



End report on process and outcomes of PM+ implementation in the Netherlands

DELIVERABLE 5.2



SCALING UP PSYCHOLOGICAL
INTERVENTIONS WITH
SYRIAN REFUGEES



This project has received funding from the European Union's Horizon 2020 Research and Innovation programme Societal Challenges under Grant Agreement No 733337.

Project acronym: STRENGTHS

Project title: Fostering responsive mental health systems in the Syrian refugee crisis

Grant agreement number: 733337 — STRENGTHS — H2020-SC1-2016-2017/H2020-SC1-2016-RTD

Work package in charge: WP5

Reporting period: 30 June 2021- 31 December 2022

Delivery date of this deliverable: 31 December 2022

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1. Executive summary

Background

The mental health burden among refugees in high-income countries (HICs) is high, whereas access to mental health care can be limited. Problem Management Plus (PM+) is a non-specialist delivered psychological intervention developed by the World Health Organization (WHO) that targets symptoms of common mental disorders in adversity-affected individuals. To improve access to mental health services for Syrian refugees, the STRENGTHS consortium investigates the effectiveness, cost-effectiveness, and implementation of PM+ for Syrian refugees in countries in Europe and the Middle East. The intervention was first culturally adapted for use among Syrian refugees through qualitative study (phase 1). We then carried out a pilot randomized controlled trial (RCT) among Syrian refugees to evaluate the study procedures and implementation of the intervention (phase 2). This pilot RCT with process evaluation (phase 3) indicated the intervention's feasibility, acceptability, and likely effectiveness and cost-effectiveness in reducing psychological distress. In phase 4 and 5, we aimed to examine the effectiveness and potential for scale-up of PM+ in reducing symptoms of common mental disorders among Syrian refugees in the Netherlands.

Methods

For study phase 4, we conducted a single-blind, randomised controlled trial among adult Syrian refugees recruited in March 2019-December 2021 (#NTR7552). Syrian adults with psychological distress (Kessler Psychological Distress Scale (K10) >15) and functional impairment (WHO Disability Assessment Schedule (WHODAS 2.0) >16) were allocated to PM+ in addition to care as usual (PM+/CAU) or CAU only. Participants were re-assessed at 1-week and 3-month follow-up. Primary outcome was depression/anxiety combined (Hopkins Symptom Checklist; HSCL-25) at 3-month follow-up. Secondary outcomes included depression (HSCL-25), anxiety (HSCL-25), posttraumatic stress disorder symptoms (PTSD Checklist for DSM-5; PCL-5), impairment (WHODAS2.0), and self-identified problems (PSYCHLOPS). Primary analysis was intention-to-treat. For study phase 5, we conducted a qualitative study among 42 respondents (20 PM+ staff, 10 key informants, and 12 PM+ participants) in December 2018-June 2021. Interviews were transcribed and translated for thematic analysis.

Results

In phase 4, participants (N=206; mean age=37yrs, 62% men) were randomised into PM+/CAU (*n*=103) or CAU (*n*=103). We found that relative to CAU only, PM+/CAU resulted in significant decreases in symptoms of depression, anxiety, PTSD, and self-identified problems

Conclusion

PM+ effectively reduces symptoms of CMDs among Syrian refugees. A strength of the fully-powered RCT was high retention at follow-up. Generalizability is limited by predominantly including refugees with resident permit. The qualitative study indicated that feasibility of wider implementation largely depends on whether barriers like stigma, attrition, fragmentation, competition, legal and financial challenges can be overcome. There are various possibilities for institutional anchoring of the innovation: in asylum centres, formal health care, and communities.

2. Preparatory work (phase 1-3)

Description of context in which study took place

The war in Syria has led to an unprecedented number of forcibly displaced people. Almost 7 million refugees have sought refuge primarily in neighboring countries as well as in Europe (UNHCHR, 2022). Exposure to severe stressors, such as violence, detention, and lack of basic needs have been widely reported (Acarturk et al., 2021). After migration, refugees may continue to experience hardships such as lengthy asylum procedures, financial insecurity, and social isolation (Schick et al. (2016). These stressors can cause an enormous psychological burden on individuals. Meta-analytic evidence shows rates of common mental disorders (CMDs) as high as 32% for depression and 31% for posttraumatic stress disorder (PTSD) among refugees and asylum seekers (Patanè et al., 2022). Prevalence rates among Syrian refugees in Turkey were 34.7% and 19.6%, respectively (Acarturk et al., 2021). Although (specialist) mental health services are available in high-income countries (HICs) such as the Netherlands, refugees/asylum seekers may not access them due to several barriers including waitlists, stigma, and communication difficulties (Satinsky et al., 2019).

To improve access to evidence-based psychological interventions in underserved communities, the World Health Organization (WHO) developed a series of scalable interventions. One of these is Problem Management Plus (PM+), developed to target depression, anxiety, and general distress in communities affected by adversity (Dawson et al., 2015). PM+ is potentially scalable due to its brevity (few sessions), transdiagnostic target (aiming at a range of symptoms instead of single disorders), task-sharing approach (delivery by non-specialist helpers without formal psychotherapy training), and potential cost-effectiveness (WHO, 2016). Earlier studies on PM+ in non-refugee samples in Pakistan and Kenya showed its effectiveness in reducing depression, anxiety, PTSD, functional impairment, and self-identified problems (Bryant et al., 2017; Rahman et al., 2016).

The STRENGTHS consortium investigates the effectiveness, cost-effectiveness, and implementation of PM+ for Syrian refugees in countries in Europe and the Middle East (Sijbrandij et al., 2017). A group version of PM+ has been evaluated among Syrian parents in a Jordanian refugee camp, with beneficial effects on depression, self-identified problems, and disciplinary parenting, but not on anxiety, PTSD, or functioning (Bryant et al., 2022). No study has yet investigated the effectiveness of PM+ for refugees in a HIC. In August 2022, the Netherlands registered 45,750 Syrian asylum seekers/refugees (UNHCR, 2022).

Description of PM+

PM+ consists of five 90-minute, weekly in-person sessions with a non-specialist helper (Dawson et al., 2015). It integrates four evidence-based behavioural strategies: stress management using diaphragmatic breathing (session 1), problem-solving (session 2), behavioural activation by re-engaging with pleasant/task-oriented activities (session 3), and accessing social support (session 4). Homework practice is scheduled following each session and reviewed in the next session. Psychoeducation is delivered in session 1 and relapse prevention in session 5. In the trials in the Netherlands, the intervention was delivered by Arabic-speaking Syrian non-specialist helpers who received 8 days of training followed by weekly face-to-face group supervision by PM+ trainers/supervisors throughout the trials. Training involved education about common mental disorders, basic counselling skills, delivery of intervention strategies and self-care (WHO, 2016). Supervision included discussion of individual cases and difficulties experienced by helpers, practice of skills and self-care (WHO, 2016). Helpers had at least high school education, a background in social work, teaching or another related field, and sufficient Dutch or English-speaking ability. Trainers/supervisors were mental

health care professionals who underwent 5-day training covering elements of the training of helpers, as well as training and supervision skills.

Cultural adaptation of PM+ (phase 1)

The PM+ manual was translated/culturally adapted for use among Syrian refugees through qualitative study (cf. Applied Mental Health Research Group, 2013) and by using a framework for the cultural adaptation of psychological interventions (Bernal & Sáez-Santiago, 2006); see (de Graaff, Cuijpers, McDaid, et al., 2020). The cultural adaptation of the PM+ programmes (i.e., manual content, training materials, program delivery) was coordinated by the DRC, thereby contributing to reports D2.1, D3.1 and D3.2. The VUA was in charge of the Rapid Qualitative Assessment (RQA) study, which contributed to the cultural adaptation of PM+ employed in the RCT.

More specifically, in this qualitative study, the VUA aimed to identify locally relevant mental health and psychosocial problems experienced by Syrian refugees, the individual and community coping methods commonly used, as well as activities Syrian refugees commonly participate in, self-care, and how these are affected by psychological distress. Additionally, input on the delivery of the program to fit the local context, and about potential barriers and facilitators to implement PM+ was obtained.

Following the generic STRENGTHS protocol for the RQA, Syrian refugees, policy makers and health professionals at local mental health care institutions were interviewed. The RQA was divided in three parts: 1) *Free list interviews*: The emphasis of the free list (FL) interviews was to identify perceived problems in the Syrian refugee community in the Netherlands. We aimed for maximum variation in terms of cultural background, gender, age, ethnicity and education level.

2) *Key informant interviews*: The emphasis of the key informant (KI) interviews with Syrian refugees was on a selection of problems identified in the FL interviews. Respondents were found through FL-respondents who perceived them knowledgeable about the Syrian refugee community in the Netherlands. Policy makers and health professionals were asked about e.g., perceived barriers and facilitators of integration PM+ in the Dutch health system.

3) *Focus group discussions*: As with the KI interviews, focus group discussions (FGD) with Syrian refugees focused on problems identified in the FL interviews.

Data collection for the RQA took place in the region of Amsterdam between May-August 2017. Four (Arabic-speaking) research assistants received a 5-day training in qualitative interview methods according to the DIME methodology.

Participants (18yrs and above) were recruited through professional and social (media) networks of the researchers and research assistants. Local organizations were identified (e.g., temporary school for refugee children from Syria, community centers) to contact Syrian refugees. Policy makers and health professionals were contacted through e-mail.

Interviews were conducted in the respondents' language (i.e., Arabic or Dutch). Interviews with Syrian respondents were carried out in a quiet room at VUA or in a community centre (e.g., Inspiratie Inc Almere, Taalklas Houten). Interviews with policy makers and health care providers were carried out in a quiet room in the VUA or in the respondent's office. Before commencing the interview, informed consent was obtained (see D9.1 and D9.9). Syrian refugees participating in the key informant interviews and focus group discussions received a compensation of 15 euros; all respondents (i.e., Syrian refugees, health professionals and policy makers) received reimbursements for any travel costs made.

Key informant interviews and focus group discussions were audiotaped and transcribed. Transcripts were translated (if carried out in Arabic) and analysed independently by two researchers (one from VUA and one from DRC). Inductive and deductive framework thematic analysis (Braun & Clarke, 2006; Gale et al., 2013; Maxwell, 2012) was used to analyse the data. See D3.1 for a detailed description of the analysis.

The results of the RQA in the Netherlands contributed to reports D2.1, D3.1 and D3.2. In this section, we provide a short overview of the results of the study conducted in the Netherlands.

Free list interviews

In total, 14 Syrian refugees (age $M=33.8$, $SD=11.1$, 57% male) were interviewed about problems and daily activities observed in the Syrian refugee community in the Netherlands.

The most frequently reported problems concerned problems with (learning the Dutch) language and social interaction. Other problems identified by Syrian refugees were cultural differences, employment issues, lack of knowledge on the public system (e.g., health, tax), education challenges and intragroup issues. Syrian refugees considered elderly people and children/youth as vulnerable groups among refugees. Daily activities Syrian refugees commonly participate in include hobbies such as sports and art, going to language school, doing voluntary work, taking care of children, activities with local community and family living in the Netherlands, shopping, studying, cooking and going to the park.

Key informant interviews and focus group discussions

Individual Syrian refugees ($n=10$), policy makers ($n=10$) and health professionals ($n=11$) were interviewed in 30-60 minute key informant interviews, and four focus groups with Syrian refugees (1 all male; 3 mixed; 14 individuals) were organized. Syrian refugees were interviewed about a selection of problems identified in the FL interviews, including problems with 'language', 'social interaction', but also more specifically about mental health problems, including: 'depression/feeling tired from the inside', 'stress and tension', and 'being in shock after the things that happened in Syria'.

The reported problems result in social isolation and depression. With regards to the mentioned psychological problems, Syrian refugees reported that these problems are the result of the emotional impact of the war, thinking about Syria, feeling frustrated in the Netherlands and being inactive, as well as not having a clear plan for the future. It was reported that Syrians typically seek for support with family and friends, online (e.g., Facebook) or through institutional supports, such as with the Dutch Refugee Council. It was also reported that it is not common in the Syrian culture to seek for help and that there is stigma around psychological care. Syrian refugees furthermore worry about the confidentiality and privacy of seeing a health professional and find they have not enough financial means to seek psychological care. For a more detailed description of the study findings and how they were used in the cultural adaptation of the PM+ programme, please see Report D3.1.

Policy makers and health professionals were asked about e.g., perceived barriers and facilitators of integration PM+ in the Dutch health system. An important implication of the RQA was the change from evaluating Group PM+ to evaluating the individual version of PM+. Key informants (KIs) mentioned several issues related to a group-based intervention. Examples are issues around privacy (mentioned by Syrian KIs) and perceived difficulties engaging Syrian participants (mentioned by health professionals). Based on these responses, and that Syrian refugees live scattered around the Netherlands which might complicate feasibility in the formation of groups for the intervention, we decided that to implement the individual version of PM+ in the Netherlands.

Cognitive interviews and adaptation workshop

After the RQA, VUA hosted individual interviews (i.e., cognitive interviews) and focus group discussions in Amsterdam organized by the DRC (31 July – 4 August 2017) (see deliverable 3.1), and participated in an adaptation workshop organized by DRC in Istanbul, Turkey (23-24 August 2017) (see Report 5.1).

Pilot randomized controlled trial (phase 2 and 3)

This section has been published as:

de Graaff AM et al (2020). Peer-provided Problem Management Plus (PM+) for adult Syrian refugees: a pilot randomised controlled trial on effectiveness and cost-effectiveness. *Epidemiology and Psychiatric Sciences* 29, e162, 1–24. <https://doi.org/10.1017/S2045796020000724>

To test the trial procedures and PM+ intervention, we conducted a pilot randomized controlled trial (RCT) among 60 Syrian refugees in Rotterdam, the Netherlands. This pilot was a single-blind, randomized controlled trial (RCT) conducted between 15 May 2018 and 23 April 2019.

Aim

The main objectives of this exploratory RCT was to inform us about the feasibility, safety and delivery of the PM+ programme; and to identify issues around training, supervision and outcome measures.

Data collection for the pilot RCT took place in Rotterdam between April 2018 and April 2019. Two (Syrian-Arabic-speaking) research assistants received a three-day training on the administration of questionnaires, general interview techniques, common mental disorders, psychological first aid and ethical research conduct. For the definitive RCT, two more research assistants were trained to carry out the assessments.

Participants

Participants were adult (18 years and above) Syrian refugees who are Arabic-speaking and report elevated levels of psychological distress and impaired daily functioning, as indicated by a score of >15 on the Kessler Psychological Distress Scale (K10) (Kessler et al., 2002) and a score of >16 on the WHO Disability Assessment Schedule 2.0 (WHODAS 2.0) (WHO, 2010).

Exclusion criteria included acute medical conditions, imminent suicide risk or expressed acute needs or protection risks (e.g., a woman who expresses that she is at acute risk of being assaulted), severe mental disorders (e.g., psychotic disorders, substance-dependence), or cognitive impairment (e.g., severe intellectual disability or dementia).

Procedures

Written informed consent (IC) was asked from all participants, or witnessed oral informed consent from illiterate participants. After IC was obtained, participants completed the two self-report measures on psychological distress (K10) and daily functioning (WHODAS 2.0). Participants who met the inclusion criteria were then assessed for suicidal ideation (PM+ manual suicidal thoughts interview) and severe disorders (PM+ manual observation checklist). The independent assessors referred individuals meeting any of the exclusion criteria to specialist support according to their needs.

Participants who met all inclusion criteria completed the baseline assessment at the same visit. This involved questionnaires on psychological distress (25-item Hopkins Symptoms Checklist; HSCL-25), trauma exposure (Trauma Experiences checklist), daily stressors (Post-Migration Living Difficulties; PMLD), posttraumatic stress (PTSD Checklist for DSM-5; PCL-5), self-identified problems (Psychological Outcomes Profiles; PSYCHLOPS), and questions on access to health services. Furthermore, the assessor administered a health service utilisation and productivity impact interview (locally adapted version of the Client Service Receipt Inventory; CSRI)(Beecham & Knapp, 2022).

The post-assessment (WHODAS 2.0, HSCL-25, PMLD, PCL-5, PSYCHLOPS, CSRI) was scheduled 6 weeks after the baseline assessment (or 1 week after the 5th PM+ session). The follow-up assessment was scheduled three months after the 5th PM+ session (WHODAS 2.0, HSCL-25, PMLD, PCL-5, PSYCHLOPS, CSRI).

All questionnaires, except the exclusion instruments (the PM+ manual's suicidal thoughts interview and assessment tool for severe disorders) and the CSRI interview were self-administered.

Results

Recruitment, randomization and blinding procedures were successful. PM+ was generally perceived positively by stakeholders, especially regarding the intervention strategies, accommodation of the intervention and the helpers. Two serious adverse events not attributable to the trial were reported. At 3-month follow-up, the HSCL-25 total score was significantly lower for the PM+/CAU group ($n = 30$) than CAU group ($n = 30$) ($p = 0.004$; $d = 0.58$). Significant differences in favour of PM+/CAU were also found for WHODAS psychosocial functioning ($p = 0.009$, $d = 0.73$), PCL-5 symptoms of PTSD ($p = 0.006$, $d = 0.66$) and PSYCHLOPS self-identified problems ($p = 0.005$, $d = 0.81$). Trial procedures and PM+ delivered by non-specialist peer-refugee helpers seemed acceptable, feasible and safe. Analyses indicate that PM+ may be effective in improving mental health outcomes and psychosocial functioning, and potentially cost-effective. These results support the development of a definitive RCT with a larger sample of refugees and a longer follow-up period.

Conclusion

The pilot RCT and process evaluation indicated that the trial procedures and PM+ delivered by peer-refugee, non-specialist helpers are acceptable, feasible and safe. PM+ is likely effective in improving mental health outcomes and psychosocial functioning in Syrian refugees, and potentially cost-effective. A fully-powered, definitive RCT with longer follow-up is needed.

3. Fully-powered RCT (phase 4)

After successful implementation of the pilot RCT with process evaluation, we implemented a fully-powered RCT with 206 Syrian refugees in the Netherlands to test the intervention's effectiveness (Deliverable 5.2, due in December 2022).

Aim

The fully-powered RCT aimed to evaluate the effectiveness of PM+ on symptoms of depression/anxiety (total score; primary outcome), and on depression, anxiety, symptoms of PTSD, functional impairment, and self-identified problems (secondary outcomes) among Syrian refugees in the Netherlands.

Methods

Ethics approval

The trial was approved by the Research Ethics Review Committee at VU Medical Center (NL61361.029.17)¹⁴ and prospectively registered in the Netherlands Trial Registry (#7552).

Participants

Adult (18 years or above) Arabic-speaking Syrian refugees were recruited through community centres, non-governmental organizations, reception centres, language schools and social media. With 'Syrian refugees' we refer to individuals from Syria who requested asylum after the start of the war in 2011 regardless of current resident status. Oral and written informed consent (IC) was obtained from all participants before screening. Participants were included if they reported elevated levels of psychological distress (Kessler Psychological Distress Scale; K10 >15)¹⁶ and impaired daily functioning (WHO Disability Assessment Schedule; WHODAS 2.0 >16).¹⁷ Participants were excluded and referred to the general practitioner/specialist services if they met any of the following criteria: acute medical conditions, imminent suicide risk (PM+ manual suicidality assessment), expressed acute needs/protection risks, indications of severe mental disorders (e.g., psychotic disorders) or cognitive impairment (e.g., severe intellectual disability; PM+ manual observation checklist).⁷ Participants were also excluded if they received ongoing treatment in specialised mental health care.

Procedures

The baseline assessment included questionnaires on demographics, clinical scales, daily functioning, stressful events, and health service utilisation (reported elsewhere). Participants were re-assessed one week and three months after the intervention (i.e., six weeks and 4.5 months after baseline). Assessments were conducted in the online questionnaire tool Survalyzer. For each assessment, participants were contacted by an Arabic-speaking assessor who sent a secured online link for the self-report questionnaires, a brief phone-based interview on health service utilisation and assisted in case of lower literacy. Participants were remunerated 8,50 Euros for both follow-up assessments. Assessors had at least a university degree and were trained on questionnaire administration, general interview techniques, CMDs, psychological first aid, and research ethics. Serious adverse events (SAEs) were recorded and monitored throughout the study.

After baseline, participants were randomised 1:1 into PM+ in addition to care as usual (PM+/CAU) or CAU alone. A randomisation list with permuted block sizes 4-6-8 was generated in R18 by an independent researcher not involved in the rest of the study. A researcher not involved in the outcome assessments informed participants about allocation using sealed opaque envelopes. Outcome assessors were masked to

group allocation. To evaluate success of masking, assessors indicated after each assessment whether group allocation was revealed.

Measures

The primary outcome concerned symptoms of depression/anxiety assessed with the 25-item Hopkins Symptom Checklist (HSCL-25)(Mahfoud et al., 2013). We used item mean scores (range 1-4) for both total scale (primary outcome) and subscales (secondary outcomes) in the analyses. To differentiate between individuals with or without probable depression/anxiety, we used a validated cut-off score of 2.10 for depression and 2.00 for anxiety(Mahfoud et al., 2013)

Secondary outcomes included the 12-item WHODAS 2.0 (Üstun, et al., 2010) to measure functional impairment. Items were rated on a 1-5 scale (total range 12-60). Sociodemographic information was collected using the demographic section (adapted) of the WHODAS 2.0 (Üstun, et al., 2010), and included gender, age, living situation, education, marital status, work status, refugee status, and time of displacement. PTSD symptoms were assessed using the 20-item PTSD Checklist for DSM-5 (PCL-5)(Ibrahim et al., 2018). Items were scored on a 0-4 scale (total range 0-80). A score of 33 or higher was used as indication of probable PTSD. Self-identified problems were assessed using the Psychological Outcomes Profiles (PSYCHLOPS) on a 0-5 scale (total range 0-20)(Ashworth et al., 2004).

Other measures included past and ongoing (severe) stressors. Number of traumatic events were assessed using a 27-item checklist (Schick et al., 2016) adapted for use in the current project. Items were scored 1 (yes) or 0 (no) (total range 0-27). Seventeen post-migration living difficulties were scored on a 0-4 scale using the Post-Migration Living Difficulties checklist (Schick et al., 2016). Items with a score of 2 (moderately serious problem) or higher were regarded positive responses and summed for analysis (range 0-17).

The reliabilities (Cronbach's α) at baseline were 0.93 (HSCL-25 total), 0.90 (HSCL-25 depression), 0.87 (HSCL-25 anxiety), 0.77 (WHODAS 2.0), and 0.93 (PCL-5). Arabic translations of validated measures were identified, and if unavailable translated/back-translated (de Graaff, Cuijpers, McDaid, et al., 2020).

Study arms

Problem Management Plus (PM+)

The PM+ helpers were Arabic (and Dutch or English) speaking Syrian refugees with at least high school education and (professional) background in education, social work or related field, and a Certificate of Conduct. Helpers received 8-day training on CMDs, basic counselling skills, delivery of intervention strategies, and self-care, followed by a practice-case. Helpers met weekly for group-supervision by a PM+ supervisor. PM+ trainers/supervisors were mental health professionals from i-Psy, VU and University of Groningen who had received 5-day training covering elements of training of helpers, and training/supervision skills. Due to COVID-19 restrictive measures (first partial lockdown in March 2020), participants were given the option for in-person or videocall sessions.

To evaluate treatment fidelity, helpers completed a checklist addressing requisite PM+ components for each session. Additionally, all PM+ participants were asked IC to audio record sessions for independent assessment of fidelity. Two assessors (ME/SH) with knowledge of the PM+ manual independently rated a random sample of 10 tapes per session (50 in total) using the PM+ checklist for adequate delivery of treatment elements (yes/no)(de Graaff, Cuijpers, McDaid, et al., 2020)

Care as usual (CAU)

CAU includes all (mental) health services ranging from primary to specialist mental health care that refugees may access in the Netherlands. For participants without a residence permit residing in a reception centre, the Central Agency for the Reception of Asylum Seekers [COA] contracted a primary care provider for on-site

mental health services (e.g., psychological counselling) or referral to external specialist services. Participants resettled in the community (with residence permit/Dutch nationality) pay mandatory basic health insurance and can access mental health services via their local general practitioner.

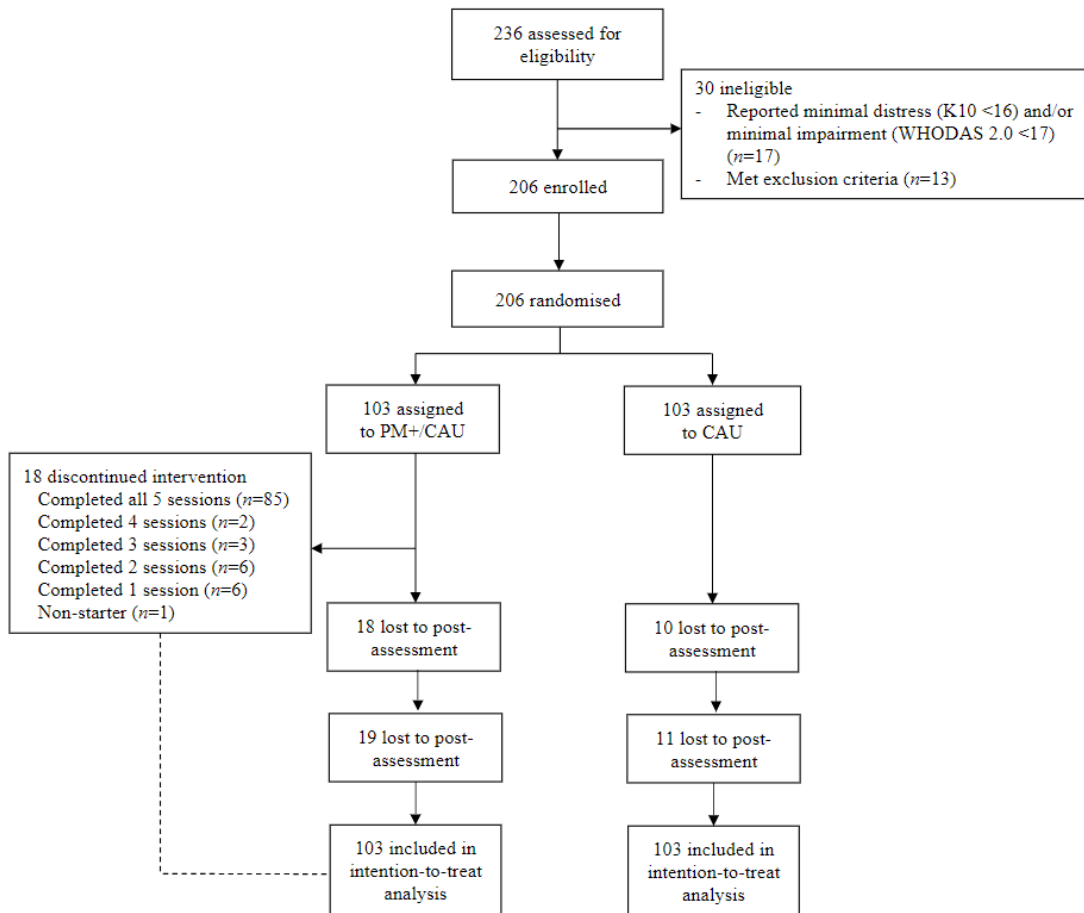
Analyses

Original power calculations were based on prior RCTs on PM+ in other populations (Bryant et al., 2017; Rahman et al., 2016), but were adapted based on the pilot RCT among Syrian refugees in the Netherlands (de Graaff, Cuijpers, Acarturk, et al., 2020). The pilot RCT indicated an effect size of $d=0.45$ in reducing HSCL-25 scores (de Graaff, Cuijpers, McDaid, et al., 2020), resulting in a required sample size of 64 per group (Cohen's $d=0.45$, power =0.90, $\alpha=0.05$, two-sided). Considering an expected 30% attrition at 3-month follow-up, we aimed to include 184 participants (92 in PM+/CAU and 92 in CAU).

The primary analysis was intention-to-treat. We used linear mixed models (LMMs) in R (R Core Team, 2021) to estimate treatment effects over the two follow-up time points on average, at 1-week and at 3-month follow-up (primary endpoint analysis), with two dummy variables for time (i.e., 1-week and 3-month follow-up), two interaction terms for condition*time, and a random intercept on subject level. Because condition itself is not added to the model, the intercept reflects the baseline value for both conditions and therefore, the analysis is adjusted for the baseline differences between conditions. In this model, the regression coefficients of the interaction terms are the effect estimates (i.e., mean difference between the two arms) at the two time-points. Treatment effects were investigated for the primary outcome of depression/anxiety (HSCL-25 total score), as well as secondary outcomes (i.e., depression, anxiety, functional impairment, symptoms of PTSD, and self-identified problems). Covariate-adjusted LMMs were performed by adding relevant covariates measured at baseline (i.e., gender, age, education, work status, number of traumatic events, post-migration living difficulties, and probable depression, anxiety, and PTSD) to the above-mentioned model for the primary and secondary outcomes. These variables were also investigated as potential effect modifiers (i.e., added in interaction with condition at 1-week/3-month follow-up) to the LMM of the primary outcome. Cohen's d was calculated by dividing the mean difference between the conditions by the raw pooled standard deviation (SD). Sensitivity analyses were carried out including participants retained at 3-month follow-up (completers) and including only participants of the PM+/CAU group who completed at least four sessions (per protocol).

The reliable change index (RCI) was calculated to evaluate whether the change scores from baseline to follow-up were reliable and clinically significant (Jacobson & Truax, 1991). The number needed to treat was estimated for depression and anxiety at 3-month follow-up using the delta method in logistic regression. Across all analyses, two-tailed tests were reported where $p < 0.05$ indicates statistical significance.

Figure 1. CONSORT flowchart



Results

Participants

Between March 2019-December 2021, 758 individuals agreed to be contacted by VU of which 236 provided IC and completed screening. Thirty participants were excluded (see Figure 1). Of the 206 included participants, 127 (61.7%) were male, and the average age was 26.5 years (range 18-69, $SD=11.7$). Randomisation resulted in 103 participants being allocated to PM+/CAU and 103 to CAU only. Sample characteristics are presented in Table 1.

Retention at 3-month follow-up was 85.4%, with data available for 84 participants (81.5%) in PM+/CAU and 92 (89.3%) in CAU. Participants lost at 3-month follow-up versus those retained did not differ in terms of baseline characteristics. At 3-month follow-up, masking was successful for 144 (81.8%) participants. There were no SAEs related to the study procedures or intervention.

In PM+/CAU, 87 participants (84.5%) attended a minimum of four PM+ sessions (see Figure 1). Of those attending at least one session, 64 (62.8%) attended in person, 25 (24.5%) online (i.e., videocalls), and 13 (12.7%) in person and online (i.e., hybrid). PM+ helper checklists indicated 97.5% of the protocol was carried out. Thirty-six participants (35.3%) provided IC for audio recordings. Independent ratings (3/50 tapes were excluded due to technical problems; interrater reliability Cohen's $\kappa=.91$) indicated on average 77.4% of the protocol was delivered adequately.

Table 1.
Baseline Characteristics

| | Full sample (N=206) | PM+/CAU (n=103) | CAU (n=103) |
|---|---------------------------|--------------------------|---------------------------|
| Gender, <i>n</i> of men (%) | 127 (61.7%) | 73 (70.9%) | 54 (52.4%) |
| Age, <i>M</i> (<i>SD</i>) [range] | 36.52 (11.72) [18-69] | 36.35 (11.97) [18-69] | 36.69 (11.52) [19-67] |
| Marital status, <i>n</i> (%) | | | |
| Never married | 70 (34.0%) | 38 (36.9%) | 32 (31.1%) |
| Currently married | 99 (48.1%) | 51 (49.5%) | 48 (46.6%) |
| Separated | 4 (1.9%) | 2 (1.9%) | 2 (1.9%) |
| Divorced | 24 (11.7%) | 8 (7.8%) | 16 (15.5%) |
| Widowed | 5 (2.4%) | 2 (1.9%) | 3 (2.9%) |
| Cohabiting | 4 (1.9%) | 2 (1.9%) | 2 (1.9%) |
| Work status | | | |
| Paid work | 36 (17.5%) | 15 (14.6%) | 21 (20.4%) |
| Non-paid work | 30 (13.6%) | 17 (16.5%) | 13 (12.6%) |
| Keeping house | 7 (3.4%) | 5 (4.9%) | 2 (1.9%) |
| Retired | 2 (1.0%) | 1 (1.0%) | 1 (1.0%) |
| Unemployed | 40 (19.4%) | 14 (13.6%) | 26 (25.2%) |
| Student (incl. language courses) | 81 (39.3%) | 46 (44.7%) | 35 (34.0%) |
| Other | 10 (4.9%) | 5 (4.9%) | 5 (4.9%) |
| Refugee status, <i>n</i> (%) | | | |
| Asylum procedure ongoing | 16 (7.8%) | 10 (8.7%) | 6 (5.8%) |
| Resident permit | 150 (72.8%) | 71 (68.9%) | 79 (76.7%) |
| Dutch citizenship | 26 (12.6%) | 13 (12.6%) | 13 (12.6%) |
| Other | 2 (1.0%) | 2 (1.9%) | 0 |
| Missing | 12 (5.8%) | 7 (6.8%) | 5 (4.9%) |
| Time elapsed (months) since arriving in the Netherlands, ^a <i>M</i> (<i>SD</i>) [range] | 44.07 (23.07) [1- 113] | 42.22 (23.57) [1- 97] | 45.94 (22.53) [2- 113] |
| Educational level, <i>n</i> (%) | | | |
| No education | 1 (0.5%) | 0 | 1 (1.0%) |
| Basic education | 29 (14.1%) | 10 (9.7%) | 19 (18.4%) |
| Technical/vocational secondary | 6 (2.9%) | 3 (2.9%) | 3 (2.9%) |
| Technical diploma | 13 (6.3%) | 7 (6.8%) | 6 (5.8%) |
| Certificate of associate degree | 18 (8.7%) | 11 (10.7%) | 7 (6.8%) |
| General secondary education | 37 (18.0%) | 21 (20.4%) | 16 (15.5%) |
| Bachelor | 82 (39.8%) | 41 (39.8%) | 41 (39.8%) |
| Master | 20 (9.7%) | 10 (9.7%) | 10 (8.7%) |
| PhD | 0 | 0 | 0 |
| Depression and anxiety (HSCL-25 total) | 2.36 (0.62) | 2.31 (0.64) | 2.41 (0.61) |
| Depression (HSCL-25 subscale), <i>M</i> (<i>SD</i>) | 2.43 (0.71) | 2.47 (0.72) | 2.38 (0.70) |
| Probable depression, <i>n</i> (%) ^b | 142 (68.9%) | 66 (64.1%) | 76 (73.8%) |
| Anxiety (HSCL-25 subscale), <i>M</i> (<i>SD</i>) | 2.20 (0.64) | 2.16 (0.66) | 2.24 (0.61) |
| Probable anxiety, <i>n</i> (%) ^c | 129 (62.6%) | 55 (53.4%) | 74 (71.8%) |
| PTSD symptoms (PCL-5), <i>M</i> (<i>SD</i>) | 34.35 (16.89) | 33.13 (17.76) | 35.57 (15.96) |
| Probable PTSD, <i>n</i> (%) ^d | 109 (52.9%) | 52 (50.5%) | 57 (55.3%) |
| Functional impairment (WHODAS 2.0), <i>M</i> (<i>SD</i>) | 29.46 (7.72) | 29.09 (8.07) | 29.84 (7.39) |
| Self-identified problems (PSYCHLOPS), <i>M</i> (<i>SD</i>) | 15.42 (3.71) | 15.25 (3.74) | 15.58 (3.69) |

| | | | |
|---|--------------------|--------------------|--------------------|
| Number of traumatic events, <i>M</i> (SD) [range] | 9.60 (5.08) [0-26] | 9.90 (5.52) [0-26] | 9.30 (4.61) [0-21] |
| PMLD, <i>M</i> (SD) [range] | 6.95 (3.55) [0-16] | 6.74 (3.59) [0-16] | 7.17 (3.51) [0-15] |

^a *n*=200; PMLD = post-migration living difficulties; PTSD = posttraumatic stress disorder; ^b based on HSCL-25 depression subscale cut-off ≥ 2.10 ; ^c based on HSCL-25 anxiety subscale cut-off ≥ 2.00 ; ^d based on PCL-5 ≥ 33

Intervention effects

Participants in the PM+/CAU intervention group had significant reductions in symptoms of depression, anxiety, PTSD, and self-identified problems relative to participants in the CAU control group.

Discussion

Summary of findings

This study evaluated a brief, behavioural intervention (PM+) for Syrian refugees with elevated levels of psychological distress in the Netherlands. Our main finding was that PM+ delivered by Syrian non-specialist helpers reduced symptoms of depression, anxiety, PTSD, and self-identified problems three months later. Furthermore, our study has shown that PM+ is safe and not associated with any adverse outcomes.

Limitations

This study has a number of limitations. First, our sample predominantly included Syrian refugees with residence permit probably hindering generalisation to asylum seekers awaiting the outcome of their asylum procedure. Second, PM+ session delivery shifted from in-person to online/hybrid sessions due to COVID-19 restrictive measures. Study effects may have been affected by this unplanned change in delivery format.

Implications

Adding PM+ to the array of available mental health services in the Netherlands may improve mental health and wellbeing for underserved populations like refugees. Beyond effectiveness, it is important to determine whether the intervention is cost-effective in a HIC (de Graaff, Cuijpers, Acarturk, et al., 2020; de Graaff, Cuijpers, McDaid, et al., 2020). We are conducting an economic evaluation to assess this and explore whether PM+ has potential for being integrated in the Dutch health care system, for example as a first step in 'stepped-care'. Scale-up in a high-income country such as the Netherlands may require political, regulatory and health system changes, including sustainable financing, policies that enable non-specialist helpers as providers, the establishment of a resource and knowledge centre to support delivery and quality of the intervention, and resources to identify potential service users (Fuhr et al., 2020a). This is an important step, especially given the steep rise of refugees in Europe since the outbreak of war in Ukraine (UNHCR, 2022). Peer-provided interventions such as PM+ may enhance responsiveness of health systems to refugees from various countries.

Long-term follow-up

Long-term follow-up assessments 12 months after baseline have been completed (last assessment was on December 12, 2022). A total of 169 (82.0%) participants were retained at 12-month follow-up (PM+: *n*=88, 85.4%; CAU: *n*=81, 78.6%). The trial is therefore completed. Due to the timing of this report, the 12-month follow-up assessment has not yet been analysed.

Conclusion

PM+ delivered by peer-providers is an effective intervention to reduce symptoms of depression, anxiety, and PTSD, as well as self-identified problems in Syrian refugees. This study is the first RCT on PM+ for refugees in

a HIC and suggests that PM+ may be of potential utility in a setting where access to specialist services is typically hampered by waitlists and communication difficulties.

4. Qualitative evaluation of PM+ implementation and potential for scale-up (phase 5)

This section has been published as:

Woodward et al (2022). Scalability of a task-sharing psychological intervention for refugees: A qualitative study in the Netherlands. *SSM Mental Health*, 2: 100171. <https://doi.org/10.1016/j.ssmmh.2022.100171>

Background and study aim

Our pilot RCT (phase 2 and 3) indicated that PM+ is feasible and acceptable among Syrian refugees in the Netherlands; and our fully-powered RCT (phase 4) showed that PM+ is effective in reducing symptoms of common mental disorders (de Graaff et al., submitted)

Little is known about how task-sharing interventions for refugees like Problem Management Plus (PM+) can be implemented on a larger scale and integrated in existing systems. We use a system innovation perspective to examine the factors influencing the potential for scaling up PM+ for refugees in the Netherlands.

Method

Ethics approval

All interviewees provided verbal and written consent before participation. Ethical approval was granted by the VU Medical Centre Medical Ethics Committee in the Netherlands (NL61361.029.17) and the London School of Hygiene & Tropical Medicine in the UK (14330-1).

Respondents

Semi-structured interviews were held with selected individuals, including PM+ staff (i.e. researchers, project workers, supervisors, and helpers), key informants (e.g. health professionals, policy advisors, and project managers), and PM+ participants (i.e. Syrian refugees participating in the STRENGTHS's RCTs).

The aim was to invite respondents familiar with PM+ (i.e. PM+ staff and participants) and those not (or less) familiar with PM+ but knowledgeable about the MHPSS system for asylum seekers and refugees in the Netherlands (i.e. key informants). Additionally, we aimed to get a mixture of male/female respondents, based in different parts of the country, and, in case of key informants, from different sectors and backgrounds (e.g. primary healthcare providers, mental health specialists, policy makers, implementers of interventions for refugees).

PM+ staff and participants were known and invited by the research team. Contacts with key informants were established by PM+ staff recommending people from their network (snowball sampling) and through online searches of relevant individuals. Interview candidates were invited through email, which included information about the study and possible participation.

Between December 2018 and June 2021 a total of 42 people were interviewed: 20 PM+ staff, 10 key informants, and 12 PM+ participants. Over half (n=24) of those interviewed were Syrian (12 PM+ participants, 11 PM+ staff (all helpers) and one key informant). Interviews explored perceptions on possible

barriers and facilitators for integrating PM+ in existing systems, including views on where and how to integrate, and whom to involve. Three different interview guides were developed for each sample. Topic guides for staff and participants also explored experiences with PM+ and were combined with interview questions for the process evaluations of PM+ RCTs to increase efficiency. Guides were piloted, with minor adaptations made to clarify questions.

Interviews were predominantly face-to-face, although some were conducted through video conferencing due to COVID-19 restrictions. Most interviews were conducted in Dutch or English by the lead author (AW: health system researcher experienced in qualitative research and Dutch national). Interviews with PM+ participants were mainly conducted by an Arabic-speaking research assistant. Arabic interviews were translated into English. All interviews were transcribed verbatim and pseudonymised (personal identifiers removed).

Qualitative analysis

Data were analysed using Nvivo 12 by the lead researcher (AW) using a combination of inductive and deductive coding. Initially descriptive coding was conducted, which “summarizes in a word or short phrase – most often in a noun – the basic topic of a passage of qualitative data” (p.88) (Saldaña, 2016). Initial codes were further refined, ordered, reordered, and categorised to form the subcategories in our results. Subcategories were then deductively organised under key elements of our conceptual framework. The final coding framework was then applied to all transcripts.

Several recommendations (Green & Thorogood, 2018) were applied to ensure rigour of our analysis. First, constant comparison was used to identify similarities and differences. The focus was on differences in influencing factors across subsystems and comparison of accounts from respondents with various backgrounds (particularly Syrian refugees compared to other interviewees). Second, initial findings were discussed with other authors and the second author (AdG) conducted quality checks of coded data to increase reliability. Third, many quotes were used in the results section to validate our interpretations. The source of each quote cited is indicated as PM+ staff (PM+S), PM+ participant (PM+P), or key informant (KI), accompanied by a randomly assigned number for each interviewee, to illustrate the variety of responses. Where needed quotes were translated into English.

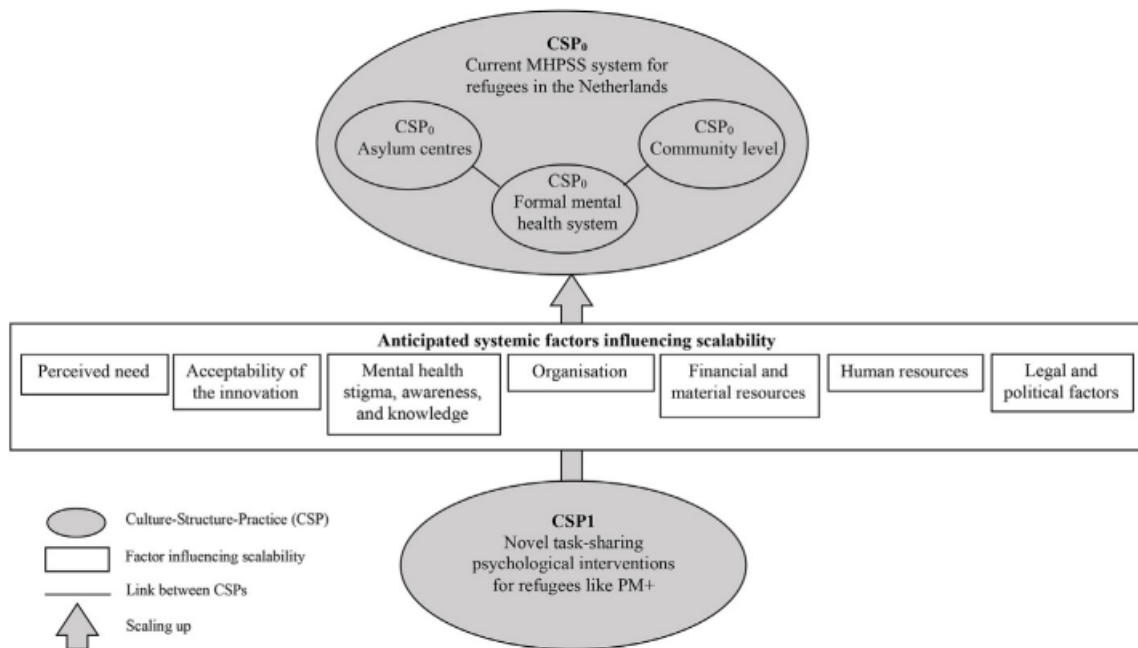
Results

In this section, we first describe the potential systemic factors (i.e. culture and structure) influencing scalability of PM+ from a whole-system perspective (i.e. MHPSS system for Syrian refugees), and then propose three scenarios for integrating the new intervention (CSP1) into existing subsystems (CSP0). Any perceived subsystem differences in factors influencing scalability are mentioned where relevant. Fig. 2 summarizes and visualises our main results. 3.1. Culture Three main scalability considerations were identified as related to culture: 1) perceived need; 2) acceptability of the innovation; 3) mental health stigma, awareness, and knowledge. 3.1.1. Perceived need Nearly all interviewees perceived a need for an intervention like PM+ for Syrian refugees: “And I think it's very much needed because a lot of them have stress issues and they are not sleeping that well” (PM+S2). Besides the high levels of stress, current challenges in the system were given as reasons for scaling up PM+. Cultural and language barriers in primary and specialist care were most often mentioned, but also lengthy waiting times and financial shortages in specialist mental healthcare:

“GGZ [specialist mental health care] and support is very white and Western oriented and very individualistic; not a place where people from a collective society feel at home at.” (KI7, project manager)

“One of the problems is communication with the doctor, like every time I want to go to the doctor, I have to look for an interpreter.” (PM+P10) “And there are also two forces that are pushing for this change. One is the difficult financial problems of the institutions and the other one are waiting lists.” (KI2, health professional)

Figure 2. Summary and visualisation of our main findings and their relationships



Most interviewees felt the main added value of PM+ is that it offers psychological support in the native language of refugees. For this reason, many interviewees believed that other target groups could benefit from PM+. Particularly adults and adolescents with similar health and health care access problems, like other refugees and migrants. Several mentioned Dutch citizens, although this was regarded less a priority as they can generally access and navigate the health system. There was consensus that PM+ scale up offers “more choice” (KI1) to the system, and potentially increases health care access: “

I do think that this [PM+] is a low-threshold chance for particular target groups that are not yet fully familiar with healthcare in the Netherlands: supporting them in their daily lives and making them more self-reliant” (PM+S14, supervisor)

However, recruitment experiences at the niche level (i.e. for research) suggest that some organisations may perceive this novel intervention as a threat rather than an opportunity:

“We notice a lot of competition with other organisations ... What we do [with PM+] is actually precisely in the middle [between psychosocial support and specialist care]. So, from both sides they say: “No but you are taking our refugees”” (PM+S13, researcher)

As many types and levels of psychological support are readily available in the Dutch mental health system, including several similar initiatives with non-specialist health workers, clarity on the added value of PM+ in such a competitive system was recommended to increase its scalability. While only PM+ individual was tested in RCTs in the Netherlands, the perceived need for various modalities of PM+ (individual, group, digital) was explored in interviews. The PM+ individual version was tested in the RCTs because “Competing interventions [other MHPSS initiatives] are mostly group interventions” (PM+S13, researcher) and findings from formative qualitative research revealed that most Syrians would feel more comfortable with one-to-one support because of confidentiality and mental health stigma. Interviews with PM+ participants confirmed this; participants appreciated receiving one-to-one support from their helper and discussing personal issues in a private setting. Key informants expressed added value in individual face-to-face contact: It allows seeing someone's body language more clearly, which is believed important in psychological care.

The definitive RCT took place during the COVID-19 epidemic, which shifted PM+ individual sessions and supervision from solely face-to-face to a hybrid format (mixture of face-to-face and online). While this hybrid structure was feasible, several expressed preferring sessions to be face-to-face and believed digital formats more useful as potential refresher sessions.

Acceptability of the innovation

Syrians were new to the idea of self-management of their problems. Although acceptance of the intervention increased after the first session and perceived positive benefits were reported. Helpers and participants spoke about the initial challenge of not giving or receiving advice on solutions for the participant's problems:

“PM+ is presenting something new, there was a protocol and 5 fixed sessions. The protocol protects the participant who receives help, as we don't offer any advice that might be affecting him ... We tell the participant, no, it is your decision. Most people were surprised about it, they said: We are coming to you seeking help and we Syrians are used to get advice.” (PM+S18, helper)

The evidence-based strategies were not novel to interviewed health professionals, although they appreciated the intervention being brief, protocolized and practical. For Syrian refugees the strategies were relatively new, which is unsurprising as psychotherapy is less common in Syria as explained by Syrian interviewees. Despite the novelty, with the support from their helper, most PM+ participants understood and applied the strategies:

“My relationship with the helper, this was helpful a lot and made me accept the strategies and correctly apply them.” (PM+P11)

“People [participants] maybe not able to understand you [helper], it varies according to the cultural level and the education level too, sometimes there is a bit of difficulty in understanding things, you need to simplify the subject or the words, and this thing sometimes I face challenges.” (PM+S16, helper)

However, PM+ helpers and participants indicated that for some participants, particularly those with more severe distress, PM+ was too short. Increased flexibility in the length and number of sessions, more time between sessions, and (online) refresher or follow-up sessions, were suggestions to accommodate those needing more long-term support.

The fact that helpers were peers was generally regarded positive by respondents. Mainly due to sharing the same native language, experiences, and cultural understanding about mental health: “We have the same experience, we have the same language, we have the same expression. So, we can more [better] understand each other.” (PM+P8)

“Also own language and someone from their own culture, and we [helpers] can normalise this for hem [participants]. And this works really well. Also important is that people are new here in this country and they can't easily express their feelings to someone they trust or share their story”. (PM+S10, helper)

“When people from the community become a bridge to their own people, I thought, especially when it comes to mental health ... when helpers are part of the community themselves with their own prejudices and their own experiences, it would be really, that would be a possibility for success.” (PM+S4, project worker)

“So the advantage is that it's [PM+] more a lesson or a course or so, that's how you could call it. It's not very stigmatising, I think” (PM+S12, supervisor) “I think we never call it a psychological intervention. I think, having role models who say:

“I did it! It's helpful. I liked it.” (PM+S11, researcher)

Many interviewees believed 'new' psychological interventions to be able to contribute to the reduction of mental health stigma amongst refugee communities: “Now today [after completing PM+] I don't see it as a

shameful thing anymore, my perspective has changed significantly.” (PM+P7) Stigma reduction is also displayed by the fact that many of the interviewed PM+ participants informed family and friends about their participation in the intervention. Some participants even shared having practiced PM techniques with their loved ones and referred them to the programme.

“My wife knows and she was encouraging me a lot and telling me to attend the program to relief myself as I am carrying so much load of my family ... Of course when she was doing the breathing exercise that I taught her and she started feeling more relaxed ... Yes [I share PM+ strategies with other people], even with my neighbours, I told my friend and he asked me who taught you?” (PM+P5)

As stigma is mostly associated with (mental) health professionals and institutions in the formal health system, the dominant viewpoint was for PM+ to be made accessible outside of this system in the social domain (i.e. community level). A related barrier is the limited mental health awareness observed amongst Syrians, “unfortunately, in our country [Syria] they don't pay much attention to mental health” (PM+P7), which reduces their ability to recognise psychological issues and felt urgency to seek support. As raised by various interviewees, refugees often express their psychological problems in physical complaints or with delay – they focus on “survival” and resettlement in initial years in host country. According to respondents, this challenge combined with a lack of knowledge amongst many Dutch health professionals about different local and cultural expressions of distress, results in severe delays in detecting mental health problems in patients of other cultures, including Syrians.

Distrust in the Dutch health system was another barrier raised in interviews. Syrian refugees may be reluctant to use health services, due to their newness to the Dutch health system, health insurance, and gatekeeper role of GPs – knowledge that is likely to grow over the years.

“Because Syrian refugees, they do not trust healthcare in the Netherlands. We have really difficult times with them [care providers]. You have to give them [Syrians] lots of information about Dutch healthcare to gain a little bit of trust. We, refugees and I, come from a different medical culture, a different system.” (K110, health professional)

Structure

Four overarching scalability considerations were identified as related to structure: 1) organisation; 2) financial and material resources; 3) human resources; and 4) legal and political factors.

Organisation

Interviews indicate MHPSS for refugees, including Syrians, is fragmented. MHPSS for asylum seekers is more centrally organised and has, according to a key informant, become more “people-oriented” over the years, which resulted in an increase in pre-integration activities for asylum seekers. However, experiences by PM+ researchers suggest the beliefs and attitudes of decision-makers in asylum centres determine what eventually gets implemented or not for asylum seekers. A mental health provider believed standardisation was needed, with the “best” and “evidence-based” interventions being rolled out across all asylum centres.

Respondents observed a shift in the mental health system from specialist and institutionalised care to preventative and community-based care, which led to increasing decentralisation of MHPSS care, including for status holders. Public health, prevention, and integration of status holders are all responsibilities of municipalities. The Netherlands has 350 municipalities, each with a slightly different culture (e.g. political ideas, needs) and structure (e.g. policies, budget), meaning PM+ is unlikely to be rolled out across all municipalities in a uniform way:

“But if we now established an idea with the municipality of Amsterdam, we are going to do it this and this way, we might have to do it entirely different in Arnhem, because it's entirely decentralised. I think that's something that's just happening. That makes it hard for us to implement it [PM+] in one way.” (PM+ S11, researcher)

A few project managers with experience in scaling up psychological interventions in municipalities recommended starting small (i.e. pilot in one municipality) and if successful replication in other municipalities. A PM+ project worker recommended testing and having various integration models:

“Perhaps you should do it this way in several municipalities and in a few other municipalities like that to see like ‘ok what works’. And maybe you need to keep both [models]. Maybe you shouldn’t want to choose. This [model] could be a better fit for this one [municipality] and the other [model] for that one. It is perhaps more beneficial in the long run to have multiple models so you can find a better fit with how it works [locally].” (KI3, project worker)

An academic interviewee spoke about the need to establish a Knowledge Centre, which can develop locally tailored PM+ packages and lobby for its local implementation. Project managers with scale up experience emphasised the social domain route requires time, persistence, and extensive lobbying and collaboration (e.g. insurers for funding; GGDs (municipal public health institutes) for organisation; knowledge institutes for monitoring and evaluation; health providers for referral).

Interviewees also talked about the importance of effective organisation of PM+ supervision and sessions. For quality and safety purposes, PM+ helpers are required to be regularly supervised by a licensed mental health professional. While interviewees believed supervision and sessions should ideally be face-to-face and therefore locally organised, experiences with PM+ implementation during the COVID-19 pandemic suggests both supervision and sessions can alternatively be delivered remotely. A hybrid structure was recommended by a PM+ supervisor: a mix of face-to-face and online. Such a structure may have advantages for both financial and human resources.

Financial and material resources

The implementation of PM+ requires financial and material resources. The largest financial posts are human resources for training, supervision, assessment, room hire, running the actual PM+ sessions, coordination and logistics, and adaptation of the manuals. Various respondents highlighted the importance of having no out-of-pocket costs for PM+ for the beneficiary during scale up. A helper explained that financing it through health insurance may, however, posit an obstacle:

“The problem according to my experience is, if you want to get help from the health insurance, you will have to pay the deductible 385 euro. I think that will reduce the number of participants.” (PM+S18, helper)

An overall shortage of funding for mental health care was highlighted. Particularly mental health institutions have suffered under austerity measures. This financial shortage is a challenge and an opportunity (given the lower costs of implementing PM+ compared to more intensive services). According to a mental health professional:

“Because there’s actually very little budget of health in the country that is allocated to mental health and there’s constant pressure on it to keep it that way or even lower it ... So we have to find ways to do things differently with the budget that we have and the other resources.” (KI2, health professional)

Several interviewees highlighted evidence of cost-effectiveness would help to inform and convince decision-makers and funders like municipalities and insurance companies. Although PM+ is anticipated to be cost-saving (e.g. fewer costs than training new psychologists), implementation at scale would require considerable funding, particularly for training and supervision:

“And what I think is a big disadvantage in the scale up of PM+ is that the training of helpers takes eight full days. And this is a huge time investment because this means you need to pay those helpers, but also the psychotherapist who gives the training. Eight full days. That is unaffordable.” (PM+S13, researcher)

Since the health system for refugees is fragmented, so are its potential funding streams. Depending on the integration scenario, interviewees mentioned different funding possibilities including more long-term and stable funding through insurance companies (separate insurance packages exist for asylum seekers and

citizens/permit holders). More shortterm and unpredictable funds were also highlighted, like ‘innovation funds’ through insurance companies, social support subsidies (WMO; Wet Maatschappelijke Ondersteuning]), and ‘prevention budgets’ available at some municipalities and larger mental healthcare institutions.

Financial reimbursement of non-specialist providers is perceived as important but complex. During experimentation two models were tested. In the pilot RCT, helpers were given time in their regular paid jobs as ‘connectors’ for PM+. In the full RCT, helpers were given a ‘voluntary’ contract and compensation, which was regarded a useful financial model for those on state benefits. Helpers appreciated the voluntary contribution, including travel reimbursements, although it was not the reason they signed up as helpers: “I never went there for the money” (PM+S20, helper). A project manager working with refugees outlined similar but also different models for contracting and incentivising refugee-providers:

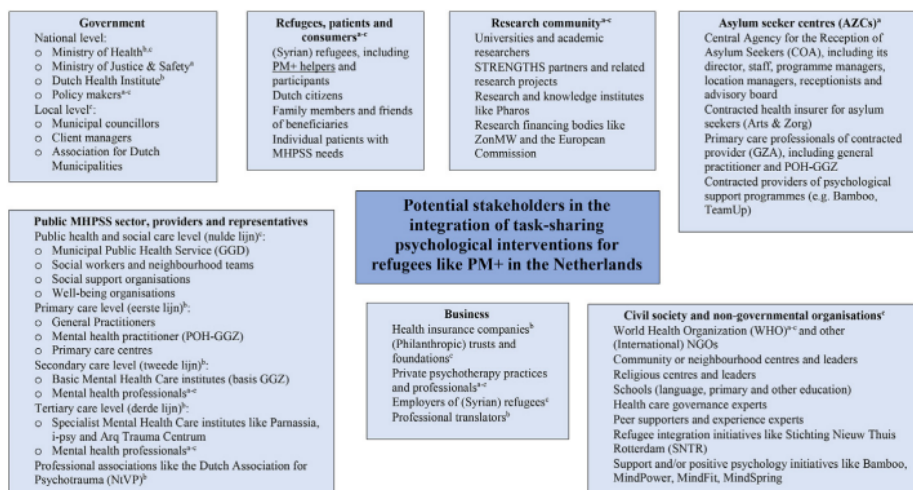
“Most people do it on an internship type of contract. Some people who are allowed to work in the Netherlands are becoming ZZZP-er [freelancer]. And some people have a contract for limited hours. A work experience position. It is all very different.” (KI3, project manager)

Overall interviewees thought helpers need more than a ‘voluntary’ contract to upkeep their motivation and, consequently, to retain experienced helpers and reduce the need for continuous recruitment and training. Moreover, another project manager remarked that in the Netherlands “you cannot give someone a voluntary contract for something you would have other people do paid” (KI6), with rules on this matter being particularly strict for care covered by health insurance. The same project manager lamented just being able to offer “small contracts” for their refugee-providers and the related retention challenge due to the unpredictable demand for their programme.

Human resources

Accounts from interviewees indicate various people with different knowledge and skills are needed for the implementation and integration of PM+. Primary roles that came forward are PM+ helpers to run the sessions and licensed mental health specialists for supervision. Additionally, one or more project coordinators are needed for various tasks including logistics, promotion, and engagement with stakeholders involved in funding (e.g. private or public donors), referral (e.g. social workers, health professionals), and monitoring and evaluation (e.g. knowledge institute). Stakeholders will differ by integration scenario (see 3.3.), including the extent to which it is broadened to other contexts (i.e. target groups and areas). Fig. 3 displays a map of mentioned stakeholders by interviewees.

Figure 3. Stakeholder map with stakeholders linked to integration scenarios: ^a Asylum centres, ^b Formal mental health system, ^c Community level



Findings on recruitment experiences of PM+ helpers, supervisors and participants in the research phase set a precedent for scaling up. PM+ staff shared it was relatively easy during both RCTs to recruit Syrian PM+ helpers. Helpers were motivated to help others, particularly fellow Syrians, and the ability to learn new skills and have new experiences:

“Now I see how much they [Syrians] suffer, they struggle to reach a psychologist, it’s difficult for them. You know our culture, so I think that such a programme [like PM+] can relieve their pain and at the same time help them. So, I liked the idea. Also, it is a new experience for me.” (PM+S17, helper)

That said, retention and workload of both helpers and supervisors/ trainers was a challenge. In the pilot trial, three out of eight trained PM+ helpers left the company. This increased the workload of the remaining five helpers who “were also doing their normal jobs [at the NGO]” (PM+S2) and meant reduced PM+ sessions per week and sometimes increased waiting time for PM+ participants. During the definitive trial a new team of helpers was trained due to attrition of previous helpers and expansion of the intervention to other parts of the Netherlands. Additionally new supervisors had to be trained as four left during the trials.

PM+ trainers/supervisors were mental health specialists from the public sector. Those interviewed for this study got involved because of an interest in refugee patient groups and being convinced by the importance of research and implementation of innovations like PM+. Supervisors were motivated by seeing helpers increase their skills and confidence. The eight-day training was described as “intense” but “fun” by a supervisor. Supervisors explained that because helpers are relatively inexperienced, supervision involved regular repetition of basic techniques. Additionally, supervisors highlighted the importance of being aware peer-providers may have similar experiences as their participants. While self-care is part of the PM+ protocol, a supervisor believed this could be emphasised more, including information about secondary traumatisation. Accounts by several helpers confirm they can be affected by participants’ stories:

“They [participants] sometimes come with intense stories and we [helpers] are of course human. But I try to always protect myself that I can find distraction or talk it through during supervision of course. Also I sometimes talk with other colleagues, which also helps.” (PM+S10, helper)

Recruitment of PM+ participants was regarded as difficult by PM+ staff. Accounts by PM+ staff indicate differences in subsystems (formal healthcare, asylum centres or community), reach, and level of integration partly explain why recruitment was somewhat less difficult in the pilot trial. In the pilot, PM+ was embedded in an NGO that was already supporting Syrians. The advantages of this integration were that: i) Helpers could be recruited from Syrian workers already part of the NGO and could make PM+ part of their paid roles; ii) Syrian families were already familiar with the organisation, helpers, and the building, enabling promotion of the intervention, trust-building, and physical access to the sessions; iii) the NGO contributed financially and logistically towards trial implementation. Another difference is that Syrian refugees were recruited from one city (Rotterdam) in the pilot trial compared to multiple cities (e.g. Amsterdam, Almere, Groningen) and eventually national level (i.e. feasible because it shifted online due to the pandemic) in the definitive trial. The definitive trial (de Graaff, submitted) required cooperation with a larger number and wider variety of organisations.

Several demographic preferences were reported. Some female participants preferred female helpers and similarly “many female helpers do not wish to help male participants” (PM+S11, researcher). Helpers had positive experiences with supporting both sexes and the location of the helper was commonly found more important (i.e. ease of travelling to sessions). A few helpers and participants spoke about the potential benefit of age matching, “it is easier to have someone from the same generation” (PM+S17, helper).

Legal and political

Interviewees mentioned several legal and policy changes and restrictions in the current system that could influence scalability. One such policy change concerns reduced financing of professional translators (see 3.2.2); interviewees believed this may increase the need for peer-provided interventions like PM+. Interviewed key informants, however, were unsure if PM+ helpers would be allowed by Dutch law to provide PM+ support and/or get paid for their work as part of the formal health system: “because we have become quite strict with certificates” (PM+S5, supervisor). Interviewees believed this might be possible under certain supervisory, payment, and accreditation “constructions”. Getting greater clarity on what PM+ helpers are allowed to do and what not, including lines of responsibility in terms of care and referral was deemed important for scale up.

Furthermore, whether PM+ would fall under ‘treatment’ or ‘prevention’ would determine the extent of legal restrictions: “If it is a medical treatment then one is of course bound by the laws applied there” (KI8, policy advisor). Since no psychological diagnosis is required for PM+ there seemed consensus the innovation would fall under ‘prevention’ in the Dutch system. Framing the innovation as ‘prevention’ and integrating it into the social domain was considered the route with the least legal hurdles. A project officer thought PM+ helpers would then only require a ‘Certificate of Good Conduct’ to be allowed to work. Several interviewees believed the innovation could be part of curative care if it conforms to “insurance rules”. They anticipated this would mean the PM+ supervisor having some direct contact with the participant, which “makes it a bit heavier than it is on paper” (KI2, health professional), and the PM+ helper having a recognised diploma, such as ‘ervaringsdeskundige’ (expert with lived experience) although this is considered a long trajectory.

Besides getting greater clarity on the specifics of the different rules and constructions, a key informant commented that if ‘task-sharing’ is part of national health plans, laws, and policies this would aid scale up. Others highlighted the importance of political will and climate at national and local level. Some observed a growing recognition amongst politicians of the need for prevention in mental health, albeit recognised its changing nature because of new elections every four years. A policy advisor believed it was vital for mental health prevention to be anchored in coalition agreements of local governments for lobbying on this matter to be successful.

Decentralisation of legal responsibilities for both mental health prevention at large and the integration of refugees from national to local authorities are another set of policy and legal changes perceived to influence scalability. This decentralisation (as mentioned under 3.2.1) makes it difficult to roll out PM+ for status holders in a uniform way across the country, as different municipalities have different political interests, capacities, and priorities. Several interviewees commented that this decentralisation has not had the desired effects, offering a window of opportunity for new ways of working such as with “semi-professionals” like PM+ helpers who “connect the two worlds: the real world of refugees and the real world of the system or the professional” (KI4, researcher). Similarly, the COVID-19 crisis creates momentum to introduce and scale up new psychological interventions, as several key informants explained it increased national attention for mental health needs.

Another legal change perceived to influence scalability are tighter regulations around data protection (i.e. GDPR). Interviewees mentioned that strict privacy rules challenged cooperation between different organisations and therefore the ability to reach Syrian refugees.

Integration scenarios

Three scenarios for the integration of PM+ (CSP1) into relevant dominant constellations (CSP0) were identified based on views of the interviewees and are described below.

Implementation in asylum centres

Care for asylum seekers is centrally organised and funded by COA. If PM+ is successful in the competitive tendering process, then it could be rolled out across all asylum centres in the country for several years. PM+ helpers would have a steady workload and be easily physically accessible to asylum seekers in the centres. A

potential barrier in this route is that some asylum seekers may not be ready to work on their mental health (often their focus is on the asylum procedure, language courses, family reunion). Additionally, asylum seekers regularly move between asylum centres, and eventually from the asylum to the community, which can interrupt PM+ sessions.

Implementation in formal mental health system

Integration in the formal mental health system, including primary health care and specialist mental healthcare, could make PM+ accessible to (Syrian) refugees settled into the community. Basic health insurance is the most sustainable funding source in this route and would lead to national coverage.

However, acceptance of a new and lay cadre by health insurers is challenged by strict regulations around quality standards (i.e. accreditation, liabilities). Additionally, if PM+ gets financed through health insurance it will probably fall under 'own risk', meaning beneficiaries need to pay up to €385 out-of-pocket, creating another financial access barrier. Aiming for regional or local coverage and institutions with available 'prevention funds' seems a more feasible route. Although constrained resources in the public mental health sector affects all institutions, if PM+ is proven cost-effective it might appeal to larger mental health institutions in regions with high numbers of refugees and long waiting lists.

The stigma associated with mental health suggests PM+ would benefit from being positioned (both physically and perceptually) outside of the formal mental health system. Primary care would likely not suffice, as refugees experience barriers in accessing this level of care for mental health purposes and GPs were considered unable to supervise PM+ helpers due to capacity restrictions. That said, primary care providers still need to be informed about PM+ and ideally play a role in referral.

Implementation at community level

The social domain was considered by interviewees as lowest threshold. Municipalities play an important role in decision-making and funding, with implementation likely through municipal public health services, civil society, or non-governmental organisations. The main challenges in this scenario are again funding, but also fragmentation. Responsibilities in this domain are decentralised across about 350 municipalities, with funding streams fragmented and often short-term. Philanthropic foundations are a possible source of alternative or supplementary funding. Strategic choices need to be made about which municipalities to target first, such as those whose priorities and interests align with PM+. Municipalities with high numbers of refugees have wider reach, but likely also have a higher existing supply of MHPSS initiatives. Rural areas have more limited supply and implementation of PM+ in these areas may benefit those currently underserved. The individual format enables the organisation of PM+ in a fragmented community system.

Discussion

Factors identified in this study are in line with the literature on the implementation of task-sharing and community-based approaches (Mendenhall et al., 2014; Pallas et al., 2013; Patel et al., 2011; Scott et al., 2018; Shalaby & Agyapong, 2020; Vandewalle et al., 2016), including the barriers and facilitators for scaling up MHPSS for refugees (Troup et al., 2021). Consequently, the factors influencing scalability identified in our study are likely transferable to other task-sharing or novel psychological approaches and to contexts outside of the Netherlands. Our integration scenarios may also be transferable to similar MHPSS task-sharing approaches for refugees in the Netherlands, such as the Mind Spring programme (ARQ, 2022). However, they are likely less transferable to other countries. This is mainly because these scenarios are dependent on the dominant constellations (CSPs), including their relationships, in the MHPSS system for refugees in a specific host country. As shown by our study, the factors influencing scalability may play out differently in each scenario (i.e. as barrier or enabler) and the key actors – the individuals or organisations who may implement the new intervention – were different in each scenario.

Systems approaches are underutilized in task-sharing for mental health research (Javadi et al., 2017) and this is the first application of the ‘system innovation perspective’ to this topic. This framework led to a focus on systemic factors and gave us insight into how identified factors will likely interact with a task-sharing psychological intervention. By taking the entire MHPSS system for refugees as the unit of analysis, we were able to identify similarities and differences in potential barriers and facilitators in various subsystems. For example, mental health stigma and legal rules are perceived more prominent barriers for scaling up in the formal mental health system compared to the community system (i.e. social domain). And scaling up in the community system is likely challenging due to fragmentation and in asylum centres because of financial competition. Such knowledge is important for actors involved in further research on and implementation of PM+ in the Netherlands, although those working on scaling up comparable innovations in health systems with similar characteristics may also learn from our findings.

Recommendations for future research and practice

Based on our findings several recommendations can be made for future research and practice (see Table 2). Mainstreaming of innovations (scaling up) is dependent on the learning that takes place during experiments at local level (deepening) and the linking and repeating of experiments in different contexts (broadening) (Bosch & Rotmans, 2008). In terms of deepening, evidence on the effectiveness and cost-effectiveness of the intervention is essential. While results from the fully powered RCT in the Netherlands are awaiting publication, results from the pilot RCT are promising (de Graaff, Cuijpers, McDaid, et al., 2020). We want to highlight the need for testing the integration scenarios identified in this study. This requires engagement with potential stakeholders; our study showed similarities but also differences in types of stakeholders for each scenario. An essential element of the structure of PM+ is for helpers to be trained and continuously supervised by a mental health specialist (Dawson et al., 2015). This means some level of integration in the specialist mental health system – part of the formal mental health system – is necessary to upkeep quality and safety. For example, PM+ supervisors are responsible for the referral of PM+ participants who need more intensive treatment. Supervisors may be linked to a yet to be established National Resource and Knowledge Centre, which organises accredited PM+ training and supports the delivery and monitoring of the intervention (Fuhr et al., 2020a). Accredited training will formalise the new roles occupied by PM+ helpers in the system, enabling their credibility (Kok et al., 2015; Vandewalle et al., 2016). And this credibility may again help overcome potential legal and financial barriers.

Our results indicate the community and asylum centre routes could both be pursued. As the community route is fragmented, scale up will be incremental here, which has the advantage that implementation can be refined during expansion (Fuhr et al., 2020b). Some areas for further learning are listed in Table 2, such as on modalities, target groups, and stakeholders. Similar to other work (Patel et al., 2022), our study showed that digital tools may be employed to build the capacity of non-specialists, including feasibility of implementing task-sharing interventions during a pandemic. It is important to keep in mind that scaling up health innovations can be a long and unpredictable journey (Côté-Boileau et al., 2019). Therefore, it may take some time before we know whether sustainable integration of PM+ in the Dutch system is feasible or not and which approach works best in this context.

Limitations

This study has several limitations. First, our study examined potential factors influencing scaling up but does not report on actual scaling-up. Second, while we interviewed a diverse sample, some types of people were underrepresented and need to be considered for inclusion in future research on this topic. For example, we only interviewed Syrian participants who had already sought MHPSS services (as they participated in a RCT on PM+) and so we did not include individuals who might be hesitant to access MHPSS services. Second, only one PM+ ‘drop-out’ was interviewed which limited our insights on those not completing all the PM+ sessions. Third, we did not interview family or close friends of PM+ participants and they may have had useful perspectives. Fourth, our results (particularly the integration scenarios) are specific to the Dutch context and may not necessarily be generalised to all refugee host countries.

Conclusion

This study highlighted a perceived need for scaling up task-sharing psychological interventions for Syrian and other refugees in the Netherlands. High levels of stress amongst Syrian refugees combined with limited access to health and interpreter services create demand for innovations like PM+. Peer-support in their native language and the beneficial health effects of the intervention were positively perceived by Syrian trial participants. Feasibility of wider implementation largely depends on whether barriers like stigma, attrition, fragmentation, competition, legal, and financial challenges can be overcome. Since the MHPSS system for refugees in the Netherlands is extremely fragmented, moving innovations like PM+ from the protected research environment into actual systems will require incremental scale up. This scalability assessment provides an understanding of the likely challenges involved in this complex process and how to address them. Actors involved in actual scale up need to seize the window of opportunity created by the increasing acceptance of task-sharing and peer-provided interventions. This trend enables getting non-specialist PM+ helpers positioned, formalised, and recognised in the system. The integration scenarios we identified need to be tested, evaluated, refined, and reported in future implementation research.

5. Research output

Published

de Graaff AM et al (2020). Peer-provided Problem Management Plus (PM+) for adult Syrian refugees: a pilot randomised controlled trial on effectiveness and cost-effectiveness. *Epidemiology and Psychiatric Sciences* 29, e162, 1–24. <https://doi.org/10.1017/S2045796020000724>

de Graaff AM et al (2020) Effectiveness of a peer-refugee delivered psychological intervention to reduce psychological distress among adult Syrian refugees in the Netherlands: study protocol, *European Journal of Psychotraumatology*, 11:1, 1694347, DOI:10.1080/20008198.2019.1694347

de Graaff AM et al (2021). A systematic review and meta-analysis of diagnostic test accuracy studies of self-report screening instruments for common mental disorders in Arabic-speaking adults. *Global Mental Health* 8, e43, 1–18. <https://doi.org/10.1017/gmh.2021.39>

Woodward et al (2022). Scalability of a task-sharing psychological intervention for refugees: A qualitative study in the Netherlands. *SSM Mental Health*, 2: 100171. <https://doi.org/10.1016/j.ssmmh.2022.100171>

Under review

de Graaff AM et al (under review). A peer-provided psychological intervention for Syrian refugees: results of a randomised controlled trial on the effectiveness of Problem Management Plus.

In preparation

Cultural adaptation of PM+ for Syrian refugees in Europe and the Middle East (lead author: DRC)

Effectiveness of PM+ at 12-month follow-up (lead author: VUA)

Effects of PM+ on post-migration living difficulties among Syrian refugees in the Netherlands and Switzerland (lead author: USZ)

Investigating the link between trauma exposure and post-displacement stressors, cortisol and DHEA with posttraumatic stress disorder symptoms in Syrian refugees (lead author: VUA)

Investigating treatment effects of PM+ on HPA-axis hormones (lead author: VUA)

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