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CLINICAL RESEARCH ARTICLE

Feasibility and acceptability of Problem Management Plus (PM+) among Syrian refugees and asylum seekers in Switzerland: a mixed-method pilot randomized controlled trial

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ABSTRACT

Background: Syrian refugees in Switzerland face several barriers in accessing mental health care. Cost-effective psychological interventions are urgently needed to meet the mental health needs of refugees. Problem Management Plus (PM+) is an evidence-based, psychological intervention delivered by trained non-specialist 'helpers'.

Objective: To assess the feasibility and acceptability of PM+ among Syrian refugees in Switzerland.

Methods: We conducted a single-blind pilot randomized controlled trial (RCT) with Syrian refugees impaired by psychological distress (K10 > 15 and WHODAS 2.0 > 16). Participants were randomized to PM+ or Enhanced Treatment As Usual (ETAU). Participants were assessed at baseline, and 1 week and 3 months after the intervention, and completed measures indexing mental health problems and health care usage. Semi-structured interviews were conducted with different stakeholders.

Results: N = 59 individuals were randomized into PM+ (n = 31) or ETAU (n = 28). N = 18 stakeholders were interviewed about facilitators and barriers for the implementation of PM+. Retention rates in the trial (67.8%) and mean intervention attendance (M = 3.94 sessions, SD = 1.97) were high. No severe events related to the study were reported. These findings indicate that the trial procedures and PM+ were feasible, acceptable and safe.

Conclusions: The findings support the conduct of a definitive RCT and show that PM+ might have the potential to be scaled-up in Switzerland. The importance, as well as the challenges, of implementing and scaling-up PM+ in high-income countries, such as Switzerland, are discussed.

Viabilidad y aceptabilidad de Enfrentar Problemas Plus (PM +) entre refugiados Sirios y solicitantes de asilo en Suiza: un ensayo controlado aleatorizado piloto de método mixto

Antecedentes: Los refugiados Sirios en Suiza enfrentan varias barreras para acceder a la atención en salud mental. Se necesitan con urgencia intervenciones psicológicas costo-efectivas, para satisfacer las necesidades de salud mental de los refugiados. Enfrentar Problemas Plus (PM + por sus siglas en inglés) es una intervención psicológica basada en la evidencia proporcionada por 'ayudantes' capacitados no especializados.

Objetivo: Evaluar la viabilidad y aceptabilidad de PM + entre los refugiados sirios en Suiza.

Métodos: Realizamos un ensayo controlado aleatorizado (ECA) piloto simple y ciego con refugiados sirios afectados por angustia psicológica (K10 > 15 y WHODAS 2.0 > 16). Los participantes fueron asignados al azar a PM + o Tratamiento usual mejorado (TUM). Los participantes fueron evaluados al inicio del estudio, 1 semana, y 3 meses después de la intervención, y completaron instrumentos que referencian problemas de salud mental y el uso de la atención médica. Se realizaron entrevistas semiestructuradas con diferentes partes relevantes.

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关键词
心理健康; 可行性; 难民; 寻求庇护者; 问题管理 Plus; 非专业提供者; 任务切换

HIGHLIGHTS

- The results of this pilot randomized controlled trial suggest that Problem Management Plus (PM+), a low-intensity psychosocial intervention delivered by non-specialized 'helpers' is a feasible, well-accepted and safe treatment option for Syrian refugees in Switzerland.

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Supplemental data for this article can be accessed here

Resultados: *N* = 59 individuos fueron asignados al azar a PM + (*n* = 31) o TUM (*n* = 28). *N* = 18 partes relevantes fueron entrevistados sobre facilitadores y barreras para la implementación de PM +. Las tasas de retención en el ensayo (67,8%) y la asistencia media a la intervención (*M* = 3,94 sesiones, *DE* = 1,97) fueron altas. No se informaron eventos graves relacionados con el estudio. Estos hallazgos indican que los procedimientos del ensayo y PM + fueron factibles, aceptables y seguros.
Conclusiones: Los hallazgos apoyan la realización de un ECA definitivo y muestran que PM + podría tener el potencial de ampliarse en Suiza. Se discute la importancia, así como los desafíos, de implementar y ampliar PM + en países de altos ingresos, como Suiza.

问题管理 Plus (PM+) 在瑞士叙利亚难民和寻求庇护者中的可行性和可接受性:一项混合方法试点随机对照试验
背景: 在瑞士的叙利亚难民在获得精神卫生保健方面面临一些障碍。迫切需要具有成本效益的心理干预措施来满足难民的心理健康需求。问题管理 Plus (PM+) 是一种由经过培训的非专业'帮手'提供的循证心理干预。
目的: 在瑞士的叙利亚难民中评估 PM+ 的可行性和可接受性。
方法: 我们对有心理困扰 (K10 > 15 和 WHODAS 2.0 > 16) 的叙利亚难民进行了一项单盲试点随机对照试验 (RCT)。参与者被随机分配到 PM+ 或强化照常治疗 (ETAU)。在基线, 干预后 1 周和 3 个月对参与者进行评估, 并完成指标化心理健康问题和医疗保健使用情况的测量。对不同利益相关者进行了半结构化访谈。
结果: 59 个个体被随机分为 PM+ (*n* = 31) 或 ETAU (*n* = 28) 。18 个利益相关者接受了关于实施 PM+ 的促进因素和障碍的访谈。试验中的保留率 (67.8%) 和平均干预出席率 (*M* = 3.94 次, *SD* = 1.97) 很高。没有报告与研究相关的重大事件。这些发现表明试验程序和 PM+ 是可行的, 可接受的和安全的。
结论: 研究结果支持选定 RCT的实施, 并表明 PM+ 可能有在瑞士扩大规模的潜力。讨论了在瑞士等高收入国家实施和拓展PM+ 的重要性和挑战。

1. Background

There are currently 82.4 million forcibly displaced people, including almost 30 million refugees and asylum seekers, as defined according to the 1951 Refugee Convention (UNHCR, 1951, 2021). Many of these individuals are from Syria, where the ongoing civil war has forced over 6 million individuals to flee their homes and seek refuge in other countries (UNHCR, 2021). While most Syrian refugees have resettled in neighbouring countries such as Turkey, Lebanon or Jordan, Switzerland has registered around 20,000 Syrian refugees and asylum seekers since the outbreak of the conflict in 2011 (Staatssekretariat für Migration, 2020).

Conflict-affected populations are at a high risk of developing mental health problems (Bogic, Njoku, & Priebe, 2015; Charlson et al., 2019; Morina, Akhtar, Barth, & Schnyder, 2018; Turrini et al., 2017). Recent studies on the prevalence of mental distress in Syrian refugees and asylum seekers revealed that 15 to 44% have symptoms of depression (Acarturk et al., 2018; Fuhr et al., 2020; Georgiadou, Zbidat, Schmitt, & Erim, 2018; Poole, Hedt-Gauthier, Liao, Raymond, & Bärnighausen, 2018; Tinghög et al., 2017), 13.5 to 36.1% report symptoms of anxiety dis-orders (Fuhr et al., 2020; Georgiadou et al., 2018; Tinghög et al., 2017) and 11.4 to 83.4% show symptoms of post-traumatic stress disorder (PTSD) (Acarturk et al., 2018; Fuhr et al., 2020; Georgiadou et al., 2018; Tingh-ög et al., 2017). Mental health problems in refugees have repeatedly been shown to be related to traumatic experiences before and during displacement (Johnson & Thompson, 2008; Mollica et al., 1998; Mollica, McInnes, Pool, & Tor, 1998; Steel et al., 2009), as well as to post-migration stressors in host societies (e.g. fear of deportation, unemployment or worries about family members back home) (Ben Farhat et al., 2018; Chen, Hall, Ling, & Renzaho, 2017; Kiselev, Pfaltz, Schick, et al., 2020; Laban, Gernaat, Komproe, Van Der Tweel, & De Jong, 2005; Miller & Rasmussen, 2010; Schick et al., 2016). Studies on these post-migration living difficulties have shown that they may have a comparable or even stronger impact on mental health than traumatic experiences (Bogic et al., 2015; Chen et al., 2017; Miller & Rasmussen, 2010).

The provision of appropriate mental health care is one of the many challenges refugee-hosting countries are facing (Sijbrandij et al., 2017; Silove, Ventevogel, & Rees, 2017). Most refugees resettle in low- and middle-income countries (UNHCR, 2021) where mental health services are scarce (Patel, 2007). However, even in well-resourced healthcare systems in high-income countries, there are barriers to accessing mental health care leading to a low uptake of mental health services (Maier, Schmidt, & Mueller, 2010; Satinsky, Fuhr, Woodward, Sondorp, & Roberts, 2019).

In Switzerland, health insurance for refugees and asylum seekers is mandatory, providing refugees and asylum seekers access to a wide range of medical services, including psychotherapy, regardless of their formal legal status. Despite formal access to health care, refugees and asylum seekers do not usually seek mental

health services and therefore neither receive proper diagnoses nor specialized treatment, resulting in a large treatment gap (Maier et al., 2010). A recent study among Syrian refugees in Switzerland identified five main barriers to accessing treatment: a) a mismatch between the perceived needs of the refugees and available health services, b) low perception of psychological distress, c) fear of stigma, d) lacking resources in the health care system (e.g. lack of funding for interpreters) and, e) communication difficulties and inadequate referrals to specialists by general practitioners (Kiselev, Pfaltz, Haas, et al., 2020). Similar barriers to accessing outpatient mental health care for refugees and asylum seekers hold true (e.g. lack of funding for treatment, lack of funding for interpreters, language, etc.) and have been reported by mental health professionals in Switzerland (Kiselev, Morina, et al., 2020; Müller, Roose, Landis, & Gianola, 2018).

To overcome these barriers and to increase service uptake amongst refugees, innovative approaches are urgently needed (Kiselev, 2020). One option might be the implementation of psychosocial interventions delivered by peers or lay providers, thereby bridging gaps between the formal health system and culturally-relevant community care. One such intervention is 'Problem Management Plus' (PM+) developed by the World Health Organization (WHO). PM+ aims to decrease mental distress in conflict-affected populations (Dawson et al., 2015). The intervention consists of five weekly sessions lasting 90 minutes, focusing on stress reduction, problem management, behavioural activation, and accessing social support. Even though PM+ is a manualized intervention, it can be flexibly and individually adapted to the participant's needs and self-identified practical problems (e.g. unemployment, interpersonal conflicts). Sessions are delivered by trained non-specialist 'helpers' who come from the same cultural background as service recipients (Dawson et al., 2015). Shifting specific tasks within the health care system from highly qualified staff (e.g. psychotherapists or psychiatrists) to staff with less extensive training (e.g. 'helpers') is referred to as a 'task-shifting' (WHO, 2008). Task shifting in mental health and psychosocial support is being employed frequently in low and middle-income countries (Galvin & Byansi, 2020; Hoeft, Fortney, Patel, & Unützer, 2018). Given the lack of adequate treatment options in high and middle-income countries, such as Switzerland, it might be a promising approach for such contexts as well. PM+ has been successfully evaluated for feasibility and effectiveness in various low- and middle-income countries (Bryant et al., 2017; Dawson et al., 2016; Khan et al., 2019; Rahman et al., 2016; Zhang, Zhang, Lin, & Huang, 2020). However, the intervention has never been applied to the Swiss context. As local circumstances can be very different (regarding, e.g. the political system, the health system, refugee policies, etc.) it is crucial to understand the local conditions and the needs of the target population to identify adequate interventions and to test their feasibility, acceptability and (cost-) effectiveness in the respective contexts.

The goal of the present study was to test feasibility and acceptability of individual PM+ among Syrian refugees in Switzerland through a pilot randomized controlled trial (RCT) and to assess the trial procedures in advance of a definitive RCT. We applied a mixed-method approach, collecting quantitative and qualitative data. The present study is part of a larger programme of work conducted by the STRENGTHS consortium, aiming to test the feasibility, (cost-) effectiveness and implementation of PM+ with Syrian refugees in countries in Europe and the Middle East (Sijbrandij et al., 2017).

2. Methods

2.1. Setting

The study was carried out at the University of Zurich at the Outpatient Clinic for Victims of Torture and War, University Hospital Zurich. The study activities (e.g. outcome assessments, PM+ sessions etc.) were conducted in Zurich as well as at two collaborating outpatient clinics in Bern and St. Gallen. The study received ethical approval from the Ethics Committees of the Canton of Zurich (BASEC Nr. 2017–0117) and was registered online. (https://www.clinicaltrials.gov/ct2/show/NCT03830008). The data were collected from December 2018 until March 2020. A CONSORT reporting checklist for pilot RCTs has been included in the appendix.

2.2. Participants

The sample consisted of Syrian refugees and asylum seekers experiencing elevated levels of psychological distress. Inclusion criteria were: 1) Syrian refugees who arrived in Switzerland after the outbreak of the Syrian civil war in 2011, 2) 18 years or older, 3) Arabic-speaking 4) elevated psychological distress (Kessler Screening Scale for Psychological Distress (K 10) > 15) (Kessler et al., 2002), and 5) impaired psychosocial functioning (WHO Disability Assessment Schedule (WHODAS 2.0 > 16) (Üstün, Kostanjsek, Chatterji, & Rehm, 2010).

Individuals with indications of a) severe cognitive impairment, b) severe mental disorders (e.g. psychosis) (assessed by the outcome assessors with the PM+ manual observation checklist (WHO, 2016)), or c) acute risk of suicide (assessed by the outcome assessors with the PM+ manual suicidal thoughts interview (WHO, 2016)) were excluded from the study. Other

exclusion criteria were: d) being under guardianship, and e) inability to follow the study procedures.

2.3. Recruitment

Participants were recruited from refugee and asylum seeker centres, community settings and through local stakeholders in the Syrian community. The recruitment process involved posting information about the study on social media (in Arabic and German), distributing leaflets and informing the Syrian community about the study at social events. Interested individuals were asked to contact the research team. The recruitment strategy focused on the German-speaking part of Switzerland, mostly on the cantons of Zurich, Bern and St. Gallen. These cantons are the major hosting regions for Syrian refugees in the German-speaking part of Switzerland (Staatssekretariat für Migration, 2020).

2.4. Training of non-specialist 'helpers' and outcome assessors

Thirteen non-specialist 'helpers' and eight lay outcome assessors were recruited. All helpers and outcome assessors were Syrians and fluent in Arabic and German or English. All of them had a diploma of higher education. Helpers participated in an eight-day training course conducted by one PM+ master trainer and one PM+ trainer, both Arabic speaking, and the research team in line with WHO training criteria. The training focused on basic counselling skills, delivering the strategies of PM+, as well as an adapted Good Clinical Practice (GCP) course and an introduction to Psychological First Aid (PFA). Before the intervention, each helper administered at least one practice case under supervision to become familiar with the intervention and all of its procedures. All helpers received continuous supervision (at the beginning on a weekly basis and later approximately once per month) by an experienced Arabic speaking clinical psychologist/psychotherapist and PM+ master trainer with extensive knowledge of the PM+ intervention. Helpers' fidelity was assessed using the EQUIP competency rating scale (Pedersen et al., 2021). For this purpose, the helper and a mock-patient simulated typical PM+ sessions in standardized form for a total of 75 minutes, focusing on the key elements of the intervention. A PM+ master trainer evaluated the helpers' performances on a 4-point scale. The items were divided into two categories: 1. 15 items included those competencies necessary for psychological interviewing and rapport building (e.g. non-verbal communication & active listening; demonstration of empathy, warmth & genuineness, etc.); 2. Ten items, which represent the technical competencies needed to properly apply the core strategies of PM+. All helpers have been identified as sufficiently competent. Furthermore, the results provided a differentiated insight on the helpers' competencies and gave indications on which competency areas can be improved in the ongoing supervisions (Hemmo et al., 2021).

Outcome assessors completed a three-day training which focused on administering the clinical assessment tools, general interviewing techniques, GCP and responding to participants' distress, including Psychological First Aid (PFA). This training was conducted by the research team and the PM+ master trainer. Outcome assessors received continuous supervision by the members of the research team and the PM+ master trainer.

Helpers and outcome assessors did not know each other and outcome assessors were blinded to the allocated treatment arm of the participants to minimize bias.

2.5. Study procedures

After potential participants contacted the research team by phone or email, they were informed about the aim of the project and the study procedures by an Arabic-speaking research assistant (RA). The RA examined whether individuals fulfilled the inclusion criteria (1–3) and sent them a personalized link to complete an online screening in order to assess their level of psychological distress and psychological functioning (inclusion criteria 4–5). Participants unable to do the online screening (e.g. due to lower-literacy) were invited to the study site to complete the assessment with assistance of the RA. Electronic informed consent was obtained prior to screening. After screening, the RA informed each participant about their result.

If inclusion criteria were met, participants were invited to a briefing regarding the study procedures, including randomized allocation to one of the treatment arms. After signing a second informed consent form for participation in the study, a baseline assessment was conducted. Baseline and follow-up assessments were conducted in Arabic using the tablet-assisted screening software MAPSS (Morina et al., 2017), with the exception of the CSRI (Client Service Receipt Inventory) on resource use administered as a paper-and-pencil standardized interview by the outcome assessors. The data were transferred and stored on the electronic data capture system SecuTrial® managed by the Clinical Trials Centre Zurich. After baseline assessment, participants were randomized to either the intervention arm (PM+) or the Enhanced Treatment as Usual (ETAU) arm. The randomization was performed by an independent RA not involved in the study by tossing a coin. Couples were randomized into the same treatment arm to minimize dropout rates or a bias due to contamination.

One week after the fifth PM+ session (intervention arm) or seven to eight weeks after the baseline assessments (ETAU arm), the RA invited participants to a post-assessment. A three month follow-up assessment

(3MFU) was scheduled around twelve weeks after the post-assessment. Each participant received a shopping voucher worth CHF 15 (approximately $15) after the post-assessment and the three months follow-up assessment. Participants also received a certificate for their participation after completion of the three months outcome assessment.

2.5.1. (Severe) Adverse events reporting

Severe adverse events were reported according to the Swiss Clinical Trials Ordinance (ClinO Art. 63 Abs 1). SAEs are defined as any event that 1) is life-threatening or results in death, 2) requires inpatient treatment not envisaged in the protocol or extends a current hospital stay, 3) results in permanent or significant incapacity or disability or 4) causes a congenital anomaly or birth defect. Adverse events were defined as any undesirable experience occurring to a subject during the study, whether or not considered related to the trial procedure or the PM+ intervention. (Severe) adverse events were monitored throughout the pilot RCT and responded to by the research team if needed. All severe adverse events which occurred during the entire duration of the study were documented and reported to the local ethics committee within 15 days of occurrence (if it could not be excluded that they were causally related to the study intervention). In addition, according to the principles set out by Ellenberg, Fleming, and DeMets (2002), all serious adverse events were reported to the Data and Safety Board Committee of the STRENGTHS consortium.

2.5.2. Treatment arms

2.5.2.1. Problem Management Plus (PM±). Participants allocated to the intervention arm received five 90-minute sessions of PM+. The sessions took place once a week in Zurich, Bern or St. Gallen, depending on the residence of the participants. Session 1 included an introduction to PM+, psychoeducational elements and stress management techniques. Session 2 was about problem solving strategies and in session 3 and 4 participants learned strategies to enhance behavioural activation and social support. In all sessions, elements from the previous sessions were reviewed and consolidated. The 5th session concluded with a general review of the programmeand relapse prevention. The material and the intervention were linguistically and culturally adapted to the needs of Syrian refugees (Akhtar et al., 2021; Bird et al., 2017).

2.5.2.2. Enhanced treatment as usual (ETAU). Participants randomized to ETAU were given a booklet explaining the Swiss health care system in Arabic (Bundesamt für Gesundheit, & Schweizerischerisches Rotes Kreuz, 2017). In addition, participants were instructed to contact their general practitioner if they required further mental health assistance. In addition, they could contact the research team at any time.

2.6. Main outcomes

The aim of this study was to assess the feasibility and acceptability of the intervention and the trial procedures using a mixed-methods approach. In addition, we tested the feasibility of collecting data on health care usage among our sample with the Client Service Receipt Inventory (CSRI).

2.6.1. Quantitative assessment of feasibility and acceptability

We focused on different areas of concern (Bowen et al., 2009; Dawson et al., 2016), such as the retention rate throughout the study, the mean intervention adherence, as well as the treatment fidelity among the helpers, the practicality (e.g. testing the trial procedures in view of the upcoming definite RCT), the demand (e.g. analysis of the participants' residence), limited efficacy (e.g. mean values of the clinical outcomes at different time points) and safety (e.g. (severe) adverse events (SAE) related to study or study intervention).

2.6.1.1. Quantitative measures. The Kessler Psychological Distress Scale (K10) assesses psychological distress over the past month (Kessler et al., 2002). The measure consists of ten items (e.g. 'In the past four weeks, about how often did you feel nervous?') and is scored on a Likert scale from 1 ('none of the time') to 5 ('all of the time'). A total score can be used as an indicator of depression or general distress. The K10 has been validated in Arab refugee populations before (Sulaiman-Hill & Thompson, 2010). In the study by Sulaiman-Hill and Thompson (2010), a cut-off of 16 or higher has been used as an indication of mild to moderate psychological distress . Cronbach's alpha in this study was $\alpha = 0.91$.

The WHODAS 2.0 is a 15-item questionnaire developed by the WHO which measures health and disability across six dimensions (cognition, mobility, self-care, getting along, life activities, and participation). Moreover, the measure also collects socio-demographic information. The first 12 items of the questionnaire assess health and disability (e.g. 'In the past 30 days, how much difficulty did you have in taking care of your household responsibilities?'). They are rated on a scale from 1 ('none') to 5 ('extreme or cannot do so') and provide a total score, with higher scores indicating more severe functional impairment. The scale contains three additional items regarding loss of (work related) days. The WHODAS 2.0 is a culturally sensitive tool and has been widely used in several cultural contexts and populations, including Syrian refugees (Akhtar, Cuijpers,

Morina, Sijbrandij, & Bryant, 2021; Üstün et al., 2010). The WHODAS 2.0 cut-off (>16) is in line with previous studies on PM+ (Bryant et al., 2017; Rahman et al., 2016). Cronbach's alpha was α = 0.87 at baseline.

Symptoms of depression and anxiety were measured with the Hopkins Symptom Checklist (HSCL-25) (Derogatis, Lipman, Rickels, Uhlenhuth, & Covi, 1974). The questionnaire consists of 25 items (range = 1–4), 15 items measuring depression (e.g. 'Crying easily') and 10 items assessing anxiety (e.g. 'Suddenly scared for no reason'), with higher scores indicating more severe depression and anxiety, respectively. The HSCL-25 is a transculturally validated tool and has been employed previously in research with Arabic speaking refugees (Lavik, Hauff, Solberg, & Laake, 1999; Schick et al., 2016). Cronbach's alpha in this study was α = 0.91 for anxiety subscale and α = 0.93 for the depression subscale at baseline.

Previous exposure to potentially traumatic events (PTE) was derived from the Trauma experiences checklist. This 27-item scale combines items of the Posttraumatic Diagnostic Scale (Foa, Cashman, Jaycox, & Perry, 1997) and the Harvard Trauma Questionnaire (Mollica et al., 1992). Based on previous research with refugee populations (e.g. Schick et al., 2016) and extensive experience from clinical work with refugees, we included additional items to cover traumatic events relevant for Syrian refugees, e.g. having been in danger during the flight, having been a civilian in a war zone, having been in a refugee camp or exposure to toxic substances. It also includes self-constructed items which might be relevant for Syrian refugees (e.g. 'Having been in danger during the flight (sea, boat, border)'). Items were rated on a dichotomous scale ('yes' or 'no'). A total sum score represents overall trauma exposure.

Post-migration stressors were assessed with the Post-Migration Living Difficulties Checklist (PMLDC) (Silove, Sinnerbrink, Field, Manicavasagar, & Steel, 1997; Steel, Silove, Bird, McGorry, & Mohan, 1999). The measure has previously been adapted to the Swiss context (Schick et al., 2016). It consists of 17 items (e.g. 'Worries about family back home') which are rated on a scale from 0 ('Was not a problem/did not happen') to 4 ('A very serious problem'). The PMLDC has frequently been employed in research with refugee populations (Nickerson et al., 2015; Schick et al., 2018, 2016).

The PTSD Checklist for DSM-5 (PCL-5) consists of 20 items and measures symptoms of posttraumatic stress (Blevins, Weathers, Davis, Witte, & Domino, 2015). The items are rated on a 5-point scale (0 = 'not at all' to 4 = 'extremely') and added up to an overall severity score, with a higher score indicating more pronounced symptom severity. The PCL-5 has been validated in displaced Arab populations (Ibrahim, Ertl, Catani, Ismail, & Neuner, 2018). Cronbach's alpha was α = 0.94 at baseline.

The Client Service Receipt Inventory (CSRI) (Beecham & Knapp, 1992) has been widely used to collect information on health and other service use in populations with mental health problems, including refugees (de Graaff et al., 2020). This was tailored to the Swiss context and translated, following gold-standard procedures (Bontempo, 1993), into Arabic for use with Syrian refugees to self-report health service utilization, out of pocket costs, receipt of informal family care and participation in employment or other productive use of time over 3 months. Appropriate unit costs for services in Switzerland were then attached to estimate health system costs from the perspective of health insurers, in addition to productivity costs to society based on notional minimum wage rates reported in different cantons. All costs are reported in 2019 Swiss Francs.

2.6.2. Qualitative evaluation of feasibility and acceptability

The aim of the qualitative evaluation was to assess the subjective perspective of several key informant groups (former PM+ participants, helpers, assessors and mental health professionals working with refugees and asylum seekers) on the feasibility and acceptability of the pilot trial, as well as PM+ and its delivery. Furthermore, the topic guide included questions on suggestions for improvement of the definite RCT regarding methodological procedures and the implementation of PM+. The topic guides for the various key informant groups can be found in the appendix.

Based on recommendations of the Design, Implementation, Monitoring and Evaluation (DIME) manual (AMHRG, 2013) we aimed at interviewing approximately 20 key informants (five per key informant group). Key informants participated in the interviews upon individual invitation by the research team according to the principles of the maximum variation method (Patton, 2015). Interviewees received CHF 20 (approximately $20) as compensation for their time. The semi-structured interviews were conducted in Arabic (participants) or German (helpers, outcome assessors and mental health professionals) by an Arabic speaking research assistant or master student of psychology.

2.7. Data analysis

The analysis of the quantitative data was predominantly descriptive as the study was not designed to detect statistically significant differences. Potential group differences in socio-structured characteristics or in psychological symptom scores at baseline were examined by independent samples t-tests (or Wilcoxon tests, if the assumptions for a parametric test were not met) or by $\chi 2$ tests. We computed treatment effect sizes for within treatment arms (baseline to 3 months follow up assessment) by calculating the

mean difference between the assessments and dividing this by the pooled standard deviation (Cohen's *d*). For the analysis of health and other service use, mean differences in the economic costs and use of health services, as well as in productivity losses between baseline and 3-month follow up between the two groups were analysed, and uncertainty in cost distribution was accounted for using bias-corrected and accelerated bootstrapping.

2.7.1. Qualitative data analysis

In the qualitative data analysis we focused on the same areas of focus as defined by Bowen et al. (2009). The qualitative data were audio recorded and then transcribed verbatim. The Arabic interviews (conducted with participants of the interventional arm) were translated into English by a professional translator, and the rest of the interviews were transcribed in the interview language (English or German). The data was analysed following thematic analysis (Braun & Clarke, 2006), combining an inductive and deductive approach. The research team discussed the findings and agreed on a final coding framework. AW then applied the final coding framework to all transcripts (N = 18), JS additionally applied the final coding framework to around 30% of the dataset (n = 5). The interrater reliability between AW and JS was k = .81, which can be interpreted as very good agreement (Wirtz, Wirtz, & Caspar, 2002). All transcripts were coded in nVivo (QSR International Pty Ltd, 2020).

3. Results

3.1. Study population and baseline characteristics

The study population consisted of N = 59 Syrian refugees who were either allocated to the intervention arm (n = 31) or to the ETAU arm (n = 28). The sample included n = 30 female and n = 29 male participants. Even though the recruitment focused mostly on three cities, interested individuals contacted the Swiss research team from all over Switzerland. Participants reported exposure to around 10 potentially traumatic events on average (M = 10.10, SD = 5.03). There were no significant differences in sociodemographic characteristics between the two arms with regards to age ($t(53) = 0.27$, $p = .79$), gender ($\chi2(1) = 0.43$, $p = .51$), length of stay in Switzerland ($t(53) = .38$, $p = .71$) or traumatic events ($z = -0.64$, $p = .52$). Participants randomized in the control arm reported significantly fewer symptoms of depression ($t(52) = -2.52$, $p = .02$), anxiety ($t(57) = -2.30$, $p = .03$) and PTSD ($t(56) = -2.15$, $p = .04$) at baseline. There was no significant difference in reported PMLD ($t(57) = -1.36$, $p = .18$). Participant characteristics are presented in Table 1. The CONSORT diagram of the study flow is presented in Figure 1.

Table 1. Participant characteristics (N = 59).

	PM+ (n = 31)	ETAU (n = 28)
	M (*SD*)/*n* (%)	*M* (*SD*)/*n* (%)
Age (years)	39.55 (10.67)*	40.27 (9.17)**
Gender		
Female	14 (45.2%)	16 (57.1%)
Male	17 (54.8%)	12 (42.9%)
Length of stay in CH (years)	3.46 (2.23)	3.24 (2.06)
Marital Status		
Never Married	7 (22.6%)	3 (10.7%)
Married	19 (61.3%)	23 (82.1%)
Separated/Divorced	5 (16.1%)	1 (3.6%)
Widowed	-	1 (3.6%)
Education		
No Education	-	1 (3.6%)
Basic Education	13 (41.9%)	12 (42.9%)
Secondary Education	12 (38.7%)	9 (32.1%)
University Degree	6 (19.4%)	6 (21.4%)
Work Permit		
Yes	23 (74.2%)	20 (71.4%)
No	8 (25.8%)	8 (28.6%)
Work Status		
Paid Work	12 (38.7%)	9 (32.1%)
Non-paid work	5 (16.1%)	9 (32.1%)
Student	3 (9.7%)	4 (14.3%)
Unemployed	9 (29.0%)	3 (10.7%)
Other	1 (3.2%)	3 (10.7%)
Missing	1 (3.2 %)	
Trauma Exposure	10.46 (4.84)	9.69 (5.30)

PM+ = Problem Management Plus; ETAU = Enhanced Treatment As Usual, CH = Switzerland.
*n = 29, **n = 26

3.2. Recruitment

Recruitment took place between December 2018 and November 2019. To include a total number of N = 59 participants in the trial, 73 individuals were screened for eligibility. Thus, 80.8% of the individuals who completed the screening were included in the trial.

In the beginning, the recruitment process was slow. After four months of recruitment, less than 15% of the anticipated study sample had been included. Thus, in April 2019 a focus group discussion on recruitment and associated problems with different stakeholders was held (former participants, key informants in the Syrian community etc.). The main findings which emerged from this exercise were that a) many Syrians did not know about the programme, that b) there was a lack of trust towards the research team, and that c) the programme and the information material were framed in a way that was not appealing to potential participants. They described the material as 'too academic' and mentioned that it contained the terms 'psychiatry' or 'mental disorders' which were considered as stigmatizing. Moreover, we learned that although individuals were interested in participating, some have not had the (financial) resources to do so as they would not be able to cover the cost of transport. Another important finding was that many Syrian refugees seemed to be occupied with immediate practical problems

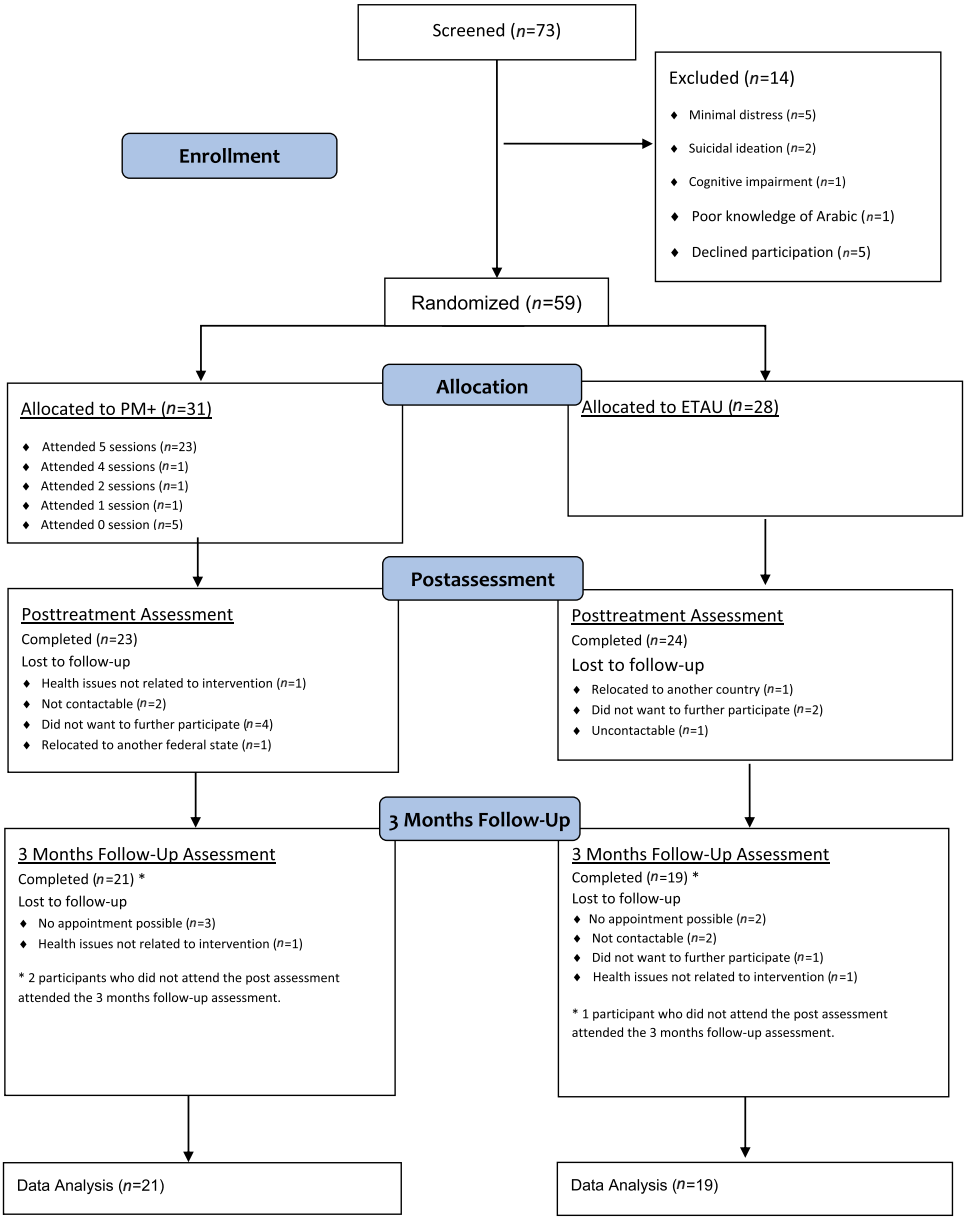

Figure 1. CONSORT flow-diagram.

(e.g. finding work or housing). Therefore, they prioritized finding a job or an apartment over reaching out for psychological support.

After integrating these results into the recruitment strategy (e.g. by asking key informants in the Syrian community to promote the study or by redesigning our information material to make it more appealing and less stigmatizing to potential participants) we were able to increase the number of screening interviews.

3.3. Assessments and retention

The assessments took around 1.5 to 2 hours. Participants were allowed to take short breaks during the assessment whenever needed. The study showed a retention rate of 67.8%. 40 of 59 participants stayed in the pilot RCT from baseline until the three months follow up assessment. There was no difference in retention between the intervention and control arms ($\chi 2(1) = 0.00$, $p = .99$).

On average, participants in the intervention arm attended four PM+ sessions ($M = 3.94$, $SD = 1.97$, range 0–5). This rate includes participants ($n = 5$) who stopped participation after baseline assessment, but were randomized in the PM+ arm. 74.2% of the participants attended all five sessions of PM+.

3.4. Clinical outcomes

Data collection with the screening software MAPSS proved to be feasible and the percentage of missing data was very low (< 5%). All clinical outcomes improved on average over time (baseline – 3MFU) in both treatment arms. All mean values and within treatment effect sizes can be found in Table 2.

Table 2. Per protocol analysis: mean values at baseline, post-assessment and three months follow up.

Treatment Arm	Measure	*n*	Baseline (*M* ± *SD*)	Post-assessment (*M* ± *SD*)	3 MFU (*M* ± *SD*)	Cohen's *d*
PM+	WHODAS 2.0	20	29.46 ± 9.31	26.13 ± 9.34*	26.96 ± 10.87	0.25
	HSCL-25: Anx	20	22.45 ± 8.48	21.00 ± 7.60**	19.55 ± 7.20	0.37
	HSCL-25: Depr	20	35.41 ± 11.09	31.09 ± 7.53**	31.61 ± 9.73	0.36
	PMLDC	21	32.71 ± 12.25	24.63 ± 9.59***	22.47 ± 11.03	0.88
	PCL-5	20	39.26 ± 18.53	26.39 ± 16.62**	28.51 ± 18.91	0.57

Note: PM+ = Problem Management Plus, 3MFU = Three months follow up assessment, Anx = Anxiety, Depr = Depression. Cohen's *d* refers to within treatment arms (baseline assessment vs. three months follow up assessment). * *n* = 16; **n* = 18; ***n* = 19

Treatment Arm	Measure	*n*	Baseline (*M* ± *SD*)	Post-assessment (*M* ± *SD*)	3 MFU (*M* ± *SD*)	Cohen's *d*
ETAU	WHODAS 2.0	18	26.64 ± 10.73	18.23 ± 5.36*	22.74 ± 10.17	0.37
	HSCL-25: Anx	19	19.00 ± 7.14	17.03 ± 8.43***	18.05 ± 5.86	0.15
	HSCL-25: Depr	17	29.86 ± 11.26	25.69 ± 9.10****	28.18 ± 9.04	0.16
	PMLDC	18	25.61 ± 11.80	17.18 ± 10.92**	20.16 ± 12.87	0.44
	PCL-5	19	26.63 ± 17.92	17.44 ± 16.19***	20.42 ± 17.17	0.35

ETAU = Enhanced Treatment As Usual, 3MFU = Three months follow up assessment, Anx = Anxiety, Depr = Depression. Cohen's *d* refers to within treatment arms (baseline assessment vs. three months follow up assessment). **n* = 13; ***n* = 16; ****n* = 18. *****n* = 17

There were no severe adverse events which were related to the study intervention.

3.5. Usage of health care services and economic analysis

The CSRI was well completed and should provide substantial information to inform cost-effectiveness analysis in a subsequent definitive trial. Table 3 provides information on mean utilization of health services and productivity loss. There was no significant difference in service use at baseline, nor at post-intervention or 3 month follow up between trial arms. While incremental costs were higher in the PM+ arm at 3 month follow up, none of these differences in costs or productivity losses were significant. Detailed information on costs and unit costs used are shown in the appendix.

3.6. Qualitative evaluation

For the qualitative evaluation, we conducted interviews with *N* = 18 interviewees. The interviewees were participants randomized into the PM+ arm (*n* = 6), helpers (*n* = 5), outcome assessors (*n* = 5) and mental health care professionals (*n* = 2, less than initially planned due to the fact that at that time only a few mental health care professionals in Switzerland (who were not involved in the study) knew about the PM+ intervention or the concept of scaling-up). The gender distribution among the interviewees was equal (9 male and 9 female), the mean age of the interviewees was *M* = 39.41 years (*SD* = 9.33). The interviews lasted between 15 and 84 minutes.

The following domains emerged during the qualitative analysis: 'Experiences with Pilot Trial', 'Experiences with PM+' and 'Suggestions for the definitive RCT and scaling-up'. The domain 'Experiences with Pilot Trial' contains statements related to the trial, e.g. to study procedures, training and supervision of staff members and recruitment. Statements around the intervention, subjective improvement of the participants or the acceptability of helpers are listed under the domain 'Experiences with PM+'. The third domain 'Suggestions for the definitive RCT and scaling-up' encompasses modifications to the trial or the interventions and open questions which would need to be clarified before implementing PM+ in Switzerland. An overview of domains and a selection of themes and subthemes can be found in Table 4.

3.6.1. Experiences with pilot trial

Overall, the pilot trial was well accepted by the PM+ participants, helpers and outcome assessors. Most PM + participants perceived their participation in the project as positive and mentioned that they would recommend the programme to fellow Syrian refugees (*n* = 5, 83%). The staff members were also mostly satisfied with the project (*n* = 9, 90%). However, some mentioned that they were not satisfied with their low workload (*n* = 2, 20%) and their financial compensation (*n* = 2, 20%). Regarding training and supervision, most staff members were satisfied (*n* = 8, 80%) but were hoping for more possibilities to exchange experiences with co-workers and the members of the research team (*n* = 4, 40%). With regards to recruitment, the participants mentioned that their first contact with the programme was either through social media (*n* = 2, 33%) or through a flyer sent out by some association or the municipality (*n* = 2, 33%). However, most of the participants joined because they received some personal feedback on the programme by someone who previously participated or someone working in the programme (*n* = 5, 83%).

3.6.2. Experiences with PM+

PM+ participants and helpers reported the delivery of the intervention as feasible and acceptable. Five major barriers towards the study and the PM+ intervention emerged: mental health stigma, distrust, lack of knowledge about mental health problems and a mismatch between the local health system and perceived needs of Syrian refugees and asylum seekers. Among these barriers, mental health stigma was mentioned most

Table 3. Mean health service utilization and productivity loss at baseline, post-assessment and three month follow up.

	Baseline			Post-assessment			3 Month Follow Up		
	M (SD)			*M (SD)*			*M (SD)*		
Service	PM+ (n = 30)	ETAU (n = 28)	95% CI	PM+ (n = 23)	ETAU (n = 20)	95% CI	PM+ (n = 21)	ETAU (n = 19)	95% CI
Community health worker (contact)	0.03 (0.18)	0.36 (1.34)	(−0.20, 0.85)	0.04 (0.21)	0.10 (0.45)	(−0.17, 0.28)	0.00	0.00	0.00
Community-based doctor (contact)	0.70 (0.99)	1.93 (4.82)	(−0.67, 3.13)	1.00 (1.60)	0.80 (1.40)	(−1.12, 0.72)	1.95 (2.67)	1.63 (2.69)	(−2.04, 1.40)
Psychiatrist (contact)	1.00 (2.46)	0.71 (2.40)	(−1.57, 0.99)	0.83 (2.68)	0.65 (2.68)	(−1.83, 1.48)	0.86 (2.03)	0.00	(−1.78, 0.07)
Psychologist (contact)	0.40 (2.19)	0.21 (1.13)	(−1.10, 0.73)	0.52 (1.73)	0.00	(−1.27, 0.23)	0.57 (2.62)	0.63 (2.75)	(−1.67, 1.79)
Social worker (contact)	0.20 (0.66)	0.18 (0.55)	(−0.34, 0.30)	0.43 (1.16)	0.05 (0.22)	(−0.90, 0.13)	0.14 (0.48)	0.21 (0.71)	(−0.33, 0.46)
Physiotherapist (contact)	0.70 (2.53)	0.86 (2.43)	(−1.15, 1.46)	2.87 (10.81)	1.75 (6.05)	(−6.45, 4.21)	2.10 (5.57)	1.27 (5.51)	(−4.38, 2.72)
Crisis service psychiatry (contact)	0.00	0.00	0.00	0.22 (1.04)	0.00	0.00	0.00	0.00	0.00
Psychiatric inpatient stay (nights)	0.00	0.68 (2.37)	(−0.24, 1.60)	0.00	0.00	0.00	0.00	0.00	0.00
Other inpatient stay (nights)	0.03 (0.18)	0.21 (0.96)	(−0.20, 0.55)	0.09 (0.29)	0.00	(−0.21, 0.04)	0.71 (1.90)	0.53 (2.29)	(−1.55, 1.17)
Psychiatric outpatient (contact)	0.20 (0.76)	0.04 (0.19)	(−0.46, 0.13)	0.00	0.00	0.00	0.00	0.00	0.00
Hospital Emergency Department (contact)	0.07 (0.25)	0.54 (1.50)	(−0.12, 1.06)	0.00	0.00	0.00	0.10 (0.30)	0.11 (0.32)	(−0.19, 0.21)
Other outpatient (contact)	0.07 (0.25)	0.07 (0.38)	(−0.17, 0.18)	0.13 (0.46)	0.00	(−0.33, 0.07)	0.19 (0.87)	0.00	(−0.59, 0.22)
Medicine (doses)	18.2 (44.6)	22.75 (63.75)	(−24.58, 33.68)	15.83 (59.18)	0.00	(−41.42, 9.77)	21.67 (39.72)	9.58 (28.70)	(−34.48, 10.30)
CAM (contact)	0.37 (1.83)	0.89 (3.97)	(−1.14, 2.19)	0.00	0.10 (0.31)	(−0.04, 0.24)	0.00	1.11 (4.58)	(−1.10, 3.31)
Productivity Loss (days)	0.83 (4.56)	1.5 (6.62)	(−2.36, 3.70)	2.17 (9.39)	0.00	(−6.24, 1.89)	0.14 (0.47)	0.42 (1.84)	(−0.63, 1.18)

often (n = 10, 56%). One helper explained the hesitant uptake of the intervention by saying "In Syria, we have our traditions. (…) when we say psychiatry, that's a very sensitive topic. It is not easy for people to enrol. When we tell them 'We meet at the hospital', it is very difficult for Syrians. They answer 'Why? I am not sick' (Helper 3). A participant confirmed this and said, 'Many Syrians deny the need for therapy and they'd rather not talk about their mental health struggle' (Participant 4).

All participants stated that they benefited from participating in the programme (n = 6, 100%). They reported four domains of subjective improvement: changes in behaviour ('After the sessions, I have learned to take it easy, to breathe in, and to relax') (Participant 3), increased knowledge on how to deal with adversities ('(a) positive thing I have learned was the ability to classify my problems') (Participant 6), improvement of psychiatric symptoms ('(to gain) self-confidence') (Participant 2) and an increase in social interactions ('I developed my communication and social skills. My relationships are beyond small talk, and more than just killing time, or going out for coffee') (Participant 4). Only one participant (17%) reported little subjective improvement as her main problem remained and she was not able to apply the strategies in her everyday life. Furthermore, four participants (67%) also stated that their family and friends have noticed this change and one participant (17%) said that after completion of the programme he was now 'able to help my friends with their problems and help them explain what they're going through the way you guys have taught me to' (Participant 5).

One participant (17%) reported a negative interaction with a facilitator and emphasized that the helpers should be specialized professionals rather than peers. Moreover, two participants (33%) stressed that the job of a helper is an important task with a lot of responsibility, which requires a certain level of professionalism and a good amount of training, 'This job is very important and very sensitive at the same time. You are able to save lives of individuals and entire families. Some people need that one word, or that one information that is able to change and save their lives' (Participant 4).

3.6.3. Suggestions for the definitive RCT and scaling-up

Participants and staff members pointed out some modifications to the programme concerning the upcoming randomized controlled trial or the wider implementation of the programme in Switzerland.

Modifications related to the definitive trial mostly concerned the recruitment process. It was recommended to use culturally-sensitive language when promoting the programme in the Syrian community (n = 5, 31%) and to increase word of mouth recommendations,

Table 4. Selection of domains, themes, subthemes and related quotes.

Domain	Theme	Subtheme	Quote
Experiences with Pilot Trial			
	Trial Procedures	Assessments	'The translations of the assessment questions was not satisfying at all. Often we had to explain the questions (to the participants)' *Assessor 3* 'Another difficulty was to gain the trust of the participants' *Assessor 2*
	Setting and Organizational Procedures	Location	'The space was great, but quite far. (. . .) I mean, it was hard because of my health condition It would've been better if it were closer.' *Participant 1*
	Recruitment Strategies		'I heard about (PM+) from two sources: I first saw it on Facebook and then (one of the employees) introduced me to it. (. . .) Although I've seen it on Facebook (. . .), I decided to join because of the human feedback.' *Participant 2*
Experiences with PM+			
	Perceived benefit		'She [the helper] would suggest solutions that worked. She'd explain in drawing. For instance, I used to have nightmares. I could never forget about Syria, in my dreams I was still in Syria. She taught me how to deal with it. She said to sit up, take a deep breath, turn on the light and tell myself I was in Switzerland' *Participant 1*
	Intervention delivery	Challenges	'To keep the distance. That was something very challenging (. . .). We share the same situation (. . .), the same story.' *Helper 5*
	Demand	Syrian refugees	'Syrians, in a direct or non-direct way, struggle with their mental health. They left their country and came to another where the society, language, the culture and the traditions are different. That alone causes psychological distress, regardless of additional rough experiences they have been through, like losing someone or having a family member arrested.' *Participant 5*
		Other refugee groups	'No refugee arriving in Switzerland is psychologically stable or at ease or with no issues.' *Participant 6*
	Perceived utility		'I think that your program is an alternative to therapy. (. . .) when coming here they don't feel like they're going to a doctor. They would come talk about their problems and find solutions to their issues. Then (. . .) after 3 or 4 sessions, they'd realize they've got psychological issues and maybe they'd overcome the stigma and go for therapy' *Participant 6*
Suggestions for the definitive RCT and scaling-up			
	Implementation of PM± into existing systems		I think [a] great disadvantage of PM+ is that it is not integrated into standard care (. . .). It would be a great benefit to the health care system if PM+ would be part of a stepped care model. (. . .) At the moment (there is no such thing as a stepped care model) and I have doubts whether this will succeed, because these are two different systems and (PM+) is not covered by the health insurance". *Stakeholder 2*
	Suggestions for improving the trial/ PM±		'The sessions could be livelier, in my opinion. Maybe have more people or have it in a park. (. . .) For instance you could go for a walk with a lady in a park, in an open space. That would make her open up more than being in a formal space would. That's in regard to the Syrian mentality.' *Participant 5* 'I would like to ask you to set up the German courses so that we'd upgrade our language skills' *Participant 3* 'I think there should be more sessions to be able to cover different types of problems' *Participant 6*

e.g. by former participants, staff members or social workers ($n = 10$, 63%). One outcome assessor illustrated this by saying 'We [Syrian refugees] only take part in [the intervention] if we hear about it from someone else' (Assessor 1). Using social media for recruitment purposes was considered to be ambiguous. One outcome assessor said using social media would help to broaden the reach whereas one of the participants stated that 'on social media, if someone's going through psychological struggle, they'll rarely actually pick up the phone and call for help. So I think it's better to have an actual person extend a helping hand' (Participant 2).

The modifications regarding the intervention concerned the content of the programme (e.g. to offer psychoeducation or even legal advice, German courses), its structure (e.g. to offer additional sessions if needed) and the setting (e.g. going to a park to deliver sessions).

When asked about a potential scale up of the PM+ intervention in Switzerland, both healthcare professionals agreed that PM+ could represent a valuable alternative to existing treatment options for refugees in Switzerland. One health care professional mentioned that even though PM+ might not sufficiently cover the needs of refugees with severe mental health problems, 'it is definitely a meaningful alternative [to the health care system] for those who are not severely ill' (Healthcare professional 2).

However, both pointed out some challenges, which will need to be clarified before a nation-wide implementation may take place, such as identifying suitable implementing agencies or options for funding. Furthermore, they critically discussed the role of trained non-specialist 'helpers'working in the health care system and where PM+ might fit in the health care system: 'Because we don't have enough specialists

(. . .) we will need to bring people in [such as trained non-specialist "helpers"] who take over important functions in this treatment concept. When we just think of the healthcare pyramid, I would primarily think of the lower and middle parts [to appoint trained non-specialist "helpers"]. Not in the upper parts where it's all about the specified supply of psychotherapy.' (Health care professional 1).

4. Discussion

The aim of the current pilot RCT was to assess the feasibility of delivery and acceptability of PM+ among Syrian refugees in Switzerland. We also assessed the trial procedures in advance of a definitive RCT. Our data show that PM+ can be regarded as acceptable and feasible to deliver. Over two thirds of the participants remained in the study from baseline assessment to the last follow-up assessment and adherence in the PM+ arm was high, with more than 74% of the participants attending all five sessions of PM+. The analysis of the participants' residence showed that there was a nationwide interest for low-intensity interventions such as PM+. The uptake of the intervention increased after the culturally-sensitive adaptation of the recruitment strategy to the Syrians' traditions and needs. There were no severe adverse events related to the intervention. Thus, it can be assumed that the participation in the trial and the PM+ intervention will not cause harm or put participants in greater distress. These findings were supported by the qualitative data. The qualitative data allowed for a deeper insight into perceptions of PM+, barriers to accessing PM+, subjective improvement among participants in the PM+ arm and suggestions for improvement for the upcoming definitive RCT and the scaling-up of the PM+ intervention in Switzerland. Finally, our analysis of the usage of the healthcare system showed that the collection of information on service use with the CSRI questionnaire was feasible. The analysis of the data revealed that service use was very low in both arms, especially the use of psychiatric inpatient or outpatient services.

The present study was the first study to evaluate the feasibility and acceptability of Individual PM+ among refugees in Switzerland. The retention rate of the trial and the mean intervention adherence were comparable to findings of other previous studies on PM+ (Dawson et al., 2016; de Graaff et al., 2020; Khan et al., 2019; Sangraula et al., 2020). The results demonstrate that PM+ cannot only be successfully delivered in low- and middle-income countries but that the intervention is also feasible to deliver in high-income settings such as the Netherlands (de Graaff et al., 2020) or Switzerland.

Switzerland is a high-income country with a health care system which, in theory, guarantees every individual access to adequate mental health care, yet the study revealed an interest and need for low-intensity interventions, such as PM+. Results reflect that current treatment options are not easily accessible to everyone (e.g. due to limited funding of interpreters) or that they do not match the beneficiaries' needs as also described by Kiselev, Pfaltz, Haas, et al. (2020). The findings of service use in our sample point in the same direction. The uptake of health care service was very low at all time points, especially the usage of mental health care. Even though this has been shown in previous research (Maier et al., 2010), in our sample there were also very few contacts with general practitioners, which is somewhat contradictory to the results of Maier et al. (2010).

The qualitative responses indicated that scaling-up PM+ may be hindered by mental health stigma because of the common belief that only individuals who are 'sick' or 'mentally retarded' would see a therapist. Mental health stigma has also been reported as a reason for a hesitant uptake of PM+ by Sangraula et al. (2020), even though their feasibility trial on PM+ was conducted in a different setting and with a different sample of participants. These findings stress the need for culturally-appropriate language when disseminating low-intensity interventions and a cultural adaptation of the intervention manual to the beneficiaries' traditions and needs to increase the acceptability, demand and effectiveness of such interventions (Harper Shehadeh, Heim, Chowdhary, Maercker, & Albanese, 2016; Heim & Kohrt, 2019; Shala et al., 2020).

The absence of (severe) adverse events and the fact that in both treatment arms the clinical outcomes improved throughout the study indicates that the participation in the trial and the PM+ intervention did not elevate the participants' level of mental distress and can therefore be perceived as safe for the participants.

Even though the quantitative reduction in clinical symptoms needs to be interpreted with caution as the small sample was not powered to detect any statistically significant differences and we did not perform any statistical analysis, the qualitative analysis revealed that most participants reported a subjective improvement after their participation in the intervention. We identified four subjective domains of improvement: changes in behaviour, increased knowledge on how to deal with adversities, improvement of psychiatric symptoms and an increase in social interactions. Furthermore, most of the participants reported that family members or friends noted an improvement in their mental health status.

This study had several limitations. One major limitation was the small sample size. However, upcoming definite RCTs within the STRENGTHS project will include larger samples and will therefore be sufficiently powered to detect significant differences between both treatment arms. Another limitation was the homogeneous sample consisting of Syrian refugees only. This limits the generalizability to other refugee groups (e.g. refugees of other ethnicities or refugees who have resettled in Switzerland long-term). If PM+ will be implemented in Switzerland, it

should be offered to various refugee groups. Thus, when designing an implementation strategy, the needs of other refugee groups need to be assessed and adequately incorporated. A third limitation was that the ETAU arm reported significantly lower symptom scores at baseline compared to the PM+ arm. Moreover, both treatment arms showed a reduction in psychological symptoms on a descriptive level. Refugees and asylum seekers frequently experience a variety of (structural) changes (e.g. change of accommodation, positive decision on asylum claim, successful family reunification) which might have an effect on the mental health of the participants (aside from their participation in an intervention). It is impossible to record all these changes and thus, this finding stresses the need for a sufficiently powered definitive RCT to assess the effectiveness of the PM+ intervention in a high-income setting. Moreover, this ambiguous finding also highlights the importance of using a mixed-method approach (as qualitative data allows for a more in-depth insight into the subjective improvement of the participants). In future trials, it might be beneficial to also interview participants in the control group to be able to assess possible structural changes which might have caused improvement in symptoms.

One major implication which arises from our findings is that the study procedures, as well as the PM+ intervention, can be feasibly and safely delivered in the Swiss context. The low drop-out rate and the high intervention attendance show that the trial and the intervention are acceptable to the participants and thus, no major modifications need to be carried out in advance of the definite RCT. The nation-wide interest for low-intensity interventions is promising for a later implementation of PM+ in Switzerland. Although various challenges will still need to be clarified before anation-wide implementation, it is important to note that both healthcare professionals agreed that PM+ might represent a meaningful alternative to already existing treatment options, especially for refugees suffering from mild to moderate psychological distress. Thus, implementing PM+ as part of a stepped-care approach with a linkage to standard mental health care for severely distressed individuals could be promising, provided the definitive RCT will be successful.

Another implication arises from the modifications to the PM+ intervention which have been proposed by various key informants. Taken together, the results highlight the need for the intervention to be more flexible (e.g. change of setting, add sessions if needed) and the need for extensive support, related to various areas of life. Shifting the setting from an outpatient clinic to a community setting would be less stigmatizing for participants and might allow participants to open up to the helpers more easily. The need for additional support reflects one of the findings from the focus group on recruitment. It seems that Syrian refugees are overburdened when integrating into Switzerland and they experience multiple stressors, including (but not limited to) mental health distress. Thus, when implementing PM+, it might be beneficial to embed the intervention into a broader network of organisations offering support for refugees. This could be organisations which provide other types of support, such as legal advice, language courses or employment assistance programmes.

5. Conclusion

The aim of the present study was to assess the feasibility of the trial and the PM+ intervention with Syrian refugees in Switzerland. The lessons learned from the study were that even though there was a nationwide interest for low-intensity psychological interventions such as PM+, the uptake of PM+ might be hampered by attitudinal barriers, such as mental health stigma. Therefore, it is of utmost importance to adapt to the needs and traditions of the target group when disseminating and implementing PM+. Another important finding was that the retention in the trial and for the PM+ intervention was high and no severe events related to the intervention or the study procedures occurred. While the results suggest that PM+ can be successfully delivered by helpers, their continuous supervision is crucial. Taken together, these results suggest that the trial and PM+, delivered by non-specialized 'helpers' is a feasible, well-accepted and safe treatment option for refugees and asylum seekers. Further research is needed to provide information on the effectiveness of the intervention in similar settings and populations.

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Data

The Vrije Universiteit Amsterdam (VU) will keep a central data repository of all data collected in the STRENGTHS project. The data will be available upon reasonable request to the STRENGTHS consortium. Data access might not be granted to third parties when this would interfere with relevant data protection and legislation in the countries participating in this project and any applicable EU legislation regarding data protection. Interested researchers can contact Dr Marit Sijbrandij at e.m.sijbrandij@vu.nl to initiate the process.

Disclosure statement

No potential conflict of interest was reported by the author (s).

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Ethical standards

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975.

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