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**The development and evaluation of a community-based
rehabilitation intervention for people with
schizophrenia in Ethiopia**

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DECLARATION BY CANDIDATE

I, Laura Asher, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

A handwritten signature in black ink, appearing to read 'Laura Asher', written in a cursive style.

06.10.2016

ABSTRACT

Background

Community-based rehabilitation (CBR) is a promising intervention to address the complex needs of people with schizophrenia in low-income countries, in particular the high levels of disability, problems accessing treatment and stigma experienced by this group. There have been few randomised controlled trials of community-based psychosocial interventions for schizophrenia using non-specialist workers, and none which have utilised a community mobilisation approach or that are set in low-income countries. This thesis presents the intervention development, piloting and evaluation plans of a CBR intervention for people with schizophrenia in Ethiopia.

Methods

A theory of change approach was used. Intervention development work, including a situational analysis, qualitative interviews and participatory workshops, was conducted to design the CBR intervention. The intervention was manualised and ten non-specialists were trained to deliver CBR. Ten people with schizophrenia and their caregivers received CBR in a 12 month pilot study. Qualitative, process and quantitative data were collected. The protocol for a cluster randomised trial to evaluate CBR, refined on the basis of the pilot findings, was produced.

Results

CBR delivered by non-specialists is an acceptable approach for people with schizophrenia in rural Ethiopia. This CBR intervention is likely to be feasible but this requires evaluation on a larger scale. CBR may improve functioning in people with schizophrenia through maximising family and community support, supporting income-generating activities, facilitating access to medication, and increasing hope. However, contextual factors, including poverty and inaccessible anti-psychotic medication, may be beyond the capacity of CBR to overcome.

Conclusion

A community-based intervention such as CBR should be provided for people with schizophrenia in low-income countries, alongside accessible anti-psychotic medication. There are indications that CBR can impact on functioning but a randomised controlled trial remains essential. The trial analysis will help to determine the 'active ingredients' of CBR that should be prioritised in scaling up.

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TABLE OF CONTENTS (VOLUME I)

1	Outline of thesis	17
1.1	Thesis structure.....	17
1.2	Contributions of the candidate.....	18
1.3	Additional study outputs.....	19
1.4	Introduction to Ethiopia	20
1.5	References	23
2	Background to thesis	24
2.1	Clinical features and course of schizophrenia	24
2.1.1	Clinical features.....	24
2.1.2	Diagnosis and classification.....	24
2.1.3	Clinical recovery and course.....	25
2.1.4	Aetiology	26
2.2	Epidemiology of schizophrenia	26
2.2.1	Incidence	26
2.2.2	Prevalence	27
2.2.3	Mortality.....	27
2.3	Disability relating to schizophrenia	28
2.3.1	Model of disability and application to schizophrenia.....	28
2.3.2	Nature of disability relating to schizophrenia	31
2.3.3	Disability, mental health and poverty	31
2.3.4	Measurement of disability.....	32
2.4	Conceptualisation of recovery	33
2.5	Disease burden and global health importance of schizophrenia	34
2.5.1	Disease burden	34
2.5.2	Global health importance.....	35
2.6	Interventions for the treatment of schizophrenia	37
2.6.1	Overview of effective interventions	37
2.6.2	Delivery of interventions for schizophrenia.....	41
2.6.3	Cost-effectiveness.....	45
2.7	Community-based rehabilitation	46
2.7.1	Background to CBR.....	46
2.7.2	Mental health and CBR.....	48
2.7.3	Other models related to CBR.....	51
2.8	Explanatory models	52
2.9	Mental healthcare in Ethiopia	53

2.9.1	Healthcare system in Ethiopia	53
2.9.2	Biomedical services for mental health	54
2.9.3	Traditional and religious care providers	56
2.9.4	Family support.....	56
2.9.5	Access to mental healthcare	57
2.9.6	Pathways to mental healthcare	57
2.10	Stigma, discrimination and human rights.....	59
2.10.1	Stigma and discrimination.....	59
2.10.2	Human rights	60
2.11	References.....	61
3	Thesis rationale, aims and objectives and overview of methodology.....	79
3.1	Rationale for thesis.....	79
3.2	Aim and objectives.....	80
3.3	Setting	80
3.4	Overview of thesis methodology.....	81
3.4.1	Development and evaluation of complex interventions.....	81
3.4.2	Introduction to theory of change.....	82
3.4.3	Use of theory of change in this thesis	84
3.5	Thesis timescale	85
3.6	References	87
4	Systematic review and meta-analysis	90
4.1	Introduction.....	90
4.2	Methods	90
4.2.1	Systematic literature search	90
4.2.2	Data extraction and quality assessment.....	93
4.3	Results.....	95
4.3.1	Overview	95
4.3.2	Study characteristics.....	96
4.3.3	Risk of bias.....	102
4.3.4	Synthesis of results	104
4.4	Discussion.....	109
4.4.1	Summary of findings	109
4.4.2	Strengths and limitations.....	111
4.4.3	Implications	111
4.5	References	114
5	Intervention development.....	117

5.1	Introduction	117
5.2	Research paper	118
5.3	Appendices	143
5.4	Supplementary references	143
6	RISE materials	144
6.1	Introduction	144
6.2	Methods	144
6.3	Intervention overview	146
6.3.1	Structure of CBR	146
6.3.2	Home visits	150
6.3.3	Terminating CBR	153
6.3.4	Links to health services	153
6.3.5	Dealing with risks	153
6.3.6	Community mobilisation	155
6.3.7	Family support groups	156
6.3.8	Supervision	157
6.4	RISE manual	157
6.5	RISE training programme	166
6.6	Conclusion	172
6.7	References	172
7	The RISE pilot study	175
7.1	Introduction	175
7.2	Methods	175
7.2.1	Setting	175
7.2.2	Participants	176
7.2.3	CBR workers and supervisors	177
7.2.4	CBR delivery and supervision	178
7.2.5	Theory of change	178
7.2.6	Data collection and analysis	181
7.2.7	Data synthesis	185
7.2.8	Ethical considerations	186
7.3	Results	186
7.3.1	Overview	186
7.3.2	Research question 1: Is the RISE CBR intervention acceptable?	187
7.3.3	Intervention adjustments to maximise acceptability	196
7.3.4	Research question 2: Is the RISE CBR intervention feasible?	199
7.3.5	Intervention adjustments to maximise feasibility	203

7.3.6	Research question 3: Can the RISE CBR intervention produce an impact and if so, how?.....	204
7.3.7	Intervention adjustments to maximise impact	222
7.3.8	Summary of results.....	222
7.4	Discussion.....	227
7.4.1	Strengths and limitations.....	227
7.4.2	Conceptual framework for improved functioning.....	229
7.4.3	Assumptions that were shown to be correct.....	230
7.4.4	Assumptions not yet confirmed	232
7.5	Conclusion	235
7.6	References	236
8	RISE trial protocol.....	240
8.1	Introduction.....	240
8.2	Research paper	246
8.3	Supplementary information.....	262
8.3.1	Piloting of trial methods.....	262
8.3.2	Supplementary statistical analysis plan	264
8.3.3	Potential limitations.....	266
8.4	Conclusion	267
8.5	Supplementary references.....	268
9	Discussion.....	269
9.1	Introduction.....	269
9.2	Thesis findings	269
9.2.1	Findings and contributions to the literature by objective.....	269
9.2.2	Cross-cutting findings.....	273
9.3	Strengths and limitations	284
9.3.1	Issues relating to theory of change.....	284
9.3.2	Qualitative methodology.....	285
9.3.3	Scope of pilot and readiness for the trial	286
9.3.4	Differences between the pilot and the trial.....	289
9.3.5	Classification of CBR: an intervention or an approach?	290
9.3.6	Sustainability of CBR.....	291
9.3.7	Enduring impact of CBR	292
9.3.8	Issues relating to the comparator (facility-based care).....	292
9.3.9	Generalisability	293
9.3.10	Scalability	293
9.3.11	Critiques of global mental health.....	295

9.4 Recommendations	298
9.4.1 Policy and programmes	298
9.4.2 Directions for future research	299
9.5 RISE trial progress	300
9.6 Conclusion	302
9.7 References	304

LIST OF APPENDICES (VOLUME II)

Appendix A (Chapter 4: Systematic review and meta-analysis)

Appendix A (i): Medline search strategy

Appendix A (ii): Reasons for exclusion of full texts

Appendix A (iii): Additional meta-analyses

Appendix B (Chapter 5: Intervention development)

Appendix B (i): Ethical approval for intervention development

Appendix B (ii): Intervention development information sheets and consent forms

Appendix B (iii): Intervention development qualitative topic guides

Appendix C (Chapter 6: RISE materials)

Appendix C (i): RISE intervention delivery forms

Appendix C (ii): RISE training manual for CBR workers

Appendix C (iii): RISE training programme for CBR workers

Appendix C (iv): RISE assessments for CBR workers

Appendix C (v): ENhancing Assessment of Common Therapeutic factors (ENACT) scale-adapted version for Ethiopia

Appendix D (Chapter 7: The RISE pilot study)

Appendix D (i): Pilot eligibility assessment form

Appendix D (ii): Detailed pre-pilot theory of change

Appendix D (iii): Pilot qualitative topic guides

Appendix D (iv): Ethical approval for the pilot and trial

Appendix D (v): Pilot information sheets and consent forms

Appendix D (vi): Pilot supplementary data

Appendix D (vii): Detailed post-pilot theory of change

Appendix E (Chapter 8: RISE trial protocol)

Appendix E (i): SPIRIT statement

Appendix E (ii): Adequacy of screening assessment form

Appendix E (iii): Trial eligibility assessment forms

Appendix E (iv): Trial information sheets and consent forms

Appendix E (v): Process data forms

Appendix E (vi): Trial qualitative topic guides

Appendix E (vii): Trial patient report forms

LIST OF FIGURES

FIGURE 1.1 LOCATION OF ETHIOPIA	21
FIGURE 1.2 MAP OF ETHIOPIA	22
FIGURE 2.1 ICF FRAMEWORK FOR DISABILITY	29
FIGURE 2.2 MODEL OF DISABILITY RELATING TO SCHIZOPHRENIA	30
FIGURE 2.3 WHO CBR MATRIX (FROM WHO CBR GUIDELINES)	47
FIGURE 3.1 KEY ELEMENTS OF THE DEVELOPMENT AND EVALUATION PROCESS (FROM MRC GUIDANCE)	82
FIGURE 3.2 THESIS TIMESCALE	86
FIGURE 4.1 FLOW CHART OF STUDY SELECTION PROCESS	95
FIGURE 4.2 COMMUNITY-BASED PSYCHOSOCIAL INTERVENTION VERSUS USUAL CARE: IMPACT ON SYMPTOM SEVERITY (SHORT TERM OUTCOMES)	105
FIGURE 4.3 COMMUNITY-BASED PSYCHOSOCIAL INTERVENTION VERSUS USUAL CARE: IMPACT ON PROPORTION RECOVERED OR IMPROVED (SHORT TERM OUTCOMES)	105
FIGURE 4.4 COMMUNITY-BASED PSYCHOSOCIAL INTERVENTION VERSUS USUAL CARE: IMPACT ON FUNCTIONING (SHORT TERM OUTCOMES)	106
FIGURE 4.5 COMMUNITY-BASED PSYCHOSOCIAL INTERVENTION VERSUS USUAL CARE: IMPACT ON ABILITY TO WORK (SHORT TERM OUTCOMES)	106
FIGURE 4.6 COMMUNITY-BASED PSYCHOSOCIAL INTERVENTION VERSUS USUAL CARE: IMPACT ON NUMBER OF READMISSIONS (SHORT TERM OUTCOMES)	107
FIGURE 4.7 COMMUNITY-BASED PSYCHOSOCIAL INTERVENTIONS VERSUS USUAL CARE: IMPACT ON NUMBER OF DAYS IN HOSPITAL (SHORT TERM OUTCOMES)	107
FIGURE 4.8 COMMUNITY-BASED PSYCHOSOCIAL INTERVENTION VERSUS USUAL CARE: IMPACT ON MEDICATION ADHERENCE (SHORT TERM OUTCOMES)	108
FIGURE 6.1 RISE HOME VISIT FORM	151
FIGURE 6.2 RISE PROTOCOL FOR PHYSICAL RESTRAINT	154
FIGURE 6.3 RISE FORM FOR COMMUNITY-AWARENESS RAISING EVENT	156
FIGURE 6.5 RISE MANUAL CHAPTER 26	161
FIGURE 6.6 RISE TRAINING SESSION 'DISABILITIES RELATING TO SCHIZOPHRENIA'	169
FIGURE 6.7 RISE TRAINING SESSION 'TAKING PART IN COMMUNITY LIFE'	170
FIGURE 6.8 RISE FIELDWORK SESSION 'COMMUNITY MOBILISATION PRACTICE'	171
FIGURE 6.9 RISE TRAINING SESSION 'COMMUNITY MOBILISATION DISCUSSION'	171
FIGURE 7.1 PRE-PILOT RISE THEORY OF CHANGE MAP	180
FIGURE 7.2 POST-PILOT RISE THEORY OF CHANGE MAP	223
FIGURE 9.1 THE ACCESS FRAMEWORK (FROM OBRIST ET AL 2007)	274
FIGURE 9.2 CONSORT DIAGRAM FOR RISE TRIAL	302

LIST OF TABLES

TABLE 2.1 FUNCTIONING PROBLEMS ASSOCIATED WITH PHYSICAL AND MENTAL ILLNESS	28
TABLE 2.2 OVERVIEW OF EVIDENCE FOR PSYCHOSOCIAL INTERVENTIONS FOR SCHIZOPHRENIA	39
TABLE 4.1 INCLUSION AND EXCLUSION CRITERIA	91
TABLE 4.2 SUMMARY OF THE DESIGN AND FINDINGS OF INCLUDED STUDIES	97
TABLE 4.3 QUALITY OF INCLUDED STUDIES	103
TABLE 6.1 RISE CBR WORKER COMPETENCIES	145
TABLE 6.2 RISE TRAINING TIMETABLE	167
TABLE 7.1 PILOT QUANTITATIVE INSTRUMENTS	182
TABLE 7.2 NUMBER OF PARTICIPANTS IN IDIS AND FGDS	185
TABLE 7.3 CBR PARTICIPANT PROCESS DATA	188
TABLE 7.4 CBR PARTICIPANT QUANTITATIVE DATA RELATING TO DISABILITY, CLINICAL STATE, DEPRESSION AND ALCOHOL USE	206
TABLE 7.5 CBR PARTICIPANT QUANTITATIVE DATA RELATING TO HEALTH FACILITY USE, DISCRIMINATION, PHYSICAL RESTRAINT AND CAREGIVER BURDEN	207
TABLE 7.6 RESEARCH QUESTION 1: SUMMARY OF ASSUMPTIONS, MAIN FINDINGS AND ADJUSTMENTS TO TRIAL INTERVENTION	224
TABLE 7.7 RESEARCH QUESTION 2: SUMMARY OF ASSUMPTIONS, MAIN FINDINGS AND ADJUSTMENTS TO TRIAL INTERVENTION	225
TABLE 7.8 RESEARCH QUESTION 3: SUMMARY OF ASSUMPTIONS, MAIN FINDINGS AND ADJUSTMENTS TO TRIAL INTERVENTION	226
TABLE 8.1 TRIAL INDICATORS FOR THE RISE THEORY OF CHANGE	241
TABLE 9.1 DIMENSIONS OF ACCESS, BARRIERS AND ROLE OF CBR IN MOBILISING LIVELIHOOD ASSETS	276

LIST OF ABBREVIATIONS

AAU	Addis Ababa University
AUDIT	Alcohol Use Disorders Identification Test
BPRS	Brief Psychiatric Rating Scale
BPRS-E	Brief Psychiatric Rating Scale- Expanded version
CBM	An international disability and development organisation
CBR	Community-based rehabilitation
CCMD	Chinese Classification of Mental Disorders
CGI	Clinical Global Impression
CI	Confidence interval
CSRI	Client Service Receipt Inventory
COPSI	COmmunity-based intervention for People with Schizophrenia in India
CPS	Current Psychiatric Status
DALY	Disability-adjusted life year
DCP-3	Disease Control Priorities 3 rd Edition
DISC- 12	Discrimination and Stigma Scale-12
DSM-IV	Diagnostic and Statistical Manual for Mental Disorders, 4 th Edition
ENACT	ENhancing Assessment of Common Therapeutic factors scale
EPRDF	Ethiopian People's Revolutionary Democratic Front
FGD	Focus group discussion
GAF	Global Assessment of Functioning
GAS	Global Assessment Scale
GDP	Gross Domestic Product
HEW	Health extension worker
ICD- 10	International Classification of Diseases-10 th Revision
ICER	Incremental cost-effectiveness ratio

ICF	International Classification of Functioning, Disability and Health
IDEAS	Indian Disability Evaluation Assessment Scale
ID	Identification
IDI	In-depth interview
IEQ	Involvement Evaluation Questionnaire
IQR	Interquartile range
LMIC	Low and middle income countries
LSHTM	London School of Hygiene and Tropical Medicine
mhGAP	Mental health Gap Action Programme
MHIN	Mental Health Innovations Network
MRC	Medical Research Council
NGO	Non-governmental organisation
OPCRIT	Operational Criteria for Research
PANSS	Positive and Negative Syndrome Scale
PHQ-9	Patient Health Questionnaire- 9
PORT	Schizophrenia Patient Outcomes Research Team
PRIME	PRogramme for Improving Mental healthcarE
RAPID	Rehabilitation And Prevention Initiative against Disabilities
RCT	Randomised controlled trial
RISE	Rehabilitation Intervention for people with Schizophrenia in Ethiopia
ROSCA	Rotating Savings and Credit Association
SDSS	Social Disability Screening Schedule
SMD	Standardised mean difference
SMR	Standardised mortality ratio
SOFAS	Social and Occupational Functioning Assessment Scale
SOP	Standard operating procedure
SPIRIT	Standard Protocol Items: Recommendations for Interventional

	Trials
UN	United Nations
WHO	World Health Organisation
WHODAS 2.0	World Health Organisation Disability Assessment Schedule Version 2.0

Other terms used in the thesis

Edir: a traditional burial association that may also offer financial or practical support to vulnerable people. Most Ethiopians are members of one or more edir groups.

Holy water: Holy water (*tsebel*) is found at sites associated with the Orthodox Christian church. People with a wide range of physical and mental illnesses attend holy water sites to bathe in and drink the water and in some cases to have the devil or spirits driven out of them by a holy water priest.

Ihadig: alternative name for the Ethiopian People’s Revolutionary Democratic Front (EPRDF), which is the ruling political coalition in Ethiopia.

Kebele: Smallest administrative unit; indicated as ‘sub-district’ in most sections of the thesis.

Khat: a flowering plant native to the Horn of Africa that contains an amphetamine-like stimulant.

Mahber: social religious meetings usually linked to the Orthodox Christian church.

1 OUTLINE OF THESIS

1.1 THESIS STRUCTURE

This thesis is comprised of a collection of research papers and chapters, which are the core outputs to date of the Rehabilitation Intervention for people with Schizophrenia in Ethiopia (RISE) project. The main body of the thesis is found in Volume One and is structured as follows.

Chapter 2 is an introduction that covers three areas. *Section A* describes the problem that this thesis aims to address, namely disability related to schizophrenia. *Section B* introduces the possible solutions to that problem, focusing on psychosocial interventions for schizophrenia and in particular community-based rehabilitation (CBR). *Section C* explores aspects of the Ethiopian context that are relevant to the implementation of CBR for schizophrenia, including existing mental health services, explanatory models, stigma and human rights.

Chapter 3 describes the rationale for the thesis as well as the aims and objectives. It also gives an overview of the theory of change framework, which guided the work presented in the thesis, the timeline and the setting for the research.

Chapter 4 presents a systematic review, which will be prepared for publication, of the effectiveness of community-based psychosocial interventions for people with schizophrenia in low and middle-income countries (LMIC).

Chapter 5 is a published paper describing the development of a CBR intervention for people with schizophrenia in Ethiopia, whilst **Chapter 6** presents the manualised materials I created to guide intervention delivery. **Chapter 7** describes the RISE pilot study, which was conducted to determine the acceptability and feasibility of the CBR intervention in practice. The pilot is presented as one chapter for clarity, but will be drafted into two research papers for publication.

Chapter 8 is a published paper presenting the protocol for the RISE cluster randomised trial of CBR for schizophrenia, which was finalised on the basis of the pilot findings.

Chapter 9 concludes the thesis with a summary of the findings and their contributions to the field of global mental health, the implications of the findings for policy, programmes and future research, as well as the limitations of the research. A summary of the RISE trial progress to date is also presented.

The appendices are found in Volume Two.

1.2 CONTRIBUTIONS OF THE CANDIDATE

I lived in Ethiopia from April 2013 until October 2015 in order to carry out the work contained in this thesis. I led on the planning, data collection, analysis and write up of all aspects of the intervention development work (Chapter 5). This work was supervised by Mary De Silva (London School of Hygiene and Tropical Medicine (LSHTM)) and Abebaw Fekadu (Addis Ababa University (AAU)). I created the entire set of RISE materials for intervention delivery, including the RISE manual, training materials (including slides and handouts) and assessments (Chapter 6). The RISE manual utilised material from the COmmunity-based intervention for People with Schizophrenia in India (COPSI) manual with permission of the author, Sudipto Chatterjee (Sangath and Parivartan Trust, India) [1]. Several colleagues contributed to revisions of the RISE manual including Charlotte Hanlon (AAU and Kings College London), Mary De Silva, Abebaw Fekadu, Julian Eaton (CBM and LSHTM) and Atalay Alem (AAU).

In relation to the RISE pilot study (Chapter 7), I led on the planning, intervention implementation, qualitative and process data collection and analysis, and quantitative analysis. I supported the supervision of CBR workers delivering the pilot CBR intervention. I am a UK public health speciality registrar with a medical background, but I have no training in clinical psychiatry. The PRogramme for Improving Mental healthcarE (PRIME) project (PI Abebaw Fekadu) had overall responsibility for quantitative data collection for the pilot. However at midline and endline I revised the questionnaires, led on data collector training, produced the EpiData databases and oversaw data quality assurance procedures. Abebaw Fekadu, Charlotte Hanlon and Mary De Silva supported the pilot implementation through discussion and critical feedback on early findings. Rahel Birhane

(intervention coordinator, AAU) was responsible for the day to day running of the CBR intervention. Alehegn Habtamu (research assistant, AAU) conducted the qualitative interviews. Charlotte Hanlon supervised the qualitative analysis.

Across all components of the RISE project I was responsible for financial management, contracting, collaborator liaison, and the hiring and training of RISE project staff and CBR workers and supervisors. Data collectors were recruited and managed by the PRIME project. I am the principal investigator and trial manager of the RISE trial and I led on the preparation of all aspects of the trial protocol (Chapter 8) with the exception of the cost-effectiveness analysis section, which was prepared by Dan Chisholm (World Health Organisation (WHO)). Abebaw Fekadu, Mary De Silva, Charlotte Hanlon and Vikram Patel supported the design of the trial. Helen Weiss (LSHTM) gave support on the statistical analysis and randomisation sections.

1.3 ADDITIONAL STUDY OUTPUTS

In addition to the research presented in this thesis, I have achieved several other outputs from the RISE study.

1. First author on a paper prepared for publication "*I cry every day and night. I have my son tied in chains*": *Physical restraint of people with schizophrenia in community settings in Ethiopia*". To be submitted to *Globalization and Health*. This paper uses qualitative data from the interviews conducted for the RISE intervention development.
2. First author on a paper in preparation for publication '*Competence of non-specialists delivering community-based rehabilitation for people with schizophrenia in Ethiopia*'. To be submitted to *BMC Psychiatry*. This paper presents process and qualitative data collected as part of the RISE pilot, as well as the adaptation and piloting of the ENACT (Enhancing Assessment of Common Therapeutic Factors) scale [2], which I led on.
3. Co-author on a published paper '*Theory of Change: a theory-driven approach to enhance the Medical Research Council's framework for complex*

interventions'. Published in *Trials*, July 2014 [3]. This paper features the RISE theory of change.

4. Co-author on a published paper, '*Systematic review of the feasibility and acceptability of psychosocial interventions for schizophrenia in low and middle income countries*'. Published in *BMC Psychiatry*, April 2015 [4]. I produced the search strategy and conducted the database searches for this review.
5. Co-author on a published paper '*Beyond the biomedical: community resources for mental health care in rural Ethiopia*'. Published in *PLoS One*, December 2015 [5]. I contributed to the data analysis and led on the discussion, using knowledge gained during the RISE intervention development.
6. Last author on a paper in preparation for publication '*Involvement of people with schizophrenia in decision-making relating to their care in Ethiopia*'. This paper presents qualitative data collected as part of the RISE pilot.

1.4 INTRODUCTION TO ETHIOPIA

Ethiopia, which is officially named the Federal Democratic Republic of Ethiopia, is a landlocked country in the horn of Africa (see Figures 1.1 and 1.2). The capital city is Addis Ababa and the country is divided into nine ethnically-based and politically autonomous regional states. There is a total population of 97 million people and the official language is Amharic. 34.4% of the population belong to the Oromo ethnic group, whilst 27% are Amhara, 6.2% are Tigray and the remaining population belong to other ethnic groups [6]. According to the 2007 national census, 43.5% of the population are Ethiopian Orthodox Christian, 33.9% are Muslim, 18.5% are Protestant and 2.7% of the population follow a traditional belief system. Ethiopia is classified by the World Bank as a low-income economy, and had a Gross Domestic Product per capita of US\$ 619.1 in 2015 [7]. Ethiopia is one of the largest recipients of donor aid in Africa, receiving almost US\$ 3 billion in 2015, and has also received substantial investment from China [8]. Whilst the country has experienced strong economic growth in the past decade, much of the population continues to live in poverty. Approximately 81% of the Ethiopian population live in

rural areas, where only 7.6% of people have access to electricity [7]. Whilst unemployment rates are low (4.5% of the total labour workforce), there are very high rates of vulnerable employment (88.8%; defined as unpaid family workers and own-account workers) [7]. Of those employed, 72.7% are estimated to work in agriculture [7]. The ruling political party is the Ethiopian People's Revolutionary Democratic Front (EPRDF), which gained power in 1991. In the 2015 election the EPRDF won all 546 of the parliamentary seats. Opposition supporters and journalists are reportedly routinely jailed to silence dissent [8]. In 2015 and 2016 there have been numerous anti-government protests and severe droughts in Ethiopia [9, 10].



Figure 1.1 Location of Ethiopia

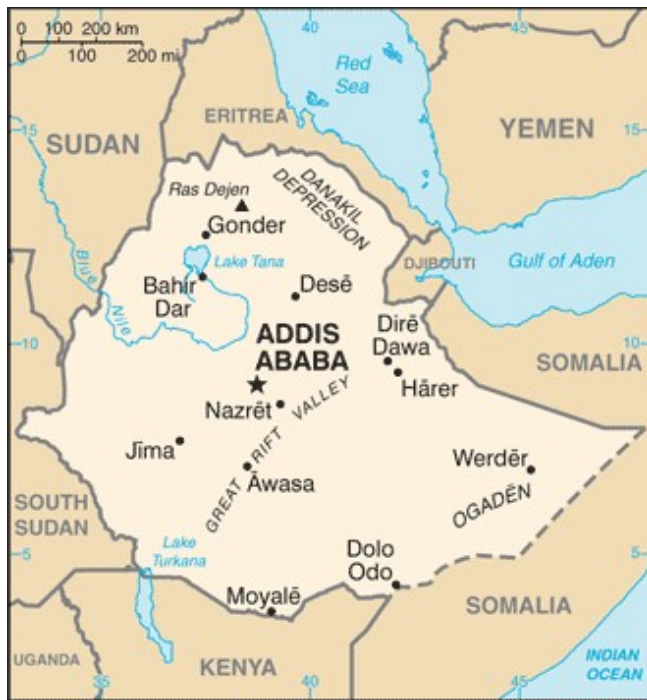


Figure 1.2 Map of Ethiopia

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2 BACKGROUND TO THESIS

SECTION A: BACKGROUND TO SCHIZOPHRENIA

2.1 CLINICAL FEATURES AND COURSE OF SCHIZOPHRENIA

2.1.1 Clinical features

Schizophrenia is a severe mental illness that is characterised by its heterogeneous presentation. In acute schizophrenia positive symptoms predominate, including those relating to reality distortion (hallucinations and delusions) and disorganisation of thoughts and behaviours. Many people with schizophrenia progress to the chronic syndrome, in which negative symptoms are prominent. Negative symptoms comprise lack of motivation, poor self-care and social withdrawal [1, 2]. Cognitive deficits are another feature of schizophrenia, including problems with learning, memory and attention [3]. Depressive symptoms such as low mood and anhedonia are also common. Negative, cognitive and depressive symptoms may all be present from the onset of the acute syndrome [1, 2].

It is widely accepted that the illness experience of schizophrenia, for example the content of delusions, differs by cultural context. There is on going debate as to whether the structure and symptom composition of schizophrenia, for example the prevalence or form of delusions, is unaffected by culture and ethnicity [4] or whether cross-cultural variations exist [5].

2.1.2 Diagnosis and classification

The diagnosis of schizophrenia is made on the basis of psychiatric assessment, structured using diagnostic criteria. The DSM-IV (Diagnostic and Statistical Manual for Mental Disorders, 4th Edition) criteria for schizophrenia were used for this research [2]. The DSM-IV describes a number of disorders that have substantial symptomatic overlap with schizophrenia, including schizoaffective disorder and schizophreniform disorder. This thesis describes the design, pilot and evaluation plans for an intervention for people with schizophrenia, schizoaffective disorder or

schizophreniform disorder. However, for clarity the term schizophrenia will be used to encompass these broader diagnoses throughout the thesis.

The validity of diagnostic criteria across cultures has been challenged [5-7]. Such criteria nevertheless represent a useful approach for categorising the experience of mental distress in order to allow comparison of research findings between settings.

2.1.3 Clinical recovery and course

Following the first psychotic episode, the course of schizophrenia tends to comprise of relapses of severe psychotic symptoms, with periods of partial remission in between. However, the course of schizophrenia is highly variable between individuals [8]. Determinants of outcome may include clinical, social and cultural factors, though the precise mechanisms are not well understood [9]. International cohort studies have demonstrated substantial heterogeneity in schizophrenia outcomes between countries [10, 11]. Traditionally, these differences have been described along the lines of ‘developed’ and ‘developing’ countries, with the latter supposedly associated with more favourable outcomes [11, 12]. The variations have been attributed to the supposed high levels of family and community support and tolerance for people with mental illness in LMIC [13]. Others have challenged these assertions, pointing to the high mortality rates in low-income settings, which could have caused differential attrition of severe cases [13-15]. Results from the Butajira Severe Mental Disorder Study in Ethiopia (the ‘Butajira cohort’) demonstrated that nearly 57% of participants experienced either an episodic course or continuous psychotic symptoms over a 10-year period, whilst only 11.8% of participants experienced a single psychotic episode followed by complete remission [16]. Unlike previous reports [10, 12], these findings indicated that outcomes in low-income settings might be comparable to, or even less favourable than, those in high-income countries. The Butajira cohort, set in the Butajira area of Southern Ethiopia, followed people with severe mental illness (schizophrenia, bipolar disorder and severe depression) from 1998 to 2013. In total 919 participants were included, 359 of whom had schizophrenia. 90% of participants were treatment naïve at recruitment to the cohort. The Butajira

cohort has given us a remarkably rich understanding of schizophrenia in the Ethiopian setting, as compared to any other low-income country, producing data on course and outcome, mortality, disability, stigma, violent victimization and caregiver burden [15-24]. These findings are relevant to this thesis as the Butajira area is adjacent to Sodo district, the setting for this research.

Different definitions of clinical recovery have been proposed, but typically relate to symptom remission and an achieved level of functioning [25-27], in some cases for a specified time period e.g. two years [25]. Several large-scale studies across high and middle-income countries have indicated that around 50% of people with schizophrenia will experience clinical recovery [10, 27].

2.1.4 Aetiology

The principal influence on the aetiology of schizophrenia is genetic; approximately 80% of the risk is inherited [28]. Several environmental and social factors have been identified, including birth complications, migration, urban living and paternal age, which interact with the genetic predisposition to produce a neuro-developmental disturbance. This disturbance is the origin of symptoms which may or may not later emerge [2]. Ethiopian explanatory models for schizophrenia will be considered in Section 2.8.

2.2 EPIDEMIOLOGY OF SCHIZOPHRENIA

2.2.1 Incidence

A 2004 systematic review found a median schizophrenia incidence rate of 15.2 (10%–90% quantile 7.7, 43.0) per 100,000 [29]. Rates were significantly higher in men compared to women, in urban areas compared to rural areas and in migrant compared to native populations [29]. With a few exceptions this review included only studies from high-income countries. A more recent review of incidence studies outside, geographically, of North America, Europe, and Australasia [30], found rates ranging from 11.0/ 100,000 in China to 58.5/ 100,000 in India. Yet of the 14 included studies, this review also did not identify any data from low-income

countries, and there was only one study from the African continent [30]. No convincing patterns between geographical areas were detected. There are currently no schizophrenia incidence estimates available from Ethiopia.

2.2.2 Prevalence

There is more information available on the prevalence of schizophrenia in LMIC. A 2005 systematic review included 188 studies conducted across 46 countries, including several low-income countries and five African nations [31]. Median lifetime prevalence was 4.0 per 1,000 persons (10%–90% quantiles 1.6, 12.1) [31]. No significant differences were found between men and women or between urban and rural sites, but the prevalence was higher in migrants compared to native-born individuals. The authors found that prevalence estimates from “least developed” countries were borderline significantly lower than those from “emerging” or “developed” sites ($p= 0.04$) [31]. However, lifetime prevalence estimates from the baseline of the Butajira cohort (which were not included in the review) are 4.7/1000 [20], slightly higher than the median estimates from the review.

2.2.3 Mortality

There is a recognized association between schizophrenia and premature mortality [32]. A 2007 systematic review of 37 articles from 25 nations found the median standardised mortality ratio (SMR) for persons with schizophrenia for all-cause mortality was 2.58 (10%-90% quantile 1.18, 5.76)[33]. At 10 years, data from the Butajira cohort showed that in rural Ethiopia the SMR in people with schizophrenia was higher at 3.03 (95% confidence interval (CI) 2.34, 3.86) compared to the general population [17]. Across all diagnoses the commonest cause of death was infectious disease (49.6%), followed by injury, including suicide (15.7%) and accidents (9.1%) [17]. Compared to a mean life expectancy of 55.7 years (95% CI 50.6, 60.8) in the general population, people with schizophrenia in Butajira have a life expectancy of 46.3 years (95% CI 41.9, 50.6) [17]. Increased mortality was predicted by a longer duration in a symptomatic state [17]. Higher mortality rates amongst people with mental illness are likely to be due to a range

of factors including poorer access to, and quality of ,healthcare [34], poverty and overburdened family support networks [17, 34] and a direct contribution of psychopathology [17]. In high-income settings where there is greater availability of atypical anti-psychotic medication, cardiovascular disease associated with metabolic syndrome (a known adverse effect of this group of drugs) is also implicated [33].

2.3 DISABILITY RELATING TO SCHIZOPHRENIA

2.3.1 Model of disability and application to schizophrenia

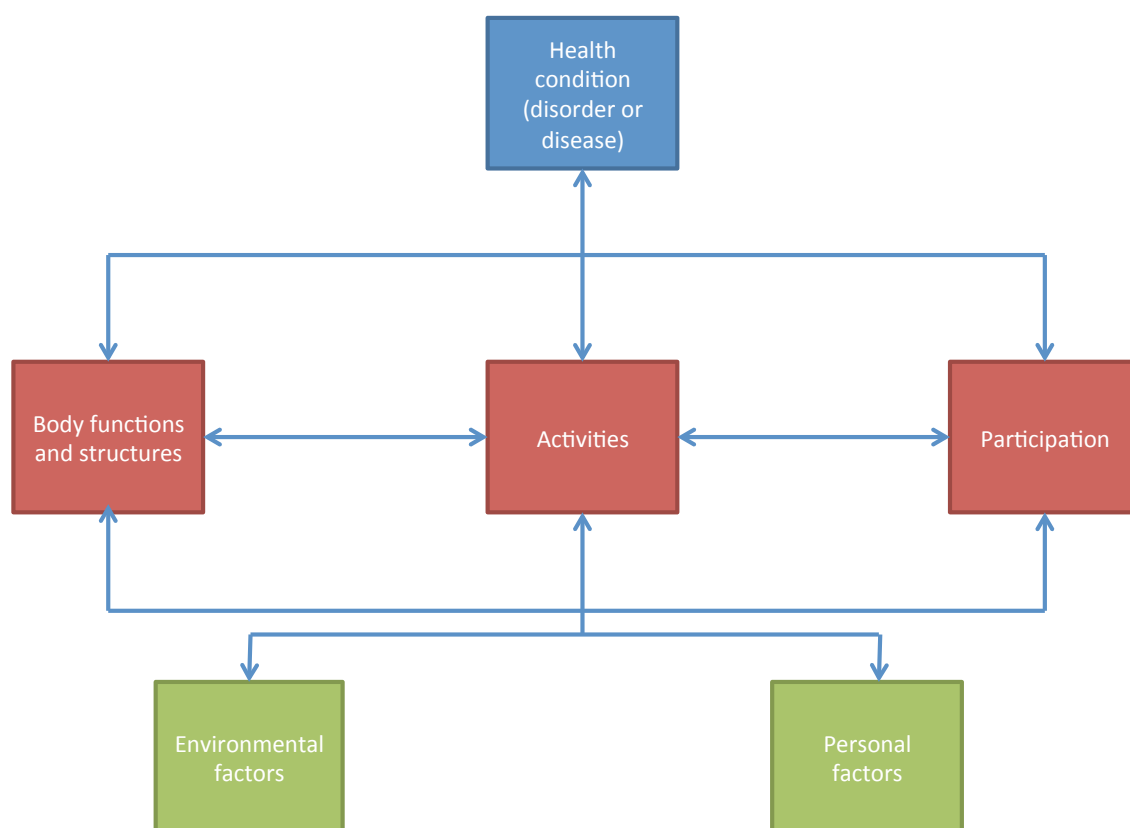
The conceptualisation of disability is multi-faceted, complex and evolving. The WHO has attempted to define and classify disability with the International Classification of Functioning, Disability and Health (ICF)[35]. A key principle of the ICF is parity between physical and mental health; hence the framework uses neutral language and does not differentiate between types and causes of disability on this basis [35]. The ICF describes three types of problems with human functioning: impairments (problems with body function and structure), activity limitations and participation restrictions. Disability signifies difficulties faced in any or all three areas of functioning. Table 2.1 gives examples of these three functioning problems for physical and mental illness.

Table 2.1 Functioning problems associated with physical and mental illness

Functioning problem	Physical illness	Mental illness
Impairment	Paralysis; blindness	Poor cognition e.g. problems with learning
Activity limitation	Problems with walking or eating	Poor self care
Participation restriction	Problems using public transport	Problems participating in community activities

Underpinning the ICF is the notion that disability arises from a combination of environmental and disease factors, echoing the principles of the United Nations (UN) Convention on the Rights of Persons with Disabilities [36]. Environmental factors, which may be either facilitators or barriers, include products and technology; the natural and built environment; support and relationships; attitudes; and services, systems, and policies [35]. The prominence of the environment in this model represents an important shift from the traditional medical model of disability, in which problems with functioning were understood solely in terms of bodily impairments [35]. Personal factors, such as age, gender and coping style, are also recognised as contributory. Figure 2.1 shows the generic conceptual model of the ICF.

Figure 2.1 ICF framework for disability

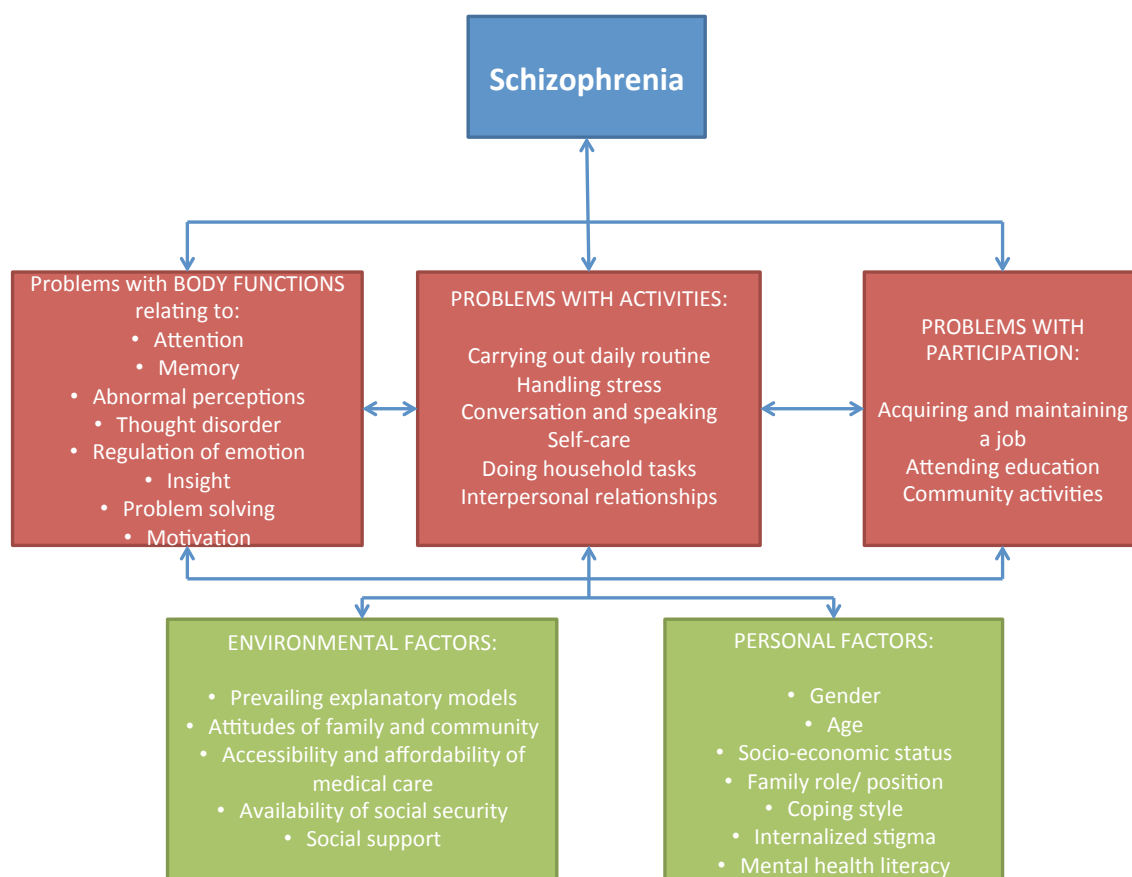


The ICF framework can be readily applied to understand the genesis of disability related to schizophrenia [37, 38]. This is demonstrated by a qualitative study in the Butajira district, which found that broader environmental factors were at least as important as clinical symptoms in shaping functioning in people with severe mental illness. These environmental factors included lack of support and low

expectations from family members; poverty; and stigma and discrimination [39]. Medication side effects and personal factors, such as a low self- expectation of capacity, were also influential [39]. Some groups have promoted the notion that psychotic symptoms, in particular hearing voices, can be a meaningful or even positive experience, rather than necessarily a disabling one [40]. However the Butajira qualitative study showed that in rural Ethiopia neither people with mental illness, nor the wider community, conceive of any functional benefit of psychotic illness [39].

Figure 2.2 gives an overview of the potential key factors contributing towards disability in people with schizophrenia, using the ICF framework. These factors could vary greatly between individuals and settings. Figure 2.2 was adapted from a diagram presented by Vroman et al [37] and modified to reflect the findings of the background literature review.

Figure 2.2 Model of disability relating to schizophrenia



2.3.2 Nature of disability relating to schizophrenia

People with schizophrenia may experience a wide range of problems with functioning, which can be classified according to the ICF definitions (see Figure 2.2). Problems with mental functions may include difficulties with cognition, such as attention and learning; hallucinations and disordered thought; difficulties expressing emotions; lack of motivation; and problems with sleep. Problems with activities may include difficulties managing a daily routine, handling stress, having a conversation, doing household tasks, self-care and problems with inter-personal relationships. Problems with participation may include difficulties in education, work, and recreation and leisure [37].

There are several studies from high-income countries demonstrating high levels of disability in people with schizophrenia [41, 42]. In a six-country cohort study of schizophrenia in Europe, 85% had some degree of disability; the prevalence remained high over several years of illness [42]. No clear relationship was found between disability levels and gender, age, onset or duration of untreated illness [42]. There are less data available on functioning in people with schizophrenia in LMICs [9]. Results from the Butajira cohort show 70.2% of participants had severe functional impairment, measured with the Global Assessment of Functioning scale [16]. Over four years of follow up and treatment there was a significant trend in functional improvement, although these changes were not as substantial as improvements in positive symptoms [19]. There was an inverse relationship between symptom scores and improvements in physical and social functioning and role limitations [19].

2.3.3 Disability, mental health and poverty

There is a general consensus that poverty and mental health are highly correlated in both high and low-income countries [43]. On the one hand people with disabilities, including those arising from mental illness, are prone to experiencing financial hardship (the 'social drift' hypothesis). This may be due to inability to work in the person with disability or their family (due to caring responsibilities) and/or increased healthcare expenditure [44-46]. In the Butajira cohort, 75% of caregivers reported financial difficulties and 53% had problems working as a

result of their relative's illness[47]. The qualitative study in Butajira found that for many people with severe mental illness, impaired functioning meant an inability to farm effectively. This in turn led to poverty, signifying that functioning problems had a powerful immediate impact on survival [39]. On the other hand people living in poverty have a greater risk of developing mental disorders [43], though this social causation pathway may apply more readily to common mental disorders compared to schizophrenia [48]. Sen's capabilities approach states that lack of development arises from social exclusion and disempowerment rather than simply lack of money [49]. These broader social factors are highly relevant to people with schizophrenia in low-income settings, and help to explain why this group experiences high levels of both poverty and disability.

2.3.4 Measurement of disability

In order to fully capture the experience of disability, it is important that measurement goes beyond simply considering impairment to assessing activities and participation [35]. The WHO Disability Assessment Schedule (WHODAS) 2.0 comprises questions about bodily, individual and societal functioning, and may be applied to both mental and physical disorders as diverse as schizophrenia and back pain [50]. The WHODAS is conceptually compatible with the ICF [51]. The 36-item version provides a profile of functioning across six activity domains (understanding and communicating, getting around, self-care, getting along with others, household and work activities, and participation in society) and a general disability score [51].

The strength of such generic methods of assessing disability is that they allow comparisons between conditions and settings. However, there are growing calls to advance our understanding of local concepts of functioning relating to mental illness, to take into account the cultural, social and economic context [13, 39, 52]. The qualitative study in Butajira found that the components of functioning most likely to be affected by severe mental illness corresponded to the WHODAS domains, as well as being broadly consistent with similar studies from other LMIC [39]. However the study found that within these broad categories there are specific tasks that may be less generalizable. For example, there was emphasis on particular types of farm work and a gendered patterning of functioning and

impairment. It follows that meaningful assessment of functioning may only be possible with instruments designed to tap into those aspects of functioning most important in that setting [52, 53].

One of the Grand Challenges for global mental health is to “Incorporate functional impairment and disability into assessment”[54]. There are several reasons why disability or functional status is of central importance in the assessment of the impact of schizophrenia and evaluations of interventions for this group.

1. Poor functioning is a core feature of schizophrenia, forming part of the diagnostic criteria [1, 2].
2. Absence of symptoms is not necessarily associated with functional recovery [55]. Though some studies have found clear correlations [50], functional impairments may not be entirely correlated with positive or negative symptoms [51, 56, 57]. It is therefore important to measure functioning separately.
3. Inability to work by the person with schizophrenia or their caregiver has important economic consequences. A stronger case for investment in mental health services may be made if high levels of disability in the population are demonstrated, and improvements in disability can be shown from an intervention [48].
4. People with schizophrenia may place greater value on improvements in social functioning compared to improvements in positive symptoms [58].

2.4 CONCEPTUALISATION OF RECOVERY

In recent decades there has been a shift in the concept of recovery relating to severe mental illnesses such as schizophrenia [27]. According to the traditional concept (often known as ‘clinical recovery’) recovery is an observable outcome, often dichotomous, which is usually determined by a clinician and whose criteria does not vary between individuals (See Section 2.1.3) [59].

More recently the concept of ‘personal recovery’ has emerged, driven by the mental health service user movement, but now prominent in mental health policy and practice in many high-income countries [59]. The key tenets of personal recovery are that it is a process and a continuum; that it is a subjective concept

which differs between individuals; and that it can only be determined by the person experiencing the mental health problem, rather than a clinician or other outsider [59]. According to one of the most influential descriptions, recovery is, “a deeply personal, unique process of changing one’s attitudes, values, feelings, goals, skills, and/or roles. It is a way of living a satisfying, hopeful, and contributing life even with limitations caused by illness. Recovery involves the development of new meaning and purpose in one’s life as one grows beyond the catastrophic effects of mental illness” [60]. A more recent conceptual framework describes five key recovery processes: connectedness; hope and optimism about the future; identity; meaning in life; and empowerment [61]. There are currently few data on rates of personal recovery [27, 59].

Little is known about the cross-cultural applicability of the recovery concept, or whether it can be meaningfully transferred to LMIC settings with limited resources to provide even basic mental health care (see Section 2.9.1) [62, 63]. The potential inability of the recovery approach to adequately address macro-level factors that may affect wellbeing (including poverty, stigma and discrimination) has also been highlighted [64]. Concepts of recovery may be influenced by ethnicity, with black and minority ethnic groups in high-income settings [61] and people with mental illness in Asia [65] and Africa [66] placing particular emphasis on the role of spirituality. Collective notions of recovery may also be an important influence [62].

2.5 DISEASE BURDEN AND GLOBAL HEALTH IMPORTANCE OF SCHIZOPHRENIA

2.5.1 Disease burden

The 2010 Global Burden of Disease study estimated that mental and substance use disorders contributed to 183.9 million disability-adjusted life years (DALYs) (95% CI 153.5 million, 216.7 million) worldwide, which equates to 7.4% (6.2, 8.6) of total disease burden [67]. Mental and substance use disorders were the fifth leading disorder category of global DALYs [67]. The burden relating to mental and substance use disorders had risen from 5.4% (4.5, 6.2) in 1990, a change largely driven by population growth and ageing [67, 68]. As proportions of all mental and substance use disorders, schizophrenia contributed 7.4% (4.9, 9.9) to the total years lived with disability, 7.1% (4.8, 10.2) to years of life lost and 7.4% (5.0, 9.9)

to DALYs [67]. The burden associated with schizophrenia peaked between 25 to 50 years of age [67].

2.5.2 Global health importance

Using disease burden instead of mortality in setting public health priorities has been central to the increased recognition of mental disorders on the global health agenda [67]. Researchers have also successfully drawn attention to the substantial global economic burden of mental illness [69, 70]. There is now a global movement striving to improve the lives of people with mental illness, primarily through improving access to treatment. This was spearheaded by two Lancet series on global mental health [71, 72], as well as a global initiative to identify Grand Challenges in mental health [54]. There has been increased funding for global mental health research and considerable international commitment has been shown with adoption of the WHO's Comprehensive Mental Health Action Plan 2013–2020. In another important step forward there is specific inclusion of mental health in the Sustainable Development Goals, which was absent from the Millennium Development Goals [73, 74]. A parallel development is the increasing inclusion of mental health into the non-communicable disease agenda [75].

Yet severe mental illness has arguably not benefitted to the same extent as common mental disorders, let alone physical health conditions, in terms of increased attention and investment [76]. This may be partly due to the limitations of using the Global Burden of Disease estimates in isolation to understand the burden of schizophrenia [68]. First, these metrics do not include excess mortality associated with schizophrenia, as only deaths directly attributable to the mental disorder are included (for example, suicide is classified as injury). Second, severe mental illnesses such as schizophrenia have lower prevalence than common mental disorders; this means that high levels of disability in individuals do not translate to a high place in the burden rankings of mental disorders. Third, the significant social and economic effects of schizophrenia, in particular the loss of economic productivity amongst both those affected and their caregivers, are not reflected in these estimates. Finally, human rights violations are not taken into account [68].

The need to increase the priority of severe mental illness such as schizophrenia has been strongly argued [76], alongside a general call to look beyond economic concerns in priority setting for mental health [77]. The young age of onset, chronic course, high levels of disability and mortality, psychological distress, family burden, social exclusion, loss of productivity and human rights violations associated with schizophrenia renders it capable of exerting a catastrophic impact on individuals and their families in low-income settings. The next section describes the potential interventions and models of care that may address the needs of people with schizophrenia in LMICs.

SECTION B: INTERVENTIONS AND MODELS OF CARE FOR SCHIZOPHRENIA

2.6 INTERVENTIONS FOR THE TREATMENT OF SCHIZOPHRENIA

2.6.1 Overview of effective interventions

There is some evidence that accessing treatment for schizophrenia does improve functional outcomes. For example a cohort study in India comparing the course of treated and untreated schizophrenia demonstrated that those not receiving treatment with antipsychotic medication are likely to have enduring disability over time [78]. However, it has also been demonstrated that outcomes, including functioning, have not improved substantially over the last 100 years despite developments in anti-psychotic medication and psychosocial interventions [79]. This suggests that the relationship between treatment and functioning is far from straightforward.

The third edition of the Disease Control Priorities (DCP-3), published by the World Bank, includes recommendations for the most effective and cost-effective interventions for schizophrenia in LMICs [68]. The DCP-3, along with the WHO's mental health Gap Action Programme (mhGAP) guidelines [80], recommends a combination of anti-psychotic medication and psychosocial interventions for the treatment of schizophrenia [68, 76]. Anti-psychotic medication has been shown to be cost-effective in treating schizophrenia [68], as well as effective at preventing relapse [81]. Drug treatments generally have most effect on positive symptoms, with typically little effect on negative symptoms [82]. With the exception of clozapine, there is little to distinguish different anti-psychotic medications (including typical and atypical antipsychotics) in terms of effectiveness. However the more burdensome side effect profile of typical anti-psychotic medication is a significant disadvantage of this group of drugs [76, 83, 84].

There are several rationales for the routine use of psychosocial interventions, a position first formally endorsed by the WHO with its 1996 Psychosocial Rehabilitation Consensus Statement [85]. First, the chronic and disabling course of schizophrenia, and the relative inefficacy of anti-psychotic medication in improving functioning [82], mean a broader supportive approach focused on rehabilitation is also required. Second, psychosocial interventions typically align

with the principles of personal recovery, for example supported employment and social skills training help individuals to achieve their personal goals [27]. Third psychosocial interventions are more likely to address problems with functioning, which may be a greater priority for people with mental illness compared to addressing positive symptoms [53].

The Schizophrenia Patient Outcomes Research Team (PORT) evidence-based recommendations, developed in the United States, include eight psychosocial interventions, all of which are recommended as an adjunct to pharmacotherapy: assertive community treatment, supported employment, cognitive behavioural therapy, family-based services, token economy, skills training, and psychosocial interventions for alcohol, substance use disorders and weight management [86]. Table 2.2 contains a summary of the evidence for each of these interventions. PORT excluded recommendations, on the basis of lack of evidence of effectiveness, for cognitive retraining/ remediation, adherence therapy and self-help or peer support groups [86].

Table 2.2 Overview of evidence for psychosocial interventions for schizophrenia (continued overleaf)

Psychosocial intervention	Systematic reviews across all settings*			Individual studies from low and middle-income countries**	
	Evidence source	Evidence of effectiveness	Quality	Evidence source	Evidence of effectiveness***
Recommended by PORT					
Assertive community treatment	2010 Cochrane review of intensive case management (38 studies- 0 LMIC) [87]	Effective at reducing hospitalisation, increasing social functioning, increasing retention in care	Moderate quality	8 studies (China [88, 89], Iran [90, 91], Malaysia [92], South Africa [93-95], Turkey [96])	May be effective at reducing admissions & relapse rates, and improving functioning.
	2015 Cochrane review of crisis intervention (8 studies- 0 LMIC [97]	Effective at reducing hospital admissions	Low – moderate quality	None identified	n/a
Supported employment	2013 Cochrane review of supported employment (14 studies – 0 LMIC) [98]	Effective at improving vocational outcomes	Low quality	1 study (Brazil) [99]	May be effective at improving cognitive function, negative symptoms and quality of life
Cognitive behavioural therapy	2012 Cochrane review of cognitive behaviour therapy (20 studies- 0 LMIC) [100]	No advantage over other therapies	Low – moderate quality	4 studies (Brazil [101, 102], China [103], Pakistan [104])	May be effective at improving psychopathology, functioning and quality of life.
Family-based services	2010 Cochrane review of family intervention (53 studies- 28 LMIC) [105] 2014 Cochrane review of brief family intervention (4 studies- 1 LMIC) [106]	May be effective at reducing relapse rates and hospitalisations No evidence for effectiveness	Low quality	Family intervention: 14 studies (China [107-114], Mexico [115], Malaysia [116], Iran [117-119], India[120], Uganda [121])	May be effective at reducing caregiver burden, improving functioning, improving treatment adherence.
	2011 Cochrane review of psychoeducation (44 studies – 33 LMIC) [122]. 2015 Cochrane review of brief psychoeducation (20 studies- 12 LMIC) [123]	Effective at reducing readmissions and relapse rates & improving adherence	Low quality	Psychosocial skills (social skills training, psychoeducation): 10 studies (Turkey [124, 125], China [126-130], Mexico [131-133])	May be effective at reducing relapse, improving functioning, and improving quality of life and adherence

Table 2.2 continued					
Psychosocial intervention	Systematic reviews across all settings*			Individual studies from LMIC**	
	Evidence source	Evidence of effectiveness	Quality	Evidence source	Evidence of effectiveness***
Recommended by PORT					
Token economy	2000 Cochrane review of token economy (3 studies- 1 LMIC) [134]	May be effective at reducing negative symptoms	Low quality	None identified	n/a
Skills training	2012 Cochrane review of life skills programme (7 studies-3 LMIC) [135]	No evidence for effectiveness	Very low quality	5 studies (China [136-139], India [140])	May be effective at improving social functioning and psychopathology
	2015 Cochrane review of social skills programme (13 studies- 5 LMIC) [141]	May be effective at improving social skills & reducing relapse rates	Very low quality		
Psychosocial interventions for alcohol and substance use	2013 Cochrane review (32 studies- 0 LMIC) [142]	No evidence	Low quality	None identified	n/a
Psychosocial interventions for weight management	2007 Cochrane review (5 non-pharmacological interventions- 0 LMIC) [143]	Effective at weight loss outcomes	Low quality	None identified	n/a
Other psychosocial interventions					
Peer support/ self-help groups	2014 systematic review of peer support (18 studies- 0 LMIC) [144]	No evidence of effectiveness	Low quality	None identified	n/a
Adherence support	2006 Cochrane review of compliance therapy (1 study- 0 LMIC)[145]	No evidence of effectiveness	Low quality	4 studies (Thailand [146], Indonesia [147], Turkey[148], Pakistan [149])	May be effective at improving medication adherence
Cognitive remediation/ retraining	2000 Cochrane review of cognitive rehabilitation (3 studies-0 LMIC)[150] 2011 systematic review of cognitive remediation (40 studies-0 LMIC) [151]	No evidence of effectiveness Effective at improving functioning & cognition	Low-Moderate quality	5 studies (Egypt [152], India [153], Brazil [154], Turkey [155], China [156])	May be effective at improving social cognition

*Systematic reviews typically have broad inclusion criteria with respect to setting (inpatient/ outpatient) **Studies listed in the table include only outpatient or community-based interventions & controlled studies & English full text available. ***No formal quality assessment was undertaken.

The strongest evidence is for intensive case management (which has evolved from assertive community treatment), family interventions and psychoeducation, with possible impacts on functioning, hospitalisations and relapse rates. However, the quality of evidence is generally low across all types of psychosocial interventions. It has also been noted that few of the recommended interventions have been implemented at scale, even in high-income countries [76]. There is generally a smaller evidence base from LMIC for these psychosocial interventions, though this is growing with several studies published in the last five years [103, 104, 117, 157]. However, much of the evidence comes from China with very low numbers of studies from sub-saharan Africa [93, 121, 158].

The DCP-3 recommends a narrower group of psychosocial interventions, for which there is evidence of effectiveness, but not cost-effectiveness, and which it is generally accepted are more feasible in low-income settings [159, 160]: Family therapy or support; CBR; and self-help and support groups [68]. There is a growing body of evidence to support these more pragmatic interventions [86]. These programmes often use a community-based approach and in some cases an explicit ‘mental health and development’ model [161]. CBR is an approach growing in prominence, that also receives a specific recommendation in the WHO’s mhGAP guidelines [80]. CBR can also be considered as a model of care, rather than a stand-alone intervention. Section 2.7 discusses CBR and related approaches in greater depth.

2.6.2 Delivery of interventions for schizophrenia

2.6.2.1 Task shifting

The task shifting of mental health care to non-specialist workers is advocated as a central approach for addressing the shortage of mental health specialists, and ultimately the treatment gap, present in Ethiopia and other LMICs [162] (see Section 2.9.2). The importance of maintaining quality of care in task shifting interventions has been highlighted, and is an area currently lacking in evidence [163]. Adequate supervision is likely to be essential, but potentially costly, to ensure high standards of care are kept [157]. A 2013 systematic review found that interventions using non-specialist workers might improve outcomes in people

with general and perinatal depression, post-traumatic stress disorder, alcohol-use disorders, and dementia in LMICs. However, much of the evidence was of low quality and the review was unable to make conclusions about task-shifting interventions for schizophrenia due to a lack of studies [162]. It has been shown that task-shifting interventions for people with mental illness have the potential to be acceptable and feasible but several issues need to be carefully considered in the development of such programmes [164]. These issues include possible distress amongst non-specialist workers; their self-perceived competence levels and potential pressure to work beyond their level of training [165]; what, if any, incentives should be provided to workers; and potential difficulties with the acceptance of non-specialist workers by health care professionals [164].

2.6.2.2 Models of community-based care

The balanced care model proposes that mental health systems should include both community and hospital-based care [166]. Community mental health care refers to care which is readily accessible to people living in the community rather than as a hospital inpatient. One of five priority Grand Challenges for global mental health is to “Provide effective and affordable community-based care and rehabilitation”, giving recognition to the substantial impact on disease-burden reduction and equity this approach is likely to have, as well as the likely immediacy of impact, and feasibility [54]. It is recommended that in low-resource settings community-based care should focus on the detection and treatment of mental illness in primary care, to include both pharmacological and psychosocial interventions. The role of specialist mental health staff is expected to be limited to the training of primary care staff, and treatment of complex cases in outpatient or inpatient settings [166]. The WHO’S mhGAP guides the integration of mental health into primary care [80], a process which is now underway in several LMICs [167-169]. In medium resource settings, the role of specialist mental health staff is recommended to extend to the provision of community mental health teams [166]. Community mental health teams typically visit service users in their place of residence, a factor seen as vital for the continuity of care of people with severe mental illness, particularly amongst those who are not able or willing to visit outpatient facilities [166].

A range of home-based care models for people with schizophrenia, using different combinations of human resources, have been implemented in LMIC in both

research projects and on-going programmes. These range from community-based care delivery by lay health workers, supervised by psychiatrists, in a controlled study and randomised controlled trial (RCT) in India (COmmunity-based intervention for People with Schizophrenia in India (COPSI)) [170, 171]; to clinical psychiatry officers delivering community mental healthcare in Ghana as part of a government programme [165, 172]; to assertive community treatment delivered by a multi-disciplinary team in a South African RCT [93, 94]. Within these home-based care models various interventions (as described in Section 2.6.1) may be delivered. The affordability and feasibility of these models inevitably decreases with increasing levels of specialist support. For example assertive community treatment is unlikely to be feasible in low-income settings like Ethiopia.

The distinction between research projects and ongoing programmes should be noted, with the former by their nature having limited timelines and a lack of integration into national policy (though they may pave the way for such initiatives). Coverage of community mental health programmes is often very low in LMICs [173], though there are some exceptions. China's nationwide '686' programme, which includes active community case finding, community-based care (including multi-disciplinary team input) and hospital care, had achieved 30% coverage of the whole population by 2011. Over a five year period the proportion of patients with severe mental illnesses without relapse for five years or longer had reportedly increased from 67% to 91% [174]. Many programmes are wholly or partly funded and run by non-governmental organisations (NGOs). Whilst NGOs often enable the development of innovative programmes targeting neglected groups, there are several disadvantages including lack of sustainability and low coverage [173, 175]. Thara et al followed up people with schizophrenia six years after the NGO-run community clinic they had attended had closed due to lack of funding. They found that only 15% of former clinic attendees were still accessing medication and associated endeavours initiated by the NGO, including a Citizen's group and self-employment schemes, had all been discontinued within six months to three years of the NGO withdrawing [176].

2.6.2.3 Innovations in community-based care for schizophrenia

There are several innovations in the delivery of community-based care for schizophrenia and other mental disorders in LMICs, many of which are at the early stages of implementation and evaluation. These include the following:

- Projects aiming to formalise collaborations between health care providers and traditional or religious healers in sub-Saharan Africa [177-179].
- Initiatives using mobile and information technologies to facilitate mental healthcare delivery and collaboration [178-181].
- Mobile clinics of mental health specialists visiting remote areas [182].
- Peer support groups in Ghana [183] and peer support workers delivering home-based care in Chile and Uganda [184-186].
- Initiatives focused on removing physical restraints from people with mental illness at home or hospital (see Section 2.10.2), for example the Chain Free Initiative in Somalia [187], targeted programmes in Indonesia [188], and the ‘unlocking and treatment’ intervention part of the ‘686’ programme in China [189].
- Social contact interventions in which the general public, or targeted groups such as students, are facilitated to have direct or indirect contact with people with mental illness. There is evidence these are the most effective intervention for short-term change in attitudes. However there are very few studies from LMIC and little evidence for the impact on behaviours or outcomes for people with mental illness [190].

2.6.2.4 Promotion of personal recovery

In high-income countries, efforts are now being made to ensure that mental health services incorporate the recovery model, both in terms of what treatments are given, and how they are given [27]. Several empirically –validated interventions have been promoted as supporting recovery principles, including peer support workers, advance directives, supported housing, and mental health dialogues (community meetings to discuss mental health issues) [62]. Core approaches proposed to foster the recovery model within mental health services include developing a shared team understanding of recovery, working in partnership with service users and raising patient expectations [191]. There has been little investigation to date as to how recovery principles can be incorporated into mental

health services in low-income settings.

2.6.3 Cost-effectiveness

The need to ensure the costs of interventions are met by financial protection measures, such as health insurance schemes, rather than borne by the individuals with mental illness and their families, has been repeatedly raised [68]. In a modelled cost-effectiveness analysis, a range of treatment options for schizophrenia were compared for Ethiopia, assuming 75% coverage [163]. Incremental cost-effectiveness ratios (ICERs) were calculated in comparison to the null scenario, which was perceived to be close to the current situation due to low coverage of most mental health interventions (see Section 2.9.2). In this study treatment with anti-psychotic medication alone (either typical or atypical) was not found to be cost-effective. The following two combinations were cost-effective: atypical antipsychotics and psychosocial treatment; and case management, atypical antipsychotics and psychosocial treatment. The annual cost of the former combination, the most cost-effective for schizophrenia, would be US\$ 18.8 million, for which 10,650 DALYS would be averted annually (with an ICER of \$1769/DALY averted) [163]. Seen in the context of other neuropsychiatric disorders scaling up services for schizophrenia may not represent the best value for money [68, 163]. For example, the Ethiopia analysis found that treatment of epilepsy with older anti-epileptic medication would cost US\$ 321/ DALY averted, and treatment of depression with newer antidepressants, psychotherapy, and maintenance treatment would cost US\$ 457/ DALY averted [163]. However, the need to incorporate other factors into priority setting in scaling up services has been highlighted [77, 163] (see Section 2.5.2).

There exist only a small handful of cost-effectiveness analyses alongside evaluations for mental illness in LMICs [157, 192]. The COPSI trial found an ICER of 2514 Indian Rupees (US\$ 37); representing the additional expenditure needed to achieve a 1-point reduction on the Positive and Negative Syndrome Scale. Community-based care cost on average 9500 rupees (US\$143) per participant more than provision of only facility-based care, with the greatest cost burden relating to supervision of lay health workers [157].

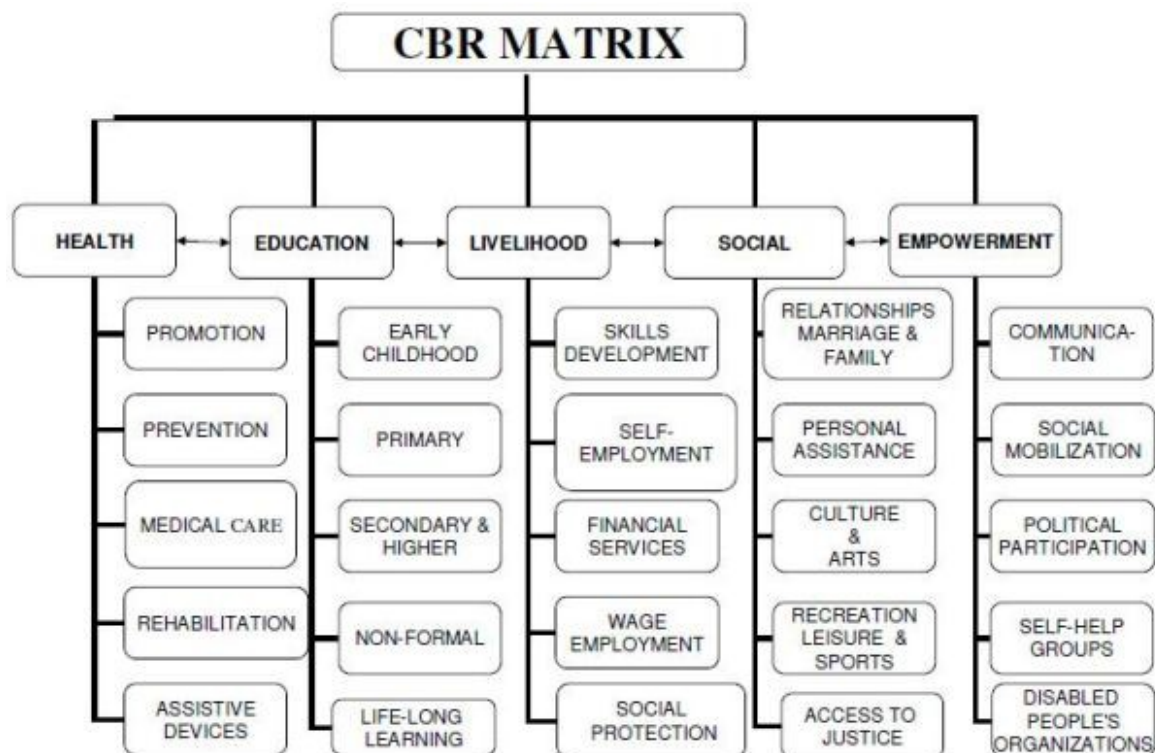
2.7 COMMUNITY-BASED REHABILITATION

2.7.1 Background to CBR

CBR is the approach advocated by the WHO for the poverty reduction, rehabilitation and social inclusion of people with disabilities in LMIC [193]. The WHO has promoted CBR since the 1978 Alma-Ata Declaration, since which time hundreds of programmes globally have employed this multi-sectoral strategy [194]. CBR projects support people with a broad range of disabilities including those associated with long-term musculoskeletal and neurological conditions such as cerebral palsy, epilepsy and arthritis; visual and hearing impairments; and intellectual impairments, for example developmental disorders [193]. The rationale for CBR is to address the widespread exclusion of people with disabilities from education, health, employment and other aspects of society. The principles of CBR are therefore closely aligned with the UN Convention on the Rights of Persons with Disabilities [36] .

The WHO's 2010 CBR guidelines present a CBR matrix consisting of five pillars: health, education, livelihood, social and empowerment (see Figure 2.3) [194]. There is an emphasis on facilitating access to appropriate governmental and non-governmental services from health, educational, vocational, and social sectors [195]. However CBR programmes are diverse and may address any or all of the five pillars depending on the local context, needs and resources. Activities may range from the provision of assistive devices to the organisation of a Rotating Savings and Credit Association (ROSCA). A ROSCA involves people with disabilities regularly paying small amounts into a common "pot", from which a lump sum is given as a loan or grant to one member at a time [194]. According to the WHO guidelines, the community should play a key role in any CBR programme, along with people with disabilities and their families. Community mobilisation may involve finding out about the community, raising awareness about disability issues, encouraging community members to support CBR activities (for example, by reducing barriers to social participation) and potentially the community-led implementation of CBR programmes. Community mobilisation is seen as the lynch- pin of creating sustainable CBR programmes [194].

Figure 2.3 WHO CBR matrix (from WHO CBR guidelines)



The personnel involved in CBR delivery vary considerably depending on the project and may include paid non-specialists, trained volunteers, family members, physiotherapists, occupational therapists, community nurses, and teachers [194, 195]. In some cases, non-specialist CBR personnel take on a task-shifting role, for example involvement in HIV treatment, care and prevention [196]. Many local CBR projects operate under the umbrella of larger organisations, such as the international disability charity CBM (www.cbm.org). Whilst many CBR programmes are run by NGOs, others are delivered in collaboration with local government or national government departments such as Ministries of Health or Education [194].

Whilst there is a growing pool of published literature on CBR [197], most studies are descriptive or only cover CBR theory with fewer studies evaluating its effectiveness [198]. A systematic review conducted in 2012 by Iemmi et al identified 15 controlled studies of CBR for a range of physical and mental disabilities. A beneficial effect of CBR was found for stroke, chronic obstructive pulmonary disease and arthritis. Iemmi et al reported that overall CBR had a

modest positive impact on people with mental disabilities including dementia, schizophrenia and intellectual impairment. However they highlighted the poor quality and non-randomised design of many of the included studies [193]. There are diverging views on what constitutes a CBR programme, with some CBR-like programmes more readily classified as community-based care and having limited community mobilisation [193]. A broad definition of CBR was employed for the Iemmi et al review, which resulted in the inclusion of a wide range of intervention types, from puppet shows for arthritis to assertive community treatment for schizophrenia. Several studies did not incorporate a substantial community mobilisation element.

2.7.2 Mental health and CBR

There are several reasons why CBR is a fitting approach to support people with severe mental illness in LMICs.

1. People with schizophrenia experience high levels of disability (see Section 2.3.2).
2. CBR targets the key environmental factors (access to health services, stigma) and personal factors (poverty, coping styles, health literacy) which create these high levels of disability (see Section 2.3.1), in particular through utilising a development approach and operating within an explicit human rights framework.
3. Family members are heavily implicated in the lives of people with schizophrenia in these settings, both in terms of experiencing the negative impacts such as stigma and economic insecurity, but also through taking on a prominent caregiving role (see Section 2.9.4). CBR explicitly engages family members.
4. CBR aligns with the personal recovery model, as there is a focus on empowerment and participation (see Section 2.4).
5. CBR is a means of providing on-going community-based care yet requires low levels of technical expertise so may be implemented by non-specialist workers (see Section 2.6.2). This is of utmost value in settings with few formal health resources such as Ethiopia (see Section 2.9.2).

6. CBR could represent one component of what is likely to be the most cost-effective model of care for Ethiopia, comprising anti-psychotic drugs and a psychosocial intervention (see Section 2.6.3).
7. CBR aims to be a sustainable approach to improving functioning in people with disabilities, particularly through the emphasis on community mobilisation.
8. There is an existing global network of CBR projects that can act as important resource to learn from in the development of mental health in CBR. This network also represents an important route for scaling up new developments in CBR for mental health.
9. CBR aims to utilise local knowledge and resources, including traditional healers where appropriate. Tapping into existing expertise and capabilities may reduce the possibility of cultural imperialism, which some have argued threatens global mental health initiatives [199, 200].

In recent years there has been an expansion of CBR projects supporting people with mental illness [201], reflected in the inclusion of a mental health supplement to the WHO CBR guidelines [194]. Globally, there are estimated to be 20 to 25 CBM-partnered CBR programmes that support people with mental illness (including but not limited to schizophrenia); around half of these are found in sub-Saharan Africa. Across these projects there is likely to be substantial variation in coverage and the nature of support provided; little evaluation has been conducted to date but this is planned (personal communication, Julian Eaton).

There may be several differences in CBR for people with mental disabilities compared to physical disabilities: differences in specific treatments (supporting access to anti-psychotic medication and providing psychosocial support compared to physiotherapy and orthopaedic devices); different potential trajectories of recovery; a greater emphasis on adults compared to children, with physical disability more likely to be detected at a younger age; and possible greater tendency towards different explanatory models for mental illness (see Section 2.8) [202]. Other challenges of incorporating mental health into CBR programmes have been identified, including the potential greater stigma within CBR workers

towards people with mental illness and concomitant unwillingness to work with this group [202].

To date, two non-randomised longitudinal evaluations by Chatterjee et al in India may represent the most comprehensive attempts to implement CBR for schizophrenia in a research or programmatic setting, in that there is a clear community mobilisation element to both [170, 171]. In the first study, 127 people with schizophrenia receiving CBR were compared to 80 participants receiving standard outpatient care. In addition to outpatient care, the CBR group received home-based support from lay health workers, focused on social and vocational rehabilitation. Family groups and local village health groups were also set up to facilitate social inclusion and enhance rehabilitation strategies. Among the 117 participants fully adherent to anti-psychotic medication, the CBR model was more effective in reducing disability compared to the outpatient care group [170]. In a subsequent cohort study of 256 people with psychotic disorders, participants received psychoeducation, adherence management support and rehabilitation focused on resuming work and social activities. Awareness-raising activities, focusing on reducing stigma and increasing social inclusion, were conducted in villages and at community gatherings. Self-help groups, comprising service users and community members, aimed to provide livelihood support through microfinance facilities and social reintegration [171]. Over a median follow up of 46 months, cohort participants showed significant reductions in disability ($p < 0.05$) [171]. Whilst these studies provide a useful blueprint of CBR for schizophrenia as well as valuable information on feasibility and acceptability, they provide only an initial indication of the possible effectiveness of such interventions.

The COPSI RCT in India used a similar model to these earlier studies for the home-based care element but incorporated minimal community mobilisation and no microfinance [157, 203]. The effectiveness of this trial is presented as part of a systematic literature review of community-based psychosocial interventions for schizophrenia in LMIC (Chapter 4).

2.7.3 Other models related to CBR

The 'mental health and development model', largely employed by the organisation BasicNeeds, shares a similar philosophy with CBR, focusing on community development and service user empowerment. However this model also encompasses health system strengthening and influencing policy [161].

BasicNeeds programmes, typically include medication provision, follow up, self-help groups, grants, occupational training and counselling [204]. A network of BasicNeeds self-help groups in Ghana have a prominent microfinance component, offering loans to mental health service users and their caregivers that are used for small enterprises. Whilst this system is reportedly beneficial for some participants, others have had difficulty repaying their loans [183]. Mental health advocacy groups may also have an important role in improving mental health policy and services [205], though such groups are currently absent from many LMICs. Stand alone mental health awareness-raising programmes have been conducted in some LMICs; one programme in Nigeria may have increased the use of community-based mental health services [206].

The relevance of CBR for people with schizophrenia, and the shape such programmes should take, is to a great extent influenced by the context. The next section explores services for mental health, explanatory models, human rights issues and stigma in the Ethiopian setting.

SECTION C: UNDERSTANDING THE ETHIOPIAN CONTEXT

2.8 EXPLANATORY MODELS

Explanatory models may exert a powerful influence on the experience of psychotic symptoms, and treatment seeking behaviour and expectations [207]. The integration of appropriate explanatory models into culturally adapted therapies may be the most important determinant of therapy effectiveness [208]. In Ethiopia, health is traditionally understood as, a “state of equilibrium among the physiological, spiritual, cosmological, ecological and social forces associated with a person” [209]. Whilst this holistic framework bears some resemblance to the biopsychosocial model, increasingly favoured to explain health and disease states in the West [210], the prominence of spiritual explanations gives a distinctive flavour to Ethiopian concepts of health. Descriptions of explanatory models for mental illness in Ethiopia have traditionally focused on supernatural explanations [211-214]. These have typically been grouped into the following: (1) Possession by evil spirits including Satan or other demons. Various behaviours are believed to leave one vulnerable to possession including falling asleep in a meadow and walking alongside a river at noon; (2) Punishment by normally benevolent guardian spirits (e.g. *Zar*) for sins (or even contemplation of sinful behaviour), broken taboos, or forgotten rituals (for example, entering a long-closed room without blessing oneself) and (3) Bewitchment or curses, such as evil eye, cast by individuals thought to possess special powers, including *Kalicha* (Muslim spirit medium) or *Debtera* (Christian cleric diviner). These persons are believed to have the capacity to make a person mentally ill, or to protect one from illness [211, 212, 215-217]. Supernatural explanatory models seem to be shared across Christian, Muslim and animistic faiths in Ethiopia [215, 216].

More recently, accounts of Ethiopian explanatory models have expanded to include a broader more pluralistic set of beliefs encompassing both supernatural and psychosocial causes; along with recognition that these apparently conflicting beliefs often exist within the same community and even the same individual [215, 216]. The capacity to hold several beliefs at once, which may be contradictory, has been described as ‘cognitive tolerance’ [218] and is a phenomenon observed in both LMIC and high-income settings [215]. In a community-based survey in

Southern Ethiopia, stress (53.9%), poverty (53.4%) and rumination (42.1%) were more frequently endorsed as causes of mental illness than supernatural explanations including God's punishment (21%), evil spirits (19.9%) and sinful acts (18.7%) [219]. Other commonly cited explanations include substance abuse (alcohol and khat), childbirth, grief and infections such as malaria [215, 216]. This shift may represent the changing beliefs of a rapidly developing society. In one community-based survey in North-Western Ethiopia, younger and better educated people were less likely to endorse supernatural explanations compared to their older less educated counterparts [215]. But this change may also be due in part to moving on from a reliance on small-scale ethnographic investigations [211, 212, 214, 217] towards representative community-based quantitative surveys [215, 219].

Alongside aetiological classifications, a system of phenomenological classification has traditionally existed in Ethiopia [213]. Qualitative work has shown that in Christian, Muslim and animistic populations there is a notion of mental illness that is conceptually equivalent to psychosis. This illness is usually described in terms of overt behavioural features, for example, talkativeness, aggression, or disrobing, rather than thought disorders [220, 221], a pattern also typical in other African countries [222]. This suggests that only those whose behaviour draws outside attention are recognised as having a mental illness in need of treatment [220]. It has been noted that whilst phenomenological models may be in use by a traditional healer, an aetiological classification (for example, spirit possession) is almost always provided for the patient, as a way to give the illness experience meaning [222].

2.9 MENTAL HEALTHCARE IN ETHIOPIA

2.9.1 Healthcare system in Ethiopia

The Ethiopian Ministry of Health operates a three-tier health care system. Level one, at the district level, is a primary health care unit comprising of a hospital (for 60 000–100 000 people), health centres (for 15 000–25 000 people) and their satellite health posts (for 3000–5000 people). Level two is a general hospital for 1–

1.5 million people and level three is a specialized hospital for 3.5–5 million people. In addition there exists a rapidly expanding private sector [223]. Health centres are staffed by health officers (four years of training) and general nurses (of degree or diploma level). Each health post covers a sub-district (*kebele*) and is staffed by two health extension workers. Health extension workers are high-school graduates with one year's training in health promotion and illness prevention. They are all women residing in the sub-district where they deliver health education and basic interventions to households.

A recent expansion of primary care facilities has reportedly improved geographical access to health services, resulting in an estimated 92.2% potential health service coverage. However, health care utilization remains low as a result of economic, sociocultural and geographical factors [224]. Health care costs are largely out-of-pocket and there are no health insurance schemes. A fee waiver is available for the poorest, with certificates given at the discretion of sub-district officials.

The WHO categorises Ethiopia as having a critical shortage of health care workers, with uneven distribution of resources, poor skill mix and high attrition of trained health professionals being particular concerns [224]. There is generally low availability of medicines due to an unreliable supply system and long procurement procedures. Availability of essential medicines is 52% in the public sector and 88% in the private sector [224].

2.9.2 Biomedical services for mental health

In Ethiopia formal mental health care is very limited and is almost entirely based in Addis Ababa and other major cities [225]. For a population of 97 million people, the main sources of care are Ammanuel Psychiatric Hospital in Addis Ababa (268 beds), two small inpatient units, four outpatients clinics and 57 nurse-led psychiatric units in other cities [226]. There is also one long stay 'psychiatric rehabilitation hospital' with 190 beds, though in reality this institution offers limited rehabilitation opportunities and no community-based support. There are currently 60 psychiatrists in Ethiopia (approximately 0.6/ 1,000,000 population) (personal communication, Dr Charlotte Hanlon). As of 2012 there were 461 psychiatric nurses (though there is no accurate estimate of the number still

working in mental health), 14 psychologists (of whom none have training in clinical psychology), three social workers and no occupational therapists working in mental healthcare in Ethiopia [226]. In the last five years several Ethiopian universities have begun training programmes in community mental health and psychiatric nursing. However it is unclear whether these developments have translated into increased provision of mental health care. Currently, mental health care is generally not available at the primary care or community level. Access to psychological therapies is only available to the tiniest minority in Addis Ababa. There are also no disability payments available or other formal social security structures in place in Ethiopia. This serious shortage of mental health specialists and facilities is common to many LMICs [159, 227].

The 2012 National Mental Health Strategy of Ethiopia represented an important development in mental healthcare provision. The Ministry of Health has committed to move towards integrating mental health into primary care, guided by the WHO's mhGAP, and is currently piloting this model in several sites across the country [168, 226, 228]. Of central importance is that prescribing privileges for anti-psychotic medication are to be extended to general nurses and health officers.

The following anti-psychotic medications are included on the Essential Drugs List for Ethiopia: chlorpromazine, clozapine, fluphenazine, haloperidol, olanzapine, risperidone and trifluoperazine [229]. In practice only chlorpromazine and haloperidol are routinely available at the primary health centre level, with fluphenazine and risperidone sporadically available at the psychiatric outpatient clinics.

Many LMICs currently devote less than 2% of their health budget towards mental health, with the majority of funds allocated to running psychiatric inpatient services [77]. Mental health expenditure for Ethiopia is not available [230]. However, the 2012 Strategy reported a recent increase in annual expenditure from 300,000 birr (£9,500) to 10,000,000 birr (£316,000) on psychotropic medications at Ammanuel Psychiatric Hospital [226]. The 2011 WHO Mental Health Atlas profile for Ethiopia reported that mental hospital expenditures formed more than 85% of the total mental health budget [231]. The 2012 Mental Health Strategy promised to allocate specific funding for the implementation of mental health in primary care [226].

2.9.3 Traditional and religious care providers

There are several types of traditional healer in Ethiopia. *Tanqway* are a type of sorcerer known to treat evil eye or spirit possession through exorcism and various rituals including preparation of tinctures and animal sacrifice [212, 232]. The Zar doctor (*balazar*) is also consulted for spirit possession, and may put his client into a trance to relieve them of the possession and/ or use beatings or burning [212]. There are also herbalists, who tend to be consulted for physical ailments [212].

Religious healers include *debtera*, *kalicha* and holy water priests. *Debtera*, associated with the Orthodox Christian faith, often deal with prevention rather than diagnosis or cure [212]. They inscribe tailored prayers on scrolls or amulets (*kitab*), sometimes written in a secret talismanic language (*asmat*), to be used by the bearer to ward off problems [217]. *Kalicha* have a similar role to *debtera* but are typically associated with the Muslim faith [233] or animistic traditions. Holy water (*tsebel*) is found at sites associated with the Orthodox Christian church. People with a wide range of physical and mental illnesses attend holy water sites to bathe in and drink the water and in some cases to have the devil or spirits driven out of them by the holy water priest [211, 217]. Holy water attenders often live around the church, sometimes in group houses of up to 15 people, whilst others visit for the day.

2.9.4 Family support

Arguably the family is the main source of care for most people with mental illness in Ethiopia [47]. This is a pattern increasingly reflected in high-income countries, though to a much lesser extent than LMIC, since the advent of deinstitutionalisation [234]. Women are more likely to take on a caring role in all settings [234]. Informal caregivers for people with mental illness experience physical, social, psychological and financial burden in low, middle and high-income countries and across cultures [234-236]. In Ethiopia there is particular emphasis on the financial burden [47]. The high burden is likely to be a reflection of the lack of formal social and financial support available in this setting. Caregivers are often

forced to neglect their own income-generating activities in order to support or supervise their relative, in addition to losing the income of the individual with mental illness. Remission has been shown to be associated with reduced caregiver burden in this context [21]. There is currently no self-advocacy movement in Ethiopia. However, the Mental Health Society, led largely by caregivers, organises awareness-raising activities.

2.9.5 Access to mental healthcare

Healthcare access is an issue of critical importance, as even the most effective treatment is rendered useless if it is not utilised. Five dimensions of access to health care have been described: availability, geographical accessibility, affordability, adequacy and acceptability [237]. User fees mean that even where it is available, mental health care is economically inaccessible to many people with mental illness in Ethiopia [238]. This is despite a one-month course of chlorpromazine typically costing only 30 birr (£1) and a monthly fluphenazine injection costing 48 birr (£1.50). On top of medication expenses the cost of travel to services is prohibitive for many people. These factors, combined with the lack of mental health services in large parts of the country, mean that the proportion of people with severe mental illness in rural Ethiopia who do not receive treatment is approximately 90% [239]. This is even greater than treatment gap estimates from other LMICS of 76–85% [77]. There is little accurate information available on either the contact or effective coverage of mental health services. A recent systematic review found only seven studies globally, none of which related to severe mental illness in LMIC [240].

2.9.6 Pathways to mental healthcare

Recent systematic reviews have shown that approximately half of individuals who seek biomedical care for mental disorders in Africa have previously chosen traditional and religious healers as their first care provider [241, 242]. An Ethiopian study found that of 1044 patients that attended Ammanuel Psychiatric Hospital over a two month period, only 41% came without having previously

sought help elsewhere. Among the remaining patients, 40% initially sought help from holy water priests or a church, 21.5% consulted doctors other than psychiatrists in private or government hospitals, 4.5% contacted herbalists, and 2% saw general nurses or psychiatric nurses [243]. A study in South Western Ethiopia found similar results, with over half having attended a religious healer (30.2%) or a herbalist (20.1%) prior to attending a psychiatric inpatient unit[244]. There is little data on time trends in use of traditional forms of care in Ethiopia or other LMIC [242].

Interventions that seek to engage people with schizophrenia in biomedical care need to be cognisant of the other treatment options available, and why they might be chosen as an alternative. The decision making processes around choosing a care provider from the diverse range of options are not fully understood [245] though studies in Butajira and North Western Ethiopia have found that biomedical care is more likely to be recommended for physical conditions compared to mental health problems [215, 220]. It has been suggested that for psychosis in particular a wide range of treatment options are likely to be sought, including both traditional and biomedical approaches, due to the severe and chronic nature of the illness [215]. Furthermore, it is proposed that many families have a pragmatic attitude towards seeking care for their relative, trying different options until they strike on something which appears to be effective [216].

People in LMICs such as Ethiopia may be more inclined to use traditional or religious healing for mental health problems not just because this provides the most obvious link to popular explanatory models. Greater accessibility and affordability of traditional healers and holy water are also likely to be important factors, along with more flexible payment options (often traditional practitioners only receive the full payment on cure) [233, 242]. Attending a traditional or religious healer may have greater cultural and social acceptability; the average rural Ethiopian may be more likely to share a worldview and lifestyle with traditional healers compared to biomedical providers [215, 233]. There may also be less stigma associated with attending a traditional healer compared to receiving a psychiatric diagnosis [242].

2.10 STIGMA, DISCRIMINATION AND HUMAN RIGHTS

2.10.1 Stigma and discrimination

It has been shown that stigma towards people with mental illness is a universal phenomenon, transcending economic and cultural boundaries [246, 247]. The issue of stigma includes problems of knowledge (misinformation), attitudes (prejudice) and behaviour (discrimination) [247]. Perceived and internalized stigma refer to the experiences of people with mental illness, whereas public stigma concerns the negative attitudes of the general population [248]. A “backbone” of public stigma across continents seems to comprise difficulty accepting that people with mental illness can take authority positions and discomfort at interactions with this group, underpinned by fear of possible violence [246]. However, differences in the extent and nature of stigma have been identified between settings, hence the phenomenon is also understood as a local experience [249]. In all settings, a low level of mental health literacy is thought to be one of the factors contributing to negative attitudes [219, 250].

In Ethiopia, high levels of internalised stigma have been found in people with schizophrenia. In one survey of psychiatric inpatients nearly all participants (97.4%) reported at least one experience of internalised stigma and 46.7% had a moderate to high mean stigma score [251]. In Ethiopia caregivers of people with mental illness are also stigmatised [22, 252], which may manifest as greater burden due an absence of community support. High levels of public stigma have been demonstrated in Ethiopia [219], with attitudes generally less favourable towards people with psychotic illness compared to other mental disorders [215]. Community-based surveys have shown greater levels of public stigma in rural areas and amongst those with lower education levels [215, 219].

Stigma may have important implications for the experiences of people with mental illness, increasing the risk of self harm [253] as well as potentially affecting access to health services, and adherence to treatment [251]. Discrimination may lead to social exclusion of people with schizophrenia and may act as a barrier to recovery [247]. The high levels of violent victimisation identified amongst participants in the Butajira cohort may be partly attributable to stigma [24].

2.10.2 Human rights

Human rights violations affecting people with mental illness in LMICs span basic civil, cultural, economic, political, and social rights. Along with lack of access to mental health care, and denial of the right to work or marry, sits the issue of physical restraint [254]. These problems, operating on a background of pervasive stigma and discrimination, may disproportionately affect people with severe mental illness compared to other mental disorders.

The restraint and confinement of people with mental illness by their family members is described in several accounts from sub-Saharan Africa and Asia [189, 255-260]. As yet the extent of restraint in community settings in Ethiopia has not been quantified. However, anecdotal evidence suggests that it is not an uncommon experience amongst people with schizophrenia in this context [261]. A relationship between lack of access to anti-psychotic medication and subsequent restraint in the community has been identified [255, 256, 262]. Yet there is a propensity towards linking restraint with misunderstandings about the aetiology of mental illness (for example that it is caused by spirit possession) and associated stigma [258, 259, 263, 264]. Whilst restraint of people with mental illness is commonplace in LMICs, its extent seems to vary between settings and the drivers behind it are likely to be contextual [256].

Since it was adopted by the UN in 2006, the Convention on the Rights of Persons with Disabilities has been ratified by 166 countries, including Ethiopia. The Convention provides a legal framework for protecting and promoting the human rights of people with physical and mental disabilities [36]. There is currently no mental health legislation in Ethiopia but the Ministry of Health has committed to developing laws which aim to protect the rights of people with mental illness [226].

This background chapter has described the problem of disability relating to schizophrenia, introduced CBR as a potential solution to this issue, and explored some of context relevant to developing a CBR programme for schizophrenia in Ethiopia. The next chapter will draw together these themes to describe the rationale, aims and objectives for the novel research conducted for this thesis.

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3 THESIS RATIONALE, AIMS AND OBJECTIVES AND OVERVIEW OF METHODOLOGY

3.1 RATIONALE FOR THESIS

Like many low-income countries, Ethiopia is making important strides towards improving care for people with mental illness, in particular through the integration of mental health into primary care. However provision of anti-psychotic medication alone is inadequate to address the complex social, economic and health needs of those affected by a chronic and highly disabling illness such as schizophrenia. CBR is a promising intervention to support people with schizophrenia in LMIC. CBR aims to reduce disability, arguably the most important outcome for individuals, their families and communities, by addressing both personal and family level issues and societal factors such as poverty, stigma and access to care. CBR is also a relatively low intensity model of care that can be delivered by non-specialists; a crucial advantage in settings with limited or absent mental health specialists.

Despite being widely advocated, to date there have been few formal evaluations of CBR for mental illness using non-specialist workers and none in low-income settings. As a highly contextualised approach, any CBR programme must fit the needs and resources of the local setting. Moreover, it is recognised that complex interventions should be subject to rigorous intervention development and piloting prior to a full evaluation in order to ensure their acceptability and feasibility. The body of work contained in this thesis is needed to address the substantial gaps in the evidence base relating to the provision of care for people with schizophrenia in low-income settings. This represents the first intervention development, piloting and planning for a trial of CBR for schizophrenia in any low-income country.

3.2 AIM AND OBJECTIVES

The overall aim of the PhD thesis is to design, pilot and create the evaluation plans for a CBR intervention for people with schizophrenia in Ethiopia. The specific objectives of the PhD thesis are:

Objective 1 (Chapter 4)

To determine the current evidence for the effectiveness of community-based psychosocial interventions for schizophrenia in LMIC.

Objective 2 (Chapters 5 and 6)

To develop an acceptable and feasible CBR intervention for people with schizophrenia in Ethiopia.

Objective 3 (Chapter 7)

To pilot the CBR intervention for people with schizophrenia to determine its acceptability and feasibility in practice and to refine the intervention in preparation for a formal evaluation.

Objective 4 (Chapter 8)

To prepare the protocol for a cluster randomised controlled trial to evaluate the CBR intervention.

3.3 SETTING

The study was conducted in Sodo district in the Gurage administrative zone of the Southern Nations, Nationalities and Peoples' Region of Ethiopia. The district is 100km from Addis Ababa and has around 170,000 inhabitants. The main town in the district is Bui. The majority of the population of Sodo live in rural areas, often in households spread out over large distances rather than concentrated in villages. The topography is variable, encompassing both cool mountainous areas and lowlands with higher temperatures. Difficult terrain covers most of the district; the only form of transport are carts and minibuses, which have no fixed departure

times and do not extent to the most remote areas. Most of the population live in one-room mud and straw houses. Around 51% of the Sodo population is estimated to be literate [1]. The majority of the population in this district are Orthodox Christian.

Sodo district is the setting for the Ethiopian arm of the PRIME project. PRIME is a five-country research consortium that aims to generate evidence on the integration and scale up of mental health into primary and maternal care settings [2]. As part of PRIME a scalable mental health care plan was developed and implemented in Sodo district across community, facility and district healthcare levels. At the facility level, PRIME trained primary care staff to identify schizophrenia and offer a package of care including psychotropic medication (oral haloperidol and chlorpromazine) and basic psychoeducation [3]; training followed the WHO's mhGAP guidelines [4]. Sodo was selected as the site for the RISE study as this gave the opportunity to develop and evaluate an adjuvant psychosocial intervention, CBR, in a setting where facility-based care was in place at the primary care level. The PRIME mental health care plan was implemented immediately before the RISE pilot study (Chapter 7) commenced. PRIME identified people with schizophrenia in Sodo using the Butajira key informant method [5] and, from December 2014, began following up those invited to access facility-based care in a 12-month treatment cohort [6]. The RISE pilot study (Chapter 7) and trial (protocol in Chapter 8) were nested in the PRIME cohort study.

3.4 OVERVIEW OF THESIS METHODOLOGY

3.4.1 Development and evaluation of complex interventions

As a multi-component intervention addressing a range of difficult issues and behaviours targeted at the individual, family and community level, within which there is flexibility to tailor to an individual's needs, CBR can readily be described as a complex intervention [7]. The 2008 Medical Research Council (MRC) guidance on developing and evaluating complex interventions recommends four phases, though these may be completed in a non-linear sequence: development, feasibility and piloting, evaluation and implementation (see Figure 3.1) [7].

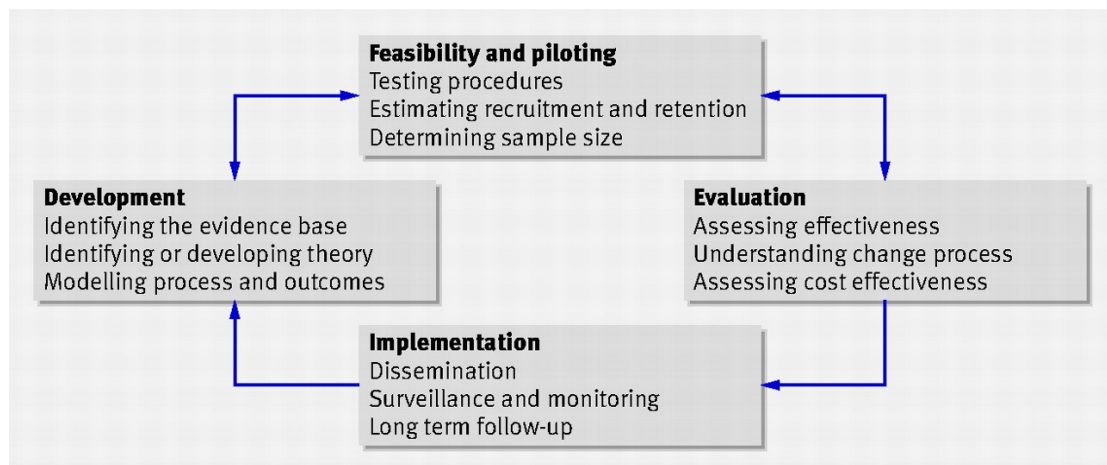


Figure 3.1 Key elements of the development and evaluation process (from MRC guidance)

Development: In this phase the existing evidence should be identified and reviewed and a theoretical model for the likely process of change should be developed [7]. Formative work to determine the likely acceptability and feasibility of the intervention can also be conducted [8, 9].

Feasibility and piloting: In this phase the intervention is tested in practice, allowing a fuller assessment of acceptability and feasibility [7]. A process evaluation, which considers intervention fidelity, mechanisms of impact and context, should ideally be conducted as part of the feasibility testing [10].

Evaluation: A range of experimental and non-experimental designs exist for the evaluation of complex interventions, with randomised studies being the most robust [7]. A process evaluation should also be conducted alongside the full trial as different issues may arise when the intervention is delivered at a larger scale [10].

Implementation: This phase incorporates the dissemination and scale up of interventions, along side their on going monitoring and long term follow up [7, 11, 12].

3.4.2 Introduction to theory of change

Theory of change is one method of theory driven evaluation, amongst a wider group including logic models, logical frameworks, outcome hierarchies and realist evaluation [13]. Theory of change has been defined as, “an approach which describes how a programme brings about specific long-term outcomes through a

logical sequence of intermediate outcomes” [13]. In another definition theory of change is, “a theory of how and why an initiative works.” [14]. Theory of change maps are often developed through participatory stakeholder workshops, though in some cases stakeholders have minimal involvement. The map is used as a framework for intervention development and evaluation, with some researchers refining the map to reflect on going research findings [13]. The map includes the following components: (i) the desired final outcome, (ii) intermediate outcomes that are needed to achieve the final outcome, (iii) interventions which are needed to move from one outcome to the next, (iv) assumptions (the contextual factors or other conditions which the causal pathway needs in order to progress), (v) rationale for each link in the pathway and (vi) indicators (to evaluate whether each intermediate outcome and the final outcome are achieved).

Theory of change strengthens the MRC framework [14], and addresses calls to incorporate a realist approach into evaluation [15], in several ways:

- **Development:** The intervention design is explicitly embedded within local context in terms of social and economic setting, and human and material resources. The theory of change map provides a structured presentation of the hypothesised process of change.
- **Piloting:** Modification of the theory of change map on the basis of testing assumptions allows a structured approach to identifying and overcoming barriers, therefore producing a more acceptable, feasible and effective intervention for evaluation. Furthermore, specifying causal assumptions about how the intervention will function permits others to assess its credibility [10].
- **Evaluation:** Trial outcomes, including intermediate outcomes, are explicitly identified on the basis of the theory of change. Process and effectiveness evaluations are combined in one approach.
- **Implementation:** Modelling the relationship between specific intervention components and outcomes may facilitate the identification of ‘active ingredients’. This is of great value in refining complex interventions for scale up and dissemination.

Theory of change is an increasingly favoured approach for the development of interventions, including in global mental health research [14]. A recent systematic review identified its use in 62 papers describing the development and /or evaluation of public health interventions [13]. Whilst traditionally CBR programmes have lacked formal monitoring and evaluation processes [16] structured approaches to evaluation are now being developed [17]. However, even the few RCTs of CBR-like interventions, whilst having followed the MRC steps, have not been guided by a theoretical model for the process of change [8, 18].

3.4.3 Use of theory of change in this thesis

Theory of change was used as a framework to guide the intervention development, piloting and trial protocol presented in this thesis. An initial theory of change map was developed and refined through theory of change workshops as part of the intervention development phase (Chapter 5). This map presented the hypothesised mechanism of change, as well as capturing important contextual issues and key assumptions. These assumptions formed the basis of research questions that I then answered -using qualitative and quantitative methods and measures of intervention fidelity- in the remaining intervention development phase and in the pilot. On the basis of on going findings, assumptions that were confirmed to be well founded were converted into rationale, or changes were made to the intervention design to fulfil assumptions (Chapter 7). Revised versions of the theory of change map were made as a visual representation of these findings. The evaluation plans outlined in the trial protocol, including primary and secondary outcomes, process data collection, and the focus of a parallel qualitative study, were shaped by the theory of change indicators (see Chapter 8).

Reflecting the participatory emphasis of the theory of change approach, people with schizophrenia and their caregivers were involved at several stages in the conduct of this research. This type of involvement is seen as an important component of efforts to safeguard the dignity and human rights of people with mental illness [19]. The UN Convention on the Rights of Persons with Disabilities ((Article 4(3)) also highlights the importance of involving people with disabilities and their caregivers in the development of policy and programmes [20].

3.5 THESIS TIMESCALE

Figure 3.2 gives an overview of the thesis timescale. The initiation of the trial prior to completion of the pilot was an intentional design to address the overall time constraints relating to the project and its funding. An initial literature review was carried out as part of the intervention development (Chapter 5). However a full systematic review and meta-analysis was subsequently carried out for completeness and to better contextualise the pilot findings within the current evidence base (Chapter 4). The next chapter presents this systematic review of community-based psychosocial interventions for schizophrenia.

	2012	2013				2014				2015				2016				2017	
	Oct- Dec	Jan- Mar	Apr- June	July- Sept	Oct- Dec	Jan- Mar	Apr- June	July- Sept	Oct- Dec	Jan- Mar	Apr- June	July- Sept	Oct- Dec	Jan- Mar	Apr- June	July- Sept	Oct- Dec	Jan- Mar	Apr- June
Intervention development work (Chapter 5)																			
Preparation of intervention materials (Chapter 6)																			
RISE CBR worker training (Chapter 6)																			
RISE pilot (Chapter 7)																			
RISE trial (protocol in Chapter 8)																			
Systematic review (Chapter 4)																			

Figure 3.2 Thesis timescale

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RESEARCH PAPER COVER SHEET

PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED FOR EACH RESEARCH PAPER INCLUDED IN A THESIS.

SECTION A – Student Details

Student	Laura Asher
Principal Supervisor	Vikram Patel
Thesis Title	The development and evaluation of a community-based rehabilitation intervention for people with schizophrenia in Ethiopia

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

Where was the work published?			
When was the work published?			
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion			
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SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	BMC Psychiatry
Please list the paper's authors in the intended authorship order:	Laura Asher, Vikram Patel, Mary De Silva
Stage of publication	Not yet submitted

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I conceived the review, wrote the protocol and search strategy, ran the searches, extracted the data, assessed risk of bias, performed the meta-analysis and wrote the initial and final drafts
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Student Signature: 

Date: 06.10.2016

Supervisor Signature: 

Date: 06.10.2016

4 SYSTEMATIC REVIEW AND META-ANALYSIS

4.1 INTRODUCTION

Community-based psychosocial interventions, including family interventions and CBR, are advocated as appropriate approaches to support people with schizophrenia in LMICs in the World Bank DCP-3 [1] and by the WHO's mhGAP [2]. An initial scoping search undertaken in April 2016 indicated that additional relevant randomised studies had been published since the Lemmi et al review of CBR was conducted in 2012 (see Section 2.7.1). This suggested that an updated review would be of value. Furthermore, the scope of the review was broadened to all community-based psychosocial interventions for schizophrenia in order to capture all potential elements of a CBR programme for this group. This was deemed appropriate for the development of a new CBR intervention, due to the broad range of psychosocial interventions and models of care that exist for people with schizophrenia in LMIC, and the challenges in defining what constitutes a CBR programme [3]. The aim of this review was to assess the effectiveness of community-based psychosocial interventions for people with schizophrenia on patient outcomes in LMIC.

4.2 METHODS

4.2.1 Systematic literature search

4.2.1.1 Eligibility criteria

Eligible interventions were any community-based psychosocial intervention delivered to people with schizophrenia or their caregivers with the aim of improving patient outcomes (see Table 4.1). Psychosocial interventions were defined as any intervention that focused on psychological and/ or social factors rather than biological factors (for example a pharmacological intervention). Interventions could have one or multiple components. Community-based interventions were defined as any intervention delivered in the participant's home or another community setting. Interventions that took place exclusively in health or other institutional facilities (hospitals, clinics, outpatient care centres or

specialised care centres) were excluded. Papers without a full text available in English were excluded due to logistical constraints. Conference abstracts, Masters dissertations and PhD theses were also excluded.

Table 4.1 Inclusion and exclusion criteria (continued overleaf)

	Included	Excluded
Publication type	Any date English language	No full text available in English. Conference abstracts, Masters dissertations, PhD Theses and unpublished studies.
Study design	Individual and cluster randomised controlled trials.	Non- randomised controlled intervention studies, case-control or cross-sectional studies. Retrospective/historical controlled cohorts.
Study population	General adult population	Interventions for children and adolescents (<18 years)
	Study conducted in a LMIC as defined by the World Bank	Study conducted in high-income country or territory
Condition of interest	Schizophrenia or schizoaffective disorder as defined in International Classification of Diseases-10 (ICD-10), DSM-IV or Chinese Classification of Mental Disorders (CCMD) confirmed by a clinical diagnosis or a validated tool. No restriction on the proportion of participants with schizophrenia or schizoaffective disorder. No restriction on comorbid mental disorders.	Other mental disorders including depression, substance abuse, bipolar disorder, anxiety disorder, epilepsy, other types of disability, brief psychotic disorders, post-partum/ puerperal psychosis, populations at risk of psychosis.
Intervention	Community-based psychosocial interventions delivered to people with schizophrenia or their caregivers with the aim of improving patient outcomes. Psychosocial interventions were defined as any intervention that focused on psychological and/ or social factors rather than biological factors (for example a pharmacological intervention), including psychological therapies, rehabilitation, psychoeducation, adherence support, stigma reduction strategies, social skills training, life skills training, self-help groups, group support sessions and livelihoods interventions. Community-based interventions were defined as any intervention delivered in the individual's home or another community setting.	Studies were excluded if the intervention took place only in health or other institutional facilities (defined as places that provide health care: hospitals, clinics, outpatient care centres, specialised care centres). The following interventions were also excluded: those specifically designed for humanitarian crisis settings; those employing solely physical therapies including yoga; interventions solely targeting depression, substance use, or smoking; interventions focusing exclusively on 'at risk' groups; interventions using telephone reminders only and involving no face to face contact; and interventions which were entirely computer-based (e.g. cognitive training).

Table 4.1 continued		
Outcome	Any patient outcomes including -Clinical outcomes (e.g. symptoms, severity, relapse, mortality) -Health service use including hospitalisation -Adherence to antipsychotic medication -Change in disability and functioning (e.g. improved coping skills, quality of life, social functioning, self-esteem) -Economic status outcomes, for e.g. return to work, employment status -Understanding of mental illness/ schizophrenia -Stigma/ discrimination	Studies were excluded if outcomes were measured in caregivers or family members only
Control Group	Any control group including treatment as usual, no intervention, treatment delivered in a health care setting or pharmacological intervention only	n/a

4.2.1.2 Information sources

Database searches were carried out on the 18th and 19th April 2016. The following databases were searched: Medline, EMBASE, PsycINFO, Global Health, CINAHL and Africa Wide information. In addition the Cochrane Library was searched for relevant systematic reviews. The included studies list of each relevant Cochrane review was searched for additional references not already identified in the previous database searches. The Clinicaltrials.gov database was searched for relevant trials; for all trials identified, a search was carried out for relevant linked publications on the clinicaltrials.gov database and on PubMed. The websites of organisations known to conduct relevant research projects and programmes, including BasicNeeds, CBM, and Sangath, were searched for relevant reports and studies. All innovation entries on the Mental Health Innovations Network (MHIN) database were reviewed for relevance and linked publications were sought on PubMed. MHIN is an online platform and database for sharing knowledge, experiences and resources relating to global mental health

(www.mhinnovation.net). Reports and guidelines relating to mental health and development or CBR were reviewed for relevant programmes, including the WHO CBR guidelines [4], WHO report on Mental Health and Development [5] and the UK government Mental Health for Sustainable Development Report [6]. Relevant literature reviews relating to CBR [3], psychosocial interventions [7, 8], task-sharing [9, 10] and packages of care [1, 11, 12] for mental illness in LMIC were also reviewed for relevant references.

4.2.1.3 Search strategy

The search identified studies covering four domains: A: Schizophrenia or schizoaffective disorder + B: community-based psychosocial intervention + C: low or middle-income country + D: controlled study. Appendix A (i) presents the search strategy that was designed for Medline; minor modifications were made as required for other databases. A broad range of search terms were used for domain B, including terms relating to psychoeducation, adherence support, family support, rehabilitation, psychotherapy and counselling, self help groups, health promotion and community-based care. For domain C, separate terms were included for each LMIC, along with generic terms such as ‘developing country’.

4.2.1.4 Study selection

The results of all database searches were downloaded to Endnote X7. Duplicates were removed and the titles and abstracts of the remaining records were screened for relevance. The full texts of those deemed to be relevant were acquired and reviewed. A final list of included eligible studies was compiled after reviewing the full text.

4.2.2 Data extraction and quality assessment

Key features and findings of each included study were extracted onto a specially designed database. Data were extracted on study characteristics (setting, design, number of participants randomised and duration of follow up), inclusion criteria, characteristics of the interventions (content, frequency and duration) and outcomes. The Cochrane Collaboration risk of bias tool was used to assess each included study [13]. A rating of low, high or unclear risk of bias was given for the following domains: sequence generation; allocation concealment; masking of

assessors; selective outcome reporting; incomplete data and other source of bias. Blinding of participants and personnel was not possible due to the nature of the interventions, therefore this criterion was not utilised.

Statistical analyses were performed using Review Manager 5.3 for Mac. For outcomes measured on continuous scales, the post-treatment mean and standard deviation in the intervention and control groups were extracted along with the sample size in each group. Where these data were presented in the paper, the information was used to calculate the standardised mean difference (SMD) for each trial in order for different outcome scales to be pooled. SMD is a summary statistic that represents the size of the intervention effect in a study relative to the variability observed in that study. The following cut offs were used to guide interpretation of the strength of effect: 0.2 represents a “small” effect, 0.5 represents a “medium” effect, and 0.8 represents a “large” effect [14]. Due to absence of relevant data in the included papers, it was not possible to take into account differences in baseline scores between treatment groups, in the calculation of SMD. Where outcomes were presented as proportions, risk ratios were calculated. For any scale where an increase in score indicates worse outcome, mean scores or proportions were inverted before calculating the SMD or risk ratio. Acknowledging the heterogeneity in interventions, random effects meta-analyses were performed with all intervention types together along with subgroup meta-analyses for each intervention type separately. Meta-analyses were also performed separately for short and long-term outcomes. Short-term outcomes were defined as those measured less than 18 months after the intervention ended, and long term outcomes more than 18 months after the intervention ended. Heterogeneity between trials was assessed using the I^2 statistic. In order to understand the impact of study quality on the findings, a sensitivity analysis was conducted excluding studies perceived to have the highest risk of bias overall; these studies comprised those with a risk of bias for allocation concealment, or for those with an unclear risk of bias for allocation concealment, those studies with a risk of bias for sequence generation or masking of outcome assessment [8].

4.3 RESULTS

4.3.1 Overview

From 9543 records, 13 records reporting 11 studies met inclusion criteria for the review (see Figure 4.1). The reasons for excluding full text articles are presented in Appendix A (ii).

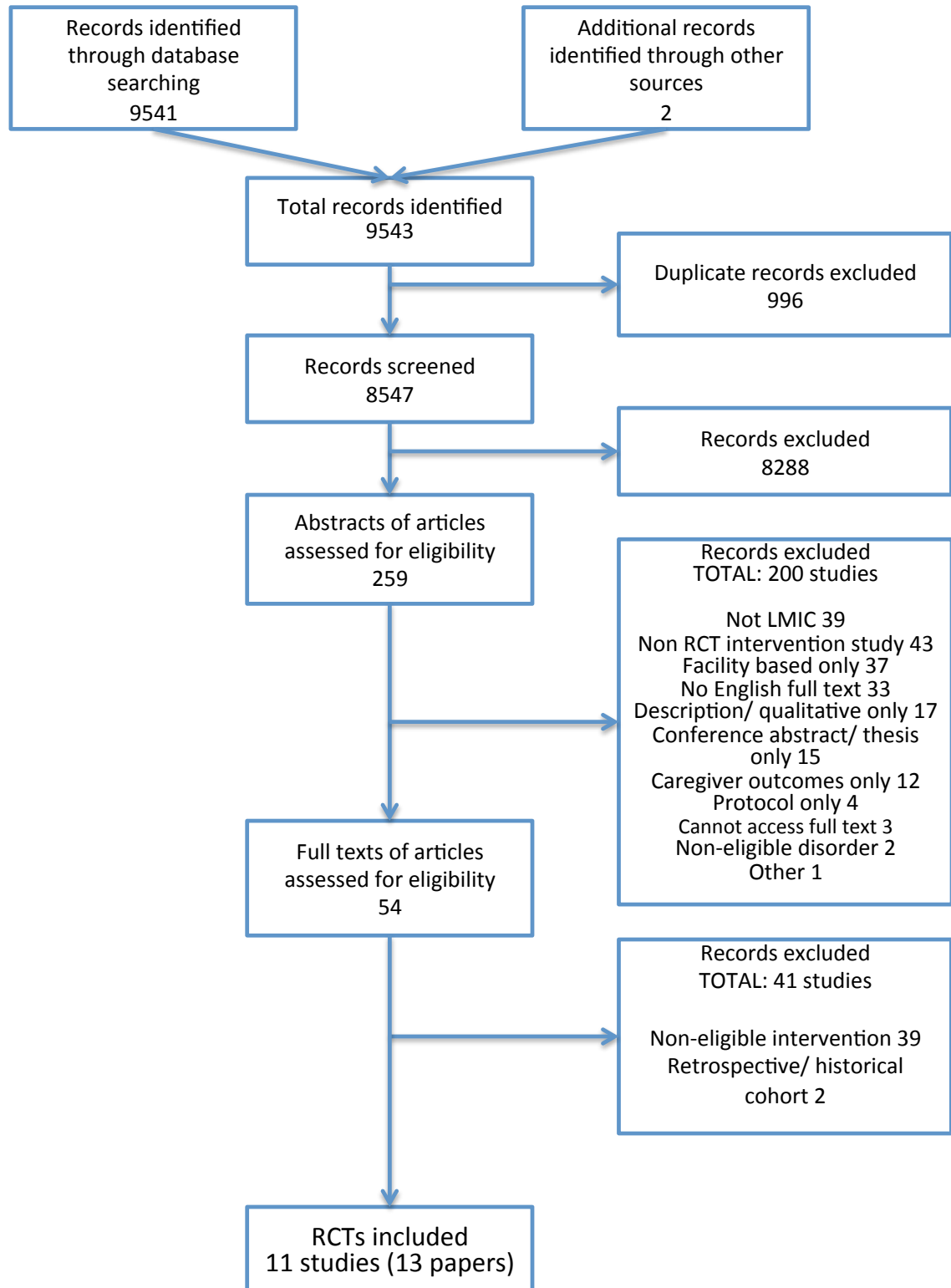


Figure 4.1 Flow chart of study selection process

4.3.2 Study characteristics

4.3.2.1 Overview

Table 4.2 gives a summary of the features of the intervention and study design for each included study. Across all included studies there were a total of 1787 participants with a median sample size of 111, ranging from 45 to 326. Five studies, reported in six papers, were conducted in China [15-20], two studies were conducted in India [21, 22] and Iran [23, 24], one study, reported in two papers, was conducted in South Africa [25, 26], and one study was conducted in Turkey [27]. All studies were conducted in upper-middle income countries apart from the two studies based in India, which is classified by the World Bank as lower-middle income. There were no studies conducted in low-income countries.

Table 4.2 Summary of the design and findings of included studies (continued overleaf)

Study and setting	Design and follow up period	Participants [I=intervention C=control]	Intervention duration and content	Personnel delivering intervention	Community involvement	Comparison group	Key results
Group A: Psychoeducation/ cognitive retraining							
Hegde 2012 [22] India	Individual 6 months	Schizophrenia n= 45 [I=22, C=23]	2 months. (i) Cognitive retraining: home visits for cognitive retraining tasks and (ii) Psychoeducation: 3 sessions 45-60min. Medication.	Researcher	None	Drug treatment and psychoeducation	Symptoms: Positive association with negative symptoms. Cognition: Positive association
Li 2005 [17] China	Cluster 9 months	Schizophrenia n=101 [I=46, C=55]	3 months. Family and patient psycho-education in hospital (8h with pt, 36 hrs with family) and then at home (2 hrs/month for 3 months post-discharge). Phases: establish trust, assess needs; psychoeducation, develop coping skills. Medication.	Trained nurse	None	Medication/ standard inpatient care	Symptoms: Positive association at 9 months; no association at 3 months. Functioning: Positive association at 9 months; no association at 3 months. Medication adherence: No association. Knowledge: Positive association
Xiang 1994 [18] China	Individual multisite 4 months	Schizophrenia and affective psychoses n=77 [I=36, C=41]	4 months. Family psychoeducation (family visits, workshop, monthly supervision). Medication.	Not stated	Health education through village wired radio network	Monthly drug treatment	Symptoms: Positive association Functioning: Positive association with work ability and poor social functioning. Medication adherence: Positive association
Zhang 1994 [19] China	Individual 18 months	Schizophrenia n=83 [I=39, C=39]	18 months. Family psychoeducation: initial home visit, then 3 monthly group sessions or individual counseling in outpatients for complex problems; non-attenders had home visits. Minimum contact every 3 months. Medication.	Counsellors	None	Outpatient care - including medication; no active follow up for non- attenders	Symptoms: Positive association Functioning: Positive association Readmission: Positive association Nb All analyses included only those not readmitted.

Table 4.2 continued							
Study and setting	Design and follow up period	Participants [I=intervention C=control]	Intervention duration and content	Personnel delivering intervention	Community involvement	Comparison group	Key results
Group B: Comprehensive family/rehabilitation intervention							
Cai 2015 [20] China	Individual multisite 18 months	Schizophrenia n= 256 [I=133, C=123]	10 weeks. Comprehensive family therapy: (i) Social skills training (medication and symptom management, community re-entry support, recreation for leisure and social independent living skills) 90–120 minutes/session, 2 sessions/ week for 10 weeks (ii) Family psychoeducation. One session/ week for 10 weeks. Medication.	Professional personnel	None	Usual care (usually monthly outpatient appointment)	Symptoms: No association Cognition: Positive association (greater improvements since baseline compared to control (p=0.002))
Chatterjee 2014 [21] India	Individual multisite 12 months	Schizophrenia n =282 [I=187, C=95]	12 months. Collaborative community based care: Home visits fortnightly for 7 months, then monthly for 5 months. Psycho-education; address stigma and discrimination; adherence management strategies; health promotion; rehabilitation strategies to improve social/vocational functioning. Medication.	Lay community health workers	Referrals to community agencies: address social inclusion, access to legal benefits, employment	Facility based care. Psychiatrist consultations. Anti-psychotic medication, information about illness, encouraged medication adherence.	Symptoms: Non-significant association (p=0.08). Functioning: Positive association. Significant differences in PANSS and IDEAS at rural site, but not at others. Medication adherence: Positive association Stigma, knowledge about schizophrenia, caregiver burden: No association.
Ran 2015 [16] [15] China	Cluster 9 months and 14 years	Schizophrenia n= 326 [I=126, C1=103, 2=97]	9 months. Psycho-educational family intervention (i) Family education 1x/month: information about schizophrenia, relapse prevention, treatment, social functioning rehabilitation (ii) Family workshops 3 monthly (iii) Crisis intervention support. Medication.	Psychiatrists and village doctors	Local village broadcast network used for health education for first 2 months.	1.Medication alone 2. Control (no intervention, medication neither encouraged nor discouraged)	Symptoms: Borderline association 9 months, no association 36 months. Functioning: No association compared to medication alone. Medication adherence: No association compared to medication alone at 9 months. Positive association 14 years. Knowledge: Positive association 9 months.

Table 4.2 continued							
Study and setting	Design and follow up period	Participants [I=intervention C=control]	Intervention duration and content	Personnel delivering intervention	Community involvement	Comparison group	Key results
Group C: Assertive community treatment/ case management/ home after care							
Botha 2014 [25, 26] South Africa	Individual 12 months and 36 months	Schizophrenia or schizoaffective disorder n= 60 [I=34, C=26]	12 months. Assertive community treatment: individual caseload max 35. Visits >50% at home, fortnightly or according to need. Focused on engagement and maintaining adherence; referral to psychologist, occupational therapist; access to psychosocial rehab program. Medication.	Key worker (social worker or nurse), supported by multi-disciplinary team (psychiatrist, psych nurse)	Strengthening access to existing community resources	Community mental health team: caseload 250+, outpatient appts 1-3 monthly; no active follow up; referral to allied health professionals. Medication.	12 months Symptoms: Positive association Functioning: Positive association Inpatient days+readmissions: Positive association Quality of life and depression: No association 36 months Inpatient days and readmissions: Positive association
Sharifi 2012 [24] Iran	Individual 12 months	Schizophrenia, schizoaffective disorder, bipolar n=130 [I=66, C=64]	12 months. Home after care Monthly visits with extra visits in first 3 months. Care plan, drug prescription, dose adjustment, psychoeducation, relapse recognition, referral to hospital. Medication.	General practitioner and social worker- plan reviewed by psychiatrist	Help family to access supportive and community resources.	Hospital outpatient service (no psychosocial component)	Symptoms: Positive association Functioning: No association Readmissions: Positive association Quality of life: No association Depression: Positive association
Ghadiri 2015 [23] Iran	Individual 20 months	Schizophrenia, schizoaffective and bipolar disorder n=120 [I=60, C=60]	20 months. Home aftercare (i) Treatment follow up (home visits/telephone and monthly outpatient visit) (ii) Family psychoeducation (six weekly 2-hr sessions), (iii) social skills training (9 monthly visits). Medication.	Not stated	Contact with local NGOs and self help groups	Usual aftercare including monthly visits by psychiatrist	Symptoms: Positive association Inpatient days and readmissions: Positive association Depression: Positive association
Sungur 2011 [27] Turkey	Individual 24 months	Schizophrenia n=100 [I=50, C=50]	24 months. Optimal case management: psychoeducation, adherence strategies, relapse recognition, crisis intervention, family intervention, stress management, social/work skills training. 120 mins every 2 weeks for 3 months at home. Then 45m every month at outpatient clinic. Medication.	Psychiatrists, psychologist, psychiatric nurses, supervised by CBT expert.	Referrals to voluntary organisations	Routine case management (outpatient clinic): psychoeducation, adherence support, crisis intervention, day hospital, referrals to rehab. 60min/month for 3 m then 45m/month. Medication.	Symptoms: Positive association Functioning: Positive association Quality of life: Positive association Caregiver burden: Positive association

4.3.2.2 Home-based care components

All interventions included a home-based element, a psychoeducation component, and in all studies the intervention group also had access to psychotropic medication. Only the South African study by Botha et al did not explicitly refer to family involvement in the intervention delivery [25, 26]. Aside from these factors the content and structure of interventions varied between studies. Three broad groups were identified, but with considerable overlap between groups and variation within groups. Group A consisted of largely single-faceted psychoeducation interventions, including three Chinese studies, Li 2005, Xiang 1994 and Zhang 1994 [17-19], and one Indian study, Hegde 2012, that provided cognitive retraining alongside psychoeducation [22]. Group B consisted of more comprehensive multi-faceted interventions including components such as family intervention, support developing social and independent living skills, medication adherence support, crisis intervention and dealing with stigma. This group included the Indian COPSI community-based care trial, Chatterjee 2014 [21], and two Chinese RCTs, Cai 2015 and Ran 2015 [15, 16, 20]. Group C comprised studies focusing on engagement with care following discharge from inpatient facilities, alongside other elements such as social skills training. In this group the South African study, Botha 2014, was based on an assertive community treatment model [25, 26], whilst two Iranian RCTs, Sharifi 2012 and Ghadiri 2015, assessed home-based aftercare services [23] [24], and a Turkish RCT, Sungur 2011, evaluated optimal case management [27].

4.3.2.3 Community involvement components

In five studies, in South Africa, India, Iran and Turkey, individuals were supported to access community resources and organisations including legal benefits, employment opportunities, and NGOs [21, 23-27]. Two Chinese studies, Xiang 1994 and Ran 2015, conducted awareness-raising about mental illness through local radio stations [15, 16, 18]. Four interventions did not include any community engagement or facilitation of support outside of the home-based intervention [17, 19, 20, 22]. Aside from referring to existing community agencies, no studies incorporated active involvement of community members to support individuals with schizophrenia.

4.3.2.4 Personnel

The primary personnel delivering the intervention varied between studies. Only in one study, Chatterjee 2014, was the intervention delivered by trained lay community health workers [21]. In the rest of the studies care was delivered by mental health professionals (two studies [15, 16, 27]), other health professionals as part of a multi-disciplinary team (three studies [17, 24-26]) or was unspecified or unclear (five studies [18-20, 22, 23]). Interventions were delivered for a median period of 12 months (range 10 weeks to 36 months). The evaluation was conducted immediately on the intervention terminating for six studies and between 6 months to 13 years after the intervention ended for the remaining five.

4.3.2.5 Comparison

Six studies compared the intervention to treatment with medication provision only (typically delivered in an outpatient clinic) and no psychosocial support [17-20, 23, 24]; two studies, Chatterjee 2014 and Hegde 2012, specified that the control included both medication and psychoeducation in an outpatient setting [21, 22]; and the South African and Turkish case management studies, Botha 2014 and Sungur 2011, used outpatient care delivered by a community mental health team as a control [25-27]. One of the Chinese family intervention studies (Ran 2015, Group B) consisted of three arms, comparing (i) a psychoeducational family intervention and medication (ii) medication only and (iii) no intervention and medication neither encouraged or discouraged [15, 16]. In this review only the intervention effects comparing the family intervention and the medication only arm are presented.

4.3.2.6 Outcomes assessed

A wide range of outcomes were assessed including symptoms (ten studies), functioning (eight studies), medication adherence (four studies), number of hospitalisations (four studies), quality of life (three studies), knowledge about schizophrenia (three studies), depression (two studies), family burden (two studies), cognitive function (two studies), length of hospital stay (two studies), and stigma and discrimination (one study). Clinical symptoms were measured with the Positive and Negative Syndrome Scale (PANSS), the Brief Psychiatric Rating Scale (BPRS), the mania rating scale and the Current Psychiatric Status (CPS-50). Functioning was measured with the Social and Occupational Functioning

Assessment Scale (SOFAS), the Social Disability Screening Schedule (SDSS), the Global Assessment of Functioning (GAF), the Global Assessment Scale (GAS), the Indian Disability Evaluation Assessment Scale (IDEAS) and 'working ability'. Depression was measured using the Hamilton Rating Scale for Depression and the Calgary Depression Scale. Quality of life was measured with the WHOQOL (Quality of Life)- BREF and the Quality of Life Scale. Caregiver burden was assessed with the burden assessment schedule and the Scale for the Assessment of Family Distress.



































































4.3.2.7 Participants and design

There were some differences in diagnoses across studies, with seven studies including only participants with schizophrenia [15-17, 19-22, 27], one study including participants with schizophrenia or schizoaffective disorder [25, 26] and three studies including participants with schizophrenia, schizoaffective disorder or bipolar disorder [18, 23, 24]. Nine studies used an individually randomised design [18-27], whilst two studies used a cluster randomised design [15-17]. Three studies were conducted across multiple sites [18, 20, 21].

4.3.3 Risk of bias

Overall studies were of low to moderate quality. Table 4.3 summarises the risk of bias for each included study. Ghadiri 2015, Sharifi 2012, Hegde 2012 and Li 2005 were rated as having a high overall risk of bias [17, 22-24]. Hegde 2012 was excluded from the synthesis of results due to the high risk of bias and the very low sample size included in the outcome analysis (n=12 in treatment group, n=11 in control group) [22]. The findings of Sharifi 2012 are not included in the meta-analysis due to incomplete data presented in the paper (no denominator is given for outcome data). Allocation concealment was adequately described in only one study, whilst procedures were unclear in ten studies. Five studies were assessed to have a high risk of outcome assessors being unblinded, with two studies having a low risk and four studies having an unclear risk. The risk of bias in relation to selective reporting was difficult to assess in seven studies, whilst one study (which had a published protocol [28]) was assessed as low risk and three studies were assessed as high risk (one of which had a published protocol [29]).

Table 4.3 Quality of included studies

	Random sequence generation (selection)	Allocation concealment (selection bias)	Blinding of outcome assessment (detection)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias	Overall risk of bias
Botha 2014							Low/ unclear
Cai 2015							Low/ unclear
Chatterjee 2014							Low
Ghadiri 2015							High
Hegde 2012							High
Li 2005							High
Ran 2015							Low/ unclear
Sharifi 2012							High
Sungur 2011							Low/ unclear
Xiang 1994							Low/ unclear
Zhang 1994							Low/ unclear

4.3.4 Synthesis of results

4.3.4.1 Symptoms and clinical status

Amongst the seven studies that reported on short-term symptom severity the pooled SMD across all intervention types was 0.95 (95% CI 0.28, 1.61; P 0.005; $I^2 = 95\%$; n = 862), representing a strong effect (see Figure 4.2). Excluding the two studies with a high risk of bias reduced the effect size (though this remained 'strong'), and the precision of the estimate decreased (SMD 0.80 (95% CI 0.07, 1.53; P 0.03; $I^2 = 94\%$; n=676)) (see Appendix A (iii)).

Amongst the two studies that reported short-term clinical status (Xiang 1994 [18] and Ran 2015 [16]) there was weak evidence of an effect; the pooled risk ratio for 'recovered or significantly improved' was 1.64 (95% CI 0.78, 3.44; n = 306) (see Figure 4.3). Ran 2015 also reported on long-term symptom severity, finding no difference between treatment arms at 14 years follow-up [15] (SMD 0.16 (95% CI -0.15, 0.47; P 0.3; n=165) comparing the experimental arm and medication control arm). There was some indication that Group B interventions (multi-component rehabilitation interventions) were less effective at reducing symptoms compared to Group A (psychoeducation focused) and Group C (case management) interventions. However this apparent finding should be viewed with caution given the overlaps between intervention type. All four Group C studies (including Sharifi 2012 [24], which was excluded from the meta-analysis due to insufficient data) found a strong association with improvements in symptoms or clinical status. Whereas, in Group B, Cai 2015 found no impact on symptoms [16] and Chatterjee 2014 found a non-significant difference in PANSS score between treatment arms (p=0.08) [21].

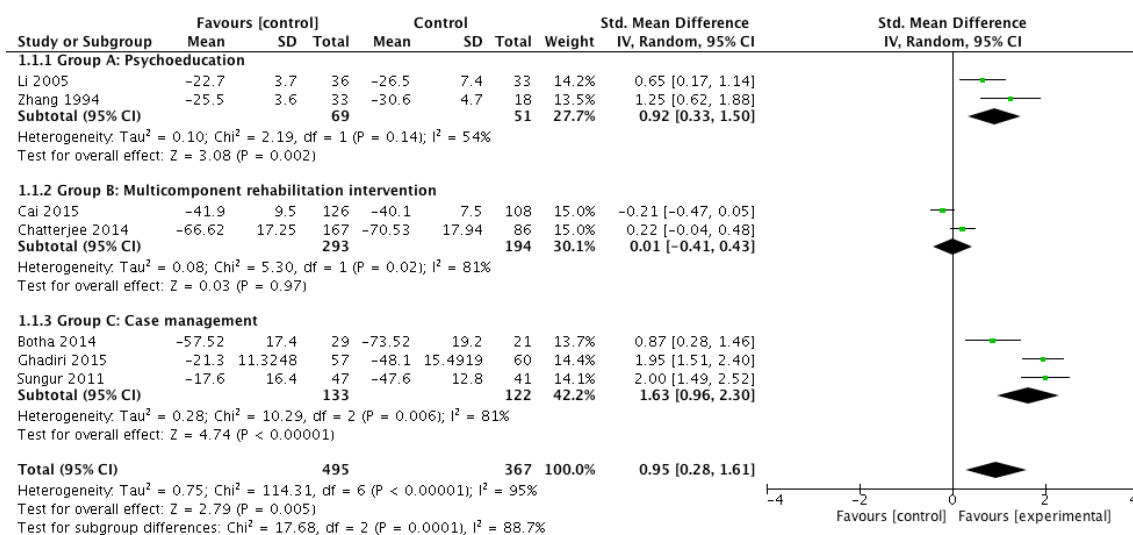


Figure 4.2 Community-based psychosocial intervention versus usual care: impact on symptom severity (short term outcomes)

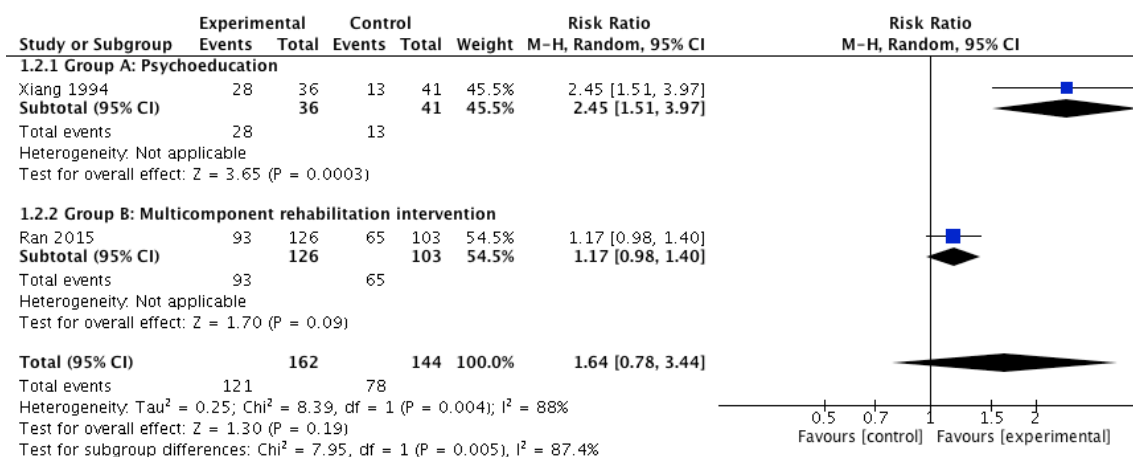


Figure 4.3 Community-based psychosocial intervention versus usual care: impact on proportion recovered or improved (short term outcomes)

4.3.4.2 Functioning

Amongst the five studies that assessed short-term functioning using a continuous scale, the pooled SMD across all intervention types was 1.12 (95% CI 0.25, 2.00; P 0.01; I² = 94%; n = 511), representing a strong effect (see Figure 4.4). All studies in this group were high quality so a sensitivity analysis was not conducted. However, the pooled results of the two studies that measured the proportion able to work in the short-term did not show an association; the pooled risk ratio was 1.09 (95% CI 0.85, 1.40; n=306) (see Figure 4.5). One of these studies, Ran 2015, also measured functioning and work ability after 14 years, but did not find an effect. Comparing

the experimental arm and medication control arm, they found an SMD of 0.16 (95% CI – 0.15, 0.47; P 0.3; n=165) for functioning and a risk ratio of 1.13 (95% CI 0.93, 1.36) for work ability [15]. Once again the Group B interventions appeared to have the least effect on functioning and work ability. Chatterjee 2014, a Group B study, found a small effect on functioning, though reductions in disability were more prominent in the rural site compared to the two better-resourced urban sites [21].

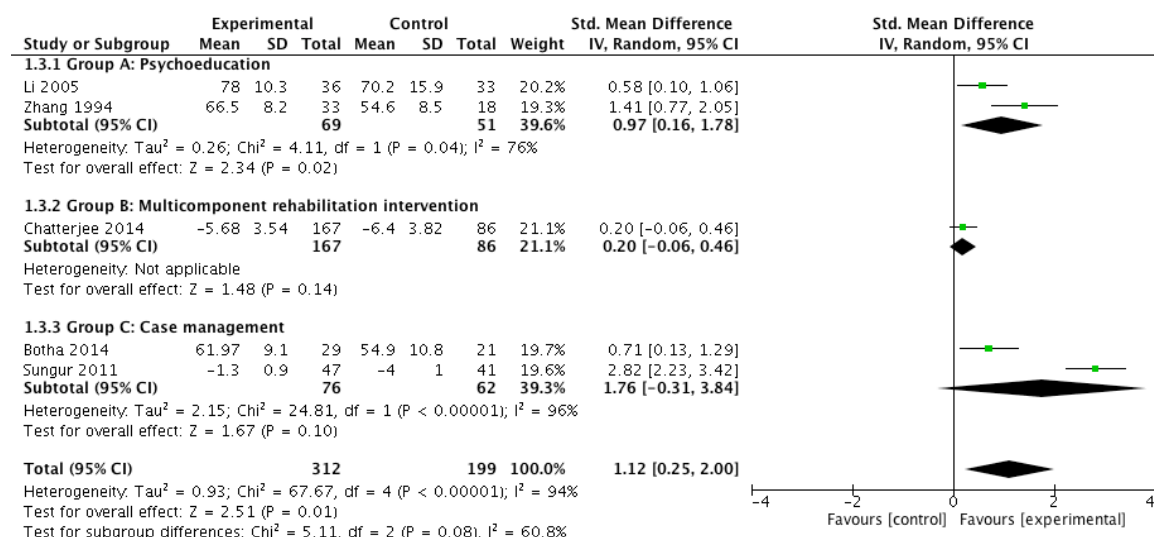


Figure 4.4 Community-based psychosocial intervention versus usual care: impact on functioning (short term outcomes)

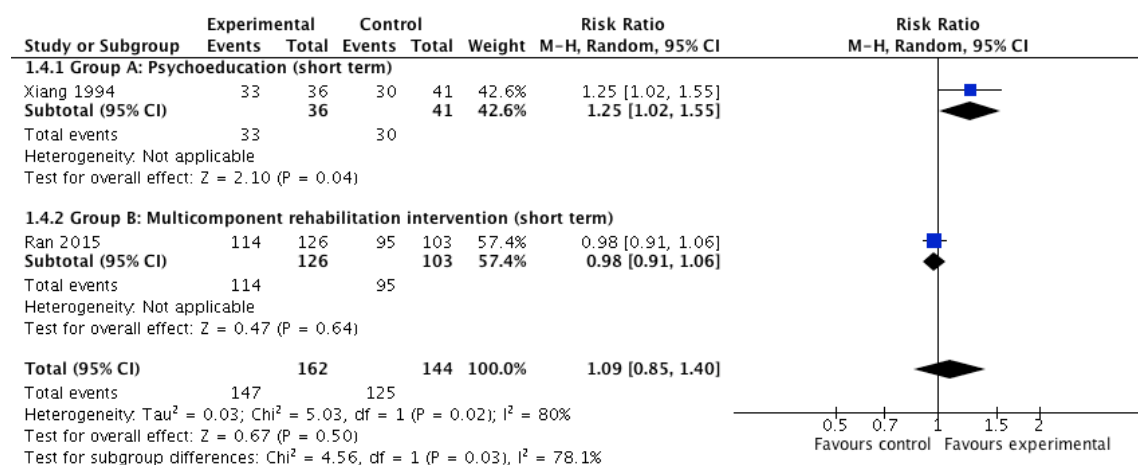


Figure 4.5 Community-based psychosocial intervention versus usual care: impact on ability to work (short term outcomes)

4.3.4.3 Readmissions and inpatient days

Two Group C (case management) studies, Botha 2014 and Ghadiri 2015, reported on the number of readmissions and number of days in hospital in the short term. The pooled SMD for number of readmissions was 0.68 (95% CI 0.27, 1.09; P 0.001; $I^2 = 33\%$; $n=167$) and the pooled SMD for number of days in hospital was 0.55 (95% CI 0.24, 0.86; P 0.0006; $I^2 = 0\%$; $n=167$), both representing a medium intervention effect (see Figures 4.6 and 4.7). The intervention effects remained when Ghadiri 2015, which had a high risk of bias, was excluded. Zhang 1994 (Group A: psychoeducation) also found a positive intervention effect on the proportion with no hospital readmissions over the 18-month period of the intervention (risk ratio 1.83; 95% CI 1.27, 2.64; $n=51$).

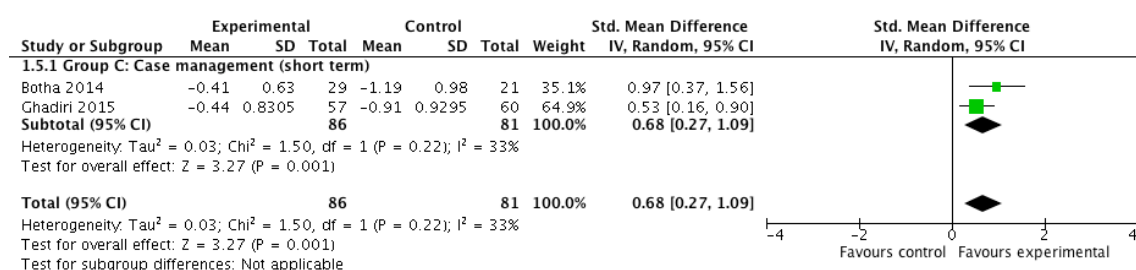


Figure 4.6 Community-based psychosocial intervention versus usual care: impact on number of readmissions (short term outcomes)

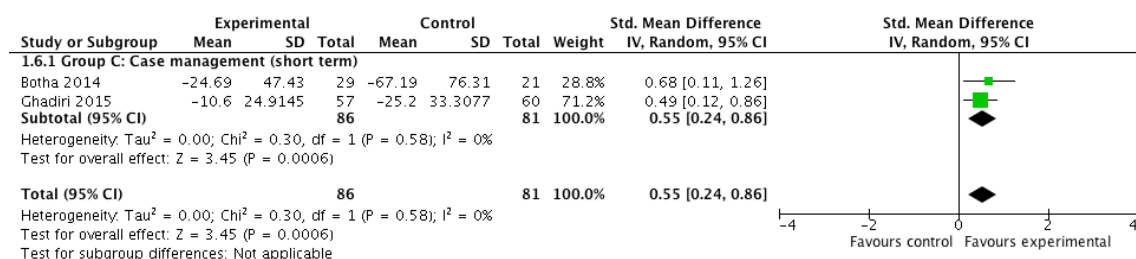


Figure 4.7 Community-based psychosocial interventions versus usual care: impact on number of days in hospital (short term outcomes)

Botha 2014 [25] also reported on long term outcomes at 2 years after the intervention terminated. They found a strong effect on readmissions (SMD 0.96; 95% CI 0.40, 1.52; P 0.0008; $n= 56$) and a medium effect on days in hospital (SMD 0.75; 95% CI 0.20, 1.30; P 0.007). It is difficult to determine if Group C (case

management) interventions confer any advantage over other types of interventions in reducing readmission rates, as this outcome was not measured for any Group B studies and only one Group A study.

4.3.4.4 Medication adherence

Two group A (psychoeducation) and two group B (multi-component rehabilitation intervention) studies reported on the proportion adherent to medication. There was a borderline significant effect including all studies (risk ratio 1.24; 95% CI 0.97, 1.57; P 0.09; I² 55%; n=648) (see Figure 4.8). However the precision of this effect was reduced with the exclusion of Li 2005, which had a high risk of bias (risk ratio 1.33; 95% CI 0.90, 1.97; P 0.16; I²=70%; n=557) (see Appendix A (iii)). No studies assessed the long-term impact on medication adherence.

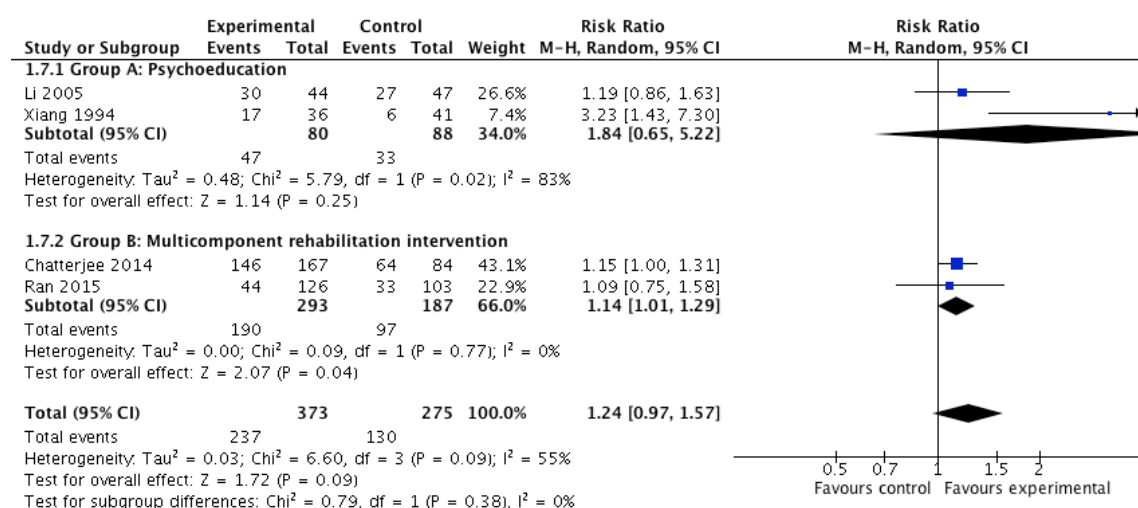


Figure 4.8 Community-based psychosocial intervention versus usual care: impact on medication adherence (short term outcomes)

4.3.4.5 Other outcomes

Three Group C (case management) studies reported on quality of life outcomes. Botha 2015 and Sharifi 2012 reported that there was no observed impact on quality of life but did not present the relevant data [24, 26]. However Sungur 2011 found a strong intervention effect on quality of life (SMD 2.05; 95% CI 1.53, 2.57; P <0.001; n=89) [27].

Of the two studies that reported caregiver burden, only Sungur 2011 found an effect (SMD 2.50; 95% CI 1.93, 3.06; $P < 0.001$) [27]. No impact on family burden was observed in Chatterjee 2014 (Group B); insufficient data were provided to calculate the SMD [21].

Two studies, Li 2005 (Group A) and Ran 2015 (Group B), reported significant improvements in knowledge and beliefs about schizophrenia [16, 17]. Li 2005 found a strong intervention effect (SMD 1.04; 95% CI 0.54, 1.55; $P < 0.001$; $n=69$). Ran 2015 reported favourable differences between treatment arms for six out of eight individual items covering caregiver beliefs and knowledge [16]. No impact on knowledge was observed in Chatterjee 2014 (Group B) (adjusted mean difference 0.34; 95% CI -0.28, 0.96; insufficient data were provided to convert to SMD) [21]. Chatterjee et al (Group B) were the only study to evaluate the impact on stigma and discrimination; they did not demonstrate an intervention effect [21].

4.4 DISCUSSION

4.4.1 Summary of findings

Overall community-based psychosocial interventions in LMICs may have beneficial impacts for people with schizophrenia including reducing symptoms, improving functioning and reducing hospital readmissions. Whilst in some cases there was a substantial impact on outcomes, in other studies such as Chatterjee 2014 the impact was slight. However this magnitude of impact may be no worse than community-based programmes in high-income countries [21]. There was evidence from only one study, of assertive community treatment in South Africa [25], that positive effects could endure for two years after the intervention terminated. Most studies did not evaluate ongoing effects. Much of the evidence was judged to be of low or unclear quality, meaning conclusions about the effectiveness of these interventions should be made with caution.

The nature of usual care, which differed considerably between studies in this review, should be taken into account when assessing the strength of the evidence. In evaluations where usual care is comprehensive (for example medication, psychoeducation and adherence support offered by psychiatrists in Chatterjee

2014 [21]), smaller gains may be expected from the provision of an adjuvant intervention compared to evaluations with a low level of usual care (for example medication only in the Chinese psychoeducation-focused RCTs [17-19]). Chatterjee et al also pointed to the greater impact on disability seen amongst the sub-group who had not previously had access to high-quality facility-based care, compared to those who had [21]. However this supposition does not necessarily hold true; for example Sungur 2011 saw some of the biggest effect sizes yet had one of the most comprehensive packages of usual care (outpatient-based case management) [27].

Several possible mechanisms for the impact of community-based psychosocial interventions present themselves. Supported engagement with treatment and an improved understanding about the nature of the illness and importance of medication, by both caregivers and the person with schizophrenia, may lead to improved medication adherence. This in turn may result in improved symptoms and therefore lower relapse rates and fewer hospitalisations. Chatterjee et al reported a trend towards improved symptoms with improved medication adherence [21], a pattern that has been identified in cohort studies in other LMICs [30]. However only four studies included in this review assessed medication adherence and overall there was a borderline intervention effect. The challenges of intervening to improve medication adherence have been noted across all settings and are not exclusive to mental disorders [31].

It is striking that all types of interventions, including psychoeducation on its own, produced a positive effect on functioning. This may be due to an improvement in symptoms. On the other hand, symptoms and functioning are not necessarily correlated [8, 32-34]. Other possible pathways to improved functioning are through the impact of improved social skills, improved self-esteem, greater caregiver support, reduced self-stigma or discrimination, or an increased sense of empowerment. However there was almost no assessment of these potential intermediary factors in the included studies. Where the outcomes of quality of life, family burden and perceived stigma were reported, there was less evidence for a beneficial effect of community-based psychosocial interventions.

4.4.2 Strengths and limitations

Strengths of this study include the exhaustive search strategy, inclusive inclusion criteria with respect to intervention content and the robust assessment of study quality. Capturing and synthesising the results of all relevant studies that share the core elements of home-based psychoeducation for schizophrenia in LMICs is a strength of this review. On the other hand, the interventions varied considerably in terms of content, intensity, duration and delivery personnel; the utility of drawing together such a diverse range of programmes is questionable. The interventions were divided into sub-groups for the meta-analysis but there was variation within groups and overlap between groups.

Whilst the search strategy captured the spectrum of intervention content that may be defined as a community-based psychosocial intervention, rehabilitation programmes based in specialist centres (e.g. [35]) were excluded. This was arguably an unhelpful division, which would not reflect the integrated programming and delivery of psychosocial interventions for schizophrenia in many settings. Outpatient-clinic based psychosocial interventions also represent an important component of services for people with mental illness in LMIC [36]. There is a growing evidence base for such interventions (e.g. [37, 38]) that also requires systematic review. Other methodological limitations of this review include the single screening of records and exclusion of reports not published in English.

4.4.3 Implications

Whilst some of the included studies discussed the feasibility and relevance of the intervention for local health systems and other LMICs [21, 25], for many studies it was not clear how or whether interventions could be integrated [17, 20]. Future research should be cognisant of the wider health system, as well as the broader social and economic setting. All but one of the included interventions were delivered by trained health care workers, often mental health specialists, or otherwise by researchers. This is likely to reflect the upper middle-income setting of nearly all included studies. Even in the COPSI trial, Chatterjee 2014, in which community-based support was delivered by lay health workers, participants received care from psychiatrists in parallel [39]. Moving forward, RCTs of

community-based psychosocial interventions are needed in low-income settings, where due to a shortage of human resources the most appropriate personnel are likely to be non-specialist or lay workers.

Another possible gap in the evidence relates to the scope of interventions. All interventions in this review focused mainly on health issues, though in some cases touching on social and livelihood elements through skills training. Furthermore there was little emphasis on community mobilisation, beyond the awareness-raising component mentioned in two studies. Where the intervention involved supporting access to community resources, there was no detail on whether or how participants accessed these resources. These broader community mobilisation and rehabilitation components form some of the key elements of CBR. As there is some evidence for the effectiveness of the included studies without these broader components, it is arguable that these elements are not required to achieve improvements in patient outcomes. However it is possible that in low-income settings with few formal health resources, no social security and where the impact of inability to work may be more profound, broader efforts to draw on local community resources and to address livelihood issues may have more relevance. It is also possible that community-based psychosocial interventions may have the greatest potential for impact in settings with weaker facility-based care.

Only three studies assessed outcomes of between 6 months and 13 years after the interventions had terminated [15, 17, 20]. Such study designs, which give valuable information on how to shape psychosocial interventions for scaling up, should be utilised where possible in future research. Of the eleven included studies, only Chatterjee 2014, is known to have conducted in-depth intervention development and piloting in advance of the full evaluation [40], as well as collecting process data [21] and conducting a qualitative analysis alongside the trial [41]. For multi-component interventions, theoretical frameworks for the process of change need to be developed to understand which elements contribute towards any impact seen, and why certain elements do or do not contribute to positive effects for participants. Full process evaluations, as well as parallel qualitative studies, are likely to be required. This is particularly pertinent in low-resource settings where low-intensity interventions, employing only the most effective components, may be more feasible. Alongside a general need for high quality evaluations of

community-based psychosocial interventions for schizophrenia, future studies also need to identify and evaluate intermediate outcomes to better understand the mechanisms through which these interventions achieve their impact.

The next chapter describes the development of a CBR intervention for people with schizophrenia in Ethiopia.

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5 INTERVENTION DEVELOPMENT

5.1 INTRODUCTION

The previous chapter presented a systematic review of the effectiveness of community-based psychosocial interventions for people with schizophrenia in LMIC. The review highlighted the need for high-quality evaluations of such interventions in low-income countries. As the only study identified in this review that was delivered by non-specialist workers, the COPSI trial by Chatterjee et al [1] offered a promising framework for a community-based intervention for schizophrenia in Ethiopia. However the potential utility of expanding to a broader CBR approach, including a community mobilisation component, was also identified. The current chapter presents a published paper on the rigorous development work undertaken to design a CBR intervention for people with schizophrenia in Ethiopia. This paper represents the 'Development' stage of the MRC framework presented in Chapter 3 [2]. The first stages of the theory of change process are described in this paper, including two theory of change workshops and the development of an initial theory of change map. The relevant appendices are listed in Section 5.3.

5.2 RESEARCH PAPER

Notes on manuscript

1. *Page 3 of manuscript (Introduction): The 'community awareness-raising' component of the PRIME mental healthcare plan was not delivered in Sodo district.*
2. *Page 14 of manuscript (Summary of final RISE intervention): The text should indicate that Phase 2 was expected to last approximately four months and Phase 3 was expected to last approximately six months (in line with Figure 2 in the manuscript)*
3. *Page 14 of manuscript (Summary of final RISE intervention): The text should indicate that family support groups were also a planned component of the intervention. Further details are provided in Chapter 6 (Section 6.3.7)*

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Student	Laura Asher
Principal Supervisor	Vikram Patel
Thesis Title	The development and evaluation of community-based rehabilitation intervention for people with schizophrenia in Ethiopia

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

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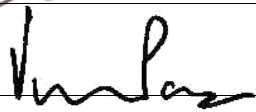
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RESEARCH ARTICLE

Development of a Community-Based Rehabilitation Intervention for People with Schizophrenia in Ethiopia

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Abstract

Background

Community-based rehabilitation (CBR) is a multi-sectoral strategy to improve the functioning and quality of life of people with disabilities. The RISE (Rehabilitation Intervention for people with Schizophrenia in Ethiopia) trial will evaluate the effectiveness of CBR for people with schizophrenia in Ethiopia. Nevertheless, the components of CBR that are both feasible and likely to prove effective in low and middle-income countries such as Ethiopia are unclear.

Methods

In this study intervention development work was undertaken to design a CBR intervention that is acceptable and feasible in the local context. The development work consisted of five phases. 1: Identify potential components of CBR for schizophrenia, 2: Situational analysis, 3: Determine feasibility of CBR (Theory of Change workshops with experts and local stakeholders), 4: Determine acceptability of CBR (16 in-depth interviews and five focus group discussions with people with schizophrenia, caregivers, health workers and community leaders) and 5: Synthesise results to finalise intervention. A Theory of Change map was constructed showing the causal pathway for how we expect CBR to achieve its impact.

Results

People with schizophrenia in rural Ethiopia experience family conflict, difficulty participating in work and community life, and stigma. Stakeholders perceived CBR to be acceptable and useful to address these problems. The focus of CBR will be on the individual developing the skills and confidence to perform their previous or desired roles and activities. To ensure

necessarily represent the official views of any of the funders.

Competing Interests: The authors have declared that no competing interests exist.

Abbreviations: CBR, Community-based rehabilitation; COPSI, COmmunity care for People with Schizophrenia in India; LMIC, Low and middle Income countries; NGO, Non governmental organisation; PRIME, PRogramme for Improving Mental healthcarE; RAPID, Rehabilitation And Prevention Initiative against Disabilities; RCT, Randomised controlled trial; RISE, Rehabilitation Intervention for people with Schizophrenia in Ethiopia; WHO, World Health Organisation.

feasibility, non-health professionals will be trained to deliver CBR and provide supervision, rather than mental health specialists. Novel components of CBR for schizophrenia included family intervention and dealing with distressing symptoms. Microfinance was excluded due to concerns about stress and exploitation. Community mobilisation was viewed as essential to ensure the effectiveness and sustainability of CBR.

Conclusion

Extensive formative research using a variety of methods has enabled the design of a culturally appropriate CBR intervention for people with schizophrenia that is acceptable and feasible.

Introduction

Many people with schizophrenia experience severe and chronic illness; in Ethiopia 38% had episodic symptoms and 19% had continuous symptoms over a 10-year period whilst 11.8% had complete remission after one episode [1]. Reflecting global patterns, in Ethiopia, people with schizophrenia have high levels of disability [2], family burden [3], stigma [4, 5], and mortality [6]. Despite this, the majority of people with schizophrenia in low and middle income countries (LMIC) do not have access to adequate care; in Ethiopia, the treatment gap is 90% [7]. Human rights violations also occur [8] and many are the victims of violence [9]. Treatment with antipsychotic medication alone is often not adequate to achieve functional recovery and social reintegration [11]. Psychosocial or psychiatric rehabilitation is recognised globally as an essential component of care for people with schizophrenia. Psychosocial rehabilitation is “a process that facilitates the opportunity for individuals... to reach their optimum level of independent functioning in the community” [12]. There is also increasing agreement that the management of schizophrenia should be guided by the principle of recovery, in which the focus is on empowerment, self-direction, personal responsibility and hope [13, 14]. The WHO’s mental health Gap Action Programme (mhGAP) recommends that schizophrenia management should include psychosocial interventions, including community-based rehabilitation (CBR), where available, although evidence from LMIC settings is limited [15, 16]. CBR is a strategy that aims to reduce disability and improve the quality of life and social inclusion of people with disabilities. CBR echoes the ethos of psychosocial rehabilitation, particularly drawing on recovery values, whilst reflecting the particular needs of low-income settings [17].

Programmes cover one or more of the CBR pillars (health, education, livelihoods, social and empowerment), focused on facilitating individuals to access existing resources [17]. CBR is put into practice through the joint endeavours of people with disabilities, their caregivers, community members and public sector services e.g. health services [18]. There is a long-standing tradition of CBR and a global network of CBR programmes, but these have historically focused on other disabilities. There is now increasing recognition that people with mental illnesses may receive substantial benefit from CBR. As such mental health has been incorporated into CBR programmes in Sri Lanka, India, West Africa, China and Latin America [17, 19–21]. A systematic review found that aspects of CBR may improve clinical outcomes and functioning for schizophrenia, dementia and intellectual disabilities in LMICs [18]. There is evidence from randomised controlled trials (RCTs) to support the effectiveness of assertive community treatment (ACT) for people with schizophrenia in South Africa [22] and psycho-educational family interventions in China [23, 24]. However no RCTs of holistic packages of CBR for

schizophrenia that involved community mobilisation (defined as “a strategy which aims to engage community members and empower them for change or action”[17]) or that focused primarily on any pillar other than health, were included [18]. The more recent COmmunity care for People with Schizophrenia in India (COPSI) trial [25] found collaborative community care modestly improved disability and symptoms in people with schizophrenia [26]. Whilst influenced by CBR, the intervention did not include community mobilisation.

In summary, CBR is a promising intervention for people with chronic and disabling schizophrenia (due to illness factors or structural factors which lead to drop out from care) particularly in low-income settings where treatment options for this group are limited. Yet there has been no systematic adaptation of comprehensive CBR for people with schizophrenia nor assessment of its effectiveness in low and middle-income countries. The Rehabilitation Intervention for people with Schizophrenia in Ethiopia (RISE) project aims to adapt CBR for people with schizophrenia in a rural Ethiopian setting and to assess its effectiveness. The RISE trial (NCT02160249) will determine whether CBR as an adjunct to facility-based care is superior to facility-based care alone in reducing disability in people with schizophrenia who remain symptomatic or disabled after six months of treatment. This will be the first comprehensive CBR programme for mental illness to be evaluated in a clinical trial in Africa. The intensive CBR intervention will be targeted at those with the greatest need. The rationale for this is (i) the aim of CBR is to reduce disability, so it is appropriate primarily for those who are disabled and (ii) to increase feasibility for scale-up by restricting the intervention to those most in need. RISE is nested in PRIME (Programme for Improving Mental healthcarE), a five-country research consortium, including Ethiopia, which aims to generate evidence on the integration of mental health into primary care in LMIC [27, 28]. As part of PRIME, primary care staff in Sodo district, Ethiopia, have been trained to deliver packages of care for people with schizophrenia including prescription of antipsychotic medication, follow-up, limited adherence support, basic psychoeducation and community awareness-raising [29]. Psychoeducation refers to the education of people with mental illness to increase their knowledge and understanding of their treatment and illness. This facility based care constitutes treatment as usual in the control arm of the RISE trial, and will be delivered in conjunction with CBR in the intervention arm.

The importance of intervention development prior to testing complex mental health interventions is widely acknowledged, particularly in LMIC [30–33]. This work helps to design an intervention that is acceptable and feasible to both its recipients and those delivering it, and is ultimately more effective. The particular benefits include:

- Ensuring the intervention is appropriate to local resources and health services structures [32, 34].
- Identifying contextually-mediated barriers to delivery [33].
- Ensuring the cross-cultural applicability and relevance [30].
- Getting buy-in from national and local stakeholders [30].

This paper summarises the formative research used to design an acceptable, feasible and sustainable CBR intervention that is likely to be effective for people with schizophrenia in Ethiopia, to be tested in a pilot and subsequently in the RISE trial. At the outset we acknowledged two key challenges. First, how to develop a CBR intervention in a setting with few public sector mental health resources. Second, how to strike the balance between an intervention which is likely to be effective and one that might realistically be scaled up in the context of limited resources in a rural LMIC setting.

Research questions

1. Which components of CBR are likely to be effective at improving functioning for people with schizophrenia?
2. Is CBR useful, acceptable and feasible from the perspective of people with schizophrenia and their caregivers?
3. What health service structures exist and how can they support CBR?
4. Is it possible to recruit, train and retain non-health workers to deliver CBR?
5. What community resources are available and are they accessible to people with schizophrenia?
6. Are community leaders willing and able to participate in CBR?
7. How can the positive effects of CBR be sustained?

Methods

This study used a range of qualitative and participatory methodologies in five phases from September 2012 to March 2014. Intervention development was guided by a Theory of Change approach [35] in conjunction with the Medical Research Council framework for complex interventions [36]. The Theory of Change map provides a graphic representation of the causal pathways through which the RISE intervention is expected to achieve its impact [35]. The map includes (i) the final outcome (improved functioning in people with schizophrenia), (ii) intermediate outcomes that are needed to achieve the final outcome, (iii) interventions which are needed to move from one outcome to the next, (iv) assumptions (the conditions which the causal pathway needs in order to progress), (v) rationale for each link in the pathway and (vi) indicators (to evaluate whether each outcome is achieved). Assumptions articulated by the Theory of Change formed the research questions to be answered. We refined the map throughout the process as assumptions were tested and turned into rationale, or the intervention design was modified to fulfil assumptions.

Ethics statement

The London School of Hygiene & Tropical Medicine Research Ethics Committee (reference 6408) and the Addis Ababa University College of Health Sciences Institutional Review Board (reference 039/13/PSY) granted ethical approval. Written informed consent was obtained from all participants in the in-depth interviews and focus group discussions. Only people with schizophrenia who had stable illness were invited to participate. Prior to conducting the interviews the psychiatrist assessed the individuals' decision-making capacity. Only individuals judged to have decision-making capacity were included; these individuals continued to the consent process. Verbal informed consent was obtained from all participants in the Theory of Change workshops and recorded in the workshop notes. Individual written informed consent was not sought from workshop participants as the workshops were a participatory planning process; the workshops were not audio-recorded; vulnerable groups, i.e. people with schizophrenia or caregivers, were not included in the workshops; and the workshop outputs were two Theory of Change maps formed by group consensus (contributions were not attributed to individual participants).

Phase 1: Identification of potential components of CBR for schizophrenia

Objectives. (i) Identify potential components of CBR and their likely effectiveness and (ii) describe how components could improve functioning.

Methods. A literature review of CBR for schizophrenia in LMIC was conducted. Other psychosocial interventions were also reviewed because CBR consists of many elements that have typically been evaluated separately. We reviewed resources from the WHO (CBR Guidelines) [17], COPSI [37], Rehabilitation And Prevention Initiative against Disabilities (RAPID) project, and other similar projects. RAPID is an Ethiopian CBR project for children with disabilities. RAPID is a local collaborator on RISE and is affiliated with CBM, an international disability and development organisation. Site visits and in-depth consultation with the RAPID management team were conducted. The collated information was used to create a draft Theory of Change map for how the CBR components could improve functioning in people with schizophrenia.

Phase 2: Situational analysis

Objectives. (i) Describe the socio-demographic characteristics, health services and community resources of Sodo and (ii) describe the situation of people with schizophrenia in this context.

Methods. We drew on work conducted by the PRIME project in Sodo district, which has been described in detail elsewhere [33, 38–40]. In brief it involved (i) reviewing a situational analysis, which comprised public domain data relating to population, health and social indicators; mental health policies and plans; mental health treatment coverage and district level services [38] (ii) reviewing resource mapping data collected using a semi-structured instrument to systematically quantify community assets, for example traditional healers and religious groups and [39] (iii) reviewing qualitative data on the acceptability and feasibility of task-sharing mental health services [33, 40]. In addition rich local data relating to prevalence [41], clinical course and outcome [1, 7, 10], disability [2], mortality [6, 42], access to health services [10], beliefs [43, 44], caregiver burden [3, 45], experiences of stigma [4, 5, 9] and use of traditional healers [43] relating to schizophrenia was reviewed.

Phase 3: Evaluation of the feasibility of CBR

Objectives. (i) Determine the feasibility of CBR components and delivery mechanisms and (ii) get local 'buy-in' for RISE.

Methods. The scoping workshop and first Theory of Change workshop involved eight experts in CBR and mental health. The second Theory of Change workshop included twenty community leaders from Sodo, including representatives of microfinance, *edir* (traditional burial association), education, police, traditional healers and religious leaders. Each workshop lasted half a day; the expert workshops were facilitated in English and the community workshop was facilitated in Amharic by an Ethiopian investigator (AF). At each workshop a large-scale (approximately 2 metres x 3 metres) draft Theory of Change map was presented to workshop participants and the various components explained. The map was refined in real time by investigators by adding notes on colour-coded paper and linking arrows. Photographs were taken of the map at the end of each workshop to maintain a visual record of the discussion. In addition, detailed minutes were taken in English by an Ethiopian research assistant. Following the workshops these visual and written records were combined to update the Theory of Change map.

Phase 4: Evaluation of the acceptability of CBR

Objectives. (i) Describe unmet needs of people with schizophrenia and (ii) determine the acceptability of CBR.

Methods. We conducted 16 in-depth interviews and five focus group discussions (including 35 participants) with people with schizophrenia, caregivers, community and religious leaders, traditional healers, RAPID CBR workers, health extension workers and primary healthcare workers (see [Table 1](#)). Health extension workers are salaried community health workers engaged in health promotion and disease prevention. Participants were identified through the district health bureau (for staff), RAPID CBR project, and Butajira psychiatric outpatient clinic. Participants were purposively selected to ensure a spread of gender, work experience, type of community leader and functioning of people with schizophrenia. Topic guides covered key issues around acceptability and feasibility. The In-depth interviews and focus group discussions were conducted in Amharic by a male Ethiopian psychiatrist and a male Ethiopian PhD student (with a Psychology MSc). Both had experience in conducting interviews and discussion groups with people with schizophrenia and caregivers. The participants were contacted by telephone or face-to-face to invite them to participate; no potential participants refused to take part. The interviews were conducted at health centres and the research office in Butajira, a private room in Bui town, and the RAPID office in Adama. Participants were given information about the purpose of the study prior to the interviews, but no other relationship between the researchers and participants was established in advance. In-depth interviews lasted between 40 and 60 minutes and focus-group discussions lasted between 60 and 120 minutes and all were audio-recorded. The investigator conducting the main analysis (LA) observed all interviews and focus groups. Debrief discussions with the interviewers were held immediately afterwards; initial impressions and observations were captured in field notes. No repeat interviews or participant checking was carried out. The audio-recordings were transcribed in Amharic, and then translated into English. A framework analysis was conducted; this approach is recognised as suitable for intervention development work as interviews are typically structured with clear a priori themes [46]. NVivo for Mac software was used to manage the data. A coding scheme was developed using a priori core themes based on the topic guide (e.g. ideal characteristics of a CBR worker); and subsequently sub-themes and new themes that emerged through reading the manuscripts. Two investigators indexed two transcripts using the codes developed. Discrepancies between applications of the coding scheme were discussed and adjustments were made where required. One investigator then indexed all transcripts using the final coding scheme. A matrix was created charting data relating to each theme against each participant. Finally,

Table 1. In-depth interviews and focus group discussion participants.

Stakeholder	Number of in-depth interviews	Number of focus group discussions
People with schizophrenia (male)	3	0
People with schizophrenia (female)	2	0
Caregivers (male)	1	1 (n = 8)
Caregivers (female)	1	1 (n = 7)
Community leaders (male)	7	0
Health extension workers	0	1 (n = 8)
Primary care workers	0	1 (n = 6)
CBR workers	2	1 (n = 6)
Total	16	5 (n = 35)

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themes were summarised and interpreted, noting associations between themes and patterns relating to participant characteristics (e.g. gender). Further interviews and focus groups were conducted until data saturation was reached.

Phase 5: Synthesis of results to finalise intervention

Objectives. (i) Finalise CBR content and delivery and (ii) develop CBR training materials.

Methods. A three-day intervention-planning workshop involved Ethiopian psychiatrists, the CBM West Africa mental health advisor, CBM Ethiopia director, RAPID manager, and the senior health administrator for Sodo. The synthesised findings of Phases 1 to 4 were presented to participants, who decided the detailed content and structure of the intervention. The final Theory of Change map is presented in [Fig 1](#).

Results

The following section details how the research questions were answered using the different methods, and how these findings contributed to the final intervention (see [S1 Table](#) for details). [Table 2](#) summarises the key themes generated from the in-depth interviews and focus group discussions (Phase 4).

1. Which components of CBR are likely to be effective at improving functioning for people with schizophrenia?

Potential components of CBR for schizophrenia were listed according to the CBR pillars (health, social, livelihood, empowerment and education- see [Table 3](#)); whilst many relate to health, other pillars were also represented. The strongest evidence related to psycho-education [[47–52](#)], family intervention [[23, 24, 53, 54](#)] and adherence support [[55, 56](#)]. Multi-component interventions were effective, but it was difficult to elucidate their 'active ingredient/s' from the results [[19, 20, 26](#)]. We took into account whether potential CBR components were likely to be effective for the 'difficult to treat' group who will participate in the RISE trial. Novel components of CBR for schizophrenia included family intervention, stress and anger management and dealing with distressing symptoms (e.g. hallucinations and delusions). A schema of how CBR components could improve functioning was incorporated into the Theory of Change map ([Fig 1](#)). Many components may act in synergy, and also through intermediate outcomes and positive feedback loops. For example rehabilitation focused on returning to farm work, as well as directly improving functioning, may improve the ability of individuals to pay for medication, which in turn improves symptoms and therefore functioning. Support with medication adherence is also likely to improve symptoms; together with a family intervention this will reduce the need for physical restraint, which would also lead to return to previous functional roles.

There was strong support for community mobilisation from all stakeholders. Disability arises due to both illness and societal factors [[57](#)] so an intervention addressing both elements is indicated. There was consensus that community leaders have a powerful influence on the views of the community and are gatekeepers to community resources needed for CBR (*"The community won't believe in things that the leaders don't believe in"* (FGD 03, health extension worker)). This was an important finding given the strong influence of stigma on the experiences and social functioning of people with schizophrenia. Structured community mobilisation was therefore prioritised to maximise the effectiveness and sustainability of CBR. As shown on the theory of change map, identification and mobilisation of community resources are intermediate outcomes that are necessary foundations for ensuring the sustainability of the family level interventions.

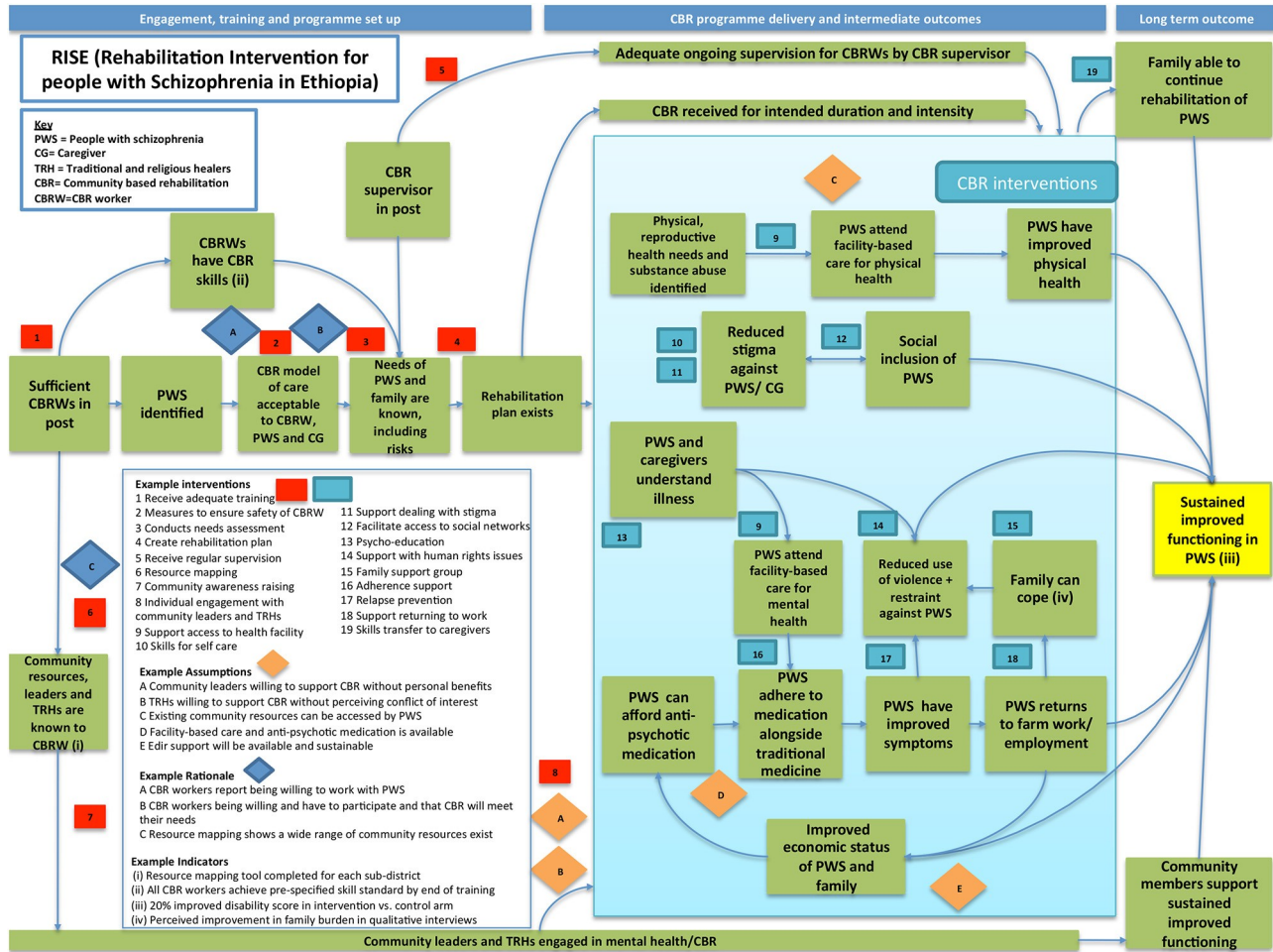


Fig 1. RISE Theory of Change map.

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2. Is CBR useful, acceptable and feasible from the perspective of people with schizophrenia and caregivers?

People with schizophrenia and caregivers were found to have a range of unmet needs and problems. Issues included conflict within families, being estranged from friends, difficulty doing housework, farm work and business and problems with self-care. Many participants with schizophrenia and caregivers reported experiences of stigma and other types of participants were aware it was a common occurrence. Instances included being called names, being laughed at or gossiped about, losing friends, being discouraged from participating in social life, and not being trusted in the workplace or in other settings. One male caregiver reported, “No institution, no organization invites persons with mental illness to participate... because they are people with problems, saying that they will ruin things... they will not perform the work properly” (FGD 01, male caregiver). Another caregiver explained, “They won’t accept their word. Even if he [her son with schizophrenia] speaks the truth, they would say, ‘he is a patient, don’t say anything back’. He is a patient. Now they say, ‘is he possessed by the devil?’” (FGD 02, female caregiver). Problems with participating in conventional community activities, for example drinking coffee with family and neighbours, attending church or mosque and attending weddings and funerals, were also reported. Participants named a variety of reasons for these problems,

Table 2. Summary of findings from in-depth interviews and focus group discussions.

Research question	Theme	Findings
Which components of CBR are likely to be effective?	<i>Necessity of community mobilisation element</i>	Community leaders have powerful influence on the community's beliefs
		Community leaders are gatekeepers to community resources
Is CBR useful, acceptable and feasible from the perspective of people with schizophrenia and caregivers?	<i>Current problems and needs</i>	Family conflict
		Estranged from friends and neighbours
		Difficulty doing housework, farm work and business
		Problems with self care
	<i>CBR content</i>	Stigma and discrimination
		Problems participating in community activities
		High caregiver burden
		CBR perceived as acceptable and useful overall
		Caregivers and community leaders thought returning to work as central to regaining functional role and economic status; people with schizophrenia concerned about stress.
		Personal experiences of physical restraint or awareness of the practice amongst most participants; best approach to address this felt to be improved access to mental healthcare
<i>CBR delivery</i>	Most participants preferred home visits	
	Some participants preferred CBR workers the same gender as participants; others had no preference	
	Desirable characteristics of CBR workers included being caring, understanding and knowledgeable, and having a good understanding of the local community	
Is it possible to recruit, train and retain field workers to deliver CBR?	<i>Willingness of CBR workers</i>	Motivation to work with people with schizophrenia.
		Fears the work could be risky or stigmatizing
	<i>Ability of CBR workers</i>	Confident of ability to do work.
		Importance of field training, top-up training and peer supervision stressed
What community resources are available in Sodo and are they accessible to people with schizophrenia?	<i>Accessibility of community resources</i>	Problems accessing community resources due to stigma, problems with social interactions, lack of motivation and being symptomatic.
	<i>Role of edir (traditional burial association)</i>	Suggested role of <i>edir</i> included financial/material support, awareness raising, higher threshold for exclusion of people with schizophrenia when not contributing
Are community leaders willing and able to participate in CBR?	<i>Willingness of community</i>	Community leaders report sense of responsibility to support people with schizophrenia.
		Caregivers sceptical that support will be available.
	<i>Willingness of traditional or religious healers to participate</i>	Healers reported willingness to signpost to health centre/ medication.
		Some reports of healers warning against medication use. Mixed views as to whether healers would receive education and change practices.
	<i>Willingness to work with either gender</i>	Community leaders state they are willing to work with CBR workers of either gender- skills are more important than gender

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Table 3. Potential components of community-based rehabilitation for schizophrenia.

HEALTH	SOCIAL	LIVELIHOOD	EMPOWERMENT	EDUCATION
Psycho-education ++	Support with self-care +	Facilitating access to social protection +	Addressing human rights -	Facilitating access to adult education -
Adherence support ++	Social skills training +	Supporting return to work +	Individual stigma reduction strategies -	
Family intervention ++	Supporting return to social activities +	Facilitating access to microfinance +	Self-help initiatives +	
Relapse prevention plan +		Mobilising community support +	Community-awareness raising -	
Support for distressing symptoms +				
Support accessing health services +				
Stress and anger management +				

Strength of evidence in literature review:

(++) Strong evidence

(+) Weak evidence/ part of multi-component study

(-) Insufficient studies.

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including side effects of medication, being unwell or unmotivated, having poor social skills, and stigmatising attitudes of community members. The range of needs highlighted the requirement for detailed needs assessments for participants. CBR would then be tailored accordingly, as opposed to a ‘one size fits all’ approach. Focusing on the participants’ expressed needs was perceived to be an important approach for maintaining engagement in the programme.

Caregivers were found to have high burden relating to financial problems (often due to costs of treatment), fear for personal safety, stigma and problems with social life. One caregiver said, “*We hide knives and tools from him because we are scared of him... Just in case he got upset all of a sudden... He might kill someone or he might destroy or burn someone’s property*” (IV02, female caregiver). Several reported that they had become ill through caring: “*We all became sick because of him*” (IV03, male caregiver). In light of this, guidance on assessing and addressing caregiver problems was added to the intervention.

All stakeholder groups viewed CBR as an acceptable and useful approach. First, because medication alone did not solve all problems; psychosocial support and rehabilitation were also needed. Second, because external ‘expert’ advice was likely to have greater influence on individuals with schizophrenia than advice from family members. Third, because an individual’s recovery could benefit the whole community, particularly if they could return to work. Finally, CBR was seen as empowering (“*[CBR] is essential for people with mental illness...to live on equal bases in terms of ways of thinking and attitude*” (FGD 01, male caregiver).

For many participants, support returning to work was crucial for improving functioning, economic status and reducing family burden. However there were mixed views from people with schizophrenia. One participant was keen to receive a business loan, whilst two others only wanted simple work, and found dealing with money stressful. Most people in Sodo are subsistence farmers, there is limited formal employment and no vocational rehabilitation facilities. Accordingly, it was decided that vocational rehabilitation, whilst important, would typically focus on developing skills required for returning to farm work or daily labouring. Due to concerns that microfinance (such as cooperative savings and loans schemes) may increase stress in participants [58, 59] or may result in exploitation, it was decided to exclude a microfinance

component from the RISE intervention. There was also particular backing for psycho-education, family support and support with adherence and accessing health services. Furthermore, the qualitative findings indicated that specific components were needed to address problems with day to day functioning (for example dressing independently) and participation in community activities (to include support with regaining specific social skills).

Some participants perceived self-help groups as useful for support and information sharing. There were examples of female caregivers and people with schizophrenia already meeting to discuss their problems. Together these findings suggested self-help initiatives could be a useful component, even without a savings and loans element.

Most participants were aware of physical restraint of people with schizophrenia, with some speaking from personal experience. The reasons for restraint included protecting the individual (from themselves or others), protection of others, as a means to transport the person to the health centre, and as a means to force the individual to take medication.

Consensus across stakeholder groups was that the best way to reduce chaining was to increase access to treatment. Community leaders felt the family should be educated about the harmful effects of chaining. There was concern amongst community leaders that unchaining may put other community members at risk. The decision was made to focus on avoiding chaining through access to treatment. The CBR worker should not instigate unchaining, but should work with the supervisor and health centre to ensure unchaining happens safely. In addition we would include pragmatic advice on how to restrain in a safe and dignified way, when it was needed as a last resort.

There are 49 herbalists, 21 *tanqway* ('sorcerers') and 27 holy water sites across the district [39]. Holy water, which is used for bathing or drinking at sites associated with the Orthodox Church, is believed to have curative properties. Holy water use reflects a prevailing belief in Ethiopian culture that severe mental illness is attributable to supernatural forces, such as possession by spirits or the shadow cast by the 'evil eye' [43, 44, 60]. The use of holy water is sanctioned by the dominant religious authorities. A visit to a holy water site may last from days to months. Whilst the Orthodox priests based at these holy water sites may provide spiritual guidance to people with mental illness, they do not typically take on an active caring role with individuals. However attendants based at holy water sites often house and feed holy water attenders for a fee paid by the family. In the current study holy water was used by several people with schizophrenia, often alongside taking medication. Primary care workers and community leaders also perceived *tanqway* to be commonly used. Previous research showed that 37% of people with schizophrenia in this area attend a traditional healer [7] and 30.9% of those obtaining treatment at Ammanuel Psychiatric Hospital in Addis Ababa had first sought help from priests or holy water sites [61]. There were experiences of medication being both encouraged and discouraged by holy water priests, and a few experiences of being restrained or beaten for refusing to take holy water. Education about the risks and benefits of holy water and traditional healing was included, with the focus on encouraging the use of medication alongside traditional treatments.

The high levels of poverty and long distances to roads, health centres and public transport meant participants would have difficulty travelling for CBR. The majority therefore wanted home visits, rather than visiting the health centre. There were no concerns about increased stigma resulting from home visits. Two people with schizophrenia who preferred CBR visits at the health facility wanted to be more active. CBR would therefore be delivered at home as standard, with health facility visits offered as an alternative in order to maximise engagement. People with schizophrenia and caregivers reported they could be flexible about the timing of visit. Nevertheless the importance of fitting around the participants' schedules was emphasised, in order to minimise dropouts from the intervention.

Several caregivers and community leaders felt that the gender of the CBR workers did not matter; it was their skills that would be important. Others felt that CBR workers should be the same gender as their clients, as this would improve their relationship. It was decided that CBR workers of both genders would be recruited, whilst acknowledging that gendered allocation of CBR workers to participants would not be possible due to the cluster design of the RISE trial.

Desirable characteristics of CBR workers included being caring, understanding and knowledgeable, and having a good understanding of the local community. CBR workers would therefore be high school completers recruited from the immediate area. CBR worker competence evaluation would include communication skills.

3. What health service structures exist and how can they support CBR?

Primary care is delivered through eight health centres, staffed by health officers and nurses. The district's first hospital is under construction. Most kebeles (sub-districts) are covered by one or two health extension workers. Health care costs are largely out-of-pocket with a free waiver available for the very poorest [38]. In mid-2014 primary care staff were trained in mental health diagnosis and treatment by PRIME. The health extension workers initially represented a potential workforce to deliver CBR and the health centre staff represented potential collaborators. However it was ultimately decided CBR should be delivered by CBR workers, recruited and trained specifically for RISE, rather than health extension workers. The rationale was that HEWs would not have time to deliver CBR on top of their usual duties. In addition there were five kebeles without a health extension worker and concerns about further drop-outs. There was consensus that CBR should be linked to health centres but that primary care staff would have minimal capacity to support rehabilitation. Two RISE supervisors will cover eight CBR workers, using one-to-one supervision, group supervision and unannounced observed home visits.

4. Is it possible to recruit, train and retain non-health workers to deliver CBR?

Community leaders and experts predicted difficulty recruiting CBR workers willing to work with people with schizophrenia. A minority were concerned that CBR workers would not be able to provide psychosocial support. However, CBR workers (for physical disabilities), and health extension workers were motivated to do the work, stating it would be rewarding and clearly needed. Yet there were also fears that the work could be dangerous or stigmatizing for CBR workers. These concerns underlined that adequate safety procedures for CBR workers were an essential intervention for CBR to succeed (including risk assessment, provision of mobile phones, training to deal with challenging situations, and, where a risk is identified, joint visits with the supervisor), whilst conveying a balanced sense of the risks associated with working with people with schizophrenia. It was decided to employ at least one male supervisor to maximise the safety of CBR workers.

Health extension workers and CBR workers were confident that with training they could undertake CBR work for schizophrenia, emphasising that the core skills of CBR workers are generic. They stressed the importance of practical training, shadowing existing CBR workers, and top-up training. Both one-to-one and group supervision were recommended, with the latter being particularly helpful for overcoming difficulties. The need for physically fit CBR workers was highlighted as there were no resources for car travel. Ability to walk long distances was therefore included in the recruitment criteria.

5. What community resources are available and accessible to people with schizophrenia?

Each kebele in Sodo district has churches, religious groups, women and youth associations. 33 kebeles have a government literacy programme, and most have a government microfinance initiative. There are no mental health users groups or disabled people's organizations [39]. The rich community resources suggested that CBR workers should do resource mapping when they first start work in a kebele. There were mixed views as to whether people with schizophrenia have problems accessing existing community resources. All kebeles have several *edir*. Although *edir* is ostensibly a burial association, there was agreement that it is "*the most important community mobilizing agent.*" (IV08, *edir leader*) and should be engaged as a conduit for social inclusion and stigma reduction. Possible examples of community mobilisation were identified, including church leaders vocalising public support for an individual or assisting the family to take them to the health facility; and *edir* groups or wealthy individuals mobilising funds from community members to provide food or shelter for people with mental illness. However there were mixed views about *edir's* potential role as a provider of social protection or material support. The intervention was therefore modified to indicate that financial support from *edir* should arise organically and not be demanded by the CBR worker.

6. Are community leaders willing and able to participate in CBR?

There were conflicting views as to whether community leaders would use their authority to support CBR without personal benefits. This was recognised as a key assumption to fulfil in order for the intervention to succeed. Female caregivers, based on their previous experiences, were sceptical that community leaders would provide support, whilst community leaders themselves described a sense of responsibility and were keen to collaborate. The importance of first raising awareness amongst community leaders was highlighted, with emphasis to be made on the benefits for the whole community of an individual's recovery. The success of community mobilisation would then be reliant on community members taking ownership of the issue and identifying for themselves the ways they could help people with schizophrenia. There were mixed views as to whether holy water priests would be receptive to education about schizophrenia and the extent to which this would change their practices. It was decided that engagement with holy water priests and traditional healers would be instigated only where the family perceived this as useful. Concerns were raised as to whether community leaders would engage with female CBR workers, but community leaders themselves reported that skills were more important than gender.

7. How can the positive effects of CBR be sustained?

RAPID uses a combination of skills transfer to caregivers, parent groups and CBR committees (consisting of leaders from a range of sectors) to ensure the positive effects of CBR continue once the CBR workers had left the area. As it would be unfeasible to create new structures to ensure sustainability, it was decided that *edir* groups should be encouraged to take ownership of CBR. Family support groups were incorporated in the intervention and skills transfer to caregivers was highlighted as a key principle of CBR.

Summary of final RISE intervention

The focus of the RISE CBR intervention will be on the individual developing the skills and confidence to perform their previous or desired roles and activities. These may relate to family life, work and community life. The intervention will be recovery oriented, emphasising hope and

the individual's strengths. [Fig 2](#) summarises the final intervention structure. Basic counselling and problem solving skills will be employed by CBR workers to deliver the intervention. The intervention is delivered in three phases. In Phase 1, lasting one to two months, there are weekly home visits and the focus is on engagement with the family and addressing core needs through compulsory modules such as "Understanding Schizophrenia". Following a needs and risk assessment, structured goal setting will be used to support individuals to select appropriate goals from a pre-defined list. In addition to four core modules, the goal selection will determine which additional CBR components the individual will receive. In Phase 2, lasting approximately five to six months, home visits are every two weeks and address the specific needs of the individual through optional modules such as "Getting Back to Work". In Phase 3, lasting approximately four months, the emphasis is on preventing relapse as well as maintaining the progress made towards addressing specific needs. The three intervention phases reflect the changing needs of participants over 12 months. The transition between phases is conditional on achievement of goals rather than specific time points.

Community mobilisation work will run alongside family-based components. Community mobilisation involves identifying local community resources and leaders, awareness-raising meetings at existing community groups (for example women's saving groups) and targeted meetings with community leaders addressing specific needs of participants (for example identifying sources of food or financial support, or encouraging patients to attend the health centre). Whilst support with medication adherence is an important component, CBR workers will not prescribe or deliver medication. Indeed participants who are unable or unwilling to take anti-psychotic medication will nevertheless continue CBR and be supported to achieve goals related to functioning, which is the primary aim of the intervention. The five-week training programme for CBR workers will include 50% practical and 50% fieldwork, and will follow a training manual adapted from the COPSI manual.

Discussion

This study is a systematic and theory-driven effort to design a CBR intervention for schizophrenia in a resource-poor setting. This preparatory work aimed at designing the RISE intervention is an innovative attempt to tailor CBR's capacity to promote inclusion and improve access to essential services to the needs of people with schizophrenia. In doing so it aims to bridge the gap between health services and a more community-oriented development model of disability [34]. Whilst integration of mental health into existing CBR programmes has typically involved in-depth consultation work, this has not usually been theory-driven. The RISE CBR intervention has important differences compared to other models of community care for schizophrenia in LMIC. First, distinct from other interventions, such as COPSI [26] and a South African ACT programme [22], there is a substantial community mobilisation element. Our results indicate that community participation is likely to be essential for improving social inclusion, as well as having a role in improving medication adherence, reducing experiences of stigma and improving economic status. Utilising the CBR model, in which community mobilisation is key, therefore represents a major strength of the RISE intervention. Second, there is no collaboration with mental health specialists [30, 33]. This reflects the reality in this setting that the majority of care for people with schizophrenia is delivered by primary care staff, who have themselves only recently been trained in mental health. Third, there is a more structured approach to setting goals for individuals and selecting intervention components compared to other interventions [26].

We compromised on immediate scalability to construct a feasible intervention. The use of specialist CBR workers instead of existing health extension workers means that additional

Phase	Month	Home visits	Community-based rehabilitation activities		
			Assessment	Community	Individual and family
I	~1-2	Weekly	<ul style="list-style-type: none"> Initial engagement Review I: <ul style="list-style-type: none"> Needs assessment Risk assessment Goal setting Rehabilitation plan 	<ul style="list-style-type: none"> Resource mapping Initial meeting with health extension worker, community leaders and traditional healers 	Core modules: <ul style="list-style-type: none"> Understanding schizophrenia Improving access to health services Dealing with human rights issues Preparing for a crisis
II	~3-6	Fortnightly	<ul style="list-style-type: none"> Review II: <ul style="list-style-type: none"> Needs assessment Risk assessment Goal setting Rehabilitation plan 	<ul style="list-style-type: none"> Targeted mobilisation with community leaders and traditional healers to increase awareness and facilitate access to community resources Community awareness-raising meetings 	Modules as indicated: <ul style="list-style-type: none"> Supporting individuals to take medication Improving physical health Dealing with distressing symptoms Improving day to day functioning Dealing with stress and anger Dealing with stigma and discrimination Taking part in community life Improving the family environment Getting back to work Improving literacy Family support groups
III	~7-12	Monthly	<ul style="list-style-type: none"> Review III: <ul style="list-style-type: none"> Needs assessment Risk assessment Goal setting Rehabilitation plan Review IV: <ul style="list-style-type: none"> Continuing care assessment 	<ul style="list-style-type: none"> Facilitate access to community resources Community awareness-raising 	Core module: <ul style="list-style-type: none"> Taking control of your health (relapse prevention) Modules as indicated: <ul style="list-style-type: none"> Any Phase II module Family support groups

Fig 2. Overview of RISE intervention structure

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resources are required to scale up CBR, and as such RISE is a proof of concept study. This was a pragmatic approach given the widespread recognition that scaling up of mental healthcare cannot be done without extra resources. The RISE intervention is designed to be scalable with limited resources, for example only people with schizophrenia who are still unwell or disabled after six months access to facility-based care are included. The RISE trial will determine whether this intervention is cost-effective and therefore a potentially suitable investment for governments and other funders including the Ethiopian Ministry of Health. The collaboration between the Ministry of Health and PRIME (in which RISE is nested) could potentially pave the way for the scale up of CBR for schizophrenia. Furthermore, by utilising CBR workers (rather than existing health workers) and collaborating with CBM we have designed an intervention that meets the needs of, and is compatible with, CBR projects for other disabilities. This will provide evidence for integration of mental health into the large network of existing CBR projects run by NGOs.

This study addresses a criticism of global mental health research by developing a socially and culturally relevant psychosocial intervention using participatory methods [62]. The Theory of Change approach allows assumptions and barriers to be articulated and tested using a range of research methods. The Theory of Change map gives a visual record of modifications to the intervention on the basis of the research findings. A set of indicators has been developed, including trial outcomes and process data. This gives us a theoretical framework that we can later use to identify which are the most important components of CBR as part of the formal evaluation in an RCT, allowing us to refine an effective intervention for scaling up.

There may have been social desirability bias, particularly from community leaders, as there may be political pressure to express support of government initiatives. As PRIME, in which RISE is nested, is a collaboration with the Ethiopian Ministry of Health, community leaders may have felt compelled to champion CBR. This could explain their different opinion regarding community support compared to female caregivers, who are not susceptible to the same pressures. As the investigators are invested in the RISE project it is possible this led to a biased interpretation of the qualitative data, emphasising a favourable opinion of CBR amongst participants. While no meaningful ownership of the Theory of Change map can be claimed by stakeholders outside of the workshops, those who participated represented relevant stakeholders, and Theory of Change was undoubtedly a useful tool throughout the process.

Conclusion

Extensive formative research using a variety of methods nested within a Theory of Change framework has enabled the design of a culturally appropriate complex mental health intervention that is acceptable and feasible to service users and providers. This CBR intervention will be finalised in a pilot and then tested in a cluster-randomised trial to determine its effectiveness and cost-effectiveness in improving functioning in people with schizophrenia in a rural district in Ethiopia.

Supporting Information

S1 Table. Summary of research questions, findings and impact on intervention design. (DOCX)

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Author Contributions

Conceived and designed the experiments: LA AF CH VP MDS. Performed the experiments: LA AF CH JE GM MDS. Analyzed the data: LA CH MDS. Contributed reagents/materials/analysis tools: JE GM VP MDS. Wrote the paper: LA AF CH JE MDS VP. Wrote the intervention manual and training materials: LA. Edited the intervention manual and training materials: AF CH GM VP MDS.

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S1 Table: Summary of research questions, findings and impact on intervention design (continued overleaf)

Research questions and assumption	Phase tested	Finding	Impact on intervention design
1. Which potential components of CBR are likely to be effective at improving functioning for people with schizophrenia?			
CBR can improve functioning in people with schizophrenia	1	Good evidence that community care, psycho-education, adherence support, and family intervention can improve functioning	<ul style="list-style-type: none"> • Include broad range of CBR components, which may contribute directly or indirectly to improved functioning.
	1, 3, 4	Some CBR components for which there is no research evidence could contribute to improved functioning via intermediate outcomes	
A community mobilisation approach is required in addition to family-based care	1	Community mobilisation is advocated by WHO CBR guidelines and has been shown in observational studies in India to improve functioning	<ul style="list-style-type: none"> • Incorporate community mobilisation, targeting leaders, to maximise effectiveness of family-based components and sustainability.
	3, 4	Community leaders have powerful influence on views and behaviour of community and may be gatekeepers to community resources.	
2. Is CBR useful, acceptable and feasible from the perspective of people with schizophrenia and their caregivers?			
CBR can address the needs of people with schizophrenia	2	High levels of disability, stigma and family burden. Most work as subsistence farmers. Few formal employment opportunities; no vocational rehabilitation facilities.	<ul style="list-style-type: none"> • Common needs will be addressed in core modules. Modules addressing other needs should be delivered if indicated by needs assessment and goal setting. • Include guidance on addressing caregivers needs • Vocational rehabilitation to focus on returning to farm work.
	3	Needs assessment and rehabilitation plan are essential. Return to work perceived as key step for improving functioning, economic status and reducing family burden.	
	4	People with schizophrenia and caregivers have diverse and varied needs. CBR components perceived to be useful for addressing needs.	
People with schizophrenia and their caregivers are willing and have time to participate in CBR	4	Near universal willingness and enthusiasm to participate. General flexibility and no concerns about not having time. CBR workers should be from local area, have a caring attitude and be knowledgeable. Mixed views on preferred gender.	<ul style="list-style-type: none"> • Recruit CBRWs from local area of both genders. • Incorporate training on empathy and building trust.

S1 Table continued			
The benefits of microfinance outweigh the risks	1	Some evidence that microfinance can increase stress	<ul style="list-style-type: none"> Facilitating inclusion in existing microfinance schemes excluded from CBR
	3	Concerns about abuse or exploitation of people with schizophrenia	
	4	Microfinance may be unacceptable to some participants	
Self-help initiatives are perceived to be beneficial	4	Self-help groups perceived to be useful for moral support and information sharing.	<ul style="list-style-type: none"> Family support groups included in CBR.
People with schizophrenia are commonly chained or restrained	3	Chaining may be a result of stigma and low awareness. Community leaders could help to reduce chaining by raising awareness.	<ul style="list-style-type: none"> CBR should address chaining but focus should be on accessing treatment. CBR workers should not initiate unchaining but should refer to health centre and supervisor CBR workers should educate families on how to chain safely.
	4	Chaining is common at home and at holy water sites. The best way to reduce it is to improve access to treatment. Community leaders concerned about safety issues related to unchaining.	
TRHs are typically used as a source of care for people with schizophrenia	2	49 herbalists, 21 <i>tanqway</i> ('witch doctors') and 27 holy water sites across the district. 37.4% of people with schizophrenia attend a traditional healer	<ul style="list-style-type: none"> Educate family about risks and benefits of TRH. Do not forbid, but encourage use alongside medication.
	3	Holy water use is common, often alongside medication.	
	4	Should aim to encourage holy water use alongside medication.	
3. What health service structures exist and how can they be utilised to support delivery of CBR?			
Health extension workers have the capacity to deliver CBR	2	HEWs not present in every kebele	<ul style="list-style-type: none"> Recruit and train a new cadre of worker, CBR workers, especially for this project
	3	Consensus that HEWs would not have the capacity to deliver CBR on top of current work; in addition high rates of drop out from HEW posts.	
Health centre staff have the capacity to support CBR	2	Primary care staff newly trained to diagnose and treat schizophrenia	<ul style="list-style-type: none"> Supervision internal to RISE rather than from the health centre. Monitor health centre attendance
	3	CBR should be linked to health centres but primary care staff will have minimal capacity to support rehabilitation. CBR supervisors should supervise CBR workers.	
Medication is available at the health centre	2	PRIME will ensure continuous medication supply to health centres	<ul style="list-style-type: none"> CBRW can facilitate free medication certificate.
	3	Free medication certificate available for minority from kebele official	

S1 table continued

4. Is it possible to recruit, train and retain field workers to deliver CBR?

CBR workers are willing to work with people with schizophrenia	3	Concerns potential CBR worker recruits may be afraid to do home visits to people with schizophrenia. Also concerns about drop out.	<ul style="list-style-type: none"> • Comprehensive safety procedures for CBR workers • Training to give a balanced sense of risk • Male and female supervisors.
	4	CBR workers, HEWs and primary care staff motivated to work with people with schizophrenia. But fears the work could be risky or stigmatizing	
CBR workers will have adequate CBR skills	1	Lay people previously trained as CBR workers in India and RAPID	<ul style="list-style-type: none"> • Training to including shadowing existing CBR workers and top-up training. • Training to include problem solving and communication skills. • 1:4 ratio of supervisors to CBR workers. One-to-one sessions and group supervision.
	3	Concerns about ability to train non-specialists to deliver CBR for schizophrenia. Importance of supervisors doing ongoing assessment of gaps in skills/knowledge. Don't need formal counselling training.	
	4	HEWS and CBR workers confident they could do CBR for schizophrenia. Importance of field training, top-up training and peer supervision	
CBR workers can overcome logistical issues to deliver CBR	2	Mainly rural, many kebeles remote from towns, roads, public transport	<ul style="list-style-type: none"> • Include willingness/ability to walk long distances in recruitment criteria
	3,4	CBR workers need to be strong, fit and capable of walking long distances	

5. What community resources are available in Sodo and are they accessible to people with schizophrenia?

Existing community resources are available	2	Rich community resources e.g. microfinance and literacy schemes, Women's and youth associations, churches, mosques and informal religious groups, and Edir groups (traditional burial association)	<ul style="list-style-type: none"> • CBR workers to conduct resource mapping when they start working in a kebele. • Potential targets for social inclusion identified e.g. edir, mahaber
	3	Agreement that <i>edir</i> is a powerful social structure. Confirmation of presence and activity of other community resources.	
Existing community resources can be accessed by people with schizophrenia	3	Mixed views on whether people with schizophrenia have problems accessing community resources. May be opportunities for income generation	<ul style="list-style-type: none"> • Assess for daily labouring opportunities. • CBR worker to facilitate access to community resources May need to liaise with relevant community/religious leaders. • Support with social skills to be included.
	4	Problems accessing community resources due to stigma, problems with social interactions, lack of motivation and being symptomatic.	

S1 table continued			
Edir support will be available and sustainable	3	Mixed views about edir's role as a provider of social protection or material support. New unions previously formed to support people with HIV-suggested this could be replicated for people with schizophrenia.	<ul style="list-style-type: none"> • More feasible to get support from existing structures i.e. Edir, than to encourage formation of new structures. • support from Edir should arise organically, not be expected by CBR worker.
	4	Suggested role of Edir: financial/material support, awareness raising, higher threshold for exclusion of people with schizophrenia when not contributing	
6. Are community leaders willing and able to participate in CBR?			
Community leaders will participate in CBR without personal benefits	3	Concerns that community leaders will not participate in CBR	<ul style="list-style-type: none"> • Include community awareness raising and engagement with community leaders at start of intervention.
	4	Community leaders report sense of responsibility to support people with schizophrenia. Caregivers sceptical support will be available.	
Traditional and religious healers will participate in CBR without perceiving a conflict of interest	3	Traditional and religious healers and CBR workers would need joint understanding of person with schizophrenia's needs. Traditional and religious healers may not be willing to discuss individuals.	<ul style="list-style-type: none"> • Engagement with traditional and religious healers to be instigated where the individual and family perceived this as a useful adjunct to family support and general community awareness-raising.
	4	Traditional healer states willingness to signpost to health centre/medication. Some reports of traditional and religious healers warning against medication use. Mixed views as to whether Traditional and religious healers would receive education and change practices.	
Community leaders will be willing to work with male and female CBR workers	3	Community leaders may only engage with male CBR workers	<ul style="list-style-type: none"> • Recruit on basis of interest and post-training competence, not gender
	4	Community leaders state they are willing to work with CBR workers of either gender- skills are more important than gender	
7. How can the positive effects of CBR be sustained?			
CBR can continue after the CBR worker has left	1	Issues with sustainability identified in previous study	<ul style="list-style-type: none"> • Skills transfer to caregiver. • Focus on <i>Edir</i> to ensure sustainability CBR committee not feasible.
	3	RAPID uses CBR committees to ensure sustainability. Transfer of skills to caregiver also essential.	

CBR= Community-based rehabilitation; RAPID= Rehabilitation And Prevention Initiative against Disabilities Project; Edir= traditional burial association; ; HEW= Health extension worker; PRIME= PProgramme for Improving Mental healthcare; kebele= sub-district

5.3 APPENDICES

- Ethical approval for intervention development (Appendix B (i))
- Information sheets and consent forms (Appendix B (ii))
- Topic guides for qualitative interviews (Appendix B (iii))

5.4 SUPPLEMENTARY REFERENCES

1. Chatterjee, S., S. Naik, S. John, H. Dabholkar, M. Balaji, M. Koschorke, M. Varghese, R. Thara, H.A. Weiss, P. Williams, P. McCrone, V. Patel, and G. Thornicroft, *Effectiveness of a community-based intervention for people with schizophrenia and their caregivers in India (COPSI): a randomised controlled trial*. *Lancet*, 2014. **383**(9926): p. 1385-94.
2. Craig, P., P. Dieppe, S. Macintyre, S. Michie, I. Nazareth, and M. Petticrew. *Developing and evaluating complex interventions: new guidance*. Medical Research Council. 2008.

6 RISE MATERIALS

6.1 INTRODUCTION

This chapter provides further details on the delivery of the RISE CBR intervention, the development of which was described in Chapter 5. The chapter also presents the materials that were developed to train the CBR workers in preparation for the RISE pilot (Chapter 7). Minor adjustments to the intervention that arose from piloting will be presented in Chapter 7.

6.2 METHODS

A list of CBR worker competencies was drawn up as part of the intervention development phase and reviewed by the project collaborators (see Table 6.1). I wrote the RISE manual using the COPSI manual as an initial template (<http://www.sangath.com/images/file/COPSI%20Manual%20Nov%202019.pdf>), with permission of its authors. The COPSI manual was extensively adapted to cover the content of the RISE CBR intervention, the RISE CBR worker competencies, and to ensure appropriateness for the Ethiopian context. Other existing materials I consulted in this process included the Mental Health Pocket Guide for Health Extension Workers produced by the Ethiopian Ministry of Health; the Mental Health and Human Rights resource pack produced by the Amaudo Itumbauzo CBR project in Nigeria; and the facilitator's guide for Psychosocial Rehabilitation Support Group Sessions created as part of the PRIME project in South Africa [1]. A large proportion of the final RISE manual consisted of entirely new material. UK and Ethiopian psychiatrists, who had expertise in CBR or community-based care, reviewed the RISE manual to create the final version. A concerted effort was made to ensure the information was understandable to lay persons i.e. CBR workers. To reflect the lack of mental health training of CBR workers, the intervention delivery was highly structured, with each process such as needs assessment divided into clear sequential steps. Care was taken to acknowledge the range of explanatory models for schizophrenia that exist in Ethiopia (see Chapter 2; Section 2.8); and to

ensure that advice was contextually appropriate (for example recognising that some families may not have access to soap for self care activities).

I developed the training programme and assessments for CBR workers from scratch, using ideas from other relevant training programmes [1]. The manager at the Ethiopian CBR project for children with disabilities (Rehabilitation And Prevention Initiative against Disabilities (RAPID)) also gave advice on how to deliver the training. The manual, training and intervention delivery materials were translated into Amharic by Ethiopian psychiatrists.

Table 6.1 RISE CBR worker competencies (continued overleaf)

	Competency	Assessment
1	Administrative	
1a	Able to complete documentation correctly	Role play
2	Professionalism	
2a	Aware of and adheres to cultural norms in terms of dress and general behaviour	Observation by trainers
2b	Demonstrates good time-keeping and attendance	Observation by trainers
2c	Demonstrates positive attitude towards people with schizophrenia (i.e. not stigmatising)	Observation by trainers
2d	Has skills to maintain own wellbeing	Observation by trainers Written test 1
3	Communication skills	
3a	Able to build trusting relationship with person with schizophrenia and their family	Role play
3b	Able to deal with difficult situations e.g. angry person, violent person	Written test 1
3c	Has good listening skills	Role play
3d	Is able to explain concepts clearly, check for understanding etc	Role play
3e	Can employ a problem solving approach	Role play
4	Referrals	
4a	Aware of circumstances in which to contact supervisor for support	Role play Written test
4b	Aware and able to follow procedures for the following scenarios: suicidal intent, neglect, violent victimisation etc.	Role play Written test
4c	Aware and able to follow procedures for following scenarios: identification of physical or mental illness in community member	Role play Written test
4d	Aware of health services available for people with mental illness	Role play Written test
5	Assessment and review	
5a	Able to assess achievement of goals on an on going basis	Role play Written test
5b	Able to conduct a needs assessment for people with schizophrenia and caregivers in conjunction with supervisor	Role play Written test
5c	Able to detect distress in caregivers on an on going basis	Written test 1
5d	Able to conduct a brief risk assessment	Role play
5e	Able to conduct goal setting and develop a rehabilitation plan in conjunction with supervisor	Role play
6	Knowledge	
6a	Has basic knowledge of mental disorders including depression, alcohol use disorder etc	Written test
6b	Has good knowledge of schizophrenia (aetiology, course etc) and medical treatment; and can identify people with schizophrenia	Written test
6c	Understands the impact of schizophrenia in terms of disability, stigma, human rights abuses and family burden	Written test
7	CBR delivery	
7a	Understands and is able to explain purpose and structure of CBR	Role play

	programme	
7b	Understands structure and purpose of RISE pilot and RISE trial	Written test 1
7c	Able to give information on schizophrenia	Role play
7d	Able to assess reasons for not accessing medication or attending health centre and apply problem solving approach to address this	Role play
7e	Able to give information on how to deal with a crisis and support development of crisis management plan	Written test
7f	Able to assess reasons for not taking medication and apply problem solving approach to address this	Role play
7g	Able to identify early warning signs with family and develop relapse prevention plan	Written test 2
7h	Able to develop plan to enable improved self-care and improve participation in household tasks	Written test 1
7i	Able to deliver family intervention	Written test 1
7j	Able to sensitively address chaining and physical abuse and take appropriate steps to address this	Written test 2
7k	Able to give advice for dealing with distressing symptoms	Written test 1
7l	Able to give advice for dealing with stress and anger	Written test 1
7m	Able to give advice to improve healthy behaviours	Written test 1
7n	Able to assess reasons for poor physical health and use problems solving to address this	Written test 2
7o	Able to give advice on dealing with stigma and discrimination	Written test 1
7p	Able to assess reasons for reduced participation in community life and apply problem solving approach to address this	Written test 1
7q	Able to assess reasons for reduced participation in vocational activities and apply problem solving approach to address this	Written test 2
7r	Able to assess literacy and basic skills and suggest steps to improve them	Written test 1
7s	Able to transfer skills to caregivers in order for family to continue CBR after end of programme	Written test
7t	Aware of procedures for ending intervention with family	Written test 1
8	Community mobilisation	
8a	Able to form good relationships with community leaders and HEWs	Written test 1,2
8b	Able to conduct community awareness-raising	Written test 2
8c	Able to engage with community leaders to facilitate CBR	Written test 1,2
8d	Able to maximise sustainability of programme through community involvement	Written test
9	Family support group	
9a	Able to organise and facilitate support groups or befriending arrangements	Written test 1,2

6.3 INTERVENTION OVERVIEW

6.3.1 Structure of CBR

The RISE CBR intervention involves three main components: (i) **Home visits** by CBR workers. It is anticipated that approximately 22 visits should be made over 12 months. (ii) **Community mobilisation**; and (iii) **Family support groups**. The intervention is delivered in three phases over a 12-month period:

Phase 1 Intensive engagement: Months ~1 and 2 (weekly home visits)

Phase 2 Stabilisation: Months ~3 to 6 (fortnightly home visits)

Phase 3 Maintenance: Months ~ 7 to 12 (monthly home visits)

CBR workers are expected to do two tasks every day. For example two home visits, or one home visit and one meeting with community leaders. Table 6.2 gives an overview of the content of CBR by phase. A set of 30 forms are used by CBR workers and supervisors to document CBR delivery (Appendix C (i)).

Table 6.2 Overview of RISE CBR intervention (continued overleaf)

Phase	Home visits			Community mobilisation	Family support group
	CBR Review	Goals	Modules		
1	CBR Review 1: <ul style="list-style-type: none"> Initial Assessment Needs Assessment Goal setting for Phase 1 Rehabilitation plan Risk Assessment Accompany to health centre 	Individual and caregiver have been informed of what schizophrenia is, available treatments, and the potential for recovery	<i>Understanding schizophrenia</i>	Task 1: Meet with health extension worker/s Task 2: Identify key community leaders Task 3: Identify key community resources Task 4: Ascertain what community mobilisation relating to mental illness has already taken place or is planned Task 5: Meet with key community leaders Task 6: Community awareness-raising events Task 7: Identify potential employment opportunities in the sub-district	[Hatched area]
		Individual is able to access medication	<i>Improving access to health services</i>		
		Individual is able to attend health centre for mental health as indicated by clinical status	<i>Preparing for a crisis</i>		
		Crisis management plan is in place	<i>Dealing with human rights issues</i>		
		Person with schizophrenia is not chained or restrained			
2	CBR Review 2: <ul style="list-style-type: none"> Needs Assessment Goal setting for Phase 2 Risk Assessment Update rehabilitation plan Invite to Family Support Group Accompany to health centre 	Individual is willing to take medication	<i>Supporting individuals to take medication</i>	Task 8: Individual meetings with sub-district leaders Task 9: Individual meetings with Edir leaders Task 10: Individual meetings with religious leaders Task 11: Individual meetings with traditional healer/ holy water priest/ attendant Task 12: Demonstrate progress of client/s to community leaders/ wider community Task 13: Community awareness raising consolidation Task 14: Facilitate employment opportunities in the sub-district Task 15: Individual meetings with literacy group leader	Family support group active
		Individual has strategies to remember to take medication			
		Individual feels side effects are improving			
		Individual feels symptoms are improving	<i>Dealing with distressing symptoms</i>		
		Individual is able to access health services for physical and sexual health needs and contraception when required	<i>Improving access to health services</i>		
		Individual has strategies to deal with stress and anger	<i>Managing stress and anger</i>		
		Individual has information to make decisions about health-related behaviours	<i>Improving physical health</i>		
		Individual has good physical, sexual and reproductive health			
		Individual is not malnourished			
		Individual has restored participation in livelihood activities, including farm work	<i>Getting back to work</i>		

Table 6.2 continued					
2		Individual participates in community life	<i>Taking part in community life</i>		
		Individual participates in religious activities if they are important to the individual			
		Person with schizophrenia is able to interact socially with neighbours and friends			
		Individual has improving ability to do parenting activities	<i>Improving the family environment</i>		
		Individual has improved relationship with family members			
		Caregiver has improved ability to cope			
		Individual has improving self-care	<i>Improving day to day functioning</i>		
		Individual has improving ability to do household tasks			
		Individual has improving self-esteem	<i>Dealing with stigma and discrimination</i>		
		Individual does not feel discriminated against			
		Individual is not the victim of physical, sexual or emotional abuse	<i>Dealing with human rights issues</i>		
Individual has basic literacy skills	<i>Improving literacy</i>				
3	CBR Review 3: <ul style="list-style-type: none"> Needs Assessment Goal setting for Phase 3 Risk Assessment Update rehabilitation Plan Accompany to health centre CBR Review 4: <ul style="list-style-type: none"> Continuing Care Assessment 	Individual has relapse prevention plan	<i>Taking control of your health</i>	Any Phase 2 Community Mobilisation task	Support group active
		Any Phase 2 goal	Any Phase 2 module		

6.3.2 Home visits

Home visits should last around 30-90 minutes and the caregiver or another family member should be present or nearby. At the initial visit CBR workers gather information on the participant's illness and home situation (see Form 1 in Appendix C (i)). A needs assessment (see Form 4 in Appendix C (i)) and goal setting (see Forms 5 and 6 in Appendix C (i)) are conducted at the beginning of each phase. CBR workers support participants to select optional goals from a pre-specified list, which was designed to incorporate all likely areas of desired change, including functioning, symptoms and stigma (See Form 6 in Appendix C (i)). Table 6.2 lists the core and optional goals for each Phase. The indicated modules linked to the selected goals are then delivered over the course of the phase. All documentation relating to each participant is filed in a 'participant logbook'. All home visits are recorded on a separate Home Visit Form (See Figure 6.1). At each visit CBR workers should do the following:

- Check general health and symptoms
- Check and record progress relating to on going goals
- Use a problem solving approach to address on going goals
- Deliver module/s: selected on the basis of the remaining goals. Modules usually take more than one visit to complete.
- Check whether the participant is taking medication regularly
- Do a brief risk assessment, assessing for suicide risk and recent restraint
- Give tasks to complete before the next session
- Plan date and content of next session

Figure 6.1 RISE home visit form (continued overleaf)

Form 11: Home visit Form					
Individual		CBR worker		Date	
Start time		Finish time			
Phase (tick)					
Phase 1		Phase 2		Phase 3	
Participants					
Who was present at the home visit? (tick)	Individual				
	Main caregiver				
	Supervisor				
	Other				
	If other, who?				
General					
Mental health and symptoms	Worse				
	Same				
	Better				
Your comments on the individual's mental health status					
Issues or questions raised relating to previous visit					
Other issues discussed					
Goal (write in →)					
Module/s underway this home visit to achieve goal	1. 2.				
Community mobilisation tasks and other tasks underway or planned to achieve goal	1. 2.				
Issues and problems					
Progress on goal by end of home visit (Tick)	Not achieved				
	Partly achieved				
	Achieved				
Goal (write in →)					
Module/s underway this home visit to achieve goal	1. 2.				
Community mobilisation tasks and other tasks underway or planned to achieve goal	1. 2.				
Issues and problems					
Progress on goal by end of home visit (Tick)	Not achieved				
	Partly achieved				
	Achieved				

Goal (write in →)			
Module/s underway this home visit to achieve goal	1. 2.		
Community mobilisation tasks and other tasks underway or planned to achieve goal	1. 2.		
Issues and problems			
Progress on goal by end of home visit (Tick)	Not achieved	<input type="checkbox"/>	
	Partly achieved	<input type="checkbox"/>	
	Achieved	<input type="checkbox"/>	
Medication			
Issues with medication			
Actions to deal with medication issues			
Risks			
Is the individual chained? (tick)	Yes	<input type="checkbox"/>	No
If yes, actions to deal with chaining			
Is there suicide risk? (tick)	Yes	<input type="checkbox"/>	No
If yes, actions to deal with suicide risk			
Other risks and actions taken			
Follow up			
Task for individual/ caregiver to complete before next session			
Time and date of next home visit			
Module for next visit			
Issues to discuss with supervisor			
Referrals e.g. to health centre			
Supervisor review			
Date reviewed with supervisor			
Actions suggested by supervisor			
Supervisor signature			

6.3.3 Terminating CBR

The aim is to continue CBR for 12 months irrespective of improvements in functioning. Participants may stop participating at any time, though the CBR worker should attempt to understand the reasons for quitting and if possible resolve any problems. At 10 -11 months CBR workers begin discussing the progress made during the CBR period, and the upcoming termination of CBR, with the individual and family. The Continuing Care Assessment (see Form 9 Appendix C (i)) is completed; this includes the identification of on going needs and formulation of a plan to address these needs once CBR has terminated.

6.3.4 Links to health services

CBR workers are expected to attend the health centre with the participant around the beginning of each phase (see Form 2 in Appendix C (i)). The aim is to gain an understanding of the participant's current treatment and to facilitate discussion between the participant and the health officers. CBR workers should also refer people with schizophrenia to the health centre, in addition to regular appointments, if suicide intent, relapse or medication side effects are identified (see Form 14 Appendix C (i)). CBR workers can refer to health extension workers for contraception, immunisations and other community health needs.

6.3.5 Dealing with risks

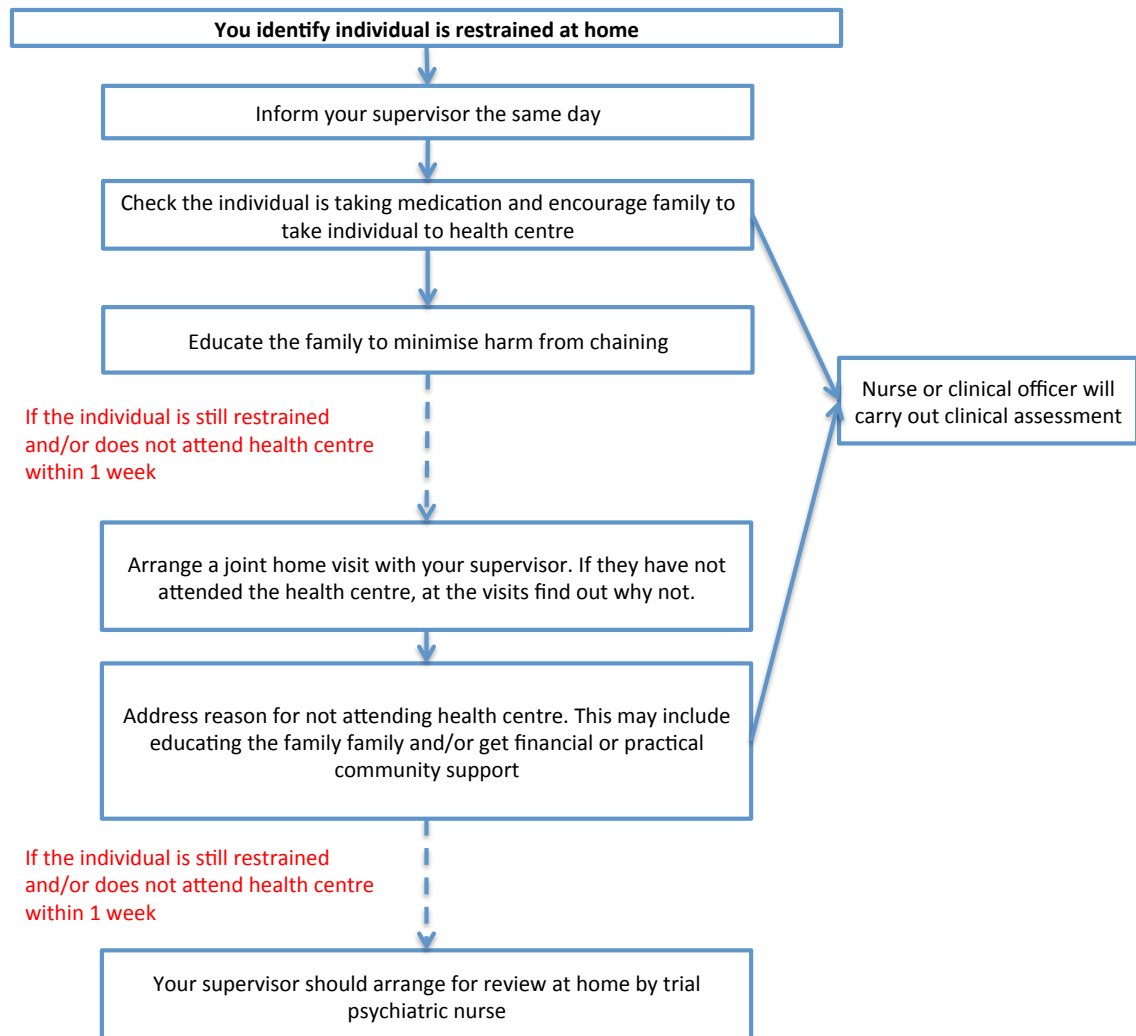
At the beginning of each phase supervisors conduct a risk assessment for each participant, covering risks such as suicide, sexual violence and neglect (see Form 7 in Appendix C (i)). There are specific protocols for the CBR worker response to the following scenarios:

- Individual is restrained at home (see Figure 6.2)
- Relapse
- Violent victimisation outside of home
- Neglect or malnourished
- Suicidal ideation

- Suicide attempt
- Intimate partner violence
- Children at risk of harm
- Sexual violence
- Death
- Emergency hospital admission
- Individual is violent or aggressive

In general the protocols ensure the participant is able to access mental health care, and indicate a psychiatric nurse review if this is not possible.

Figure 6.2 RISE protocol for physical restraint



6.3.6 Community mobilisation

Table 6.2 lists the community mobilisation tasks. Core tasks should be completed around the time participants are in Phase 1 and optional tasks when participants are in Phase 2 and 3. All documentation relating to each sub-district is filed in a 'sub-district logbook'. Figure 6.3 presents one section of the sub-district logbook, which is designed to record community awareness-raising events (see Appendix C (i) Forms 10.1 to 10.11 for full logbook). This form was designed to be used by CBR workers in conjunction with the relevant section in the RISE manual.

Figure 6.3 RISE form for community-awareness raising event

Form 10.6: Sub-district Logbook (Task 6: Community awareness raising event/s)		
CBR worker		Supervisor
Sub-district		
Date		
Location		
Number of participants		
Topic	Tick when discussed	Comments
Introduce self and role		
Basic explanation of schizophrenia		
Causes of schizophrenia		
Possibility of recovery		
Importance of medication		
Need for community support		
Importance of treating people with schizophrenia well and as equals		
Importance of helping people to get treatment so they don't need to be chained		
Other issues raised		
Actions agreed		
Date and time of subsequent meeting if arranged		

6.3.7 Family support groups

CBR workers begin trying to set up family support groups from Phase 2 onwards. The aim is to set up one group for each sub-district. These groups can include caregivers and people with schizophrenia who are not acutely unwell. Caregivers and people with schizophrenia who are not participating in CBR (for example because they were assessed as having insufficiently high levels of disability) may also participate. Existing networks are built upon where possible. There is no savings and loan element anticipated; instead the groups provide a forum for

discussing problems and sharing potential solutions. Meetings are held at a mutually convenient location and time and are expected to be monthly. CBR workers begin by leading the meetings, but attempt to transfer leadership to a participant after the group is established.

6.3.8 Supervision

CBR supervisors and an intervention coordinator oversee the frequency, content and quality of CBR. Supervisors conduct monthly unannounced observed CBR sessions, monthly group supervision, and individual supervision every two to four weeks. Group supervision involves CBR workers sharing difficulties and discussing ways to overcome challenges. Supervisors also attend the initial visit, needs assessment and goal setting together with the CBR workers. The intervention coordinator supports the group supervision and individual supervision sessions. Top-up training sessions are given by the intervention coordinator to address any weak areas or poor practice identified by the supervisors. A project psychiatric nurse can be contacted directly by CBR workers, supervisors and the intervention coordinator to address urgent or serious clinical issues that are not addressed through usual care at the health centre. The psychiatric nurse and intervention coordinator can discuss clinical issues with a designated psychiatrist when required.

At the beginning of each phase supervisors conduct a CBR worker safety assessment for each participant, for example assessing the remoteness of the home and history of violence in the participant (see form 24 in Appendix C (i)). Appropriate measures are put into place on the basis of the assessment, for example in high risk cases only joint visits with the supervisor are allowed until the risk is assessed to be downgraded.

6.4 RISE MANUAL

CBR delivery is guided by a 200 page manual that was designed to cover all the RISE competencies (see Table 6.1; see Appendix C (ii) for the full manual).

Vignettes were used to illustrate the text; these were based on experiences reported by people with schizophrenia in the intervention development phase, presented in a highly anonymised form. The RISE manual comprised of the following three sections:

SECTION A: Understand what schizophrenia is and the problems it causes

This section includes information about schizophrenia, anti-psychotic medications, disability and human rights. See Figure 6.4 for an example chapter from Section A.

SECTION B: Learn how to help people with schizophrenia and their families through CBR

This section includes basic counseling and problem solving skills, needs assessment, goal setting, basic risk assessment, steps to deliver the four core and 11 optional modules and the community mobilisation tasks. See Figure 6.5 for an example chapter from Section B. Each module chapter uses the format:

- What is the problem?
- Why does this problem happen?
- Why is it important to help with this problem?
- How can we help?

SECTION C: Know how you will be supported to deliver CBR

This section includes CBR worker wellbeing, supervision structures and response to difficult situations such as suicidal ideation. A step-by-step guide covering section B in a briefer format was also provided to CBR workers for use on home visits.

Chapter 4 Disabilities related to schizophrenia

What is disability?

Disability is when a person cannot do the activities that we would normally expect them to do, given their age and social circumstances. Disability can include:

- Problems with the body, for example blindness
- Problems with doing physical activities, for example walking
- Problems doing usual work and social activities, for example going to market.

What causes disabilities?

Disabilities in people with schizophrenia are caused by **a combination of the social environment in which the person lives and the illness itself**. For example,

- An individual may not be allowed to vote at the sub-district meeting because of stigma and discrimination in the community (see Chapter 6).
- A person who doesn't have any family may not work because they are not being encouraged to do so.
- Problems with self-care may result from lack of motivation, a symptom of the illness.

What limitations do people with schizophrenia have?

People with schizophrenia usually experience many types of disability. These include:

1. Problems with self-care

This includes problems with washing, dressing, brushing hair and eating at the right time.

2. Problems doing household tasks

This includes problems with cooking, washing clothes, chopping wood or fetching water.

3. Problems with social interactions and participating in community life

This includes problems with having conversations with people and problems attending church, funerals or Edir meetings.

4. Problems in working

This includes problems doing farm work, trading or business.

5. Problems in looking after children

This includes problems giving children love, feeding and clothing them.

6. Problems with marital relationships

This includes not getting on well and arguing a lot.

What is the impact of having disabilities?

Disability may be more upsetting to the individual than the symptoms themselves. For example, finding it difficult to drink coffee with others may be more distressing than hearing voices. Disabilities may result in problems with money. For example, having problems with farm work is likely to mean the individual has less money. Disabilities may also have a big impact on the rest of the family. For example if a mother with schizophrenia finds it difficult to look after her children, other family members may need to help out. These family members may then have trouble looking after their own farm properly (see Chapter 5).

Yosef's story

Yosef does not often wash or dress himself. He no longer helps on the family's farm. He does not contribute to Edir anymore, instead he relies on his parent's contributions. He doesn't have any friends any more and does not go to Church.

How do we assess disabilities?

You will learn how to assess what kinds of disabilities people with schizophrenia have as part of the Needs Assessment (see Chapter 12).

How do we work with individuals to improve their situation?

The aim of rehabilitation is to work with individuals to improve their situation so they are less disabled and can get back to their usual activities. Rehabilitation should be an empowering process. This means the needs and wishes of the individual are at the centre of the work. Rehabilitation isn't about 'doing things' to or for people who are disabled. It is about working together to improve their life and work towards recovery. Recovery can mean different things to different people. It doesn't usually mean that an individual is 'cured' of schizophrenia. Instead it means that things have improved in a way that is important to that person. You will see that all of CBR is focused towards rehabilitation.

Summary

- Disability is when an individual cannot do the activities we would normally expect
- Disability is caused by a combination of the social environment and the illness
- People with schizophrenia can have problems with: self-care, household tasks, participating in community life, working, looking after children and marital relationships

Chapter 26 Module: Taking part in community life

What problems do people with schizophrenia have taking part in community life?

It is common for people with schizophrenia to have problems doing the usual activities in the community. People may have problems with:

- Attending weddings and funerals
- Drinking coffee with friends and neighbours
- Visiting relatives
- Taking part in Edir meetings
- Participating in the practical activities of Edir
- Participating in subdistrict meetings
- Attending church or mosque
- Participating in religious groups, such as mahaber or lika
- Going to market
- Participating in other community organisations, such as the Women's association

Why do people with schizophrenia have problems taking part in community life?

- The illness makes them unmotivated to go outside
- The illness gives them problems with social skills, such as difficulties starting a conversation or taking turns to speak
- Medication side effects, such as drowsiness, make it difficult to get the energy to walk somewhere and socialise.
- The family does not let the individual attend community events because they are worried they will behave strangely or do something embarrassing
- Community members may have stigmatising attitudes towards people with schizophrenia. This means they may ignore the individual, not allow them to participate in activities, not respect their opinion or even shout names at them.

Why is it important to take part in community life?

- To feel part of the community
- Improve their sense of well-being
- Improve their self-confidence
- Reduce stigma towards them

- Reduce burden on the family
- Keep the person engaged in useful tasks
- Distract from distressing symptoms like hallucinations and delusions.

What can we do to help people with schizophrenia take part in community life?

Principles

- Focus on the areas where there are problems, and which are important to the individual to change
- Establish what is normal for the household and the individual
- Involve the family at every stage of the process. The aim is for them to be able to support the individual to do the activities when you are not there.

1. Explain why you are doing this module

Explain to the individual and family that problems taking part in community life are common in people with schizophrenia. Give reasons why people with schizophrenia have these problems.

2. Discuss what problems the individual has

Discuss what problems the individual has had taking part in community life

3. Identify the activities the individual wants to do

Find out which community activities the individual would like to do but is having difficulty with at the moment. You should refer back to the latest needs assessment.

4. Identify barriers and suggest ways to overcome them

You should discuss with the individual and their caregiver why they think they are having problems taking part in these community activities. Look at the Section 26.2 for suggestions. The most appropriate approach for helping individuals to take part in community life will depend on the types of barriers. You should also use the problem solving approach to help you (see Section 10.5). You can suggest some or all of the following:

a. Improve social skills

- Ask the individual and family member to think about what social skills they need to do the community activities they would like to be involved in. These might include:
 - Greeting others
 - Listening to others

- Asking for information
- Expressing an opinion, for example about their own treatment.
- Saying sorry when this is needed
- Eating with others in a polite way

Now discuss with the individual and caregiver which things the individual has problems with.

Focus on these things.

- Ask the individual to practice these skills with you. For example,
 - Ask them to show you how they would greet a neighbour they met at church.
 - Ask them to show you how they would ask the price of something, for example cabbage at the market
- Give encouragement, including smiles and praise, when the individual shows they can do the skill
- Ask the individual to try the skills in a real life situation

b. Invite neighbours or relative for coffee

Suggest that the family invite neighbours or relatives to the home to drink coffee. This can be a chance to practice talking to familiar people in a familiar environment.

c. Family member accompanies the person to community activities

Suggest that a family member goes with the individual to the community activity for the first few times. This will give the individual more motivation and confidence. The family member may be worried that the individual will behave in an embarrassing way. Suggest that they start with activities that are close to the house and involve fewer people. For example it may be less stressful to go to the grain mill together, than to attend a funeral with many guests.

d. Engage with community leaders

With the help of the individual and the caregiver, identify key people within the community who may be able to help the individual to get back to usual activities. Consider:

- Religious leaders, who may be able to help the person go to church, mosque or a religious group (mahber or lika)
- Edir leaders, who may be able to help the person contribute to Edir and participate in the Edir activities
- Leaders of Youth Association, Women's Association or sub-district leaders, who may be

able to help the person attend meetings and contribute to sub-district affairs

If you have not already done so, it may be appropriate for you to meet with the leader to give them information about schizophrenia and to see how they can help. See Tasks 8, 9 and 10 in Community Mobilisation Chapter 31. Alternatively the caregiver may be willing to approach the leader independently.

e. Use approaches from other modules

Some of the approaches from other modules may also contribute towards helping individuals to take part in community life, for example:

- Community-awareness raising (see Chapter 31), which aims to reduce stigma and discrimination towards people with schizophrenia
- Improving adherence and improving side effects (see Chapter 20)
- Giving the individual strategies to deal with stigmatising attitudes (see Chapter 28)
- Improving the attitude of the family towards the individual (see Chapter 25)
- Dealing with distressing symptoms such as hallucinations, lack of motivation and problems with organisation (see Chapter 22)

f. Acting as a role model

The way you behave in the sub-district can have a big impact on other people’s attitudes. When you see the individual outside whilst not in a home visit, greet them, as you would do anyone else. Showing the community that the individual is just like other people may be one way to reduce stigma.

You can use Table 6 as a guide for which approach to use in which circumstances:

Table 6 Approaches to support individuals to take part in community life

Problem	Approach
Lack of motivation	<input type="checkbox"/> Family member accompanies <ul style="list-style-type: none"> • Invite neighbours or relatives • <i>‘Dealing with distressing symptoms’ module</i>
Medication side effects	<input type="checkbox"/> <i>Address side effects</i>
Problems with holding a conversation	<ul style="list-style-type: none"> • Practice social skills • Invite neighbours or relatives
The family does not let the individual attend community events	<ul style="list-style-type: none"> • <i>‘Improving the family environment’ module</i> • Invite neighbours or relatives
Stigma and discrimination from community	<ul style="list-style-type: none"> • Engage with community leaders • Acting as a role model • <i>‘Dealing with stigma and discrimination’ module</i> • <i>Community awareness raising task</i>

5. Make a plan

Discuss with the individual which specific community activity to focus on first, and agree the steps to start participating again. Make sure everyone knows what their role is.

Follow up

Make sure you follow up progress on participating in community activities at the next home visit. Discuss what strategies were tried and which ones helped. Practice social skills again if you agree this may help. If relevant, make contact with community leader to facilitate engagement in community activities

Sara's story

Since she became unwell Sara has had problems visiting her sisters in the neighbouring sub-district. This is something she used to enjoy a lot. Often she doesn't go because she doesn't have the energy to leave the house. She is also worried that she doesn't have anything to say. Berhan discusses with Sara and Alemu, Sara's husband, how they can change the situation. Sara suggests that she could invite her sisters to visit her first of all as this will require less energy. Then if this goes well, Alemu can try to support her to visit them. Berhan helps Sara to practice how to greet people and how to start a conversation. They all agree to try and invite the sisters within the next two weeks, which is when Berhan will visit again.

Summary

- Many people with schizophrenia have problems taking part in community life such as attending church or funerals.
- Helping individuals take part in community life is good for improving self confidence, reducing stigma, and reducing the burden on the family
- Ways to help individuals take part in community life: improve social skills, invite neighbours for coffee, family member accompanies, and engaging community leaders

6.5 RISE TRAINING PROGRAMME

The RISE training programme was designed to address the knowledge and skills needed to achieve the CBR worker competencies (see Table 6.1). The training was closely tied to the RISE manual (see Section 6.4 and Appendix C (ii)). CBR workers received five weeks training, which was equally split between classroom teaching and fieldwork. CBR supervisors participated in the general training, and I also gave them one-to-one training on all aspects of supervision.

Classroom-based training was delivered in Amharic by psychiatrists and coordinators from RAPID, the Ethiopian CBR project supporting children with disabilities. I directly trained all RISE trainers to deliver their sessions, including guidance on the preferred interactive teaching style. See Table 6.3 for the training timetable. Classroom teaching was highly structured using prepared slides and included small group activities, such as role-plays, whole group discussions, viewing specially prepared 'good' and 'bad' communication skills videos, and quizzes. Games and icebreakers were used in between sessions. Fieldwork included shadowing trained CBR workers at the RAPID project, observing psychiatric nurse clinics and making home visits to persons with schizophrenia who were part of the Butajira cohort. Fieldwork and classroom teaching days typically alternated, with consecutive days covering linked topics where possible. After each fieldwork day CBR workers had half a day to discuss their experiences, guided by the trainers.

Table 6.3 RISE training timetable (continued overleaf)

	Method	Session	Trainer
Week 1			
Monday AM	Classroom	Introduction to training	RISE team
Monday PM		Introduction to CBR	
		CBR for schizophrenia I	
		CBR for schizophrenia II	
		CBR for schizophrenia III	
	Overview of RISE pilot and trial		
Tuesday AM	Classroom	Introduction to mental illness	Psychiatrist
Tuesday PM		Introduction to schizophrenia I	
		Introduction to schizophrenia II	
	Medicines for schizophrenia		
Wednesday AM	Classroom	Disability	RAPID supervisor
Wednesday PM		Impact on family	
		Stigma	
		Human rights	
	Importance of the community		
Thursday AM	Classroom	Initial visit	Psychiatrist
Thursday PM		Communication skills	
		Problem solving and trusting relationship	
	Needs assessment		
Friday AM	Classroom	Goal Setting I	Psychiatrist
		Goal setting II	
Friday PM	Assessment		RISE team
Week 2			
Monday AM	Classroom	Intro to RAPID	RAPID CBR worker/ supervisor
Monday PM	Practice in field	Needs assessment and goal setting	
Tuesday AM	Discussion	Needs assessment and goal setting	RAPID supervisor
Tuesday PM	Classroom	Daily functioning	
		Improving physical health	
Wednesday full day	Practice in field	Daily functioning & Improving physical health	RAPID CBR worker/ supervisor
Thursday AM	Discussion	Daily functioning & Improving physical health	RAPID supervisor
Thursday PM	Classroom	Family support groups	
		Dealing with stress and anger	
Friday full day	Practice in field	Family groups & Dealing with stress and anger	RAPID CBR worker/ supervisor
Saturday AM	Discussion	Family groups & Dealing with stress and anger	RAPID supervisor
Saturday PM	Classroom	Community mobilisation I and II	
Sunday AM	Classroom	Community life	RAPID supervisor
		Getting back to work	
Week 3			
Monday AM	Practice in field	Community mobilisation	RAPID CBR worker/ supervisor
Monday PM	Discussion	Community mobilisation	RAPID supervisor
Tuesday full day	Day off		
Wednesday full day	Assessment		RISE team
Thursday AM	Classroom	Understanding schizophrenia	Psychiatrist
Thursday PM		Preparing for a crisis	
		Risk assessment	
	Dealing with human rights issues		
Friday full day	Practice in field	Understanding schizophrenia & Preparing for a crisis, risk assessment, human rights	Psychiatric nurse

Table 6.2 continued			
Week 4			
Monday AM	Discussion	Understanding schizophrenia & Preparing for a crisis, risk assessment, human rights	Psychiatrist
Monday PM	Classroom	Accessing healthcare	
		Supporting individuals to take medication	
Tuesday full day	Practice in field	Accessing healthcare & Supporting medication	Psychiatric nurse
Wednesday AM	Discussion	Accessing healthcare & Supporting medication	Psychiatrist
Wednesday PM	Classroom	Family intervention	
		Dealing with distressing symptoms	
Thursday full day	Practice in field	Family intervention & distressing symptoms	Psychiatric nurse
Friday full day	Day off		
Saturday AM	Discussion	Family intervention & distressing symptoms	Psychiatrist
Saturday PM	Classroom	Taking control of your illness	
		Dealing with stigma	
Week 5			
Monday AM		Documentation	RISE team
		Dealing with other problems	
Monday PM	Classroom	Improving literacy	
		CBR worker wellbeing	
		Supervision	
Tuesday full day	Practice in field	Taking control of illness & Dealing with stigma	Psychiatric nurse
Wednesday AM	Discussion	Taking control of illness & Dealing with stigma	Psychiatrist
Wednesday PM	Classroom Visit to health centre	Link to health centre	RISE team
		Dealing with difficult situations	
Thursday full day	Revision		RISE team
Friday full day	Revision		RISE team

Four example lesson plans are presented in Figures 6.6, Figure 6.7, Figure 6.8 and Figure 6.9 and the entire training outline is presented in Appendix C (iii).

Assessment included written tests in the form of multiple choice questions and vignettes at week 3 and week 5, observations by trainers, self-reported competence assessments and standardised role-play assessments at weeks 1, 3 and 5 (see Appendix C (iv)). Psychiatrists and supervisors assessed CBR competence by rating role-plays using the ENACT scale [2], adapted for Ethiopia (see Appendix C (v)). The adaptation and piloting of the ENACT and the CBR worker competence data are being written up for publication, but are not presented in detail in this thesis. CBR workers were to be excluded if they scored <40% on the post training written test or rated as 'needs improvement' on >20%

ENACT items on the final role play assessment. All CBR workers were above these thresholds so proceeded to the pilot.

Figure 6.6 RISE training session 'Disabilities relating to schizophrenia'

Disabilities related to schizophrenia (Wednesday Week 1)		
Reference: RISE manual Chapter 4		
Competencies		
<ul style="list-style-type: none"> 6c: Understands the impact of schizophrenia in terms of disability, stigma, human rights and family burden 		
Steps	Resources	Timing
1. Tell the group what we mean by disability	Powerpoint 11	5 mins
2. Ask the trainees what types of disabilities might be related to schizophrenia. Write their answers on the flip chart.	Flip chart	15 mins
3. Teach the following points: <ul style="list-style-type: none"> What types of disabilities people with schizophrenia may have. Use the examples the group gave. What causes disabilities 	Powerpoint 11	15 mins
4. Ask the trainees to read Yosef's story. Divide into groups of 3. One participant should read the vignette. Each group should discuss what disabilities Yosef has and what might have caused them.	Manual	25 mins
5. Ask for feedback on from each group.		
6. Teach the following points: <ul style="list-style-type: none"> Remind the group what we mean by rehabilitation and recovery 	Powerpoint 11	5 mins
7. Ask the group what recovery might mean to Yosef	Flip chart	10
8. Quiz	Powerpoint 11	5
Total		80

Figure 6.7 RISE training session 'Taking part in community life'

Taking part in community life (Sunday Week 2)		
Reference: RISE manual Chapter 26		
Competencies		
<ul style="list-style-type: none"> 7p: Able to assess reasons for reduced participation in community life and apply problem solving approach to address this 		
Steps	Resources	Timing
1. Ask the group what problems people with schizophrenia might have with taking part in community life. Write the answers on the flip chart.	Flip chart and pen	10
2. Tell the group about: <ul style="list-style-type: none"> Common problems with taking part in community life, using the group's examples Why people with schizophrenia might have problems with taking part in community life Why it is important to improve problems with taking part in community life 	PowerPoint 28	10
3. Describe the steps to improve problems taking part in community life <ul style="list-style-type: none"> Principles Explain why you are doing this module Ask for problems with taking part in community life Agree what community activities the individual wants to do Discuss barriers and do problem solving to decide how to overcome problems 	PowerPoint 28	15
4. <i>In threes, one trainee should pretend to be the caregiver, one trainee the person with schizophrenia and one trainee should pretend to be the CBR worker. Take it in turns to take each role. The CBR worker should work with the person with schizophrenia to practice the following social skills:</i> <ul style="list-style-type: none"> Greeting others Asking for information Expressing an opinion 5. After each role play the trainees playing the caregiver and person with schizophrenia and should feedback to the person playing the CBR worker: any good things they did, any thing they did less well, something they can improve on for next time.	Handout 18	25
6. Ask each group to make one comment about the role play e.g. what they found difficult.		10
7. In groups of three the trainees should discuss how they could solve the problem vignettes. <i>Suggest as many ways as you can think of to deal with the following problems. Decide which are not good suggestions and which are good suggestions. Select the best one</i> <ol style="list-style-type: none"> Betty used to go to market but doesn't anymore. She says she is too tired to go. Daniel used to vote at the sub-district meetings but doesn't any more. Last time he went people ignored him. Henok doesn't go to weddings or funerals because his parents are worried he will shout at people and be embarrassing. Solomon used to contribute to Edir by making payments by himself and helping with the tasks at funerals e.g. erecting the tent. His family say he shouldn't do this now he is ill. Tigist used to go to church but now she doesn't go. She doesn't have any friends in the sub-district now and she is worried she will have trouble talking to people. 	Handout 19	15
8. Ask each group to feedback their suggestions for solving the problems.		10
Total		100

Figure 6.8 RISE fieldwork session 'Community mobilisation practice'

Community Mobilisation Practice (Monday Week 3)		
Reference: Chapter 31		
Competencies		
<ul style="list-style-type: none"> • 8a: Able to form good relationships with community leaders and health extension workers • 8b: Able to conduct community awareness raising • 8c: Able to engage with community leaders to facilitate CBR • 8d: Able to maximise sustainability of programme through community involvement 		
<ul style="list-style-type: none"> • Trainees should accompany RAPID CBR workers to a community mobilisation activity e.g. community awareness raising, meeting with community leader/head teacher • They should observe the activity and discuss some of the following points with the CBR worker <ul style="list-style-type: none"> ○ Previous meetings, awareness raising activities ○ Skills needed to work with community leaders ○ Skills needed to give information to the community ○ Topic discussed ○ Challenges of working with community leaders or wider community ○ Benefits of community mobilisation work ○ How/ whether community mobilisation work helps CBR to continue after the CBR workers have left • The trainee should write notes so they can remember and discuss what they did and learnt the following day. 		

Figure 6.9 RISE training session 'Community mobilisation discussion'

Community mobilisation discussion (Monday Week 3)		
Reference: Chapter 31		
Competencies		
<ul style="list-style-type: none"> • 8a: Able to form good relationships with community leaders and HEWs • 8b: Able to conduct community awareness raising • 8c: Able to engage with community leaders to facilitate CBR • 8d: Able to maximise sustainability of programme through community involvement 		
Steps	Resources	Timing
<p>Ask each trainee in turn to share with the group their experience in the field. Use the following prompts:</p> <ul style="list-style-type: none"> • Describe the community mobilisation activity they observed • Topics discussed • Benefits and challenges of the work • Skills needed for the work • What have they learnt; how can they use the information in their own work • Anything that was confusing • Anything that was difficult or challenging • Any thing that was interesting or surprising <p>Encourage the group to ask each other questions and discuss amongst themselves</p>	Flip chart	120

6.6 CONCLUSION

This chapter has given an overview of the RISE CBR worker training and the CBR intervention delivery structure and content. The next chapter will describe the implementation of this intervention in a 12 month pilot study.

6.7 REFERENCES

1. Brooke-Sumner, C., *Psychosocial Rehabilitation for Schizophrenia in South Africa: Developing a community-based approach to promote recovery in Dr Kenneth Kaunda District*, in *School of Human Sciences, College of Humanities*. 2015, University of KwaZulu-Natal.
2. Kohrt, B.A., M.J. Jordans, S. Rai, P. Shrestha, N.P. Luitel, M.K. Ramaiya, D.R. Singla, and V. Patel, *Therapist competence in global mental health: Development of the ENhancing Assessment of Common Therapeutic factors (ENACT) rating scale*. *Behav Res Ther*, 2015. **69**: p. 11-21.



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Student	Laura Asher
Principal Supervisor	Vikram Patel
Thesis Title	The development and evaluation of a community-based rehabilitation intervention for people with schizophrenia in Ethiopia

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

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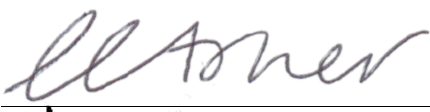
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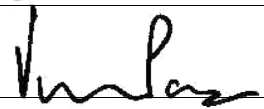
Where is the work intended to be published?	Social Science and Medicine
Please list the paper's authors in the intended authorship order:	Laura Asher, Charlotte Hanlon, Rahel Birhane, Helen Weiss, Julian Eaton, Alehegn Habtamu, Vikram Patel, Abebaw Fekadu, Mary De Silva
Stage of publication	Not yet submitted

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I wrote the study protocol and the CBR worker training manual and training materials. I led on the intervention implementation, qualitative and process data collection and analysis, and quantitative analysis. For midline and end line quantitative data collection I revised the questionnaires, led on data collector training, produced the EpiData databases and oversaw data quality assurance procedures. I wrote the initial and final drafts of the paper.
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Student Signature: 

Date: 06.10.2016

Supervisor Signature: 

Date: 06.10.2016

7 THE RISE PILOT STUDY

7.1 INTRODUCTION

Chapter 5 presented the intervention development work undertaken to design a CBR intervention for schizophrenia that is acceptable, feasible and culturally appropriate for the Ethiopian context. Chapter 6 described the structure and content of the RISE CBR intervention in more detail. This chapter describes a 12 month pilot of this intervention, representing the 'Feasibility and piloting' phase of the MRC framework [1]. Structured using the theory of change framework, this chapter explores how and why the RISE CBR intervention may improve functioning, as well as its acceptability and feasibility in practice, and details the adjustments made to the intervention in preparation for an cluster randomised trial (Chapter 8).

7.2 METHODS

7.2.1 Setting

This study was set in Sodo district in Southern Ethiopia, which is described in Chapter 3 (Section 3.3) and Chapter 5. Sodo district is the setting for the Ethiopian arm of the PRIME project [2], which involves the integration of mental health services into primary care. At the start of the pilot study primary care staff could only refer complex cases to the psychiatric nurse-led outpatient clinic in Butajira hospital, which lies 30km away in the neighbouring district. During the pilot study a new psychiatric nurse-led outpatient clinic was set up at the general hospital in Bui. Fluphenazine depot injections were sometimes available at these clinics. Psychiatric nurses at these clinics could also refer patients to Ammanuel Psychiatric Hospital in Addis Ababa; however these referrals are rarely made in practice. There was no free medication provision by PRIME, hence at the start of this study health care costs were out-of-pocket with a fee waiver available for the poorest, given at the discretion of sub-district officials. From December 2014 people with schizophrenia were invited by PRIME to access this new service and

were followed up in the 12 month PRIME cohort study [3]. RISE pilot participants were recruited at the baseline of this cohort study.

7.2.2 Participants

This pilot study was conducted between December 2014 and December 2015. The participants were ten people with schizophrenia and their families living in four sub-districts of Sodo. Only one participant per CBR worker was selected because this was perceived to be an appropriate initial workload for the newly trained CBR workers, as well as a suitable sample size for the in-depth analysis planned. The four sub-districts were selected for convenience; they were all linked to the health centre that saw the earliest implementation of mental health into primary care, and cohort study recruitment, by PRIME. In the selected sub-districts, the intervention coordinator assessed consecutive PRIME cohort recruits for RISE pilot eligibility by reviewing data routinely collected at PRIME baseline (see Appendix D (i)). There were no specific exclusion criteria. Participants meeting all of the following criteria were included:

- 1) Participant in PRIME cohort study
- 2) Resident in sub-district for >6 months and no immediate plans to leave the sub-district
- 3) Has a primary caregiver who is willing to participate in the study
- 4) Age ≥ 18 years
- 5) Diagnosis of schizophrenia spectrum disorder (schizophrenia, schizoaffective disorder or schizophreniform disorder) using DSM-IV criteria (assessed using the Operational Criteria for Research (OPCRIT) [4]) [5] and
- 6) Evidence of enduring or disabling illness demonstrated by one or more of the following:
 - (i) Brief Psychiatric Rating Scale – Expanded version (BPRS-E) score ≥ 52 [6]
 - (ii) 36-item WHODAS 2.0 score ≥ 35 [7]

(iii) Continuous illness over the preceding six months, assessed using the Life Chart Schedule (LCS) [8]

(iv) Symptomatic in three or more out of the last six months, assessed using the Longitudinal Interval Follow-up Evaluation (LIFE) [9] or

(v) Clinical Global Impression (CGI) score \geq four (at least moderately ill) [10].

Details of these instruments are provided in Table 7.1. The final criterion allowed us to include the group expected to benefit the most from CBR and also reflects the threshold at which CBR could realistically be offered in this resource-constrained setting. Eligible participants were given information about the study by the intervention coordinator in a way appropriate to the participants' literacy level.

7.2.3 CBR workers and supervisors

The CBR workers were recruited to the following essential criteria: (1) completed tenth grade education (secondary school), (2) resident in Sodo district, and (3) interest in community work. Previous experience of community work and high attainment in school examinations were desirable. Degree level applicants were excluded. There were 220 applications in response to local adverts, which were ranked and 50 selected for examination using the criteria. The examination included multiple-choice questions on appropriate ways to support people with schizophrenia. Twenty applicants proceeded to the interview on the basis of ranked scores, from which 12 successful applicants were finally selected. One CBR worker dropped out after two weeks training. Due to a misdiagnosis at PRIME cohort recruitment, one CBR worker exclusively supported a man with intellectual disability during the RISE pilot, hence his data are not reported in this chapter. Of the ten CBR workers presented here there was an equal gender split and half had some experience in health or community work, though none had mental health experience. CBR workers received a salary equivalent to health extension workers (approximately £60/ month) and a transport allowance. One male and one female supervisor were recruited to the minimum criteria of a diploma level qualification and experience in community work; they received a salary of approximately £180/month. The intervention coordinator had an MSc in Pharmacology.

7.2.4 CBR delivery and supervision

Two or three CBR workers were based in each sub-district and each CBR worker supported one person with schizophrenia and their caregiver over a 12 month period. The CBR intervention and supervision arrangements are described in detail in Chapter 6. CBR supervisors and CBR workers used public transport (carts or minibuses) to travel to participants' home or travelled on foot. All participants received both CBR and usual care at the health centre. During the pilot I provided close support to the CBR supervisors and the intervention coordinator as the pilot was considered part of the training period for CBR workers, supervisors and the intervention coordinator. As such I was present at all group supervision meetings and some individual supervision meetings. My role was to observe and guide supervision to ensure intervention fidelity and participant safety. By the midpoint of the pilot period, as expected, the intervention coordinator had largely taken over this role, though I continued to provide input when required. I also continued to interact with CBR workers and supervisors at the fortnightly to monthly feedback meetings throughout the pilot period (see Section 7.2.6.3).

7.2.5 Theory of change

Theory of change was used to guide the evaluation of the pilot. Figure 7.1 presents the RISE theory of change map that was produced prior to the pilot (see Appendix D (ii) for the detailed version); this was a refined version of the theory of change map presented in Chapter 5. This pre-pilot theory of change map identified 'Sustained improved functioning in people with schizophrenia' as the desired long-term outcome (yellow box in Figure 7.1). Intermediate outcomes included those related to the programme delivery (green boxes in Figure 7.1) and causal pathways to improved functioning (blue boxes in Figure 7.1). In addition thirteen assumptions were identified, for example '1b: CBR can address the needs of people with schizophrenia' (orange boxes in Figure 7.1). Assumptions represent what needs to be in place, or 'true', in order to proceed through intermediate outcomes and ultimately to achieve the final outcome. Assumptions were grouped into three overarching research questions.

1. Is the RISE CBR intervention acceptable?
2. Is the RISE CBR intervention feasible?
3. Can the RISE CBR intervention produce an impact and if so, how?

The pilot evaluation was designed to answer these research questions and to test the assumptions. The evaluation was also responsive; issues emerging early on in the pilot were explored in more depth at the later stages of data collection.

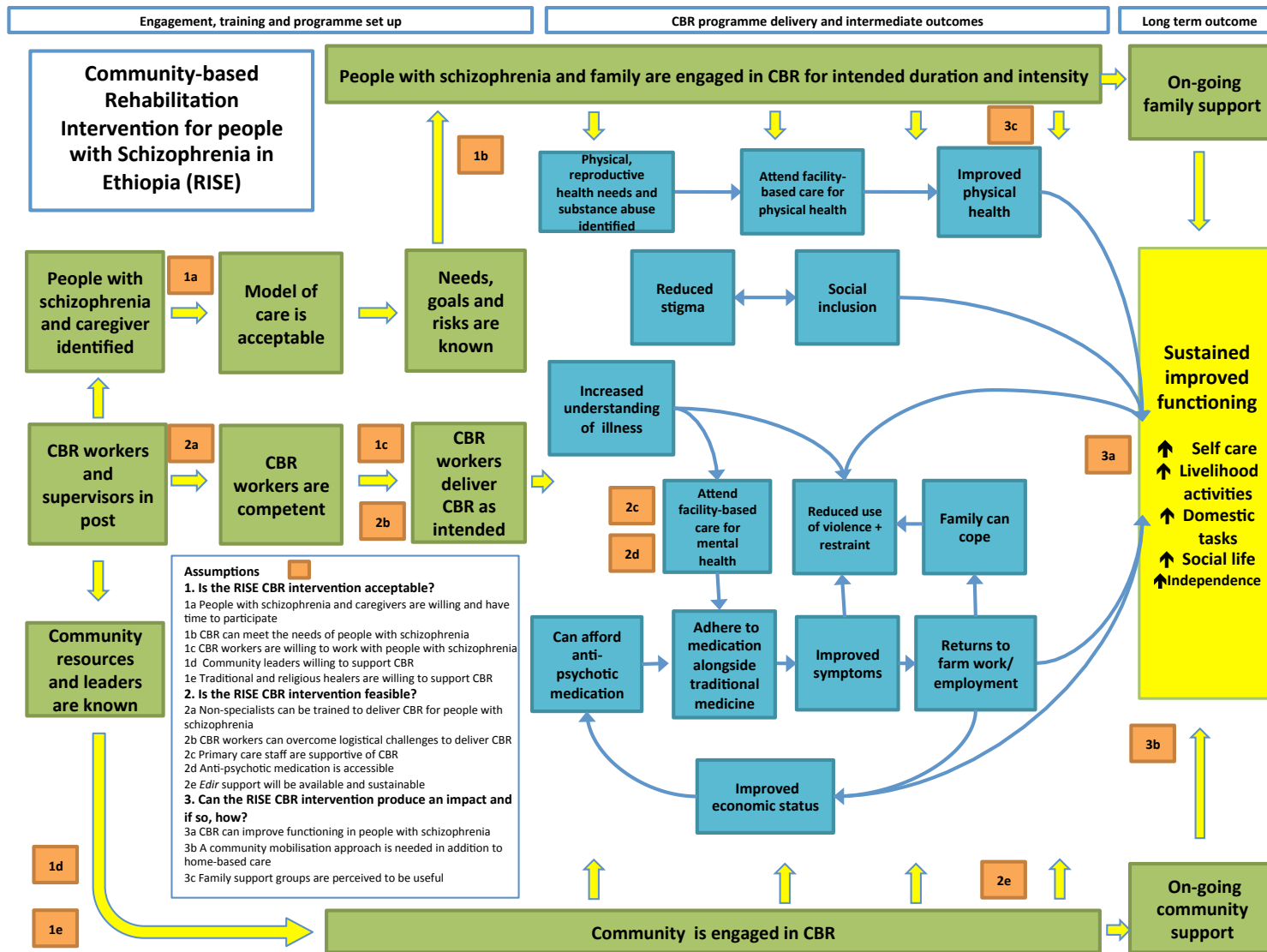


Figure 7.1 Pre-pilot theory of change map

7.2.6 Data collection and analysis

7.2.6.1 Quantitative

Quantitative data collection took place at baseline, six and 12 months. Trained lay data collectors interviewed people with schizophrenia using a structured questionnaire comprising the following assessment tools: an adapted version of subscale 1 (unfair treatment) of the Discrimination and Stigma Scale-12 (DISC-12) [11], an adapted version of the Client Service Receipt Inventory (CSRI) to determine health facility use [12, 13], questions about episodes and duration of physical restraint, the Alcohol Use Disorders Identification Test (AUDIT) to detect hazardous drinking [14] and an amended version of the Patient Health Questionnaire- 9 (PHQ-9) [15, 16] to measure depression. Data collectors administered a structured questionnaire to caregivers which comprised of the Involvement Evaluation Questionnaire (IEQ) to measure caregiver burden [17] and the proxy-reported 36-item WHODAS 2.0 [7, 18] to measure disability amongst people with schizophrenia. A psychiatric nurse rated the CGI to determine the overall clinical impression [10], the BPRS-E to measure symptom severity [6] and the LCS to determine illness course [8]. Details of the instruments are summarised in Table 7.1 and the instruments are presented in Appendix E (vii). All instruments have been validated or adapted for use in Ethiopia, including translation into Amharic. Trained research assistants verified questionnaires immediately after data collection, and any missing items or discrepancies were clarified with the participants. At baseline, data were double entered onto an Epidata Entry Version 3.1 database. Six and 12-month data were entered onto an Epidata EntryClient (Version v2.0.4.16) database and managed using Epidata Manager v2.0.6.52. Descriptive summaries of socio-demographic and outcome data were prepared using Stata Version 12 [19]. All databases were password protected and only accessible to authorised personnel. All forms and questionnaires that include patient data were anonymised, identifiable only through the unique identification number.

Table 7.1 Pilot quantitative instruments (continued overleaf)

Outcome	Instrument/s
Lay data collector: patient-reported	
Depression (see Appendix E (vii); pages 425-426 Volume II)	The Patient Health Questionnaire- 9 (PHQ-9) [15, 16] incorporates DSM-IV depression diagnostic criteria with other leading major depressive symptoms. Each item is rated as '0' (not at all) to '3' (nearly every day). The item 'Feeling bad about yourself' was excluded at baseline as part of the initial adaptation for Ethiopia by PRIME, but reintroduced at midline and endline. This item was excluded from summary scores at all time points to allow time points to be compared. Possible range for the adapted version is 0 to 24 with higher scores indicating greater severity.
Health service utilisation (see Appendix E (vii); pages 428-429 Volume II)	An adapted version of the Client Service Receipt Inventory (CSRI) [12, 13], developed for PRIME, was used to enquire systematically about the utilisation of biomedical and traditional services and associated costs (direct and indirect).
Physical restraint (see Appendix E (vii); pages 430-431 Volume II)	A set of questions on the duration, frequency, perpetrator and reasons for physical restraint. At baseline episodes in the participant's lifetime were recorded. Episodes in the last six months were recorded at midline and endline.
Alcohol use (see Appendix E (vii); pages 432-433 Volume II)	The Alcohol Use Disorders Identification Test (AUDIT) is a 10-item tool, which was used to detect hazardous drinking [14]. Possible score range is 0-40 with higher scores indicating greater severity.
Discrimination (see Appendix E (vii); pages 434-436 Volume II)	Measured using subscale 1 (unfair treatment) of the Discrimination and Stigma Scale Version 12 (DISC-12) [11]. Original version includes 21 items asking the participant if they have experienced different types of discrimination relating to their mental illness. All items are rated on a 4-point likert scale (0 'Not at all' to 3 'A lot'). Due to PRIME's initial adaptation of DISC-12 for Ethiopia, at baseline the DISC-12 did not include items relating to 'Unfair treatment in accessing welfare benefits' and 'Privacy'. These items were introduced at midline and endline but these items were excluded from summary scores at all time points to allow time points to be compared.
Lay data collector: caregiver-reported	
Disability (see Appendix E (vii); pages 442-447 Volume II)	36-item WHODAS 2.0 [7]. Six domains: understanding and communication, getting around, self-care, getting along with people, life activities and participation in society. Total scores are converted to compute a 0-100 range summary with higher scores indicating higher levels of disability. At baseline data collection, both people with schizophrenia and caregivers could contribute to the WHODAS responses, due to different procedures utilised by PRIME at that time point. At midline and endline only caregiver responses were used.
Caregiver burden (see Appendix E (vii); pages 461-468 Volume II)	Involvement Evaluation Questionnaire (IEQ) [17]. This is a 31-item questionnaire assessing aspects of caregiving including tension, worrying, urging and supervision. All items are scored on 5-point Likert scales (0 never to 4 always). A 27-item sumscore can be computed (range 0 to 108).

Table 7.1 continued	
Psychiatric nurse-rated instruments	
Symptom severity (see Appendix E (vii); pages 402-411 Volume II)	Brief Psychiatric Rating Scale- Expanded version (BPRS- E) [6]. Focuses on symptoms of psychosis, but also has items covering the symptom domains of somatic concerns, anxiety, depression and mania. Each symptom is rated along a seven-point severity continuum (1 to 7). Total score is obtained by adding the ratings for each of the 24 items. Range is 24 to 168 with higher score indicating greater severity.
Clinical impression (see Appendix E (vii); pages 412 Volume II)	Clinical Global Impression (CGI)- illness severity [10]. Rated on a seven point score ranging from 1, when the patient is assessed to have no illness, to 7, when the patient is among the most severely ill. The scale is completed entirely based on clinical judgment.
Relapse (see Appendix E (vii); pages 413 Volume II)	Life Chart Schedule (LCS) [8]. The symptoms section will be administered in order to determine the course type and number of relapses.

7.2.6.2 Qualitative

Qualitative data were collected at two months and 12 months into the pilot. A total of 40 in-depth interviews (IDIs) were conducted with 21 individuals comprising people with schizophrenia, caregivers, supervisors, primary care-based health officers and community members (see Table 7.2). Two focus group discussions (FGDs) were held with the 10 CBR workers at two months and two FGDs were held at 12 months. The topic guides addressed the research questions, namely the acceptability, feasibility and perceived impact of CBR, with specific questions guided by the assumptions and issues arising from on going process data collection (see Appendix D (iii)). Two people with schizophrenia, both with co-morbid intellectual disability, were assessed not to have the cognitive capacity to participate in IDIs. Two caregivers and a man with schizophrenia declined to participate in IDIs at two months despite having given consent at recruitment. This individual with schizophrenia participated at 12 months; however an additional caregiver did not wish to participate at 12 months as their relative with schizophrenia had died during the pilot. All ten CBR workers and the two supervisors were included. The two health officers who provided facility-based mental health care to participants were included. Three community members engaged in CBR- a priest, a health extension worker and a businessman- were selected purposively to ensure coverage of different roles. All participants received modest remuneration for their time and transportation costs (with the exception

of CBR participants for the two month interviews). The IDIs and FGDs were conducted in Amharic by an Ethiopian research assistant with a social work Masters who had experience in qualitative work with people with schizophrenia and caregivers [20]. IDIs and FGDs were conducted at participants' homes or in a research office. IDIs lasted between 11 and 140 minutes (mean 46 minutes). The audio-recordings were transcribed in Amharic, and then translated into English. I discussed and clarified any ambiguous translations or cultural references with the research assistant.

To triangulate the data the linked patient, caregiver, and CBR worker interviews for two months and endline were read in concert. The aim was to construct a narrative for each participant, whilst acknowledging that no single version of events could be considered the 'truth'. Note was made of changes and contradictions in experiences and opinions over time and between linked persons with schizophrenia, caregivers, CBR workers and community members. A thematic analysis was conducted, using NVivo for Mac software to manage the data [21, 22]. After independently coding two transcripts, Charlotte Hanlon and I discussed differences and made adjustments to the coding scheme. I indexed all transcripts using the final coding scheme, then collated the codes into themes. The coding framework was based around a priori high-level themes aligned with the assumptions, for example 'Assumption 1a: People with schizophrenia and caregivers are willing and have time to participate in CBR'. An inductive approach was employed to identify sub-themes, in this case specific reasons for participation and non-participation. Attention was paid to the tension between expected sub-themes and those not anticipated, as well as associations with participant characteristics. Deviant cases were identified and incorporated into the framework. I used a contextualist approach, retaining focus on reported experiences, but trying to understand how the social context shaped those experiences and the way they were spoken about.

Table 7.2 Number of participants in IDIs and FGDs

Participant type	2 months		12 months	
	IDIs	FGDs	IDIs	FGDs
Men with schizophrenia	4	0	5	0
Women with schizophrenia	3	0	3	0
Male caregivers	1	0	1	0
Female caregivers	7	0	6	0
CBR supervisors	2	0	2	0
CBR workers	1	2 (n=10)	0	2 (n=10)
Health officers	2	0	0	0
Community members	0	0	3	0
Total	20	2 (n=10)	20	2 (n=10)

7.2.6.3 Process data

Process data were compiled using a range of sources to determine the fidelity, quality and intensity of intervention delivery [23]. Sources included (i) Implementer self-report: Fortnightly to monthly review meetings in which CBR participants' progress and barriers faced were discussed with each CBR worker. These were recorded on an excel spreadsheet, which was checked by the intervention coordinator for accuracy, (ii) Documentary analysis of CBR worker completed 'sub-district' logbooks, 'participant' logbooks and supervisor's logbook, comprising the completed intervention delivery forms described in Chapter 6 and presented in Appendix C (i). Data on quantitative measures of implementation were extracted onto process data forms (see Appendix E (v)) and double entered onto Epidata EntryClient databases and (iii) structured observations of CBR workers using the adapted ENACT to assess CBR quality [24]. The full ENACT data is not presented in this thesis. A descriptive analysis of process data was conducted using Stata version 12.

7.2.7 Data synthesis

Qualitative, quantitative and process data were synthesised to provide detailed understandings of how the intervention was delivered in practice, in particular to

explore the extent to which each theory of change assumption was met and the barriers to meeting the assumptions. For any assumptions that were not initially met, iterative adjustments were made to the delivery model or intervention content as appropriate, to ensure that the final intervention package was acceptable, feasible, and ultimately likely to lead to improvements in functioning. Furthermore, where assumptions were not fully met in the pilot, improvements were made to the trial evaluation plans for the assessment of acceptability, feasibility or impact.

7.2.8 Ethical considerations

Ethical approval was obtained from the LSHTM Research Ethics Committee and the Addis Ababa University College of Health Sciences Institutional Review Board (see Appendix D (iv)). Written consent to participate was sought from each participant. If a person with schizophrenia was deemed not to have capacity to consent, permission was sought from the caregiver and assent from the person with schizophrenia. Only the two participants with co-morbid intellectual disability were assessed to not have the capacity to consent. Where the participant was unable to write, a thumb impression was recorded, along with the signature of a witness to confirm accurate explanation of the study. See Appendix D (v) for the information sheets and consent forms.

7.3 RESULTS

7.3.1 Overview

The CBR participants were five male and five female people with schizophrenia aged between 19 and 60 years. All female participants were illiterate whilst male participants had between five and eight years of school education. All caregivers were female (wives, mothers, sisters and a daughter) except one male benefactor who was unrelated to the participant. Two participants did not have active caregivers. The median duration of illness was 10 years (range 1 to 30 years) and two participants had co-morbid intellectual disability. Half of participants were

treatment naïve prior to the pilot commencing; only one participant was actively taking medication at the start of the pilot.

Key process and quantitative data are presented in Tables 7.3, 7.4 and 7.5. Linked identification (ID) numbers are used for people with schizophrenia, CBR workers and community members; 'B' and 'E' indicate baseline (2-month) and endline (12-month) qualitative interviews respectively. For clarity qualitative, quantitative and process findings are summarised for each of the 13 assumptions, grouped into the three research questions. Adjustments to the intervention and trial evaluation that were made on the basis of these findings are summarised at the end of each set of assumptions. Tables 7.6, 7.7 and 7.8 contain a summary of the research questions, assumptions, findings and adjustments.

7.3.2 Research question 1: Is the RISE CBR intervention acceptable?

7.3.2.1 Assumption 1a: People with schizophrenia and caregivers are willing and have time to participate in CBR

Participants received 21 home visits on average (range 17- 27 visits) (see Table 7.3). This almost matched the anticipated total of 22 visits because although visits reduced or stopped during periods of disengagement, CBR workers tended to 'catch up' and do additional visits once participants were engaged again.

Table 7.3 CBR participant process data

ID	Months CBR received	Number home visits	Optional modules undertaken/ optional modules indicated (%)*	Optional goals achieved /optional goals selected (%)*	Meetings with community members relating to participant	Referrals to health centre/ heath extension worker
1	12	22	5/7 (71.4)	8/11 (73)	1	2
2 **	12	21	5/5 (100)	4/9 (44)	0	2
3 **	10***	17	5/5 (100)	2/10 (20)	0	1
4	8	19	4/5 (80)	1/8 (13)	3	2
5	12	17	5/5 (100)	8/9 (89)	10	1
6	11	19	4/4 (100)	6/8 (75)	0	0
7	12	24	7/7 (100)	8/8 (100)	5	1
8	11	27	7/7 (100)	7/11 (64)	4	4
9	12	23	4/5 (80)	6/9 (67)	1	1
10	12	22	6/7 (85.7)	5/6 (83)	0	2
Mean	11.2	21.1	5.4/5.7 (91.7)	5.5/8.9 (62)	2.4	1.6

*All participants started all core modules and achieved all four core goals **Co-morbid intellectual disability *** Participant (ID 3) died during pilot period

The majority of CBR participants reported welcoming the service, at least initially, usually because they felt CBR was of clear benefit. Several suggested it was a relief to get support. By the end of the pilot most CBR workers and participants described a good relationship, with several describing close bonds like friends or family.

"[The caregiver] received us warmly. I also had a very good relationship with both of them. We had a very good time. We were like friends [...] I regret that I didn't have pictures taken with [the CBR participant] before he left for Addis for work."

(male CBR worker -8-E)

For one caregiver, the fact the CBR worker was from the local area was an important foundation for their relationship.

“Interviewer: Was [the CBR worker] the kind of person you can put your trust in?”

Respondent: Yes. We have become family. She is from this area. She knows many things about us. It is difficult for a person who lives far away [from us] to understand our situation.”

(female caregiver-10-E)

CBR workers felt that a trusting relationship was essential for engagement with CBR and led to positive outcomes. Most CBR participants said they could rely on the CBR worker, with one caregiver emphasising the importance of confidentiality.

“[The CBR worker] told us that we can count on him and call him when we experience some problems. He told us that he will try to solve the problem by cooperating with us [...] Other individuals might not keep the secret confidentially. For example, if they heard that he has mental illness, they may say that he is “crazy” [...] It is better to tell [the CBR worker] and get advice from him. This is because he is a teacher and will keep the secret confidential.”

(female caregiver-7-E)

The majority of CBR participants were happy to receive regular visits at home, with several caregivers saying they disregarded the time cost and potential stigma as long as CBR was helpful.

“I didn’t worry about shortage of time, because [CBR] was very useful for me [...] It is for our own good. I would be very happy to learn the whole day, let alone for two hours”

(female caregiver-1-E)

However, some participants also disengaged for short periods for various reasons: some stayed away from home for several weeks, either in Addis Ababa visiting relatives or at holy water sites to receive treatment for schizophrenia or musculoskeletal problems. One CBR worker felt that the tapered reduction to monthly home visits damaged the close relationship with the participant and made engagement harder to maintain. For three participants, clashes over the CBR workers’ recommendation to take medication contributed to unwillingness to participate in CBR. These participants felt that CBR workers ignored valid concerns about side effects and ‘nagged’ them to continue medication in a way that one older man felt was infantilising.

"[The CBR worker] reminded me to take the medication properly, but I was not happy with her reminder... I thought she considered me as a child. However I understood that it is helpful"

(man with schizophrenia -1-B)

According to the CBR workers these issues were largely resolved by minimising the emphasis on medication and allowing home visits to continue without conflict. However in one case these disagreements led to a complete break down of trust and contributed to the participant quitting CBR at around eight months.

"It is boring when such advice is given repeatedly. I think the advice you got once could help you in your life [...] When [the CBR worker] nags me repeatedly, I tell him that I don't want to continue [CBR] He always created stress in my life."

(woman with schizophrenia -4-E)

A further two participants withdrew at 11 months, both of whom had demonstrated considerable improvements in functioning since the pilot commenced. In one of these cases, CBR was terminated as the participant moved to Addis Ababa for work. The other man, whose social and livelihood functioning rose appreciably during the pilot, with apparent contribution from CBR, explained:

"I didn't return [the CBR worker's] calls because I thought 'I have recovered from my illness'. I have also completed the lesson that was planned for one year [...] I have recovered because of the medication that was prescribed. There are doctors here. I can go to them, if my illness relapses."

(man with schizophrenia -6-E)

A minority of participants complained that CBR visits were too long and interrupted their work, with the potential to lose customers or livestock.

"When I am at the farm with the oxen...I feel irritated when [the CBR worker] came because thirty minutes is too much for me... The farm work is a tiresome work as it needs much dedication [...] Unless the discussion with her is after the harvest work, it will be too long"

(man with schizophrenia -1-E)

It was often easier for female participants to take part as they could do domestic tasks, such as handicrafts, whilst simultaneously talking with the CBR worker. In several cases CBR workers successfully adjusted visit timings to fit in with

participants' schedules or reduced the frequency of visits. Nevertheless there were some complaints that CBR sessions were too boring or that the information was easy to forget. Several participants requested written materials to refer back to. One man with schizophrenia did not like to meet alone with the female CBR worker, due to his concerns that they would be suspected of having a romantic relationship. Only one participant expressed serious concerns that he could be stigmatised by home visits; he counteracted this by telling neighbours they were for political purposes.

"When people ask me why [CBR workers] are coming to my house, I tell them that I am a member of ihadig [the ruling political party] and that I am being interviewed. They will be afraid."

(man with schizophrenia -6-E)

Several CBR workers reported initial difficulties finding a caregiver willing to engage in CBR, despite caregivers having been recruited at baseline. Whilst for some this was resolved with careful negotiations, two participants had minimal family input. One of these participants successfully completed 12 months of CBR. CBR workers were trained to directly ask participants at each home visit if they were experiencing suicidal thoughts or had recently been restrained. Whilst CBR participants said it was acceptable to discuss these sensitive topics, CBR workers themselves were divided. Overall it was felt that enquiring carefully, or indirectly, was the most appropriate approach.

In general CBR participants could not perceive any negative effects of community mobilisation work. However, one man with schizophrenia was unhappy with information about schizophrenia being given to the wider community, suggesting this could result in interference from outsiders.

"I should know these things [about mental illness]. I don't care if the society knows [this information] or not. If you teach elders, when something happens ... in my family, they will come to negotiate [with] us. At that time when I talk loudly they will say, "you are mad". I am not happy with them being taught."

(man with schizophrenia -8-E)

One optional community engagement task, to invite people with schizophrenia to describe their experience of recovery in a public forum, was not carried out in any

sub-district. This was due to difficulty identifying a participant who had time and who was willing and confident to speak in public. The supervisors felt that this activity could have had a powerful impact on public attitudes.

7.3.2.2 Assumption 1b: CBR can address the needs of people with schizophrenia

All participants achieved all core goals, which related to understanding schizophrenia, accessing health services, preparing a crisis management plan and not being restrained. Achieving these goals took longer than the anticipated one to two months; nine participants had however achieved the core goals by three months. Participants selected on average nine optional goals (range 6-11) over the 12 month period, of which on average 5.5 (62%) were achieved (range 13-100%) (see Table 7.3). There was initially a tendency to select more goals than would be achievable in the time frame. The most commonly selected goals were strategies to deal with stress and anger (which 5/6 participants achieved), participation in community life (which 4/7 achieved) and participation in livelihood activities (which 6/6 achieved). Three participants selected the goal to improve literacy, however none of them started the relevant module. This was due to a lack of local literacy groups and prioritisation of other goals. Desired improvements in functioning were often tied to a wish to fulfil gendered roles, generally domestic tasks for women and earning income to support the family for men.

The lowest proportions of optional goals were achieved by the two participants with co-morbid intellectual disability (2 out of 10 goals and 4 out of 9 goals achieved) and the participant who quit at 8 months (1 out of 8 goals achieved). At the beginning of the intervention the caregivers of both women with co-morbid intellectual disability reported particularly high hopes for change (*“When I first saw [the CBR worker], I thought as my daughter [has] got mercy from God. That was my first impression.”* Female caregiver-2-B). These families, and some others, expected complete recovery after a few weeks of taking anti-psychotic medication. The caregivers and CBR workers later expressed disappointment that the expected transformation had not materialised.

The majority of participants demonstrated agency in relation to CBR participation, disengaging if the service did not meet their needs, and articulating concerns in the

interviews. A few participants were seemingly passive, particularly at baseline interviews, implying that they only participated as CBR was not doing any harm, or that they did not have the right to question the trained CBR worker.

“I: What should she improve in her teaching?”

R: What could I say? She is a trained worker ... I simply accepted what she told me.”

(woman with schizophrenia -10-B)

There was an almost unanimous expectation that the CBR project would provide financial support or free medication, despite explanations to the contrary at recruitment. This expectation reportedly arose from a culture of hand-outs by NGOs and the receipt of a time compensation payment at baseline data collection, which took place immediately before recruitment to the pilot. Given the crippling poverty in which many participants lived, the inability of CBR to provide financial support created significant disappointment and confusion. Indeed, lack of funds prevented participants from accessing many things that CBR workers were advocating: proper nutrition, capital to start up a small business, and most crucially anti-psychotic medication. One supervisor noted the powerful effect of poverty on people’s capabilities to respond to advice.

“We didn’t expect perfection. But we thought [the CBR participants] were capable of implementing what we taught them. [Before CBR] they were not aware that they had to take the medication for their illness. We thought they would take the medication, if we had taught them that they have to take the medication. But they may not be able to take the medication, even if they wanted to, if they don’t have money. Your expectation will change when you go to their houses and observe their life situation.”

(female supervisor-E)

Several CBR workers spent the first few weeks negotiating with participants to continue CBR despite this perceived gap. In most cases participants finally accepted what CBR could offer and were happy to continue. However in one case these issues, along with disagreements about medication (see Section 7.3.2.1), contributed to the participant withdrawing from the programme.

“I went there two, three times and taught them about the illness and the medication. I didn’t bring any financial benefit. Then after [that] their attitude has changed [...] The [CBR participant] directly told us that she won’t continue CBR unless [financial] aid is given to her [...] She was saying that her child is sick and we are only teaching about medication and tell her to bring medication. She was complaining [that we were] not doing anything for her.”

(male CBR worker -4-B)

Even at endline interviews several CBR participants, CBR workers and community leaders raised the provision of financial aid or free medication as an area for improvement, despite the various gains that had proved achievable without it being available.

7.3.2.3 Assumption 1c: CBR workers are willing to work with people with schizophrenia

CBR workers were willing, and in some cases highly motivated, to work with people with schizophrenia, provided they received on-going training and supervision. None of the selected CBR workers withdrew from the programme. There was a shift towards improved attitudes towards people with schizophrenia over time, including minimised fears of violence and increased expectations of recovery, through the experience of working with this group during the pilot.

“my perception of a mentally ill person has changed after I visited [the CBR participant] [...]. My confidence was very little at the start. I used to think that mentally ill people always carried daggers to hurt people. But when I entered the house, I understood that he is not that kind of person. I have learned a lot from this. I have learnt that a mentally ill person can recover from his illness if the ill person gets proper treatment.”

(male CBR worker- 8-E)

However procedures to ensure CBR safety, for example risk assessments, were still felt to be important by supervisors. In addition, two CBR workers noted that whilst not all people with schizophrenia are violent, there are cases where this is true.

Some CBR workers and supervisors described stressful situations, often related to participants wanting to quit CBR or medication, and also sadness at the difficult circumstances of participants, or worry they would not improve. Peer support, which took place in group supervision sessions, but also during informal meetings,

was clearly appreciated by several CBR workers. Talking with other CBR workers was a chance to gain new perspectives on how to overcome problems, or simply a relief to discuss issues.

7.3.2.4 Assumption 1d: Community leaders are willing to support CBR without benefits for themselves

Meetings with community leaders (community mobilisation task 5) were held in all four sub-districts, though most CBR workers initially encountered difficulties arranging them. Some community leaders were too busy, whilst others were suspicious the project was related to a political opposition party and awaited permission from the district health bureau. Several CBR workers felt community leaders were expecting a financial benefit from participation, though this was never made explicit. Most CBR workers felt this expectation was resolved by piggybacking onto existing gatherings, for example official sub-district meetings.

“It took [the community leaders] a long time to accept what we were doing. We had a very big challenge to do the work because it was election time. We made the [sub-district] chairman participate in our discussion and he approved of the work we were doing and gave us a letter of permission. Then we started doing the work after two months. We faced many problems at the start, but we succeeded finally.”

(male CBR worker -8-E)

Awareness-raising events with general community members (community mobilisation task 6) were held in all sub-districts (mean five meetings per sub-district; range 2-7), as part of planned meetings for Women’s groups, *edir* (burial association) groups and sub-district development meetings, with up to 100 participants attending. CBR workers had a generally positive reception with active participation from attendees, though some participants only warmed to CBR after understanding the benefits to their community. Several participants stressed the importance of CBR workers maintaining anonymity of CBR participants when speaking at public meetings.

Targeted mobilisation of community figures (community mobilisation tasks 8 to 11) was attempted for six participants, including with a priest, government officials, a judge, an agricultural worker, a health extension worker, an *edir* leader and a businessman; these efforts led to actual support being provided for four

participants (see Section 7.3.6.2). The three community members interviewed were universally positive about their encounters with CBR. Giving support was portrayed as a gratifying experience, especially when improvements were seen in the CBR participants' wellbeing and apparent life chances.

"You feel happy when you help someone whose economy is below you. When you see improvement in the person you are helping, you will be satisfied. I am very glad since I have helped him. I got happiness."

(male benefactor-7-E)

All three community members had made some sacrifice- whether time, money, or broken property- but none perceived this as a real hardship, despite, in one case, the unease of other community members.

"Some of them, because they don't know [about mental illness], some ask why I talk with [the man with schizophrenia], "he is crazy, he has lost his mind why would you talk to him?" When they say such kinds of things, [I say] no this is not right. We should show them love, include them in any society, include them in social activities."

(priest-5-E)

7.3.2.5 Assumption 1e: Traditional and religious healers are willing to support CBR

No traditional healers were identified during resource mapping by CBR workers. Furthermore, there was no known use of traditional healers by any participants during the pilot. Whilst two people with schizophrenia visited holy water sites, these were located outside of Sodo district. There was therefore little potential for, and no attempt at, targeted CBR engagement with traditional or religious healers.

7.3.3 Intervention adjustments to maximise acceptability

The recommended duration of Phase 1 was extended to three months (from one to two months), to give enough time for the important but sometimes slow processes of building a solid relationship with participants and the wider community and developing a clear understanding of what CBR could and could not offer. This also gave more time to address the core goals. Phase 2 could also be extended from four

to five months to give more time to achieve optional goals. CBR worker refresher training was given to encourage a focus on fewer more pertinent and achievable goals; in particular to focus on maintaining progress on goals in Phase 3, rather than embarking on several new areas. Relapse prevention became an optional module for Phase 2, to recognise the differing needs of participants. In addition, how to strike the balance between realism and hope in recovery was covered; and the potential impact of co-morbid intellectual disability on the likely magnitude of changes in functioning.

At consent and the initial visit greater emphasis was made on the inability of CBR to provide financial support, to try to prevent misunderstanding and resentment later on. Medication subsidy by the RISE project was considered (to be implemented in both arms of the trial); but this was ruled out due to insufficient funds within the research project and an inability to identify an alternative source of funding (including from the district health bureau). Microfinance was not seriously considered as an addition to the CBR intervention. This was thought not to be a sustainable or scalable approach to CBR delivery, as well as being beyond the financial and logistical capacity of the project to implement. Furthermore, at recruitment to the pilot a considerable source of stress for one CBR participant was his difficulty repaying a previous loan from a government microfinance scheme; this validated concerns raised during the intervention development (see Chapter 5). This meant that a rotating savings and credit association, which theoretically can be run without external financial input (see Chapter 2, Section 2.7.1), was also discounted.

Several further adjustments were made to maximise participant engagement in CBR, including altering the frequency, duration, timing and location of visits to fit with the needs of participants and allowing seasonal adjustments. For example, whilst Phase 1 may be extended, home visits could also be held fortnightly if participants preferred this. However, there was no compulsory reduction in the total number of visits, as several participants clearly found benefits from more intensive support. CBR workers were encouraged to ring ahead of visits if possible and telephone contact between monthly visits in Phase 3 became standard. It was decided that whilst initial engagement from a named caregiver was required, CBR

should continue if the caregiver disengaged, on the basis that those without active caregivers were likely to be most vulnerable.

Refresher training was given to CBR workers to emphasis aspects of the recovery-oriented model of care, such as collaborative goal-setting. In particular additional training was given on striking a balance between encouraging medication adherence and accepting the person with schizophrenia's wishes if they did not want to or could not afford to take it. It was clarified with CBR workers that people with schizophrenia can continue CBR despite not being willing or able to take medication. As the existing goal setting framework did not adequately capture important but less tangible activities such as leading the family, a new potential goal 'The person with schizophrenia can fulfil their family role' was added. Finally, written materials were created for participants to aid recall of information covered in home visits.

Community mobilisation meetings were limited to those attached to another planned meeting, in order to ensure better attendance and minimise expectation of per diem amongst community leaders. The optional activity to share personal experiences of recovery in a public forum (community mobilisation task 12) was retained in the intervention design despite not being implemented in the pilot; it was felt from a larger pool of people with schizophrenia with a longer duration of treatment willing and able candidates might be identified. Similarly, it was decided to retain the module 'Improving literacy' on the basis that adult literacy groups may be available in other sub-districts (as identified in the intervention development phase).

7.3.3.1 Changes to the evaluation of acceptability

A structured assessment of the extent to which CBR had met the participants' needs was added to the trial evaluation plan (see Appendix E (v)).

7.3.4 Research question 2: Is the RISE CBR intervention feasible?

7.3.4.1 Assumption 2a: Non-specialists can be trained to deliver CBR for people with schizophrenia

Competence varied between CBR workers but overall was good. CBR workers completed all required assessments (including needs assessments, goal setting and rehabilitation plans) for all participants at each phase (with the exception of the participant who quit at eight months). Overall, CBR workers undertook 91.7% of indicated modules (i.e. those linked to the selected goals), suggesting competence at selecting the appropriate components of CBR for participants (see Table 7.3). Many participants seemed to consider CBR workers as experts, describing them as knowledgeable, able to explain clearly and give constructive advice.

“The CBR worker has both the ability to understand and explain issues. ...okay... he both explains in a way which is understandable to us and listens and understands what we tell him. ...eh... we even ask him [that] which is not clear to us..”

(man with schizophrenia-6-B)

Most CBR participants described the calm and pleasant manner of the CBR workers, as well appreciating their ability to listen (*“she asked me how I am feeling and I told her what I really feel”* (female caregiver-1-B)). However, using repeated ENACT assessments, some weak areas were identified across CBR workers including: using a problem-solving approach, assessing physical health and substance use, conducting a basic risk assessment and, as described above, giving advice and seeking feedback on the advice given, without lecturing the participant (see Section 7.3.2.1). The CBR workers who supported participants with co-morbid intellectual disability criticised the lack of training on the different treatment and communication issues for this group. However in general problems with competence were not a barrier to successful CBR delivery.

Direct contact between the CBR workers and the study psychiatric nurse was uncommon, with only two referrals over 12 months, one for suicidal ideation and one for relapse. Apart from these occasions all mental health care was received through usual facility-based care. Most facility-based care was delivered at the health centre, with two referrals to the psychiatric nurse led outpatient clinic.

Contact between the CBR workers and CBR supervisors was less frequent than planned; CBR workers, on average, had ten individual supervision sessions, received 5.4 unannounced observed home visits and attended eight group supervision sessions (compared to an anticipated minimum of 12 sessions of each supervision mode). The supervisors and some CBR workers felt that supervision had an important role in guiding CBR workers; three CBR workers said supervisors were responsive and available. Most CBR workers and supervisors described a convivial rapport, more similar to a peer relationship than exhibiting a clear hierarchy (*"The relationship between the CBR workers and me is not like a worker and a boss. Rather it is a brotherly sisterly relation."* (female supervisor-B)). But there were indications from both sides that this did not always function well for CBR delivery. On the one hand, one supervisor felt that CBR workers did not always ask for support in a timely manner.

"The CBR workers were not informing us when they faced challenging situations. They were trying to solve them on their own.... We constantly told them to call and notify us of the challenging situations they encounter and not to wait until we meet after a week or two. We constantly reminded them that it would be difficult for us to control these kinds of situations, if we didn't act on time."

(female supervisor- E)

On the other hand, one CBR worker indicated her supervisor did not contribute much to her work and was often unavailable (*"I don't get the support that I need on the time I need it"* (female CBR worker-9-E)). Another CBR worker commented that whilst supervisors were good at identifying skill gaps, refresher training was slow to materialise.

7.3.4.2 Assumption 2b: CBR workers can overcome logistical challenges to deliver CBR

CBR workers raised some practical challenges with delivering CBR. However, long distances between households, difficult terrain and patchy public transport were issues that were largely manageable in the pilot due to the low workload and narrow geographical area. Instead, concerns were raised that these logistical issues would be more problematic when the intervention was delivered on a larger scale. Lack of transportation emerged as a particular issue for attending community meetings, which typically began at 6am before CBR workers were able

to reach the site. Problems with the phone network sometimes made it difficult to arrange home visits and supervision meetings. Despite these issues there was strong support for home visits from CBR workers and supervisors to encourage engagement and to best understand the family environment.

“Their house is the best place to meet [CBR participants]. You can observe their family relationships, if you go to their house. You can observe their agreements and disagreements physically. You can give them practical advice, if you know how they are living. Going to their houses is also very useful to meet their neighbours and do community work.”

(female supervisor-E)

7.3.4.3 Assumption 2c: Primary care staff are supportive of CBR

CBR workers accompanied participants to primary care appointments on average twice over 12 months (range 1-3 times). Some caregivers and people with schizophrenia expressed a preference for attending the health centre with the CBR worker present as they appreciated support to explain issues and make requests to health officers about their treatment. In addition, CBR workers made fourteen referrals to the health centre relating to eight participants for medication reviews, often due to side effects, physical illness, relapse and suicidal ideation (see Table 7.3). Health centre staff described a productive working relationship with CBR workers, which enhanced the quality of care they could provide by improving follow up. No negative impact of CBR on their work was reported, though one health officer felt the CBR worker’s role was initially unclear.

“[CBR workers] don’t have negative influence on our work. But, I think their presence is useful for us to give better treatments to patients [...] We have a very good relationship...they directly come to us when they encounter problems and need our help.”

(health officer)

However one CBR worker felt that, in contrast to the aims of CBR, health officers were narrowly focused on medication and did not consider the broader social needs of people with schizophrenia.

“Even the way we discuss with the health staff is not right as they always focus on the need for medication. They instead don’t see the issue from other dimensions. They don’t see the issue from multiple perspectives”.

(male CBR worker- 4-E)

7.3.4.4 Assumption 2d: Anti-psychotic medication is accessible

There were various difficulties with the accessibility of anti-psychotic medication. The majority of CBR participants reported that medication, particularly the depot injection, was not affordable. In some cases this led to gaps in medication access or worries about how this could be maintained and the impact on the person with schizophrenia.

“Now the main problem is the boy refuses to take the [oral] medicine and the injection is expensive and I am poor and a newcomer to the town, I have no one to help me [...] the medicine had [brought] improvement. Now my problem is the money to buy the medicine. I have no capacity. The boy who was having improvement is going to be ill”

(female caregiver-8-B)

At least two participants had initially bought medication using the time compensation payment they received at baseline data collection. As this was a one-off payment they could not afford to purchase medication on an on going basis. Four CBR workers endeavoured to obtain the medication fee waiver for their participant, none of which were successful. According to one CBR worker disagreement amongst officials as to who deserved support underlay these difficulties. Only one male CBR participant stated that he did not wish to receive free medication. Several participants also reported frustration at medication not always being available at the health centre or not being dispensed due to a lack of a pharmacist, or a lack of receipts, or because the person with schizophrenia’s caregiver had not accompanied them. Only one caregiver remarked that the health centre would be geographically inaccessible during the rainy season. CBR participants who were required to attend the hospital in the neighbouring district faced some problems, including difficulty making the journey whilst acutely unwell, lack of public transport and lack of funds to pay for transport. All participants reported medication side effects, most commonly drowsiness and weakness but also reduced appetite. These effects were frequently intolerable,

particularly as the impeded the physical labour on which livelihoods, and cohesive households, often depended.

“The tablet they were giving me...made me clumsy and unable to work [...] It makes you drowsy and you will doze off in your seat. If you take it at night, it will make you sleep until noon. Do you think my wife will stay with me if I can't provide?”

(man with schizophrenia -6-E)

Side effects resulted in interrupted adherence despite medication also conferring benefits. Others stopped medication once they felt well, or because they saw no positive impact, and one participant feared addiction. One CBR participant interrupted medication whilst at holy water, believing the two treatments were not compatible (*“You can't pin your hope on two things”* (female caregiver-10-E)). Another stopped medication altogether due to her family's strong belief that the illness was caused by spirit possession, along with a lack of perceived impact on her symptoms.

7.3.4.5 Assumption 2e: *Edir* (burial association) support will be available and sustainable

There were no examples of *edir* (burial association) groups providing practical or financial support for CBR participants, as had been anticipated. This was due to a lack of firm interest or engagement from *edir* groups or in other cases people with schizophrenia and caregivers not wishing to be the recipients of support from such organisations. CBR workers also felt this potential aspect of CBR was not emphasised in the training. *Edir* groups were however used as a hub to raise awareness about schizophrenia.

7.3.5 Intervention adjustments to maximise feasibility

To support physical access to CBR workers and participants in remote locations, the transport allowance for CBR workers was augmented and increased access to the project vehicle was planned for supervisors in the trial. In addition, due to the long journeys on foot, the average number of participants per CBR worker in the trial was reduced from ten to eight to ensure feasibility. CBR worker refresher

training was given on weaker areas, including risk assessment, problem solving and communication skills. A more compact step-by-step guide was produced for CBR workers, including protocols for managing difficult situations. Intervention forms were amended iteratively to improve usability, including the addition of specific prompts to assess physical health and substance abuse on the home visit form.

A more thorough orientation on the aims and structure of CBR was prepared for health centre staff; however no attempts were made to include health officers in CBR itself, for example setting rehabilitation goals, as this was not perceived to be feasible. A better understanding of how to access or advocate for the medication fee waiver was established. As discussed above, medication subsidy was considered but ultimately ruled out. *Edir* support was eliminated as a CBR strategy; instead efforts were focused on mobilising support from individuals.

7.3.5.1 Changes to evaluation of feasibility

Additional questions were added to the adherence measure to determine if medication unavailability and unaffordability acted as barriers to adherence, and if the participant had accessed free medication.

7.3.6 Research question 3: Can the RISE CBR intervention produce an impact and if so, how?

7.3.6.1 Assumption 3a: CBR can improve functioning in people with schizophrenia

Changes in functioning

Overview

Most CBR participants began the study with high levels of disability (baseline median WHODAS 49.6 (IQR (interquartile range) 26.0, 61.0), which decreased considerably over the 12-month pilot period (endline median WHODAS 14.2 (IQR 1.3, 40.5)) (see Table 7.4). However, the two women with co-morbid intellectual disability did not experience substantial improvements, and one of these

participants died during the pilot due to a physical illness. Amongst those with improvements, changes were seen in livelihood activities, domestic activities, social participation and self-care, though several barriers to achieving change were identified. In general there was good agreement between qualitative, quantitative and process data.

Table 7.4 CBR participant quantitative data relating to disability, clinical state, depression and alcohol use

CBR participant ID	Disability (WHODAS total)			Clinical global impression			Depression (PHQ-9 total)			Alcohol use (AUDIT total)		
	0 m	6 m	12 m	0 m	6 m	12 m	0 m	6 m	12 m	0 m	6 m	12 m
1	15.2	0	59.4	Missing	2	4	2	3	9	7	15	10
2 *	70.9	79.4	70.0	7	5	5	11	9	2	0	2	0
3 *	58.3	93.8	Participant died	4	7	Participant died	13	19	Participant died	0	0	Participant died
4	45.7	20.2	2.6	4	2	1	13	5	13	5	5	7
5	61.0	51.6	21.5	3	3	4	10	12	8	22	13	2
6	26.0	12.8	Participant refused	5	2	Participant refused	15	2	Participant refused	27	4	Participant refused
7	24.2	28.9	0	6	4	2	4	11	1	3	6	4
8	62.8	8.2	14.0	7	1	2	12	1	4	0	16	3
9	41.9	3.8	0	6	3	2	6	0	1	4	4	0
10	53.5	34.1	14.5	4	2	1	10	7	3	0	0	0
Median (interquartile range) or %	49.6 (26.0, 61.0)	24.5 (8.2, 51.6)	14.2 (1.3, 40.5)	0% borderline /normal	50% borderline /normal	62.5% borderline /normal	10.5 (6,13)	6 (2,11)	3.5 (1.5,8.5)	3.5 (0,7)	4.5 (2,13)	2.5 (0,5.5)

*Co-morbid intellectual disability

Table 7.5 CBR participant quantitative data relating to health facility use, discrimination, physical restraint and caregiver burden

CBR participant ID	Health facility use (number visits for mental health in previous 3 months)			Discrimination (total DISC-12)			Physical restraint**			Caregiver burden (IEQ total)		
	0m	6m	12m	0 m	6 m	12 m	0m	6m	12m	0 m	6 m	12 m
1	3	1	1	2	0	0	Yes	No	Yes	35	48	59
2 *	2	3	1	0	3	0	No	No	No	69	56	47
3 *	1	0	Participant died	2	0	Participant died	No	No	Participant died	43	21	Participant died
4	0	2	2	29	11	7	No	No	No	37	19	22
5	1	3	2	35	34	24	Yes	No	No	Missing	27	33
6	1	0	Participant refused	1	0	Participant refused	Yes	No	No	61	26	Participant refused
7	0	2	3	0	0	0	No	No	No	37	21	36
8	0	3	0	4	4	0	No	Yes	No	70	27	28
9	0	3	1	0	0	0	No	No	No	56	16	16
10	0	1	0	2	0	0	Yes	No	No	46	55	15
Median (IQR) or %	50% ≥1 visit	80% ≥1 visit	75% ≥1 visit	2 (0,4) 70% any discrimination	0 (0,4) 40% any discrimination	0 (0,3.5) 25% any discrimination	40%	10%	10%	46 (37,61)	26.5 (21,48)	30.5 (19,41.5)

*Co-morbid intellectual disability

Livelihood activities

Some CBR workers bemoaned the lack of formal employment opportunities or capital to start small businesses and one reported that people with schizophrenia were routinely excluded from employment or microfinance initiatives.

“When we talk to the [sub-district] management about giving [CBR participants] jobs in cooperatives, they ask us if they have fully recovered and become normal. They think they will not pay their credit back if they haven’t recovered fully from their illness and become normal. If they want to raise cattle, for instance, they will not be given land.”

(male CBR worker-4-E)

Despite these barriers, through the support of the CBR workers five participants started new income-generating activities, including selling farm produce, handicrafts and local alcohol, and daily labouring, whilst two more continued or intensified previous work. One man needed considerable persuasion to stop begging, which was proving relatively lucrative. All types of participants felt participating in livelihood activities to be the most important possible change. This was sometimes difficult to achieve or sustain, in one case because of alcohol dependence, in others due to medication side effects. Some CBR workers stressed that work goals should be realistic, tailored and desirable to participants, for example incorporating more breaks than usual and based around existing skills where possible, an opinion reached in some cases through initially setting sights too high.

Domestic tasks

Greater participation in household tasks, such as preparing food and fetching water, was reported for three female participants and one unmarried man. However the caregivers of the two women with co-morbid intellectual disability were disappointed in the lack of progress in domestic work. Two female participants also began actively caring for their infants.

“Previously [the CBR participant] even didn’t breastfeed her baby, instead she viewed him as a wild beast. ...Now she is caring by feeding him properly. In the past she wasn’t able to prepare food. When we went to her home, we found her asleep. There were so many problems related to her life. Now she got all these improvements of feeding her children properly and doing household activities.”

(male CBR worker-4-B)

Improved independence and social life

Some participants developed increased independence, manifested for two women as being able to safely leave the house unaccompanied. For others independence meant being able to earn money, buy their own food and support themselves and their family. Drinking coffee with others and attending church and social occasions such as weddings and funerals were highlighted as important changes in social functioning achieved by several participants. Improvements in social interactions, in particular peacefully greeting and listening to others, were also noted.

“What was amazing was, [the CBR participant] was not attending wedding ceremonies, or mahber [social religious meetings]. She was also not going to church. Now she has started going to church. I have seen her at the church on Christmas and Epiphany. This is a pleasant change.”

(female CBR worker-10-E)

Improved self care

Self care, including the maintenance of personal hygiene and wearing clothes properly, reportedly improved in all eight participants where this had been a problem initially. In some cases the change was dramatic.

“I used to grow my beard for more than one year and my hair was infested with pests, because I didn’t wash it for four or five months [...] I wasn’t changing my clothes. But now I have started washing my clothes and my hair. The [CBR] training has helped me to become a better person.”

(man with schizophrenia -5-E)

Likelihood of enduring improvements in functioning

At endline, although several CBR participants felt sad that CBR was finishing, most felt confident they could maintain the progress they had made. In striking contrast, several CBR workers were pessimistic that positive impacts on functioning would endure after home visits stopped. CBR workers suggested that ongoing family and community support was essential for gains in wellbeing to be maintained. Some felt this would not be sustained due to the long duration of illness and a lack of ongoing motivation from the caregivers.

"for the positive impact [of CBR] to continue for the future, I don't think it will continue. It is because the gaps are visible. ...eh... As the time in between visiting their home is becoming longer, the gap will be wider. ...eh... The care [her family] give to her when I go there is different from when I am not there. When I go there they care for her a lot but when I went there by chance, it was not good. Though they give her care and attention [now], I think this will continue with minimal commitment."

(female CBR worker-2-E)

How CBR improves functioning

The pathways to improved functioning differed between participants and the type of functioning, with anti-psychotic medication and CBR work at the individual, family and community level having varying degrees of influence. However, general conclusions can be drawn (indicated in the blue boxes on the post-pilot theory of change - Figure 7.2). In many cases intermediate outcomes, and improved functioning, seem to have a positive influence on each other; this is represented on the theory of change map by two-way arrows.

Increased understanding of mental illness and human rights

As a direct result of psychoeducation delivered by CBR workers, several participants reported an improved understanding of the symptoms, causes and treatment of schizophrenia, with particular appreciation of the potential benefits of medication. Some CBR workers stressed that understanding increased gradually over time, alongside improvements in the person with schizophrenia.

Increased family stability and care; and reduced caregiver burden

Involving family members in CBR was seen to be central to improving functioning. Several CBR workers and supervisors noted that the family environment was pivotal in shaping the illness experience of people with schizophrenia, for better or worse. Until these often disruptive and strained environments were stabilised, it was found, improvements in participants were difficult.

“There is a huge disagreement between family members and that has an impact on the mentally ill patient. It is the problem within the family that makes the patient to be disturbed, angry, go out of the house, avoid themselves, not care for themselves, not eat food and not keep their hygiene.”

(male supervisor-E)

In several instances CBR workers acted as mediators in family conflicts, in some cases involving community elders to arbitrate.

“ [the man with schizophrenia] was expelled from home because he kicked his mother [...] He was roving the streets and was unable to stay at home because of his illness. But his family didn't understand that. But the family relationship improved significantly after I gave them the lesson from the module about interpersonal relationships in the family [...] he asked for her forgiveness and they started living together happily [...] I always feel happy about the improvements we saw.”

(male CBR worker -8-E)

In one case the CBR worker negotiated household tasks to be divided fairly between the participant and other family members, drawing on their growing understanding of the illness to ensure the participant was given sufficient rests. By the end of the pilot most caregivers described strategies they had learnt to avoid aggravating their relative, including communicating calmly, removing or avoiding stressors and telling them of plans in advance.

“This person is sick and we prepare how to pass the time of the illness. We know how to manage the relapse. I know my husband’s behaviour more than anyone. When he feels angry, I pass that with a smile. I also take the children away from him.”

(female caregiver-1-B)

Aided by CBR workers, some caregivers began facilitating self care for the first time, for example by buying the person with schizophrenia soap or encouraging them to wash. Improvements in self-care seemed to be related to caregivers appreciating that people with schizophrenia *deserve* to be clean as much as them giving practical guidance and the individual being less symptomatic. In some cases family members also had a role in supporting social participation.

A linked and important impact of improved functioning was the reduction in caregiver burden. IEQ scores reduced between baseline and six months, and then plateaued at 12 months (median 46.0 (baseline) vs 26.5 (six months) vs 30.5 (12 months) (see Table 7.5)). Several caregivers described relief from the constant worry about their relative that came with improvements in their health. There was also less need to supervise their relative through fear of them harming themselves or others, or simply becoming upset due to being left alone, meaning daily tasks could be completed more easily. Others welcomed the increased contribution to communal work.

“Now his condition is improved. He can move by himself. Earlier, I had a fear of [him] committing suicide or hurting others. Now, I didn’t fear that much [...] Earlier not only he, but also I, couldn’t go out of the home. But now thanks to God I can go anywhere.”

(female caregiver-8-E)

Increased access to mental healthcare and increased anti-psychotic medication adherence

For many families CBR had a role in improving access to mental health care, which meant being reviewed by health officers at the health centre and accessing anti-psychotic medication. At baseline half of participants reported making one or more visits to a health facility in the last three months; this increased to 80% at 6

months and 75% at 12 months (see Table 7.5). CBR workers took practical steps to improve access, including: showing participants where and how to buy medication, reminding them to attend follow up, checking if medication was available at the health centre and escorting them to appointments. CBR workers were sometimes successful in encouraging the wider family to accompany people with schizophrenia on this journey to the health facility; this was particularly important when travel to the outpatient clinic in the neighbouring district was required. Early on in the pilot there was optimism that this support alone would be sufficient to result in improved access.

“most of [the CBR participants] didn’t have a belief that schizophrenia could be treated through modern treatment ... There was no habit to go to the health centre. Even those who went there interrupted it [...] However now as they got awareness from CBR, they follow their appointment properly. Therefore they now understood that the treatment has an important impact on their health.”

(male supervisor-B)

As discussed above, issues around affordability and acceptability of medication later became apparent. In three cases, CBR workers tried to address these issues by successfully facilitating local benefactors or extended family members to purchase medication where the participants could not afford it. CBR workers also advised caregivers how to support adherence, and directly reminded and encouraged participants. However supervisors felt that a concerted effort was needed to keep participants adherent in spite of disabling side effects; few participants consistently took medication through the pilot. Family members also learnt how to recognise and respond to relapse.

“We know when the illness is about to relapse. She will start getting upset easily and she will also start talking to herself. We will give her the medication, if we have it at home. Or, we will go out to the health centre to bring the medication [...] Her lesson has changed us a lot. It is a big deal for us, to know where to take her [when her illness relapses].”

(female caregiver-10-E)

Reduced relapse and symptoms

The proportion assessed as normal or borderline on the CGI (clinical global impression) rose from zero at baseline to 62.5% at endline (Table 7.4); this change was also reflected in the BPRS-E (baseline median 52.5 (IQR 39, 62) vs endline median 25.2 (24, 59.5) (see Appendix D (vi)). Furthermore, the proportion assessed as having no psychotic episodes in the last six months on the LCS rose from 0% at baseline to 62.5% at endline (see Appendix D (vi)). For many participants, simply taking medication had resulted in them becoming 'healthy' or 'well'. Whilst a priest spoke of one man with schizophrenia gaining a 'peaceful and free mind' through treatment, for most CBR workers and caregivers being healthy was associated with a reduction in behaviours such as collecting objects, shouting insults, throwing stones, wandering away from home and talking to themselves. Three caregivers emphasised that medication enabled their relative, and therefore the whole family, to sleep better. In many cases improvements in symptoms led to better functioning. For example, for two participants a reduction in persecutory ideas made socialising easier whilst labouring or farm work became possible for others.

The median PHQ-9 (depression) scores decreased over the pilot from 10.5 (IQR 6,13)) at baseline to 3.5 (IQR 1.5,8.5) at endline (Table 7.4). A 'see-sawing' effect was seen in two participants, with scores either much higher or lower at six months, compared to baseline and endline. It was difficult to directly tally these patterns with the participants' accounts in qualitative interviews. One man described the value of improved functioning, as well as strategies suggested by the CBR worker, to cope with suicidal thoughts.

"I used to get depressed when I sit at home. I used to cry and go outside the house. These things have reduced now. I have built my own house and have started making my bed and living like other people [...] When I was sitting alone at night, I used to think that it would be better if I hang myself or throw myself into a river than live like this. But I have significant improvements after [the CBR worker] advised me to go outside, watch TV and relax, when I feel low and bad ideas come to my mind."

(man with schizophrenia -5-E)

By the end of the pilot several people with schizophrenia reported feeling calmer and less stressed. This was attributed in part to improvements in the family environment and taking medication, but also to stress and anger management strategies learnt from the CBR worker.

"[the CBR worker] has told me to go outside the house when me and my wife start fighting. But she has almost stopped nagging me after his advice. I also go outside, when I see changes in her face. Both of us calm down when I get back home."

(man with schizophrenia -6-E)

Increased income

Increased participation in livelihood activities brought various benefits: improved self-esteem, reduced caregiver burden, a shift in community attitudes, but perhaps most importantly income. Increased income in turn brought the ability to pay for food, to support the wider family and to make financial contributions to community organisations; however only one CBR participant explicitly mentioned that increased income allowed them to purchase medication. The role of the CBR worker varied. In one case they identified a local grain mill owner interested in employing their participant, in another case they directly guided the participant to plan and undertake farming activities; in other cases the CBR worker simply encouraged and monitored handicraft or alcohol production.

"What I did for my patient was to make her do the job she was doing in the past. So, she started distilling araki [local gin] to cover her household expenses. Doing some work will help them generate income and they will be happy because they will be able to do whatever they want. They will not expect anything from anyone. This time the community will start thinking that they can take care of themselves and do some work."

(female CBR worker-10-E)

Improved physical health and appearance

CBR workers had some successes in supporting physical wellbeing. For example two people with schizophrenia were referred to the health centre for musculoskeletal problems that were proving a barrier to undertaking physical

labour. Yet one woman with schizophrenia, whose family were highly resistant to the CBR worker's efforts to facilitate treatment, ultimately died of an undiagnosed physical illness. Three of the four male participants who exhibited problem drinking cut down during the course of the pilot (baseline median AUDIT 3.5 (IQR 0, 7) vs endline 2.5 (0, 5.5)), with some indications that simple advice from the CBR workers played a role (see Table 7.4).

Increased social inclusion

At baseline, seven of the participants reported any experience of discrimination; by endline only the two participants who initially had the highest scores continued to report discrimination (Table 7.5). The qualitative data indicated that for some people with schizophrenia social non-participation was apparently a personal choice- albeit one shaped by their illness- driven by a dislike of crowds and noise, or disputes with neighbours. However there were some reports of social exclusion due to the stigmatising attitudes of community members. The priest described how a change in attitudes had reduced social exclusion.

“Before, [the man with schizophrenia] was considered to be crazy and he wasn't allowed to participate in any activities in the community. But today he participates in activities the community. They take care of him [...] He is healed and today he is healthy and is now working [...] he wasn't invited to weddings, or to attend funerals [...] However, today the community supports him, the community has embraced him, lovingly gets close to him and gives him advice.”

(priest-5-E)

Notably the account of the man supported by this priest directly contradicted the priest's own account. For this man, whose social isolation apparently endured despite improvements in symptoms and functioning, re-integration was problematic due to his single status. He believed this in turn was due to persistent negative perceptions the community had of him as a result of domestic violence inflicted on his ex-wife whilst he was unwell. According to this man, CBR had not assisted with the social exclusion he experienced; this was also reflected in his DISC score, which remained high at the end of CBR, despite some improvement (see Table 7.5).

“The medication and the [CBR] education have helped me a lot in my recovery [...] But, I have to start a social life [...] I am living alone. I don’t go to anyone’s funeral and no one will bury me if I die [...] No one invited me to attend their weddings and no one will tell me to go with them to mourn for a dead person [...] No one invites me because I am living alone and I don’t have a social life [...] I don’t have edir and other social life. I don’t go to other people’s houses to drink coffee [...] I am lonely.”

(man with schizophrenia -5-E)

In a similar pattern, one woman with schizophrenia described being unable to attend church as she was too scared to go alone and her sisters did not accompany her; this contradicted the local health extension worker and her caregiver who both reported she had started attending.

Decreased stigma and abuse

In some cases there were important shifts in the negative attitudes of caregivers, which increased the dignity and respect with which they treated their family member and in one case ended physical abuse. At baseline, four participants reported ever having been restrained. During the pilot there were two instances of physical restraint (of one and three days duration) indicated in the qualitative and quantitative data. In one case the CBR worker helped to resolve the situation by negotiating with the caregiver and encouraging access to treatment.

“They told me [the man with schizophrenia] was tied up because he was fighting with [the caregiver] over taking some household property outside the house [...] They tied [the man with schizophrenia] up on Monday night. I went there at the appointment time on Tuesday. So, I met [the caregiver], talked to her and listened about him. We took [the man with schizophrenia] to the appropriate place and he was released. So, [CBR] visits are very important. The burden she was carrying was heavy. We told her that he was showing the symptoms of mental illness and that he will get better if he is taken to the hospital and takes his medication properly and had him released.”

(male CBR worker -8-E)

This man was also the only participant who described learning strategies to deal with stigmatising comments.

"I benefited from [the CBR worker's] education [...] The CBR worker taught me that whatever someone says to me, I don't have to respond to him. Arguments will affect my health condition."

(man with schizophrenia -8-E)

Increased self esteem and hope

Increased self esteem and a growing sense of hope that life could improve seemed to underpin sustained changes in functioning; whilst functioning – participation in work, social life or improved self care- likewise fostered a feeling of self-worth. For some people with schizophrenia the fact of receiving support at all, and therefore feeling valued, whether by family, CBR workers or community members, appeared to have an independent effect on wellbeing. Often the knowledge that the illness could improve was transformational, whilst for others the CBR workers themselves were great motivators.

"[the CBR worker] tells me I will get better. She motivates me to be strong [...] If she didn't come I would be ill, I would be in bed...If she wouldn't come who would teach me this whole thing? [...] She makes me feel better"

(woman with schizophrenia -9-E)

Self-esteem manifested in various ways including participants taking pride in their appearance and work, feeling equal to others (such as not accepting donations of left over food), and being assertive at home and in the community.

"When he eats he wants to get good food [...] when he goes to parties he doesn't accept leftovers, he wants good food and he wants to be seated and served like normal people. He says he is not less than anyone, he is fine"

(male caregiver-7-E)

7.3.6.2 Assumption 3b: A community mobilisation approach is needed in addition to home-based care

Community mobilisation work had three linked areas of positive impact: increased awareness about mental illness, identification of previously untreated psychosis and increased support for people with schizophrenia. CBR workers, community leaders and two caregivers felt that CBR had increased understanding about mental illness amongst the general population, in particular that difficult behaviours may be a symptom of schizophrenia, and that the illness is treatable. Several participants suggested that visibly improved functioning in people with schizophrenia, through work or attending church, was a turning point in changing community attitudes. There was general agreement that improved community attitudes can furthermore potentially have a profound impact on reducing mistreatment and social exclusion. However, few participants, and no people with schizophrenia, provided concrete examples of awareness affecting inclusion. However one caregiver did imply that raised awareness meant she received support from neighbours that would otherwise have been absent.

“When he was ill in the past, he used to get drunk and speak louder. The people in the neighbourhood heard him and they used to care and feel pity for me. They understood that taking care of a patient is very difficult. So if the people had the awareness about the illness and understood the symptoms of the illness, they will help.”

(female caregiver-6-E)

Several participants reported that the local presence of CBR had meant other people with schizophrenia, who were not enrolled in the CBR programme, had accessed treatment for the first time. This occurred as a result of public awareness-raising meetings, CBR workers being seen making home visits or through family networks.

“We have a credit association of about 23 women in our neighbourhood. [The CBR worker] asked us if there are mentally ill members in our families and advised us to take the ill people to the health centre. The women also gave her information about the [mentally ill people] in their houses or in their neighbourhood. One of the women, for instance, told her that her brother is mentally ill. [The CBR worker] told her to take him to the health centre and he is showing significant improvement now.”

(female caregiver-1-E)

There were four participants for whom CBR workers mobilised tangible community support. In one case the CBR worker identified and supported local businessmen to provide a house, regular funds for food and medication, and employment opportunities to a man who was initially homeless.

“[The man with schizophrenia] has a person helping him with food, there is another person who covers his expense for his medication, another person also gave him a place to stay. There are also people who are arranging to help him get a job. The CBR worker has played a big role in arranging for ...people to help him in every aspect and make him become successful and profitable; a very huge role in helping them get free treatment. It is because of the CBR worker’s role that these opportunities were created for him.”

(male supervisor-E)

In another case a local priest contacted by the CBR worker became an important source of moral support and advice, as well as mediating in a conflict between the participant and his brother. One supervisor commented that participants were more likely to listen to the advice of respected community elders than CBR workers. In a third case a local judge took on an advocacy role requesting a medication fee waiver for a CBR participant, as well as giving him a small loan to start up a business. In the final case the local health extension worker invited a participant to live in her home for several weeks, supporting her with medication and social activities, until relations with the participant’s family improved sufficiently for her to return home. Linking with health extension workers also proved useful for identifying the homes of CBR participants, accessing community leaders and, in one case, facilitating access to nutritional support for the infant of a woman with schizophrenia. Those providing support had generally had minimal

previous involvement in the CBR participant's life, which had been enhanced and formalised by CBR.

"I used to feel very sad when I saw [the man with schizophrenia] in the street... I used to give him some food or some small things and encouraged him. I was giving him some unsustainable support [...] There was no fixed thing. I used to forget him and pass him. But now there is someone in the middle who can ask for him and arrange for us to meet"

(benefactor-7-E)

In parallel to successes with community mobilisation, CBR workers also faced some difficulties in changing attitudes, accessing or sustaining support from elders. For example the support with medication payments described above reportedly stopped after six months, despite the efforts of the CBR worker. It was also difficult to find benefactors anywhere except the wealthier urban areas.

7.3.6.3 Assumption 3c: Family support groups are perceived to be useful despite not having a savings and loans element

There was limited success in implementing family support groups. Only one sub-district set up a group, which ended after three meetings. One of the participants did report that it had been useful, feeling it was a relief to discuss her problems.

"[the family support group] was good. It is good to get relief. I think it is helpful for us as it gives us relief from our daily suffering...yes... It is even very helpful and refreshing as we meet. Is it not good to rest?"

(woman with schizophrenia -4-E)

The lack of a savings and loan element was not given as a reason for lack of participation. Instead there were either too few participants in a sub-district, participants did not feel comfortable discussing their personal lives or the person with schizophrenia was too ill to be left unattended. Of note is that two caregivers and a participant had all informally discussed the benefits of medication with other families affected by schizophrenia, only one of which was participating in CBR.

7.3.7 Intervention adjustments to maximise impact

It was envisaged that adjustments aimed at improving acceptability and feasibility would also have knock-on benefits for the impact of CBR. CBR worker refresher training was given to encourage a focus on fewer more pertinent and achievable goals; in particular to focus on maintaining progress on goals in Phase 3, rather than embarking on several new areas. Relapse prevention became an optional module for Phase 2, to recognise the differing needs of participants. In addition, how to strike the balance between realism and hope in recovery was covered; and the potential impact of co-morbid intellectual disability on the likely magnitude of changes in functioning. Community mobilisation was maintained as a compulsory component of CBR, with no major adjustments. Family support groups were designated as an optional component of CBR, depending on the wishes of participants in each sub-district.

7.3.7.1 Changes to the evaluation of impact

To better understand pathways to improved functioning, a focus on concepts of recovery and perceived barriers and facilitators to recovery was incorporated into the trial qualitative evaluation.

7.3.8 Summary of results

The results were summarised in a revised post-pilot theory of change (see Figure 7.2) (see Appendix D (vii) for detailed version). Assumptions that were met (shown to be correct) were converted to rationale (purple boxes in Figure 7.2). Assumptions that were not fully met due to substantial barriers and those which the pilot evaluation were not able to adequately evaluate (such as those that required assessment at scale or through randomisation) were retained; these outstanding assumptions represent areas for monitoring in the trial (orange boxes in Figure 7.2). A refined conceptual framework for the pathways through which CBR impacts on functioning was also included in the theory of change (blue boxes in Figure 7.2).

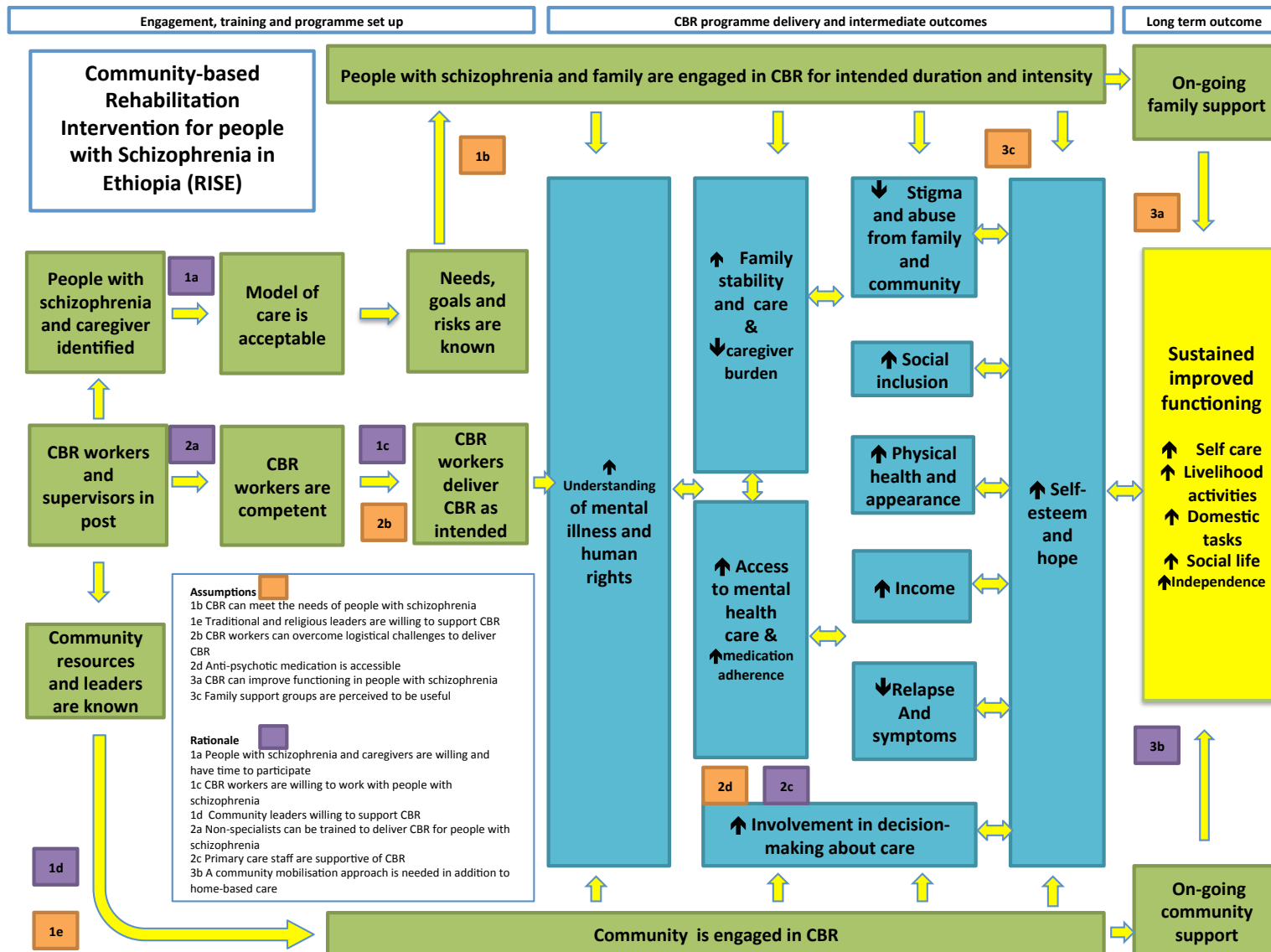


Figure 7.2 Post-pilot RISE theory of change map

Table 7.6 Research question 1: Summary of assumptions, main findings and adjustments to trial intervention

Assumption	Main findings	Adjustments to intervention	Conclusion
Research question 1: Is the RISE CBR intervention acceptable?			
1a: People with schizophrenia and caregivers are willing and have time to participate in CBR	<p>Process: Three participants dropped out before 12 months (1 x 8 months, 2 x 11 months). Mean home visits 21 (range 17-27)</p> <p>Qualitative: Most welcomed CBR; Close relationships often formed with CBR workers. Disengagement due to improved functioning, disagreements over medication use, and participants visiting holy water/ relatives. Some issues about home visits interfering with work- for men. Some issues with engaging suitable caregiver. Some participants wanted written information. Community mobilisation generally acceptable.</p>	Extend Phase 1 to 3 months. Adjust frequency, duration & location of visits to fit needs of participants. Maintain phone contact between visits. Provide written materials for CBR participants. Top up training on recovery model- balance between encouraging medication and accepting if cannot or will not take it. Clarify that participants can continue CBR despite not taking medication. CBR worker training on focusing on fewer more achievable goals.	Assumption shown to be correct and converted to rationale, as majority received adequate CBR. Monitor in trial (process and qualitative) as increased flexibility may be more difficult at scale.
1b: CBR can meet the needs of people with schizophrenia	<p>Process: All participants achieved all core goals. Between 6-11 optional goals selected, of which between 1-8 achieved. Tendency to select too many goals, not achievable in time frame. Some caregivers disappointed in slow progress, especially if comorbid intellectual disability.</p> <p>Qualitative: Participants often wanted to resume gendered family role. Poverty was a major issue which CBR could not directly address- leading to some disengagement with CBR.</p>	Better explanation on lack of financial support. Add extra potential goal 'Person with schizophrenia can fulfill family role'. Top up training to ensure focus on fewer more achievable goals. Focus on maintaining goals in phase 3, rather than starting several new ones. <i>Trial evaluation:</i> Add focused qualitative interviews around recovery. Add endline process assessment on whether CBR met need.	Keep as assumption as unresolved issues around impact of CBR in particular the ability of CBR to alleviate poverty (quantitative and qualitative)
1c: CBR workers are willing to work with people with schizophrenia	<p>Process: No CBR worker withdrawals.</p> <p>Qualitative: Attitudes changed over time (concerns about violence more realistic; increased expectation of recovery). Group supervision helpful.</p>		Assumption shown to be correct and converted to rationale.
1d: Community leaders willing to support CBR without benefits for themselves	<p>Process: Awareness raising and meetings with community leaders conducted in all sub-districts. Targeted mobilisation of community leaders attempted for six participants.</p> <p>Qualitative: Initial difficulty arranging meetings. Some community leaders implied per diem needed for meetings exclusively for CBR. Otherwise community figures happy to participate.</p>	Only do community meetings attached to another planned meeting- better attendance and minimize expectation of per diem. For individual engagement target those unlikely to ask for personal benefit.	Assumption shown to be correct and converted to rationale. Monitor at scale in trial (qualitative and process)
1e: Traditional healers willing to support CBR	<p>Process: No CBR engagement with traditional healers- holy water sites out of district.</p>		Keep as assumption and monitor in trial (qualitative and process)

Table 7.7 Research question 2: Summary of assumptions, main findings and adjustments to trial intervention

Assumption	Main findings	Adjustments to intervention	Conclusion
Research question 2: Is the RISE CBR intervention feasible?			
2a: Non specialists can be trained to deliver CBR for people with schizophrenia	Process: All CBR workers retained. Some variation in abilities. Areas needing additional training: risk assessment, physical health/substance use assessment; problem solving, eliciting feedback, normalisation of feelings, coping mechanisms; comorbid intellectual disability. Supervision frequency less than anticipated (mean 10 individual sessions, 8 group sessions, 5.4 unannounced visits) Qualitative: Participants happy with manner & knowledge of CBR workers. CBR workers and supervisors mostly happy with training and support; sometimes slow response to difficult situations.	Top up training given on weak areas and how to support people with comorbid intellectual disability. Produced more compact step-by-step guide with difficult situation flow charts, added details about side effects. Improved forms- made easier to use. Keep supervision expectations the same.	Assumption shown to be correct and converted to rationale.
2b: CBR workers can overcome logistical challenges to deliver CBR	Process and qualitative: Time consuming to access some households due to long distances and shortage of public transport. Difficulty arranging visits/ supervision due to telephone network problems. Importance of home visits to ensure engagement and understand family environment.	Increase transport allowance for CBR workers and increase access to project vehicle for supervisors. Reduce average number of participants per CBR worker for trial.	Keep as assumption. Need to monitor in trial as greater number participants per CBR worker and longer distances.
2c: Primary care staff are supportive of CBR	Process: CBR workers accompanied to health centre twice on average over 12 months. 14 referrals to health centre for 8 participants. Qualitative: Health officers good relationship with CBR workers once understand each roles. Feel CBR is beneficial.	At project start give orientation to CBR project and CBR workers, with clearer explanation of expectations.	Assumption shown to be correct and converted to rationale.
2d: Anti-psychotic medication is accessible	Process: Medication supply issues at health centre; can't prescribe without receipt. Qualitative: Difficulties affording medication. Attempts to access medication fee waiver unsuccessful. Many problems with side effects, commonly reported weakness which caused problems with doing farm work which needed to survive. Some issues with not taking alongside holy water.	Gain better understanding of how to access medication fee waiver. <i>Trial evaluation:</i> Additional medication adherence questions to assess affordability and availability	Keep as assumption and monitor in trial (qualitative, process and quantitative)
2e: Edir support will be available and sustainable	Process: Edir groups used for awareness raising but no financial support. Groups and some CBR participants not interested. Qualitative: Individual businessmen used as benefactors in urban area. Some doubts about sustainability.	Edir support not included as component; focusing efforts on individuals may be more successful.	Remove assumption. Amend community support to include businessmen.

Table 7.8 Research question 3: Summary of assumptions, main findings and adjustments to trial intervention

Assumption	Main findings	Adjustments to intervention	Conclusion
Research question 3: Can the RISE CBR intervention have an impact and if so, how?			
3a: CBR can improve functioning in people with schizophrenia	<p>Quantitative: Substantial improvements in disability, symptoms, alcohol use, depression, discrimination and caregiver burden over the pilot period.</p> <p>Qualitative: Increased understanding about mental illness preceded increased family support and access to healthcare. This led to increased functioning by improving symptoms, decreasing stigma/abuse and social inclusion and increasing income. Improved livelihood most important outcome for many. Increased hope and self-esteem underpinned and sustained functioning progress. Overly ambitious goals in some cases.</p>	Envisage that adjustments to improve acceptability and feasibility will lead to improvements in impact.	Keep as assumption. Monitor in trial (quantitative) as randomised evaluation required
3b: A community mobilisation approach is required in addition to home-based care	<p>Process: Improved attitudes and knowledge from awareness-raising led in some cases to signposting other people with schizophrenia to health centre. Tangible support facilitated for 4 participants (medication, housing, moral/spiritual support, food). Financial support from community was only available in urban area for people with schizophrenia with obvious needs.</p>	No major adjustments.	Assumption shown to be correct and converted to rationale. Monitor specific aspects in trial (qualitative and process)
3c: Family support groups are perceived to be useful despite not having savings and loans element	<p>Process: 1 group set up- 3 meetings.</p> <p>Qualitative: One woman with schizophrenia found it relieved stress. Groups not set up as too few participants; did not want to discuss problems; too ill to attend.</p>	Family support groups were designated as an optional CBR component depending on the wishes of participants in each sub-district.	Keep as assumption and monitor in trial (qualitative and process)

7.4 DISCUSSION

7.4.1 Strengths and limitations

Using a mixed methods approach this pilot study produced rich insights on the acceptability, feasibility and potential impact of CBR for schizophrenia in Ethiopia over a 12 month period. A particular strength of this study was the inclusion of all of the key players implicated in CBR: people with schizophrenia, caregivers, CBR workers, supervisors, community members and primary care staff. In several cases triangulation laid bare discrepancies between narratives, with people with schizophrenia tending to offer less positive accounts of the acceptability and impact of CBR. This highlighted the importance of incorporating service user perspectives, including those who have disengaged from the service, in the development and evaluation of mental health interventions. Furthermore, in a relatively nascent field in which there is a propensity to gather views on hypothetical services [20, 25], this study joins a small group of reports investigating acceptability and feasibility in the practical application of complex mental health interventions in LMICs [26, 27].

Another key strength of this study was the systematic use of a theoretical framework, theory of change, to guide the MRC approach to developing and evaluating complex interventions. I identified and tested assumptions for how the intervention will work, and using the findings I refined the intervention for evaluation in a cluster randomised trial. Both the pilot evaluation and intervention design were responsive [23], allowing emerging questions to be investigated, and the findings to be acted upon. For example, during feedback meetings CBR workers raised concerns about the sensitivity of suicide risk assessments; this issue was then explored in qualitative interviews with CBR participants, and the CBR workers were subsequently given refresher training guided by the findings. Moreover, adjustments were made to the trial evaluation to better explore the likely pathways to improved functioning. For example, more incisive questions on impediments to medication access were incorporated into trial data collection, as this was identified as a key issue for CBR impact in the pilot.

There are some limitations to this study. There is a likelihood of observer bias as the investigators and some respondents were internal to the project and had a

vested interest in the intervention's success. The qualitative interviewer may have, consciously or unconsciously, led people with schizophrenia and caregivers to express supportive views of CBR. CBR workers themselves may have reported positive outcomes to demonstrate their competence in order to secure their employment. I attempted to analyse the qualitative data dispassionately; however there may have been a tendency to emphasise positive responses. This may have been compounded by low expectations amongst people with schizophrenia and caregivers; the "sense that 'any mental health care' was something to be grateful for" has previously been identified amongst service users in rural Ethiopia [20]. A further bias favouring CBR may have arisen due to the close relationships with CBR workers; participants may have tried to avoid 'getting them into trouble'. These concerns are allayed to some extent by the clear criticisms of CBR that several people with schizophrenia and CBR workers voiced and that are incorporated into the analysis. However, no community members who were unwilling to participate in CBR were interviewed; this may have given a skewed impression of acceptability from the perspective of this group. In relation to CBR impact, potential bias was somewhat mitigated through triangulation with quantitative outcomes, which generally showed good agreement.

However, another limitation of this study is the inability to make conclusive judgements on the impact of CBR. Positive changes may be expected over time, irrespective of any additional support; improvements were seen over time even in the control arm of the COPSI trial [28]. In particular it is not possible to determine what changes were attributable to CBR rather than simply medication. Half of participants were treatment naïve prior to the pilot commencing. Our results suggest that CBR effects little change without facility-based care in place, but it is equally possible that facility-based care or medication produces an impact irrespective of CBR provision. The role of the trial will be to determine the effectiveness of facility-based care alone versus facility-based care plus CBR. Furthermore the trial analysis will help to elucidate the potential mediating role of medication adherence (and other intermediate outcomes) on the causal pathway through which CBR impacts on functioning. A final limitation was the use of both patient and caregiver responses in the completion of the baseline WHODAS, in contrast to the proxy (caregiver) only responses used at midline and endline. However, as people with schizophrenia in this setting have been found to report

lower levels of disability in comparison to their caregivers (Kassahun Habtamu, personal communication) this discrepancy would most likely serve to underestimate the apparent decrease in WHODAS score at midline and endline compared to baseline.

7.4.2 Conceptual framework for improved functioning

Despite the limitations described above, some tentative conclusions can be made as to the potential effect of CBR on the lives of people with schizophrenia. This study found that overall the RISE CBR intervention may have a positive impact. A heightened understanding of mental illness and human rights seemed to lead to enhanced family support and increased access to mental health care. These fundamental changes may have paved the way for decreased stigma, increased social inclusion, improved physical health and appearance, reduction in symptoms, and increased income. Intermediate steps to improved functioning were often valued as positive outcomes in their own right. Improvements in functioning and psychotic and depressive symptoms were reflected in both quantitative and qualitative data. Improved functioning appeared to be sustained by increased self-esteem and vice versa.

The pilot findings prompted four major changes to the conceptual framework illustrating how CBR may improve functioning (compare Figures 7.1 and 7.2). First, a recognition that there is rarely a set sequence of intermediate outcomes that produce improved functioning. Instead, whilst some changes are more fundamental than others, it is likely that most outcomes positively affect each other and synergistically lead to improvements in functioning. This is reflected in the elimination of distinct pathways and the bi-directional arrows introduced throughout the conceptual framework. Second, increased hope and self-esteem was a new intermediate outcome that had not been acknowledged prior to the pilot. The fact that CBR workers recognised the importance of, and managed to increase, hope amongst participants indicates that CBR can successfully utilise a recovery-oriented model of care [29, 30]. The empowerment of people with mental illness has been identified as an important “non-specific” characteristic of successful mental health interventions in LMIC [31].

Third, increased involvement in decision-making about care was included as an intermediate outcome alongside increased access to mental health care. For some participants, medication was needed alongside CBR to impact functioning. However, excessive persuasion to take medication by CBR workers, despite the individual being unable or unwilling to do so, represented one of the least acceptable elements of the intervention. The inclusion of this intermediate outcome recognises the importance of respecting the wishes of people with schizophrenia with regards to the treatment they receive, despite the limited choices available, to ensure engagement with care and to minimise stress. These issues will be discussed in more detail in Chapter 9 (Section 9.2.2.2).

Fourth, increased family stability and care was included as an intermediate outcome, as an adjustment from ‘The family can cope’ in the pre-pilot framework. This reflects the powerful influence that the family environment was found to have, for better or worse, on the person with schizophrenia, shifting from a perception that families are simply parallel, and passive, victims of the illness. This study showed that families are central to the success of the CBR intervention, in terms of facilitating engagement with the CBR worker and supporting rehabilitation and access to medication. This finding aligns with calls to consider the person with mental illness and their family as the unit of intervention delivery in the rural Ethiopian context [32]. There was some indication that CBR workers successfully supported families to reduce expressed emotion and that this brought palpable benefits to people with schizophrenia. The prominence of this effect fits in with the fact that family intervention has the some of the strongest evidence of effectiveness across all types of psychosocial interventions for schizophrenia in any setting [33].

7.4.3 Assumptions that were shown to be correct

Six of the assumptions relating to intervention performance were found to be well founded, and were therefore converted to rationales in the theory of change (see purple boxes in Figure 7.2). Most of these rationales related to acceptability, reflecting the overall willingness of people with schizophrenia, caregivers, CBR workers, community members and health centre staff to participate in or support

CBR (*rationales 1a, 1c and 1d*). As in other similar studies, concerns about the safety of community health workers delivering home care to people with mental illness were raised in the planning stages [25, 34], but did not materialise as an issue in practice [34] (*rationale 1c*). This may reflect the safety procedures implemented in the pilot, but also the small group of participants, amongst whom there were no incidents of aggressive behaviour. The reduction in stigmatising attitudes towards people with schizophrenia seen in CBR workers after starting work echoes evidence that social contact is the most powerful means of reducing stigma in the short term [35]. The health officers' perception of community-level mental health workers as useful rather than a threat or hindrance (*rationale 2c*) is perhaps not surprising as CBR addressed a need for outreach work identified by primary care staff in Sodo [25]. However the importance of clarifying the role of community health workers, raised here, had also previously been highlighted in studies examining the acceptability of task-shifting for other mental disorders from the perspective of primary care staff [36].

Although there were some major challenges relating to acceptability from the perspective of people with schizophrenia, it was felt these were surmountable with adjustments to the intervention, in particular through supplementary training for CBR workers on how to communicate about medication and increased flexibility in the mechanics of intervention delivery, such as timing and frequency of sessions (*rationale 1a*). Instances of disengagement towards the end of CBR may not have reflected a lack of acceptability, but rather that CBR had reached its natural conclusion for those individuals; indeed it may be indicative of CBR's success that one participant was functioning well enough to leave for Addis Ababa to find work. Potential stigma was a concern for a minority of participants, similar to findings from the COPSI pilot in India [26]. Disengagement due to time constraints, of both people with schizophrenia and caregivers, was a more significant issue in this pilot. The importance for acceptability of community workers, in this case CBR workers, being from the local area reflected findings from formative studies relating to common mental disorders [36].

The confirmation that non-specialists can be trained to deliver CBR for schizophrenia (*rationale 2a*) supports findings from the COPSI pilot, trial and earlier linked studies in India [26, 28, 37, 38]. This work also adds to a growing

body of evidence for common mental disorders in other LMIC [39-41]. The fact that in the RISE pilot this was achieved without routine clinical review or supervision by psychiatrists, unlike other comparable studies [28, 39-41], could represent a significant and novel achievement. Thorough training is likely to have been important [25, 36] and CBR workers may have also benefited from the highly structured nature of the intervention. Yet my own involvement in CBR worker supervision (see Section 7.2.4) arguably made a substantial contribution to CBR worker competence. The trial, throughout which I will have no direct supervisory role, will allow us to determine whether the non-specialist supervision arrangements are truly feasible.

It was decided the assumption that community mobilisation is required was, on balance, well founded (*rationale 3b*). An unexpected benefit of this work was that people with previously untreated psychosis were identified and sign-posted to the health facility. Gains in social inclusion, and the potential role of the community, were contested findings in this study, and therefore demand particular attention in the trial qualitative evaluation.

7.4.4 Assumptions not yet confirmed

Six assumptions could not be confirmed using the pilot data and therefore remain areas for assessment in the trial. First was the assumption (*1b*) that CBR can meet participants' needs. Poverty was the foremost problem for most pilot participants; the lack of immediate and tangible financial benefit from CBR was a key acceptability issue, prompting several participants to question the purpose of participation. It was clear that whilst expectations may be low amongst participants, for most this did not translate into 'blind' unquestioning engagement if needs are not met. This validates the assertion of Padmanathan et al that people with mental illness in LMIC are unlikely to engage in psychosocial interventions that do not meet their needs [36]. However, her supposition that interventions that have been designed for cross-cultural applicability, as RISE was, will inevitably meet the needs of participants does not take into account the potency of external factors such as the absence of employment opportunities. In a trial of collaborative care for common mental disorders in India, lay health counsellors initially

encountered complaints that they were not offering financial support to participants or addressing social difficulties [42]. In that setting the issue was overcome by improving referral systems to welfare schemes and other agencies [42]. Yet in a low-income setting such as Ethiopia the absence of social security or even local NGOs who can offer additional support means participants are wholly reliant on the CBR programme to meet their needs.

In this study there was some evidence that the person with schizophrenia's basic needs can be addressed through identifying willing benefactors, but these were seen as precarious links requiring intensive input and there was uncertainty about their sustainability. These interventions were also only possible in urban areas where there are wealthy donors available. In many rural areas there may be rich community resources in terms of social and cultural life [43], but very few 'spare' financial and material resources to tap into. The RISE CBR intervention did not attempt to establish new formal structures at the sub-district level to continue aspects of CBR after the pilot was completed. Such efforts, which are proposed by the WHO CBR guidelines [44], were deemed at the intervention development stage to be unfeasible for the time frame of the RISE pilot. Yet in the pilot there was also a lack of interest from existing social organisations, such as *edir* (burial association) groups, in providing financial support (*assumption 2e*). Some participants expressed disinterest in receiving support from *edir*; perhaps a more discrete means of support would have been more attractive. There was little firm data to fully explore this issue. For whatever reason this arose, the inability of CBR workers to link their efforts to a permanent social forum or structure may have important implications for sustainability. Other attempts by CBR workers to circumvent the hardship of participants, by accessing the medication fee waiver, were also unsuccessful. Though there were several successes in supporting income-generation, important challenges also emerged including a lack of formal employment opportunities (meaning one participant moved to the capital city to work).

A key threat to the feasibility of CBR was the absence of continuously available and affordable medication with an acceptable side effect profile (*assumption 2d*). This issue represents another external factor that proved insurmountable for CBR workers in the pilot. The logistics of intervention delivery (*assumption 2b*) require

further evaluation at scale. There are indications that CBR can improve functioning (*assumption 3a*), but a randomised evaluation remains essential. A larger pool of participants may also provide the opportunity to evaluate the utility of family support groups (*assumption 3c*) and acceptability of CBR for traditional and religious healers (*assumption 1e*).

The lack of engagement with traditional healers, such as herbalists or *tanqway* (who are 'sorcerers' and are distinct from Orthodox Christian healers such as holy water priests), was surprising given previous findings that they are numerous in this district [43]; and *tanqway* in particular are consulted for psychotic illness in all parts of Ethiopia (see Section 2.9.3). Possible reasons why CBR workers did not identify any traditional healers (for example, for inclusion in awareness-raising) include that, by chance, no healers were present in the pilot sub-districts; because this group tends to remain hidden from public life; or possibly due to reluctance by CBR workers to engage with this group. People with schizophrenia may have been less likely to seek treatment from healers during the pilot as formal mental healthcare was newly available in the district, and promoted by CBR. It is also conceivable that participants hid their use of traditional healers from CBR workers due to taboo or concern that CBR workers would discourage this. It should be noted that two participants did openly use holy water, but the sites were outside of the participants' sub-districts so CBR workers did not attempt to engage with them. In the pilot CBR workers were restricted to conducting community mobilisation work within their allocated sub-district to maintain comparability to the trial intervention (which would be restricted in this way to avoid contamination between clusters (see Chapter 8)).

7.5 CONCLUSION

Overall CBR is an acceptable approach for people with schizophrenia in rural Ethiopia. CBR is likely to be feasible but this requires further evaluation on a larger scale. CBR may have the capacity to improve functioning in people with schizophrenia through maximising family and community support, facilitating access to mental health services and anti-psychotic medication, facilitating income-generating activities and increasing hope and self-esteem. However some of the contextual factors that shape illness experience, including poverty and inaccessible anti-psychotic medication, seem to be beyond the capacity of CBR to overcome. This may limit the potential impact of CBR on the lives of people with schizophrenia in rural Ethiopia.

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8 RISE TRIAL PROTOCOL

8.1 INTRODUCTION

The previous chapter presented the RISE pilot, which generated evidence on the acceptability and feasibility of CBR for schizophrenia in practice. This chapter contains a published protocol for a cluster randomised controlled trial to evaluate the RISE CBR intervention. This trial, which aims to determine the effectiveness of CBR, will represent the 'Evaluation' phase of the MRC framework [1]. The RISE trial began in September 2015, nine months into the 12 month RISE pilot.

The trial evaluation plans were refined using the post-pilot theory of change map (see Figure 7.2 in Chapter 7), which outlines the hypothesised pathway through which the intervention works and impacts on the primary outcome of the trial (functioning). Table 8.1 indicates how each intermediate outcome on this pathway will be evaluated in the trial with one or more indicators. Achievement of indicators will be assessed using qualitative, quantitative and process data. A theory of change approach is beneficial because it combines the process and outcome evaluations and can therefore assess not just whether, but how and why the intervention had the observed effect. Conversely if no effect is seen this approach helps to distinguish between intervention failure and implementation failure.

The main section of this chapter is the published trial protocol (Section 8.2). Supplementary information is then presented on the following subjects: how the trial methods were piloted, and what changes were implemented to arrive at the final methods described in the protocol; additional elements of the statistical analysis plan to assess the validity of the theory of change; and potential limitations to the trial design (Section 8.3).

Table 8.1 Trial indicators for the RISE theory of change (continued overleaf)

Theory of change intermediate outcome	Indicator	Trial data type				Data source
		Primary outcome	Secondary outcome	Qualitative	Process	
CBR workers and supervisors are in post	10 CBR workers and two supervisors retained for 18 month duration of trial				✓	Staff recruitment data
People with schizophrenia and caregivers are identified	182 participants identified across 54 sub-districts; on average 2- 3 eligible and consenting participants identified in each sub-district				✓	Participant recruitment data
Community resources and leaders are known	Community engagement tasks 2 and 3 (identify community resources and leaders) completed in all sub-districts within three months				✓	Sub-district logbook
	Community engagement tasks 5 and 6 (meetings with community leaders and awareness raising events) completed in all sub-districts within three months				✓	Sub-district logbook
Community is engaged in CBR	Good quality engagement with community leaders			✓		Endline IDI with community leaders; FGD with CBR workers
	≥1 individual mobilisation of community leader/ member in each sub-district (tasks 8-11)				✓	Sub-district logbook
CBR model of care acceptable to CBR workers and participants	Reported acceptability of model of care by CBR workers and participants			✓		Endline IDIs with participants and FGDs with CBR workers
Needs, goals and risk relating to participants are known	Needs assessment, goal setting, risk assessment and rehabilitation plan completed for each participant at beginning of Phases 1, 2 and 3				✓	Participant logbooks

Table 8.1 continued						
Theory of change intermediate outcome	Indicator	Trial data type				Data source
		Primary outcome	Secondary outcome	Qualitative	Process	
CBR workers are competent	<i>No CBR worker rated as 'needs improvement' on any ENACT items</i>				✓	ENACT assessments at baseline and 12 months
CBR workers deliver CBR as intended	<i>All CBR workers have minimum of 10 observed unannounced home visits</i>				✓	Supervisor logbooks
	<i>All CBR workers have minimum of 12 face to face supervision sessions</i>				✓	Supervisor logbooks
	<i>CBR workers attend 80% group supervision sessions</i>				✓	Supervisor logbooks
	<i>Supervision perceived to be useful and of appropriate frequency</i>			✓		Endline CBR worker FGD
People with schizophrenia are engaged in CBR for intended duration and intensity	<i>90% participants receive all core modules in first 3 months</i>				✓	Participant logbooks
	<i>Participants undertake, on average, 90% modules indicated by goal setting</i>				✓	Participant logbooks
	<i>All participants continue to receive CBR visits for 12 months</i>				✓	Participant logbooks
	<i>Participants receive approximately 22 home visits over 12 months (ideal CBR receipt)</i>				✓	Participant logbooks
	<i>Participants receive 10 or more home visits over 12 months (minimum adequate CBR receipt)</i>				✓	Participant logbooks
On going family support	<i>Continuing Care Form completed for all participants by 12 months</i>				✓	Participant logbooks
	<i>Family and CBR worker feel family are able to continue support by 12 months</i>			✓		Endline CBR worker FGD and participants IDI
On going community support	<i>Reported on going community support at 12 months</i>			✓		Endline CBR worker FGD, participants IDI, community members IDI

Table 8.1 continued						
Theory of change intermediate outcome	Indicator	Trial data type				Data source
		Primary outcome	Secondary outcome	Qualitative	Process	
Improved understanding of mental illness and human rights	Reported improvement in understanding directly or indirectly attributable to CBR			✓		Endline CBR worker FGD, participants IDI
Improved family stability and care and reduced caregiver burden	Perceived improvement in family burden, family stability and care directly/indirectly attributable to CBR			✓		Endline CBR worker FGD, participants IDI
	Lower FIS Burden, IEQ scores (worrying and tension subscales) and caregiver PHQ-9 scores in the intervention compared to the control arm		✓			IEQ, FIS Burden, Caregiver PHQ-9 12 months
	Higher IEQ scores (urging and supervision) in the intervention compared to the control arm		✓			IEQ 12 months
Improved access to mental healthcare and increased medication adherence	Increased % with ≥1 visit to health facility for mental health in last 3 months in intervention compared to control arm		✓			Adapted CSRI baseline and 12 months
	Reported attendance to facility for mental health directly or indirectly attributable to CBR			✓		Endline CBR worker FGD, participants IDI
	Medication fee waiver obtained when required			✓		Endline CBR worker FGD
	Reported ability to pay for anti-psychotic medication directly or indirectly attributable to CBR			✓		Endline CBR worker FGD, participants IDI
	Lower % stop taking medication because unaffordable & greater % received anti-psychotic medication for free in intervention compared to control arm		✓			Adapted medication adherence questions at 12 months
	Greater proportion adhering to medication sometimes or always in intervention arm compared to control arm		✓			Medication adherence question

Table 8.1 continued						
Theory of change intermediate outcome	Indicator	Trial data type				Data source
		Primary outcome	Secondary outcome	Qualitative	Process	
Reduced stigma and abuse against people with schizophrenia	<i>Perceived reduction in stigma, violence and use of restraint directly or indirectly attributable to CBR</i>			✓		Endline CBR worker FGD, participants IDI, community members IDI
	<i>Reduced incidence of restraint in last 6 months in intervention arm compared to control arm</i>		✓			Restraint questions 12 months
Social inclusion of people with schizophrenia	<i>Perceived improvement in social inclusion after 12 months directly or indirectly attributable to CBR</i>			✓		Endline CBR worker FGD, participants IDI, community members IDI
	<i>Lower DISC-12 scores in intervention arm compared to control arm</i>		✓			DISC-12 12 months
Improved physical health and appearance	<i>Perceived improvement in physical health after 12 months directly or indirectly attributable to CBR</i>			✓		Endline CBR worker FGD, participants IDI
	<i>Greater BMI in intervention arm compared to control arm</i>		✓			BMI 12 months
	<i>Lower AUDIT scores in intervention arm compared to control arm</i>		✓			AUDIT 12 months
	<i>Reported attendance to facility for physical health directly or indirectly attributable to CBR</i>			✓		Endline CBR worker FGD, participants IDI 12 months
	<i>Increased % with ≥1 visit to health facility for physical health in last three months in intervention arm compared to control arm</i>		✓			Adapted CSRI baseline and 12 months
Increased income	<i>Perceived improvement in income or economic status directly or indirectly attributable to CBR</i>			✓		Endline CBR worker FGD, participants IDI
	<i>Greater economic activity in intervention arm compared to control arm</i>		✓			Economic activity 12 months

Table 8.1 continued						
Theory of change intermediate outcome	Indicator	Trial data type				Data source
		Primary outcome	Secondary outcome	Qualitative	Process	
Improved symptoms and reduced relapse	<i>Perceived improvement in symptoms directly or indirectly attributable to CBR</i>			✓		Endline CBR worker FGD, participants IDI
	<i>Lower BPRS-E, CGI, PHQ-9 scores in intervention arm compared to control arm</i>		✓			BPRSE, CGI and PHQ-9 12 months
	<i>Fewer relapses in last 6 months, measured by LCS and LIFE, in intervention arm compared to control arm</i>		✓			LCS and LIFE 12 months
Increased involvement in decision making about care	<i>Perceived greater ability to enact desired treatment choices directly or indirectly attributable to CBR</i>			✓		Endline CBR worker FGD, participants IDI
	<i>Reported use of medication alongside traditional medicine, if desired, directly or indirectly attributable to CBR</i>			✓		Endline CBR worker FGD, participants IDI
Increased self esteem and hope	<i>Perceived improvement in hope and/ or self-esteem directly or indirectly attributable to CBR</i>			✓		Endline CBR worker FGD, participants IDI
	<i>Lower PHQ-9 scores in intervention arm compared to control arm</i>		✓			PHQ- 9 12 months
Sustained improved functioning	<i>WHODAS scores 20% lower in intervention arm compared to control arm at 12 months</i>	✓				WHODAS 12 months
	<i>Perceived improvement in functioning directly or indirectly attributable to CBR</i>			✓		Endline CBR worker FGD, participants IDI

IDI: In-depth interview, FGD: Focus group discussion, ENACT: Enhancing Assessment of Common Therapeutic factors rating scale, FIS: Family interview schedule, IEQ: Involvement Evaluation Questionnaire, PHQ-9: Patient Health Questionnaire, DISC: Discrimination and Stigma Scale-12, CSRI: Client Service Receipt Inventory, AUDIT: Alcohol Use Disorder Identification Test, BPRS-E: Brief Psychiatric Rating Scale- Expanded version, CGI: Clinical Global Impression, LCS: Life Chart Schedule, LIFE Chart: Longitudinal Interval Follow-up Evaluation, WHODAS: WHO Disability Assessment Schedule

8.2 RESEARCH PAPER

The Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement is found in Appendix E (i).

Ethical approvals for the trial are found in Appendix D (iv).

Minor corrections on manuscript:

1. *Page 2: Mortality was incorrectly reported as two times greater than general population; this should read 'three times greater' [2]*
2. *Page 4: Literacy rates in Sodo were incorrectly reported as 45%; this should read '51%' [3]*
3. *Page 6: inclusion criteria (4) should state 'aged 18 years or older'*
4. *Page 6: inclusion criteria inclusion criteria (6) (b) should read 'patient or proxy-reported WHODAS \geq 35'*
5. *Page 9: Involvement Evaluation Questionnaire*



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RESEARCH PAPER COVER SHEET

PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED FOR EACH RESEARCH PAPER INCLUDED IN A THESIS.

SECTION A – Student Details

Student	Laura Asher
Principal Supervisor	Vikram Patel
Thesis Title	The development and evaluation of a community-based rehabilitation intervention for people with schizophrenia in Ethiopia

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

Where was the work published?	Trials		
When was the work published?	24 th June 2016		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion			
Have you retained the copyright for the work?*	Yes	Was the work subject to academic peer review?	Yes

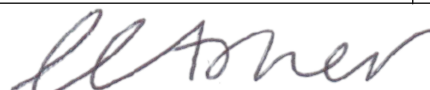
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SECTION C – Prepared for publication, but not yet published

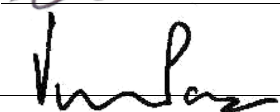
Where is the work intended to be published?	
Please list the paper's authors in the intended authorship order:	
Stage of publication	Choose an item.

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I led on the overall design of the trial and the methods. I wrote the initial and final drafts of the paper.
--	--

Student Signature: 

Date: 06.10.2016

Supervisor Signature: 

Date: 06.10.2016

STUDY PROTOCOL

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Community-based Rehabilitation Intervention for people with Schizophrenia in Ethiopia (RISE): study protocol for a cluster randomised controlled trial

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Abstract

Background: Care for most people with schizophrenia is best delivered in the community and evidence-based guidelines recommend combining both medication and a psychosocial intervention, such as community-based rehabilitation. There is emerging evidence that community-based rehabilitation for schizophrenia is effective at reducing disability in middle-income country settings, yet there is no published evidence on the effectiveness in settings with fewer mental health resources. This paper describes the protocol of a study that aims to evaluate the effectiveness of community-based rehabilitation as an adjunct to health facility-based care in rural Ethiopia.

Methods: This is a cluster randomised trial set in a rural district in Ethiopia, with sub-district as the unit of randomisation. Participants will be recruited from an existing cohort of people with schizophrenia receiving treatment in primary care. Fifty-four sub-districts will be randomly allocated in a 1:1 ratio to facility-based care plus community-based rehabilitation (intervention arm) or facility-based care alone (control arm). Facility-based care consists of treatment by a nurse or health officer in primary care (antipsychotic medication, basic psychoeducation and follow-up) with referral to a psychiatric nurse-led outpatient clinic or psychiatric hospital when required. Trained community-based rehabilitation workers will deliver a manualised community-based rehabilitation intervention, with regular individual and group supervision. We aim to recruit 182 people with schizophrenia and their caregivers. Potential participants will be screened for eligibility, including enduring or disabling illness. Participants will be recruited after providing informed consent or, for participants without decision-making capacity, after the primary caregiver gives permission on behalf of the participant. The primary outcome is disability measured with the 36-item WHO Disability Assessment Schedule (WHODAS) version 2.0 at 12 months. The sample size will allow us to detect a 20% difference in WHODAS 2.0 scores between treatment arms with 85% power. Secondary outcomes include change in symptom severity, economic activity, physical restraint, discrimination and caregiver burden.

Discussion: This is the first trial of community-based rehabilitation for schizophrenia and will determine, as a proof of concept, the added value of community-based rehabilitation compared to facility-based care alone in a low-income country with scarce mental health resources.

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Keywords: Schizophrenia, Psychosis, Community-based rehabilitation, Disability, Cluster randomised trial, Ethiopia, Low-income country

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Background

Schizophrenia can be a severe, chronic and disabling condition, which places a high social and economic burden on individuals [1], families [2] and society. The majority of people with schizophrenia in sub-Saharan Africa do not have access to adequate care [3]. Over half of the people with schizophrenia in Ethiopia experience continuous or episodic illness over a 10-year period [4], where the treatment gap is estimated to be 90 % [5, 6]. Mortality is high; the standardised mortality ratio for people with schizophrenia in Ethiopia is twice that of the general population [7]. People with schizophrenia are also likely to experience stigma and discrimination [8, 9] and human rights violations [10].

According to global consensus, supported by scientific review of the evidence and the experience of mental health system experts, a comprehensive mental health system includes both community- and hospital-based components of care [11, 12] and should incorporate both medication and psychosocial interventions [13, 14]. Relatively low-intensity psychosocial community-based programmes, which are likely to be most feasible, have been shown to be effective in low- and middle-income country (LMIC) settings [15–17]. To date such programmes have typically involved four groups: the patient, family members, a community-based non-specialist key worker and a psychiatrist [14]. In particular, the World Health Organisation's (WHO's) mental health Gap Action Programme (mhGAP) recommends community-based rehabilitation (CBR) as an adjunct to medication for schizophrenia [18]. CBR is a general approach with the aim to improve the quality of life and social inclusion of people with disabilities [19] and is typically delivered by trained lay workers from the local community. Key pillars of a CBR programme include interventions that promote health, education, livelihood, and social life. In addition there is a cross-cutting emphasis on empowerment, such as supporting people with disabilities to make their own decisions. CBR is put into practice through the joint endeavours of people with disabilities, their caregivers, community members and relevant governmental and non-governmental services, including health services [20].

CBR programmes have traditionally focussed on people with physical disabilities. There is increasing recognition that people with mental disorders may also receive benefit from a service model that integrates mental health and economic development [21, 22]. CBR may impact on clinical and disability outcomes in people with schizophrenia by improving understanding of the illness, increasing adherence to antipsychotic medication, reducing stigma and improving social functioning.

Globally there are a few examples of CBR programmes for people with mental disorders [17, 23–30]. A systematic review found that CBR may improve clinical outcomes

and functioning for schizophrenia, dementia and intellectual disabilities in LMICs [20]. However, no randomised controlled trials (RCTs) of CBR for schizophrenia that involved community mobilisation (defined as 'a strategy which aims to engage community members and empower them for change or action' [19]), or focussed primarily on any CBR pillar other than health, were included [20]. Furthermore, there were no studies set in countries defined by the World Bank as being low-income [20]. The more recent COmmunity care for People with Schizophrenia in India (COPSI) trial [31], a study from India (a middle-income country), found that collaborative community care modestly improved disability and symptoms in people with schizophrenia [17]. The greatest effects were seen in rural areas with fewer formal mental health resources. Whilst influenced by CBR, the intervention did not include community mobilisation, and participants had access to psychiatrists as a key component of care.

To our knowledge there has been no previous randomised trial investigating the impact of a comprehensive CBR programme, including both home-based care and a structured community mobilisation element, on outcomes in people with schizophrenia. Furthermore, the effectiveness of CBR for schizophrenia has not previously been examined in a low-income setting, such as Ethiopia, which has minimal formal mental health resources. Currently, most people with schizophrenia in rural Ethiopia will never have access to a psychiatrist, psychiatric nurse or other mental health professional. However, mental health care is being scaled up in Ethiopia by training general health workers, largely in primary care, to deliver care for people with mental disorders. This process illustrates the Ethiopian Ministry of Health's efforts to improve access to mental health care [32].

Extensive formative research using a variety of methods nested within a Theory of Change framework has enabled the design of a culturally and contextually appropriate CBR intervention for people with schizophrenia that is acceptable and feasible to service users and providers in rural Ethiopia [33, 34]. The CBR intervention, which includes home-based care, community mobilisation and family support groups, has been piloted. This paper presents the protocol for the Rehabilitation Intervention for people with Schizophrenia in Ethiopia (RISE) project, a cluster randomised trial, which will evaluate the effectiveness of this CBR intervention.

Objectives

Primary objective

To evaluate the effectiveness of CBR as an adjunct to facility-based care (FBC), compared to FBC alone, in reducing disability related to schizophrenia at 12 months,

measured by the WHO Disability Assessment Schedule (WHODAS) version 2.0 in patients with evidence of poor response or lack of engagement in care over the preceding 6 months.

Secondary objectives

1. To evaluate the effectiveness of CBR plus FBC compared to FBC alone in reducing clinical symptoms, reducing relapse, increasing medication adherence, improving economic activity, reducing physical restraint, reducing discrimination, and improving nutritional status in people with schizophrenia.
2. To evaluate the effectiveness of CBR plus FBC compared to FBC alone in reducing family burden, stigma and depression, and improving economic activity in caregivers of people with schizophrenia
3. To explore the acceptability and feasibility of CBR from the perspective of (1) those receiving the treatment, (2) their families, and (3) those delivering the treatment.

4. To determine the cost-effectiveness of CBR plus FBC compared to FBC alone.
5. To investigate the process through which CBR achieves its impact.

Primary hypothesis

People with schizophrenia who receive CBR in addition to FBC will experience greater reductions in disability compared to those who receive only FBC, to the order of 20 % absolute difference in WHODAS 2.0 score between groups, over a 12-month period.

Methods

Study design

The design is a cluster randomised controlled trial with sub-district (pre-defined administrative unit consisting of several villages together) as the unit of randomisation. The study flow chart is presented in Fig. 1. From 58 sub-districts in the study district, four sub-districts were sites for the pilot and the remaining 54 sub-districts will be included for the actual trial; 27 will be randomly allocated to the intervention arm (FBC plus CBR) and 27

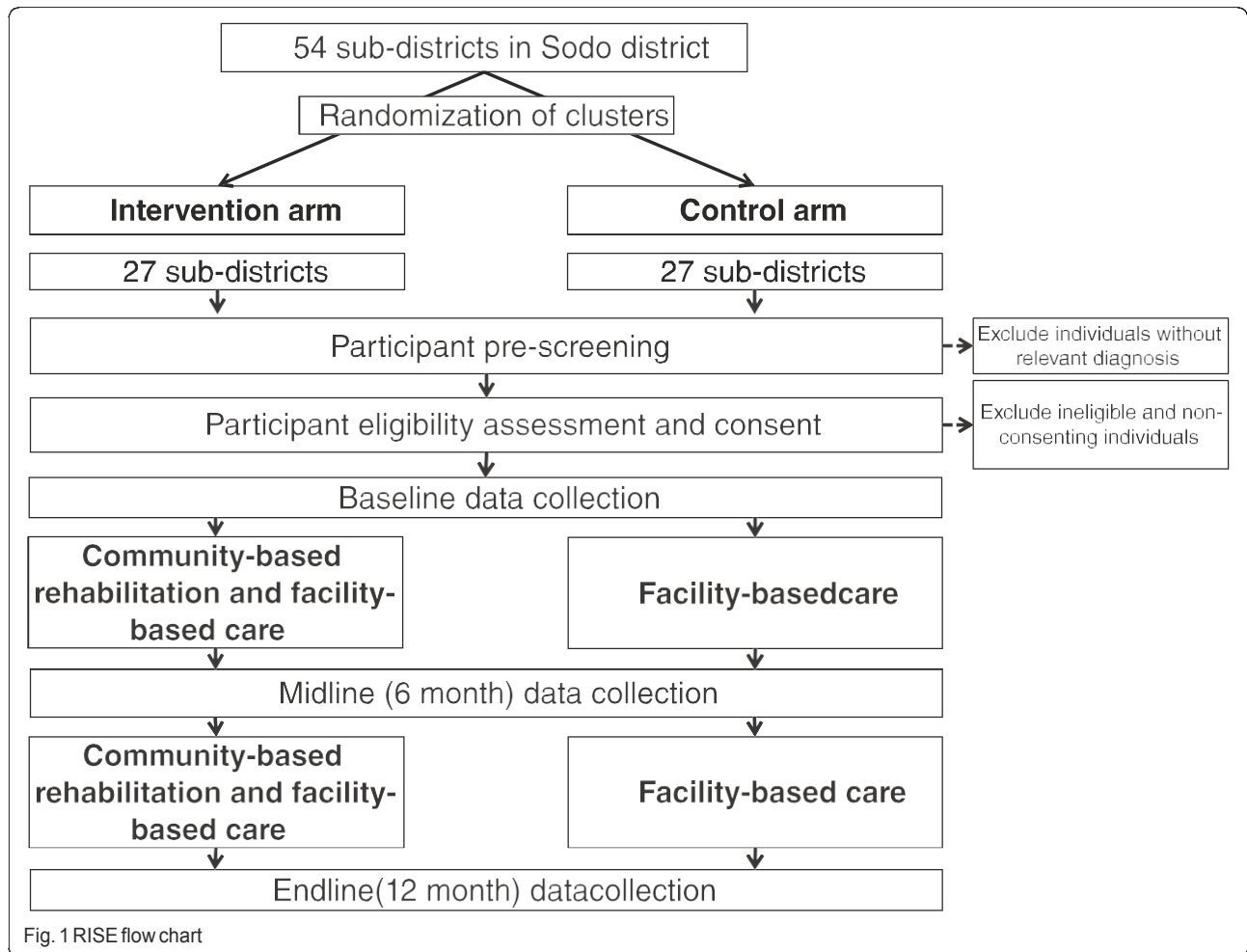


Fig. 1 RISE flow chart

randomly allocated to the control arm (FBC alone). In total, 182 participant dyads (patients and their caregivers) will be recruited. On average there will be 3.4 participant dyads per sub-district.

Cluster randomisation is the chosen method of randomisation because first, CBR includes community-level elements and family support groups, based on sub-districts, so individual randomisation is not possible; second, it is logistically more convenient to concentrate CBR workload in fewer sub-districts; and third there is increased acceptability if all participants in a sub-district are allocated to either intervention or control arms. This paper follows the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) recommendations for trial protocols (see Additional file 1).

Setting

The trial will take place in Sodo district, Gurage Zone, Southern Nations, Nationalities and Populations Region (SNNPR) in Ethiopia. The administrative town of Sodo, Bui, lies 100 km from Addis Ababa. Sodo district has a population of 170,000 persons in 58 sub-districts: four urban and 54 rural. Most people live in one-room mud and straw houses and work as subsistence farmers. About 45% of the population are literate and the majority are Orthodox Christian by religion.

There is a psychiatric nurse-led outpatient clinic at the general hospital in Bui. There is a similar unit at Butajira hospital, which is 30 km away from Bui in the neighbouring district. Primary health care is delivered through eight primary health care centres staffed by health officers and general nurses. Each health centre oversees between four and 11 health posts, staffed by two health extension workers (HEWs). Each health post covers a sub-district, with a population of 2800–5000 people. Health care costs are largely out-of-pocket with a free waiver available for the poorest; in practice a tiny minority of the population are likely to be in receipt of this waiver.

Context of the study

The RISE trial is nested in PRIME (PRogramme for Improving Mental healthcare). PRIME is a multicountry research consortium that aims to generate evidence on the implementation and scaling up of packages of care for priority mental disorders in primary health care in LMICs [35, 36]. As part of the PRIME project, a comprehensive mental health care plan was developed for Ethiopia [37–39] and, from December 2014, facility-based care for schizophrenia was embedded in primary health care centres in Sodo district. Health officers and nurses were trained in the detection and treatment of schizophrenia, including the prescription of anti-psychotic medication and psychoeducation. Training

followed the WHO's mhGAP and evidence-based guidelines [18, 40], adapted for the Ethiopian context. PRIME identified people with schizophrenia in Sodo using the Butajira key informant method [41] and, from December 2014, began following up those invited to access FBC in a 12-month treatment cohort. A subsample of the PRIME cohort participants will be recruited to the RISE trial at the PRIME 6-month data collection. The rationale for recruiting into the trial after participants have had 6 months access to FBC is that if this intervention were scaled up in a resource-poor setting such as Ethiopia, it would only be made available for those with enduring illness or poor treatment outcomes.

Interventions

Facility-based care

FBC will be available to all participants in the RISE trial. The frequency of contact with FBC will be determined by clinical need. Within formal health care, FBC is a three-tier system, but the majority of care will be delivered at tier 1, which is primary care (Table 1).

Community-based rehabilitation

Intervention development

The CBR intervention was constructed through in-depth intervention development work as described in detail elsewhere [34, 42]. The work included a literature review, situational analysis [43, 44], an intervention development workshop, participatory meetings, qualitative interviews with a range of stakeholders, including people with schizophrenia, their caregivers, psychiatrists and community leaders, and collaboration with an existing CBR project, RAPID (Rehabilitation And Prevention Initiative against Disabilities). RAPID is an Ethiopian CBR project for children with disabilities.

CBR worker recruitment and training

Eleven CBR workers were recruited according to the criteria: (1) completed tenth grade education (secondary school), (2) resident in Sodo district, and (3) interest in community work. Training lasted for 5 weeks and comprised an equal split of classroom teaching and field work, including home visits to people with schizophrenia and on-the-job training at RAPID. Psychiatrists and CBR trainers from RAPID delivered the training. Competency was assessed using role-plays and patient vignettes.

Pilot

A 12-month pilot was conducted. The pilot included ten people with schizophrenia and their families living in four sub-districts not involved in the main trial. The aims of the pilot were to determine the acceptability and feasibility of the CBR intervention and to refine the intervention and trial design as needed. Major

Table 1 Facility-based care three-tier system for the treatment of mental illness

Location	Staff	Tasks	Referral
Tier 1: primary care			
Eight health centres across Sodo district	Health officers and nurses	<ul style="list-style-type: none"> • Prescribe antipsychotic medication (oral haloperidol or chlorpromazine) and monitor response • Manage side-effects • Monitor suicide risk • Review physical health • Screen for substance misuse • Provide basic psychoeducation (information about schizophrenia) • Provide regular follow-up 	<ul style="list-style-type: none"> • Refer to tier 2 in the following scenarios: <ul style="list-style-type: none"> o Active suicidal intent o Inadequate oral intake of fluid or food o Risk of violence to others and/or risk of serious self-neglect o Persistently non-adherent to medication o Acutely disturbed and not manageable at home o Pregnancy/breastfeeding o Medical complications o Unmanageable side-effects
Tier 2: general secondary care			
Psychiatric outpatient clinic at Butajira Hospital	Psychiatric nurse	<ul style="list-style-type: none"> • Specialist review • Initiate depot injection where required 	<ul style="list-style-type: none"> • Refer to tier 3 when inpatient care is required • Refer back to tier 1 for follow-up
Tier 3: specialist care			
Ammanuel Psychiatric Hospital, Addis Ababa	Psychiatrist	<ul style="list-style-type: none"> • Specialist review • Inpatient admission where required 	<ul style="list-style-type: none"> • Refer back to tier 1 and/or tier 2 for follow-up

adjustments to the intervention and trial design were made prior to the trial starting. Minor adjustments may be made to the latter components of the CBR intervention on the basis of pilot findings.

Trial CBR delivery

One or two CBR workers will be attached to each health centre and each will cover two or three sub-districts. Each CBR worker will have approximately eight people with schizophrenia under their care. The delivery of CBR for schizophrenia will be the only task for the CBR workers. CBR delivery will commence immediately after recruitment into the trial and will continue for 12 months. The CBR visits will take place at the participants' home and last 30–90 minutes. The intervention is delivered in three phases (Table 2). In phase 1, lasting 2 to 3 months, there are weekly home visits and the focus is on engagement with the family and addressing core needs through compulsory modules such as 'Understanding Schizophrenia'. In phase 2, lasting approximately 5 to 6 months, home visits are every 2 weeks and address the specific needs of the individual through optional modules such as 'Getting Back to Work'. In phase 3, lasting approximately 4 months, the emphasis is on preventing relapse as well as maintaining the progress made towards addressing specific needs. CBR workers conduct community mobilisation work and may run family support groups alongside the home visits. The detailed content of CBR at each phase of the intervention is described in Table 1. Flexibility will be encouraged according to the needs of the individual participant and their caregiver. CBR delivery will be guided by a manual that outlines steps for the delivery of each module and community engagement task, procedures for referral

and how to deal with difficult situations, for example, suicidal ideation. Two supervisors will maintain an overview of the frequency, content and quality of the home visits by CBR workers for each participant. Supervision will include monthly unannounced observed sessions, with individual face-to-face supervision and group supervision every 2 to 4 weeks. Unannounced visits will take place only with the prior permission of participants. The trial coordinator will attend group supervision monthly and conduct a paper-based review of all cases every 2 weeks with each supervisor. The coordinator will ensure the on-going fidelity of CBR delivery and guide top-up training sessions for CBR workers where required.

Selection and randomisation of clusters

We will aim to include all 54 sub-districts in Sodo district (after excluding the four pilot sub-districts). The randomisation of sub-districts into CBR plus FBC and FBC arms will be stratified by health centre. A minimisation algorithm [45] will be employed to ensure balance for (1) urban/rural location, (2) number of potential participants (i.e. cases of schizophrenia in the PRIME cohort) in the sub-district, and (3) mean WHODAS 2.0 score in the sub-district at PRIME cohort baseline. All these factors may potentially impact on the primary outcome. PRIME cohort baseline WHODAS 2.0 scores will only provide an estimate of the disability level of potential participants as this data will not be available for the entire pool of trial participants and will not represent disability levels at the time of recruitment. The allocation sequence will be generated randomly from the set of optimal sequences [46]. An independent statistician will generate the allocation list for sub-districts. This list

Table 2 RISE community-based rehabilitation (CBR) intervention outline

Phase	Months	Visits	CBR activities		
			Assessment and family engagement	Community mobilisation	Family-level interventions
1: Intensive engagement	~1–3	Weekly	<ul style="list-style-type: none"> Developing therapeutic alliance with family Needs assessment Risk assessment Goal setting for phase 1 Rehabilitation plan 	<ul style="list-style-type: none"> Resource mapping for sub-district, e.g. churches, schools, <i>edir</i> groups (traditional burial association), Women's Association, literacy groups, religious groups and traditional healers Initial awareness-raising and mobilisation, targeting health extension worker, community leaders and traditional healers Awareness raising meeting/s with general public in sub-district 	<p>Core modules:</p> <ul style="list-style-type: none"> Understanding schizophrenia Improving access to health care Dealing with human rights issues Preparing for a crisis
2: Stabilisation	~4–8	Fortnightly	<ul style="list-style-type: none"> Update needs assessment Risk assessment Goal setting for phase 2 Update rehabilitation plan 	<ul style="list-style-type: none"> Facilitate access to relevant community resources Consolidate mobilisation and awareness raising 	<p>Optional modules:</p> <ul style="list-style-type: none"> Supporting individuals to take medication Improving the family environment (coping skills, marital problems) Improving day-to-day functioning Taking part in community life Getting back to work Dealing with distressing symptoms Dealing with stigma and discrimination Improving physical health Dealing with stress and anger Improving literacy Family support groups Taking control of your illness (relapse prevention and management)
3: Maintenance	~9–12	Monthly	<ul style="list-style-type: none"> Update needs assessment Risk assessment Goal setting for phase 3 Update rehabilitation plan Prepare for termination Continuing care assessment 	<ul style="list-style-type: none"> Consolidate access to community resources Consolidate awareness raising and mobilisation 	<p>Core module:</p> <ul style="list-style-type: none"> Taking control of your illness (relapse prevention and management) if not completed in phase 2 <p>Optional modules</p> <ul style="list-style-type: none"> Any of the phase 2 modules

is will be kept securely by the trial coordinator and utilised to determine allocation status of new recruits.

Participant inclusion criteria

There are no specific exclusion criteria. Participants must meet all of the following criteria to be included: (1) be a participant in the PRIME cohort study or not engaged in FBC but resident in Sodo district, (2) have been resident in the sub-district for more than 6 months and have no immediate plans to leave the sub-district, (3) have a primary caregiver who is willing to participate in the study, (4) be aged 18 years older, (5) have a diagnosis of schizophrenia spectrum disorder (schizophrenia, schizoaffective disorder or schizophreniform disorder) using *Diagnostic and Statistical Manual of Mental Disorders, version four* (DSM-IV) [47] criteria, and (6) have evidence of enduring or disabling illness demonstrated by one or more of the following: (a) Brief Psychiatric Rating Scale – Expanded version (BPRS-E) score ≥ 52 (equivalent to at least 'moderately ill' on the Clinical Global Impression (CGI) scale) [48], (b) 36-item WHODAS 2.0

score ≥ 35 , (c) have continuous illness over the preceding 6 months, as assessed using the Life Chart Schedule (LCS), (4) be symptomatic in 3 out of the last 6 months, as assessed using the LIFE chart, or (e) have a CGI score ≥ 3 (at least 'mildly ill'). The final criterion allows us to include the group expected to benefit the most from CBR and also reflects the threshold at which CBR could realistically be offered in this resource-constrained setting.

Participant flow

Participant identification

PRIME aimed to detect all people with schizophrenia in Sodo by training key informants (HEWs and community leaders) to identify possible cases. This method was successful at identifying people with psychosis in previous Ethiopian studies, including in the neighbouring district [41, 49, 50]. Possible cases of schizophrenia were invited to their health centre for diagnosis and treatment. If they attended, a psychiatric nurse conducted a diagnostic interview using the OPCRIT (Operational Criteria for

Research), an operational criteria checklist for psychotic and affective illness [51, 52]. The OPCRIT facilitated the nurse to determine if participants had a DSM-IV diagnosis. Substantial inter-rater reliability and convergent validity of the OPCRIT has been demonstrated in other settings [53] and there is good experience of using OPCRIT in a clinical trial of schizophrenia in the neighbouring district [54]. All confirmed cases of schizophrenia spectrum disorders were offered FBC and, where they consented, were recruited into the PRIME cohort. Prior to RISE recruitment a psychiatrist conducted an additional paper-based diagnosis review of all PRIME cohort participants using the clinical instruments completed at baseline, including the OPCRIT. Where the psychiatrist deemed the diagnosis unclear, a repeat clinical assessment by the psychiatric nurse will be completed prior to RISE recruitment.

Participant recruitment

Participants for the RISE trial will be primarily recruited from people who were identified and received a diagnosis of a schizophrenia spectrum disorder at the baseline of the PRIME cohort and their caregivers, and were living in the sub-districts selected to participate in the RISE trial. However, we will recruit from up to four pools of potential participants, known as recruitment levels.

Level 1 recruitment comprises recruitment from the PRIME cohort at the 6-month data collection interview, which takes place at the health centre. *Level 2 recruitment* comprises recruitment from PRIME cohort drop-outs, i.e. those who do not attend the PRIME 6-month data collection. *Level 3 recruitment* comprises recruitment from those who were identified by key informants but have never attended FBC. This group had some baseline data collected through a home visit by PRIME as part of a non-engagement study. *Level 4 recruitment* comprises recruitment from those individuals who were identified by key informants as potential cases with schizophrenia after the recruitment for the PRIME cohort had ended. Level 1 recruitment will take place at consecutive pairs of health centre catchment areas, determined by the PRIME data collection schedule. For levels 2, 3 and 4 recruitment, all sub-districts will be covered equally to avoid unequal recruitment by treatment arm. RISE recruitment will take place either at the health centre at PRIME data collection or at a follow-up visit at the participant's home.

The aim of incorporating non-PRIME cohort participants is that these non-engagers in care are likely to have more complex needs, and be more symptomatic and disabled. They are, therefore, the individuals who are likely to receive the most benefit from CBR. Some of these individuals will not be accessing care because they

are currently well, and will be excluded from the trial using the standard recruitment criteria.

Within each CBR worker area, the transition from one recruitment level to the next will continue until approximately eight participants have been recruited for each CBR worker. The aim is to ensure CBR workers have equal workloads, to ensure CBR delivery is as uniform as possible. If it is not possible to recruit eight participants in any particular CBR worker area (after exhausting all recruitment levels), recruitment will continue at other CBR worker areas whilst aiming to keep the number of participants per CBR worker as equal as possible. Recruitment will proceed to the next recruitment level/s until a maximum of 12 participants per CBR worker are recruited. This is because the maximum feasible workload for CBR workers is expected to be 12 participants. There may be slight adjustments to the number of participants recruited per CBR worker depending on drop-out of CBR workers or other unforeseen factors.

Recruitment procedures

The recruitment procedures for each of these groups will be detailed in dedicated Standard Operating Procedures (SOPs). Potential participants in the PRIME cohort will have their eligibility for the RISE trial checked by the trial coordinator or trial nurse using PRIME 6-month data (i.e. WHODAS 2.0, BPRS-E, CGI, LIFE chart and LCS). Eligible participants will be invited to join the RISE trial by a trial nurse. They will be given information about the trial in a way appropriate to the participants' literacy level, which may include verbal information. The trial nurse will then conduct the consent procedures.

Participants not in the PRIME cohort will have an initial consent taken, before data is collected on the eligibility instruments, including the diagnostic interview. Those who are eligible will then be consented to take part in the RISE trial. Those who consent (or, for those without decision-making capacity, whose caregiver consents on their behalf) will complete the full RISE baseline data collection.

Allocation

The randomisation of sub-districts to intervention and control arms will take place before recruitment. The rationale is that it is necessary to commence delivery of the CBR intervention immediately after recruitment. The trial coordinator will keep the sub-district allocation list secure on a password-protected document. To reduce selection bias, the potential participant will not be informed of the allocation of their sub-district until after they have consented to participate and all baseline data collection is complete. The trial nurse will also be blind to the allocation. The trial coordinator will assign a unique trial identifier (ID) to each new participant and

Table 3 Summary of outcome measures

Outcome	Instrument
Psychiatric nurse-administered interview with patient	
Symptom severity	Brief Psychiatric Rating Scale – Expanded version (BPRS- E) [62]. A 24-item instrument focussing on psychotic symptoms, but also covering somatic concerns, anxiety, depression and mania. Individual BPRS-E items and total score are sensitive to change in persons with persistent schizophrenia [63]. The scale has been previously used in Ethiopia [64] and has recently been shown to have good inter-rater reliability (>0.8 comparing psychiatric nurses and psychiatrists) in this setting (personal communication, Dr Charlotte Hanlon) [65]. As the scale is clinician-rated this allows for sociocultural sensitivity. Inter-rater and test-retest reliability as well as internal consistency are also high in high-income settings [66]
Clinical impression	Clinical Global Impression (CGI). A widely used assessment tool, comprising three scales, to determine overall illness severity and efficacy of intervention [67]
Relapse	Life Chart Schedule (LCS) including course type and relapses [68]. Longitudinal Interval Follow-up Evaluation: DSM-IV version (LIFE). A semi-structured interview to determine the subject's psychiatric course since the last interview [69]. Satisfactory validation has been conducted in Ethiopia and the reliability data is currently being analysed. Any necessary adjustments will be made on the basis of the inter-rater reliability assessments (personal communication, Dr Girmay Medhin)
Lay data collector-administered interview with the patient	
Disability	Patient-reported 36-item WHODAS (Disability Assessment Schedule) 2.0 [55]. A validated indigenous functioning scale, specific to the Ethiopian context [70]
Economic activity	Measure covering current employment, subsistence farming work, income, and hunger due to lack of resources
Discrimination	Section 1 of the Discrimination and Stigma Scale-12 (DISC-12) [71]
Medication adherence	Adapted Morisky Medication Adherence Scale (MMAS) [72]. This scale has previously been utilised for antipsychotic medication adherence [31, 73]. Good construct validity has been demonstrated in Ethiopia (personal communication, Dr Charlotte Hanlon) [65]. A 5-point nominal scale measuring frequency of adherence [31]
Health service use and costs including engagement with FBC for schizophrenia and physical health conditions	An adapted version of The Client Service Receipt Inventory (CSRI) will enquire systematically about the costs (direct and indirect) of help-seeking from biomedical, traditional and religious healers [74, 75]. The CSRI has been translated into Amharic and found to be acceptable and feasible [76]
Access to community interventions (including CBR components)	Including person administering the component, and satisfaction
Physical restraint	In the preceding 1 and 6 months. Includes assessment of duration, perpetrator, setting and reason for restraint
Nutritional status	Measurement of weight (kg) and height (m) will be carried out [77] and body mass index (weight in kg/(height in m) ²) calculated
Depression	The Patient Health Questionnaire- 9 (PHQ-9). A 9-item scale which scores each of the 9 DSM-IV criteria for depressive disorders as '0' (not at all) to '3' (nearly every day) [78]. Shown to be valid in the Ethiopian setting [79]
Alcohol use disorder	The AUDIT (Alcohol Use Disorders Identification Test) is a ten-item tool to detect hazardous drinking [80]
Social support	Oslo-3 Social Support Scale [81]
Serious adverse events	Occurrence of serious adverse events (for example, suicide attempt and hospitalisation for medical emergency) in the last 6 months
Lay data collector interview with the primary caregiver	
Patient disability	The 36-item WHODAS 2.0 proxy version will assess functional impairment from the caregiver's perspective [82, 83]
Economic activity of caregiver	Employment, subsistence farming work, income, and hunger due to lack of resources
Caregiver burden	The Burden Section of the WHO 'Family Interview Schedule'. This scale, covering financial strain and work difficulties has been previously used in Ethiopia for persons with schizophrenia [2].

Table 3 Summary of outcome measures (*Continued*)

Caregiver depression	A scale developed for PRIME will quantify the time burden of caring for their relative with schizophrenia, the type of work that was stopped or reduced and the amount of money lost. The Involvement Engagement Questionnaire (IEQ) will be used as an additional measure to assess caregiver burden.
Stigma	PHQ-9[78, 79]
Patient medication adherence	Section of the WHO 'Family Interview Schedule'; previously used in Ethiopia [8]
	The 5-point nominal scale developed for the COPSI study will be used [31]

CBR community-based rehabilitation, DSM-IV Diagnostic and Statistical Manual of Mental disorders, version four, FBC facility-based care

will determine the allocation of all new recruits using the secure allocation list. Recruitment and participant flow will be closely monitored by the trial coordinator and any protocol deviations recorded and reported.

Outcome assessments

Quantitative

All outcomes are individual-level and will be assessed at 6 and 12 months (Table 3). Baseline RISE data will be extracted from 6-month PRIME cohort data and 6-month RISE data will be extracted from 12-month PRIME cohort data. Twelve-month RISE data will be collected independently of the PRIME cohort. Trained lay data collectors will collect all data except for symptom severity, clinical course, overall clinical impression of illness severity and improvement, and medication, for which a trained psychiatric nurse will be used. Patient outcomes will be collected with the caregiver present according to participant preference and when the patient does not have the capacity to answer questions independently. Data will be collected directly from the patient where possible (except for caregiver-reported outcomes). Items will be recorded as missing in the scenario that the caregiver is not present due to patient refusal, and the patient is unable or unwilling to respond. Quality will be assured through systematic observations of data collection by a research assistant (for lay data collectors) or psychiatrist (for psychiatric nurse data collectors), and by verification of all patient record forms. Regular meetings will be held to provide feedback to data collectors.

In order to reduce information bias data collectors will be masked to sub-district allocation; participants will be requested not to divulge treatment allocation to data collectors; participants from different sub-districts will be allocated to each data collector; identical methods for follow-up will be employed in each arm; and those involved in data analysis will be masked to sub-district allocation.

Loss to follow-up will be minimised by reminding participants to attend the interview shortly before they are due, either by telephone or by a home visit. Participants who do not attend will receive a home visit to ask them

to attend at an alternative time. Data collection will take place at the health centre except for participants who do not attend after three invitations. These participants will receive a home visit for data collection. Participants will receive a modest fee for transport and time compensation.

The primary outcome is proxy report of patient disability which will be measured with the 36-item WHO DAS (Disability Assessment Schedule) 2.0 [55], through interviewing the caregiver. WHODAS 2.0 was developed as single generic instrument for assessing health status and disability relating to a range of health conditions across cultures and settings. It covers understanding and communication, getting around, self-care, getting along with people, life activities and participation in society. Sociocultural adaptation and validation (convergent validity, construct validity and responsiveness to change) of the WHODAS 2.0 in persons with schizophrenia has been completed in Ethiopia (personal communication, Kassahun Habtamu). Issues arising during the adaptation included items not having obvious direct translations and representing uncommon experiences in the rural Ethiopian setting (for example, 'staying by yourself for a few days'). These issues were largely resolved through iterative adjustments to the translation following piloting. The proxy WHODAS 2.0 interview is designed to be answered by a friend, relative or carer. The rationale for using the proxy version for the primary outcome is that this may give a more valid picture of disability level. A separate study in the neighbouring district found that whilst scores from patient- and proxy-reported versions are moderately correlated, there is a difference, with the caregiver scores tending to be higher (greater disability) (personal communication, Kassahun Habtamu). Patients may not have enough insight to answer accurately and, therefore, underreport disability. They may also be too unwell to answer all questions, increasing the amount of missing data. Table 3 lists the secondary outcomes, which include patient-reported WHODAS 2.0, symptom severity, relapse, medication adherence, economic activity in the patient and caregiver, discrimination, health service use and costs, physical restraint, nutritional status, caregiver burden, caregiver depression and caregiver

stigma. All instruments have been adapted for use in Ethiopia; further details on validation and reliability are also given in Table 3.

Process data

Process data will be compiled using a range of sources to determine the quality and intensity of intervention delivery. These include (1) CBR worker 'sub-district' logbooks, including type and number of community engagement tasks completed, (2) CBR worker 'participant' logbooks including home visit forms (modules undertaken, duration and travel time) and assessment forms, (3) monthly observation of CBR visits by supervisor and completion of the ENACT (Enhancing Assessment of Common Therapeutic factors) rating scale [56] adapted and validated for the Ethiopian context. The adapted ENACT assesses communication skills, engagement with the individual, family and community, assessment of medication adherence, physical health, substance use and suicide risk assessment, (4) observation of CBR home visits by an external clinician (psychiatric nurse or psychiatrist) to complete the ENACT, providing an independent assessment of CBR worker skills, (5) CBR worker competency assessment by supervisor (rating of 1 to 3 given for each of 47 CBR competencies, e.g. ability to conduct community awareness raising meeting), (6) CBR worker self-assessed competency form, (7) supervisor logbook including number of supervision sessions attended, (8) health centre records to determine frequency of contact with participant, and (9) participant-reported structured assessment of the extent to which CBR met their needs.

Qualitative

In-depth interviews (IDIs) will be conducted at baseline and 12 months with a sub-sample of patients and caregivers to gather information on the impact of CBR and other factors on the experience of illness and recovery. Around eight to ten participant dyads from each treatment arm will be included depending on when theoretical saturation is reached. After gaining separate informed consent, interviews will be audio-taped, transcribed in Amharic and then translated into English prior to conducting a thematic analysis. IDIs will be conducted with four to eight community leaders to understand their role in CBR and their perception of its potential impact. IDIs and FGDs will be conducted with CBR workers and supervisors to understand their experience of delivering CBR and its perceived impact on participants. One or two focus groups will also be held with health centre nurses to understand their experience of working with CBR workers.

Power calculation

We estimate that 182 participant dyads (mean 3.4 participants/sub-district) will be available for recruitment. Assuming that there is 23 % attrition, the final sample size for analysis will be 140 participant dyads in 54 sub-districts (mean 2.6 participants/sub-district). This sample size will allow us to detect a 20 % absolute difference in WHODAS 2.0 scores between treatment arms with 85 % power and 5 % significance, assuming a k (coefficient of variation) of 0.14 and a within-cluster standard deviation (SD) of 16. The value of k was extracted from symptom severity data by sub-district from an RCT in Butajira evaluating trimethoprim as an adjuvant treatment for schizophrenia ($k = 0.11$) [57]. A more conservative estimate of k has been used to account for the potential therapist effect; each CBR worker will cover around three sub-districts and CBR intensity and quality may differ by CBR worker. The mean WHODAS 2.0 in intervention and control arms and within-cluster SD were derived from an Indian study of people with schizophrenia [58].

The estimate of 182 participant dyads available for recruitment was arrived at using (1) the total adult population of Sodo district, (2) the local prevalence of schizophrenia (0.05 %) [59], (3) an estimate that 60 % of cases will be detected and agree to participate in the PRIME cohort, (4) an assumption that 70 % of cases will be eligible for RISE, based rates of continuous illness found in a previous study in the neighbouring district of Butajira [5], and (5) an assumption that approximately 80 % of eligible cases will agree to participate, based on previous recruitment rates in the Butajira cohort study [5].

Data management

All data collection and management will follow Good Clinical Practice (GCP) guidelines and SOPs. Each participant has a unique ID that will enable all data reported for each participant to be identified. Blinding will be maintained during data collection, entry, processing and primary data analysis. Data is collected on paper Patient Report Forms (PRF) and double entered onto electronic Case Report Forms on EpiData Entry Client (2.0.7.22). Data will be managed using EpiData Data Manager (2.0.8.56).

All databases will be password-protected and only accessible to authorised personnel. Data cleaning based on frequency distributions and logic checks will follow standard procedures with reference to source documents as required. The data system is designed to ensure that all data changes are documented and that there is no undocumented deletion of entered data, i.e. an audit trail will be in place. Systematic checks will be carried out to ensure that the audit trail is functioning correctly. Data and all appropriate

documentation will be stored for a minimum of 5 years after the completion of the study, including the follow-up period.

Data analysis

Data analysis will take place using Stata, version 13. The primary outcome analysis will be masked until the analysis is finalised and approved by all investigators. Adequate CBR will be defined as having received a minimum of ten home visits by a CBR worker. We will not define adequate treatment for the FBC arm a priori. Sociodemographic and clinical characteristics (including WHODAS 2.0 score) of eligible PRIME cohort participants who did and did not consent to RISE will be compared using chi-square tests and *t* tests. Loss-to-follow-up will be compared by treatment arm at 6 and 12 months to assess bias due to loss to follow-up. Of those who enrolled, descriptive summaries of sociodemographic and clinical characteristics, presented by treatment arm, will be produced for baseline data. CBR worker characteristics such as age, gender, education level and post-training competency will be described.

Endpoint data will be analysed under intention-to-treat assumptions. An individual-level analysis will be conducted using a multilevel, mixed-effects regression model to compare the WHODAS 2.0 score between treatment arms, accounting for clustering at sub-district and CBR worker levels. The WHODAS 2.0 distribution will determine the model used. If zero-inflation is detected, a zero-inflated negative binomial model will be considered [60]. Adjustment will be made for baseline WHODAS 2.0 score and covariates unbalanced at baseline. Logistic regression will be used to assess which baseline variables are associated with missing outcome data. Baseline variables that predict missing outcome will be included in the regression models as fixed covariates to meet the assumption that outcome data is missing at random. Multiple imputation methods will then be used for participants with missing outcome data.

Sensitivity analyses will include a complete case analysis and a complier average causal effect (CACE) analysis [61]. We will also assess whether there is a dose-response relationship between degree of adherence to CBR (i.e. number of sessions) and the primary outcome. A further analysis will be undertaken to understand which the active components of CBR are. Process data on which CBR components were received, and in what quantity, will be utilised. Potential correlations between different components will be taken into account.

Exploratory sub-group analyses by baseline symptom severity and antipsychotic medication adherence will be completed, although the study will not be powered to investigate such differential effects. A longitudinal analysis will be conducted using a random-effects

model. Three levels (CBR worker, sub-district and individual) and two time points (6 and 12 months) will be included. Secondary and tertiary outcomes will be analysed using mixed-effects linear regression models or logistic regression depending on the data type.

Cost-effectiveness analysis

Direct costs of the treatment will be estimated by deriving a monetary value for each component of the treatment based on actual costs, and applying these to each individual based on the process indicators, which reflect the actual uptake of the treatment. Other health care costs and other patient- or family-borne costs will be computed and compared at 6 and 12 months, and subsequently related to changes in disability and clinical symptoms. Incremental cost-effectiveness ratios will be calculated to illustrate the extra cost incurred (if any) to produce a unit improvement in the main outcome of disability-adjusted life years (DALYs) calculated from the 36-item WHODAS 2.0. In the event that dominance is not shown, i.e. the intervention is more effective but the costs are also more than the FBC group, incremental cost-effectiveness ratios will be computed, together with their confidence intervals (using bootstrapping techniques to overcome expected skewness of cost data). Cost-effectiveness acceptability curves will also be derived in order to show the probability of any cost-effective advantages for the FBC plus CBR group at a range of 'willingness to pay' threshold levels.

The results from the quantitative and qualitative work will be combined to give an overall assessment of the intervention effectiveness.

Trial management and monitoring

The trial is sponsored by the London School of Hygiene and Tropical Medicine. A Data Safety and Monitoring Board (DSMB) has been convened to assure the continuing safety of research participants. A clinical monitor will carry out onsite monitoring visits prior to the trial commencing, at recruitment, and at 6-month and 12-month follow-up. The trial coordinator will carry out day-to-day monitoring and will also review recruitment rates, withdrawals and losses to follow-up. All protocol violations will be recorded and included in reports of trial findings.

Confidentiality

Trial-related assessments will take place in private locations. A unique ID number will be linked to patient details in hard and soft copy formats that are kept in secure locations. Signed consent forms will be kept securely in a locked cupboard. All documentation that includes patient data will be anonymised, but identifiable

through the ID number. Names of patients will not be quoted or published.

Discussion

Human rights violations and the high disability burden of schizophrenia make the condition a priority area for public health action. The importance of rehabilitation services for schizophrenia in scaling up mental health care is recognised by the WHO [18] and the Ethiopian government [32]. There is emerging evidence that CBR for schizophrenia is effective at improving disability outcomes in middle-income settings, yet there is no evidence on whether CBR can work in a setting with even fewer mental health resources, such as Ethiopia. The RISE trial will determine the added value of CBR compared to FBC alone. This will help to determine, for scaling-up services, the importance of a dedicated rehabilitation service in addition to FBC.

Trial status

Recruitment complete; trial ongoing.

Additional file

Additional file 1: SPIRIT checklist – RISE trial protocol. A checklist of the full protocol components according to the SPIRIT criteria. (PDF 106 kb)

Abbreviations

BPRS-E, Brief Psychiatric Rating Scale – Expanded version; CBR, Community-based rehabilitation; CGI, Clinical Global Impression; COPSI, Community care for people with Schizophrenia in India; DSM-IV, *Diagnostic and Statistical Manual of Mental Disorders, version four*; ENACT, ENhancing Assessment of Common Therapeutic Factors; FBC, Facility-based care; FGD, Focus group discussion; HEW, Health extension worker; IDI, In-depth interview; IRB, Institutional Review Board; LCS, Life Chart Schedule; LMICs, Low- and middle-income countries; LSHTM, London School of Hygiene and Tropical Medicine; mhGAP, Mental health Gap Action Programme; PRIME, PRogramme for Improving Mental health care; RCT, Randomised controlled trial; RISE, Rehabilitation Intervention for people with Schizophrenia in Ethiopia; SOP, Standard Operating Procedure; WHO, World Health Organisation; WHODAS 2.0, WHO Disability Assessment Schedule, version 2.0

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Authors' contributions

LA, MDS, CH, HW, VP and AF designed the trial and contributed to the methods. HW and GM provided specific inputs on the sample size calculation, data management and analysis plan. RB provided specific inputs on the CBR delivery and participant flow sections. DE provided specific input on the data management, monitoring and trial management sections. CH

provided specific input on the qualitative section. LA wrote the first and final drafts of the manuscript. All authors reviewed and approved the final draft.

Competing interests

The authors declare that they have no competing interests.

Ethical approval and consent to participate

Ethical approval has been obtained from the LSHTM Research Ethics Committee (reference 0735-2), the Addis Ababa University College of Health Sciences Institutional Review Board (reference 083/13/Psy) and the Ethiopian National Research Ethics Review Committee (reference 310/048/2015). The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions. Any major protocol amendments will be reported to all ethics committees and not implemented until approval is received. All approved amendments will be reported to the sponsor, DSMB, trial registry and clinical monitor.

Consent for publication

Permission to conduct the trial in Sodo district was sought from the Sodo District Health Office before randomisation of the sub-districts. Information about the study will be given to patients and caregivers by a trained psychiatric nurse or trial nurse. A patient information sheet is available for participants to read. The majority of participants will be illiterate, and some patients will have cognitive difficulties, so information will be given orally using non-technical language. Sufficient time will be allowed for consideration of the information. Consent to enter the study will be independently sought from each patient and, separately, from their caregivers. The trained nurse will assess the decision-making capacity of the patient. If the patient is deemed not to have capacity this will be documented and consent will be sought from the caregiver and assent from the patient. Information about the study will still be given to the patient, appropriate to their level of understanding. It is appropriate to seek consent from the caregiver because this study relates directly to schizophrenia, a debilitating clinical condition from which the patient suffers, and it is expected that the study may produce a benefit to the participant. This benefit is anticipated to outweigh the risks, which are thought to be minimal. Signed participant consent will be obtained and recorded using a form that is in compliance with GCP guidelines and the Helsinki Declaration. Where the participant is unable to write, a thumb impression will be recorded, along with a witness's signature.

The right of the participant to refuse to participate without giving reasons will be respected. Distress due to participation in the study or unwillingness to participate in the trial will be monitored by the trial staff and CBR workers. If these circumstances are detected and cannot be resolved through discussion with the CBR supervisor or other trial staff the participant will not be recruited or will be withdrawn. All participants are free to not participate or to withdraw at any time without giving reasons and without prejudicing their further treatment. Patients unable to consent for themselves will be given opportunities to do so when they are clinically stable.

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8.3 SUPPLEMENTARY INFORMATION

8.3.1 Piloting of trial methods

8.3.1.1 Overview

The piloting of several trial procedures took place during the RISE pilot; these included application of the inclusion criteria, process data collection and estimation of attrition. Other aspects could not be fully piloted until the PRIME cohort 6 month data collection commenced, including outcome data collection and data management. Twenty eight standard operating procedures (SOPs) were created to guide the step-by-step implementation of all aspects of the trial, such as informed consent and adverse event management and reporting. Adjustments to the protocol or SOPs were made where necessary to maximise feasibility. Additional training was given to trial staff where issues were identified.

8.3.1.2 Estimation of available sample size and attrition

Whilst PRIME cohort recruitment was still on going it was recognised that detection and recruitment rates of people with schizophrenia spectrum disorder in Sodo district were lower than expected. As a result of this the additional recruitment levels three and four, as described in the protocol, were added to identify people with schizophrenia who were not initially recruited to the PRIME cohort. Furthermore, as discussed in Chapter 7, there were some instances of both disengagement from CBR and refusal to participate in endline data collection in the pilot. The estimated attrition rate was therefore increased from 15% to 23% in the sample size calculation.

8.3.1.3 Appropriateness of inclusion criteria and consent procedures

After assessing eligibility for the RISE pilot, the recruiting psychiatric nurse was asked to give their opinion as to whether each eligible and non-eligible individual would have benefited from receipt of CBR (see Appendix E (ii)). There was perfect agreement between the inclusion criteria results and the nurse's opinion; hence no changes were made to the eligibility criteria on this basis. However, due to lower than expected numbers of PRIME cohort recruits with RISE-eligible diagnoses (231 participants compared to 324 expected participants), a slightly lower threshold

was given for the criteria 'Evidence of enduring or disabling illness' in the trial compared to the pilot. The CGI threshold was adjusted from 4 (moderate illness) to 3 (mild illness). The final version of the eligibility assessment forms are presented in Appendix E (iii).

A psychiatric nurse was found to have incorrectly applied the OPCRIT diagnostic assessment at the PRIME cohort baseline. This participant was initially recruited to the RISE pilot; the error was revealed due to concerns raised by the CBR supervisor at the first CBR visit, after which the individual received a repeat clinical assessment. This assessment indicated a diagnosis of intellectual disability only, as opposed to schizophrenia with co-morbid intellectual disability. As a result of these issues, and as described in the protocol, an additional paper-based diagnostic assessment was implemented prior to the trial recruitment. Whilst a repeat clinical assessment was conducted where a discrepancy was found, psychiatrist-led clinical diagnostic assessments were not possible for all potential trial participants due to resource constraints.

Information sheets and consent forms for the trial recruitment, the initial consent for non-PRIME cohort participants and the qualitative study are presented in Appendix E (iv). Informed consent procedures were found to be acceptable and feasible.

8.3.1.4 Data collection and management

Process data collection forms were tested during the RISE pilot. Minor modifications were made to increase ease of use. The final version of the process data collection forms for participants, sub-districts and CBR workers are presented in Appendix E (v). Topic guides for the qualitative interviews are presented in Appendix E (vi).

The trial patient report form for endline data collection is presented in Appendix E (vii). All instruments were translated into Amharic prior to use. PRIME baseline questionnaires and PRIME 6 month questionnaires completed prior to trial recruitment were reviewed for systematic errors and missing data. Several erroneous patterns were found which were then addressed in targeted refresher training for data collectors prior to trial recruitment.

Furthermore, once trial baseline data collection commenced, entered data were reviewed for systematic errors by checking the frequency and distribution of each variable and consistency between linked variables. In general there were low levels of missing data, skip rules were correctly applied and data appeared to be internally consistent. However there was a tendency for the distribution of the Butajira functioning scale data to cluster at the extremes of the ordinal scale i.e. at 0 “none” (no problems with functioning) or 5 “cannot do task”. On the basis of these findings, which were supported by research assistant observations of data collection, additional training was given to data collectors. It was noteworthy that a similar clustering effect was not seen with WHODAS data, which may reflect the greater emphasis on this outcome in the data collector training, including the need to specify the five possible responses to the participant for each of the 36 items. Due to concerns that data collectors may be unmasked, resulting in detection bias, at the end of each endline assessment the assessors will be asked whether they have become unmasked to participant allocation during the course of the assessment. Furthermore to minimise bias the primary outcome (proxy-reported WHODAS) is the first instrument administered in the participant interviews.

A RISE data management manual was created. Once trial data management procedures commenced, minor adjustments were made to the Epidata databases and additional training was given to data entry clerks to address arising issues.

8.3.2 Supplementary statistical analysis plan

Further details were added to the statistical analysis plan to evaluate the validity of the theory of change. These secondary analyses will be carried out whether or not the primary analysis indicates that CBR has an impact on disability as they may give useful insights into the reasons for a null result.

First, to evaluate the hypothesised causal pathways to improved functioning, a mediation analysis is planned. Midline (6 month) data will be used for potential mediators and endline (12 month) data for disability, in order to elucidate the temporal relationship between mediators and the primary outcome. This is pertinent given the potential for reciprocal relationships between mediators (intermediate outcomes) and disability, for example between income and

disability (see Figure 7.2 in Chapter 7). In the first instance this analysis will involve adjusting for potential mediators one at a time in the regression examining the impact of CBR on disability, measured with the WHODAS-36. The potential mediators are family stability and care (IEQ), access to mental health care (adapted CSRI), medication adherence (adapted Morisky scale), discrimination (DISC-12), income (economic activity measure) and symptom severity (BPRS-E). The PHQ-9 may be considered as a proxy measure for increased hope. If, for example, an observed association between intervention arm and disability is attenuated when symptom severity is adjusted for, this may indicate that symptom severity lies on the causal pathway to reductions in disability. Multiple mediators that are hypothesised to be part of the same pathway may then be considered in one model, such as medication adherence and symptom severity. Examining the causal mechanisms of CBR could have an important role in refining the intervention for further evaluation or scale up. For example, if CBR was found to act in large part through the pathway of increased medication adherence that could lend support to an intervention more narrowly focused on medication access and adherence support.

Second, within the intervention arm, an analysis will be undertaken to determine the quantity and components of CBR that are needed to impact on functioning. This will entail creating categories of exposure to CBR components, such as community mobilisation present/absent and family support group present/absent. The impact on disability of exposure to these components will be examined using regression models. The impact on disability of the number of home visits received will also be examined, as described in the protocol paper. The mediation models described above may then be incorporated into this analysis. This analysis could help to determine the importance of including broader CBR components in a scaled up intervention. For example, if participants who were linked to community mobilisation had significant improvements in functioning compared to those who were not, this could indicate that a robust community mobilisation element is an important CBR component. However, the quantity of home visits or community mobilisation provided by CBR workers may be correlated with disability or severity of illness, particularly for optional components. It would therefore be important to adjust for baseline disability and/ or symptom severity.

8.3.3 Potential limitations

It is argued in the published protocol that using the proxy-reported WHODAS will give a more valid representation of disability compared to the patient-reported version. However, there are drawbacks to utilising a proxy-reported outcome. First, this is a less patient-centred approach in which the caregivers' views are arguably valued above those of the person with schizophrenia. Second, some of the disability reported by caregivers may be related to stigmatising attitudes towards people with mental illness, expressed as low expectations of their relative's functional capacity. Third, is the possibility that the caregiver has not observed the full spectrum of the individual's behaviour so is unable to accurately report on functioning [4]. The latter issue is arguably of less importance in the rural Ethiopian setting where family members often reside in a one-roomed home. However it should not be disregarded given the issues of caregiver disengagement identified in the pilot.

We attempted to mitigate the possibility of recruiting participants without a diagnosis of schizophrenia spectrum disorder. Ideally inter-rater reliability of the OPCRIT would have been determined, comparing psychiatric nurse and psychiatrist ratings.

Some intermediate outcomes on the theory of change map were assessed mainly with qualitative rather than quantitative data: 'Understanding of mental illness and human rights', 'Involvement in decision-making about care' and 'Increased self-esteem and hope'. Bonnell et al argue it is difficult to assess causal relationships in the evaluation of complex interventions using only qualitative data [5]. Whilst 'Increased self-esteem and hope' may be measured with the PHQ-9, this instrument is designed to measure depression and is arguably not a valid measure of this construct. Instruments to assess aspects of personal recovery such as these have been developed in the UK [6]. However careful development or adaptation work would be needed prior to utilising such quantitative instruments in the Ethiopian context. In the meantime these issues and experiences arguably lend themselves well to an exploratory qualitative approach.

Another limitation to the evaluation relates to the lack of cluster- level outcomes, specifically on awareness about mental illness and attitudes towards people with schizophrenia amongst the general population. This information could have enabled greater insights into the potential impact of CBR on public attitudes, and also the influence of this factor on outcomes for individuals with schizophrenia.

8.4 CONCLUSION

This chapter has presented a protocol for a cluster randomised trial that aims to determine the effectiveness of CBR for schizophrenia. Piloting of the trial methods has allowed preparation for a high-quality evaluation. The trial design and analysis have been carefully shaped to enable understanding of not just whether, but how, CBR impacts upon functioning. The next chapter will discuss the findings and implications of the work presented in this thesis as well as its conclusion.

8.5 SUPPLEMENTARY REFERENCES

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9 DISCUSSION

9.1 INTRODUCTION

This chapter will begin with a summary of the thesis findings in relation to each objective and the contribution of these findings to the global mental health and wider literature (Section 9.2.1). Three cross-cutting themes – access to mental health care, the personal recovery model and poverty - will then be explored in greater depth (Section 9.2.2). The strengths and limitations of the thesis methodology will then be discussed (Section 9.3). The following section will cover recommendations relating to policy, programmes and future research directions (Section 9.4). This will include reflections on how the ‘Implementation’ stage of the MRC framework may manifest. The final sections will discuss the potential impact of the work contained in the thesis and its overall conclusion, as well as a summary of the RISE trial progress to date.

9.2 THESIS FINDINGS

9.2.1 Findings and contributions to the literature by objective

9.2.1.1 Objective one: The evidence for the effectiveness of community-based psychosocial interventions for schizophrenia in LMIC

The systematic review presented in Chapter 4 identified 11 RCTs in five middle-income countries. Community-based psychosocial interventions may have beneficial impacts for people with schizophrenia including reducing symptoms, improving functioning and reducing hospital readmissions. However the quality of evidence was often low. The content of included interventions varied considerably from single-faceted psychoeducational interventions, to multi-component rehabilitation-focused interventions, to case management-type interventions typically delivered following discharge from inpatient care. A third of the included studies did not incorporate any community involvement, only two studies included community awareness-raising, and none explicitly employed the broader aspects of community mobilisation that are encouraged in the WHO’s CBR guidelines [1].

Whilst interventions appear to be effective without community mobilisation, this type of approach may be advantageous in low-income settings with fewer social welfare and health resources.

A previous systematic review of CBR for mental and physical disabilities was conducted in 2012 [2]. The systematic review presented in this thesis brings up to date our knowledge of the evidence base for community-based psychosocial interventions in LMIC and therefore represents an important contribution to the literature. Ten new records were identified in addition to the three RCTs relating to schizophrenia that were included in the Lemmi review; seven of these ten studies were published during or post 2012. Furthermore the review served to highlight pressing gaps in the research literature. In particular there is a need for high quality RCTs of community-based psychosocial interventions for schizophrenia delivered by non-specialists in low-income countries, which assess the importance of a community mobilisation approach and integrate process and qualitative evaluations.

9.2.1.2 Objective two: The design of an acceptable and feasible CBR intervention for people with schizophrenia in Ethiopia

The intervention development work presented in Chapter 5 employed a range of participatory methodologies to address this objective, structured using a theory of change framework. This paper joins a small group of publications that describe the systematic development of a mental health intervention for a LMIC setting [3-5], and is one of only small handful that have employed the theory of change framework [6]. This work was an innovative attempt to tailor CBR's capacity to promote inclusion and improve access to essential services to the needs of people with schizophrenia. It was found that a CBR intervention delivered by non-specialists was likely to be acceptable and feasible to a range of relevant stakeholders, including people with schizophrenia, caregivers, primary care staff and community leaders. The final intervention involved home visits, community mobilisation and family support groups over a 12 month period. Novel features of the RISE intervention include the fact that it is designed to be delivered in the context of minimal or absent specialist mental health supervision; and the

inclusion of a substantial community mobilisation component. The RISE intervention was designed to be delivered by a new cadre of community-health workers, as utilising existing health extension workers or primary care staff was deemed to be unfeasible.

The RISE materials presented in Chapter 6 guide intervention delivery in a more structured way than previous psychosocial interventions for schizophrenia, such as in the COPSI trial [3]. The RISE manual also includes detailed steps to conduct community mobilisation tasks, including resource mapping; establishing relationships with community leaders; conducting awareness-raising events; mobilising financial, practical or emotional support from individual community members; and facilitating income-generating opportunities. The RISE materials, which will be made freely available, are therefore of unique value to the field of global mental health implementation, in particular to interventions involving non-specialist workers.

9.2.1.3 Objective three: Pilot of the CBR intervention for people with schizophrenia to determine its acceptability and feasibility in practice

As presented in Chapter 7, qualitative, quantitative and process data, again structured around a theory of change framework, allowed an in-depth analysis of the CBR pilot from a range of perspectives. This pilot demonstrated that overall the RISE CBR intervention could have a positive impact on the lives of people with schizophrenia through maximising family and community support, facilitating access to mental health services and anti-psychotic medication, facilitating income-generating activities and increasing hope and self-esteem. The hypothesised causal pathways to functioning were adjusted on the basis of the pilot findings, namely by the introduction of improved family stability and care, increased hope, and involvement in decision-making about care as intermediate outcomes. There were some concerns as to whether any gains in functioning would endure after CBR had terminated. Several assumptions were confirmed as reasonable, including the competence of CBR workers and the acceptability of CBR from the perspective of CBR workers, community leaders and health centre staff. Community mobilisation was confirmed as an important component of CBR, but there was little firm evidence that community support would be sustainable. Concerns around acceptability from the perspective of people with schizophrenia were felt to be

resolvable with supplementary training for CBR workers and increased flexibility of intervention delivery. However some contextual issues, such as poverty and inaccessible anti-psychotic medication, may be beyond the capacity of CBR to influence. These issues require further monitoring in the RISE trial, along with other assumptions that require assessment at a larger scale.

The RISE pilot represents a significant contribution to the global mental health literature. A particular achievement is the demonstration that a community-based intervention for people with schizophrenia can be acceptable and feasible, and possibly produce a positive impact, when delivered by non-specialists with almost no input from mental health professionals. Most previous relevant studies were set in middle-income countries and featured clinical reviews by psychiatrists, including the COPSI trial in India [7]. The concomitant threats of substantial mental illness burden and the dearth of mental health specialists experienced by low-income countries render the RISE pilot findings of particular importance.

A further contribution of this pilot study relates to the comprehensive application of the theory of change approach. A recent systematic review of the application of theory of change in developing and evaluating public health interventions noted several shortcomings in the identified studies. In general there was little detail, and often no diagrammatic representation, of the theory of change, making it difficult for the reader to judge the validity of the expected pathways [8]. Furthermore only two of the 62 included studies explicitly identified and tested assumptions, despite this being a core part of the theory of change [8]. The RISE pilot study may be used as a detailed blueprint to guide the use of theory of change for the development and evaluation of complex mental health interventions. For researchers or policy makers in other settings, this study may also provide useful insights into the challenges and opportunities for delivery of similar interventions, as well as helping to determine how to replicate this intervention [9].

9.2.1.4 Objective four: The protocol for a cluster randomised controlled trial to evaluate the CBR intervention

As described in Chapter 8, the RISE trial is a carefully designed and rigorous evaluation of CBR for schizophrenia with several measures in place to minimise potential bias. As such the trial will be an important contribution to an evidence

base currently characterised by the poor quality of many studies (see Chapter 4). Furthermore the trial will join a small group of RCTs across all mental disorders and interventions that is set in a low-income country [10-13]. The RISE trial will therefore represent a key addition to the field, especially given the urgent need for the implementation of evidence-based mental health interventions in these settings. To our knowledge this will also be the first RCT of comprehensive CBR for schizophrenia, including a community mobilisation element, in any setting.

In the recent systematic review there were no examples of theory of change being used to inform the design of RCTs [8]. The RISE trial design therefore represents an innovative use of theory of change. Bonnell et al noted that whilst hypothesised causal pathways are frequently described, there is often no attempt to test the pathways [14]. In this study, a theory of change approach was used to design the evaluation, in particular to select and modify outcome measures to determine whether the intervention functions as expected. The statistical analysis was then designed to assess the validity of the hypothesised causal pathways. Qualitative analysis will be used to enrich and challenge quantitative findings.

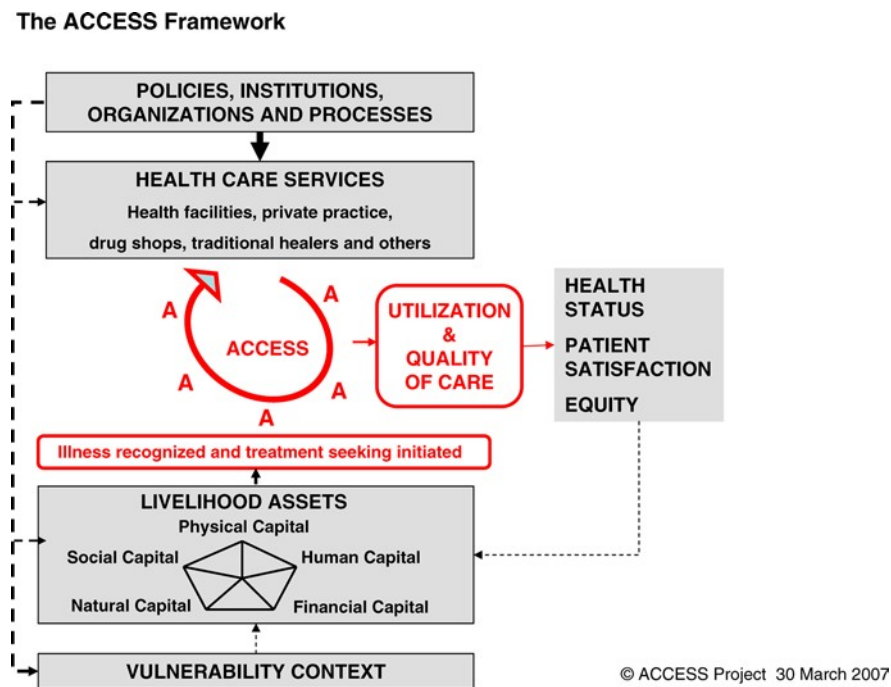
9.2.2 Cross-cutting findings

9.2.2.1 Access to mental health care and anti-psychotic medication

Access to mental healthcare, which is understood as both access to a competent mental health provider and anti-psychotic medication, was a pertinent issue to each of the objectives addressed in this thesis. In the systematic review, usual care differed considerably between included studies but in all cases it incorporated at least access to anti-psychotic medication. It is therefore implicit that community-based interventions such as CBR are usually designed to supplement a basic mental health service, which is assumed to be present. It follows that 'Anti-psychotic medication is accessible' was identified as an assumption in the theory of change developed in the intervention development phase. Moreover, 'Improving access to mental health care' was designated as a core CBR module, reflecting the fact that this is an area of need for many people with schizophrenia in rural Ethiopia [15]. Additionally, 'Improved access to mental health care' was included as an intermediate outcome on the causal pathway to improved functioning. The

potential role of CBR in improving access in each of the five dimensions (availability, geographical accessibility, affordability, adequacy and acceptability) can be grasped by considering the ACCESS framework developed by Obrist et al (see Figure 9.1) [16].

Figure 9.1 The ACCESS framework (from Obrist et al 2007)



According to the ACCESS framework, in the context of livelihood insecurity the degree of health service access obtained depends on two factors: 1) the health care services, policies, institutions, organisations and processes in place and 2) the livelihood assets, comprising human, social, natural, physical and financial capital, that potential service users can mobilise [16]. CBR can be conceptualised as a means of galvanising livelihood assets in order to increase access. In the pilot study the actual ability of CBR to mobilise these livelihood assets, and therefore increase access to mental health care, was assessed. Despite the recent integration of mental health in primary care in Sodo, CBR workers encountered several difficulties in improving access to mental health care and medication; this was a key acceptability and feasibility issue that also threatened to ‘block’ the causal pathway to improved functioning. I had initially hypothesised that having a low level of facility-based care would make it easier to demonstrate the effectiveness of an adjuvant intervention such as CBR (see Chapter 4, Section 4.4.1). The pilot findings allow a more nuanced conclusion, namely that a minimum level of facility-based care seems to be required in order for CBR to function. It is also possible that

most of the effect of CBR is mediated through increased access and adherence to medication; methods to test this possibility were described in Chapter 8 (Section 8.3.2). Table 9.1 presents the pre-existing barriers associated with each dimension of access, and the ability of CBR to address these barriers. Recommendations arising from the body of work in this thesis are also listed in Table 9.1. These recommendations are presented as the contextual changes needed in addition to CBR, in relation to health services, policies and processes, to successfully address these barriers. Some of these issues changed, often for the better, during the trial; these early findings will be discussed below (see Section 9.5).

Table 9.1 Dimensions of access, barriers and role of CBR in mobilising livelihood assets

Dimension of access	Degree of access and barriers	Potential for CBR to mobilise livelihood assets	Recommendations for contextual changes needed to improve access (health services, policies and processes)
Geographic accessibility	Moderate Barriers: Main issue is accessing hospital (e.g. for depot injection). Health centre generally accessible	Moderate Social capital: encouraging family members to help to transport people with schizophrenia to health facility	Consolidate integration of mental health in primary care. Expand remit of primary care to cover depot injections
Availability	Moderate Barriers: Erratic supply of anti-psychotic medication in health centres	Poor	Improved systems for the supply and financing of anti-psychotic medication
Affordability	Poor Barriers: User fees for medication; poor access to medication fee waiver; no health insurance	Moderate Human capital: Advocating for medication fee waiver Human/ financial capital: facilitating income generation Social capital: asking extended family members to pay for medication	Universal free medication for schizophrenia or health insurance scheme
Acceptability	Poor Barriers: side effects often intolerable. Some issues with taking medication alongside holy water.	Moderate Human capital: give knowledge to go back to health centre to manage side effects or review dose. Human capital: give psychoeducation to encourage to take medication alongside holy water.	Greater choice of medication with better side effect profile. Incorporate training on treatment preferences/ shared decision making into mhGAP training.
Adequacy	Good	Moderate Human capital: improve communication between primary care staff and people with schizophrenia	Inclusion of holistic approach in training. Supervision of prescribing practices.

On the whole there was good **geographical access** to the health centres in the pilot, though problems occasionally arose when participants were required to travel to the hospital in the neighbouring district to receive a depot injection. In some cases CBR workers successfully encouraged extended family members to accompany the individual on the journey (*mobilisation of social capital*). These findings suggest that aside from emergencies and the most remotely located households it is not usually necessary to provide a service through which medications are brought to the home. However, treatment options for the most severely ill or complex cases, for example depot injections, should be available in primary care to avoid travel to specialist centres.

The pilot study showed that the **availability** of a mental health workforce in primary care did not always equate to anti-psychotic medication being available. The distinction between personnel and products has not always been made clear in previous local studies of accessibility to mental healthcare [15]. Erratic provision of anti-psychotic medication arose due to failings in the supply and financing systems. Though the precise cause of these issues was usually opaque, it is possible that they were due to teething problems experienced by a new service. Aside from checking availability in advance to prevent a wasted journey by participants, CBR workers had little capacity to address this issue in the pilot. More robust supply and financing systems are needed, led by the Ministry of Health and supported by regional and district health administrations, to ensure a continuous supply of psychotropic medication is provided to primary care.

The **affordability** of medication was a significant issue for several pilot participants. CBR workers supported income generation (*mobilisation of financial capital*), but it was not always clear if this translated into greater ability to pay for medication. There was no success in accessing the medication fee waiver in the pilot. It is therefore apparent that without some form of universal subsidy, anti-psychotic medication will remain inaccessible to many Ethiopians. It is unlikely that anti-psychotic medication will be subsidised either in the scale up of the PRIME programme which has begun across the Gurage Zone, or in the national scale up of mental health in primary care. A national health insurance scheme is however planned for Ethiopia.

There were significant issues with the **acceptability** of anti-psychotic medication in the pilot study. Low rates of anti-psychotic medication adherence are not unique to this study or even this setting [17]. In an US RCT comparing different anti-psychotic medications (including both first and second generation drugs), 74% of the 1,432 participants had discontinued their medication by 18 months [18]. A cross-sectional study in Southern Ethiopia found that, even amongst inpatients in a psychiatric unit, only 19.6% of people with schizophrenia were completely adherent to their anti-psychotic medication [19]. Aside from the issues of availability and affordability, the most common reasons for non-adherence are ineffectiveness and intolerable side effects [17, 18, 20], which were also important issues amongst the pilot participants. Read et al described how in Ghana non-adherence arose from the mismatch between the disabling effects of anti-psychotic medication and the notion of “health as strength” [21]. There are arguably similar processes at play in Ethiopia. Moreover, sedating side effects of medication tangibly impeded functioning, the very thing CBR professed to help.

In contrast to the near universal experience of sedating side effects, causal attributions played a minor role in determining the acceptability of medication in the pilot. Irrespective of their explanatory model, participants were generally willing to try anti-psychotic medication. This may demonstrate the pluralism of illness beliefs that exists in Ethiopia [22, 23], and possibly the level of desperation reached by people with schizophrenia and their families. However one participant stopped her medication when at the holy water site, implying that receiving the treatments together would render both ineffective. In another case the fact that medication was not only ineffectual but brought more problems was seen as evidence that the illness had a spiritual cause, and contributed to the participant stopping medication.

There was little specific information on the **adequacy** of care received at the health centre, though one CBR worker felt that primary care staff did not take account of the broader social needs of people with schizophrenia. CBR workers may have a role in improving communication between primary care staff and people with mental illness to ensure their wider needs are taken into account. This kind of holistic approach should also be addressed in the training of primary care staff in mental health, though the time capacity of such staff to truly address

broader issues also needs to be considered. It is also possible that improved prescribing practices by primary care workers could reduce the prevalence of intolerable side effects.

9.2.2.2 Poverty and livelihoods

The issue of poverty was the second cross-cutting theme across all objectives. There is good understanding that poverty is both a principal cause and consequence of disability related to mental illness [24, 25]. The importance of incorporating poverty alleviation in mental health interventions in LMIC has therefore been repeatedly highlighted [24, 26-28], yet none of the community-based interventions identified in the systematic review involved explicit attempts to alleviate poverty. During the intervention development, support returning to work was seen as a crucial component of CBR, and the lynchpin for improved functioning and economic status. Microfinance schemes are incorporated into some CBR programmes [1] and are also used in the BasicNeeds mental health and development model [29]. Such an approach could arguably have been incorporated into the RISE CBR intervention. An RCT using a general population sample in South Africa found that the provision of small loans was associated with increased stress [30], whilst other studies from sub-Saharan Africa have concluded that microfinance can exacerbate poverty [28]. In the intervention development phase it was felt these negative effects could be even more prominent amongst persons with schizophrenia, hence a microfinance component was avoided. Furthermore, such a scheme may have jeopardised the sustainability and scalability of CBR as it may require an on going supply of financial capital that could substantially increase the running costs of the intervention.

'Getting back to work' was however included as an optional CBR module, and increased income was identified as an intermediate outcome on the causal pathway to improved functioning (as well as an effect of improved functioning). The pilot study suggested that a failure to effectively grapple with poverty, particularly in a setting where medication costs are out of pocket, may be unacceptable to participants and therefore doom any intervention to failure. In the pilot CBR workers had some success at facilitating income-generating activities, without providing microfinance. This was achieved by setting up opportunities for daily labouring, or simply encouraging home production of alcohol or handicrafts.

There were also some instances where CBR workers tapped into family and community networks to improve access to food. However, the question of whether CBR can truly address poverty, or just circumvent it by making medication more affordable, was not fully resolved and requires further investigation in the trial. The impact of CBR on economic status will be assessed with qualitative, quantitative and process data, as well as through a general assessment of whether CBR can meet the needs of people with schizophrenia.

9.2.2.3 Recovery-oriented approach

The issues around using a recovery-oriented approach was the third cross-cutting theme across all objectives. In the systematic review, some studies employed recovery principles, such as linking to self-help groups and focusing on human rights. In the intervention development stage, it was decided to focus the intervention around recovery principles, such as emphasising the participants' own goals and the importance of hope; however these elements were mainly included to ensure the acceptability of the intervention. In the pilot stage it emerged that not only could CBR have a powerful impact on hope and self-esteem amongst participants, but that this was an important part of the causal pathway to improved functioning. There were some indications that CBR participants experienced other personal recovery processes, relating to connectedness, identity and meaning in life [31]. A contributory factor to increased self-esteem and hope may have been the close and trusting relationships between some participants and CBR workers, in which CBR workers saw participants as "any normal person". Being considered a person rather than just 'a patient' is thought to have an important role in the recovery process for many people with mental illness [32]. Conversely, a 'them and us' attitude between service users and mental health professionals has been noted to impede recovery [32]; this may have been minimised in this study due to CBR workers being non-specialists, from the local area.

There were also two important challenges relating to increased hope. First is the possibility of raising unrealistic hopes amongst people with mental illness and their families, which is a potential problem with the personal recovery approach in any setting [33]. The issue may have been exacerbated by the difficulty, previously identified in Nepal, in training non-specialists to foster feasible expectations for

improvement [34]. In the pilot, the absence of real changes in functioning was particularly disappointing to caregivers of both women with comorbid intellectual disability; it is likely that hopes were built too high initially. It isn't known how the women with schizophrenia themselves perceived this issue as they were assessed not to have the cognitive capacity to participate in qualitative interviews. Second is a broader issue around the applicability of the recovery model in LMIC. This study showed that factors external to the illness itself often meant basic wishes and goals could not be brought to fruition. For example, gaining salaried work was not possible due to a lack of employment opportunities and medication doses were missed due to an erratic supply at the health centre. These findings demonstrate that it is difficult to be truly empowered in a context that is disempowering in so many ways. Furthermore, these findings nicely exemplify that the genesis of disability lies in the combination of illness and environmental factors (see Chapter 2; Section 2.3.1). However there are ways for CBR to address these issues. For example, it became clear that goals should be realistic and relevant [34], such as aiming towards home-based income generation such as handicrafts, rather than paid employment. The findings also suggest that targeted training is needed on differing expectations for functioning of people with co-morbid schizophrenia and intellectual disability. White et al propose that the capabilities approach, rather than the recovery approach, should be used to guide global mental health initiatives; this model identifies the sources of social inequality and structural violence that may hamper individuals from engaging in the behaviours that they value [35]. The qualitative study alongside the trial will explore experiences of, and barriers to, personal recovery. The role of spirituality, which has been raised as potentially having an important influence on recovery [36, 37], will be explored. It is hoped the results of this work will advance understanding of the applicability of this model to the LMIC context.

Further difficulties in the application of the recovery model related to anti-psychotic medication. In all parts of the world there is generally an assumption that medication non-adherence signifies poor judgment by the person with schizophrenia and presents a problem to be solved through education, encouragement or altering the medication [33]. Furthermore, as highlighted by Read [21], global mental health discourse tends to unquestioningly drive towards increasing access and adherence to anti-psychotic medication for people with

schizophrenia [38]. There is less recognition of the difficulties people with schizophrenia, globally, have with long-term adherence to medication. The mhGAP intervention guide for psychosis does mention the need to take into account treatment preferences [39], which is a key component of a recovery-orientated model of care [32]. However there is generally little emphasis on this issue in strategies for scaling up mental health services in LMIC. Although the CBR training was explicitly framed in recovery terms, CBR workers nonetheless found it challenging to accept participants' choices not to continue treatment. A key reason for this is likely to be the fact there was little discussion of issues around capacity nor any nuanced training on how to support informed decision making in people with schizophrenia. This was underpinned by a tendency in the RISE training manual to frame adhering to medication as the only logical option (the pre-specified, if optional, goal was: "Person with schizophrenia is willing to take medication"). It is arguable that CBR training was guilty of an "abuse", rather than a "use", of the recovery model, namely through promoting the incorrect notion that "services can make people recover through effective treatment"[40]. Moreover, and despite the friendly relations between many CBR workers and participants, it is likely that CBR workers adopted the same paternalistic approach to giving health advice that is pervasive in Ethiopian clinical settings. With further training and experience, it is hoped that in the trial CBR workers will develop an important role in helping people with schizophrenia to negotiate the treatment choices available to them, as well as identifying problems with side effects early in order for changes to be made to dosage or medication. However the underlying issue is the manifest lack of choices available to people with schizophrenia in this setting. For many people the only 'choices' are which of two first generation anti-psychotic medications to take (chlorpromazine or haloperidol), and at what dose. This issue is beyond the scope of CBR to address. Two important implications from this study are therefore the need to shift towards respecting patient choice within both primary care and interventions such as CBR, but perhaps more importantly to ensure more real choices are available and can be enacted.

There are three key reasons why the personal recovery model may not be appropriate for rural Ethiopia. First is the fact that people may have a preference for a paternalistic mode of care, as this is the normative model in Ethiopia for both physical and mental health [41]. To make the assumption that an approach

increasingly favoured in the West is suitable in other contexts is arguably an example of the imposition of Western values and treatment models (see Section 9.3.11). There has been little culture of self-determination amongst people with mental illness in Ethiopia; for example there is no self-advocacy movement, such as has been seen in other sub-Saharan African countries [42]. Second, the recovery model requires that opportunities and resources actually exist for individuals to make choices about their employment, social life, living arrangements and so on [43]. As discussed above, options for meaningful life changes are often highly limited in the rural Ethiopian setting, due to the high levels of poverty, poor infrastructure, lack of supported housing and lack of employment opportunities. Third, there may be challenges in operationalizing a highly individualized approach such as recovery, whilst using a standardized and manualized psychosocial intervention [44].

However, there are also arguments to support the use of the recovery model in Ethiopia. First, there was evidence from the pilot that a paternalistic approach is not always acceptable, especially in terms of medication advice. Furthermore, CBR delivery may entail a therapeutic relationship that is unusual for the Ethiopian setting; that is, between older, sometimes male, participants and often younger, sometimes female, CBR workers. More collaborative goal setting is likely to be more acceptable in such scenarios. Second, whilst recovery might “look different” in low-income settings [44], the same principles may apply. The pilot showed that seemingly modest achievements, such as successfully maintaining a vegetable patch, could hold great significance for participants in terms of self-esteem, motivation and income. Mental health researchers and practitioners may need to adjust expectations about what a meaningful change might look like. Third, the RISE CBR intervention was designed to be highly personalized to the individual’s own needs and goals through repeated needs assessments and the joint selection of appropriate optional modules. In summary, the recovery model may be a useful approach for low-income settings, but this requires further investigation. In the first instance qualitative methodologies may be most appropriate to explore the applicability of the model to different contexts such as Ethiopia.

9.3 STRENGTHS AND LIMITATIONS

9.3.1 Issues relating to theory of change

The theory of change approach provided a unifying framework to progress through each stage of the MRC framework for developing and evaluating complex interventions [45]. All aspects of the MRC guidance on the process evaluation for complex interventions were considered: implementation, context, and mechanisms of change [9]. Moreover, causal assumptions and outcomes were also incorporated into the same model. A strength of this work is that it has laid the groundwork to unpack the 'black box' of CBR. In the future this will allow me to understand which elements of CBR are fundamental to its functioning and which are not, and therefore how to best replicate observed effects in other settings [9].

However, there were some limitations relating to the application and scope of theory of change in this thesis. First, there was limited ownership of the theory of change by stakeholders, in particular by people with schizophrenia and caregivers. Whilst it has been argued that full stakeholder participation is not always feasible or necessary for theory of change [46], the lack of meaningful involvement may have had important ramifications for the RISE study. In particular the final outcome of 'sustained improved functioning' was determined a priori without the input of stakeholders. During the pilot study it emerged that the overriding priorities for people with schizophrenia and their families were income generation and livelihoods. Whilst livelihoods and functioning are inextricably linked, it is conceivable that placing livelihoods as the final outcome would have resulted in the design of a different intervention, which would have been better placed to truly address the needs of participants. Second, unintended consequences of the intervention were not captured on the theory of change [6], such as non-CBR participants potentially being deprioritised for access to scarce medication (see RISE trial progress in Section 9.5). Third, the final theory of change had less clear causal pathways compared to earlier iterations, presenting instead multiple bidirectional connections between levels of intermediate outcomes. Whilst this may be a valid representation of the likely process of change, testing the validity of the causal pathways may be challenging.

9.3.2 Qualitative methodology

Approaches to qualitative analysis can be broadly categorised into realist methods and constructionist methods. Realist approaches, such as interpretative phenomenological analysis, give primacy to the reported experiences of participants. Constructionist approaches, such as discourse analysis, are interested in the way events and experiences, and the way they are spoken about, may reflect various discourses operating within society [47]. It has been argued that thematic analysis can be used across epistemological approaches. Thematic analysis can identify themes through an inductive (data-driven) approach or through a deductive (theoretical) approach [47]. In the RISE pilot analysis I tended towards a realist approach; within this, overarching themes were identified a priori, whilst sub-themes were drawn from the data. Taking a realist approach meant that, whilst not taking all speech purely at face value, I generally identified sub-themes by examining the surface (semantic) meanings of the data. In contrast, a latent approach to identifying themes would have involved drawing out the underlying ideas or assumptions that underpinned what is actually articulated by participants [47]. Whilst I used a realist approach, I did use the data to assess the salience of my a priori themes. In Sections 7.4.2- 7.4.4 I discussed how the theory of change, and the assumptions that underpin it, were adjusted using the pilot findings.

There were two main rationales for using a more realist approach. First, the overarching aim of this qualitative analysis was to determine the acceptability, feasibility and potential impact of CBR. This meant that it was appropriate to retain focus on participants' experiences of receiving or delivering the intervention, rather than necessarily looking beneath these accounts for underlying discourse. Nevertheless the findings were contextualised by considering the social and economic setting in which experiences took place. A further way that context was taken into account was to discuss with the interviewer any non-verbal cues in the participant that may have indicated discomfort in discussing certain topics. Second, the interviews were conducted by a research assistant, then transcribed and translated to English prior to analysis. I did not observe the pilot qualitative interviews as it was felt by the research team that my presence, as a Western researcher, would generate additional expectations from CBR participants that they would receive financial benefits from the project. Furthermore, it is possible

that nuances in the way participants expressed themselves, and potentially revealed underlying meanings, were lost in translation [48]. Despite clarifying with the interviewer any text and cultural idioms that were initially unclear, in sum these issues meant I had some 'distance' from the participants and the data. If it had been feasible, a social constructionist analysis may have given a richer understanding of how environmental or structural factors influence the genesis of disability in rural Ethiopia, and how these may act as barriers to the effectiveness of CBR. However attempting this approach would have implied a deeper connection with the participants, and the language they used, than was actually possible.

An ethnographic approach, for example by observing CBR participants in the daily lives, could also have given an additional dimension to the findings. However, as discussed above, it was felt that my presence would greatly risk altering the participants' expectations of, and therefore participation in, CBR. I did however gain some understanding of the typical home and work environment of people living in rural Ethiopia through separate field trips to non-CBR participants' homes.

9.3.3 Scope of pilot and readiness for the trial

The MRC guidance highlights three key roles of pilot studies: (i) testing procedures, (ii) estimating recruitment and retention and (iii) determining sample size [45]. Traditionally, pilot studies are designed so that these three areas can be assessed and the results interpreted prior to commencing the full evaluation or trial. The RISE pilot design differed from this approach in that it was a rolling pilot. The first nine months of the pilot took place prior to the trial commencing, meaning many of the early findings could be used to adjust the trial procedures in advance of the trial starting. However, the last three months of the pilot overlapped with the trial. Whilst minor iterative adjustments to the trial procedures were still possible, overall there was no clear hiatus between the pilot and the trial. This is arguably a major limitation of the RISE study, and the implications of this are discussed below. The RISE pilot study nevertheless achieved some, but not all, of the MRC objectives.

(i) Testing procedures

Nearly all procedures for the full trial were tested in advance. The pilot gathered rich data on the acceptability of CBR, and also assessed in detail whether CBR can be delivered as intended. However feasibility was assessed using a smaller geographical area and workload than was planned for the trial; the implications of this shift in scale are discussed in Section 9.3.4. Most procedures to be used during the trial were assessed during the pilot including: data collection, data entry, CBR adherence rates, and eligibility assessment. The adjustments made on the basis of this piloting are presented in Chapter 8 Section 8.3.1. The safety of CBR, from the perspective of both participants and CBR workers, was also assessed using process data and qualitative interviews. The importance of using a pilot to train research staff, in particular to strengthen the skills needed to conduct the trial according to GCP principles, has been highlighted [49]. The RISE pilot gave us the chance to practice adherence to GCP guidelines and make adjustments to procedures accordingly, for example the detection and initial reporting of serious adverse events was piloted. The RISE pilot also fulfilled an important role in increasing the CBR workers' and supervisors' experience of delivering the intervention in preparation for the trial.

Arguably an important omission is that a control group was not integral to the RISE pilot. It has been proposed that use of a control group in pilot studies “allows for a more realistic examination of recruitment, randomization, implementation of interventions, blinded assessment procedures, and retention in blinded interventions.”[49]. The rationale for not using a ‘RISE-specific’ control group was that facility based care, which represents usual care and the control arm of the trial, was piloted as part of the PRIME study alongside the RISE CBR pilot. The PRIME team responded to emerging findings in the delivery of facility-based care, for example by adjusting supervision procedures for primary care staff. The use of a control group as an integral part of the RISE pilot was therefore deemed unnecessary. An independent statistician carried out the randomization of clusters in advance of recruitment; it would have been impractical to ‘pilot’ this process. Most other trial procedures could be piloted without use of a separate control group.

(ii) Estimating recruitment and retention

Rates of recruitment, refusal and retention were estimated from the pilot study, though once again this was based on small numbers; the alterations made on the basis of the pilot are described in Chapter 8 Sections 8.3.1.2 and Section 8.3.1.3.

(iii) Determining sample size

The RISE pilot was not used to estimate effect sizes and variance, nor to adjust the sample size calculation. This was due to the small sample size and also the fact that the trial began before the pilot was completed. In fact the MRC guidance and others suggest that pilot study results should be used cautiously in the determination of sample size as effects sizes are likely to be smaller and show greater variability than when the intervention is delivered at scale [45]. The MRC guidance also proposes that pilot data can be used for initial analysis to understand potential interactions [45]. Due to the small sample size only a descriptive analysis was conducted for the RISE pilot; however qualitative data were used to refine the conceptual framework for how CBR may impact on functioning. These pathways will then be tested in the trial analysis (see Chapter 8 Section 8.3.2).

On balance, the pilot work presented in this thesis does demonstrate readiness to progress to a full trial of CBR. Many of the MRC objectives for a pilot were addressed. However, the fact that the trial commenced three months prior to the completion of the pilot created some challenges in the development and evaluation process. This schedule meant that whilst findings evident in the earlier stages of the pilot could be successfully translated into adjustments to the trial intervention or evaluation design (see Chapter 7), issues arising later could not. For example, it was only towards the end of pilot that it was possible to grasp the full implications of frequent home visits for reduced acceptability in some participants. It was difficult to consider changing the intervention structure at this stage as the trial had already commenced. Furthermore whilst a responsive approach to intervention development is encouraged [9, 14], there are sometimes practical challenges to implementing this. In this study, trial protocol amendments had to be reviewed by three ethics committees and the data and safety monitoring board; this was often a time-consuming process that occasionally led to delays in conducting the research.

9.3.4 Differences between the pilot and the trial

There were three areas of differences between the pilot and the trial, relating to the participants, the intervention and the setting, that were planned in advance and did not arise due to adjustments made on the basis of the pilot findings. In the pilot, participants were recruited immediately after facility-based care for schizophrenia was implemented into local health centres by PRIME. This meant that five of the ten participants were treatment naïve at the pilot baseline and only one was receiving treatment at the time of recruitment. In contrast, the trial was designed to include participants who had had access to facility-based care for at least six months prior to recruitment. It is therefore arguable that the pilot and trial participants may have different needs; important conclusions from the pilot, and the way the intervention was shaped by the pilot findings, may therefore have had less relevance to the trial participants. For example, supporting access to facility-based care may have less relevance to trial participants who are already habituated to attending the local health centre. Trial participants may also have better controlled illness after several months of taking anti-psychotic medication. The impact of the latter difference should be minimised by having almost identical eligibility criteria between the pilot and trial.

Elements of the supervision arrangements also differed between the pilot and trial. As part of the pilot process data collection I conducted fortnightly feedback meetings with CBR workers and supervisors. As well as providing valuable information on the implementation of CBR, these meetings acted as training sessions for CBR workers and CBR supervisors (who had no previous experience of CBR). I was also present at group supervision meetings and some individual supervision meetings during the pilot. In contrast, during the trial supervision and refresher training was entirely led by the supervisors and intervention/trial coordinator. My role was to remotely help to resolve occasional emerging challenges in intervention delivery that had not arisen during the pilot. These differences were implemented deliberately and reflect the fact that the aim of the pilot was to further develop the intervention, whereas the trial intervention was designed to be scalable. According to MRC guidance on the process evaluation of complex interventions, continuous quality improvement activities are suitable during piloting but it is not usually appropriate for researchers to conduct such

activities during effectiveness studies [9]. My changing role between the pilot and trial was therefore appropriate. However, as my role during the pilot was arguably one of implementer rather than simply evaluator, the intervention may function differently in the trial. CBR quality in the trial may be reduced, and therefore CBR may be less effective than expected. On the other hand, we would expect CBR worker competence to improve over time with increased experience. CBR quality will be monitored with external ENACT assessments throughout the trial.

The CBR worker workload and area of coverage are much greater in the trial compared to the pilot. This may mean that the intervention is less feasible than it appeared to be in the pilot. Furthermore CBR workers may have provided more intensive support and/or conducted more community mobilisation work in the pilot than will be possible in the trial. Three CBR workers did provide over the expected 22 home visits over 12 months. However, this was only minimally more intensive (23, 24 and 27 visits were provided in these cases), and additional visits tended to be related to encouraging engagement in CBR rather than the delivery of CBR modules. On the basis of the pilot findings, I also accounted for the greater travel distances in the trial by decreasing the anticipated CBR workload and increasing transport allowance. Finally, some contextual changes were seen in the trial compared to the pilot, in relation to the availability of anti-psychotic medication. These will be discussed below (see Section 9.5).

9.3.5 Classification of CBR: an intervention or an approach?

Throughout this thesis CBR has been referred to as an 'intervention'. Referring to CBR as an intervention aligns it, and allows it to be readily compared to, other types of psychosocial interventions for schizophrenia. The systematic review (Chapter 4) found that psychosocial interventions for schizophrenia in LMIC are diverse and comprise both multifaceted interventions, and also single component interventions, such as psychoeducation or family intervention. Furthermore the term intervention reflects the fact that I developed a unified conceptual framework (theory of change) for how the various components of CBR work synergistically to improve functioning.

The alternative view is that it is misleading to describe CBR as an intervention. Instead CBR may be better described as a package of care, a treatment model or simply an 'approach'. These terms better acknowledge the fact that whilst aiming to achieve similar goals, that is the improved quality of life and social inclusion of people with disabilities, CBR programmes in general can cover a range of elements to fit in with the local context and the needs of participants. Indeed the diversity of such programmes is arguably one of CBR's defining features. Moreover, within the RISE intervention there are a range of components which individuals may receive, or not, depending on their particular needs and wishes. These include a choice of 11 optional modules (from strategies to deal with anger, to support getting back to work), targeted mobilisation of financial or practical support from community members and participation in family support groups. The great number of potential permutations might make it challenging to create a fidelity measure for the RISE CBR intervention. On the other hand, core components of CBR were specified in the intervention design; these comprise the receipt of the four core modules by individuals and the local delivery of seven core community mobilisation tasks, such as community awareness-raising events. Process data were collected in the pilot and trial to determine whether these core components were carried out as planned. As discussed in Chapter 8 (Section 8.3.2), a sensitivity analysis will be conducted on trial data to elucidate the impact of receiving different components of CBR on disability, including both core and optional components. It is conceivable that a fidelity scale could be created from this information, specifying the receipt of components that are needed for impact on disability.

In summary CBR may be best described as a package of care, but this 'package' can nevertheless be evaluated as a unified intervention in a cluster randomised trial. A theory of change framework can be used to understand which parts of the CBR package were implemented in practice, how these components contribute to changes in functioning, and ultimately, how the entire CBR package exerts its impact.

9.3.6 Sustainability of CBR

According to the WHO's CBR guidelines, sustainability should be a guiding principle for all CBR projects [1]. Attempts to formalise support from *edir* groups

were found to be unfeasible in the pilot, and the creation of new formal structures to continue some aspects of CBR was ruled out at the intervention development stage. However it is possible that some of the successes relating to the community mobilisation work (for example, the financial support from local benefactors) may continue in a self-propelling fashion once CBR has finished. A limitation of the pilot and trial evaluations is that we are unable to determine the extent to which these informal support mechanisms will continue.

9.3.7 Enduring impact of CBR

Due to time and resource constraints there is no planned long term follow up of pilot or trial participants. Simply gathering stakeholder opinions as to whether the positive impacts of CBR are likely to endure is of interest (and it is noteworthy that several pilot CBR participants were pessimistic). However this approach does little to inform us whether receiving 12 months of CBR confers an enduring advantage to individuals after home visits have terminated.

9.3.8 Issues relating to the comparator (facility-based care)

It is arguable that a more consistent form of facility-based care should have been provided by the research project for all pilot and trial participants, for example by providing free medication. This would have allowed a 'cleaner' evaluation of CBR, more akin to an efficacy trial. The results of such a trial may have been more useful to policy-makers on the assumption that financing and scaling up of an adjuvant intervention, such as CBR, is unlikely to occur without more fundamental service provision, such as free anti-psychotic medication, already being in place. Yet the RISE trial is able to answer what are possibly more important questions: first, does CBR offer any additional benefit in the context of a real-life mental health care system characterised not only by several barriers to access but also inconsistencies and rapid changes in service provision? And second, by what means can CBR successfully navigate this system to improve access to mental health care? This is a more pragmatic approach given that there is no immediate prospect of free anti-psychotic medication being made available in Ethiopia.

9.3.9 Generalisability

Pilot and trial participants were restricted to those with enduring or disabling illness; and those with this level of illness after six months access to facility-based care, in the case of trial participants. The rationale for this design was that if this intervention were scaled up in a resource-poor setting such as Ethiopia, it is likely to be rationed for a similar group. Yet there is an alternative argument that this 'difficult to treat' group may not represent the population of patients who would most benefit from the intervention, nor the group to whom the intervention would be delivered were it to be scaled up in other settings. This may limit the generalisability of the trial results.

The inclusion of participants with co-morbid intellectual disability was a pragmatic design decision that reflects the likely range of conditions that would be included at the implementation stage of CBR for schizophrenia. This therefore improves the generalisability of the results.

9.3.10 Scalability

The RISE materials will be made freely available via the Mental Health Innovations Network (www.mhinnovation.net). We anticipate that they will be relevant for researchers, NGOs and policy-makers in Ethiopia and other LMICs. If this CBR intervention is found to be effective it could be readily incorporated into the large global network of CBR programmes for people with disabilities [1]. The CBR intervention was developed in collaboration with CBM, which is an international disability organisation linked to numerous CBR projects around the world. The RISE CBR intervention design, training materials and manual will be used to guide or expand the inclusion of mental health into existing CBM-partnered CBR projects in Ethiopia and other LMICs. It is possible that individual programmes would adapt the RISE CBR intervention for their own needs. For example a set 12 month intervention may not be appropriate for programmatic settings; instead people with schizophrenia may participate in CBR for shorter or longer periods according to their needs. It is conceivable this more flexible approach would be more acceptable and feasible.

As part of a forthcoming endeavour, the RISE project will also be used as a case study in the creation of a set of CBM guidelines for best practice relating to CBR and mental health (personal communication, Julian Eaton). Whilst these represent exciting applications of the RISE CBR intervention, the coverage of existing CBR programmes is generally low, and would be unable to reach the whole population of people with schizophrenia who require support and who may benefit from CBR.

Formal health systems represent another route for scaling up community-based psychosocial interventions such as CBR. From one perspective, if it is found to be effective, the RISE CBR intervention offers a scalable model of community care for settings with scarce mental health resources. The CBR workers and also the main supervisors are non-specialists, thereby addressing the shortage of mental health professionals in low-income countries such as Ethiopia. Although the RISE intervention featured psychiatric nurse and psychiatrist input when required, there was no routine supervision by mental health specialists. Running costs can be kept low as there are few outgoings apart from staff salaries: there is no microfinance element, no medication provision and, whilst office space is required, overhead costs can be kept at a minimum as the intervention is delivered at participants' homes. In addition, non-specialists are likely to require lower salaries compared to psychiatric nurses or other specialists. The COPSI trial found that much of intervention cost stemmed from the cost of supervision by psychiatric social workers and psychiatrists [7]. Training can be completed in a relatively short period of five weeks, compared to the one-year training for health extension workers in Ethiopia. This means the CBR programme could be rapidly initiated, though on going on-the-job training is required as demonstrated in the pilot study.

However, the use of a new cadre of workers, rather than existing health extension workers or primary care staff, also renders the intervention difficult to implement on a national level in the short term. It is highly unlikely that policy makers in LMIC such as Ethiopia would prioritise a purely schizophrenia, or even mental health, focused work force at the community level. It is also possible that the RISE intervention would be seen as too intensive or lengthy for implementation at a large scale. Yet the RISE pilot and trial nevertheless hold value as proof of concept studies. LMIC such as Ethiopia are typically at the early stages of developing community-based mental health services. To maintain momentum in this process

it is important to evaluate interventions that may not be immediately implemented, but which are likely to be valuable at the later stages of systems development. It is recognised that increased resources, including greater numbers of personnel, are critical to achieving universal access to mental healthcare. Studies such as RISE help to determine the potential shape of the future workforce and models of care. A strength of the RISE trial is the economic evaluation that is planned; the results of this evaluation will help policy makers to determine whether it is worth investing in this additional human resource.

9.3.11 Critiques of global mental health

In the last decade the field of global mental health has emerged, with the primary agenda of scaling up services for people with mental health problems, especially in LMIC [50]. Several criticisms of global mental health have been voiced [51-53]. First, it is proposed that 'Western' diagnoses of mental disorders should not be exported to settings that have traditionally used alternative explanatory models and labels for distress or disturbed behavior [53], and that this is a form of 'medical imperialism' [51]. This is supported by the fact that the validity of psychiatric diagnostic criteria are also being questioned in the West [54]. Second, core global mental health initiatives, such as the WHO's mhGAP, are regarded as suffering from an over reliance on psychotropic medication, and this too is thought to represent an imposition of Western values and solutions. Again, the fact that psychotropic medications have limited effectiveness and result in adverse effects has been highlighted [55]. The possibility has also been raised that the aim or consequence of global mental health efforts is to create new markets for 'Big Pharma' [56]. Third, it has been argued that the scale up of biomedical services will marginalize or eliminate faith and traditional healing [57], a possibility that some have argued is akin to colonial practices of outlawing traditional health systems [53]. It is suggested that these traditional healing practices, along with general community support, may contribute to better outcomes amongst people with mental disorders in the 'global South' [53]. Fourth, that the social and structural determinants of mental health are not taken into account and that global mental health efforts amount to the 'medicalization of everyday distress' [57]. Finally, there are the criticisms that the lived experiences of the people experiencing

distress are ignored in the field of global mental health [53] and that truly collaborative partnerships between institutions in the North and South are absent [56].

These critiques raise important issues, and in responding it should be noted at the outset that CBR was first initiated by the WHO following the International Conference on Primary Health Care in 1978 and the resulting Declaration of Alma-Ata [1]. Whilst the concept and scope of CBR has since evolved with the input of people from low-income countries, and many projects are now initiated from within these settings, it is ultimately a model of care with Western origins. However, the RISE project exemplifies why, in some cases, the criticisms that have been put to global mental health are questionable or unfounded. First, I have endeavored to develop a deep understanding of explanatory models for mental illness in Ethiopia, through reading local qualitative and ethnographic studies and through discussions with local researchers and practitioners. Even if such experiences are given a different name and explanation, there is no doubt that what in the West we know as schizophrenia often leads to immense suffering in those affected and their families. Far from ignoring contextual issues, I spent more than two years examining the impact of mental illness on individuals and families in Sodo district in rural Ethiopia and, more specifically, attempting to develop a locally acceptable and effective response. For example, whilst biomedical accounts of mental illness were given as part of psychoeducation, CBR workers were also trained to acknowledge and understand other explanatory models that participants may have. Second, the underlying rationale for CBR is that psychotropic medication alone is insufficient to address the complex psychosocial needs of people with schizophrenia. Yet whilst CBR workers do not have prescribing privileges they certainly endorse such forms of treatment. As explained by Patel, it would be “unethical to withhold what biomedicine has to offer, simply because it was ‘invented’ somewhere else.” [58]. CBR may have an important role in helping people with schizophrenia to navigate choices around psychotropic medication. An important pilot finding was the need for honest discussion of the risks and benefits, and for CBR workers to respect the wishes of those who chose not to use this form of treatment (see Section 9.2.3.3).

Third, traditional and religious healers were directly consulted in the intervention development phase and the CBR intervention was designed to encourage engagement with these practitioners, for example for them to contribute to the moral or practical support of participants. However, in the pilot there were no examples of this type of engagement, which may indicate that this work is not as acceptable or feasible as was hoped. The lack of engagement was partly due to popular holy water sites being outside of the district and therefore impractical for CBR workers to reach. Some types of traditional healers are known to be taboo and 'hidden' within their communities; this means that identifying and approaching these healers may have felt undesirable to CBR workers and participants (see Chapter 7 Section 7.4.4). There was little evidence that traditional practitioners themselves were opposed to engaging in CBR, though this possibility cannot be discounted. There may be opportunities to assess this further in the trial. CBR workers were successfully trained not to challenge the use of holy water or other treatments by their participants, as long as they were not associated with abusive practices. Some pilot participants did continue to use holy water whilst receiving CBR. The fact that some families in rural Ethiopia resort to physical restraining their relatives indicates that existing care systems, including traditional forms of care, are unable to address all the needs of people with mental illness. Attempts by CBR workers to engage participants in biomedical care are therefore justified.

Fourth, a central aim of CBR is to address the social and structural determinants of disability. Whilst the work contained in this thesis was carried out largely within a Department of Psychiatry, I explicitly used a social model of disability to frame the project (see Chapter 2 Section 2.3.1). The extensive intervention development work and piloting was carried out with the explicit objective of determining the local needs of people with mental illness and creating an intervention to address those expressed needs. Locally appropriate responses were developed, for example through mobilizing informal community support. Finally, whilst there were challenges in successfully addressing poverty and supporting livelihoods, the work in this thesis was not an exercise in simply 'importing' a Western model of care. Extensive efforts were made to seek the views of people with schizophrenia, their caregivers and the wider community through qualitative interviews and participatory workshops. The information gained was central to the intervention design and subsequent amendments. This project arose from a knowledge gap

identified by colleagues at the Department of Psychiatry at Addis Ababa University, and the entire project was completed in partnership with this research group. Indeed it would have been impossible to conduct the work without their full support. I learnt a huge amount through collaborating with investigators at this world-leading centre for psychosis research.

In summary, CBR is not an approach that is indigenous to Ethiopia. However in this project I made numerous efforts to ensure it was nevertheless an acceptable and appropriate model of care, which is designed to be useful to those accessing it.

9.4 RECOMMENDATIONS

9.4.1 Policy and programmes

The 2012 Ethiopian National Mental Health Strategy [59] laid out plans to improve the availability and accessibility of mental healthcare and highlighted the importance of rehabilitation services for people with severe mental illness. Yet the realisation of these plans remains in the early stages and there is little detail on the resources or services that will be provided to support rehabilitation. The following recommendations are formulated on the basis of the thesis findings to address the current gaps in care.

1. In LMIC such as Ethiopia, a community-based intervention such as CBR should be provided as an adjuvant service in addition to facility-based care for people with schizophrenia who experience high levels of disability. The community-based service should include home visits as standard and should involve the individual's family. Community-based care should be linked to facility-based care, rather than existing as a stand-alone service.
2. Non-specialists, such as CBR workers, who are recruited from the local area, should deliver community-based interventions. Non-specialist workers represent the most feasible option.
3. The fundamental aims of the community-based service should be to support livelihoods, to improve understanding of schizophrenia, to maximise family stability and care for the individual, and to facilitate engagement with

primary care. The service should follow recovery principles and incorporate a shared decision-making approach.

4. A facility-based service for mental health should be provided in primary care in line with the WHO's mhGAP guidelines. The workforce providing this service should be adequately trained and supervised.
5. Robust supply and financing systems should be set up to ensure there is continuous provision of psychotropic medication to primary care. Primary care treatment options should be expanded to include depot injections, atypical anti-psychotic medications (which may have a more acceptable side effect profile) and anti-cholinergic medications to help manage extra-pyramidal side effects. More acceptable medication may improve the acceptability of community-based services such as CBR, as well as improving medication adherence, which could increase the impact. Home-based provision of medication should be available for emergency situations and the most remotely located households.
6. Anti-psychotic medication should either be made free for all people with schizophrenia or available through a workable, transparent and accessible national health insurance scheme.

9.4.2 Directions for future research

1. A briefer or less intensive version of the CBR intervention could be developed to create a more readily scalable model. This would require careful analysis of the trial data to determine which components of CBR, and in what quantity, are essential for its effectiveness. For example, if community mobilisation proves to have minimal contribution to the impact of CBR this element could be eliminated. Conversely if most of the effect of CBR is through one particular pathway (such as family support, livelihood support or adherence support), these components could be prioritised for inclusion. A further RCT of the refined intervention would then be needed.
2. More research is needed to explore the applicability of the recovery model in LMIC contexts. The exploratory qualitative work underway alongside the trial should provide a foundation for this. Future research may involve the

adaptation of quantitative measures of personal recovery, such as the Questionnaire about the Process of Recovery [60].

3. Further evaluations are needed to examine the enduring effects of CBR. Ideally participants would be followed up for at least 12 months after the intervention has terminated. Three key research questions could be addressed (i) For how long and to what extent does any positive impact of functioning acquired through 12 months of CBR endure? (ii) To what extent does improved family support and community support endure following termination of CBR, and what is their role in sustaining improved functioning? And (iii) Do hypothesised causal pathways function beyond, but not within, the 12-month time frame? For example public attitudes may be slow to change and affect social inclusion.
4. Research is needed on the effectiveness of strategies to implement and scale up those interventions that have been shown to be effective at the evaluation stage [61], which in the future may include CBR for schizophrenia. The theory of change method could be extended to support this implementation stage [6].
5. Research governance and ethics procedures should evolve to reflect the needs of researchers developing and evaluating complex interventions. This would address the delays I faced when seeking repeated ethical approvals for the trial, due to minor adjustments to the protocol based on the pilot findings. Systems need to be in place to absorb on going iterative adjustments to the intervention design as the research progresses, whilst maintaining high ethical standards.

9.5 RISE TRIAL PROGRESS

In total 166 participants were recruited across 48 clusters (sub-districts). In the intervention arm (CBR plus facility-based care) there are 79 participants in 24 clusters and in the control arm (facility-based care) there are 87 participants in 24 clusters (see Figure 9.2). No participants with co-morbid intellectual disability were recruited. The expected total sample size was 182 participants in 54 clusters. The reason for the lower than expected recruitment rate was primarily due to

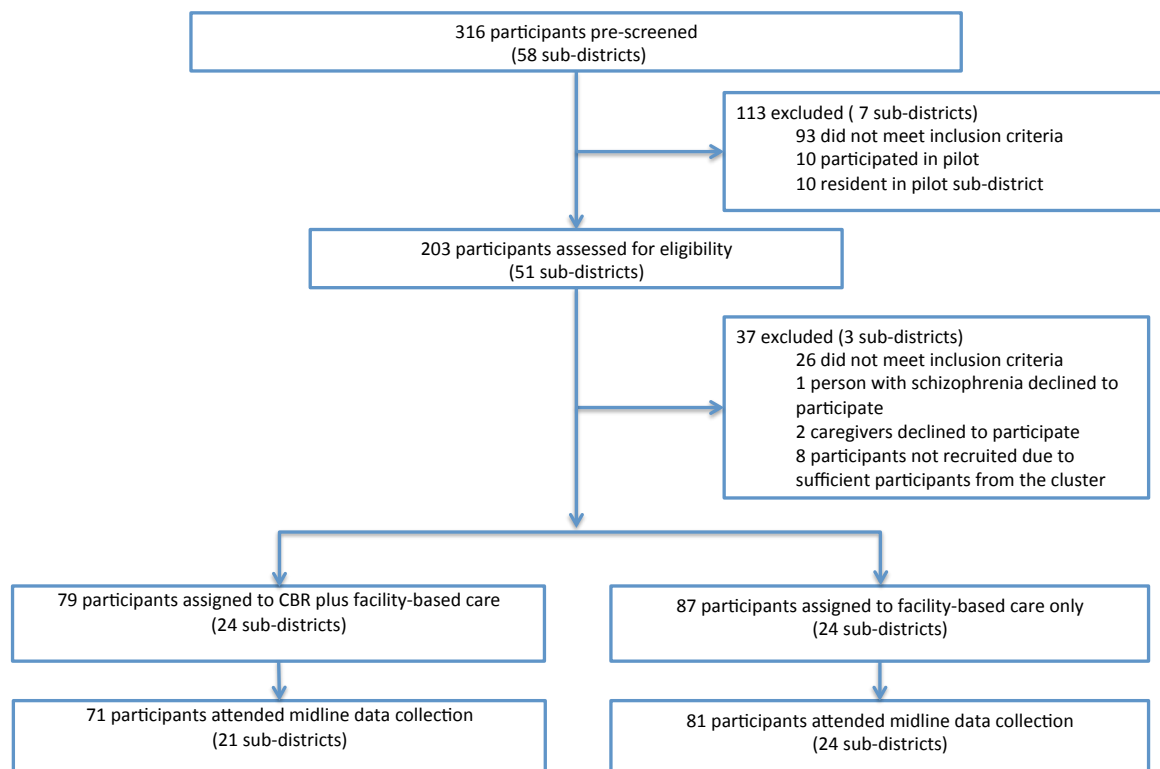
lower than expected numbers identified by the PRIME cohort. However, the high proportion that consented to RISE largely made this up for this; only three participants did not consent to participate out of those who were eligible. This actual sample size will give 81% power to detect a 20% difference in WHODAS between treatment arms at 12 months, using the same assumptions listed in the trial protocol paper (Chapter 8) and accounting for 23% attrition of participants and loss of four clusters (i.e. assuming 128 participants in 44 clusters are available for the analysis). At midline (6 month) data collection 151 participants (91%) were retained in 45 clusters. Of the 15 participants who were lost to follow up eight were in the intervention arm and seven were in the control arm; 11 participants were temporarily absent from their place of residence, one had moved permanently to another district and two had died. In the first 13 months of the trial (until mid October 2016) there have been four serious adverse events: one death by suicide (in the control arm), two deaths due to other causes (one each in the control arm and intervention arm) and one suicide attempt (in the control arm).

During the trial, medication availability appears to have improved with depot injections now sporadically available in some health centres. In some cases CBR workers have also negotiated with health centre staff for their CBR participant/s to receive one of the few available doses. Whilst acting as an advocate is arguably in keeping with the aims of CBR, this approach does not address the systemic unavailability of medication. Due to the limited pool of medication, those not receiving CBR may actually have less access to medication than before CBR was operating locally, as CBR workers may ensure it is all allocated to their participants. This is therefore a worrying development that could ultimately serve to increase rather than decrease inequalities in access across the whole of the local population with schizophrenia. This also further underlines the need for universal measures for improving access to medication.

The medication fee waiver was obtained by CBR workers for 18 participants in the trial. A further eight participants had accessed the waiver prior to commencing CBR; data are not yet available on the number of control arm participants accessing the fee waiver. Moreover the local health administration began providing free anti-psychotic medication for all service users at one of the eight health centres during the trial period. This provision, which is available for participants in

both arms of the trial who are utilising that health centre, may minimise differences between the trial arms in relation to medication access and therefore functioning.

Figure 9.2 CONSORT diagram for RISE trial



9.6 CONCLUSION

The work presented in this thesis attempted to resolve a central conundrum: how best to support some of the world's most vulnerable people whilst utilising only minimal resources? The RISE pilot demonstrated that CBR delivered by non-specialists might be an acceptable and feasible approach to support people with schizophrenia in rural Ethiopia. Some CBR workers found it challenging to accept the choices of people with schizophrenia, and this was a threat to the acceptability of the intervention. A recovery-oriented model of care, in particular greater emphasis on the involvement of people with schizophrenia in decision-making,

may tackle some of these issues. This study also highlighted that the fundamental unmet need for accessible and affordable medication must also be addressed. Livelihoods are the biggest priority for many people with schizophrenia and their families. Whilst there were promising indications that CBR can impact on poverty it is not yet known whether this intervention can effect real and lasting change. The RISE trial will help to determine whether CBR can impact on a range of outcomes in people with schizophrenia, including functioning and economic activity.

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