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STUDY PROTOCOL

Effectiveness of a peer-refugee delivered psychological intervention to reduce psychological distress among adult Syrian refugees in the Netherlands: study protocol

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ABSTRACT

Background: Syrian refugees face multiple hardships and adversities which put them at risk for the development of mental health problems. However, access to adequate mental health care in host countries is limited. The WHO has developed Problem Management Plus (PM+), a brief, scalable psychological intervention, delivered by non-specialist helpers, that addresses common mental disorders in people affected by adversity. This study is part of the STRENGTHS project, that aims to evaluate peer-refugee delivered psychological interventions for Syrian refugees in Europe and the Middle East.

Objective: To evaluate the effectiveness and cost-effectiveness of the peer-refugee delivered PM+ intervention among Syrian refugees with elevated levels of psychological distress in the Netherlands.

Methods: PM+ will be tested in a randomized controlled trial (RCT) among Arabic-speaking Syrian refugees in the Netherlands aged 18 years and above with self-reported psychological distress (Kessler Psychological Distress Scale; K10 >15) and impaired daily functioning (WHO Disability Assessment Schedule; WHODAS 2.0 >16). Participants (N = 380) will be randomized into care as usual with PM+ (CAU/PM+, n = 190) or CAU only (CAU, n = 190). Baseline, 1-week post-intervention, and 3-month and 12-month follow-up assessments will be conducted. Primary outcomes are symptoms of depression and anxiety. Secondary outcomes are functional impairment, posttraumatic stress disorder symptoms, self-identified problems, anger, health and productivity costs, and hair cortisol concentrations. A process evaluation will be carried out to evaluate treatment dose, protocol fidelity and stakeholder views on barriers and facilitators to implementing PM+.

Results and Conclusions: PM+ has proved effectiveness in other populations and settings. After positive evaluation, the adapted manual and training materials for individual PM+ will be made available through the WHO to encourage further replication and scaling up.

Trial registration: Trial registration Dutch Trial Registry, NL7552, registered prospectively on March 1, 2019. Medical Ethics Review Committee VU Medical Center Protocol ID 2017.320, 7 September 2017.

Efectividad de una intervención psicológica brindada por un refugiado aotro para reducir el malestar psicológico entre refugiados Sirios en los Países Bajos: estudio piloto

Antecedentes: Los refugiados sirios atraviesan muchas dificultades y adversidades, las cuales los ponen en riesgo para el desarrollo de problemas de salud mental. Sin embargo, el acceso a servicios de salud mental en los países que albergan a refugiados es limitado. La Organización Mundial de la Salud (OMS) ha desarrollado la intervención de Gestión de Problemas Plus (PM+, por sus siglas en inglés), una intervención psicológica breve, en etapas, realizada por facilitadores no especialistas, y que está dirigido al abordaje de los

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PALABRAS CLAVE
Salud mental del refugiado; ensayo clínico aleatorizado; intervención psicológica; cambio de tarea; consejero no especialista; trastorno mental frecuente; depresión; ansiedad; trastorno de estrés postraumático; cortisol en cabello

关键词
难民心理健康; 随机对照试验; 心理干预; 任务转移; 非专业咨询师; 常见精神障碍; 抑郁; 焦虑; 创伤后应激障碍; 头发皮质醇

HIGHLIGHTS
- Despite availability of adequate mental health services in high-income countries such as the Netherlands, refugees face various barriers in accessing these services.
- Brief, non-specialist helper delivered psychological interventions can be effective in reducing

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trastornos mentales más comunes en personas afectadas por la adversidad. Este estudio es parte de un proyecto más grande llamado STRENGTHS, cuyo objetivo es evaluar las intervenciones psicológicas brindadas por un refugiado a otro adaptadas para refugiados sirios en Europa y Medio Oriente.
Objetivo: Evaluar la efectividad y costo-efectividad de la adaptación de la intervención PM+ brindada por un refugiado a otro, en refugiados sirios con niveles elevados de malestar psicologico en los Países Bajos.
Métodos: La adaptación de la intervención PM+ será evaluada en un ensayo clínico aleatorizado en refugiados sirios de habla árabe en los Países Bajos, en mayores de 18 años, con malestar psicológico auto-reportado (mediante la Escala de Kessler para Malestar Psicológico, K10>15) y deterioro en el funcionamiento diario (Registro de Evaluación de Discapacidad de la OMS; WHODAS 2.0 >16). Los participantes (N=380) serán distribuidos aleatoriamente en un grupo de tratamiento usual con PM+ (TU/PM+, n=190) y en uno de solo tratamiento usual (TU, n=190). Se tomarán evaluaciones de base, luego de la primera semana de la intervención, luego de los tres meses, y luego de los 12 meses. Estas evaluaciones serán asistidas por una aplicación de auto-entrevista con soporte de audio para tablet. Los resultados primarios son los síntomas de depresión y ansiedad. Los resultados primarios son los síntomas de depresión y ansiedad. Los resultados secundarios son el deterioro funcional, síntomas de estrés traumático, problemas auto-identificados, ira, costos en salud y productividad, y concentraciones de cortisol en el cabello. Se realizará un proceso de evaluación para valorar las opiniones de los interesados respecto a las barreras y facilitadores para implementar la intervención PM+, así como la dosis del tratamiento y la adherencia al protocolo.
Discusión: La intervención PM+ ha mostrado efectividad en otras poblaciones y escenarios. Luego de obtener una evaluación positiva de la PM+ en refugiados sirios, se harán disponibles manuales y material de entrenamiento para PM+ individual a través de la OMS, de manera que se incentive la posterior replicación de la intervención y se aumente progresivamente su aplicación.

psychological distress, i.e. depression and anxiety.
• This paper describes a protocol to evaluate Problem Management Plus (PM+) delivered by peer-refugee helpers to Syrian refugees in the Netherlands in a definite randomized controlled trial, comparing PM+ and usual care with usual care alone.

由难民同伴提供以减轻荷兰境内成年叙利亚难民心理困扰的心理干预的有效性：研究方案

背景：叙利亚难民面临着多重艰辛和逆境，使他们面临心理健康问题发展的风险。但是，在居住国获得足够精神卫生保健的机会有限。世卫组织开发了'问题管理增强版（PM+）'这项由非专业帮助者提供的简短，可扩展的心理干预措施，旨在解决受逆境影响者常见的精神障碍。本研究是更大的STRENGTHS项目的一部分，该项目旨在评估由难民同伴提供的适用于欧洲和中东境内叙利亚难民的心理干预措施。
目标：评估荷兰境内心理困扰水平较高的叙利亚难民得到的由同伴提供的改编版PM+干预的效果及成本。
方法：将采用随机对照试验（RCT）考查改编版PM+干预，样本为荷兰境内18岁及以上且自我报告具有心理困扰（《凯斯勒心理困扰量表》；K10> 15）及日常功能受损（《世界卫生组织组织残疾评估表》；WHODAS 2.0> 16）的讲阿拉伯语的叙利亚难民。380名参与者将被随机分为有PM+的日常护理组（CAU/PM+，n = 190）或日常护理组（CAU，n = 190）。使用带有音频支持的平板电脑辅助式自我访谈软件在基线及干预后1周，3个月和12个月进行追踪评估。主要结果是抑郁和焦虑症状。次要结果是功能损伤，创伤后应激障碍症状，自我认同问题，愤怒，健康与生产力成本以及头发皮质醇浓度。过程评估将对利益相关者对于实施PM +的障碍与辅助及治疗剂量与方案保真性的观点进行评估。
讨论：PM +已在其他人群和环境中证明有效。在得到对叙利亚难民中PM+干预的积极评估后，将通过世卫组织提供个人版PM +的改编手册和培训材料，以鼓励进一步复制和扩展。

1. Background

Since the outbreak of the Syrian civil war in 2011 over 12 million Syrians have been displaced. In the Netherlands, 31.500 Syrian refugees have been registered (UNHCR, 2019).

The war in Syria has led to an excessive number of civilian casualties (Devi, 2018). High rates of war-related trauma have been reported, with the majority of Syrian refugees having experienced at least three traumatic events during or after their migration (Ibrahim & Hassan, 2017). Seeking refuge in Europe is a risky and stressful journey (Ben Farhat et al., 2018). Once arrived in Europe, refugees may face uncertainty about their asylum applications, problems with integration, loss of social networks and social status, discrimination, worries about family in Syria, and restricted economic opportunities (Kirmayer et al., 2011; Laban, Gernaat, Komproe, Van Der Tweel, & De Jong, 2005).

Refugees are at increased risk to develop depression, anxiety, posttraumatic stress disorder (PTSD) and related somatic health symptoms (Silove, Ventevogel, & Rees, 2017). A recent study among Syrian refugees in the Netherlands found that 41% report psychological distress (Dagevos, Huijnk, Maliepaard, & Miltenburg, 2018). Studies among Syrian refugees in camp and non-camp settings in Europe report prevalence rates ranging from

14.5–44% for depression (Georgiadou, Zbidat, Schmitt, & Erim, 2018; Poole, Hedt-Gauthier, Liao, Raymond, & Bärnighausen, 2018), 13.5–92% for anxiety (Ben Farhat et al., 2018; Georgiadou et al., 2018) and 11.4–83.4% for PTSD (Acarturk et al., 2018; Georgiadou et al., 2018).

Studies have shown that trauma exposure and symptoms of PTSD (Schumacher et al., 2019; Stalder et al., 2017) and depression (Knorr, Vinberg, Kessing, & Wetterslev, 2010) are associated with altered hypothalamic-pituitary-adrenal (HPA) axis function, suggesting HPA hyperactivity in depression (Knorr et al., 2010) and both hypo- (Schumacher et al., 2019) and hyperactivity in PTSD (Stalder et al., 2017), although some meta-analyses found no relationship (Klaassens, Giltay, Cuijpers, van Veen, & Zitman, 2012; Meewisse, Reitsma, de Vries, Gersons, & Olff, 2007). Inconsistencies across findings have been explained by the use of different time points or methods of cortisol assessment across studies, or factors such as type of trauma (ongoing versus single trauma) (see Fragkaki, Thomaes, & Sijbrandij, 2016).

In the past decade, researchers have started to examine hair cortisol concentrations (HCC), which is an economical, non-invasive and reliable method to capture long-term cortisol levels (Steudte-Schmiedgen, Kirschbaum, Alexander, & Stalder, 2016). HCC was found to be lower in trauma-exposed individuals and individuals with PTSD than in non-trauma exposed individuals (Steudte et al., 2013). Factors such as time since trauma-exposure, and number and severity of traumatic events seem to differentially influence HCC (Steudte-Schmiedgen et al., 2016). A recent meta-analysis showed that HCC was higher in trauma-exposed populations with recent or ongoing stress than in trauma-exposed populations with past or absent stress (Stalder et al., 2017; Steudte-Schmiedgen et al., 2016).

Interestingly, a recent study in war-affected adolescents suggested that a brief psychosocial intervention decreased HCC for adolescents with cortisol hypersecretion, whereas it increased HCC in adolescents with hyposecretion relative to controls (Dajani, Hadfield, van Uum, Greff, & Panter-Brick, 2018). Psychological interventions targeting the reduction of daily stress may thus have the potential to normalize cortisol levels, particularly in populations exposed to high levels of ongoing stress, such as refugees. Although these results are promising, the effects of psychological interventions on the reduction of HCC deserve further study.

Despite the availability of specialized mental health services, there are numerous barriers to the delivery and uptake of psychological interventions for refugees (WHO, 2015). These include communication difficulties such as language barriers and interpreter costs (Satinsky, Fuhr, Woodward, Sondorp, & Roberts, 2019), stigma around mental illness (Hassan, Ventevogel, Jefee-Bahloul, Barkil-Oteo, & Kirmayer, 2016), waitlists (Satinsky et al., 2019), and difficulties navigating within a foreign health care system (Dorn et al., 2011). Treatment programmes usually focus on single psychiatric disorders (such as PTSD), whereas many refugees suffer from multiple psychological problems (Thabet, Abed, & Vostanis, 2004). Furthermore, culturally adapted psychological interventions may be more effective compared with interventions to which no (cultural) adaptations have been made (Harper Shehadeh, Heim, Chowdhary, Maercker, & Albanese, 2016). However, there is a lack of mental health interventions adapted for people from Syria.

The WHO has developed the scalable Problem Management Plus (PM+) intervention, which is part of a new generation of short, less expensive and trans-diagnostic (i.e. not condition-specific) interventions to reduce common mental health symptoms and improve psychosocial functioning. PM+ is based on the WHO treatment guidelines for conditions related to stress (WHO, 2013) and includes empirically supported cognitive behavioural therapy strategies, such as stress management, problem solving, behavioural activation and strengthening social support. The intervention covers five weekly face-to-face sessions of 90 minutes with a non-specialist helper. PM+ has been positively evaluated in two randomized controlled trials (RCTs) with 421 female victims of gender-based violence in Nairobi, Kenya (Bryant et al., 2017) and 346 primary care patients in Peshawar, a conflict-affected rural area in Pakistan (Rahman et al., 2016). Participants in the PM+ group had better outcomes on psychological distress, PTSD and daily functioning compared to participants in the enhanced usual care group (Bryant et al., 2017; Rahman et al., 2016). A group version of PM+ was effective in reducing psychological distress and improve functioning in females in Swat, Pakistan (Rahman et al., 2019).

The aim of the current study is to evaluate the effectiveness and cost-effectiveness of the adapted version of individual PM+ for Syrian refugees in the Netherlands impaired by elevated levels of psychological distress on symptoms of depression and anxiety. In addition, we will assess the effect of PM+ on functional impairment, symptoms of PTSD, self-identified problems, anger, health and productivity costs, and HCC. Furthermore, we will examine the processes of implementation, mechanisms of impact, and contextual influences through a process evaluation.

2. Methods

2.1. Design

This study is part of the EU Horizon2020 STRENGTHS project that aims to evaluate scalable psychological interventions for Syrian refugees in a series of trials in eight countries in Europe and the Middle East (see Sijbrandij et al., 2017). In the Netherlands, we will conduct a single-blind RCT comparing care as usual with PM+ (CAU/PM+) to CAU alone in 380 study participants. A flowchart of the study design is shown in Figure 1. A process evaluation will be conducted to examine barriers and facilitators to implementing PM+, and PM+ dose and protocol fidelity.

2.2. Participants

We will include 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). Information about the cut-off values is presented under 'screening measures'.

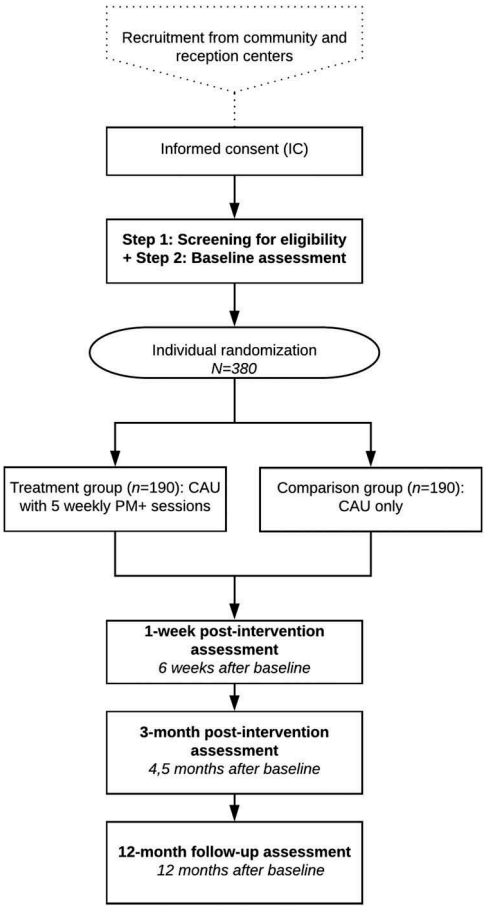

Figure 1. Flowchart.

Exclusion criteria include 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), cognitive impairment (e.g. severe intellectual disability or dementia), and receipt of current specialized psychological treatment.

2.3. Procedure

The PM+ intervention will be implemented within i-Psy (Parnassia Groep), a country-wide transcultural mental health care institution. Participants will be recruited from the community (i.e. Syrian refugees with a residence permit), as well as from reception centres (i.e. Syrian refugees awaiting their asylum request) through i-Psy, (non-governmental) organizations, and social media.

Written informed consent (IC) will be asked from all participants, or witnessed oral informed consent from illiterate participants. The witness will be any adult person (not related to the participant and not part of the research team) who the participant is comfortable having present during consent, and who is willing to act (and sign) as the witness. The project has been approved by the Research Ethics Review Committee of the VU Medical Centre, the Netherlands (Protocol ID: NL61361.029.17, 7 September 2017).

After IC is obtained, participants will be asked to complete the two self-report measures on psychological distress (K10) and daily functioning (WHODAS 2.0). Participants who meet the inclusion criteria will be assessed for suicidal ideation (PM+ manual suicidal thoughts interview) and severe disorders (PM+ manual observation checklist). The independent assessors will refer individuals meeting any of the exclusion criteria to specialist support according to their needs.

Participants who meet all inclusion criteria will complete the baseline assessment at the same visit. This involves questionnaires on depression and anxiety (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), anger (Trait Anger Scale; STAS-T), and questions on access to health services. Furthermore, the assessor will administer a health service utilization and productivity impact interview (locally adapted version of the Client Service Receipt Inventory; CSRI).

The post-assessment (WHODAS 2.0, HSCL-25, PMLD, PCL-5, PSYCHLOPS, CSRI) is scheduled 6 weeks after the baseline assessment (or 1 week after

the 5th PM+ session). The follow-up assessments are scheduled 3 months after the 5th PM+ session (WHODAS 2.0, HSCL-25, PMLD, PCL-5, PSYCHLOPS, STAS-T, CSRI) and 12 months after baseline (all 3-month follow-up measures and the Traumatic Experiences checklist, except the STAS-T). We also measure hair cortisol concentrations (HCC) at baseline and 3-month follow-up to investigate the effect of PM+ on HCC.

All questionnaires, except the exclusion instruments (the PM+ manual's suicidal thoughts interview and assessment tool for severe disorders) and the CSRI interview are self-administered on a tablet with audio functions (cf. Morina et al., 2017). Independent Arabic-speaking assessors with at least a degree-level will carry out the assessments. Assessors will receive a three-day training on the administration of questionnaires, use of the tablets, general interview techniques, common mental disorders, psychological first aid and ethical research conduct. The assessors are blinded to treatment allocation.

2.4. Sample size

Power calculations were carried out by the VUmc Department of Epidemiology and Biostatistics. Based on previous RCTs on PM+ (Bryant et al., 2017; Rahman et al., 2016), we aim for a conservatively estimated small to medium Cohen's *d* effect size of 0.4 in the PM+ group at 3-months follow-up. Power calculations suggest a minimum sample size of 133 participants per group (power = 0.90, $\alpha = 0.05$, two-sided). Taking into account an expected 30% attrition rate at the 3-month follow-up, we aim to include a total number of 380 participants (190 in the CAU/PM+ group and 190 in the CAU group).

2.5. Randomization

After baseline, participants will be randomized into the CAU/PM+ group or CAU group. Permuted blocks randomization will be performed using computerized software on a 1:1 basis and by means of sealed opaque envelopes. Household members will be randomized together to decrease the risk of contamination. The first PM+ session will be scheduled within one week after the baseline assessment.

2.6. Problem management plus (PM+)

We will test individual PM+ delivered by Syrian peer-refugees. During this 5-week intervention, a new treatment strategy is introduced in every session and subsequently reviewed in all following sessions. Stress management is practiced in session 1 using a slow breathing exercise. Problem management is taught in session 2 using a step-by-step plan to proactively manage practical problems. Behavioural activation is introduced in session 3 by encouraging the participant to re-engage with pleasant and task-oriented activities. Strategies to strengthen social support are discussed in session 4. Homework assignments are carried out between the sessions and relapse prevention strategies are discussed in session five (Dawson et al., 2015; Sijbrandij et al., 2017).

The adaptation of the PM+ intervention and development of training materials was coordinated by the Danish Red Cross in collaboration with the WHO and partners in STRENGTHS. Adaptations were made according to a framework for the cultural adaptation of psychological interventions (Bernal & Sáez-Santiago, 2006), and involved a literal translation by an Arabic-speaking translator, qualitative interviews with stakeholders such as Syrian refugees and mental health professionals (cf. Applied Mental Health Research Group, 2013), and cognitive testing of the literally translated manual. The core components of the PM+ intervention (e.g. breathing exercise) were retained, while case examples were rephrased to fit the context of Syrian refugees.

PM+ will be delivered by Arabic-speaking male and female refugees from Syria who have completed high school, have a background in education, social work, health care or another related field, and with sufficient speaking ability in Dutch or English. They will receive eight days of training, followed by two practice cases, and close supervision by trained PM+ trainers and supervisors throughout the trial. The training of helpers (ToH) involves education about common mental disorders, basic counselling skills, delivery of intervention strategies and self-care (Rahman et al., 2016).

PM+ trainers and supervisors will be licenced mental health care professionals. They will be trained in a five-day training-of-trainers (ToT) programme. The ToT covers the elements of the ToH as well as training and supervision skills (Rahman et al., 2016). Face-to-face supervision of helpers will take place on a weekly basis. The supervisors themselves will be supervised fortnightly by the master trainer who provided the ToT. This training model has previously been successfully implemented (Dawson et al., 2015).

2.7. Care as usual

Care as usual (CAU) includes all (mental) health services available to refugees in the Netherlands. Health care for asylum seekers is organized and financed on a national level by the Central Agency for the Reception of Asylum Seekers (COA). Health care, including mental health care for adults is

provided by a COA-contracted insurer, and public health care is provided by Community Health Services, Regional Medical Emergency Preparedness and Planning (GGD-GHOR) and the Centre for Youth and Family (CJZ). Resettled Syrian refugees with a residence permit have to pay a basic health insurance, and have access to health services through their local general practitioner (Fuhr et al., in press; Kroneman et al., 2016).

2.8. Screening measures

An overview of all study measures is provided in Table 1. The WHODAS 2.0 is a generic instrument to assess health and disability and is used across all diseases, including mental, neurological and substance use disorders. It is easy to administer, applicable across cultures and can be used in all adult populations. The cross-culturally validated 12-item version covers difficulties that people experience due to their illness across six domains during the last 30 days (WHO, 2010). Difficulties are scored on a five-point Likert scale ranging from 1 (none) to 5 (extreme), before summation (range 12–60). In line with the earlier RCTs on PM+ a cut-off of >16 will be used (Bryant et al., 2017; Rahman et al., 2016). The WHODAS will also be administered as secondary outcome measure.

The K10 will be used to measure psychological distress. Ten items related to depression and anxiety are rated on a five-point Likert scale, before summation (range 10–50). The K10 has been validated in Arabic-speaking populations (Fassaert et al., 2009; Sulaiman-Hill & Thompson, 2010). In a study among Kurdish and Afghan (former) refugees and asylum seekers in New Zealand and Australia the following cut-off scores were used: 10–15.9 (low risk of psychological distress), 16–21.9 (moderate levels of distress consistent with a diagnosis of moderate depression and/or anxiety disorder), 22–29.9 (high level of distress) and 30 or more (possibility of very high or severe levels of distress) (Sulaiman-Hill & Thompson, 2010). In the current study, we will use a score of >15 as an indication of moderate to high levels of psychological distress.

Sociodemographic information (sex, age, education, work, marital status and time elapsed since displacement) will be collected through items based on the demographic section of the WHODAS 2.0.

2.9. Primary outcomes

The primary outcomes are the level of depression and anxiety 3 months after the post-assessment (or fifth PM+ session), as measured by the HSCL-25. The HSCL-25 is a self-report questionnaire for symptoms of psychological distress (Derogatis, Lipman, Rickels, Uhlenhuth, & Covi, 1974). Items are rated on a four-point (1–4) Likert scale. Item mean scores can be calculated for the depression (15 items) and anxiety subscales (10 items). The HSCL-25 has been used with Syrian refugees (e.g. Acarturk et al., 2016).

2.10. Secondary outcomes

Posttraumatic stress symptoms during the past week will be measured through the 20-item PTSD Checklist for DSM-5 (PCL-5) (Blevins, Weathers, Davis, Witte, & Domino, 2015). Items are rated on a 0–4 scale and add up to a total severity score of 80, with higher scores indicating worse symptomatology.

Table 1. Overview of measures.

			Assessment time points					
Concept	Measure	Admin. and #items [b]	Screening	Baseline	PM+ sessions	1-week post-interv.	3-month post-interv.	12-month follow-up
Daily functioning	WHODAS 2.0	SR; 12 items	X			X	X	X
Psychological distress	K10	SR; 10 items	X					
Suicidal thoughts	PM+ manual interview	INT	X					
Severe disorders	PM+ manual checklist	INT	X					
Psychological distress (depression/anxiety)	HSCL-25 [a]	SR; 15 + 10 items		X		X	X	X
Posttraumatic stress	PCL-5	SR; 20 items		X		X	X	X
Self-identified problems	PSYCHLOPS	SR; 4 items		X		X	X	X
Anger	STAS-T	SR; 10 items		X			X	
Trauma exposure	Traumatic experiences checklist	SR; 27 items		X				X
Post-migration stressors	PMLD	SR; 17 items		X			X	X
Health service utilization	CSRI	INT		X		X	X	X
Health care access	Own survey	SR		X				
HCC	Hair sample	INT		X			X	
Treatment fidelity	PM+ checklist	SR (helper)			X			

[a] Primary outcome measure; [b] number of items on which scale/total score is based; HCC = hair cortisol concentrations; SR = self-report; INT = interview; WHODAS 2.0 = WHO Disability Assessment Schedule 2.0; K10 = 10-item Kessler Psychological Distress Scale; HSCL-25 = 25-item Hopkins Symptoms Checklist; PCL-5 = PTSD Checklist for DSM-5; PSYCHLOPS = Psychological Outcomes Profiles; STAS-T = Trait Anger Scale; PMLD = Post-Migration Living Difficulties; CSRI = Client Service Receipt Inventory

The PCL-5 has been validated in war-affected adults from Syria and Iraq (Ibrahim, Ertl, Catani, Ismail, & Neuner, 2018).

Self-identified problems will be measured using the PSYCHLOPS, a patient-generated outcome measure as an indicator of change after therapy (Ashworth et al., 2004). The questionnaire consists of four questions covering three domains: problems (2 questions), function, and wellbeing. Participants are asked to give free text responses to the problem and function domains, and these responses are scored on a 0–5 scale (range 0–20). The PSYCHLOPS has been used in primary care populations across several countries (Czachowski, Seed, Schofield, & Ashworth, 2011; Rahman et al., 2016).

Trait anger will be measured using a modified version of the 10 trait anger items of the State-Trait Anger Scale (STAS-T) (Spielberger, Jacobs, Russell, & Crane, 1983). Scores range from 1 (almost never) to 4 (almost always; total range 10–40).

Health service utilization, receipt of informal family care and impacts on participation in employment (where entitled to work) will be measured through an adapted version of the CSRI. Appropriate unit costs for service contacts will be attached to calculate changes in health service utilization and health care costs, while minimum wage rates will be used to conservatively value changes in informal care and work-related productivity. We adapted the original CSRI (Beecham & Knapp, 1992) for use in Syrian refugees in the Netherlands. Given that study participants may be unfamiliar with the Dutch health care system, we decided to administer this questionnaire as an interview.

HCC will be measured through hair samples of ~100 strands of hair, collected as close as possible to the scalp at the vertex posterior. Scalp-near 3-cm hair segments, allowing for the examination of cumulative cortisol levels over a 3-month period will be analysed to determine cortisol content at baseline and 3-month follow-up.

2.11. Other measures

Trauma exposure will be measured using a self-constructed 27-item list recoding traumatic experiences. It includes items from the Harvard Trauma Questionnaire (HTQ) (Shoeb, Weinstein, & Mollica, 2007), and the Posttraumatic Diagnostic Scale (PDS) (Foa, Cashman, Jaycox, & Perry, 1997), and has been adapted to include specific traumatic experiences of Syrian refugees experienced before, during or after the flight. Items are scored as 1 (yes) or 0 (no), with a total range of 0–27.

Post-migration stressors will be assessed using the Post-Migration Living Difficulties checklist (PMLD) (Silove, Sinnerbrink, Field, Manicavasagar, & Steel, 1997). This 17-item scale examines the extent to which post-migration challenges have been of concern to the individual over the past 12 months. Items are rated on a five-point scale, ranging from 0 (not a problem) to 4 (a very serious problem). Items scored at least 2 (a moderately serious problem) are considered positive responses, yielding a total count of living difficulties (range 0–17). This scale has previously been used in Arabic speaking refugees (Schick et al., 2016).

Access to health services will be assessed using a self-constructed survey.

2.11.1. Translation and adaptation of the measures

Validated Arabic-language measures were selected when available. Measures were pilot-tested through cognitive interviews with Arabic-speaking Syrians. Instruments without Arabic translation were translated and back-translated. Discrepancies in translation were discussed item-by-item and resolved through consensus between the translators. These steps are in line with the WHO-guidelines on the translation and adaptation of research instruments (WHO, 2018).

2.12. Process evaluation

The mechanisms, challenges and successes of the intervention will be explored through semi-structured interviews with key informants, including PM+ participants, helpers, policy makers and health professionals, until saturation is reached. We will use purposive sampling to select a diverse range of respondents. IC will be obtained from all participants, including consent to audio record the interview. An interview will last between 30–60 minutes.

Additionally, PM+ dose (i.e. number of sessions completed), and treatment fidelity and quality will be assessed. All PM+ participants will be asked for IC to audio record the PM+ sessions for protocol adherence purposes. A random sample of 10% of the audio recordings will be coded by an independent researcher with in-depth knowledge of PM+. Helpers will complete fidelity checklists addressing the PM+ components during the sessions (cf. Bryant et al., 2017; Rahman et al., 2016).

2.13. Trial monitoring and adverse events reporting

The VU research team has full access to the trial dataset. Adverse events (AE) or serious adverse events (SAE) are defined as any undesirable experience occurring to a participant during the study, whether or not considered related to the trial

procedure or the PM+ intervention. All SAEs will be recorded in Castor EDC trial monitoring software (Castor EDC, 2019) and reported to the SB and to the Central Committee on Research Involving Human Subjects within 7 days (in case of death or life-threatening situation) or 15 days (all other SAEs) after being informed about the event. SAEs will be followed-up until they have abated or until a stable situation has been reached, and if necessary, referral to a general physician will be made.

3. Analysis

To measure comparisons at baseline between the two treatment groups, t-test (continuous variables) or chi-square tests (categorical variables) will be conducted for normally distributed data; Mann-Whitney tests will be conducted for continuous non-normally distributed data.

Both intention-to-treat (ITT) analysis, including all randomized participants (N = 380), and completers' analysis will be carried out. The main conclusion will be based on the ITT analysis. To estimate the treatment effect, a linear mixed model will be employed for the primary endpoint analysis, which will have treatment as fixed effects, baseline measurement of primary endpoint as covariate, and subject as random effects. The mean difference between the two arms at each assessment with its 95% confidence interval will be derived from the mixed model. The effects of PM+ on secondary outcomes (i.e. functional impairment, symptoms of PTSD, self-identified problems, anger, health and productivity costs, and HCC) will be examined using linear mixed models with treatment as fixed effects, baseline measurement as covariate, and subject as random effects. Covariate-adjusted mixed model of primary endpoint will also be performed by adding relevant covariates at baseline (e.g. gender, age, education, baseline levels of depression, anxiety, PTSD, traumatic experiences, post-migration living difficulties, and HCC hypo- versus hypersecretion, etc.) to the above-mentioned model.

For the economic analysis incremental cost-effectiveness ratios (ICERs) will be generated comparing changes in mean costs and primary outcomes from a payer and societal perspective between the two arms. Non-parametric bootstrapping analyses to derive 95% confidence intervals around ICERs, and cost-effectiveness acceptability curves will be generated showing the likelihood that PM+ would be cost-effective at different willingness-to-pay thresholds.

Descriptive analyses will be carried out in SPSS and hierarchical linear modelling analyses in R version 3.6.0. Across all analyses, two-tailed tests will be reported with $p < 0.05$.

Interview transcripts from the process evaluation will be analysed thematically following the framework approach (Pope, Ziebland, Mays, & Mays, 2000) using NVivo version 11 (QSR International Pty Ltd, 2015).

4. Discussion

In this RCT we aim to evaluate the effectiveness and cost-effectiveness of the peer-refugee delivered PM+ intervention among Syrian refugees in the Netherlands impaired by symptoms of psychological distress. Within the larger STRENGTHS project, other RCTs with different modes of delivery (see Sijbrandij et al., 2017) will be conducted among Syrian refugees in Europe and the Middle East, which will strengthen external validity of trial findings and provide a potential model for scaling up in both high- and low-income settings.

Prior research to PM+ has shown that brief interventions delivered by non-specialist helpers are effective in decreasing symptoms of psychological distress, including depression, anxiety and PTSD (Bryant et al., 2017; Rahman et al., 2016, 2019). To our knowledge, this is one of the first RCTs to evaluate brief, non-specialist helper-delivered psychological interventions for refugees in high-income countries and provides a unique opportunity for global lessons on the mechanisms of identifying, recruiting, training and supervising peer-refugee helpers.

The Netherlands is a high-income setting where specialized mental health interventions are available to refugees and migrants, but access is limited due to various barriers (Lamkaddem et al., 2014; Satinsky et al., 2019). By offering PM+ we hope to contribute to overcoming barriers to accessing care, thereby reducing the treatment gap for Syrian refugees in the Netherlands. After positive evaluation of the adapted PM+ intervention, the manual and training materials will be made available through the WHO to encourage scaling up.

Disclosure statement

No potential conflict of interest was reported by the authors.

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