reported elsewhere as acceptable
Sherbourne 1991[186]	Social Support Survey[186]	Development and evaluation
Suurmeijer 1995[374]	The Social Support Questionnaire (SSQ) consists of two parts: the Social Support Questionnaire for Transactions (SSQT) and the Social Support Questionnaire for Satisfaction with the supportive transactions (SSQS)	Development and validation
Tan 2001[375]	The Chronic Pain Coping Inventory (CPCI) has 65 items that measure 11 coping strategies that patients might use to cope with or manage their chronic pain.[376] One of the strategies measured is seeking social support	Psychometric data available elsewhere
Tan 2005[377]	The CPCI has 65 items that measure 11 coping strategies that patients might use to cope with or manage their chronic pain.[376] One of the strategies measured is seeking social support	Further validation of the CPCI
Thompson 1993[378]	Short version of the Social Support Questionnaire (SSQ-6)	Discriminant validity. Adequate reliability and validity shown elsewhere
Trief 1995[379]	Social Support Questionnaire (SSQ)[354]	Discriminant validity
Weir 1996[380]	Social support was measured using the Duke-UNC Functional Social Support Questionnaire[381]	Validity established elsewhere
Yu 2004[382]	Psychometric testing of the Chinese version of the Medical Outcomes Study Social Support Survey (MOS-SSS-C) against the Chinese version of the Multidimensional Perceived Social Support Survey	Yes, psychometric evaluation of this scale

IRGL, Impact of Rheumatic Disease on General Health and Lifestyle.

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TABLE 84 Additional social support measures from specialist texts

Social support measure	What it measures	Length	Comments
Inventory of Socially Supportive Behaviours (ISSB)[383]	Types of support: emotional, instrumental, information appraisal and socialising	40 items/ 10 minutes	Not designed to provide information on the people who provided resources or appraisal of the support
Arizona Social Support Interview Schedule (ASSIS)[383]	Measures several aspects of social support plus identifies social support network membership and satisfaction with social support	15–20 minutes	Interview
Perceived social support from family and friends[384]	Perceived social support	8 minutes	Does not cover health care
Social Network Scale (SNS)[385]	Network size, number of people respondent feels close to, number of relatives in network and network density	8 items	Does not cover health care
Lubben Social Network Scale (LSNS)[386]	Social network scale for use with older people	10 items	Does not cover health care
Family Relationship Index[387]	Social support within the family	?	Does not cover health care
Social Support Appraisals Scale (SS-A) and Social Support Behaviours Scale (SS-B)[388,389]	Social support from family and friends	?	Does not cover health care
Network typology: the Network Assessment Instrument[390]	Classifies a person into a network type	8 questions	Those administering the questions need to go on a training course
Weinert and Brandt[391] – part 2 of the Personal Resource Questionnaire[392]	Family and social support	25-item Likert scale	Lengthy

TABLE 85 Reduced list of measures based on mapping our aims onto the test

Measure	Description	Comment
Social Support Survey[186]	21 items	Measures both social and health support ($n = 4$ studies)
Chronic Pain Coping Inventory (CPCI)[376]	8-item scale	Only measures social interaction ($n = 2$ studies)
CIRS[185]	65 items (there is a 22-item version)	Lengthy and impractical. Shorter 22-item version includes social and health support ($n = 3$)
Norbeck Social Support Questionnaire[362]	9 items	Interview
Social Support Questionnaire for Transactions (SSQT) and the Social Support Questionnaire for Satisfaction with the supportive transactions (SSQS)[374]	23 items	Interview
Social Support Questionnaire (SSQ)[354]	27 items/15 minutes (also a short-form version including 6 items)	Does not cover health care

Appendix 4 Development of the new intervention

Facilitator training course: outline

Saturday

Time	Content
09.30–10.00	Introduction to selves and course
	Evaluation sheets
	1-minute introductions
10.00–10.30	Background to project
	Group facilitation (flip chart difficulties and what to do)
	Course overview and explanations
10.30–10.45	Day 1 – the course
	Session 1: rules of group (practice facilitation, generate rules, use flip chart)
	Exercise group facilitation: ice-breaker with dominant person
10.45–11.30	Session 2: pain education DVD, discussion, DVD, discussion
Break	
11.40–11.45	Explain about lunch and tasters
11.45–12.00	Session 3: the unwanted guest (someone to read and facilitate)
12.00–12.15	Session 4: discuss pain – bad and not so bad (describe session only)
12.15–12.30	Session 5: pain cycle – show diagram. Allocate a facilitator, discuss why stay in cycle, make a list of unhelpful behaviours (including depression list). Ask group how to escape from cycle. Show diagram
12.30–12.45	Depressive symptoms – read out
Lunch	
13.30–14.00	Distress and suicidal intent (allocate facilitator and answer question). Go through protocol and questions
14.00–14.15	Session 6: posture (trainer to show)
14.15–14.30	Session 7: relaxation (allocate someone to read script)
14.30–14.35	Evaluation forms – end of day
14.35–14.45	Day 2 – session 8: reflections (allocate facilitator to carry out this)
14.45–15.15	Session 9: depressive symptom list, problems, brainstorm solutions, goals, actions (separate and carry out group discussions)
Break	
15.30–16.00	Session 10: pros and cons (allocate facilitator). Choose a con and reframe it
	Brainstorm reasons that stop us doing things

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Sunday

Time	Content
09.30–10.00	Session 11: errors in thinking
	Scenario 1: allocate person to read out statement, group to discuss it and why illogical and then try and reframe it
	Go through unhelpful thinking (based on session 10 discussions)
	Read scenario 2. Allocate facilitator to enable group to identify unhelpful ways of thinking
10.00–10.20	Session 12: carry out exercises 1 and 3 (trainer)
10.20–10.35	Session 13: allocate facilitator to brainstorm ways to manage pain
10.35–10.45	Recap posture from last session and carry out balancing (trainer)
10.45–11.00	Breathing, relaxation and visualisation (allocate)
Break	
11.10–11.20	Session 16: reflections and feedback (allocate or skip if time short)
11.20–11.30	Session 17: run through and ask questions (trainer)
11.30–12.15	Session 18: role plays (assign parts), discuss each (allocate facilitators)
12.15–12.45	Session 19: listening skills (trainer to lead)
Lunch	
13.30–13.45	Session 20: sleep (allocate facilitator to generate ideas for solving sleep problems)
13.45–14.00	Session 21: intimacy – trainer to lead and discuss with them (can leave out if they wish)
14.00–14.20	Session 22: anger and frustration (allocate facilitator to read and lead discussion and to ask: 'when was the last time you had fun?')
14.20–14.30	Session 23: stretches (trainer to lead brief run through)
14.30–14.45	Session 24: mindfulness explanation and practice relaxation
14.45–15.00	Go through buddying idea, mention contract, suggest participants buddy up
15.00–15.15	Follow-up
15.15–15.30	Evaluation of the course, debrief, choose course dates

Appendix 5 Feasibility study

Bengali questionnaire

Participant ID No.:.....

Barts and The London School of Medicine and Dentistry

COPERS
MANAGING PAIN • LIVING LIFE

কোপার্স – নাছোরবান্দা ব্যাথা আয়ত্ত করার ফলপ্রসূতা গবেষণা

মূল প্রশ্নমালা

গোপনীয়

প্রিয় অংশগ্রহণকারী,

কোপার্স কোর্সে অংশগ্রহণ করার আগে আপনার বহুদিনের ব্যাথার বর্তমান হাল-অবস্থা ও এই ব্যাথা নিয়ে কিভাবে বেঁচে আছেন তা সম্বন্ধে জানাই হচ্ছে এই প্রশ্নমালার মূল লক্ষ্য। প্রশ্নগুলি মন দিয়ে পড়বেন। যদি এই প্রশ্নমালা নিয়ে কোন সমস্যা থাকে, তবে দয়া করে ০২০ ৭৮৮২ ৭০৮৭ নম্বরে ফোন করবেন।

অধ্যায় ১ – আপনার ব্যাথা সম্বন্ধে

১) আপনার ব্যাথা কতদিন ধরে রয়েছে? (দয়া করে একটিতে দাগ (✓) দিন)

০ – ৬ মাস	৭ – ১২ মাস	১ – ২ বছর	২ – ৩ বছর	৪ – ৫ বছর	৬ – ১০ বছর	১০ বছরের বেশি
☐	☐	☐	☐	☐	☐	☐

২) ০ থেকে ১০ এর মাপকাঠিতে (যেখানে ০ মানে হচ্ছে 'ব্যাথা নেই' আর ১০ মানে হচ্ছে 'সবচেয়ে বেশি ব্যাথা'), বিগত ১ সপ্তাহ ধরে আপনার ব্যাথা কেমন?
(দয়া করে একটিতে দাগ (✓) দিন)

ব্যাথা নেই ... সবচেয়ে বেশি ব্যাথা

০	১	২	৩	৪	৫	৬	৭	৮	৯	১০
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

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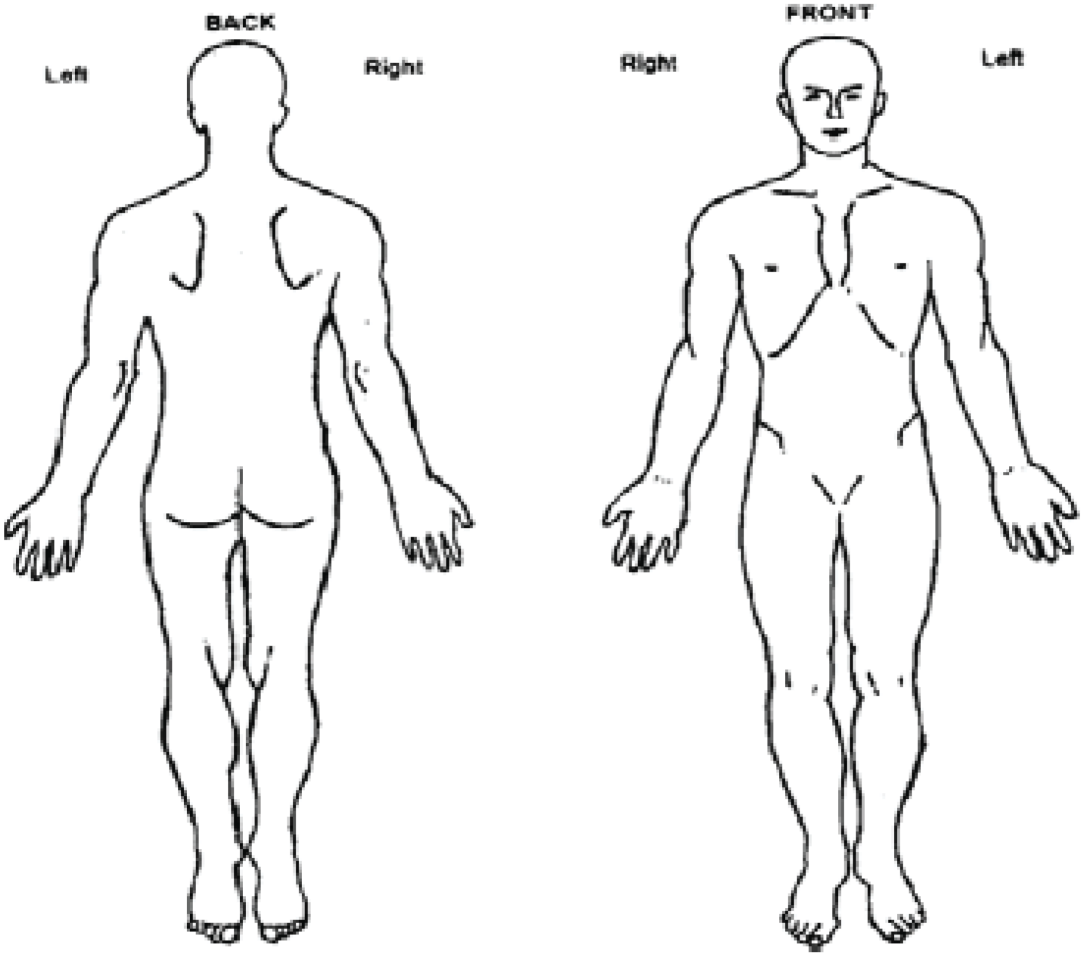
Participant ID No.:.....

অধ্যায় ১ - আপনার ব্যাথা সম্বন্ধে ...

৩) <u>বিগত ১ সপ্তাহ ধরে</u> আপনার ব্যাথা শরীরের কোন কোন জায়গায় ছিল তা দাগ দিয়ে আঁকুন।



Participant ID No.:.....

অধ্যায় ২ – জীবনের মান

আপনার ব্যাথার বর্তমান হাল-অবস্থা অনুযায়ী পর্যাপ্ত ঘরে দাগ (✓) দিন

১) সচলতা (দয়া করে একটিতে দাগ (✓) দিন)

- আমার চলাফেরা করতে কোন সমস্যা হয় না ☐
- আমার চলাফেরা করতে কিছু সমস্যা হয় ☐
- আমি বিছানায় আবদ্ধ রয়েছি ☐

২) নিজের যত্ন (দয়া করে একটিতে দাগ (✓) দিন)

- আমার নিজের যত্ন নিতে কোন সমস্যা হয় না ☐
- আমার গোসল বা কাপড় পড়তে কিছু সমস্যা হয় ☐
- আমি নিজে কাপড় পড়তে বা গোসল করতে পারি না ☐

৩) স্বাভাবিক কাজ-কর্ম যেমন চাকরি, ব্যাবসা, পড়ালেখা, ঘরের কাজ বা বিনোদন (দয়া করে একটিতে দাগ (✓) দিন)

- আমার স্বাভাবিক কাজ-কর্ম করতে কোন সমস্যা হয় না ☐
- আমার স্বাভাবিক কাজ-কর্ম করতে কিছু সমস্যা হয় ☐
- আমি স্বাভাবিক কাজ-কর্ম করতে পারি না ☐

৪) ব্যাথা/বেদনা (দয়া করে একটিতে দাগ (✓) দিন)

- আমার কোন ব্যাথা বা অস্বস্তি নেই ☐
- আমার কিছু ব্যাথা বা অস্বস্তি আছে ☐
- আমার প্রচন্ড ব্যাথা বা অস্বস্তি আছে ☐

৫) অধিক দুশ্চিন্তা / মন-বিষন্নতা (দয়া করে একটিতে দাগ (✓) দিন)

- আমি অধিক মাত্রায় দুশ্চিন্তিত বা মন-বিষন্ন নই ☐
- আমি কিছুটা অধিক মাত্রায় দুশ্চিন্তিত বা মন-বিষন্ন ☐
- আমি অতি অধিক মাত্রায় দুশ্চিন্তিত বা মন-বিষন্ন ☐

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Participant ID No.:.....

অধ্যায় ৩ - আত্ম-বিশ্বাস

দয়া করে ইঙ্গিত করুন যে বর্তমানে আপনার ব্যাথা থাকা সত্যেও আপনি নিচের সব কাজ-কর্ম গুলো কতটুকু বিশ্বাস বা আস্থার সাথে করতে পারেন। ০ মানে হলো একদমই আস্থা নেই আর ৬ মানে হলো পুরোপুরি আস্থা রয়েছে। মনে রাখবেন, এই প্রশ্নগুলোর মাধ্যমে আমরা আপনাকে জিজ্ঞেস করছিনা যে আপনি এই কাজ-কর্মগুলো করতে পারছেন কি না, বরং বর্তমানে আপনি কতটুকু আত্ম-বিশ্বাস এর সাথে তা করতে পারছেন।

১) ব্যাথা থাকা সত্যেও আমি কাজ-কর্ম করতে পারছি (দয়া করে একটিতে দাগ (✓) দিন)

আত্ম-বিশ্বাস একদম নেই — **পুরোপুরি আত্ম-বিশ্বাসী**

০	১	২	৩	৪	৫	৬
☐	☐	☐	☐	☐	☐	☐

২) ব্যাথা থাকা সত্যেও আমি ঘরের কাজ করতে পারছি (দয়া করে একটিতে দাগ (✓) দিন)

আত্ম-বিশ্বাস একদম নেই — **পুরোপুরি আত্ম-বিশ্বাসী**

০	১	২	৩	৪	৫	৬
☐	☐	☐	☐	☐	☐	☐

৩) ব্যাথা থাকা সত্যেও আমি আমার পরিবার-পরিজন বা বন্ধু-বান্ধবদের সাথে সামাজিকতা করতে পারছি (দয়া করে একটিতে দাগ (✓) দিন)

আত্ম-বিশ্বাস একদম নেই — **পুরোপুরি আত্ম-বিশ্বাসী**

০	১	২	৩	৪	৫	৬
☐	☐	☐	☐	☐	☐	☐

৪) অনেক পরিস্থিতিতে আমি আমার ব্যাথাকে আয়ত্ত করতে পারছি (দয়া করে একটিতে দাগ (✓) দিন)

আত্ম-বিশ্বাস একদম নেই — **পুরোপুরি আত্ম-বিশ্বাসী**

০	১	২	৩	৪	৫	৬
☐	☐	☐	☐	☐	☐	☐

৫) ব্যাথা থাকা সত্যেও আমি কাজ করতে পারছি (কাজ বলতে ঘরের কাজ অথবা বেতনধারী কাজ হতে পারে) (দয়া করে একটিতে দাগ (✓) দিন)

আত্ম-বিশ্বাস একদম নেই — **পুরোপুরি আত্ম-বিশ্বাসী**

০	১	২	৩	৪	৫	৬
☐	☐	☐	☐	☐	☐	☐

Participant ID No.:.....

অধ্যায় ৩ – আত্ম-বিশ্বাস ...

৬) ব্যাথা থাকা সত্যেও আমি অনেক কিছুই করতে পারছি, যেমন শখের কাজ বা বিনোদনমূলক কাজ (দয়া করে একটিতে দাগ (✓) দিন)

আত্ম-বিশ্বাস একদম নেই						পুরোপুরি আত্ম-বিশ্বাসী
০	১	২	৩	৪	৫	৬
☐	☐	☐	☐	☐	☐	☐

৭) আমি ঔষধ ছাড়াই নিজের ব্যাথা সামাল দিতে পারছি (দয়া করে একটিতে দাগ (✓) দিন)

আত্ম-বিশ্বাস একদম নেই						পুরোপুরি আত্ম-বিশ্বাসী
০	১	২	৩	৪	৫	৬
☐	☐	☐	☐	☐	☐	☐

৮) ব্যাথা থাকা সত্যেও আমি আমার জীবনের মূল লক্ষ্যগুলি অর্জন করতে পারছি
(দয়া করে একটিতে দাগ (✓) দিন)

আত্ম-বিশ্বাস একদম নেই						পুরোপুরি আত্ম-বিশ্বাসী
০	১	২	৩	৪	৫	৬
☐	☐	☐	☐	☐	☐	☐

৯) ব্যাথা থাকা সত্যেও আমি সাধারণ জীবন যাপন করতে পারছি (দয়া করে একটিতে দাগ (✓) দিন)

আত্ম-বিশ্বাস একদম নেই						পুরোপুরি আত্ম-বিশ্বাসী
০	১	২	৩	৪	৫	৬
☐	☐	☐	☐	☐	☐	☐

১০) ব্যাথা থাকা সত্যেও আমি আস্তে আস্তে কর্মঠ হচ্ছি (দয়া করে একটিতে দাগ (✓) দিন)

আত্ম-বিশ্বাস একদম নেই						পুরোপুরি আত্ম-বিশ্বাসী
০	১	২	৩	৪	৫	৬
☐	☐	☐	☐	☐	☐	☐

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Participant ID No.:.....

অধ্যায় ৪ - মন-মেজাজ

নিচের প্রশ্নগুলি পড়ুন এবং <u>বিগত ১ সপ্তাহ ধরে</u> আপনার অনুভূতি কেমন ছিল তা অনুযায়ী একটিতে দাগ দিন।

উত্তর দেওয়ার সময় বেশি সময় নিবেন না। যেই উত্তর আপনার মনের মধ্যে সবচেয়ে আগে আসে সেটাই সম্ভবত আপনার জন্য প্রযোজ্য।

১) আমি উত্তেজনা বা মানসিক চাপ অনুভব করি (দয়া করে একটিতে দাগ (✓) দিন)		২) আমি আগের মত এখনও সব কিছু উপভোগ করতে পারে (দয়া করে একটিতে দাগ (✓) দিন)	
বেশির ভাগ সময়	☐	এখনও তাই	☐
অনেক সময়	☐	এতটা না	☐
মাঝে মধ্যে	☐	একটু একটু	☐
একদমই না	☐	একদমই না	☐

৩) আমি এক ধরনের ভয় অনুভব করি, যেন আমার খারাপ কিছু একটা হবে (দয়া করে একটিতে দাগ (✓) দিন)		৪) আমি হাসতে পারি এবং জীবনের মজার দিকগুলো উপভোগ করতে পারি (দয়া করে একটিতে দাগ (✓) দিন)	
অবশ্যই হ্যা, এবং খুব বাজে ভাবে	☐	আগে যেমন এখনও তাই	☐
হ্যা, তবে খুব বাজে ভাবে না	☐	এখন এতটা না	☐
একটু তবে তা আমাকে দুশ্চিন্তিত করে না	☐	অবশ্যই এখন এতটা না	☐
একদমই না	☐	একদমই না	☐

৫) আমার মনে দুশ্চিন্তা আসে (দয়া করে একটিতে দাগ (✓) দিন)		৬) আমি আনন্দ উপভোগ করি (দয়া করে একটিতে দাগ (✓) দিন)	
বেশির ভাগ সময়	☐	একদমই না	☐
অনেক সময়	☐	প্রায় সময় না	☐
মাঝে মধ্যে	☐	কোন কোন সময়	☐
খুবই কম	☐	প্রায় সময়	☐

Participant ID No.:.....

অধ্যায় ৪ - মন-মেজাজ...

৭) আমি আরাম করে বসতে পারি এবং শিথিল হতে পারি (দয়া করে একটিতে দাগ (✓) দিন)		৮) আমি আগের তুলনায় নিস্তেজ হয়ে গেছি (দয়া করে একটিতে দাগ (✓) দিন)	
অবশ্যই	☐	প্রায় সব সময়	☐
সাধারণত	☐	অনেক সময়	☐
প্রায় সময় না	☐	মাঝে মধ্যে	☐
একদমই না	☐	একদমই না	☐

৯) আমার ভিতর থেকে ভয় অনুভব করি (দয়া করে একটিতে দাগ (✓) দিন)		১০) আমি নিজের যত্নের প্রতি উদাসিন (দয়া করে একটিতে দাগ (✓) দিন)	
একদমই না	☐	অবশ্যই	☐
মাঝে মধ্যে	☐	দরকারমত যত্ন আমি নেই না	☐
অনেক সময়	☐	দরকারমত যত্ন বোধ হয় আমি নেই না	☐
প্রায় সময়	☐	আগের মত যত্ন আমি নেই	☐

১১) আমি অস্থির অনুভব করি (দয়া করে একটিতে দাগ (✓) দিন)		১২) আমি আশা ও আনন্দ নিয়ে অনেক কিছু করি (দয়া করে একটিতে দাগ (✓) দিন)	
অবশ্যই অনেক বেশি	☐	ঠিক আগের মতই	☐
খুব বেশি	☐	আগের চেয়ে কম	☐
খুব বেশি না	☐	আগের চেয়ে অবশ্যই বেশ কম	☐
একদমই না	☐	একদমই না	☐

১৩) আমি মাঝে মধ্যে হঠাৎ করে আতঙ্কিত অনুভব করি (দয়া করে একটিতে দাগ (✓) দিন)		১৪) আমি একটি ভাল বই, রেডিও বা টিভির অনুষ্ঠান উপভোগ করতে পারি (দয়া করে একটিতে দাগ (✓) দিন)	
অবশ্যই অনেক সময়	☐	প্রায়	☐
প্রায় সময়	☐	মাঝে মধ্যে	☐
প্রায় সময় না	☐	প্রায় না	☐
একদমই না	☐	একদমই না	☐

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Participant ID No.:.....

অধ্যায় ৫ – আয়ত্ত করা

নিচে কয়েকটি বাক্য আছে। প্রতিটি বাক্যের সত্যতা মূল্যায়ন করুন এবং সেই অনুসারে একটি ঘরে দাগ দিয়ে তা উল্লেখ করুন। ০ মানে 'কখনই সত্য না' আর ৬ মানে 'সব সময় সত্য'।

১) আমার ব্যাথার মাত্রা যতই থাকুক না কেন, আমি জীবন-যাপন করে যাচ্ছি
(দয়া করে একটিতে দাগ (✓) দিন)

কখনই সত্য না						সব সময় সত্য
০	১	২	৩	৪	৫	৬
☐	☐	☐	☐	☐	☐	☐

২) আমার বহুদিনের ব্যাথা থাকা সত্যেও আমি জীবন ভালো যাচ্ছে (দয়া করে একটিতে দাগ (✓) দিন)

কখনই সত্য না						সব সময় সত্য
০	১	২	৩	৪	৫	৬
☐	☐	☐	☐	☐	☐	☐

৩) ব্যাথা অনুভব করাটাই স্বাভাবিক (দয়া করে একটিতে দাগ (✓) দিন)

কখনই সত্য না						সব সময় সত্য
০	১	২	৩	৪	৫	৬
☐	☐	☐	☐	☐	☐	☐

৪) আমার ব্যাথা নিয়ন্ত্রণের জন্য আমি আনন্দের সাথে আমার জীবনের মূল্যবান কিছু জিনিস কুরবানী করতে রাজী আছি (দয়া করে একটিতে দাগ (✓) দিন)

কখনই সত্য না						সব সময় সত্য
০	১	২	৩	৪	৫	৬
☐	☐	☐	☐	☐	☐	☐

৫) আমার জীবন ভালোভাবে যাপন করার জন্যে আমার ব্যাথা নিয়ন্ত্রণ করা জরুরী নয়
(দয়া করে একটিতে দাগ (✓) দিন)

কখনই সত্য না						সব সময় সত্য
০	১	২	৩	৪	৫	৬
☐	☐	☐	☐	☐	☐	☐

৬) আমার বহুদিনের ব্যাথা থাকা সত্যেও আমি সাধারণ জীবন যাপন করছি, যদিও কিছু পরিবর্তন ঘটেছে (দয়া করে একটিতে দাগ (✓) দিন)

কখনই সত্য না						সব সময় সত্য
০	১	২	৩	৪	৫	৬
☐	☐	☐	☐	☐	☐	☐

Participant ID No.:.....

অধ্যায় ৫ – আয়ত্ত করা...

৭) আমার ব্যাথা নিয়ন্ত্রণের জন্য মনোযোগী হওয়া প্রয়োজন (দয়া করে একটিতে দাগ (✓) দিন)

কখনই সত্য না						সব সময় সত্য
০	১	২	৩	৪	৫	৬
☐	☐	☐	☐	☐	☐	☐

৮) আমি বিভিন্ন কাজের সময়ে ব্যাথা অনুভব করি (দয়া করে একটিতে দাগ (✓) দিন)

কখনই সত্য না						সব সময় সত্য
০	১	২	৩	৪	৫	৬
☐	☐	☐	☐	☐	☐	☐

৯) আমার বহুদিনের ব্যাথা থাকা সত্যেও আমি পরিপূর্ণভাবে জীবন-যাপন করছি
(দয়া করে একটিতে দাগ (✓) দিন)

কখনই সত্য না						সব সময় সত্য
০	১	২	৩	৪	৫	৬
☐	☐	☐	☐	☐	☐	☐

১০) আমার জীবনের অন্য লক্ষ্যের তুলনায় ব্যাথা নিয়ন্ত্রণ করা খুব জরুরি নয়
(দয়া করে একটিতে দাগ (✓) দিন)

কখনই সত্য না						সব সময় সত্য
০	১	২	৩	৪	৫	৬
☐	☐	☐	☐	☐	☐	☐

১১) আমার জীবনে কিছু গুরুত্বপূর্ণ পদক্ষেপের আগে ব্যাথা সম্বন্ধে চিন্তা ও অনুভূতি বদলাতে হবে
(দয়া করে একটিতে দাগ (✓) দিন)

কখনই সত্য না						সব সময় সত্য
০	১	২	৩	৪	৫	৬
☐	☐	☐	☐	☐	☐	☐

১২) আমার ব্যাথা থাকা সত্যেও আমি একটি নির্দিষ্ট ধারায় জীবন যাপন করছি
(দয়া করে একটিতে দাগ (✓) দিন)

কখনই সত্য না						সব সময় সত্য
০	১	২	৩	৪	৫	৬
☐	☐	☐	☐	☐	☐	☐

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Participant ID No.:.....

অধ্যায় ৫ – আয়ত্ত করা...

১৩) আমি কোন কিছু করার সময় আমার ব্যাথা নিয়ন্ত্রণে রাখার ব্যাপারে প্রাধান্য দেই
(দয়া করে একটিতে দাগ (✓) দিন)

কখনই সত্য না						সব সময় সত্য
০	১	২	৩	৪	৫	৬
☐	☐	☐	☐	☐	☐	☐

১৪) কোন গুরুত্বপূর্ণ পরিকল্পনা করার আগে আমার ব্যাথা নিয়ন্ত্রণ করা অবশ্যক
(দয়া করে একটিতে দাগ (✓) দিন)

কখনই সত্য না						সব সময় সত্য
০	১	২	৩	৪	৫	৬
☐	☐	☐	☐	☐	☐	☐

১৫) আমার ব্যাথা বেড়ে গেলেও আমি আমার দায়িত্ব পালন করতে পারি
(দয়া করে একটিতে দাগ (✓) দিন)

কখনই সত্য না						সব সময় সত্য
০	১	২	৩	৪	৫	৬
☐	☐	☐	☐	☐	☐	☐

১৬) আমার ব্যাথা নিয়ে খারাপ চিন্তা বদলাতে পারলে আমার নিজের জীবনের উপর ভালো নিয়ন্ত্রণ থাকবে (দয়া করে একটিতে দাগ (✓) দিন)

কখনই সত্য না						সব সময় সত্য
০	১	২	৩	৪	৫	৬
☐	☐	☐	☐	☐	☐	☐

১৭) আমার ব্যাথা বেড়ে যাবে সেই ভেবে আমি কিছু পরিস্থিতি এড়িয়ে চলি
(দয়া করে একটিতে দাগ (✓) দিন)

কখনই সত্য না						সব সময় সত্য
০	১	২	৩	৪	৫	৬
☐	☐	☐	☐	☐	☐	☐

১৮) ব্যাথা নিয়ে আমার যত দুশ্চিন্তা ও ভয় আছে, তা আসলে সত্য (দয়া করে একটিতে দাগ (✓) দিন)

কখনই সত্য না						সব সময় সত্য
০	১	২	৩	৪	৫	৬
☐	☐	☐	☐	☐	☐	☐

Participant ID No.:.....

অধ্যায় ৫ – আয়ত্ত করা...

১৯) আমার জীবন-যাপন করার জন্য আমার ব্যাথা পরিবর্তন করতে হবে না তা ভেবে আমি স্বস্তি পাচ্ছি (দয়া করে একটিতে দাগ (✓) দিন)

কখনই সত্য না						সব সময় সত্য
০	১	২	৩	৪	৫	৬
☐	☐	☐	☐	☐	☐	☐

২০) আমার যখন ব্যাথা থাকে তখন আমার কিছু করতে যুদ্ধ করতে হয়
(দয়া করে একটিতে দাগ (✓) দিন)

কখনই সত্য না						সব সময় সত্য
০	১	২	৩	৪	৫	৬
☐	☐	☐	☐	☐	☐	☐

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অধ্যায় ৬ – সামাজিক জীবন

নিচে কয়েকটি বাক্য আছে। প্রতিটি বাক্যের সাথে আপনি কতটা দৃঢ়ভাবে বিরোধ করছেন বা একমত হচ্ছেন সেই অনুসারে একটি ঘরে দাগ দিয়ে তা উল্লেখ করুন।

১) আমি অনেক মজার কিছু করছি (দয়া করে একটিতে দাগ (✓) দিন)		২) বেশির ভাগ দিনেই আমি যে সকল জিনিস করে তৃপ্তি পাই তার মধ্য থেকে কিছু করছি (দয়া করে একটিতে দাগ (✓) দিন)	
দৃঢ়ভাবে বিরোধ করছি	☐	দৃঢ়ভাবে বিরোধ করছি	☐
বিরোধ করছি	☐	বিরোধ করছি	☐
একমত হচ্ছি	☐	একমত হচ্ছি	☐
দৃঢ়ভাবে একমত হচ্ছি	☐	দৃঢ়ভাবে একমত হচ্ছি	☐

৩) আমার জীবনকে যতটুকু সম্ভব পরিপূর্ণ করার চেষ্টা করছি (দয়া করে একটিতে দাগ (✓) দিন)		৪) আগামী কয়েক দিনের মধ্যে নিজের জন্য মজার কিছু করার পরিকল্পনা করছি (দয়া করে একটিতে দাগ (✓) দিন)	
দৃঢ়ভাবে বিরোধ করছি	☐	দৃঢ়ভাবে বিরোধ করছি	☐
বিরোধ করছি	☐	বিরোধ করছি	☐
একমত হচ্ছি	☐	একমত হচ্ছি	☐
দৃঢ়ভাবে একমত হচ্ছি	☐	দৃঢ়ভাবে একমত হচ্ছি	☐

৫) আমার মনে হয় আমি সক্রিয়ভাবে জীবনে জড়িত রয়েছি (দয়া করে একটিতে দাগ (✓) দিন)	
দৃঢ়ভাবে বিরোধ করছি	☐
বিরোধ করছি	☐
একমত হচ্ছি	☐
দৃঢ়ভাবে একমত হচ্ছি	☐

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অধ্যায় ৭ – সার্বিক স্বাস্থ্য

এই প্রশ্নগুলো আপনার স্বাস্থ্যের ব্যাপারে আপনার মতামত জানতে চাইবে। এই তথ্য আপনার অনুভূতি ও আপনার দৈনন্দিন কাজ-কর্ম কতটুকু করতে পারছেন তা বুঝতে সাহায্য করবে।

দয়া করে প্রতিটি প্রশ্নের উত্তর দিন একটি দাগ দিয়ে। আপনি যদি কোন প্রশ্নের উত্তর সম্বন্ধে অনিশ্চিত থাকেন, তাহলে যতটুকু সম্ভব ভালোভাবে উত্তর দিবেন।

১) সব মিলিয়ে, আপনি কি বলবেন আপনার স্বাস্থ্য (দয়া করে একটিতে দাগ (✓) দিন)

চমৎকার	খুব ভালো	ভালো	মুটা মুটি	খারাপ
☐	☐	☐	☐	☐

২) এক বছর আগের তুলনায়, সব মিলিয়ে, আপনার বর্তমান সার্বিক স্বাস্থ্যের অবস্থা কেমন মনে হয় (দয়া করে একটিতে দাগ (✓) দিন)

বেশ ভালো	একটু ভালো	প্রায় সমান	একটু খারাপ	বেশ খারাপ
☐	☐	☐	☐	☐

নিচের জিনিসগুলো আপনি একটি গতানুগতিক দিনে হয় তো করেন। আপনার বর্তমান স্বাস্থ্যের অবস্থা কি এই সব কর্মকান্ড সীমিত করছে ? যদি তাই হয়, তাহলে কতটুকু ?

৩ক) প্রবল কর্মকান্ড যেমন দৌড়াদৌড়ি, ভারি জিনিস বহন, তেজপূর্ণ খেলাধুলা (দয়া করে একটিতে দাগ (✓) দিন)		৩খ) পরিমিত কর্মকান্ড যেমন টেবিল সরানো, ভ্যাকুম ক্লীনার ধাক্কা দেওয়া, চলাফেরা করা, হালকা খেলাধুলা করা (দয়া করে একটিতে দাগ (✓) দিন)	
হ্যা, বেশ সীমিত	☐	হ্যা, বেশ সীমিত	☐
হ্যা, কিছুটা সীমিত	☐	হ্যা, কিছুটা সীমিত	☐
না, মোটেও সীমিত নই	☐	না, মোটেও সীমিত নই	☐
৩গ) বাজার হাট থেকে তুলে শাক-সবজি বহন করে নিয়ে আসা (দয়া করে একটিতে দাগ (✓) দিন)		৩ঘ) কয়েক তলা সিড়ি বেয়ে উপরে উঠা (দয়া করে একটিতে দাগ (✓) দিন)	
হ্যা, বেশ সীমিত	☐	হ্যা, বেশ সীমিত	☐
হ্যা, কিছুটা সীমিত	☐	হ্যা, কিছুটা সীমিত	☐
না, মোটেও সীমিত নই	☐	না, মোটেও সীমিত নই	☐

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Participant ID No.:.....

৩ঙ) এক তলা সিড়ি বেয়ে উপরে উঠা (দয়া করে একটিতে দাগ (✓) দিন)		৩চ) মাথা নোয়ানো, হাঁটু গেড়ে বসা বা ঝুকে পড়া (দয়া করে একটিতে দাগ (✓) দিন)	
হ্যা, বেশ গীমিত	☐	হ্যা, বেশ গীমিত	☐
হ্যা, কিছুটা গীমিত	☐	হ্যা, কিছুটা গীমিত	☐
না, মোটেও গীমিত নই	☐	না, মোটেও গীমিত নই	☐
৩ছ) এক মাইল থেকে বেশি হাটা (দয়া করে একটিতে দাগ (✓) দিন)		৩জ) কয়েক শত গজ হাটা (দয়া করে একটিতে দাগ (✓) দিন)	
হ্যা, বেশ গীমিত	☐	হ্যা, বেশ গীমিত	☐
হ্যা, কিছুটা গীমিত	☐	হ্যা, কিছুটা গীমিত	☐
না, মোটেও গীমিত নই	☐	না, মোটেও গীমিত নই	☐
৩ঝ) এক শত গজ হাটা (দয়া করে একটিতে দাগ (✓) দিন)		৩ঞ) নিজেকে গোসল করানো বা কাপড় পড়ানো (দয়া করে একটিতে দাগ (✓) দিন)	
হ্যা, বেশ গীমিত	☐	হ্যা, বেশ গীমিত	☐
হ্যা, কিছুটা গীমিত	☐	হ্যা, কিছুটা গীমিত	☐
না, মোটেও গীমিত নই	☐	না, মোটেও গীমিত নই	☐

<u>বিগত ৪ সপ্তাহ ধরে,</u> আপনার শারীরিক অবস্থার কারণে কাজ-কর্ম বা অন্য কর্মকান্ডের ক্ষেত্রে নিচে উল্লেখিত সমস্যাগুলো হয়েছিলো কি?

৪ক) কাজ অথবা অন্য কর্মকান্ড কমিয়ে দেওয়া (দয়া করে একটিতে দাগ (✓) দিন)		৪খ) যতটুকু চেয়েছিলেন তার চেয়ে কম পরিমাণে কাজ বা অন্য কিছু সম্পন্ন করা (দয়া করে একটিতে দাগ (✓) দিন)	
সব সময়	☐	সব সময়	☐
প্রায় সময়	☐	প্রায় সময়	☐
কিছু সময়	☐	কিছু সময়	☐
অল্প সময়	☐	অল্প সময়	☐
কোন সময় না	☐	কোন সময় না	☐

Participant ID No.:.....

৪গ) কাজ বা অন্য কর্মকান্ড সীমিত করা (দয়া করে একটিতে দাগ (✓) দিন)		৪ঘ) কাজ-কর্ম করতে কষ্ট হয়েছে (দয়া করে একটিতে দাগ (✓) দিন)	
সব সময়	☐	সব সময়	☐
প্রায় সময়	☐	প্রায় সময়	☐
কিছু সময়	☐	কিছু সময়	☐
অল্প সময়	☐	অল্প সময়	☐
কোন সময় না	☐	কোন সময় না	☐

বিগত ৪ সপ্তাহ ধরে, আপনার আবেগ-অনুভূতি অবস্থার কারণে কাজ-কর্ম বা অন্য কর্মকান্ডের ক্ষেত্রে নিচে উল্লেখিত সমস্যাগুলো হয়েছিলো কি (যেমন মানষিক চাপ বা মন-বিষণ্ণতা) ?

৫ক) কাজ অথবা অন্য কর্মকান্ড কমিয়ে দেওয়া (দয়া করে একটিতে দাগ (✓) দিন)		৫খ) যতটুকু চেয়েছিলেন তার চেয়ে কম পরিমাণে কাজ বা অন্য কিছু সম্পন্ন করা (দয়া করে একটিতে দাগ (✓) দিন)	
সব সময়	☐	সব সময়	☐
প্রায় সময়	☐	প্রায় সময়	☐
কিছু সময়	☐	কিছু সময়	☐
অল্প সময়	☐	অল্প সময়	☐
কোন সময় না	☐	কোন সময় না	☐
৫খ) কাজ অথবা অন্য কর্মকান্ড আগের চেয়ে কম সতর্ক হয়ে করা (দয়া করে একটিতে দাগ (✓) দিন)			
সব সময়	☐		
প্রায় সময়	☐		
কিছু সময়	☐		
অল্প সময়	☐		
কোন সময় না	☐		

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৬) <u>বিগত ৪ সপ্তাহ ধরে</u> আপনার সাধারণ সামাজিক কর্মকান্ডের ক্ষেত্রে আপনার সার্বিক স্বাস্থ্য বা আবেগ-অনুভূতি জনিত সমস্যা কতটুকু বাধা হয়ে দাঁড়িয়ে ছিলো ? (দয়া করে একটিতে দাগ (✓) দিন)

একদমই না	সামান্য	মাঝারি	অনেক	প্রচন্ড
☐	☐	☐	☐	☐

৭) <u>বিগত ৪ সপ্তাহ ধরে</u> আপনি কতটুকু শারীরিক ব্যাথায় ভোগছেন ? (দয়া করে একটিতে দাগ (✓) দিন)

একদমই না	খুব হালকা	হালকা	মাঝারি	প্রচন্ড	খুব প্রচন্ড
☐	☐	☐	☐	☐	☐

৮) <u>বিগত ৪ সপ্তাহ ধরে</u> আপনার ঘরের ও বাহিরের কাজের ক্ষেত্রে আপনার ব্যাথা কতখানি বাধা হয়ে দাঁড়িয়ে ছিলো ? (দয়া করে একটিতে দাগ (✓) দিন)

একদমই না	সামান্য	মাঝারি	অনেক	প্রচন্ড
☐	☐	☐	☐	☐

নিচের প্রশ্নগুলোর মাধ্যমে বিগত ৪ সপ্তাহ ধরে আপনার অনুভূতি ও আপনার অবস্থা সম্বন্ধে জানা হবে। প্রতিটি প্রশ্নের উত্তর যথারিতি একটি ঘরে দাগ দিয়ে উল্লেখ করুন।

৯ক) আপনি কি প্রাণবন্ত অনুভব করেছিলেন ? (দয়া করে একটিতে দাগ (✓) দিন)		৯খ) আপনি কি বেশি সন্ত্রস্ত বা নার্ভাস ছিলেন ? (দয়া করে একটিতে দাগ (✓) দিন)	
সব সময়	☐	সব সময়	☐
প্রায় সময়	☐	প্রায় সময়	☐
কিছু সময়	☐	কিছু সময়	☐
অল্প সময়	☐	অল্প সময়	☐
কোন সময় না	☐	কোন সময় না	☐
৯গ) আপনি কি এতটাই বিচলিত ছিলেন যে কোন কিছুতেই আপনার মন উৎফুল্ল হওয়ার নয়? (দয়া করে একটিতে দাগ (✓) দিন)		৯ঘ) আপনি কি প্রশান্ত ও স্থির অনুভব করেছিলেন ? (দয়া করে একটিতে দাগ (✓) দিন)	
সব সময়	☐	সব সময়	☐
প্রায় সময়	☐	প্রায় সময়	☐
কিছু সময়	☐	কিছু সময়	☐
অল্প সময়	☐	অল্প সময়	☐
কোন সময় না	☐	কোন সময় না	☐

Participant ID No.:.....

৯ঙ) আপনার মধ্যে কি অফুরন্ত প্রাণ শক্তি ছিলো ? (দয়া করে একটিতে দাগ (✓) দিন)		৯চ) আপনার কি মন ভেঙে গিয়েছিলো বা মন বিষণ্ন ছিলো? (দয়া করে একটিতে দাগ (✓) দিন)	
সব সময়	☐	সব সময়	☐
প্রায় সময়	☐	প্রায় সময়	☐
কিছু সময়	☐	কিছু সময়	☐
অল্প সময়	☐	অল্প সময়	☐
কোন সময় না	☐	কোন সময় না	☐
৯ছ) আপনার কি মনে হচ্ছিলো যে আপনার শরীরে আর শক্তি নেই ? (দয়া করে একটিতে দাগ (✓) দিন)		৯জ) আপনি কি খুশি ছিলেন? (দয়া করে একটিতে দাগ (✓) দিন)	
সব সময়	☐	সব সময়	☐
প্রায় সময়	☐	প্রায় সময়	☐
কিছু সময়	☐	কিছু সময়	☐
অল্প সময়	☐	অল্প সময়	☐
কোন সময় না	☐	কোন সময় না	☐
৯ঝ) আপনার কি খুব ক্লান্ত লাগছিলো ? (দয়া করে একটিতে দাগ (✓) দিন)			
সব সময়	☐		
প্রায় সময়	☐		
কিছু সময়	☐		
অল্প সময়	☐		
কোন সময় না	☐		

১০) বিগত ৪ সপ্তাহ ধরে, আপনার সাধারণ সামাজিক কর্মকান্ডের (পরিবার পরিজন ও বন্ধু-বান্ধবদের সাথে মিলা-মিশা) ক্ষেত্রে আপনার সার্বিক স্বাস্থ্য বা আবেগ-অনুভূতি জনিত সমস্যা কতটুকু সময় বাধা হয়ে দাঁড়িয়ে ছিলো ? (দয়া করে একটিতে দাগ (✓) দিন)

সব সময়	প্রায় সময়	কিছু সময়	অল্প সময়	কোন সময় না
☐	☐	☐	☐	☐

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Participant ID No.:.....

নিচের বাক্য গুলো আপনার ক্ষেত্রে কতটুকু সত্য বা মিথ্যা ?

১১ক) অন্য মানুষের তুলনায় আমি সহজে অসুস্থ হয়ে পড়ি (দয়া করে একটিতে দাগ (✓) দিন)		১১খ) অন্য সবার মত আমিও সুস্থ (দয়া করে একটিতে দাগ (✓) দিন)	
একদম সত্য	☐	একদম সত্য	☐
অনেকটা সত্য	☐	অনেকটা সত্য	☐
জানি না	☐	জানি না	☐
অনেকটা মিথ্যা	☐	অনেকটা মিথ্যা	☐
একদম মিথ্যা	☐	একদম মিথ্যা	☐
১১গ) আমার স্বাস্থ্য আরো খারাপ হবে (দয়া করে একটিতে দাগ (✓) দিন)		১১ঘ) আমার স্বাস্থ্য চমৎকার (দয়া করে একটিতে দাগ (✓) দিন)	
একদম সত্য	☐	একদম সত্য	☐
অনেকটা সত্য	☐	অনেকটা সত্য	☐
জানি না	☐	জানি না	☐
অনেকটা মিথ্যা	☐	অনেকটা মিথ্যা	☐
একদম মিথ্যা	☐	একদম মিথ্যা	☐

Participant ID No.:.....

অধ্যায় ৮ – আরো কিছু তথ্য

১) জন্ম তারিখ

২) লিঙ্গ (দয়া করে একটিতে দাগ (✓) দিন)				৩) থাকার ব্যবস্থা (দয়া করে একটিতে দাগ (✓) দিন)			
পুরুষ	☐	নারী	☐	একা	☐	একা নই	☐

৪) আপনার ইংরেজী ভাষার উপর দক্ষতা কেমন? (দয়া করে একটিতে দাগ (✓) দিন)			
সাবলীল	ভালো	মুটা-মুটি	খারাপ
☐	☐	☐	☐

5. What is your ethnic group? (please choose one section from A to E then tick one box to best describe your ethnic group or background)

A. White Please tick (✓) one		B. Black or Black British Please tick (✓) one	
British	☐	Caribbean	☐
Irish	☐	African	☐
Any other white background (write below)	☐	Any other black background (write below)	☐
C. Asian or Asian British Please tick (✓) one		D. Mixed Please tick (✓) one	
Indian	☐	White & Black Caribbean	☐
Pakistani	☐	White & Black African	☐
Bangladeshi	☐	White & Asian	☐
Any other Asian background (write below)	☐	Any other mixed background (write below)	☐

E. Other ethnic group Please tick (✓) one			
Chinese	☐	Arab	☐
Other ethnic group (write below)	☐		

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Participant ID No.:.....

অধ্যায় ৮ - আরো কিছু তথ্য...

৬) আপনার ক্ষেত্রে কোনটি প্রযোজ্য (দয়া করে একটিতে দাগ (✓) দিন)

- কর্মরত (ফুল-টাইম বা পার্ট-টাইম, চাকুরি অথবা ব্যবসা) ☐
- বর্তমানে কাজে নেই কিন্তু কাজ খোঁজছি ☐
- স্কুল, কলেজ অথবা ইউনিভার্সিটিতে ফুল-টাইমে পড়ছি ☐
- দীর্ঘদিনের অসুস্থতার কারণে কাজ করতে পারছিনা ☐
- নিজের ঘর-সংসার দেখাশুনা করছি ☐
- কর্মরত জীবন থেকে অবসর নিয়েছি ☐
- অন্য কিছু (দয়া করে নিচে লিখুন) ☐

৭) আপনি ফুল-টাইম পড়ালেখা (যেমন স্কুল, কলেজ বা ইউনিভার্সিটি) যখন ছাড়েন, তখন আপনার বয়স কত ছিলো? (দয়া করে একটিতে দাগ (✓) দিন)

- আমি কোন পড়ালেখা করি নাই ☐
- ১২ বছর বা তার চেয়ে কম বয়স পর্যন্ত ☐
- ১৩ থেকে ১৬ বছর বয়স পর্যন্ত ☐
- ১৭ থেকে ১৯ বছর বয়স পর্যন্ত ☐
- ২০ বছর বা তার চেয়ে বেশি বয়স পর্যন্ত ☐
- আমি এখনো পুরোদমে পড়ালেখা করছি ☐
- অন্য কিছু (দয়া করে নিচে লিখুন) ☐

প্রশ্নমালা পূরণ করার জন্য ধন্যবাদ

দয়া করে সাথে দেওয়া ফ্রী-পোস্ট খামে ভরে নিরিক্ষক দলের কাছে, অথবা নিচের ঠিকানায় পাঠিয়ে দিন

FREEPOST, CENTRE FOR HEALTH SCIENCES, COPERS STUDY (Dr D. Carnes Rm 1.08).

Feedback from facilitators and participants

Facilitator and observer feedback on the intervention

Session	Observer/facilitator notes/facilitator focus group	Study team discussion
Introduction	• Egg timer works well • Provide reading material at the start • Simplify aims and define better • Nerves of facilitators evident • High levels of participant input from the start • Mixed participant expectations; some negative • More time for talking about health beliefs and acknowledgement of current medical treatments • Clearly communicate aims	• Challenge negative expectations at the start • Continuous slideshow of previous participants' quotations in the background
DVD	• Consider those with specific diagnoses causing pain • Denervation conflicts with message on DVD • Most groups identified with Charlie and Lisa • Leave out 'Where does Charlie's pain come from?' • Do not read out background scenario • Make the DVD shorter, just keep the pain pathway	• Change questions used for discussion, e.g. 'How do you feel about consultant saying there's no cure?' • Show Charlie going to a course • Use positive quotations from real people at the end • More about cortical/cerebral involvement (e.g. the limbic system and emotion, e.g. happiness) • Educate facilitators to answer questions about medical treatments (denervation) • Acknowledge specific causes of pain (osteoporosis)
Unwelcome guest	• Often taken literally/be upfront about analogy • When prompted analogy works well • Do this before lunch on first day • Change 'unwelcome' to 'uninvited'? • Often misperceived until the penny drops • Anticipation of medical treatment undermines acceptance process	• Change analogy to gatecrasher at a party • Get facilitators to focus on pain
Pain/mood	• Aim of pain/mood diary not clear – better as flip chart? • Literacy issues for Bengali group • Prompting for things other than weather and environmental factors • Pain/mood diary not always used; could leave out • Jenny's holiday not always used but still required as backup • Hard concept to embed pain/mood relationship (may need different method)	• Get rid of pain/mood diary as it encourages hypervigilance • Keeping bearable or not linking pain to emotions • Do this as buzz groups and feedback
Pain cycle	• Move depressive symptoms or spend less time on it • Pain cycle works well; people resonate with concept • Facilitators must take care not to spend too long on presentation; more discussion needed • Pain cycle is very powerful and works very well	• Reorder to (1) things that keep you in the cycle, (2) depressive symptoms list and (3) things that move you out of the cycle • Need clearer instructions for facilitators

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Session	Observer/facilitator notes/facilitator focus group	Study team discussion
Stretching, movement, posture	• More of it • Well received • Some participants had difficulty standing up to perform exercises because of limited mobility • Adapt to include seated postures too	• Provide handouts for exercise
Relaxation visualisation	• Well received • Provide a recording in CD or MP3 format • Need to remind participants why this is useful for pain	
Reflections	• Get all members of the group to present feedback • Works well and by the follow-up groups virtually unfacilitated • Good for embedding concepts and going over content • Good for motivation • Role models evolve and emerge here • Follow-up session had the worst attendance	
CBT	• For all sessions, make the aim clearer and put in the context of pain. Laypeople are very important in these sessions	• Reorder the sessions: (1) unhelpful thoughts, (2) barriers to change – reframing cons to cans and (3) goal-setting
CBT: goal-setting	• More time needed for this • Simplify whole process, especially 'SMART' goal exercise (consider language/literacy) • Use an example generated by group (or as backup, 'I can no longer walk to the shops to do my own shopping') • Small groups work well with more unfacilitated interaction	• Choose sleep as the example for goal-setting in small groups
CBT: pros and cons and barriers	• Clarify aim • Too much material in this session – move unhelpful thoughts into session 11 • Overall pros and cons work well – lots of content • Reframing the group's cons to cans works well	• Carry out only one reframing
CBT: unhelpful thoughts	• Start session with unhelpful thoughts list • Simplify unhelpful thoughts list (consider language/literacy) • Use an example that relates to pain or group's own example • Too much material – move/remove reframing (slide 17) • Important material – worked well • ABCDE checklist not used; no time really • Use negative statements from participants more effectively as examples of unhelpful thoughts	• Use laminated cards of unhelpful thoughts for prompting throughout and use in game to identify the unhelpful thoughts in a scenario in two groups • Get participants to give examples of unhelpful thoughts
CBT: attention control	• Move to before lunch to help with food analogy • Need to use humour with this session • Clarify aim – emphasise 'Don't think about pain' • Works well when penny drops	

Session	Observer/facilitator notes/facilitator focus group	Study team discussion
CBT: coping strategies	• Physical examples remembered frequently • Sometimes takes a lot of prompting • Application of these skills not so clear • Worked well for some groups	
Communication: GP consulting	• Not always relevant (not all frequent GP attendees) • Distinction between role plays not always immediately obvious • Shifting focus to what GP hears and what the GP can do really important	• Facilitators should have extra guidance to help them to focus the session on GPs' point of view • Merge this session with role play
Communication: role play	• Generally worked well providing the 'acting' was good	• Make role play optional/backup • Obtain a real example from the group
Communication: listening skills	• Instructions need to be crystal clear • Worked well for most • Get facilitator to apply to other relationships (friends, etc.)	• Change the word topic to hobbies – something you like doing or used to like doing
Communication: intimacy	• Some in the groups are single • Worked better for some groups than others • Disclosure uncomfortable • Unsure if this session works well	• Delete
Communication: anger	• Situation taken literally – aim not clear – emphasise contrast in scenarios • Act as role play instead? • Worked well on the whole • Group and course fatigue at this point sets in	• Delete if short of time as not perceived as crucial to the learning about pain
Sleep	• Lots of content generated • Often addressed at different stages throughout the course so facilitators consolidate information • Rushed?	• Delete session but use as an example for goal-setting
Tasters	• Make aim clear? • On the whole well received but must keep them voluntary	• Keep in but perhaps make them less physical (e.g. problem-solving, team games)
Buddying up	• Often rushed and process confused • Ad hoc • Not much feedback • Improve process by providing a venue • Have cross-fertilisation between groups • Online forum	• No contract. Keep informal
Other general suggestions	• More variation in learning modes – small groups, games • Have something positive to take home on the first day • Do something practical on the first day • Make structure clearer • What about core content and peripheral content that can be dropped if necessary? • Make course longer because there is too much content	

ABCDE, A = activating event, B = beliefs, C = consequences, D = disputing and E = effects; SMART, Smart, Achievable, Relevant and Timed goals.

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Facilitator and observer feedback about processes and training

Session	Observer/facilitator notes/facilitator focus group	Study team discussion
Facilitation process	• Need to draw out quiet people • Laughter really useful • Informal atmosphere helps (especially getting up whenever felt like it for tea and coffee) • Examples very useful • Need to set scene otherwise purpose unclear • Need for summarising to end sessions and link into new ones • Summarising helps put things into context • Let group self-regulate • Need to keep referencing and linking back to concepts previously covered • Preparation important • Harder to facilitate small groups • Assess learning process as you go along • Must be a minimum group size • Start off as didactic teaching then relax into group process • Facilitators need to believe in the content • Allow facilitators to eject very difficult participants • Pair inexperienced with experienced • Ensure that facilitators prepare together beforehand	• Summarise at end of each day – what have you learnt? • More signposting, more linking
Facilitation training	• Training required for controlling dominant people going off topic • Need for more facilitator training to improve confidence • Train facilitators to be more flexible • Facilitators need to be more familiar with CBT materials • Facilitators need confidence • See an experienced facilitator in action (DVD) • Obtain expertise in dealing with difficult situations • Observe a course beforehand • Experiential learning time • The current training course is only content based	• Longer training required and partner less-experienced tutors with experienced tutors

Emergent themes from participants' feedback questionnaires

Q11: If you can, name three things you learned today that are important to you

Themes	Illustrative quotations
Social aspects	
This was a recurrent theme. The social aspect was beneficial to different participants in different ways: the group experience, pain-specific interaction, several types of communication (e.g. family, health professionals) and the activities-based social interaction	*there are people in the same situation as me* Day 1, E7
The social interaction between pain participants enabled group members to learn from each other's coping strategies	*Other people's experiences can help me, meeting others in pain and discussing experiences and methods* Day 1, E7
Knowledge and learning	
Participants valued three areas in particular, the mind–body and therapy components, the CBT components and the pain education (DVD)	*Reminded distraction/absorption is something that can put pain in background rather than foreground* Day 1, E1 *I've learnt how to cope/change negative thinking about myself in relation to other people. (The unhelpful thoughts checklist is very useful here.)* Day 1, E1
The pain education covered general information about pain pathways, the link with mood and the limited impact that medicine has on chronic pain. Most participants found this useful; however, some found the content too simplistic and others found it too complex and the DVD did not cover diagnosed conditions very well	*That acceptance of my pain is crucial* Day 2, E1 *overcoming difficulties by acceptance* Day 1, E1
Mood	
This theme was linked to pain education. Participants liked pain and mood being linked together. Several participants grasped the idea and wrote it on the evaluation form as a learnt theme. This suggested that the concept being taught was memorable	*mood and pain go together* Day 1, E4 *mood effects pain* Day 1, E1

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Question 12: What parts of this course today, if any, did you enjoy or value the most? Please tell us why it was valuable for you

Themes	Illustrative quotations
Discussion/social interaction	
Participants related personal accounts of how they manage their pain; they found that this was a very valuable aspect for group members	*Discussing other people's pain relief methods and what helps others that will also work for me. Just meeting other people who are similar to me* *Day 1, E1*
Participants appreciated that they were not alone and could seek ways of relieving themselves from their pain	*group discussion, sharing, listening to people's experience* *Day 1, E7*
Relating learning to self/personal experience	
Relating the content taught in the course to personal experience was valuable for some participants who were able to relate things to themselves	*planning/setting goals. This will help me with changing my life/become more active* *Day 2, E7*
Participants were able to recognise methods of helping themselves. This demonstrated their willingness to take away what they had learnt and try to implement it	*how to sleep. I picked a few points to use. No sleep and pain has been a big issue for me* *Day 3, E2*

Question 13: What parts of this course today, if any, did you least enjoy? Please tell us why

Themes	Illustrative quotations
Social content	
Participants mentioned a number of different contents that were less valuable. The intimacy session was mentioned by a few participants. It is difficult to know whether this is because they believed the content was irrelevant or because the discussion was awkward for some	*talking about sex although I seemed to be the only one contributing. Was quite embarrassed afterwards* *Day 3, E4*
Disruption	
Dominant group members were deemed to be disruptive to the group. Facilitators need to be aware of dominant/disruptive participants who steer away from the session topic and steer the group back into discussion or close off discussion to continue the session. Poor facilitation skills resulted in lost time and alienating participants	*the cross talking. This group is easily distracted onto irrelevant topics* *Day 2, E2*
Poor timing	
For some participants, the course appeared to be too short. They felt that this resulted in the course content being taught briefly and presented in a rushed manner	*I found it a bit rushed due to the fact it has to be crammed into 3 days* *Day 1, E1*
Many participants wanted a longer course. The timing allocated to each session was an issue too	*too much time spent on personal histories* *Day 1, E2*
Disclosure discomfort	
Not all participants liked disclosing information about themselves. For those who were shy about speaking out in a group, the discussions were nerve-racking for them	*Introducing myself, not at ease with strangers but a good ice breaker* *Day 2, E3*
Lack of personal relevance	
The need for personal relevance was important for engaging participants in the course and optimising interest	*some of the points made did not seem relevant* *Day 1, E3*

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Q14: Do you feel that the content was relevant and applicable to you? In what ways could relevance and applicability be improved?

Themes	Illustrative quotations
Cause of pain	
Some participants felt that there should be more focus on known causes of pain. Some were quite sure of their own explanation for their pain and were resistant to learning	*I still find my pain is purely from over-activity and not mood* Day 2, E7
Applicability of content	
A variety of responses with many people identifying with the scenarios in the video and others feeling that they were not in enough pain or that pain was more specific from a particular diagnosis	*Wondered if I was slightly here under false pretences as not in serious pain all day every day* Day 1, E1 *Yes, very relevant. Charlie in the video was me* Day 1, E7
Relevance of learning from others (sharing)	
Most enjoyed learning from others	*I really, really got a lot out of the other participants and would have loved to spend more time in facilitated discussion* E1, Day 2

Q15: Do you have any comments about facilitation?

Themes	Illustrative quotations
Listening, communication and empathy	
Participants highlighted the need for facilitators to be attentive and responsive towards participants. The importance of receiving participants well and responding to them accordingly, with understanding, reinforced the skills required as a facilitator. Facilitators need to deliver information to participants and listen to and counsel them	*They are very good; they listen and respond appreciatively to everyone* Day 2, E6
Tutors' backgrounds	
For a few courses there were lay tutors who had experienced chronic pain. Participants picked up on this	*Both are good communicators and it helps that they are also pain sufferers so we are not being lectured* Day 1, E1
People management	
An important characteristic that facilitators need to attain is good people management. Handling dominant participants and off-topic discussions is vital for good facilitation as this can cause annoyance among other group participants	*It was quite good. There was one attendee who took up a bit too much time talking and I think he could have been managed slightly more assertively by the facilitators* Day 3, E4

Question 16: Suggestions

Themes	Illustrative quotations
Whole course/structure	
Suggestions for the course included comments on the course length. Many participants mentioned that the course was too short	*That perhaps longer need to be spent on the topics and 3 long days for people with chronic pain is not ideal. Maybe session every morning over 1 week* Day 2, E1
For those who found the course beneficial and interesting, there was a desire for the course duration to be extended	*whilst it was relevant and applicable, in a few weeks I will probably forget it. To maintain the benefits, further sessions at regular spaced out intervals would be helpful* Day 1, E6
Discussion/social interaction	
The course provided a social platform for the participants. The theme social interaction/discussion emerged in many answers and illustrated the influence on the participants	*Only encouraging more people to open up during discussion time, maybe moving around the room and asking people individually – start in a different position each time obviously within time frames* Day 3, E1
Flexibility (individual participant needs)	
There was a desire for course content to be personalised for participants to optimise relevance	*Most of the day was about back trouble but I also have knee trouble and would have liked the course to touch on other areas of pain* Day 1, E1
Content	
Participants wanted more exercise. They liked the practical side to the course, which included relaxation/breathing and stretching and posture exercises	*If they can arrange more exercises handouts for the standing and posture, balance and movement, stretching exercises would be helpful* Day 2, E3

Themes from the participant interviews

Themes	Illustrative quotations
Clarity of aims	
Overall, the aims were not clear	*I do not know what the aim was* E2 *I did not know what to expect* Non-attender
Motivation	
The main reason for attending the course was out of curiosity. Indifference characterised responses	*I thought I'd give it a try* E3 *I wanted to learn and see how I can cope with my pain* E3 *I did not see much benefit for myself* Non-attender
Positive aspects	
The participants did learn from the DVD but they took away different things	*it's [pain] not damaging, but just more pain not damage* E1 *Actually that video was brilliant, that guy was me* E4
Others commented on the unwelcome guest, listening skills session, the pain cycle, goal-setting, breathing and exercise, movement and the hand massage	

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Themes	Illustrative quotations
Negative aspects	
Sitting down for long periods, disclosure was too intense, the DVD was too much like school, the DVD talked about unknown pain not diagnosed conditions, the timing and work, the relevance of the tasters, too rushed, too chaotic, the relevance of photography	*I did not see the relevance of photography* B2 *it was not well thought through, it was chaotic* E3 *the course was pressurised, we moved on too quickly* E1
Learning	
Overall, participants felt that they needed time to embed their learning	*you can forget your pain if your mind is occupied by something* B2 *I still have pain but I'm learning to deal with it* E4
Social interaction	
The discussion, meeting people and learning from others was by far the most strongly talked about aspect of the course. However, courses needed sufficient people (six or more) and good facilitation to let everyone talk and to be informal	*we are all in it together, we did not have to pretend about our pain* E2 *It's a forum to talk about pain without burdening other people who do not understand* E4 *I was not the odd one out* E1 *everyone offered suggestions, we learned from each other* B2 *we all self-helped, we came a component of one, instead of individuals* E2
Effect of others	
Negative, disruptive and dominant participants needed to be controlled by the facilitators	*I felt overwhelmed by the intellectuals in the group* E3 *I know I'm not alone, there are others suffering like me* B3 *he was so bad I felt sorry for him, he made me feel better* E3 *I would not have come if it had been mixed gender* B2
Repercussions/outcomes from the course	
Some reported no changes since the course; however, others reported that they had either gone back to work or were renegotiating working hours. One group had organised a trip and others had implemented action plans and goals. Distraction and relaxation techniques had been used since the course	*the course has not changed me at all* E3 *it put me on a path* E2 *I'm not moaning so much* E2 *It's changed my life, every day I set my self a new goal like a new exercise* E4 *I thought all that stuff was mumbo jumbo and nonsense but that relaxation technique was good* E4 *I'm working from home now* E4 *I now go to work* E3 *I do stuff despite my pain, I'm not panicking as much* E1

Themes	Illustrative quotations	
Changes suggested		
These included extra time, less time, evenings and weekend courses for working people, more information prior to and during the course, more follow-up, better and clearer aims, changing the DVD so less didactic, more time spent on exercise and lifestyle advice such as financial advice		
Facilitation		
Good facilitation meant good 'control' of the group – managing conversation, disruption, etc. Laughing, joking and anecdotes were appreciated along with informality	*the facilitators have to let everyone speak*	*E3*
	discussion could have been controlled a bit more	*E2*
Buddying		
Buddying did not always work but there were examples of when it worked really well	*I did not get a chance to get one person's number*	*E3*
	we all wrote our names down on a piece of paper	*E2*
	we have kept in touch	*E2*
Material		
Although there were requests for more material, there was not much evidence from the interviewees that they referred to it afterwards		

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Appendix 6 Methods

Costing the intervention

TABLE 86 Assumptions used for costing the COPERS intervention

Item	Assumptions
Number of participants	The base-case costing scenario was based on the average number of participants enrolled on the course across the two centres (London and Midlands). Sensitivity analyses were conducted for each centre as well as for the minimum and maximum number of participants enrolled on the course
Facilitator costs	Facilitators were paid a fixed fee per session. Consequently, given that facilitators were either self-employed or conducted the courses during their free time, on-costs (pension and National Insurance contributions) were not included. The analysis assumed no overheads
Administrator costs	Costs were determined using a fixed daily rate; estimations include 24% salary on-costs (pension and National Insurance contributions).[245] The analysis assumed no overheads
Trainer costs	Costs were determined using a fixed daily rate; estimations include 24% salary on-costs according to 1. The analysis assumed no overheads
Facility costs	Courses were run in multiuse settings. The same daily rate was used for all venues. The analysis assumed no overheads
Course running costs	It was assumed that the cost of course materials (relax packs, DVDs and handouts) depended on the number of participants. Other costs (facility, hospitality, facilitators' fees and travel) were assumed to be independent of the number of participants enrolled. The base-case costing scenario included some wastage of course materials. Sensitivity analyses were conducted assuming no wastage of course materials

Health economic costs

TABLE 87 Unit costs used for costing consultations

Costing item	Unit cost (£)	Cost of contact (£)	Assumption	Reference
Acute medicine ambulatory assessment unit	106	106.00		Non-24-hour A&E/casualty department: not leading to admitted. Average cost of HRG codes B01Z, VB02Z, VB03Z, VB04Z, VB05Z, VB06Z, VB07Z, VB08Z, VB09Z and VB11Z[246]
Community pharmacy	69	11.50	Duration of contact 10 minutes	Per hour of patient-related activities including qualifications (p. 172)[245]
Counselling	59	59.00		Per consultation (p. 53)[245]
Dietitian	34	28.33	Duration of contact 50 minutes	Per hour including qualifications (p. 216)[245]
Dispensing assistant	25	4.17	Clinical support worker, duration of contact 10 minutes	Per hour of patient-related work (p. 179)[245]
GP surgery	58	58.00		Per-patient contact lasting 17.2 minutes, excluding direct care staff costs, with qualification costs (p. 183)[245]

continued

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TABLE 87 Unit costs used for costing consultations (*continued*)

Costing item	Unit cost (£)	Cost of contact (£)	Assumption	Reference
GP telephone	24	24.00		Per telephone consultation lasting 7.1 minutes, excluding direct care staff costs, with qualification costs (p. 183)[245]
Health-care assistant telephone	21	5.25	Clinical support worker, duration of contact 15 minutes	Per hour (p. 179)[245]
Health-care assistant surgery	25	10.42	Clinical support worker, duration of contact 25 minutes	Per hour of patient-related work (p. 179)[245]
Home visit nurse/GP	70/101	85.50	50% nurse, 50% GP; duration of visit 1 hour nurse and 23.4 minutes GP	Per hour of home visiting nurse (including qualifications and travel) (p. 175) and per out-of-surgery GP visit lasting 23.4 minutes (including qualifications and travel) (p. 183)[245]
New medicine service (pharmacist)	69	11.50	Duration of contact 10 minutes	Per hour of patient-related activities including qualifications (p. 172)[245]
NHS walk-in service	56	56.00		A&E services: walk-in centres: not leading to admitted. Average cost of HRG codes VB01Z, VB02Z, VB03Z, VB04Z, VB05Z,VB06Z, VB07Z, VB08Z, VB09Z and VB11Z[246]
Nurse specialist surgery	49	20.42	Duration of contact 25 minutes	Per hour including qualifications (p. 178)[245]
Nurse specialist telephone	49	12.25	Duration of contact 15 minutes	Per hour including qualifications (p. 178)[245]
Nurse surgery	53	22.08	Duration of contact 25 minutes	Per hour of face-to-face contact including qualifications (p. 180)[245]
Nurse telephone	41	10.25	Duration of contact 15 minutes	Per hour including qualifications (p. 180)[245]
Out of hours	70	70.00	GP surgery contact cost plus 20% for out of hours including nights, weekends and bank holidays	Per patient contact lasting 17.2 minutes, excluding direct care staff costs, with qualification costs (p. 183)[245]
A&E, no admission	173	173.00		Ambulance services – see and treat or refer: HRG code ASS01[246]
Phlebotomist surgery	25	6.25	Clinical support worker, duration of contact 15 minutes	Per hour of patient-related work (p. 179)[245]
Physician's assistant surgery	91	30.33	Duration of contact 20 minutes	Per hour of client contact, nurse advanced (includes lead specialist, clinical nurse specialist, senior specialist), including qualifications (p. 181)[245]
Physiotherapy	33	19.25	Duration of contact 35 minutes	Per hour including qualifications (p. 167)[245]
Psychologist	136	136.00	Duration of contact 1 hour	Per hour of client contact (p. 171)[245]

TABLE 88 Unit costs used for costing investigations

Costing item	Unit cost (£)	Assumption	Reference
Complex echocardiogram	85		Direct access: diagnostic services. HRG code EA45Z[246]
Electrocardiogram monitoring and stress testing	61		Direct access: diagnostic services. HRG code EA47Z[246]
Minor cardiac procedures	74		Direct access: diagnostic services. HRG code EA44Z[246]
Complex oesophageal, stomach or duodenum procedures	569		Direct access: diagnostic services. HRG code FZ81B[246]
Minor therapeutic or diagnostic general abdomen procedures	34		Direct access: diagnostic services. HRG code FZ13C[246]
Minor lower genital tract procedures category 2	33		Direct access: diagnostic services. HRG code MA23Z[246]
Other infections (genitourinary medicine)	70		Direct access: diagnostic services. HRG code WA10Z[246]
CT scan	114	Average cost for different types of CT scan, ≥ 19 years	Direct access: diagnostic imaging. HRG codes RA08A, RA09A, RA10Z, RA11Z, RA12Z,RA13Z and RA14Z[246]
DEXA scan	75		Direct access: diagnostic imaging. HRG code RA15Z[246]
MRI scan	185	Average cost for different types of MRI scan, ≥ 19 years	Direct access: diagnostic imaging. HRG codes RA01A, RA02A, RA03Z, RA04Z, RA05Z, RA06Z and RA07Z[246]
Nuclear medicine	454	Average cost for nuclear medicine categories 1–8	Direct access: diagnostic imaging. HRG codes RA35Z, RA36Z, RA37Z, RA38Z, RA39Z, RA40Z and RA42Z[246]
Simple echocardiogram	62		Direct access: diagnostic imaging. HRG code RA60A[246]
Ultrasound scan	57	Average cost for different types of MRI, ≥ 19 years	Direct access: diagnostic imaging. HRG codes RA23Z, RA24Z, RA25Z, RA26Z and RA27Z[246]
Radiography plain film	30		Direct access: diagnostic services. HRG code DAPF[246]
Examination, follow-up or special screening, with complications	26		Direct access: diagnostic services. HRG code WA20Y[246]
Biochemistry	1		Direct access: pathology services. HRG code DAP841[246]
Cytology	18		Direct access: pathology services. HRG code DAP838[246]
Haematology	3		Direct access: pathology services. HRG code DAP823[246]
Histology/histopathology	31		Direct access: pathology services. HRG code DAP824[246]
Immunology	8		Direct access: pathology services. HRG code DAP830[246]

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TABLE 88 Unit costs used for costing investigations (*continued*)

Costing item	Unit cost (£)	Assumption	Reference
INR anticoagulant monitoring	21		All NHS trusts and NHS foundation trusts – outpatient attendances data[246]
Microbiology/virology	8		Direct access: pathology services. HRG code DAP831[246]
Other pathology	6		Direct access: pathology services. HRG code DAP842[246]
Phlebotomy	3		Direct access: pathology services. HRG code DAP839[246]
Full pulmonary function testing	52		Direct access: diagnostic services. HRG code DZ52Z[246]
Lung volume studies	73		Direct access: diagnostic services. HRG code DZ45Z[246]
Simple airflow studies (e.g. spirometry)	54		Direct access: diagnostic services. HRG code DZ44Z[246]
Other procedures for non-trauma	26		Direct access: diagnostic services. HRG code HB99Z[246]
Diagnostic vascular radiology or other transluminal diagnostic procedures	69		Direct access: diagnostic services. HRG code QZ16A[246]
Examination, follow-up or special screening, without complications	32		Direct access: diagnostic services. HRG code WA20W[246]
24-hour blood pressure monitoring	32	Diagnostic services – examination, follow-up or special screening, without CC	Direct access: diagnostic services. HRG code WA20Y[246]
24-hour Holter ECG	61	Diagnostic services – electrocardiogram monitoring and stress testing	Direct access: diagnostic services. HRG code EA47Z[246]
ECG	61	Diagnostic services – electrocardiogram monitoring and stress testing	Direct access: diagnostic services. HRG code EA47Z[246]
Faecal microscopy: culture and sensitivity	8	Pathology services – microbiology/virology	Direct access: pathology services. HRG code DAP831[246]
Faecal occult blood test	6	Pathology services – other	Direct access: pathology services. HRG code DAP842[246]
Fasting glucose	1	Pathology services – biochemistry	Direct access: pathology services. HRG code DAP841[246]
Gastroscopy	31	Diagnostic services – minor endoscopic or percutaneous, hepatobiliary or pancreatic procedures, ≥ 19 years	Direct access: diagnostic services. HRG code GB04D[246]
Helicobacter pylori antigen test	8	Pathology services – immunology	Direct access: pathology services. HRG code DAP830[246]
Histopathology	31	Pathology services – histology/ histopathology	Direct access: pathology services. HRG code DAP824[246]
Nail mycology	8	Pathology services – microbiology/virology	Direct access: pathology services. HRG code DAP831[246]
Nasal swab	8	Pathology services – microbiology/virology	Direct access: pathology services. HRG code DAP831[246]

TABLE 88 Unit costs used for costing investigations (*continued*)

Costing item	Unit cost (£)	Assumption	Reference
Skin histology	31	Pathology services – histology/histopathology	Direct access: pathology services. HRG code DAP824[246]
Sputum analysis	8	Pathology services – microbiology/virology	Direct access: pathology services. HRG code DAP831[246]
Sputum culture	8	Pathology services – microbiology/virology	Direct access: pathology services. HRG code DAP831[246]
Stool sample	8	Pathology services – microbiology/virology	Direct access: pathology services. HRG code DAP831[246]
Stool sample *H. pylori* test	8	Pathology services – immunology	Direct access: pathology services. HRG code DAP830[246]
Throat swab for microscopy: culture and sensitivity	8	Pathology services – microbiology/virology	Direct access: pathology services. HRG code DAP831[246]
Urine microalbumin and creatinine	1	Pathology services – biochemistry	Direct access: pathology services. HRG code DAP841[246]
Urine pregnancy test	1	Pathology services – biochemistry	Direct access: pathology services. HRG code DAP841[246]
Vaginal swab microscopy: culture and sensitivity	8	Pathology services – microbiology/virology	Direct access: pathology services. HRG code DAP831[246]
Wound swab culture	8	Pathology services – microbiology/virology	Direct access: pathology services. HRG code DAP831[246]

CC, clinical consultation; CT, computerised tomography; DEXA, dual-energy X-ray absorptiometry; ECG, electrocardiography; INR, international normalised ratio; MRI, magnetic resonance imaging.

TABLE 89 Unit costs used for costing referrals to primary care

Costing item	Unit cost (£)	Cost of consultation (£)	Assumption	Reference
Acupuncture	33.00	19.25	Duration of contact 35 minutes	Per hour including qualifications. Community physiotherapist (p. 167)[245]
Audiology	56.48	56.48		Audiology – outpatient attendances. HRG code 840[246]
Chiropody	30.00	30.00	Duration of contact 60 minutes	Per hour, community chiropodist/ podiatrist (p. 170)[245]
Community diabetes team	49.00	20.42	Duration of contact 25 minutes	Per hour, nurse specialist surgery including qualifications (p. 178)[245]
Community lymphoedema service	49.00	20.42	Duration of contact 25 minutes	Per hour, nurse specialist surgery including qualifications (p. 178)[245]
Community mental health team	2528.00	2528.00		Average cost per case, community mental health team for adults with mental health problems (p. 200)[245]
Community physiotherapy	33.00	67.38	3.5 sessions; duration of contact 35 minutes	Per hour including qualifications (p. 167)[245]
Community rehabilitation	2749.00	2749.00		Per episode, community rehabilitation unit (p. 42)[245]

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TABLE 89 Unit costs used for costing referrals to primary care (*continued*)

Costing item	Unit cost (£)	Cost of consultation (£)	Assumption	Reference
Continence service	49.00	20.42	Duration of contact 25 minutes	Per hour, nurse specialist surgery including qualifications (p. 178)[245]
Dietetics	34.00	28.33	Duration of contact 50 minutes	Per hour including qualifications (p. 216)[245]
District nursing	58.00	101.50	3.5 contacts; duration of contact 30 minutes	Per hour of patient-related work, community nurse (district nursing sister, district nurse), including qualifications (p. 175)[245]
Deep vein thrombosis service	21.00	21.00		Outpatient attendances. HRG code 324[246]
Exercise/weight loss/ lifestyle programme	174.00	174.00		Per person, public health interventions, physiotherapy/physical activity (p. 117)[245]
GPSI dermatology	58.00	58.00		Per patient contact lasting 17.2 minutes, GP surgery excluding direct care staff costs, with qualification costs (p. 183)[245]
Home treatment team	58.00	101.50	3.5 contacts; duration of contact 30 minutes	Per hour of patient-related work, community nurse (district nursing sister, district nurse) including qualifications (p. 175)[245]
Minor ailments clinic	69.00	11.50	Duration of contact 10 minutes	Per hour of patient-related activities, community pharmacist including qualifications (p. 172)[245]
Nursing care	58.00	101.50	3.5 contacts; duration of contact 30 minutes	Per hour of patient-related work, community nurse (district nursing sister, district nurse) including qualifications (p. 175)[245]
Occupational therapy	33.00	16.50	Duration of contact 30 minutes	Per hour including qualifications (p. 168)[245]
Optometry	61.01	61.01		Optometry. Outpatient attendances. HRG code 662[246]
Orthotics	93.00	93.00		Unit cost taken from Secondary User Service database (London centre download)
Other GP for minor surgery	58.00	58.00		Per patient contact lasting 17.2 minutes, excluding direct care staff costs, with qualification costs, (p. 183)[245]
Physiotherapy	33.00	67.38	3.5 contacts; duration of contact 35 minutes	Per hour including qualifications (p. 167)[245]
Podiatry	30.00	30.00	Duration of contact 60 minutes	Per hour, community chiropodist/ podiatrist (p. 170)[245]
Pulmonary rehabilitation	2749.00	2749.00		Per episode, community rehabilitation unit (p. 42)[245]
Psychology IAPT	136/65	100.50	50% psychologist, 50% counselling; duration of contact 1 hour	Per hour of client contact, psychologist (p. 171), counselling (p. 53)[245]
Rehabilitation	2749.00	2749.00		Per episode, community rehabilitation unit (p. 42)[245]

TABLE 89 Unit costs used for costing referrals to primary care (*continued*)

Costing item	Unit cost (£)	Cost of consultation (£)	Assumption	Reference
Social services	214.00	107.00	Duration of contact 30 minutes	Per hour of face-to-face contact, social worker (adult services) including qualification costs (p. 183)[245]
Stop smoking clinic	46–179	135.50	Mid-range	Per person, public health interventions, drug therapies for smoking cessation (p. 117)[245]
Bereavement care service	59.00	59.00		[a]Counselling, per consultation (p. 53)[245]

GPSI, GP with a special interest.

a 5 Department of Health. *Bereavement Care Services: A Synthesis of the Literature. Final Report of Review Commissioned by DH to Support Implementation of the End of Life Care Strategy*. URL: www.gov.uk/government/uploads/system/uploads/attachment_data/file/215799/dh_123810.pdf (accessed 18 November 2013).

Prescription costing flow chart

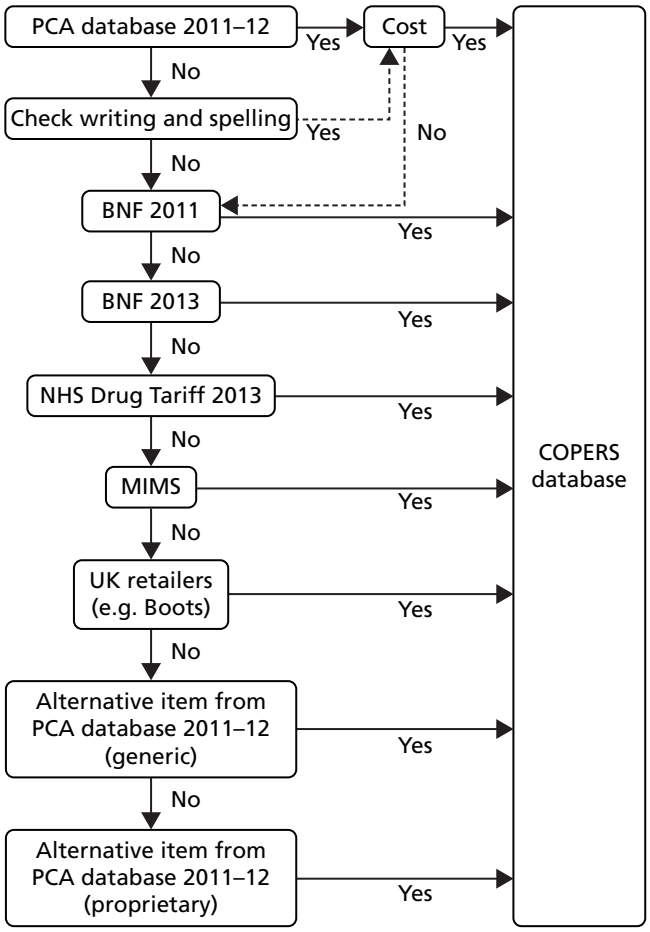

FIGURE 58 Prescription costing flow chart. MIMS, Monthly Index of Medical Specialties.

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General practice and patient information sheets

Warwick Medical School

Barts and The London School of Medicine and Dentistry

COPERS STUDY

COping with persistent **P**ain, **E**ffectiveness **R**esearch into **S**elf-management

GENERAL PRACTICE INFORMATION SHEET

What is the purpose of the study?

To conduct a randomised controlled trial to explore the effectiveness and cost effectiveness of a newly developed self-management course for those with chronic musculoskeletal pain.

What will happen if my practice takes part in the study?

If you take part, you will help to identify patients living with chronic pain and recruit them for the COPERS study. We will ask you to search your electronic records, use your existing knowledge of patients and put up adverts in the public areas of your surgery to help generate patient interest. The identified patients will be screened by the clinician for suitability. Those eligible for inclusion will be sent an invitation letter from the clinic, with an attached reply slip to complete if they are interested and a patient information leaflet. The study team (who are trained and CRB checked) will then follow up patients who have indicated they might be interested in taking part. Interested patients can contact the study team directly via email, phone or reply slip, we will send them a baseline questionnaire and a trial consent form and enrol them in the study once consent is confirmed and they are randomised.

The study team will provide the envelopes, information leaflets, consent forms, postage stamps and pre-paid envelopes. The General Practice will be required to print out the invitation and reminder letters on clinic headed paper and provide the study team with an anonymised list of patients they have contacted (i.e. gender, age and ethnicity).

We will also need to review patient records at 12 months; patient consent will have been sought for this.

The general practices participating in the study will receive payment for their part in recruiting participants to the study.

What does the study involve for patients?

Patients will be asked to participate in a two arm randomised controlled trial. One arm of the trial will be the intervention, the self-management group based course, and the other the control or relaxation arm of the trial. Those on the course will be booked onto a three day course (10.00 till 3.00 every other day over a week) with a two hour follow up two weeks later. The course will teach them techniques to manage their pain. This will include: pain education, acceptance, cognitive behavioural therapy, attention control and distraction, relaxation, imagery, visualisation, posture and movement. Those in the control arm will be given a relaxation pack with instructions about relaxation technique and an audio CD.

Participants will be required to complete a baseline questionnaire, a self-efficacy questionnaire 12 weeks after randomisation and two further questionnaires at 6 and 12 months.

What happens next and who can I ask if I have any questions?

Please return the reply slip indicating whether you would like to take part in the study.

Please contact Dr Dawn Carnes on **020 7882 2546** if you have queries. Alternatively you can email at ***d.carnes@qmul.ac.uk***. The correspondence address is Dr Dawn Carnes, COPERS Study Manager,

Centre for Primary Care and Public Health, Barts and The London School of Medicine and Dentistry, 2 Newark Street, London, E1 2AT.

Has the study got approval and who is it funded by?
The study has been approved by Cambridgeshire 4 Research Ethics Committee (**11/EE/0046)** and by (Research Governance office at PCT or new consortia). Indemnity insurance and sponsorship is provided by Barts and The London Joint Research Office, 5 Walden St, London E1 2EF. The study is funded by the National Institute for Health Research. **ISRCTN: 24426731**

Who is responsible for this study?
Professor Stephanie Taylor, Centre for Primary Care and Public Health, Barts and The London School of Medicine and Dentistry, 2 Newark Street, E1 2AT and Professor Martin Underwood at Warwick Medical School, Clinical Trials Unit, Gibbet Hill Road, Coventry CV4 7AL.

WE LOOK FORWARD TO YOUR SUPPORT IN THE STUDY

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We would like to take part in the study.

Practice

Name……

Key

Contact……

Address……

……

……

Email ……

Telephone number(s) ……

Convenient times to contact us……

Signed……

Date……

Please sign and return this form in the **FREEPOST** envelope provided.

Office Use Only

Date received ……

DOI: 10.3310/pgfar04140

Participant Information Leaflet V6 25.5.11 fp

COPERS STUDY

COping with persistent **P**ain,
Effectiveness **R**esearch into
Self-management

Participant Information

London **020 7882 2546**

Warwick **024 7657 2905**

Barts and The London School of Medicine and Dentistry

Warwick Medical School

The COPERS study team thank you for taking an interest in our research.

The type of research study we are doing is called a randomised controlled trial. Please read the following information carefully. If you have any queries please call us.

What is the purpose of the study?

The COPERS study is comparing a chronic pain management course with a relaxation programme plus usual GP care. The trial will help us identify which approach is more effective and for whom. The study measures how all the people in the trial cope with their pain at different time points. We hope that the results will help to improve the outlook for people with chronic pain in the future.

What is a randomised controlled trial?

This is a study where people are chosen at random (by chance alone) to be in one of two treatment or intervention groups. The two groups of people are compared to find out any differences between interventions.

What is the difference between the two interventions in the trial?

If you are allocated to the course we will invite you to attend a short course led by two tutors. The course runs over 3 days from 10 am to 2.45 pm each day, with a 2 hour follow up session two weeks later. During the course you will be encouraged to talk with others who have chronic pain and think about your own lifestyle, experiences and behaviours. There will be up to 12 people in a group. The course will include sessions about:

- Understanding your pain
- Pain and mood
- Dealing with unhelpful thinking
- Communication skills
- Attention control techniques
- Activity
- Posture and stretching

The courses will be run by a healthcare professional and a person who has chronic pain and has been trained to run the course.

If you are in the relaxation group we will send you a booklet with advice about chronic pain management and a relaxation CD. We will give you instructions about relaxation and how to use a relaxation CD. You will be asked to practise and use the relaxation techniques for 3 weeks. You can continue to receive your usual healthcare whilst taking part in the COPERS study.

Some courses may be audio recorded for quality control purposes only.

How long does the study last?

You will be asked to remain in the study for 12 months. After you have either done a course or completed the relaxation programme we will contact you with a short questionnaire at 12 weeks (this will take about 5 minutes to complete and return to us). We will then contact you again at 6 months, and one year, to fill in follow-up questionnaires (these will take around 10-20 minutes to complete).

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Do I have to take part?

No. It is up to you to decide whether you want to take part. You are free to change your mind and withdraw from the study at any time and you do not have to give a reason why. Your decision will not affect the care you receive from the NHS in any way. We would however with your consent continue to use data already collected from you.

What will happen to me if I take part?

First make sure you have read all the information and are satisfied that we have answered all your questions. Then fill out the trial consent form and the baseline questionnaire and post them back to us using the FREEPOST envelope provided (no stamp is required).

When we receive your trial consent form and baseline questionnaire we make sure your details are stored with an anonymous study identification number. We will then telephone you to check you are happy to be in the study and understand the process. We will then randomly allocate you to the course or relaxation group.

If you are allocated to the course we will agree a course date suitable for you and if you are allocated to the relaxation group we will post out your booklet and CD and instructions.

Are there any risks in taking part?

We do not foresee any risks to your health in taking part in the study.

Who will know that I am taking part?

The only people who will know that you are taking part are the study team and your GP.

What will you do with the results of the study?

We will present the findings in a study report and in medical journals. You will not be identified in any of the publications. The study team will make sure that you know about the results through a newsletter and you can look at our website: www.icms.qmul.ac.uk/chs/pctu/current_projects/copers/25507.html

Will my details be kept confidential?

Yes. Your personal details will be kept strictly confidential from outside sources. Any information about you which leaves your GP practice will have your name and address removed so that you cannot be recognised from it. The only reason we would break confidentiality would be in an emergency. If your own health, or somebody else's health was in danger, we would contact your GP.

Who is responsible for this study?

Professor Stephanie Taylor (London), Professor Martin Underwood (Warwick). The National Institute for Health Research has funded the study (This is a government funded research body). The Cambridgeshire 4 Research Ethics Committee approved the study and Queen Mary University of London provide the indemnity insurance cover.

What happens if there is a problem?

Queen Mary University of London has agreed that if in the unlikely event that you are harmed as a result of your participation in the study, you will be compensated, provided that, on the balance of probabilities, an injury was caused as a direct result of the intervention you received during the course of the study. These special compensation arrangements apply where an injury is caused to you that would not have occurred if you were not in the trial. These arrangements do not affect your right to pursue a claim through legal action.

If you have a complaint:

Please contact Patient Advisory Liaison Service if you have any concerns regarding the care you have received, or as an initial point of contact if you have a complaint.

Please telephone **020 7377 6335** or email **pals@bartsandthelondon.nhs.uk**

Who should I contact if I need more information?

Dr Dawn Carnes, Study Manager, who will be happy to answer any queries. Telephone: **020 7882 2546** or email: **d.carnes@qmul.ac.uk**

THANK YOU FOR YOUR TIME

If you would like a large print version of this information sheet please call 020 7882 2546

ISRCTN: 24426731

Participant questionnaires

COPERS STUDY

COping with persistent Pain, Effectiveness Research into Self-management

BASELINE QUESTIONNAIRE

Confidential

Dear Participant.

The aim of this questionnaire is to find out your current health state and feelings about living with chronic pain before you participate in the COPERS study. Please read the questions carefully. If you have any difficulties with the questionnaire please call the study team in London 020 7882 2546 or Warwick 024 7657 2905.

THANK YOU for being part of our study. We look forward to receiving your questionnaire.

COPERS Study Team

Section 1. ABOUT YOUR PAIN

Please answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. How is your health in general? Please tick (✓) one

Very good	Good	Fair	Bad	Very bad
☐	☐	☐	☐	☐

2. How long have you had your pain? Please tick (✓) one

0 – 3 months	4 – 12 months	13 months – 2 years	3 – 4 years	5 – 6 years	7 - 10 years	More than 10 years
☐	☐	☐	☐	☐	☐	☐

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Participant ID No.:……

Section 1. ABOUT YOUR PAIN continued...

3. How would you rate your pain on a 0-10 scale at the present time, that is right now, where 0 is 'no pain' and 10 is 'pain as bad as could be'? Please tick (✓) one

No pain										Pain as bad as could be
0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

For the following questions with a scale of 0-10, please tick one number/box only.

4. In the past six months, how intense was your worst pain rated on a 0-10 scale where 0 is 'no pain' and 10 is 'pain as bad as could be'? Please tick (✓) one

No pain										Pain as bad as could be
0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

5. In the past six months, on average, how intense was your pain rated on a 0-10 scale, where 0 is 'no pain' and 10 is 'pain as bad as could be'? (That is, your usual pain at times you were experiencing pain) Please tick (✓) one

No pain										Pain as bad as could be
0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

6. About how many days in the last six months have you been kept from your usual activities (work, school or housework) because of this pain? Please tick (✓) one

- **0 – 6 days** ☐
- **7 – 14 days** ☐
- **15 – 30 days** ☐
- **31 or more days** ☐

Participant ID No.:……

Section 1. ABOUT YOUR PAIN continued...

7. In the past six months, how much has this pain interfered with your daily activities rated on a 0-10 scale where 0 is 'no interference' and 10 'unable to carry on activities'? Please tick (✓) one

No interference										Unable to carry on activities
0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

8. In the past six months, how much has this pain changed your ability to take part in recreational, social and family activities where 0 is 'no change' and 10 is 'extreme change'? Please tick (✓) one

No change										Extreme change
0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

9. In the past six months, how much has this pain changed your ability to work (including housework) where 0 is 'no change' and 10 is 'extreme change'? Please tick (✓) one

No change										Extreme change
0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

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Participant ID No.:……

Section 2. QUALITY OF LIFE

Please tick which statements best describe your own health state today.

1. Mobility Please tick (✓) one

- I have no problems walking about ☐
- I have some problems walking about ☐
- I am confined to bed ☐

2. Self-care Please tick (✓) one

- I have no problems with self-care ☐
- I have some problems washing or dressing myself ☐
- I am unable to wash or dress myself ☐

3. Usual activities such as work, study, housework family or leisure Please tick (✓) one

- I have no problems with performing my usual activities ☐
- I have some problems with performing my usual activities ☐
- I am unable to perform my usual activities ☐

4. Pain/Discomfort Please tick (✓) one

- I have no pain or discomfort ☐
- I have moderate pain or discomfort ☐
- I have extreme pain or discomfort ☐

5. Anxiety/Depression Please tick (✓) one

- I am not anxious or depressed ☐
- I am moderately anxious or depressed ☐
- I am extremely anxious or depressed ☐

Participant ID No.:……

Section 3. CONFIDENCE

Please indicate how *confident* you are that you can do the following things at present, despite the pain, where 0 is 'not at all confident' and 6 is 'completely confident'.

**** Remember, these questions are not asking whether or not you have been doing these things, but rather how confident you are that you could do them at present, despite the pain.**

1. I can enjoy things, despite the pain Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

2. I can do most household chores (e.g. tidying up, washing dishes etc), despite the pain Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

3. I can socialise with my friends or family members as often as I used to, despite the pain Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

4. I can cope with my pain in most situations Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

5. I can do some form of work, despite the pain ('work' includes housework, paid and unpaid work) Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

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Participant ID No.:……..

Section 3. CONFIDENCE continued ...

6. I can still do many of the things I enjoy doing, such as hobbies or leisure activity, despite the pain Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

7. I can cope with my pain without medication Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

8. I can still accomplish most of my goals in life, despite the pain Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

9. I can live a normal lifestyle, despite the pain Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

10. I can gradually become more active despite the pain Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

Participant ID No.:…….

Section 4. MOOD

Please read each item and tick the reply which comes closest to how you have been feeling in the past week.

Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought out response.

1. I feel tense or "wound up" Please tick (✓) one		**2. I still enjoy the things I used to enjoy** Please tick (✓) one	
Most of the time	☐	**Definitely as much**	☐
A lot of the time	☐	**Not quite as much**	☐
From time to time, occasionally	☐	**Only a little**	☐
Not at all	☐	**Hardly at all**	☐

3. I get a sort of frightened feeling as if something awful is about to happen Please tick (✓) one		**4. I can laugh and see the funny side of things** Please tick (✓) one	
Very definitely and quite badly	☐	**As much as I always could**	☐
Yes, but not too badly	☐	**Not quite so much now**	☐
A little but it doesn't worry me	☐	**Definitely not so much now**	☐
Not at all	☐	**Not at all**	☐

5. Worrying thoughts go through my mind Please tick (✓) one		**6. I feel cheerful** Please tick (✓) one	
A great deal of the time	☐	**Not at all**	☐
A lot of the time	☐	**Not often**	☐
From time to time but not too often	☐	**Sometimes**	☐
Only occasionally	☐	**Most of the time**	☐

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Participant ID No.:……

Section 4. MOOD continued ...

7. I can sit at ease and feel relaxed
Please tick (✓) one

- ☐ Definitely
- ☐ Usually
- ☐ Not often
- ☐ Not at all

8. I feel as if I am slowed down
Please tick (✓) one

- ☐ Nearly all of the time
- ☐ Very often
- ☐ Sometimes
- ☐ Not at all

9. I get a sort of frightened feeling like "butterflies" in the stomach
Please tick (✓) one

- ☐ Not at all
- ☐ Occasionally
- ☐ Quite often
- ☐ Very often

10. I have lost interest in my appearance
Please tick (✓) one

- ☐ Definitely
- ☐ I don't take as much care as I should
- ☐ I may not take quite as much care
- ☐ I take just as much care as ever

11. I feel restless as though I have to be on the move
Please tick (✓) one

- ☐ Very much indeed
- ☐ Quite a lot
- ☐ Not very much
- ☐ Not at all

12. I look forward with enjoyment to things
Please tick (✓) one

- ☐ As much as I ever did
- ☐ Rather less than I used to
- ☐ Definitely less than I used to
- ☐ Hardly at all

13. I get sudden feelings of panic
Please tick (✓) one

- ☐ Very often indeed
- ☐ Quite often
- ☐ Not very often
- ☐ Not at all

14. I can enjoy a good book or radio or TV programme Please tick (✓) one

- ☐ Often
- ☐ Sometimes
- ☐ Not often
- ☐ Very seldom

Participant ID No.:……

Section 5. COPING

Below you will find a list of statements. Please rate the truth of each statement as it applies to you by ticking one response, where 0 is 'never true' and 6 is 'always true'.

1. I am getting on with the business of living no matter what my level of pain is Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

2. My life is going well, even though I have chronic pain Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

3. It's OK to experience pain Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

4. I would gladly sacrifice important things in my life to control this pain better Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

5. It's not necessary for me to control my pain in order to handle my life well Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

6. Although things have changed, I am living a normal life despite my chronic pain Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

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Participant ID No.:……

Section 5. COPING Continued...

7. I need to concentrate on getting rid of my pain Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

8. There are many activities I do when I feel pain Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

9. I lead a full life even though I have chronic pain Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

10. Controlling pain is less important than other goals in my life Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

11. My thoughts and feelings about pain must change before I can take important steps in my life Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

12. Despite the pain, I am now sticking to a certain course in my life Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

Participant ID No.:…….

Section 5. COPING continued ...

13. Keeping my pain level under control takes first priority whenever I'm doing something Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

14. Before I can make any serious plans, I have to get some control over my pain Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

15. When my pain increases, I can still take care of my responsibilities Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

16. I will have better control over my life if I can control my negative thoughts about pain Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

17. I avoid putting myself in situations where my pain might increase Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

18. My worries and fears about what pain will do to me are true Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

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Participant ID No.:……

Section 5. COPING continued ...

19. It's a relief to realise that I don't have to change my pain to get on with my life Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

20. I have to struggle to do things when I have pain Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

Participant ID No.:…….

Section 6. SOCIAL LIFE

Below you will find a list of statements. Please indicate how strongly you agree or disagree with the following statements by ticking the response which best describes you now.

1. I am doing interesting things in my life Please tick (✓) one	**2. Most days I am doing some of the things I really enjoy** Please tick (✓) one
Strongly disagree ☐	**Strongly disagree** ☐
Disagree ☐	**Disagree** ☐
Agree ☐	**Agree** ☐
Strongly agree ☐	**Strongly agree** ☐

3. I try to make the most of my life Please tick (✓) one	**4. I have plans to do enjoyable things for myself over the next few days** Please tick (✓) one
Strongly disagree ☐	**Strongly disagree** ☐
Disagree ☐	**Disagree** ☐
Agree ☐	**Agree** ☐
Strongly agree ☐	**Strongly agree** ☐

5. I feel like I am actively involved in life Please tick (✓) one
Strongly disagree ☐
Disagree ☐
Agree ☐
Strongly agree ☐

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Participant ID No.:……

Section 7. FURTHER DETAILS

1. Date of birth	**2. NHS number**
	You can find this number on your prescriptions

3. Gender Please tick (✓) one	**4. Living arrangements** Please tick (✓) one
Male ☐ **Female** ☐	**Alone** ☐ **With others** ☐

5. Describe your English language fluency Please tick (✓) one

Fluent	**Good**	**Below Average**	**Poor**
☐	☐	☐	☐

6. What is your ethnic group? (please choose **one** section from A to E then **tick one** box to best describe your ethnic group or background)

A. White Please tick (✓) one	**B. Black or Black British** Please tick (✓) one
British ☐	**Caribbean** ☐
Irish ☐	**African** ☐
Any other white background (write below) ☐	**Any other black background** (write below) ☐
C. Asian or Asian British Please tick (✓) one	**D. Mixed** Please tick (✓) one
Indian ☐	**White & Black Caribbean** ☐
Pakistani ☐	**White & Black African** ☐
Bangladeshi ☐	**White & Asian** ☐
Any other Asian background (write below) ☐	**Any other mixed background** (write below) ☐

E. Other ethnic group Please tick (✓) one	
Chinese ☐	**Arab** ☐
Other ethnic group (write below) ☐	

Participant ID No.:…….

Section 7. FURTHER DETAILS continued ...

7. Which of the following best describes you? Please tick (✓) one

- **Employed (full or part time, including self employment)** ☐
- **Unemployed and looking for work** ☐
- **At school or in full time education** ☐
- **Unable to work due to long term sickness** ☐
- **Looking after your home/family** ☐
- **Retired from paid work** ☐
- **Other** (please write below) ☐

8. How old were you when you left full time education (e.g. school, college or university? Please tick (✓) one

- **I did not receive a formal education** ☐
- **Age 12 or less** ☐
- **Age 13 to 16** ☐
- **Age 17 to 19** ☐
- **Age 20 or over** ☐
- **I am still in full time education** ☐
- **Other** (please write below) ☐

THANK YOU FOR FILLING IN THE QUESTIONNAIRE

Please return to the study team using the FREEPOST envelope provided (no postage stamp required)

HEAD OFFICE: COPERS STUDY
CENTRE FOR PRIMARY CARE AND PUBLIC HEALTH, BLIZARD INSTITUTE,
2 Newark Street, London, E1 2AT

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Participant ID No.....

Barts and The London School of Medicine and Dentistry

Warwick Medical School

COPERS STUDY

COping with persistent **P**ain, **E**ffectiveness **R**esearch into **S**elf-management

FOLLOW-UP QUESTIONNAIRE

AT 12 WEEKS

Confidential

Dear Participant.

The aim of this questionnaire is to find out your current feelings about living with chronic pain after you participated in the COPERS study. Please read the questions carefully. If you have any difficulties with the questionnaire please call the study team on 020 7882 2546.

THANK YOU for being part of our study. We look forward to receiving your questionnaire.

COPERS Study Team

Section 1. CONFIDENCE

Please indicate how *confident* you are that you can do the following things at present, despite the pain, where 0 is 'not at all confident' and 6 is 'completely confident'.

**** Remember, these questions are not asking whether or not you have been doing these things, but rather how confident you are that you could do them at present, despite the pain.**

1. I can enjoy things, despite the pain Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

2. I can do most household chores (e.g. tidying up, washing dishes etc), despite the pain Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

3. I can socialise with my friends or family members as often as I used to, despite the pain Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

4. I can cope with my pain in most situations Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

5. I can do some form of work, despite the pain ('work' includes housework, paid and unpaid work) Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

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Section 1. CONFIDENCE continued ...

6. I can still do many of the things I enjoy doing, such as hobbies or leisure activity, despite the pain Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

7. I can cope with my pain without medication Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

8. I can still accomplish most of my goals in life, despite the pain Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

9. I can live a normal lifestyle, despite the pain Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

10. I can gradually become more active despite the pain Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

THANK YOU FOR FILLING IN THE QUESTIONNAIRE

Please return to the study team using the FREEPOST envelope provided (no postage stamp required)

HEAD OFFICE: COPERS STUDY
CENTRE FOR PRIMARY CARE AND PUBLIC HEALTH, BLIZARD INSTITUTE,
2 Newark Street, London, E1 2AT

Participant ID No.:.....

COPERS
MANAGING PAIN • LIVING LIFE

Barts and The London School of Medicine and Dentistry

Warwick Medical School

COPERS STUDY

COping with persistent **P**ain, **E**ffectiveness **R**esearch into **S**elf-management

FOLLOW-UP QUESTIONNAIRE AT 6 MONTHS

Confidential

Dear Participant.

The aim of this questionnaire is to find out your current health state and feelings about living with chronic pain after you participated in the COPERS study. Please read the questions carefully. If you have any difficulties with the questionnaire please call the study team on 020 7882 2546.

THANK YOU for being part of our study. We look forward to receiving your questionnaire.

COPERS Study Team

Section 1. ABOUT YOUR PAIN

Please answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. How is your health in general?: Please tick (✓) one

Very good	Good	Fair	Bad	Very bad
☐	☐	☐	☐	☐

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Section 1. ABOUT YOUR PAIN continued...

For the following questions with a scale of 0-10, please tick one number only.

2. How would you rate your pain on a 0-10 scale at the present time that is, right now, where 0 is 'no pain' and 10 is 'pain as bad as could be'?
Please tick (✓) one

No pain										Pain as bad as could be
0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

3. In the past six months, how intense was your worst pain rated on a 0-10 scale where 0 is 'no pain' and 10 is 'pain as bad as could be'? Please tick (✓) one

No pain										Pain as bad as could be
0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

4. In the past six months, on average, how intense was your pain rated on a 0-10 scale, where 0 is 'no pain' and 10 is 'pain as bad as could be'? (That is, your usual pain at times you were experiencing pain) Please tick (✓) one

No pain										Pain as bad as could be
0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

5. About how many days in the last six months have you been kept from your usual activities (work, school or housework) because of this pain? Please tick (✓) one

- **0 – 6 days** ☐
- **7 – 14 days** ☐
- **15 – 30 days** ☐
- **31 or more days** ☐

Section 1. ABOUT YOUR PAIN continued...

6. In the past six months, how much has this pain interfered with your daily activities rated on a 0-10 scale where 0 is 'no interference' and 10 'unable to carry on activities'? Please tick (✓) one

No interference										Unable to carry on activities
0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

7. In the past six months, how much has this pain changed your ability to take part in recreational, social and family activities where 0 is 'no change' and 10 is 'extreme change'? Please tick (✓) one

No change										Extreme change
0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

8. In the past six months, how much has this pain changed your ability to work (including housework) where 0 is 'no change' and 10 is 'extreme change'? Please tick (✓) one

No change										Extreme change
0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

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Section 2. QUALITY OF LIFE

Please tick which statements best describe your own health state today

1. Mobility Please tick (✓) one

- **I have no problems in walking about** ☐
- **I have some problems in walking about** ☐
- **I am confined to bed** ☐

2. Self-care Please tick (✓) one

- **I have no problems with self-care** ☐
- **I have some problems washing or dressing myself** ☐
- **I amunable to wash or dress myself** ☐

3. Usual activities such as work, study, housework family or leisure
Please tick (✓) one

- **I have no problems with performing my usual activities** ☐
- **I have some problems with performing my usual activities** ☐
- **I amunable to perform my usual activities** ☐

4. Pain/Discomfort Please tick (✓) one

- **I have no pain or discomfort** ☐
- **I have moderate pain or discomfort** ☐
- **I have extreme pain or discomfort** ☐

5. Anxiety/Depression Please tick (✓) one

- **I amnot anxious or depressed** ☐
- **I am moderately anxious or depressed** ☐
- **I am extremely anxious or depressed** ☐

Section 3. CONFIDENCE

Please indicate how *confident* you are that you can do the following things at present, despite the pain, where 0 is 'not at all confident' and 6 is 'completely confident'.

**** Remember, these questions are not asking whether or not you have been doing these things, but rather how confident you are that you could do them at present, despite the pain.**

1. I can enjoy things, despite the pain Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

2. I can do most household chores (e.g. tidying up, washing dishes etc), despite the pain Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

3. I can socialise with my friends or family members as often as I used to, despite the pain Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

4. I can cope with my pain in most situations Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

5. I can do some form of work, despite the pain ('work' includes housework, paid and unpaid work) Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

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Section 3. CONFIDENCE continued ...

6. I can still do many of the things I enjoy doing, such as hobbies or leisure activity, despite the pain Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

7. I can cope with my pain without medication Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

8. I can still accomplish most of my goals in life, despite the pain Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

9. I can live a normal lifestyle, despite the pain Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

10. I can gradually become more active despite the pain Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

Section 4. MOOD

Please read each item and tick the reply which comes closest to how you have been feeling in the past week.

Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought out response.

1. I feel tense or "wound up" Please tick (✓) one		**2. I still enjoy the things I used to enjoy** Please tick (✓) one	
Most of the time	☐	**Definitely as much**	☐
A lot of the time	☐	**Not quite as much**	☐
From time to time, occasionally	☐	**Only a little**	☐
Not at all	☐	**Hardly at all**	☐

3. I get a sort of frightened feeling as if something awful is about to happen Please tick (✓) one		**4. I can laugh and see the funny side of things** Please tick (✓) one	
Very definitely and quite badly	☐	**As much as I always could**	☐
Yes, but not too badly	☐	**Not quite so much now**	☐
A little but it doesn't worry me	☐	**Definitely not so much now**	☐
Not at all	☐	**Not at all**	☐

5. Worrying thoughts go through my mind Please tick (✓) one		**6. I feel cheerful** Please tick (✓) one	
A great deal of the time	☐	**Not at all**	☐
A lot of the time	☐	**Not often**	☐
From time to time but not too often	☐	**Sometimes**	☐
Only occasionally	☐	**Most of the time**	☐

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Section 4. MOOD continued ...

7. I can sit at ease and feel relaxed
Please tick (✓) one

- Definitely ☐
- Usually ☐
- Not often ☐
- Not at all ☐

8. I feel as if I am slowed down
Please tick (✓) one

- Nearly all of the time ☐
- Very often ☐
- Sometimes ☐
- Not at all ☐

9. I get a sort of frightened feeling like "butterflies" in the stomach
Please tick (✓) one

- Not at all ☐
- Occasionally ☐
- Quite often ☐
- Very often ☐

10. I have lost interest in my appearance
Please tick (✓) one

- Definitely ☐
- I don't take as much care as I should ☐
- I may not take quite as much care ☐
- I take just as much care as ever ☐

11. I feel restless as though I have to be on the move Please tick (✓) one

- Very much indeed ☐
- Quite a lot ☐
- Not very much ☐
- Not at all ☐

12. I look forward with enjoyment to things Please tick (✓) one

- As much as I ever did ☐
- Rather less than I used to ☐
- Definitely less than I used to ☐
- Hardly at all ☐

13. I get sudden feelings of panic
Please tick (✓) one

- Very often indeed ☐
- Quite often ☐
- Not very often ☐
- Not at all ☐

14. I can enjoy a good book or radio or TV programme Please tick (✓) one

- Often ☐
- Sometimes ☐
- Not often ☐
- Very seldom ☐

Section 5. COPING

Below you will find a list of statements. Please rate the truth of each statement as it applies to you by ticking one response, where 0 is 'never true' and 6 is 'always true'.

1. I am getting on with the business of living no matter what my level of pain is Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

2. My life is going well, even though I have chronic pain Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

3. It's OK to experience pain Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

4. I would gladly sacrifice important things in my life to control this pain better Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

5. It's not necessary for me to control my pain in order to handle my life well Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

6. Although things have changed, I am living a normal life despite my chronic pain Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

7. I need to concentrate on getting rid of my pain Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

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Section 5. COPING Continued...

8. There are many activities I do when I feel pain Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

9. I lead a full life even though I have chronic pain Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

10. Controlling pain is less important than other goals in my life Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

11. My thoughts and feelings about pain must change before I can take important steps in my life Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

12. Despite the pain, I am now sticking to a certain course in my life Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

13. Keeping my pain level under control takes first priority whenever I'm doing something Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

14. Before I can make any serious plans, I have to get some control over my pain Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

Section 5. COPING continued ...

15. When my pain increases, I can still take care of my responsibilities Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

16. I will have better control over my life if I can control my negative thoughts about pain Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

17. I avoid putting myself in situations where my pain might increase Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

18. My worries and fears about what pain will do to me are true Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

19. It's a relief to realise that I don't have to change my pain to get on with my life Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

20. I have to struggle to do things when I have pain Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

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Section 6. SOCIAL LIFE

Below you will find a list of statements. Please indicate how strongly you agree or disagree with the following statements by ticking the response which best describes you now.

1. I am doing interesting things in my life Please tick (✓) one

- **Strongly disagree** ☐
- **Disagree** ☐
- **Agree** ☐
- **Strongly agree** ☐

2. Most days I am doing some of the things I really enjoy Please tick (✓) one

- **Strongly disagree** ☐
- **Disagree** ☐
- **Agree** ☐
- **Strongly agree** ☐

3. I try to make the most of my life Please tick (✓) one

- **Strongly disagree** ☐
- **Disagree** ☐
- **Agree** ☐
- **Strongly agree** ☐

4. I have plans to do enjoyable things for myself over the next few days Please tick (✓) one

- **Strongly disagree** ☐
- **Disagree** ☐
- **Agree** ☐
- **Strongly agree** ☐

5. I feel like I am actively involved in life Please tick (✓) one

- **Strongly disagree** ☐
- **Disagree** ☐
- **Agree** ☐
- **Strongly agree** ☐

Section 8. PRIVATE HEALTHCARE USE

These questions are about any PRIVATE healthcare use outside the NHS over the last 6 months for your chronic pain.

1. In the last 6 months how many times have you seen the following people privately for your pain?

	Number of visits
Private doctor	☐
Private nurse	☐
Private physiotherapist	☐
Osteopath	☐
Chiropractor	☐
Acupuncturist	☐
Other (please specify) _____	☐
Other (please specify) _____	☐

2. In the last 6 months, have you had any tests or treatments done privately?
For example, scans, x-rays, blood tests or injections etc.

Description of test	Number of tests
_____	☐
_____	☐
_____	☐
_____	☐
_____	☐
_____	☐
_____	☐

3. In the last 6 months how much money have you spent on medicines for your pain?
For example, pain relief tablets, gels, homeopathic remedies etc.

Description	Amount £
_____	☐
_____	☐
_____	☐
_____	☐

4. In the last 6 months have you bought any devices or disability aids for your pain?
For example, a TENS machine, walking stick, strapping, mobility scooters etc.

Description	Amount £
_____	☐
_____	☐
_____	☐
_____	☐

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Section 8. PRIVATE HEALTHCARE USE continued ...

5. In the last 6 months, how many times have you been admitted for private hospital care and stayed overnight?

Reason and Duration	Number of nights
1) _____	☐
_____	
_____	
2) _____	☐
_____	
_____	
3) _____	☐
_____	
_____	

Comments

_____

6. In the last 6 months, how much money have you spent on any of the following because of your pain?

	£
Help at home For example, cleaning and cooking	☐
Personal care For example, washing and dressing	☐
Transport For example, taxis	☐
Household maintenance For example, gardening and repairs	☐
Other (please specify)	☐

_____

_____

_____

_____

_____

_____

THANK YOU FOR FILLING IN THE QUESTIONNAIRE

Please return to the study team using the FREEPOST envelope provided (no postage stamp required)

HEAD OFFICE: COPERS STUDY
CENTRE FOR PRIMARY CARE AND PUBLIC HEALTH, BLIZARD INSTITUTE,
2 Newark Street, London, E1 2AT

Participant ID No.:……..

Barts and The London School of Medicine and Dentistry

COPERS MANAGING PAIN • LIVING LIFE

Warwick Medical School

COPERS - COping with persistent Pain, Effectiveness Research in Self-management

FOLLOW UP QUESTIONNAIRE AT 12 MONTHS

Confidential

Dear Participant.

The aim of this questionnaire is find out your current health state and feelings about living with chronic pain after you participated in the COPERS study. Please read the questions carefully. If you have any difficulties with the questionnaire please call the study team on 020 7882 2546.

Section 1. ABOUT YOUR PAIN

Please answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. How is your health in general?: Please tick (✓) one

Very good	Good	Fair	Bad	Very bad
☐	☐	☐	☐	☐

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Section 1. ABOUT YOUR PAIN continued...

For the following questions with a scale of 0-10, please tick one number only.

2. How would you rate your pain on a 0-10 scale at the present time, that is right now, where 0 is 'no pain' and 10 is 'pain as bad as could be'?
Please tick (✓) one

No pain										Pain as bad as could be
0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

3. In the past six months, how intense was your worst pain rated on a 0-10 scale where 0 is 'no pain' and 10 is 'pain as bad as could be'? Please tick (✓) one

No pain										Pain as bad as could be
0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

4. In the past six months, on average, how intense was your pain rated on a 0-10 scale, where 0 is 'no pain' and 10 is 'pain as bad as could be'? (That is, your usual pain at times you were experiencing pain) Please tick (✓) one

No pain										Pain as bad as could be
0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

5. About how many days in the last six months have you been kept from your usual activities (work, school or housework) because of this pain?
Please tick (✓) one

- **0 – 6 days** ☐
- **7 – 14 days** ☐
- **15 – 30 days** ☐
- **31 or more days** ☐

Section 1. ABOUT YOUR PAIN continued...

6. In the past six months, how much has this pain interfered with your daily activities rated on a 0-10 scale where 0 is 'no interference' and 10 'unable to carry on activities'? Please tick (✓) one

No interference **Unable to carry on activities**

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

7. In the past six months, how much has this pain changed your ability to take part in recreational, social and family activities where 0 is 'no change' and 10 is 'extreme change'? Please tick (✓) one

No change **Extreme change**

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

8. In the past six months, how much has this pain changed your ability to work (including housework) where 0 is 'no change' and 10 is 'extreme change'? Please tick (✓) one

No change **Extreme change**

0	1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

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Section 2. QUALITY OF LIFE

Please tick which statements best describe your own health state today

1. Mobility Please tick (✓) one

- I have no problems in walking about ☐
- I have some problems in walking about ☐
- I am confined to bed ☐

2. Self-care Please tick (✓) one

- I have no problems with self-care ☐
- I have some problems washing or dressing myself ☐
- I am unable to wash or dress myself ☐

3. Usual activities such as work, study, housework family or leisure
Please tick (✓) one

- I have no problems with performing my usual activities ☐
- I have some problems with performing my usual activities ☐
- I am unable to perform my usual activities ☐

4. Pain/Discomfort Please tick (✓) one

- I have no pain or discomfort ☐
- I have moderate pain or discomfort ☐
- I have extreme pain or discomfort ☐

5. Anxiety/Depression Please tick (✓) one

- I am not anxious or depressed ☐
- I am moderately anxious or depressed ☐
- I am extremely anxious or depressed ☐

Section 3. CONFIDENCE

Please indicate how *confident* you are that you can do the following things at present, despite the pain, where 0 is 'not at all confident' and 6 is 'completely confident'

**** Remember, these questions are not asking whether or not you have been doing these things, but rather how confident you are that you could do them at present, despite the pain**

1. I can enjoy things, despite the pain Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

2. I can do most household chores (e.g. tidying up, washing dishes etc), despite the pain Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

3. I can socialise with my friends or family members as often as I used to, despite the pain Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

4. I can cope with my pain in most situations Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

5. I can do some form of work, despite the pain ('work' includes housework, paid and unpaid work) Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

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Section 3. CONFIDENCE continued ...

6. I can still do many of the things I enjoy doing, such as hobbies or leisure activity, despite the pain Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

7. I can cope with my pain without medication Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

8. I can still accomplish most of my goals in life, despite the pain Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

9. I can live a normal lifestyle, despite the pain Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

10. I can gradually become more active despite the pain Please tick (✓) one

Not confident						Completely confident
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

Section 4. MOOD

Please read each item and tick the reply which comes closest to how you have been feeling in the past week.

Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought out response.

1. I feel tense or "wound up" Please tick (✓) one		**2. I still enjoy the things I used to enjoy** Please tick (✓) one	
Most of the time	☐	**Definitely as much**	☐
A lot of the time	☐	**Not quite as much**	☐
From time to time, occasionally	☐	**Only a little**	☐
Not at all	☐	**Hardly at all**	☐

3. I get a sort of frightened feeling as if something awful is about to happen Please tick (✓) one		**4. I can laugh and see the funny side of things** Please tick (✓) one	
Very definitely and quite badly	☐	**As much as I always could**	☐
Yes, but not too badly	☐	**Not quite so much now**	☐
A little but it doesn't worry me	☐	**Definitely not so much now**	☐
Not at all	☐	**Not at all**	☐

5. Worrying thoughts go through my mind Please tick (✓) one		**6. I feel cheerful** Please tick (✓) one	
A great deal of the time	☐	**Not at all**	☐
A lot of the time	☐	**Not often**	☐
From time to time but not too often	☐	**Sometimes**	☐
Only occasionally	☐	**Most of the time**	☐

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Section 4. MOOD continued ...

7. I can sit at ease and feel relaxed
Please tick (✓) one

- Definitely ☐
- Usually ☐
- Not often ☐
- Not at all ☐

8. I feel as if I am slowed down
Please tick (✓) one

- Nearly all of the time ☐
- Very often ☐
- Sometimes ☐
- Not at all ☐

9. I get a sort of frightened feeling like "butterflies" in the stomach
Please tick (✓) one

- Not at all ☐
- Occasionally ☐
- Quite often ☐
- Very often ☐

10. I have lost interest in my appearance
Please tick (✓) one

- Definitely ☐
- I don't take as much care as I should ☐
- I may not take quite as much care ☐
- I take just as much care as ever ☐

11. I feel restless as though I have to be on the move Please tick (✓) one

- Very much indeed ☐
- Quite a lot ☐
- Not very much ☐
- Not at all ☐

12. I look forward with enjoyment to things Please tick (✓) one

- As much as I ever did ☐
- Rather less than I used to ☐
- Definitely less than I used to ☐
- Hardly at all ☐

13. I get sudden feelings of panic
Please tick (✓) one

- Very often indeed ☐
- Quite often ☐
- Not very often ☐
- Not at all ☐

14. I can enjoy a good book or radio or TV programme Please tick (✓) one

- Often ☐
- Sometimes ☐
- Not often ☐
- Very seldom ☐

Section 5. COPING

Below you will find a list of statements. Please rate the truth of each statement as it has applies to you by ticking one response, where 0 is 'never true' and 6 is 'always true'.

1. I am getting on with the business of living no matter what my level of pain is Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

2. My life is going well, even though I have chronic pain Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

3. It's OK to experience pain Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

4. I would gladly sacrifice important things in my life to control this pain better Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

5. It's not necessary for me to control my pain in order to handle my life well Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

6. Although things have changed, I am living a normal life despite my chronic pain Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

7. I need to concentrate on getting rid of my pain Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

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Section 5. COPING Continued...

8. There are many activities I do when I feel pain Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

9. I lead a full life even though I have chronic pain Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

10. Controlling pain is less important than other goals in my life Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

11. My thoughts and feelings about pain must change before I can take important steps in my life Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

12. Despite the pain, I am now sticking to a certain course in my life Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

13. Keeping my pain level under control takes first priority whenever I'm doing something Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

14. Before I can make any serious plans, I have to get some control over my pain Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

Section 5. COPING continued ...

15. When my pain increases, I can still take care of my responsibilities Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

16. I will have better control over my life if I can control my negative thoughts about pain Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

17. I avoid putting myself in situations where my pain might increase Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

18. My worries and fears about what pain will do to me are true Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

19. It's a relief to realise that I don't have to change my pain to get on with my life Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

20. I have to struggle to do things when I have pain Please tick (✓) one

Never true						Always true
0	1	2	3	4	5	6
☐	☐	☐	☐	☐	☐	☐

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Section 6. SOCIAL LIFE

Below you will find a list of statements. Please indicate how strongly you agree or disagree with the following statements by ticking the response which best describes you now.

1. I am doing interesting things in my life Please tick (✓) one

- **Strongly disagree** ☐
- **Disagree** ☐
- **Agree** ☐
- **Strongly agree** ☐

2. Most days I am doing some of the things I really enjoy Please tick (✓) one

- **Strongly disagree** ☐
- **Disagree** ☐
- **Agree** ☐
- **Strongly agree** ☐

3. I try to make the most of my life Please tick (✓) one

- **Strongly disagree** ☐
- **Disagree** ☐
- **Agree** ☐
- **Strongly agree** ☐

4. I have plans to do enjoyable things for myself over the next few days Please tick (✓) one

- **Strongly disagree** ☐
- **Disagree** ☐
- **Agree** ☐
- **Strongly agree** ☐

5. I feel like I am actively involved in life Please tick (✓) one

- **Strongly disagree** ☐
- **Disagree** ☐
- **Agree** ☐
- **Strongly agree** ☐

Section 8. PRIVATE HEALTHCARE USE

These questions are about any PRIVATE healthcare use outside the NHS over the last 6 months for your chronic pain.

1. In the last 6 months how many times have you seen the following people privately for your pain?

	Number of visits
Private doctor	☐
Private nurse	☐
Private physiotherapist	☐
Osteopath	☐
Chiropractor	☐
Acupuncturist	☐
Other (please specify) _____	☐
Other (please specify) _____	☐

2. In the last 6 months, have you had any tests or treatments done privately?

For example, scans, x-rays, blood tests or injections etc.

Description of test	Number of tests
_____	☐
_____	☐
_____	☐
_____	☐
_____	☐
_____	☐
_____	☐

3. In the last 6 months how much money have you spent on medicines for your pain?

For example, pain relief tablets, gels, homeopathic remedies etc

Description	Amount £
_____	☐
_____	☐
_____	☐
_____	☐

4. In the last 6 months have you bought any devices or disability aids for your pain?

For example, a TENS machine, walking stick, strapping, mobility scooters etc

Description	Amount £
_____	☐
_____	☐
_____	☐
_____	☐

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Section 8. PRIVATE HEALTHCARE USE continued ...

5. In the last 6 months, how many times have you been admitted to hospital and stayed overnight?

Reason and Duration	Number of nights
1) _____	☐
_____	
_____	
2) _____	☐
_____	
_____	
3) _____	☐
_____	
_____	

Comments

_____

6. In the last 6 months, how much money have you spent on any of the following because of your pain?

	£
Help at home For example, cleaning and cooking	☐
Personal care For example, washing and dressing	☐
Transport For example, taxis	☐
Household maintenance For example, gardening and repairs	☐
Other (please specify)	☐
_____	
_____	
_____	
_____	
_____	
_____	

THANK YOU FOR FILLING IN THE QUESTIONNAIRE

Please return to the study team using the FREEPOST envelope provided (no postage stamp required)

HEAD OFFICE: COPERS STUDY
CENTRE FOR PRIMARY CARE AND PUBLIC HEALTH, BLIZARD INSTITUTE,
2 Newark Street, London, E1 2AT

Detailed recruitment process

Participants were to be recruited in three ways:

1. electronic searches using the clinic databases
2. GP/clinician referrals during face-to-face consultations
3. advertisements in clinics.

The electronic searches were conducted by clinic staff with the support of a primary care research network research officer and/or the COPERS research study team pending appropriate NHS approvals.

We tested a search strategy to identify the most appropriate patients using GPs' electronic patient registers. A general practice staff member conducted several searches of the practice electronic records to identify the most appropriate domains and search terms; these search results were reviewed by a clinician in the practice to check the appropriateness of the sample. Two people then independently searched the clinic records electronically using the same search instructions to test the reliability of the output and the search method and subsequent validity.

The first stage of the search was to identify registered patients who had consulted within the last 3 months; then, within this group, the second stage was to search for prescribing information about repeat prescriptions for antidepressant medication, hypnotics and analgesia. Finally, we searched by symptoms: low back pain, backache, musculoskeletal, connective tissue disorders and pain. This generated a list of potential participants. Each clinic designated a key contact to liaise with the primary care research network and the study team; these personnel were trained to conduct their own searches by the study team and were given a study manual outlining the standard protocols necessary for the study. They were given support and advice as required.

From previous searches and test runs we estimated that this type of search yielded around 5% of the registered patients, which supported other epidemiological research estimates that 5–10% of the population experience chronic pain.

A list of potential participants was produced and screened by the clinicians to check suitability; no vulnerable people were to be approached (see inclusion and exclusion criteria in *Chapter 9*). The study team was provided with a pooled anonymous data set to allow response rates to be calculated. This list contained gender, age (not date of birth) and ethnicity (if recorded). Once the list had been finalised the study representative printed off invitation letters from the patients' GP or clinician. These were placed in preprepared envelopes that contained the consent to approach form, a patient information leaflet and a Freepost envelope to return the consent to approach form to the study team. A single postal reminder was sent after 10–14 days. Any interested patients were able to complete a consent to approach form and send this to the study team, or telephone or e-mail the study team directly to express interest and find out more about the study. Those who found out about the study from the waiting room advertisements contacted the study team directly or picked up an invitation pack from the GP receptionists. In these cases the study team screened and checked suitability to participate by using the inclusion and exclusion criteria as a checklist. GPs and clinicians were informed of all patients enrolled into the study but they were not informed of their allocation.

Informed consent procedures

Consent was requested for participation in the trial, audio-recording of the courses, the use of anonymised data and permission to check health records at 12 months (for extracting data about health-care resource use). The consent process was as follows: (1) the expression of interest, either by mailed form or by telephone or e-mail, triggered the mailing of a COPERS cover letter, the patient information sheet, the trial consent form and the baseline questionnaire; and (2) any patients who wanted to be part of the study returned their signed trial consent form and the baseline questionnaire.

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Participants were then telephoned to:

- introduce the study team
- check that consent was valid and informed (at this point the consent form was countersigned by the study team member and confirmed as valid if appropriate)
- check their questionnaire for completeness
- It was at this point that participants were formally enrolled in the study.

Participants were then randomised and informed of their allocation. If allocated to the control group they were told about the process involved, were sent a relaxation CD with instructions and the *Pain Toolkit* booklet and were asked to continue with their usual GP care. They received further questionnaires at 12 weeks and 6 and 12 months. If allocated to the intervention they were offered the opportunity of participating in a course.

Criteria for withdrawal

All participants were free to withdraw from the study at any time and without having to give any explanation. On formal withdrawal from the study we ceased to collect further data.

Relaxation information

COPERS
MANAGING PAIN • LIVING LIFE

Barts and The London
School of Medicine and Dentistry

Warwick
Medical School

COPERS STUDY

COping with persistent **P**ain, **E**ffectiveness **R**esearch into **S**elf-management

Relaxation CD Training Pack

London **020 7882 2546**

Warwick **024 7657 2905**

Contents

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Introduction

Relaxation is not all about sitting in front of the TV or having a glass of wine to chill out at the end of the day. It involves body awareness to gradually relax all of the muscles until the tension is released from your body and your mind is calm. There are different ways to help the relaxation process such as breathing exercises and mind focussing techniques like repeating a word such as “calm” or “relax” quietly in your head to help ‘still’ your mind.

For this relaxation course we are going to use ‘sequential muscle relaxation’ and breathing exercises as our basic relaxation sequence. We are then going to build on this using the mind focussing techniques of ‘visualisation’ and ‘mindfulness’ to help calm the mind.

What is sequential muscle relaxation?

Sequential muscle relaxation means you become aware of all of the areas of your body from top to toe in sequence and you concentrate on relaxing the muscles for each body area before you move on to the next. This ensures that you don’t forget to relax common areas that hold tension such as the forehead, jaw, shoulders and hands.

What are mind focussing techniques?

Visualisation is a technique where you use your imagination to recreate the details of a place where you would naturally feel more relaxed. This might be a favourite holiday destination, a familiar calming place you have experienced in the past or somewhere you may have read about. The idea is to focus you mind on recreating all the sights, sounds, smells and other sensations that you experience in this relaxing place. You become immersed and engrossed in the place.

Mindfulness is a type of meditation technique. Whilst sitting still and relaxing most people have a continuous stream of thoughts popping into the mind. One type of mindfulness exercise is to acknowledge each thought as it comes along and imagine placing it on leaf which floats away downstream (or on a cloud drifting past in the sky) then drawing your attention back to the present. The idea is not to fight the thoughts but to let them come and go naturally but returning your focus to your relaxation practice each time.

Both of these mind focussing techniques enhance the relaxation by calming the mind.

How can these techniques help me?

Relaxation benefits people with chronic pain in two main ways. First it reduces muscle tension and stiffness which may be contributing to your pain and secondly it calms the mind and improves mood which in turn helps to further reduce muscle tension. In addition you may also find that if practised regularly, your sleep patterns may improve and you have more energy as a result.

You might say that it’s too difficult to relax with chronic pain, but if you practise relaxation can be achieved even though your pain may not disappear completely.

Relaxation takes practice just like any other skill. When you become more accomplished at it you may find you are able to relax in any situation without the need for voice guidance. The benefits of relaxation increase if you can learn to relax your body in a noisy stressful situation or when you feel particularly anxious or agitated.

How do you know it works?

You might think that relaxation techniques and meditation skills are just for those practising yoga or tai chi but it is used in many healthcare fields. For example, people suffering from heart disease are encouraged to use relaxation techniques to reduce the amount of stress related hormones like adrenaline and cortisol in the blood which have negative impacts on the body's heart and blood circulatory system.

Arthritis support organisations (Arthritis Research UK and Arthritis Care) also recommend relaxation techniques for pain caused by muscle tension around joints. In addition, mental health charities such as the Mental Health Foundation and Mind support the use of relaxation techniques to reduce stress levels and anxiety.

Research in people with fibromyalgia, chronic pain, heart disease, low back pain and other chronic diseases has shown that relaxation and mind focussing techniques may have positive effects on physical function and self-confidence in ability to do things as well as improvements in mental health.

The COPERS team are interested in finding out how relaxation techniques impact on chronic pain sufferers in the long term. We have provided you with a CD to help you learn to relax.

What's on the CD?

The CD has 3 audio tracks on it suitable for playing on your computer or your CD player. If you would like the tracks in MP3 format for your portable music player you can either ask the study team to send you a CD with the MP3s or if you have an Internet connection you can download them from our COPERS website under the link 'patient information'
www.icms.qmul.ac.uk/chs/pctu/current_projects/copers/25507.html
The files are between 9 and 15 Mb in size.

TRACK 1: Relaxation and breathing (about 11 minutes)

TRACK 2: Relaxation and visualisation (about 12 minutes)

TRACK 3: Relaxation and mindfulness (about 11 minutes)

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Suggested Training Programme

Getting started

When you start the training, try to find somewhere quiet and peaceful. This will help you to concentrate. Also make sure you have enough time to spare, you will need about 10 minutes.

Making yourself comfortable

Ensure that as much of your body is supported as possible including your arms and feet. You can be lying down or seated (after a lot of practice people can relax whilst standing and in any environment). If you are seated use the arms of the chair to rest your arms with your feet flat on the floor. Make sure your legs and arms are not crossed. Don't worry if you have to shift around and move a bit during the relaxation; just make sure you are as comfortable as you can be. Finally, make sure you are warm, particularly your hands and feet.

You can practise relaxation at any time of the day. You may find that the relaxation sends you to sleep. This is fine but make sure that you do not have any pressing engagements or responsibilities that you should be alert for. It can be used to 'recharge your batteries' before they run down completely or it can be used to help you get to sleep.

You do not have to do all of the three relaxation exercises if you don't want to. Choose which one(s) works for you. If you find that you can't complete the whole guided session don't worry, just do as much as you can. Similarly, if you have time to stay in your relaxed state for longer than the voice guidance suggests to then feel free to do so. Think of it as beneficial 'time out' for yourself.

How often and when?

Try to do one of the relaxation practices **once** per day for the three weeks of the study and as much as you can thereafter.

It might be easier to incorporate it into your normal routine for example: before your morning coffee or at bed time.

Note: If you try the relaxation straight after a meal your body will probably go into a sleepy state while it digests food so you are more likely to doze off before you complete the relaxation sequence.

Further information

British Heart Foundation	Mental Health Foundation	Get Self Help
www.bhf.org.uk	**www.mentalhealth.org.uk**	**www.getselfhelp.co.uk**

COPERS MP3 downloads and further information about the study are available from **www.icms.qmul.ac.uk/chs/pctu/current_projects/copers/25507.html**

Relaxation scripts

TRACK 1 – Relaxation and breathing

Script *(read slowly with a calm low voice)*

Please make yourself comfortable; ensuring that as much of your body is supported as possible including your arms and feet. If you are seated rest your arms on the arms of the chair, with your feet flat on the floor. Make sure you legs and arms are not crossed. Don't worry if you have to shift around and move a bit during the relaxation; just make sure you are as comfortable as you can be. Finally, make sure you are warm, particularly your hands and feet.

First, close your eyes, feeling your body supported and just listen to the noises around you. You may hear some noise outside, focus on it.....really listen to what you can hear.

Pause (count slowly 1 and 2 and 3 and 4)

Now focus on the noises in the room around you. What can you hear? Really listen to the sounds around you.

Pause (count slowly 1 and 2 and 3 and 4)

Now become aware of the sound of your own breathing, in and out. Listen to the air as it moves around and through you, your abdomen gently rising and falling as you breathe.

Pause (count slowly 1 and 2 and 3 and 4)

Now slow your breathing down, and take a slightly longer breath in, all the way in, and pause for a very small moment before you breathe out again. Let the breath out of your body nice and slowly and controlled, all the way out.

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Remember, slow your breathing down, and take a slightly longer breath in, all the way in, and pause for a very small moment before you breathe out again. Let the breath out of your body nice and slowly and controlled, all the way out.

Just nice slow easy breathing, letting your body relax, feeling heavy and supported.

Pause (count slowly 1 and 2 and 3 and 4)

Now you are going to focus on different parts of your body and just check that they are nice and relaxed.

First of all think about your feet, just relax them. All loose and floppy. Then your ankles and calves, nice and relaxed, letting any muscle tension disappear, nice and relaxed.

Pause (count slowly 1 and 2 and 3 and 4)

Focus on your knees, relax them, feel any tension disappear, breathing in and out.

Pause (count slowly 1 and 2 and 3 and 4)

Now bring your attention to your upper legs. Make sure the muscles are relaxed. Breathe in and out and on the outward breath really relax and feel any tension disappear.

Pause (count slowly 1 and 2 and 3 and 4)

Become aware of your buttocks, pressing down. Just relax, sinking down, nice and heavy, nice and relaxed.

Pause (count slowly 1 and 2 and 3 and 4)

Now think about your lower back muscles. Breathe in and out, nice and slowly, nice and relaxed. Focus on your tummy muscles, letting everything go loose, just relax.

Pause (count slowly 1 and 2 and 3 and 4)

Now to your shoulders. Let them hang into a relaxed position. Nice and loose. Let your arms feel nice and heavy, relaxed. Feel the tension disappear from your upper arms, your elbows, your forearms, your wrists, your hands and your fingers. Let everything relax, nice and loose nice and floppy.

Pause (count slowly 1 and 2 and 3 and 4)

Focus on the muscles in your neck, let them go, feel the tension disappear, let your neck relax. You're nice and relaxed nearly everywhere, so think about any tension you may hold in your head and face. Notice how your forehead feels, if it's creased and frowning let your eyebrows fall and your forehead smooth out. Let them relax, breathing in and out. Next think about your eyes, relax your eyes and also your cheeks, just let the tension drift away, breathe in and out.

Pause (count slowly 1 and 2 and 3 and 4)

Relax your jaw and relax your mouth. Feel your whole body nice and relaxed.

Enjoy this moment and know when you are tense you can always do this on your own and feel the tension disappear.

Pause (count slowly 1 and 2 and 3 and 4)

Breathing nice and slowly, and start to become more aware of the sound of your breathing, in and out.

Now start to notice the sounds around you, gradually becoming more aware of the room, aware of your toes and your fingers.

And when you are ready just slowly open your eyes. Gently wiggle your fingers and toes. Breathe deeply and stretch.

END

Text adapted from http://www.getselfhelp.co.uk/relax.htm

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TRACK 2 – Relaxation and visualisation. Script *(read slowly with a calm low voice)*

Please make yourself comfortable; ensuring that as much of your body is supported as possible including your arms and feet. If you are seated rest your arms on the arms of the chair, with your feet flat on the floor. Make sure you legs and arms are not crossed. Don't worry if you have to shift around and move a bit during the relaxation; just make sure you are as comfortable as you can be. Finally, make sure you are warm, particularly your hands and feet.

First, close your eyes, feeling your body supported and just listen to the noises around you. You may hear some noise outside, focus on it.....really listen to what you can hear.

Pause (count slowly 1 and 2 and 3 and 4)

Now focus on the noises in the room around you. What can you hear? Really listen to the sounds around you.

Pause (count slowly 1 and 2 and 3 and 4)

Now become aware of the sound of your own breathing, in and out. Listen to the air as it moves around and through you, your abdomen gently rising and falling as you breathe.

Pause (count slowly 1 and 2 and 3 and 4)

Now slow your breathing down, and take a slightly longer breath in, all the way in, and pause for a very small moment before you breathe out again. Let the breath out of your body nice and slowly and controlled, all the way out.

Remember, slow your breathing down, and take a slightly longer breath in, all the way in, and pause for a very small moment before you breathe out again. Let the breath out of your body nice and slowly and controlled, all the way out.

Just nice slow easy breathing, letting your body relax, feeling heavy and supported.

Pause (count slowly 1 and 2 and 3 and 4)

Now you are going to focus on different parts of your body and just check that they are nice and relaxed.

First of all think about your feet, just relax them. All loose and floppy. Then your ankles and calves, nice and relaxed, letting any muscle tension disappear, nice and relaxed.

Pause (count slowly 1 and 2 and 3 and 4)

Focus on your knees, relax them, feel any tension disappear, breathing in and out.

Pause (count slowly 1 and 2 and 3 and 4)

Now bring your attention to your upper legs. Make sure the muscles are relaxed. Breathe in and out and on the outward breath really relax and feel any tension disappear.

Pause (count slowly 1 and 2 and 3 and 4)

Become aware of your buttocks, pressing down. Just relax, sinking down, nice and heavy, nice and relaxed.

Pause (count slowly 1 and 2 and 3 and 4)

Now think about your lower back muscles. Breathe in and out, nice and slowly, nice and relaxed. Focus on your tummy muscles, letting everything go loose, just relax.

Pause (count slowly 1 and 2 and 3 and 4)

Now to your shoulders, let them hang into a relaxed position. Nice and loose. Let your arms feel nice and heavy, relaxed. Feel the tension disappear from your upper arms, your elbows, your forearms, your wrists, your hands and your fingers. Let everything relax, nice and loose nice and floppy.

Pause (count slowly 1 and 2 and 3 and 4)

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Focus on the muscles in your neck, let them go, feel the tension disappear, let your neck relax. You're nice and relaxed nearly everywhere, so think about any tension you may hold in your head and face. Notice how your forehead feels, if it's creased and frowning let your eyebrows fall and your forehead smooth out. Let them relax, breathing in and out. Next think about your eyes, relax your eyes and also your cheeks, just let the tension drift away, breathe in and out.

Pause (count slowly 1 and 2 and 3 and 4)

Relax your jaw and relax your mouth. Feel your whole body nice and relaxed.

Enjoy this moment and know when you are tense you can always do this on your own and feel the tension disappear.

Pause (count slowly 1 and 2 and 3 and 4)

Whilst you are in this relaxed state, imagine a place where you can feel content, calm and happy.

Pause (count slowly 1 and 2 and 3 and 4)

Recall the details of this place. Whereabouts are you? What can you see around you? How are you passing the time? What are you wearing? Are you with anyone else? What are they doing in this scene? Really focus in on the details of the scene.

Pause (count slowly 1 and 2 and 3 and 4)

Consider the air temperature. Can you feel any sensations on your skin? Are there any smells or sounds. How do you feel when you are here? Remember this place where you feel calm and happy. You can go back to it whenever you want.

I am going to pause for a moment know and let you enjoy your place of tranquillity and contentment.

Pause

Breathing nice and slowly, and start to become more aware of the sound of your breathing, in and out.

Now start to notice the sounds around you, gradually becoming more aware of the room, aware of your toes and your fingers.

And when you are ready just slowly open your eyes. Gently wiggle your fingers and toes. Breathe deeply and stretch.

END

Text adapted from http://www.getselfhelp.co.uk/imagery.htm

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TRACK 3 – Relaxation and mindfulness of thoughts

Script *(read slowly with a calm low voice)*

Please make yourself comfortable; ensuring that as much of your body is supported as possible including your arms and feet. If you are seated rest your arms on the arms of the chair, with your feet flat on the floor. Make sure you legs and arms are not crossed. Don't worry if you have to shift around and move a bit during the relaxation; just make sure you are as comfortable as you can be. Finally, make sure you are warm, particularly your hands and feet.

First, close your eyes, feeling your body supported and just listen to the noises around you. You may hear some noise outside, focus on it.....really listen to what you can hear.

Pause (count slowly 1 and 2 and 3 and 4)

Now focus on the noises in the room around you. What can you hear? Really listen to the sounds around you.

Pause (count slowly 1 and 2 and 3 and 4)

Now become aware of the sound of your own breathing, in and out. Listen to the air as it moves around and through you, your abdomen gently rising and falling as you breathe.

Pause (count slowly 1 and 2 and 3 and 4)

Now slow your breathing down, and take a slightly longer breath in, all the way in, and pause for a very small moment before you breathe out again. Let the breath out of your body nice and slowly and controlled, all the way out.

Remember, slow your breathing down, and take a slightly longer breath in, all the way in, and pause for a very small moment before you breathe out again. Let the breath out of your body nice and slowly and controlled, all the way out.

Just nice slow easy breathing, letting your body relax, feeling heavy and supported.

Pause (count slowly 1 and 2 and 3 and 4)

Now you are going to focus on different parts of your body and just check that they are nice and relaxed.

First of all think about your feet, just relax them. All loose and floppy. Then your ankles and calves, nice and relaxed, letting any muscle tension disappear, nice and relaxed.

Pause (count slowly 1 and 2 and 3 and 4)

Focus on your knees, relax them, feel any tension disappear, breathing in and out.

Pause (count slowly 1 and 2 and 3 and 4)

Now bring your attention to your upper legs. Make sure the muscles are relaxed. Breathe in and out and on the outward breath really relax and feel any tension disappear.

Pause (count slowly 1 and 2 and 3 and 4)

Become aware of your buttocks, pressing down. Just relax, sinking down, nice and heavy, nice and relaxed.

Pause (count slowly 1 and 2 and 3 and 4)

Now think about your lower back muscles. Breathe in and out, nice and slowly, nice and relaxed. Focus on your tummy muscles, letting everything go loose, just relax.

Pause (count slowly 1 and 2 and 3 and 4)

Now to your shoulders. Let them hang into a relaxed position. Nice and loose. Let your arms feel nice and heavy, relaxed. Feel the tension disappear from your upper arms, your elbows, your forearms, your wrists, your hands and your fingers. Let everything relax, nice and loose nice and floppy.

Pause (count slowly 1 and 2 and 3 and 4)

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Focus on the muscles in your neck, let them go, feel the tension disappear, let your neck relax. You're nice and relaxed nearly everywhere, so think about any tension you may hold in your head and face. Notice how your forehead feels, if it's creased and frowning let your eyebrows fall and your forehead smooth out. Let them relax, breathing in and out. Next think about your eyes, relax you eyes and also your cheeks, just let the tension drift away, breathe in and out.

Pause (count slowly 1 and 2 and 3 and 4)

Relax your jaw and relax your mouth. Feel your whole body nice and relaxed.

Enjoy this moment and know when you are tense you can always do this on your own and feel the tension disappear.

Pause (count slowly 1 and 2 and 3 and 4)

Whilst in your relaxed state, start to notice the thoughts that come into your mind. As you notice each thought, imagine putting those words onto a leaf as it floats by on a stream. Put each thought that you notice onto a leaf, and watch it drift on by, meandering on the surface of the water. There's no need to look for the thoughts, or to remain alert waiting for them to come. Just let them come, and as they do, place them onto a leaf.

Your attention will wander, particularly so at first, and that's okay - it's what your mind does. As soon as you notice your mind wandering, gently bring your focus back to the thoughts, placing them onto the leaves and watching them drift by.

Pause and give about 1 minute to allow time to visualise

Breathing nice and slowly, and start to become more aware of the sound of your breathing, in and out.

Now start to notice the sounds around you, gradually becoming more aware of the room, aware of your toes and your fingers.

And when you are ready just slowly open your eyes. Gently wiggle your fingers and toes. Breathe deeply and stretch.

END

Text adapted from http://www.getselfhelp.co.uk/imagery.htm

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Statistical analysis plan

Improving the self-management of chronic pain: COPERS

Statistical Analysis Plan

Version: 1.0
Date: 03/10/2013

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1. INTRODUCTION

Purpose of statistical analysis plan

The purpose of this document is to provide details of the statistical analyses and presentation of results to be reported within the principal paper(s) of the COPERS trial. Subsequent papers of a more exploratory nature (including those involving baseline data only) will not be bound by this strategy but will be expected to follow the broad principles laid down within it. Any exploratory, post-hoc or unplanned analyses will be clearly identified as such in the respective study analysis report.

The structure and content of this document provides sufficient detail to meet the requirements identified by the International Conference on Harmonisation (ICH) and PCTU_SOP_SP 01_Statistical Analysis.

The ethics application was submitted in Feb 2011, and approval was granted on 18/03/2011.

The following were reviewed in preparation for a preliminary version of this document:

- ICH E9 Guidance on statistical principles for clinical trials
- ICH E3 Structure and content of clinical study reports
- CONSORT guidelines for the reporting of randomised trials

Stephen Bremner was responsible for the original statistical analysis strategy in the protocol. Brennan Kahan and Karla Diaz-Ordaz have written the statistical analysis plan under the direction of Sandra Eldridge. Dawn Carnes, Kate Homer, Martin Underwood, and Stephanie Taylor have also contributed to the writing of this statistical analysis plan. Sandy Smith has designed the database to collate and store the data from the questionnaires.

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This document has been developed prior to examination of unblinded trial data. This plan is intended not to change or contradict the general aims of the protocol, but rather expand
on them. In the event of a discrepancy the analyses described here will supersede those in earlier
documents.

2. STUDY OBJECTIVES AND ENDPOINTS

2.1 Primary Objective

- To test the effectiveness and cost-effectiveness of a group self-management courses for people with persistent pain.

2.2 Secondary objectives

- To test the hypothesis that treatment effectiveness is moderated by baseline self-efficacy
- To test the hypothesis that long-term (12 month) effectiveness is mediated by change in self-efficacy between baseline and three months.

2.3 Outcome measures

Primary outcome

The primary outcome is the disability subsection of the Chronic Pain Grade questionnaire (CPG disability) (Von Korff, 1992) at 12 months post randomisation.

This outcome is a composite of three questions assessing the extent to which the participant's pain has interfered with or changed their ability to perform their daily activities, work, or take part in recreational, social, and family activities in the previous six months. Each of the three questions is rated on a scale of 0-10,

with 0 reflecting no change or interference, and 10 reflecting extreme change or interference.

The primary outcome is the mean of these three questions, multiplied by 10; i.e. if X1, X2, and X3 represent the three questions, and Y represents the primary outcome, then Y=10*(X1+X2+X3)/3. The primary outcome is therefore recorded on a scale from 0-100, with higher scores reflecting larger interference or change in the participant's ability to perform daily activities, work, or take part in recreational, social, and family activities.

Secondary outcomes

1) CPG disability at 6 months post randomisation
2) CPG pain intensity score at 6 and 12 months post randomisation.
3) PSEQ (Pain Self-Efficacy Questionnaire) score at 6 and 12 months post randomisation
4) HADS (Hospital Anxiety and Depression Scale) Anxiety score at 6 and 12 months post randomisation
5) HADS (Hospital Anxiety and Depression Scale) Depression score at 6 and 12 months post randomisation
6) CPAQ (Coping Pain and Acceptance Questionnaire) score at 6 and 12 months post randomisation
7) HEIQ (Health Education Impact Questionnaire) Social integration score at 6 and 12 months post randomisation
8) EQ-5D at 6 and 12 months post randomisation
9) Census global health question at 6 and 12 months post randomisation
10) Total Defined Daily Doses (Total DDD) consumed of psychotropic drugs up to 12 months post-randomisation
11) Total DDD consumed of analgesics (including all opioids and other CNS drugs) for pain up to 12 months post randomisation
12) Total DDD consumed of weak opioids up to 12 months post randomisation
13) Total DDD consumed of strong opioids up to 12 months post randomisation
14) Proportion of participants using weak opioids at 12 months post randomisation (defined as having received a prescription for a weak opioid up to twelve weeks before the 12 month follow-up date)
15) Proportion of participants using strong opioids at 12 months post randomisation (defined as having received a prescription for a strong opioid up to twelve weeks before the 12 month follow-up date)

A guide to how outcomes are derived is available in the appendix.

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3. STUDY METHODS

3.1 Overall study design and plan

Target for randomisation: 391 intervention and 294 control participants

Date of first randomisation: 6th September 2011

Date of last randomisation: 18th July 2012

Trial design: Individually randomized, parallel group

Blinding: It was not possible to blind participants. Data entry and telephone follow-up are blinded

Randomised Interventions: Intervention with usual care vs Modified attention control (relaxation) with usual care

Target allocation ratio: 1:1.33 (control: intervention)

3.2 Selection of study population

Inclusion criteria:

- Adults (aged 18 or over) with chronic musculoskeletal pain

The International Association for the Study of Pain (IASP) defines chronic pain as that which has

persisted beyond normal tissue healing time - usually interpreted as three months (IASP 1986).

Examples include osteoarthritis, any chronic musculoskeletal pain, chronic widespread pain and

fibromyalgia; we excluded inflammatory arthritis such as rheumatoid arthritis. We included people with chronic pain and a past history of cancer where the chronic pain arose from non-malignant causes.

Exclusion criteria:

- Inability to give informed consent
- Not fluent in English
- Serious active co-morbidity that is more disabling to the individual than chronic pain
- Serious mental health issues that would make it difficult for an individual to participate in the group course
- People with a life expectancy of less than six months
- Substance misuse that would make it difficult for an individual to participate in the group course
- People with chronic pain arising from malignant disease because this requires specific management

3.3 Method of treatment assignment and randomisation

Participants were assigned to the intervention or control group in a 1.33 to 1 ratio (intervention: control) using stratified permuted blocks with randomly varying block lengths of 7 and 14. Site of recruitment was used as a stratification factor. Treatment assignments were carried out via a remote computerized randomisation service.

3.4 Treatment masking (blinding)

All parties were blind to allocation up to the point of randomisation and all baseline data were
collected by self-completed questionnaire prior to randomisation.

After allocation, we could not blind researchers to participants' treatment allocation in their own location.

Follow-up data collected by telephone by trial research personnel was blind to treatment allocation (the London team collected data from Warwick site participants and vice versa). Because participants were aware of their treatment allocation, we used a standardised script asking participants not to divulge their allocation to the data collector. All other data were collected by self-completed

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questionnaires and / or electronic databanks returned to the trial team for data entry.

The statistician analysing the data will not be blinded once any information on allocation has been received. As far as possible, data cleaning and checking by the statistician will be completed prior to information about which participants are in the control group and which in the intervention group being disclosed to them.

3.5 Sample size

The sample size calculation was based on detecting a standardised mean difference of 0.3 in pain related disability between intervention and control groups, with a power of 80% at the 5% significance level. This effect size was commensurate with the largest change seen in a recent systematic review of expert patient programmes[2], and also with the sort of change effected by interventions for other chronic pain syndromes, such as low back pain, on any continuous outcome measure[3]. A simple sample size calculation indicated that we would require data on 350 subjects. We inflated the sample size because of the possibility of a 'clustering' effect in the group intervention arm and chose the ratio between intervention and control participants to increase statistical efficiency [4]. Using an intra-cluster correlation coefficient (ICC) of 0.1, and assuming on average nine individuals providing data from each group results in 480 individuals needed with 275 in the intervention group and 205 in control the control group (1.33:1 intervention:control). Allowing, conservatively, for a 30% loss to follow-up (from an average of 13 individuals recruited per group) we sought to randomise 685 participants (391 intervention participants and 294 controls).

3.6 Trial Consent

Consent was gained for: participating in the trial, audio-recording the intervention sessions and accessing medical records at 12 months.

4. DATA COLLECTION

Data were collected at four time points: baseline, 12 weeks, 6 months and 12 months post randomisation. All data were collected via postal self- report questionnaires, except for data about participant co-morbidities and use of pain related medication, which were obtained from the participant's GP record.

Recruitment began in August 2011, finished in July 2012; follow-up was complete d in August2013.

4. 1 Baseline data collection

Descriptive data:

- Age
- Gender (Male/Female)
- Ethnicity (White, Black or Black British, Asian or Asian British, Mixed, Other)
- English language fluency (Fluent, Good, Below Average, Poor)
- Age at which formal education ended (no formal education, age 12 or less, age 13 to 16, age 17 to 19, age 20 or over, still in full time education, other)(
- Employment status (employed, unemployed and looking for work, at school or in full time education, unable to work due to long term sickness, looking after home or family, retired from paid work, other)
- Number of body systems affected by co-morbid conditions (musculoskeletal, cardiovascular, tegumental, gastrointestinal, genitourinary, mental health, ENT/optical, respiratory, neurological, endocrine/metabolic/immune, other)
- Time kept from usual activities due to pain in last 6 months (0-6 days, 7-14 days, 15-30 days, 31 or more days)
- Site recruited (London, Warwick)
- Duration of pain (0-3 months, 4-12 months, 13 months to 2 years, 3-4 years, 5-6 years, 7-10 years, more than 10 years)
- Living arrangements (lives alone, lives with others)
- Overall CPG score

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Outcomes measured at baseline:

- CPG disability
- CPG pain intensity
- HADS Anxiety
- HADS Depression
- EQ-5D
- PSEQ
- CPAQ
- HEIQ
- Census global health question
- Total amount of drugs taken above the DDD in three months prior to randomization (psychotropic, weak opioids, strong opioids, analgesics)
- Opioids prescriptions (strong and weak opioids)

4.2 Twelve weeks data collection

- PSEQ

4.3 Six months data collection

- CPG disability
- CPG pain intensity
- HADS Anxiety
- HADS Depression
- EQ-5D
- PSEQ
- CPAQ
- HEIQ
- Census global health question
- Private healthcare use during previous 6 months (In addition to the core seven questionnaires (4.1 (b) above) at six months we also asked participants about their non-NHS health care resource use: private health care hospital stays, private tests, private consultations, privately purchased prescriptions/meds and devices and expenditure on social support such as transport and home help in the previous 6 months)

4.4 Twelve months data collection

- CPG disability
- CPG pain intensity
- HADS Anxiety
- HADS Depression
- EQ-5D
- PSEQ
- CPAQ
- HEIQ
- Census global health question
- Private healthcare use during previous 6 months (see 6 month data collection for details)
- Total amount of drugs taken above the DDD during follow-up (psychotropic, weak opioids, strong opioids, analgesics)
- Opioids prescriptions (strong and weak opioids)
- Other courses or activities attended during follow-up outside of COPERS trial: pain management course, expert patient programme or other self management course, other wellness or wellbeing course, return to work course, frequency of relaxation techniques (never, rarely, daily, weekly, monthly)

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5. GENERAL ISSUES FOR STATISTICAL ANALYSIS

5. 1 Blinding of the statistical analysis

Analysis cannot be blinded because of the allocation ratio. As far as possible all cleaning and checking of the data will be done before the statistician has access to the allocation codes.

5. 2 Database

We will use a Microsoft™ Access 2007 bespoke database incorporating SQL and VBA programming code developed by PCTU.

Data quality

Single data entry was performed. 100% data entry check was performed for the primary outcome (CPG disability), EQ-5D, and randomisation code. This was performed by somebody other than the person who entered the data, and involved checking the values entered on the database matched the questionnaire. A subset (approximately 10%) of questionnaires at baseline, 12 weeks, 6 months, and 12 months were checked by comparing the values entered on the database to the questionnaire.

Database lock

Once the trial team has completed all data entry and checking, the database will be date stamped and transferred to a read-only location on the appropriate server. The statistician responsible for the analysis will conduct or oversee additional data checks. Any necessary changes will be communicated to the appropriate member of the data management team as detailed in PCTU SOP PCTU_DM_04. This process will be repeated until the statistician and data management team are

satisfied that all identifiable errors have been corrected. At this point, the database will be locked by removing access rights. After database lock, the database will be date stamped and transferred to a read-only location on the appropriate server. This dataset will be used for analysis. The database will not be locked until version 1.0 of the Statistical Analysis Plan has been finalised and signed off.

5. 3 Analysis software

The analysis will be carried out using Stata version 12. Other packages such as R, SAS, or REALCOM may be used if necessary.

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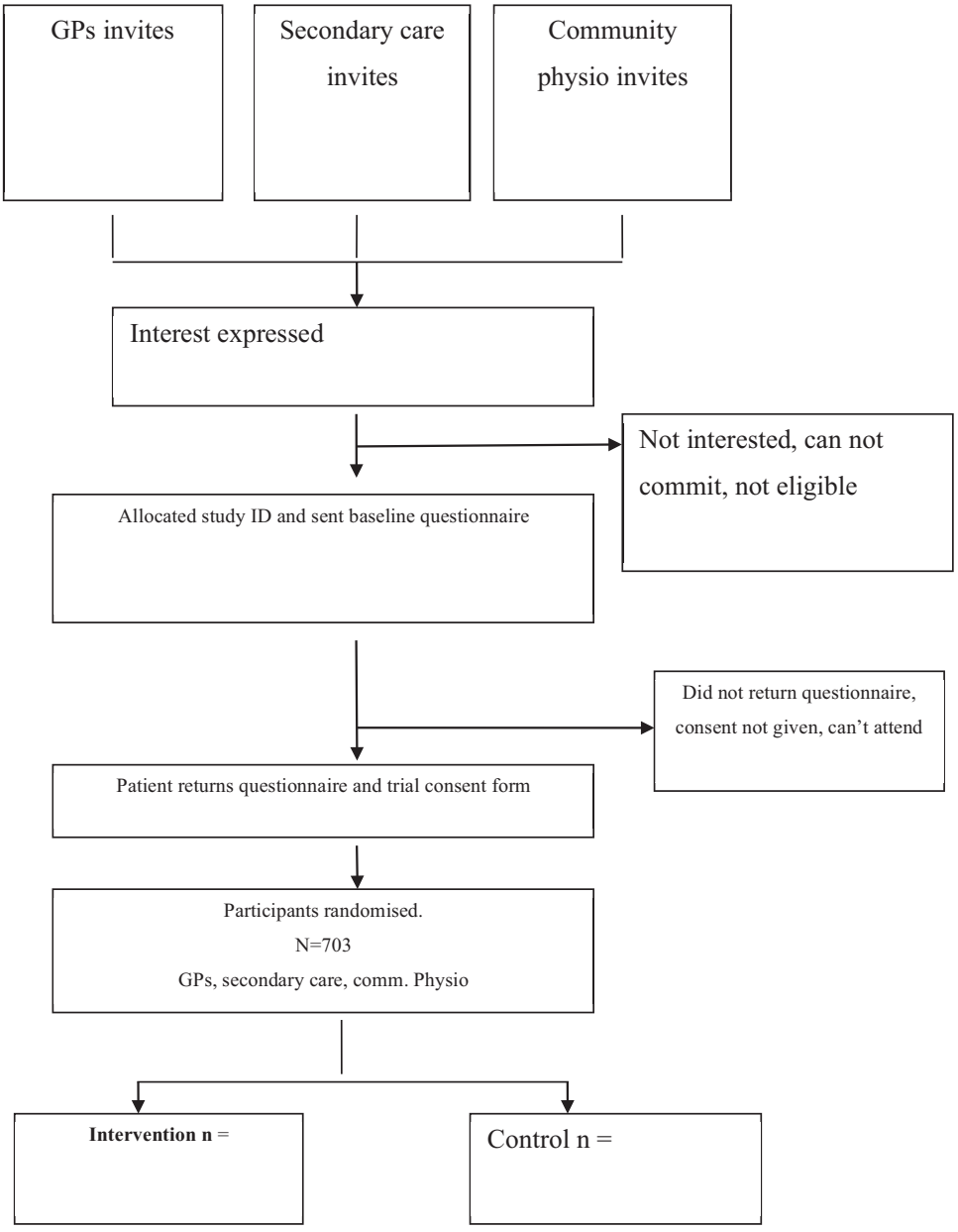
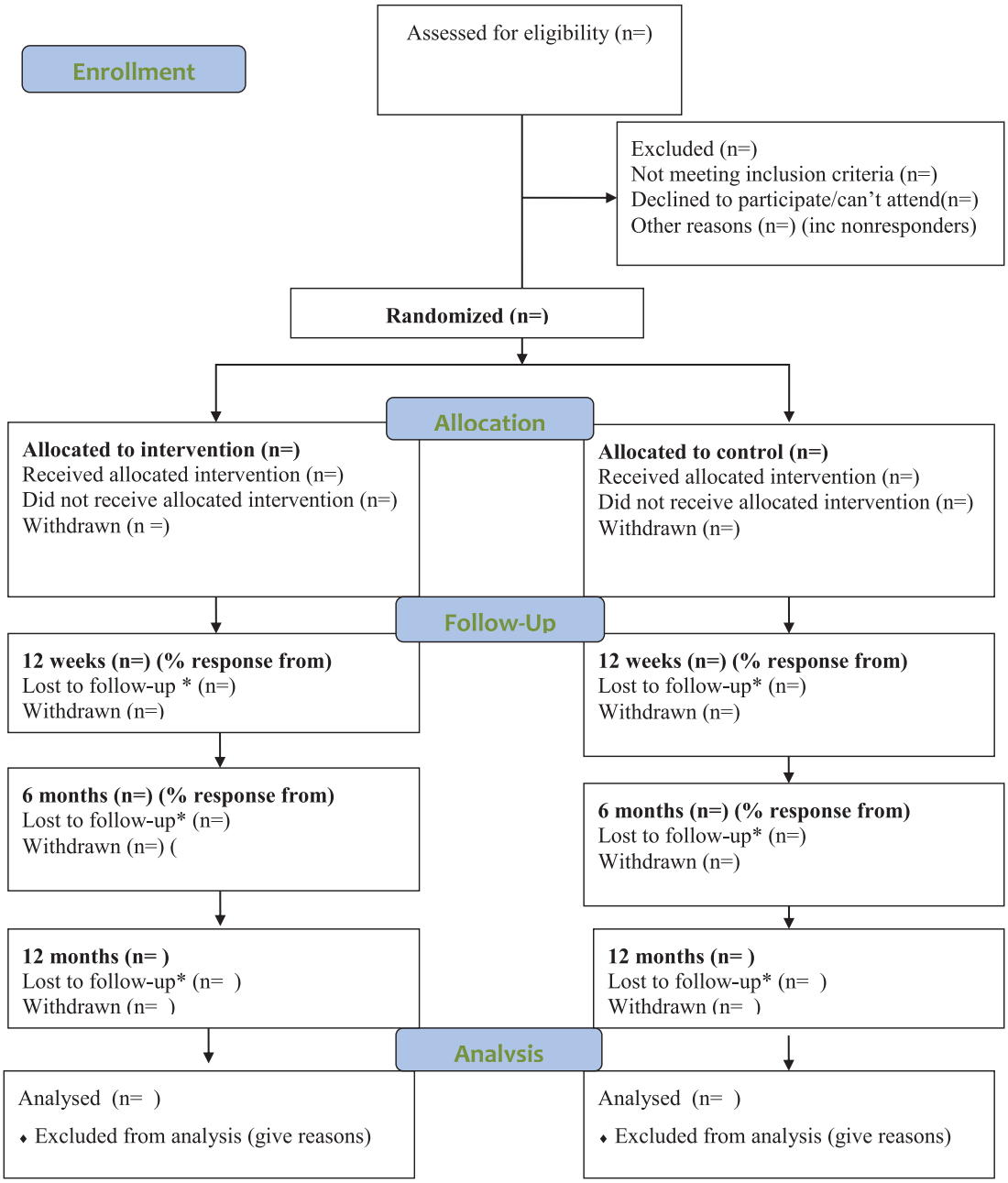
6. DESCRIPTIVE ANALYSES OF TRIAL

6. 1 Recruitment flow chart



6. 2 COPERS CONSORT Flow Diagram



*Loss to follow up = moved or phone number changed

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6.3 Representativeness of sample

The age, gender and ethnic profile of randomised participants will be examined to see if they are typical of the UK population with chronic pain. For example one UK population survey showed the age in a sample of people with chronic pain to have a mean and SD of 55 and 16.7, and the proportion of males being 41% (399/966) (Parsons et al 2007). We will also examine the gender of participants who expressed an interest in the trial (were assigned a study ID), but were not randomised

Certain baseline characteristics will be compared between participants who were lost to follow-up vs. other participants (table 9). Overall numbers lost to follow-up will be included in the CONSORT flow chart.

7. ANALYSIS PRINCIPLES

7.1 GENERAL ANALYSIS PRINCIPLES

The main analysis for each outcome will use intention-to-treat (ITT) principles, meaning that all participants with a recorded outcome will be included in the analysis, and will be analysed according to the treatment group to which they were randomised. More information on which participants will be included in each analysis is available in sections 7.2 and 7.4. All p-values will be two sided, and the significance level is set at 5%.

Analyses for all outcomes will be presented as:

- The number of participants included in the analysis, by treatment group;
- A summary measure of the outcome, by treatment group (e.g. mean (SD) for continuous outcomes, number (%) for binary outcomes, etc). Only participants with a completely recorded outcome will be used to calculate the summary measure (e.g. participants who complete only 1 of 3 components of the CPG disability score will not be included in the calculation of the summary measure);
- A treatment effect, with a 95% confidence interval;
- A two-sided p-value.

All analyses will account for clustering by course in the intervention arm. Participants in the control arm (who do not attend courses), will act as their own cluster (i.e. each participant in the control arm will belong to a ‘course’ where they are the only member).

Site of recruitment (London or Midlands), age, gender, and the HADS depression score at baseline will be included as covariates in each analysis. Additionally, for continuous outcomes (CPG disability, CPG pain intensity, PSEQ, HADS Anxiety, HADS Depression, CPAQ, HEIQ, and EQ-5D), the outcome measured at baseline will be included in the analysis. Continuous covariates (age, HADS depression

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score, outcome measured at baseline) will be assumed to have a linear relationship with the outcome.

7.2 Primary analysis

The primary outcome (CPG disability at 12 months) will be analysed using a mixed-effects linear regression model, with 'course' as a random effect. Restricted maximum likelihood (REML) will be used. The model will include site of recruitment, age, gender, HADS depression score, and CPG disability at baseline as covariates.

All participants who completed at least one of the three questions which form the CPG disability score at either 6 or 12 months will be included in the analysis. Participants who did not fill out any portion of the CPG disability score at either 6 or 12 months will be excluded from the analysis. It should be noted that CPG disability will be analysed separately at 6 and 12 months.

Multiple imputation (MI) will be used to account for participants who have an observed outcome at 6 months, but are missing the outcome at 12 months, as well as participants who completed some, but not all, of the questions on the CPG disability score at 12 months. 20 imputations will be performed, and results will be combined using Rubin's Rules. Only participants who will be included in the analysis will be included in the imputation model. Imputation will be performed separately within each treatment arm. The imputation model will include the three questions which form the CPG disability score at baseline, 6 months, and 12 months, as well as site of recruitment, age, gender, the HADS depression score at baseline, and employment status (employed or in full time education vs not employed or in full time education) (14 variables in total). In the intervention arm, multilevel imputation will be performed, with 'course' included in the imputation model as a random effect.

Missing data in any of the covariates to be adjusted for in the analysis (site of recruitment, age, gender, HADS depression score, CPT disability and baseline) will be accounted for using the same multiple imputation model as above.

Sensitivity analyses

Method of accounting for missing data

We will perform three sensitivity analyses for the primary outcome to assess the robustness of the results to other methods of account for missing data. The first sensitivity analysis involves specifying a different imputation model than that used in the primary analysis, and the last two sensitivity analyses involve re-analyse the primary outcome using two approaches which are not based on MI.

- We will determine which baseline covariates are associated with loss to follow-up, and include them in the imputation model. The analysis model will be the same as that described in 7.2, except for the inclusion of additional covariates in the imputation model.
- We will perform a complete case analysis, where all participants who did not complete all components of the CPG disability score at 12 months will be excluded from the analysis. The analysis model will be the same as that described in 7.2, except missing baseline covariates will be replaced using mean imputation.
- We will analyse the three components which form the CPG disability score at 12 months, rather than the CPG disability score itself. This will be done by performing a multivariate analysis, where each of the three components from the 12 month score are included in the model as outcomes (i.e. each participant will have three outcomes). A three-level mixed-effects model will be used, with random effects for ‘course’ and for participant. Treatment-by-question interactions will be included, allowing the treatment effect to vary for each of the three components. An overall treatment effect for CPG disability at 12 months will be estimated using the *lincom* function in Stata to combine the treatment estimates from the three separate components. As above, missing baseline covariates will be replaced using mean imputation.

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Participants with no completed follow-ups

The primary analysis has assumed that the excluded participants (those not completing any questions on the CPG disability questionnaire at both 6 and 12 months) were missing at random (i.e. they were missing based on the covariates included in the analysis model). To assess the robustness to departures from this assumption, the primary outcome will be assessed under a range of missing-not-at-random scenarios. This will be done using the formula $\Delta = \Delta_{primary} + Y_1P_1 - Y_2P_2$, where Δ is the treatment effect under the missing-not-at-random scenario, $\Delta_{primary}$ is the treatment effect from the primary analysis, Y_1 and Y_2 are the assumed mean responses for participants with missing data in treatment groups 1 and 2 respectively, and P_1 and P_2 are the proportion of participants who were excluded from the analysis in groups 1 and 2 respectively. The standard error for Δ is assumed to be approximately equal to the standard error for $\Delta_{primary.}$ Y_2 will be varied between 10, 25, 50, 75, and 90, and for each value of Y_2, Y_1 will be set to Y_2 - 10, Y_2, and Y_2 + 10. For example, for $Y_2 = 25$, Y_1 will vary between 15, 25, and 35.

Re-definition of primary endpoint

The primary outcome is a composite of three questions. The first question (Q1) assesses to what extent the participant's pain has interfered with daily activities in the previous six months. This is assessed on a scale of 0-10, with higher scores indicating more interference. The last two questions assess to what extent the participant's pain has changed their ability to (a) take part in recreational, social, and family activities (Q2); and (b) work (Q3). Both these questions are measured on a scale from 0-10, with higher scores indicating more extreme change.

For the last two questions, higher change scores are meant to represent a higher *negative* change, however it is possible that some participants have misinterpreted this, and have recorded a high score to indicate a large positive change. We will therefore perform a sensitivity analysis by redefining the outcome for participants

whose scores indicate they may have misinterpreted the intended direction of the questions relating to change.

For participants with a score of 2 or less for Q1 (indicating very little interference in daily activities) *and* a score of 8 or higher on either Q2 or Q3 (intending to indcate an extreme negative change in their ability to take part in social activities or to work), we will assume the participant has misinterpreted the intended direction of the scale for Q2 or Q3 (as it is inconsistent for the pain to have had very little interference in daily activities, and for there to have been an extreme negative change in the participant's ability to take part in activities or work). We will therefore rescore Q2 or Q3 based on a reverse scale (i.e. a score of 10 will be rescored as 0, 9 will be rescored as 1, and 8 will be rescored as 2). We will then re-analyse the outcome using the same method as for the main analysis

7.3 Subgroup analyses

Subgroup analyses will be performed for the primary outcome (CPG disability at 12 months). All subgroup analyses analyses will be performed using the same analysis model as for the primary outcome, but will also include the subgroup of interest and a treatment-by-subgroup interaction. Interaction tests will be considered significant at the 5% level. No correction will be made for multiple tests.

The following subgroups will be assessed:

(i) Non-pain:

- Co-morbidity: ≤3 vs. >3 co-morbidities, including musculoskeletal
- Living arrangements: living alone vs. living with others
- Baseline self-efficacy: PSEQ score 0-20 (not likely to be confident) vs. 21-39 (more likely to be confident and to self manage) vs. ≥40 (confident) (Nicholas 2006, 2007)
- Socioeconomic status (SES) (based on Index of Multiple Deprivation 2010, calculated from participant postcodes via GIS: lower social class (less than observed median in data) vs higher social class (equal or greater than observed median in data)

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(ii) Pain-related:

- Pain duration: 0-12 months vs 13 months to 4 years vs 5 or more years
- Baseline pain intensity: CPG intensity score 0-3 (low) vs 4-7 (medium) vs 8-10 (high)
- Baseline pain-related disability: CPG disability score 0-3 (low) vs 4-7 (medium) vs 8-10 (high)
- Baseline depression: HADS depression score <11 vs ≥11

7.4 Analysis of secondary outcomes

CPG disability at 6 months

This outcome will be analysed using the same methods as CPG disability at 12 months.

CPG pain intensity, HADS Anxiety, HADS Depression, and HEIQ at 6 and 12 months

These outcomes will be analysed using the same methods as CPG disability at 6 and 12 months.

PSEQ at 6 and 12 months

This outcome will be analysed using the same methods as CPG disability at 6 and 12 months, except the individual components of the PSEQ score at 12 weeks will also be included in the imputation model.

CPAQ at 6 and 12 months

This outcome will be analysed using the same methods as CPG disability at 6 and 12 months, with the exception of how CPAQ at baseline is included in the MI model. CPAQ is a composite of 20 questions – including each of these questions at each time point in the imputation model would lead to 60 variables being included (20 questions at baseline, 20 at 6 months, and 20 at 12 months) which may cause problems. We will therefore include only the individual questions for CPAQ at 6 and 12 months in the imputation model, and include the full CPAQ score at baseline (leading to 41 variables rather than 60). For participants who are missing CPAQ at baseline, we will use mean imputation.

EQ-5D at 6 and 12 months

The EQ-5D will be analysed using the same analysis model as the primary outcome (i.e. mixed-effects linear regression model, with course as a random effect, adjusted for site of recruitment, age, gender, HADS depression score, and EQ-5D at baseline).

All participants who fully complete the EQ-5D score at either 6 or 12 months will be included in the analysis. EQ-5D scores with missing components will be regarded as completely missing.

MI will be used to account for participants who are missing the outcome at either 6 or 12 months. The MI strategy will be the same as that for the primary and other secondary outcomes, except instead of imputing the individual components of the EQ-5D score, we will impute the whole score.

Census global health question at 6 and 12 months

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This outcome will be analysed using a mixed-effects ordered logistic regression model, with 'course' as a random effect. Site of recruitment, age, gender, HADS depression score, and the outcome at baseline will be included as fixed covariates.

All participants who completed the census global health question score at either 6 or 12 months will be included in the analysis.

MI will be used to account for participants who are missing the outcome at either 6 or 12 months. The MI strategy will be the same as that for the primary and other secondary outcomes, except we will impute the whole score (as there are no individual components).

Total DDDs up to 12 months post-randomisation for psychotropic drugs, drugs for pain, weak opioids, and strong opioids

These outcomes will be analysed using a mixed-effects linear regression model, with 'course' as a random effect. Restricted maximum likelihood (REML) will be used. The model will include site of recruitment, age, gender, HADS depression score, and Total DDD in 3 months before randomisation at baseline as covariates. All participants who have data on Total DDD up to 12 months post-randomisation will be included in the analysis. Mean imputation will be used for missing baseline covariates.

Proportion of participants using weak opioids and strong opioids at 12 months post-randomisation

These outcomes will be analysed using a mixed-effects logistic regression model, with 'course' as a random effect. The model will include site of recruitment, age, gender, HADS depression score, and weak or strong (depending on outcome) opioid use at baseline (defined as a prescription for weak or strong) opioids in the 12 weeks before randomization) as covariates. All participants who have data on whether they had had a weak/strong opioid prescription at 12 months will be included in the analysis.

7.5 Adherence-adjusted analysis

As a secondary analysis, CPG disability, CPG pain intensity, PSEQ, HADS anxiety, HADS depression, CPAQ, HEIQ, and EQ-5D, all at 12 months will be re-analysed to obtain a complier average causal effect of treatment (CACE). We define 'compliers' as those who attend more than half of the course (i.e. those present for at least 12 of the 24 course components). The compliers can only be observed in the intervention arm, where an indicator variable will indentify whether the individual complied. The compliers' class is unobserved in the control arm.

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We assume the Stable Unit Treatment Value Assumption (SUTVA), namely: (a) no interference between study units (the outcome for each participant depends only on their own treatment assignment and not the treatment assignment of any other participant), and (b) consistency, which implies that the observed outcome for each participant will equal one of the potential outcomes, no matter how the treatment was received.

In addition for identification, we assume (a) monotonicity: there are no defiers; and (b) exclusion restriction: treatment allocation only has an effect on outcome through treatment received and the effect of assignment is completely mediated by treatment exposure. .

Under the assumptions stated above, we will use randomisation as an instrumental variable for treatment received and obtain a CACE treatment estimate by a two-stage least square instrumental variable regression (using STATA command `ivregress`). We will run two analyses, one without any covariates and another one which includes all the baseline covariates included in the primary analysis models, namely CPG disability score at baseline, site of recruitment, age, gender, and the HADS depression score at baseline. The covariate-adjusted CACE will be considered the primary CACE analysis.

We will assume that missing data are missing at random and use the same multiply imputed datasets produced for the primary analyses. We will analyse each of multiply imputed sets, using robust estimation for the variance (using the option `vce(cluster clustvar)`) to account for the possible clustering by course group; finally obtaining MI estimates using Rubin's rules as before.

7.6 Mediator analyses

We will perform a mediator analysis to obtain the direct and indirect effects of treatment on the CPG disability score at both 6 and 12 months, using self-efficacy (PSEQ) at 12 weeks as a mediator.

We will use a structural linear mean model that allows for the interaction of randomisation with moderator, and perform an instrumental variable analysis (`ivregress` in STATA), using the interaction of randomization and baseline PSEQ as an instrument for the mediator, and including the interaction between randomisation and PSEQ at 12 weeks in the model.

To study the combined effect of compliance and self-efficacy, we will do a second mediation analysis. Let Y denote the outcome (CPG disability score), R the group as randomised, C the binary compliance (as defined in Section 7.5) and S the self-efficacy measure (PSEQ, the mediator). We will use the following structural model:

$E[Y_i(R=1) - Y_i(R=0)| , C_i = 1 \ \& \ S_i = s] = \beta_c c + \beta_s s + \beta_{cs} cs$, where β_{cs} represents the effect moderation of self-efficacy on those that comply.

This equation implies an exclusion restriction – the expected treatment effect being zero when less than half of the sessions are attended (though we allow for a self-efficacy to have a non-zero effect on outcome). For identification, we will use randomisation as an instrument for compliance, and randomisation by PSEQ at baseline interaction as an instrument for the mediator.

We will test the strength of the instruments using `estat firststage` post-estimation command in STATA. Low values of the R^2 or F statistic of the joint correlation of the mediator and the two instruments are indicative of weak instruments (rule of thumb F statistic less than 10 indicates weak instruments, Stock and Yogo 2005). If the instruments are weak, the estimates will still be unbiased but the standard error obtained by 2SLS are incorrect; in this case, we will use LIML estimation.

For both instrumental variable regressions, we will use the same multiply imputed datasets as the primary analyses and analyse each of them using the robust standard

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error estimate (`vce(cluster clustvar)`) to account for possible clustering by session groups; finally obtaining MI estimates using Rubin's rules as before.

As a sensitivity analysis to our instrumental variables approach, assuming that there is no unmeasured mediator-outcome confounding, we will use the same structural mean model as above on the complete cases, and fit the model with the `paramed` command in STATA which allows for treatment-mediator interactions. We will include CPG disability score, HADS score, HEIQ , CPAQ and EQ5D at baseline in the model as they are considered to be a priori mediator-outcome confounders (by randomisation, there is no confounders of treatment-outcome, and treatment-mediator associations).

For the model estimating the combined effect of compliance and mediator, we will assume we measured all confounders of the mediator-outcome and compliance-outcome associations, these are CPG disability score, HADS score, HEIQ , CPAQ and EQ5D at baseline and include them in the model, which we will fit to the complete case dataset using the command `paramed` in STATA.

7.7 Additional data summaries

The following additional data summaries will be produced:

- The mean (SD) for the change from baseline for CPG disability, CPG pain intensity, PSEQ, HADS anxiety, HADS depression, CPAQ, HEIQ, and the EQ-5D at both 6 and 12 months.
- The effect size (based on Cohen's D, i.e. the treatment effect divided by the standard deviation) for CPG disability, CPG pain intensity, PSEQ, HADS anxiety, HADS depression, CPAQ, HEIQ, and the EQ-5D at both 6 and 12 months.

8. Tables

The following tables will be produced:

Table 1 – baseline characteristics

	Intervention (n=…)	**Control (n=…)**
Age (years) – mean (SD)		
Male – no. (%)		
Living arrangements – no. (%)		
Alone		
With others		
Ethnicity – no. (%)		
White		
Black		
Asian		
Mixed		
Other		
English language fluency – no. (%)		
Fluent		
Good		
Below average		
Poor		
Age at which formal education ended – no. (%)		
No formal education received		
12 years or less		
13 to 16 years		
17 to 19 years		
20 years or later		
Still in full time education		

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Other		
Employment status – no. (%)		
Employed, including self employed (full or part time)		
Unemployed and looking for work		
At school or in full time education		
Unable to work due to long term sickness		
Looking after home/family		
Retired from paid work		
Other		
Time kept from usual activities due to pain in past 6 months		
0-6 days		
7-14 days		
15-30 days		
31 or more days		
State of health – no. (%)		
Very good		
Good		
Fair		
Bad		
Very Bad		
Duration of pain – no. (%)		
0-3 months		
4-12 months		
13 months – 2 years		
3-4 years		
5-6 years		
7-10 years		
More than 10 years		
CPG overall – mean (SD)		

CPG disability – mean (SD)		
CPG pain intensity – mean (SD)		
PSEQ – mean (SD)		
HADS depression – mean (SD)		
HADS anxiety – mean (SD)		
CPAQ – mean (SD)		
HEIQ – mean (SD)		
EQ-5D – mean (SD)		
Number of co-morbidities – median (IQR)		
Total amount of drugs taken above the Defined Daily Dose (DDD) in three months prior to randomisation		
Psychotropic – median (IQR)		
Weak opioids – median (IQR)		
Strong opioids – median (IQR)		
Analgesics (including opioids, non-opioids, NSAIDS and other CNS drugs, and oral and topical preparations)– median (IQR)		
Drugs taken orally for neuropathic pain – median (IQR)		
NSAID analgesics (both oral and topical) – median (IQR)		
Proportion of participants prescribed weak opioids – no. (%)		
Proportion of participants prescribed strong opioids – no. (%)		

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Table 2 – Number (%) of participants included in each analysis

	Intervention (n=…)	**Control (n=…)**
CPG disability		
CPG pain intensity		
PSEQ score		
HADS Anxiety score		
HADS Depression score		
CPAQ score		
HEIQ score		
EQ-5D		
Census global health question		
Total amount of drugs taken above the Defined Daily Dose (DDD) in up to 12 months post-randomisation		
Psychotropic		
Weak Opioids		
Strong Opioids		
Analgesics (including opioids and other CNS drugs)		
Proportion of participants using opioids at 12 months post-randomisation		
Weak opioids		
Strong opioids		

Table 3 – Main results for primary and secondary outcomes

	Intervention (n=…)	Control (n=…)	Treatment effect (95% CI)	P-value
CPG disability – mean (SD)				
12 months				
6 months				
CPG pain intensity – mean (SD)				
12 months				
6 months				
PSEQ score – mean (SD)				
12 months				
6 months				
HADS Anxiety score – mean (SD)				
12 months				
6 months				
HADS Depression score – mean (SD)				
12 months				
6 months				
CPAQ score – mean (SD)				
12 months				
6 months				
HEIQ score – mean (SD)				
12 months				
6 months				
EQ-5D – mean (SD)				
12 months				
6 months				
Census global health question – mean (SD)				

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12 months				
6 months				
Total amount of drugs taken above the Defined Daily Dose (DDD) in up to 12 months post-randomisation – median (IQR)				
Psychotropic				
Weak opioids				
Strong opioids				
Analgesics (including opioids and other CNS drugs)				
Proportion of participants using opioids at 12 months post-randomisation – no. (%)				
Weak opioids				
Strong opioids				

Table 4 – Results from sensitivity analyses for primary outcome

	Treatment effect (95% CI)	**P-value**
Main analysis		
Complete case analysis		
Multivariate analysis		
Different imputation model		
CACE analysis		
Re-definition of primary outcome		

Table 5 –Subgroup analyses for primary outcome (CPG disability at 12 months)

Subgroup	Intervention – mean (SD)	Control – mean (SD)	Treatment effect (95% CI)	P-value for interaction
Non-pain				
Co-morbidity				
0-3 (n=…)				
4 or more (n=…)				
Living arrangements				
Living alone (n=…)				
Living with others (n=…)				
PSEQ				
0-20 (n=…)				
21-39 (n=…)				
40-60 (n=…)				
Socioeconomic status				
Lower (n=…)				
Higher (n=…)				
Pain related				
Pain duration				
0-12 months (n=…)				
13 months to 4 years (n=…)				
5 or more years (n=…)				
CPG intensity				
0-3 (n=…)				
4-7 (n=…)				
8-10 (n=…)				
CPG disability				
0-3 (n=…)				

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4-7 (n=…)				
8-10 (n=…)				
HADS depression score				
0-10 (n=…)				
11-21 (n=…)				

Table 6 – Courses and activities outside of COPERS during follow-up period

	Intervention (n=…)	**Control (n=…)**
Courses or activities attended during follow-up period outside of the COPERS trial		
Pain management – no. (%)		
Expert participant programme or other self-management course – no. (%)		
Other wellness or wellbeing courses – no. (%)		
Return to work courses – no. (%)		
Received psychological counseling or therapies – no. (%)		
Frequency of practicing relaxation and/or meditation during follow-up period – no. (%)		
Daily		
Weekly		
Monthly		
Rarely		
Never		

Table 7 – Change from baseline summaries

	Change from baseline – mean (SD)	
Outcome	**6 months**	**12 months**
CPG disability		
CPG pain intensity		
PSEQ score		
HADS Anxiety score		
HADS Depression score		
CPAQ score		
HEIQ score		

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EQ-5D		

Table 8 – Standardised differences based on Cohen's D

Outcome	Treatment effect (95% CI)
CPG disability	
12 months	
6 months	
CPG pain intensity	
12 months	
6 months	
PSEQ score	
12 months	
6 months	
HADS Anxiety score	
12 months	
6 months	
HADS Depression score	
12 months	
6 months	
CPAQ score	
12 months	
6 months	
HEIQ score	
12 months	
6 months	
EQ-5D	
12 months	
6 months	

*Effect sizes were calculated by dividing the treatment effect and the confidence limits by the estimated standard deviation

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Table 9 – Differences between responders and participants lost to follow-up

	Responder (n=…)	Lost to follow-up (n=…)	Odds ratio for non-response (95% CI)	P-value
Age (years) – mean (SD)				
Male – no. (%)				
Ethnicity – no. (%)				
White				
Black				
Asian				
Mixed or other				
English language fluency – no. (%)				
Fluent or good				
Below average or poor				
Age at which formal education ended – no. (%)				
Employment status – no. (%)				
Employed				
Other				
CPG disability at baseline – mean (SD)				
CPG pain intensity at baseline – mean (SD)				
PSEQ at baseline – mean (SD)				
HADS depression at baseline – mean (SD)				
HADS anxiety at baseline – mean (SD)				
CPAQ at baseline – mean				

(SD)				
Number of co-morbidities – median (IQR)				

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Table 10 – ICC estimates

Outcome	ICC
CPG disability	
12 months	
6 months	
CPG pain intensity	
12 months	
6 months	
PSEQ score	
12 months	
6 months	
HADS Anxiety score	
12 months	
6 months	
HADS Depression score	
12 months	
6 months	
CPAQ score	
12 months	
6 months	
HEIQ score	
12 months	
6 months	
EQ-5D	
12 months	
6 months	
Census global health question	
12 months	
6 months	
Total amount of drugs taken above the Defined Daily Dose (DDD) up to 12 months post-randomisation	
Psychotropic	
Weak opioids	

Strong opioids	
Analgesics	
Proportion of participants using opioids at 12 months post-randomisation	
Weak opioids	
Strong opioids	
Compliance	
Continuous scale (0-24 components attended)	
Binary scale (attended 12 or more components)	

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Appendix I. Methods of calculating derived variables

CPG disability at 6 months

This is derived in the same method as the CPG disability score at 12 months (as described in section 2.3).

CPG pain intensity score at 6 and 12 months.

This is a composite of three questions which assess the participant's pain intensity at present, and the maximum and average intensity over the past 6 months. Each question is scored on a scale of 0-10. The outcome is the mean of the three questions, multiplied by 10. Its range is from 0-100, with higher scores indicating worse pain.

PSEQ (Pain Self-Efficacy Questionnaire) score at 6 and 12 months

This is a composite of 10 questions which ascertain the participant's level of confidence to live a normal life despite their pain. Each question is scored on a scale of 0-6. The outcome is the sum of all 10 questions. Its range is 0-60, with higher scores indicating higher levels of confidence.

HADS (Hospital Anxiety and Depression Scale) Anxiety score at 6 and 12 months

This is a composite of 7 questions which ascertains the extent of the participant's anxiety (these are the odd number questions of the HADS questionnaire). Each question has four answers ranging from not experiencing a symptom at all scored as 0, to experiencing a symptom nearly all the time scored as 3. The outcome is the sum of each question. Its range is 0-21, with higher scores indicating more severe anxiety.

HADS (Hospital Anxiety and Depression Scale) Depression score at 6 and 12 months

This is a composite of 7 questions which ascertains the extent of the participant's depression (these are the even number questions of the HADS questionnaire). Each question has four answers ranging from not experiencing a symptom at all scored as 0, to experiencing a symptom nearly all the time scored as 3. The outcome is the sum

of each question. Its range is 0-21, with higher scores indicating more severe depression.

CPAQ (Coping Pain and Acceptance Questionnaire) score at 6 and 12 months

This is a composite of 20 questions which ascertain the participant's ability to cope with their pain. Each question is scored on a scale of 0-6, with 0 indicating the statement is never true, and 6 indicating the statement is always true. There are two subscales: Pain Willingness and Activities Engagement. The statements in the Pain Willingness subscale are reverse scored, so that an answer of 'Always true' gives a score of 0, and a score of 'Never true' gives a score of 6. The outcome is the sum of each question. Its range is 0-120, with higher scores indicating a better ability to cope.

HEIQ (Health Education Impact Questionnaire) score at 6 and 12 months

This is a composite of 5 questions which ascertain the extent to which the participant is able to enjoy life. Each question has four answers ranging from Strongly Agree (scored as 4) to Strongly Disagree (scored as 1). The outcome is the sum of each question. It's range is 4-20, with higher scores indicating more enjoyment in life.

EQ-5D at 6 and 12 months

This is a composite of 5 questions which ascertain whether the participant has any problems with mobility, self-care, performing their usual activities, pain or discomfort, or anxiety or depression. Each question has three answers ranging from 'No problems' (scored as 1) to the worst category (scored as 3). The outcome score will be derived using the method described in the SPSS manual.

CPG overall (baseline variable)

The CPG overall score is a composite of the CPG disability, the CPG pain intensity, and another question assessing the number of days off usual activities due to pain. This question has four categories: 0-6 days, 7-14 days, 15-30 days and 31 or more days. Categories are assigned 0 points for 0-6 days through to 3 points for 31 + days.

CPG pain intensity is grouped as <50 vs ≥ 50, and CPG disability is grouped as 0 (0-29 points), 1 (30-49 points), 2 (50-69 points), or 3 (70-100 points). An overall

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disability score is then formed by adding the points from the grouped CPG disability score (range 0-3) to the points assigned for the number of days off work (range 0-3), giving an overall range of 0-6.

CPG Calculation

Grade 0 Pain free: No pain problems in the last 6 months

Grade I Low pain disability and low pain intensity: Characteristic pain intensity <50 and <3 disability points

Grade II Low disability-high intensity: Pain intensity of 50 or more and <3 disability points.

Grade III High disability- moderately limiting: 3-4 disability points, regardless of pain intensity

Grade IV High disability – severely limiting: 5-6 disability points

Drugs Data Analysis

Total Defined Daily Doses (Total DDD) consumed
The Total DDD for each drug is defined as:

$$\text{Total DDD}_{\text{DrugA}} = (\text{Strength}_{\text{MedA}} \times \text{quantity}_{\text{MedA}})/\text{DDD}_{\text{MedA}}$$

The Total DDD for a group of medications (e.g. the Total DDD for opioids) is the sum of the Total DDD for each drug within that medication group (e.g. each drug which is considered an opioid). For example, if there are three drugs (drugs A, B, and C), the $\text{TotalDDD}_{\text{opioid}}$ is defined as:

$$\text{TotalDDD}_{\text{opioid}} = \text{TotalDDD}_{\text{DrugA}} + \text{TotalDDD}_{\text{DrugB}} + \text{TotalDDD}_{\text{DrugC}}$$

The DDD (used in the denominator of the calculation for the TotalDDD) is determined in the first instance by the WHO register, then by precedent in other trials (OPERA and TOIB), and then by clinician consensus. For compound drugs, e.g. co-codamol we will separate out components (paracetamol & codeine) and work out the DDD for each component drug.

Data
Medications used over a 15 month period have been collected from GP participant records. We extracted drug name and strength used, plus quantity and the dates i.e. number of times the medication was prescribed. We have used the prescription cost analysis database to attach a cost to each individual preparation used. Using the World Health Organization (WHO)-defined daily dose for each drug we will generate number of days of medication used by *British National Formulary* chapter and subchapter.

Outcomes

We consider the following outcomes:

1) Total Defined Daily Doses (Total DDD) consumed of psychotropic drugs (Table 11) up to 12 months post randomisation
2) Total DDD consumed of all analgesics up to 12 months post randomisation

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3) Total DDD consumed of weak opioids up to 12 months post-randomisation (as defined by BNF 4.7.2 are codeine, dihydrocodeine and meptazionol)
4) Total DDD consumed of all NSAID analgesics (oral and topical combined) up to 12 months post randomisation
5) Total DDD consumed of all CNS drugs for neuropathic pain (see Table11) up to 12 months post-randomisation
6) Total DDD consumed of strong opioids up to 12 months post-randomisation (as defined by BNF 4.7.2, all opioids prescribed other than the ones listed above as weak)

Calculations for psychotropic drugs will be based on BNF subchapters 4.1, and 4.3, opioids based on BNF paragraph 4.7.2, and analgesics including opioids based on BNF paragraphs 4.7.1, 4.7.2, 4.7.3, and paragraphs10.1.1, 10.2.2, and 10.3.2.

Relevant Drugs

We will work out DDD for BNF chapter 4 and 10 groups of drugs, these are drugs used for treating chronic pain (see table below). We will exclude all drugs administered as injections, but we will include soluble drugs, gels and liquids.

Table 11- Pain related drugs

	Chapter	Subchapter	Paragraph	Comments
Psychotropic drugs	4. Central Nervous System	4.1. Hypnotics and Anxiolytics	4.1.1 Hypnotics 4.1.2.Anxiolytics	NOT: chloral and derivatives, clomethiazole or antihistamines
		4.3. Antidepressant drugs	4.3.2 Monoamine-oxidase inhibitors 4.3.3. Selective serotonin re-uptake inhibitors 4.3.4 Other anti depressant drugs	

Analgesic drugs		4.7 Analgesics	4.7.1 Non opioid analgesics 4.7.2. Opioid analgesics 4.7.3 Neuropathic and functional pain	4.8.1 Gabapentin and pregabalin feature as an anti-epileptic but also feature in 4.7.3 Neuropathic and functional pain For this analysis 4.3.1 tricyclic anti-depressants are included in section 4.7.3
	10. Musculoskeletal and joint diseases (exclude steroids, DMARDS)	10.1 Drugs used in rheumatic diseases and gout	10.1.1 Non-steroidal anti inflammatories	Exclude aspirin No steroids
		10.2 Drugs used in neuromuscular disorders	10.2.2 Skeletal muscle relaxants	
		10.3 Drugs for the relief of soft tissue inflammation	10.3.2 Rubefacients and other topical anti-rheumatics	Not enzymes

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Appendix 7 Fidelity, adherence and competence

Adherence and competence assessment sheets

Day 1, session 2: pain information – adherence

COPERS course code:

Reviewer:

Review date:

Aim: to increase understanding about chronic pain.

Item number	Item	Adherence measure	Comments
1	Was the DVD played?	Yes (2)	
		Unsure (1)	
		No (0)	
2	Did the facilitator(s) pose Q1 (What do you think about the consultant saying that pain comes from the muscles?) after 5 minutes 35 seconds of the DVD?	Yes (2)	
		Unsure (1)	
		No (0)	
3	Did the facilitator(s) pose Q2 (What do you think about this model of pain? Is it missing anything?) after 9 minutes 24 seconds of the DVD?	Yes (2)	
		Unsure (1)	
		No (0)	
4	Did the facilitator(s) pose Q3 (How do you feel about the consultant saying there is no cure?) after 12 minutes 13 seconds of the DVD?	Yes (2)	
		Unsure (1)	
		No (0)	
5	Did the facilitator(s) pose Q4 (How do you feel about the Bert Trautmann example?) at the end of the DVD?	Yes (2)	
		Unsure (1)	
		No (0)	
6	Did the facilitator(s) reiterate the aims of the course as explained at the end of the DVD?	Yes (2)	
		Unsure (1)	
		No (0)	
	Total adherence score		
	Percentage adherence score (total adherence score/12 × 100)		

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Day 1, session 2: pain Information – competence

	Item	Competence measure	Comments
Introduction	Did the facilitator(s) introduce the aims/rationale of the session?	Yes (2)	
		Unsure (1)	
		No (0)	
Discussion	Did the facilitator(s) create opportunities for discussion and encourage individual disclosure of narratives and participation?	Yes (2)	
		Unsure (1)	
		No (0)	
Summary	Did the facilitator(s) consolidate/embed the group's learning at the end of the session?	Yes (2)	
		Unsure (1)	
		No (0)	
Linking	Did the facilitator(s) link the completed session to other sessions?	Yes (2)	
		Unsure (1)	
		No (0)	
	Total competence score		
	Percentage competence score (total competence score/8 × 100)		

Overall session impression score ('How well did you think the overall aims of the session were met?')

Excellent			Did not go well	Comments
1	2	3	4	

Day 1, session 3: acceptance: the uninvited guest – adherence

COPERS course code:

Reviewer:

Review date:

Aim: to relate the scenario about the unwanted and uninvited guest to chronic pain.

Item number	Item	Adherence measure	Comments
1	Did the facilitator(s) read the street party story to the group?	Yes (2)	
		Unsure (1)	
		No (0)	
2	Did the facilitator(s) ask the group to discuss how the women handled the issue of the 'uninvited guest'?	Yes (2)	
		Unsure (1)	
		No (0)	
3	Did the facilitator(s) encourage the group to relate to the story of the 'uninvited guest' as an analogy for their pain?	Yes (2)	
		Unsure (1)	
		No (0)	
	Total adherence score		
	Percentage adherence score (total adherence score/6 × 100)		

Day 1, session 3: acceptance: the uninvited guest – competence

	Item	Competence measure	Comments
Introduction	Did the facilitator(s) introduce the aims/rationale of the session?	Yes (2)	
		Unsure (1)	
		No (0)	
Discussion	Did the facilitator(s) create opportunities for discussion and encourage individual disclosure of narratives and participation?	Yes (2)	
		Unsure (1)	
		No (0)	
Summary	Did the facilitator(s) consolidate/embed the group's learning at the end of the session?	Yes (2)	
		Unsure (1)	
		No (0)	
Linking	Did the facilitator(s) link the completed session to other sessions?	Yes (2)	
		Unsure (1)	
		No (0)	
	Total competence score		
	Percentage competence score (total competence score/8 × 100)		

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Overall session impression score ('How well did you think the overall aims of the session were met?')

Excellent			Did not go well	Comments
4	3	2	1	

Day 1, session 5: the pain cycle, unhelpful emotions and behaviours – adherence

COPERS course code:

Reviewer:

Review date:

Aim: to explain the pain cycle and understand the process and the unhelpful things that we do to keep us in that cycle.

Item number	Item	Adherence measure	Comments
1	Did the facilitator(s) show and explain the persistent pain cycle to the group?	Yes (2)	
		Unsure (1)	
		No (0)	
2	Did the facilitator(s) ask the group to generate a list of unhelpful things that may keep them in the pain cycle?	Yes (2)	
		Unsure (1)	
		No (0)	
3	Did the facilitator(s) distribute and/or mention handout 1? (Unhelpful coping strategies.) Please refer to reviewer guidance below	Yes (2)	
		Unsure (1)	
		No (0)	
4	Did the facilitator(s) distribute and/or mention handout 2? (Depressive symptom checklist.) Please refer to reviewer guidance below	Yes (2)	
		Unsure (1)	
		No (0)	
5	Did the facilitator(s) ask the group to generate a list of things that they could do to escape from the pain cycle?	Yes (2)	
		Unsure (1)	
		No (0)	
6	Did the facilitator(s) distribute and/or mention handout 3? (Escape routes from the pain cycle.) Please refer to reviewer guidance below	Yes (2)	
		Unsure (1)	
		No (0)	
	Total adherence score		
	Percentage adherence score (total adherence score/12 × 100)		

Reviewer guidance: if, on listening to the audio-recording, the score for this item is 'unsure' (1) or 'no' (0), please refer to the observation notes for this session to determine whether the handouts were/were not distributed and amend the adherence score accordingly.

Day 1, session 5: the pain cycle, unhelpful emotions and behaviours – competence

	Item	Competence measure	Comments
Introduction	Did the facilitator(s) introduce the aims/rationale of the session?	Yes (2)	
		Unsure (1)	
		No (0)	
Discussion	Did the facilitator(s) create opportunities for discussion and encourage individual disclosure of narratives and participation?	Yes (2)	
		Unsure (1)	
		No (0)	
Summary	Did the facilitator(s) consolidate/embed the group's learning at the end of the session?	Yes (2)	
		Unsure (1)	
		No (0)	
Linking	Did the facilitator(s) link the completed session to other sessions?	Yes (2)	
		Unsure (1)	
		No (0)	
	Total competence score		
	Percentage competence score (total competence score/8 × 100)		

Overall session impression score ('How well did you think the overall aims of the session were met?')

Excellent			Did not go well	Comments
4	3	2	1	

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Day 2, session 9: identifying problems, goal-setting, action planning – adherence

COPERS course code:

Reviewer:

Review date:

Aim: to help the participants identify problems, brainstorm solutions, set goals and devise action plans, as a means of escaping the pain cycle.

Item number	Item	Adherence measure	Comments
1	Did the facilitator(s) explain the process of identifying problems, brainstorming solutions, thinking about advantages/disadvantages to solutions and goal-setting?	Yes (2) Unsure (1) No (0)	
2	Did the facilitator(s) explain the SMART process to the group?	Yes (2) Unsure (1) No (0)	
3	Did the facilitator(s) distribute and/or mention handout 5 (SMART)? Please refer to reviewer guidance below	Yes (2) Unsure (1) No (0)	
4a	Did the facilitator(s) go through an example of the SMART process with the group?	Yes (2) Unsure (1) No (0)	
4b	Group exercise: did the facilitator(s) divide the participants into smaller groups/ pairs to tackle a chosen problem on their own?	Yes (2) Unsure (1) No (0)	
5	Group exercise: were the groups given the opportunity to give feedback about the process of problem-solving?	Yes (2) Unsure (1) No (0)	
6	Did the facilitator(s) distribute and/or mention handout 6 (goal-setting examples)? Please refer to reviewer guidance below	Yes (2) Unsure (1) No (0)	
7	Did the facilitator(s) distribute and/or mention handout 7 (tips for a good night's sleep)? Please refer to reviewer guidance below.	Yes (2) Unsure (1) No (0)	
	Total adherence score		
	Percentage score (total adherence score/16 × 100)		

Smart, Smart, Achievable, Relevant and Timed goals.

Reviewer guidance: if, on listening to the audio-recording, the score for this item is 'unsure' (1) or 'no' (0), please refer to the observation notes for this session to determine whether the handouts were/were not distributed and amend the adherence score accordingly.

Day 2, session 9: identifying problems, goal-setting, action planning – competence

	Item	Competence measure	Comments
Introduction	Did the facilitator(s) introduce the aims/rationale of the session?	Yes (2)	
		Unsure (1)	
		No (0)	
Discussion	Did the facilitator(s) create opportunities for discussion and encourage individual disclosure of narratives and participation?	Yes (2)	
		Unsure (1)	
		No (0)	
Summary	Did the facilitator(s) consolidate/embed the group's learning at the end of the session?	Yes (2)	
		Unsure (1)	
		No (0)	
Linking	Did the facilitator(s) link the completed session to other sessions?	Yes (2)	
		Unsure (1)	
		No (0)	
	Total competence score		
	Percentage competence score (total competence score/8 × 100)		

Overall session impression score ('How well did you think the overall aims of the session were met?')

Excellent			Did not go well	Comments
4	3	2	1	

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Day 2, session 10: barriers to change, unhelpful thinking – adherence

COPERS course code:

Reviewer:

Review date:

Aim: to introduce ideas about unhelpful thoughts, automatic thoughts and errors in thinking.

Item number	Item	Adherence measure	Comments
1	Did the facilitator(s) distribute handout 8 (typical unhelpful/negative thoughts and thinking)?	Yes (2) Unsure (1) No (0)	
2	Did the facilitator(s) read the titles and describe the unhelpful thoughts in the list to the group for their consideration?	Yes (2) Unsure (1) No (0)	
3	Did the facilitator(s) use the unhelpful thought 'flash cards' to generate group discussion?	Yes (2) Unsure (1) No (0)	
4	Did the facilitator(s) read the 'Sam's morning' scenario to the group with appropriate pauses for participants to 'spot' and name the negative thoughts?	Yes (2) Unsure (1) No (0)	
5	Did the facilitator(s) distribute and/or mention handout 9 (unhelpful thoughts checklist)? Please refer to reviewer guidance below	Yes (2) Unsure (1) No (0)	
6	Did the facilitator(s) invite the group to consider 'Sam's morning' again from an unemotional standpoint?	Yes (2) Unsure (1) No (0)	
	Total adherence score		
	Percentage adherence score (total adherence score/12 × 100)		

Reviewer guidance: if, on listening to the audio-recording, the score for this item is 'unsure' (1) or 'no' (0), please refer to the observation notes for this session to determine whether the handouts were/were not distributed and amend the adherence score accordingly.

Day 2, session 10: barriers to change, unhelpful thinking – competence

	Item	Competence measure	Comments
Introduction	Did the facilitator(s) introduce the aims/rationale of the session?	Yes (2)	
		Unsure (1)	
		No (0)	
Discussion	Did the facilitator(s) create opportunities for discussion and encourage individual disclosure of narratives and participation?	Yes (2)	
		Unsure (1)	
		No (0)	
Summary	Did the facilitator(s) consolidate/embed the group's learning at the end of the session?	Yes (2)	
		Unsure (1)	
		No (0)	
Linking	Did the facilitator(s) link the completed session to other sessions?	Yes (2)	
		Unsure (1)	
		No (0)	
	Total competence score		
	Percentage competence score (total compliance score/8 × 100)		

Overall session impression score ('How well did you think the overall aims of the session were met?')

Excellent			Did not go well	Comments
4	3	2	1	

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Day 2, session 11: barriers to change, reframing negatives to positives – adherence

COPERS course code:

Reviewer:

Review date:

Aim: to identify reasons why people stay in the pain cycle and barriers to change.

Item number	Item	Adherence measure	Comments
1	Did the facilitator(s) ask the group to consider the 'cons' of pain?	Yes (2)	
		Unsure (1)	
		No (0)	
2	Did the facilitator(s) ask the group to consider the 'pros' of pain?	Yes (2)	
		Unsure (1)	
		No (0)	
3	Did the facilitator(s) use a flip chart to encourage a consideration of the 'pros' and 'cons' of pain?	Yes (2)	
		Unsure (1)	
		No (0)	
4	Did the facilitator(s) use the example of 'going to the gym' (slide 16) to demonstrate reframing 'cons' to 'cans'?	Yes (2)	
		Unsure (1)	
		No (0)	
5	Did the facilitators(s) use the group-generated 'cons' of pain and ask the group to reframe them to 'cans'	Yes (2)	
		Unsure (1)	
		No (0)	
	Total adherence score		
	Percentage adherence score (total adherence score/10 × 100)		

Day 2, session 11: barriers to change, reframing negatives to positives – competence

	Item	Competence measure	Comments
Introduction	Did the facilitator(s) introduce the aims/rationale of the session?	Yes (2)	
		Unsure (1)	
		No (0)	
Discussion	Did the facilitator(s) create opportunities for discussion and encourage individual disclosure of narratives and participation?	Yes (2)	
		Unsure (1)	
		No (0)	
Summary	Did the facilitator(s) consolidate/embed the group's learning at the end of the session?	Yes (2)	
		Unsure (1)	
		No (0)	
Linking	Did the facilitator(s) link the completed session to other sessions?	Yes (2)	
		Unsure (1)	
		No (0)	
	Total competence score		
	Percentage competence score (total competence score/8 × 100)		

Overall session impression score ('How well did you think the overall aims of the session were met?')

Excellent			Did not go well	Comments
4	3	2	1	

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Day 2, session 12: attention control and distraction – adherence

COPERS course code:

Reviewer:

Review date:

Aim: to learn how to focus the mind away from pain thoughts.

Item number	Item	Adherence measure	Comments
1	Did the facilitator(s) ask the group NOT to think about food for 30 seconds?	Yes (2) Unsure (1) No (0)	
2	Did the facilitator(s) ask the group what happened when they tried not to think about food?	Yes (2) Unsure (1) No (0)	
3	Did the facilitator(s) ask the group NOT to think about their pain for 30 seconds?	Yes (2) Unsure (1) No (0)	
4	Did the facilitator(s) ask the group if their pain felt better or worse as they focused on it?	Yes (2) Unsure (1) No (0)	
5	Did the facilitator(s) ask the group to close their eyes and recall a time when they were content calm and happy?	Yes (2) Unsure (1) No (0)	
6	Did the facilitator(s) ask the group what happened to their pain while they were doing this exercise?	Yes (2) Unsure (1) No (0)	
	Total adherence score		
	Percentage adherence score (total adherence score/12 × 100)		

Day 2, session 12: attention control and distraction – competence

	Item	Competence measure	Comments
Introduction	Did the facilitator(s) introduce the aims/rationale of the session?	Yes (2)	
		Unsure (1)	
		No (0)	
Discussion	Did the facilitator(s) create opportunities for discussion and encourage individual disclosure of narratives and participation?	Yes (2)	
		Unsure (1)	
		No (0)	
Summary	Did the facilitator(s) consolidate/embed the group's learning at the end of the session?	Yes (2)	
		Unsure (1)	
		No (0)	
Linking	Did the facilitator(s) link the completed session to other sessions?	Yes (2)	
		Unsure (1)	
		No (0)	
	Total competence score		
	Percentage competence score (total competence score/8 × 100)		

Overall session impression score ('How well did you think the overall aims of the session were met?')

Excellent			Did not go well	Comments
4	3	2	1	

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Appendix 8 Results: number of participants in each analyses

TABLE 90 Number of participants included in each analysis

Analysis[a]	Control ($N = 300$), *n* (%)	Intervention ($N = 403$), *n* (%)
CPG pain-related disability score	278 (93)	374 (93)
CPG pain intensity score	260 (87)	364 (90)
PSEQ score	270 (90)	373 (93)
HADS anxiety score	261 (87)	364 (90)
HADS depression score	261 (87)	364 (90)
CPAQ score	261 (87)	364 (90)
heiQ score	261 (87)	363 (90)
EQ-5D score	275 (92)	372 (92)
Census global health question	260 (87)	364 (90)
Drug data up to 12 months post randomisation	258 (86)	350 (87)

a For CPG pain-related disability, CPG pain intensity, PSEQ, HADS anxiety, HADS depression, CPAQ, heiQ, EQ-5D and the census global health questionnaire, the same number of participants were included in the analyses at both 6 months and 12 months.

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