



STUDY PROTOCOL



Feasibility and acceptability of Problem Management Plus with Emotional Processing (PM+EP) for refugee youth living in the Netherlands: study protocol

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ABSTRACT

Background: Refugee youth experience hardships associated with exposure to trauma in their homelands and during and after displacement, which results in higher rates of common mental disorders. The World Health Organization (WHO) developed Problem Management Plus (PM+), a non-specialist-delivered brief psychological intervention, for individuals who have faced adversity. PM+ comprises problem-solving, stress management, behavioural activation and strengthening social support. However, it does not include an emotional processing component, which is indicated in trauma-exposed populations.

Objective: This pilot randomized controlled trial (RCT) aims to evaluate the feasibility and acceptability of PM+, adapted to Syrian, Eritrean and Iraqi refugee youth residing in the Netherlands, with and without a newly developed Emotional Processing (EP) Module.

Methods: Refugee youth ($N = 90$) between 16 and 25 years of age will be randomized into PM+ with care-as-usual (CAU), ($n = 30$), PM+ with Emotional Processing (PM+EP) with CAU ($n = 30$) or CAU only ($n = 30$). Inclusion criteria are self-reported psychological distress (Kessler Psychological Distress Scale; $K10 > 15$) and impaired daily functioning (WHO Disability Assessment Schedule; $WHODAS 2.0 > 16$). Participants will be assessed at baseline, one-week post-intervention and three-month follow-up. The main outcome is the feasibility and acceptability of the adapted PM+ and PM+EP. The secondary outcomes are self-reported psychological distress, functional impairment, post-traumatic stress disorder (PTSD) symptom severity and diagnosis, social support, and self-identified problems. The pilot RCT will be succeeded by a process evaluation including trial participants, participants' significant others, helpers, and mental health professionals ($n = 20$) to evaluate their experiences with the PM+ and PM+EP programmes.

Results and Conclusion: This is the first study that evaluates the feasibility of PM+ for this age range with an emotional processing module integrated. The results may inform larger RCTs and implementation of PM+ interventions among refugee youth.

Trial Registration: Registered to Dutch Trial Registry, NL8750, on 3 July 2020. Medical Ethical Committee of the Amsterdam University Medical Centre, location Vrije Universiteit Medical Centre, Protocol ID: 2020.224, 1 July 2020.

Viabilidad y aceptabilidad del programa Enfrentando Problemas Plus con Procesamiento Emocional (EP+PE) para jóvenes refugiados que viven en los Países Bajos: Protocolo de investigación

Antecedentes: Los jóvenes refugiados experimentan dificultades relacionadas con la exposición al trauma en sus países de origen, tanto durante como después del desplazamiento. Esto resulta en tasas más elevadas de trastornos mentales comunes. La Organización Mundial de la Salud (OMS) desarrolló el programa Enfrentando Problemas Plus (EP+), una intervención psicológica breve brindada por personal no especializado para individuos que han sido expuestos a la adversidad. EP+ abarca la resolución de problemas, el manejo del estrés, la activación conductual y el fortalecimiento del soporte social. Sin embargo, no incluye un componente de procesamiento emocional, el cual es indicado en poblaciones expuestas al trauma.

Objetivo: Este piloto de un ensayo clínico controlado y aleatorizado (ECA) tiene como objetivo evaluar la viabilidad y la aceptabilidad de EP+ adaptado para jóvenes refugiados sirios, eritreos

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关键词

难民青年; 可塑干预; 常见心理健康问题; 抑郁; 焦虑; 创伤后应激障碍

HIGHLIGHTS

- This protocol describes a feasibility study in which an adapted version of Problem Management Plus (PM+) with an Emotional Processing module is evaluated for refugee youth.
- The findings will also indicate the feasibility of training non-specialists to deliver this intervention.

e iraquíes que residen en los Países Bajos, con y sin un módulo de Procesamiento Emocional (PE) recientemente desarrollado.

Métodos: Se aleatorizará a un grupo de refugiados jóvenes ($N=90$) de entre 16 a 25 años a un grupo EP+ con atención habitual (AH), ($n=30$), a un grupo EP+ con Procesamiento Emocional (EP+PE) con AH ($n=30$), o un grupo de solamente AH ($n=30$). Los criterios de inclusión son el completar los cuestionarios de autoreporte de malestar psicológico (Escala de Malestar Psicológico de Kessler; $K10 >15$) y de deterioro del funcionamiento diario (Cuestionario de Evaluación de la Discapacidad de la OMS; WHODAS 2.0 >16). Los participantes serán evaluados al inicio del estudio, una semana después de la intervención y a los 3 meses del seguimiento. El resultado principal es la viabilidad y aceptabilidad del programa EP+ adaptado y del EP+PE. Los resultados secundarios son el autoreporte de malestar psicológico, la discapacidad funcional, los síntomas de severidad y diagnóstico del trastorno de estrés posttraumático (TEPT), el soporte social y los problemas autoidentificados. Luego de concluido el piloto del ECA, se procederá a una evaluación del proceso que incluirá a los participantes del ensayo, a las personas significativas de los participantes, a los colaboradores y a los profesionales de la salud mental ($n=20$) para evaluar sus experiencias con los programas EP+ y EP+PE.

Resultados y conclusiones: Este es el primer estudio que evalúa la viabilidad de EP+ para este grupo de edad y con un módulo integrado de procesamiento emocional. Los resultados pueden brindar información al elaborar ECAs más grandes y a la implementación de intervenciones de EP+ entre jóvenes refugiados.

问题管理增强版与情绪加工 (PM+EP) 对居住在荷兰的难民青年的可行性和可接受性:研究方案

背景: 难民青年经历了在家乡以及移居期间和之后创伤暴露相关的困境, 这导致了更高的常见精神障碍发生率。世界卫生组织 (WHO) 为面临逆境的个人开发了问题管理增强版 (PM+), 一种非专业人士的简短心理干预。PM+ 包括解决问题, 压力管理, 行为激活和加强社会支持。然而, 它不包括在创伤暴露人群中有所体现的情绪加工部分。

目的: 本初步随机对照试验 (RCT) 旨在评估有或无新开发的情绪加工 (EP) 模块的 PM+ 适用于居住在荷兰的叙利亚, 厄立特里亚和伊拉克难民青年的可行性和可接受性。

方法: 年龄在 16 至 25 岁之间的难民青年 ($N=90$) 将随机分为 PM+ 与常规护理组 (CAU) ($n=30$), PM+ 和情绪加工 (PM+EP) 与 CAU 组 ($n=30$) 或仅 CAU 组 ($n=30$)。纳入标准是自我报告的心理困扰 (Kessler 心理困扰量表; $K10 >15$) 和受损的日常功能 (WHO 残障评估表; WHODAS 2.0 >16)。参与者将在基线, 干预后一周和三个月随访时接受评估。主要结果是调整后的 PM+ 组和 PM+EP 组的可行性和可接受性。次要结果是自我报告的心理困扰, 功能障碍, 创伤后应激障碍 (PTSD) 症状的严重程度和诊断, 社会支持和自我认同的问题。初步 RCT 将通过包括试验参与者, 参与者的主要他人, 帮助者和心理健康专业人员 ($n=20$) 的过程评估来完成, 以评估他们在 PM+ 和 PM+EP 计划中的体验。

结果和结论: 这是第一项通过整合情绪加工模块对此年龄段评估 PM+ 可行性的研究。结果可能会为更大的 RCT 和在难民青年中实施 PM+ 干预提供信息。

1. Background

Every year thousands of people have to leave their countries due to large-scale conflicts, wars, and disasters. The number of forcibly displaced people worldwide reached 79.5 million at the end of 2019, with about half of them being children (UNHCR, 2020).

Eventhough many conflict-affected children manifest resilience (Sleijpen, Haagen, Mooren, & Kleber, 2016), evidence suggests an increased risk of developing poor mental health outcomes (Fazel & Betancourt, 2018). However, studies focusing on adolescent refugees are limited. The prevalence of common mental disorders in young refugees in high-income countries (HICs) is substantially higher than their non-refugee counterparts; 10.3% vs. 32.8%, for depression; 19.0% vs. 52.7% for posttraumatic stress disorder (PTSD); and 8.7% vs. 31.6% for anxiety disorders (Kien et al., 2019). A recent study among Swedish youth (19–25 years) has shown that PTSD stands out as a major disorder among young refugees. Compared to Swedish-born youth, unaccompanied refugees had

a nearly six-fold elevated risk, and accompanied refugees had a three-fold higher risk of PTSD (Björkenstam et al., 2020).

There is a concerning gap between the high prevalence of mental health problems in refugee youth and the utilization of mental health services. Studies in HICs showed that refugee youth utilize mental health services less than their host-country peers, such as in Denmark (Barghadouch et al., 2016) and the Netherlands (Bean, Eurelings-Bontekoe, Mooijaart, & Spinhoven, 2006). Barriers to seeking mental health care include language problems, lack of knowledge about the health system, cultural differences and stigma (Sijbrandij et al., 2017).

To address these barriers, scalable and culturally sensitive treatments that are delivered by trained non-professional helpers from the communities have been developed. These helpers usually have the same cultural background as the people to whom they deliver interventions. One such intervention is Problem Management Plus (PM+; WHO, 2016), which aims

to relieve common mental disorders through simplified evidence-based strategies such as problem-solving and behavioural activation (Dawson et al., 2015). Several studies have demonstrated its effectiveness in adults through individual (Bryant et al., 2017; Rahman et al., 2016) and group format (Rahman et al., 2019). Even though the intervention is mainly designed for communities affected by crises in low- and middle-income countries (LMICs), it might be feasible for refugees in HICs (de Graaff et al., 2020). Up to today, PM+ studies included adults (over 18 years old) and this is the first PM+ study including participants under age 18.

PM+ is a transdiagnostic intervention, which is desirable for refugee populations who exhibit high levels of comorbidity. However, PM+ lacks a trauma-specific component (e.g. exposure) which is indicated for populations with relatively high levels of PTSD (ISTSS, 2018). PM+ was effective at reducing PTSD symptoms at 3-month follow-up assessments (Rahman et al., 2016, 2019), even without retrieval of traumatic memories being a component of the intervention. To further elucidate the contribution of traumatic memory retrieval in reducing PTSD symptoms, this study seeks to compare PM+ with PM+ including an emotion processing component (PM+EP). During EP, participants will be asked to identify one significant distressing memory and two pleasurable memories, which is added to a graphical representation (a jigsaw puzzle with three pieces, each piece representing a significant event). By constructing a life story, the participant is provided the opportunity to adequately contextualize significant events, which may facilitate the recognition of interrelated emotional networks of experiences (cf., Schauer, Neuner, & Elbert, 2005). Since this module will be added to a transdiagnostic intervention to reduce psychological distress, the distressing event may be a traumatic event, or any other adverse event with negative impact. Previous research has shown that interventions that include exposure to traumatic memories can be safely administered to adolescents by task-shifting (Rossouw, Yadin, Alexander, & Seedat, 2018). Further, studies have shown that processing positive memories can also result in positive mental health outcomes (Contractor, Banducci, Jin, Keegan, & Weiss, 2020) so we included pleasurable events as well. We investigate whether this module will be feasible for refugee youth, and acceptable in promoting psychosocial functioning.

The primary objective of this pilot randomized controlled trial (RCT), is to evaluate the feasibility and acceptability of the PM+ and PM+EP intervention for Syrian, Eritrean and Iraqi refugee youth in the Netherlands. Additionally, this pilot RCT aims to assess the trial procedures in preparation for a future larger RCT evaluating the effectiveness of PM+ interventions with refugee youth.

2. Method/design

2.1. Design and setting

The current study is embedded in the REMAIN project, coordinated by the department of clinical neuroscience at Karolinska Institutet in Sweden. The pilot RCT will be conducted in a community setting in the Netherlands. The study consists of three arms comparing adapted individual PM+ with Care-as-Usual (PM+/CAU), PM+EP with CAU (PM+EP/CAU) and CAU only (see Figure 1).

2.2. Participants

Participants will be Syrian, Eritrean and Iraqi asylum-seeking and refugee youth, between 16 and 25 years of age, living in the Netherlands. These three refugee groups constitute the top three conflict-affected asylum-seeking groups in the Netherlands for this age range (Central Bureau for Statistics, 2020). We chose this age category to align it with the other studies within REMAIN.

Eligible participants will have (1) elevated levels of psychological distress measured by the Kessler-10 Psychological Distress Scale (K10 > 15; Kessler et al., 2002) and (2) reduced psychosocial functioning measured by the WHO Disability Assessment Schedule (WHODAS 2.0 > 16; WHO, 2010). Exclusion criteria are (1) an acute medical condition, (2) imminent suicide risk (assessed by PM+ manual suicidal thought interview), (3) indication of psychotic disorders and substance-dependence (assessed by PM+ manual observation checklist), (4) indication of severe cognitive or neurological impairment (assessed by PM+ manual observation checklist), (5) receiving specialized mental health treatment and (6) change in dosage of psychotropic medicine during the past two months.

Participants who have received one of the active treatments, their family members or close others, PM+ facilitators (helpers), and mental health specialists within participating organizations will be invited for the process evaluation.

2.3. Procedure

Participants for the RCT will be approached through varied community sources including service providers, non-government organizations (NGOs), and social media. All participants will provide oral and written informed consent, either in Dutch or in their native language. Consenting participants will be invited to complete self-report screening measures for the psychological distress by the K10 and the assessing functional impairments by the WHODAS 2.0. Demographic information will be collected and their eligibility as per the exclusion criteria will be assessed. Eligible participants will be invited for the

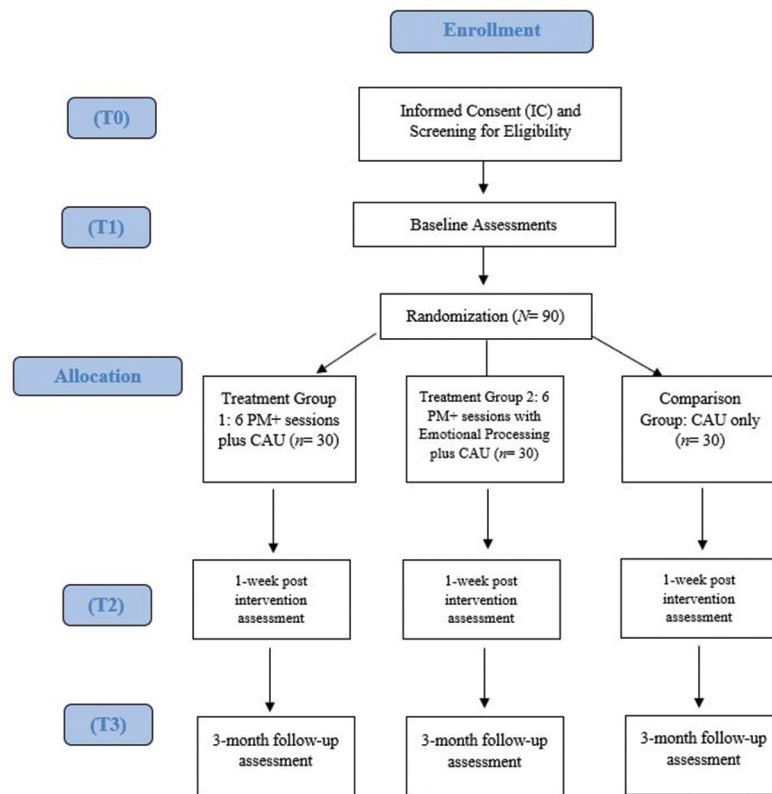


Figure 1. CONSORT diagram.

baseline assessment. Participants will then be randomized into one of the three conditions (PM+/CAU, PM+EP/CAU, or CAU). Those allocated to the intervention groups (PM+/CAU and PM+EP/CAU) will be assigned to a helper to schedule sessions. The first session will take place no longer than one week after the pre-intervention assessment. The assessments and sessions will be administered through teleconferencing, when COVID-19 restrictions require to do so, or participants prefer this.

The post-intervention assessment will take place within 1 week after completion of the sixth session

(participants can take up to 11 weeks to complete six sessions). The follow-up assessment will be conducted three months after the sixth PM+ session (i.e. 4 months and 2 weeks after baseline) (see Table 1).

2.3.1. Assessors

Trained and supervised assessors will carry out the consent and screening procedures. They will be blinded to the allocation of the participants and assist them during the assessments if needed. The assessors will be recruited by the VU and receive a three-day training on questionnaire administration, basic

Table 1. Overview of the measures.

Concept	Measure	Administration and Number of Items	Assessment time periods				
			Screening	Baseline	PM+/PM+ EP sessions	1-week post-int.	3-month follow-up
Daily Functioning	WHODAS 2.0	SR: 12 items				✓	✓
Psychological Distress	K10	SR: 10 items	✓				
Suicidal thoughts	PM+ manual interview	INT	✓				
Severe disorders	PM+ manual checklist	INT	✓				
Psychological distress	HSCL-25	SR: 25 items	✓				
Adverse life events	Trauma Experiences Checklist	SR: 27 items		✓		✓	✓
Self-identified problems	PSYCHLOPS	SR: 4 items		✓			✓
Social Support	Bonding Social Capital	SR: 1-item		✓		✓	✓
Post-migration stressors	PMLD	SR: 20 items		✓		✓	✓
PTSD Symptom Severity/ Diagnosis	CAPS-5	INT		✓		✓	✓
Range of Services Reached	CSRI	SR: 2-items		✓			✓
Treatment fidelity	PM+ checklist	SR (helper)			✓		✓

SR: Self-report; INT: Interview; WHODAS 2.0: WHO Disability Assessment Schedule 2.0; K10: 10-item Kessler Psychological Distress Scale; HSCL-25: Hopkins Symptom Checklist-25; PSYCHLOPS: Psychological Outcomes Profiles; PMLD: Post-Migration Living Difficulties; CSRI: Client Service Receipt Inventory; CAPS-5: Clinician-Administered PTSD Scale for DSM-5.

interviewing skills, common mental health disorders, psychological first aid (PFA) and ethics of research. There will be at least two assessors, one fluent in Arabic the other fluent in Tigrinya. Both assessors will be fluent in Dutch.

2.3.2. Process evaluation

After the trial, participants will be approached for the process evaluation by using purposive sampling to reach maximum variation. For the PM+ treatment groups, participants will be approached to ensure variation in terms of their gender, age, country of origin, PM+ intervention (PM or PM+EP) and completion of the programme (drop out/completed). Family members or close others of the consenting participants will be interviewed. Helpers will be approached considering the variation in gender, age, country of origin, and the type of PM+ programme provided. PM+ trainers/supervisors will be directly approached to participate in the interviews.

The main aim of the process evaluation is to understand the perceptions of the key actors took part in this study about the feasibility of the intervention and the possibility of scaling up. Using a semi-structured topic list with interview questions, participants will be asked their overall impressions on the intervention, rapport with the PM+ helper, intervention adherence, feasibility of assessment procedures and integration of PM+ to Dutch healthcare.

2.4. Sample size

Since this is a pilot feasibility trial no power calculations have been carried out. A total number of 90 refugee youth (30 in each arm) will be included in the study, allowing us to evaluate the feasibility and acceptability of the intervention in the proposed setting, as well as drop-out rates for a future definitive trial. For the process evaluation, 20 participants will be interviewed.

2.5. Randomization

An independent researcher, not involved in the study, will carry out randomization using a random numbers table generated by computerized software. Randomization will be done on a 1:1:1 basis, stratified by the cultural background of the participant (Syrian, Eritrean, Iraqi) in random block sizes of 3, 6 and 9.

2.6. Instruments

2.6.1. Screening measures

The K10 (Kessler et al., 2002) will be used to screen for psychological distress during the last 30 days. The questions are rated on a scale of 1 to 5, with the total score ranging from 10 to 50 and higher scores

representing higher levels of distress. The K10 has been used with adolescent populations in prior research (Jaisooriya et al., 2017). In the current study, we will use a score of >15 in line with previous studies with refugee populations (e.g. de Graaff et al., 2020). The instrument is available in Arabic (Sulaiman-Hill & Thompson, 2010), Tigrinya (Asfar, Born, Oostrom, & van Vugt, 2019) and Dutch (Fassaert et al., 2009).

The WHODAS 2.0 measures health and disability on the following six domains: 1) Cognition, 2) Mobility, 3) Self-care, 4) Getting along, 5) Life activities, and 6) Participation (WHO, 2010). Difficulties are scored on a 1 (*none*) to 5 (*extreme*) scale, higher scores indicating worse functional impairment (range: 12–60). We will use a score of >16 as an indication of decreased functionality (cf. Bryant et al., 2017). To make the WHODAS 2.0 a better fit for youth, minor changes were applied: ‘Taking care of your household responsibilities?’ was changed into ‘Participating in household chores’. Community activities listed under item 4 (*festivities, religious or other activities*) were replaced with *clubs, after school activities, religious or other activities*. The WHODAS 2.0 has an Arabic version (cf. de Graaff et al., 2020) and it will be translated to Tigrinya and Dutch.

2.6.2. Feasibility measures

The primary outcome of this study will be the feasibility and acceptability of the delivery of PM+ and PM+EP in refugee youth. Feasibility will be decided on using the following criteria: a) 70% recruitment and consent rates, b) 70% attendance of sessions and assessments, c) 75% protocol adherence, d) maximum 10% presence of adverse events and no serious adverse events, e) fewer than 15% missing items on outcome measures, and f) qualitative assessments from the process evaluation (see Table 2).

2.6.3. Other measures

Secondary outcome measures will be administered to inform about possible effectiveness and preparation for a future definitive trial of PM+EP (see Table 1). The Hopkins Symptom Checklist-25 (HSCL-25) assesses symptoms of depression and anxiety. The items are rated on a 4-point Likert scale, ranging from 1 (never) to 4 (always) (range = 25–100). The depression subscale includes 13 items, the anxiety subscale includes 10 items and 2 items correspond to somatic symptoms. The Arabic (de Graaff et al., 2020) and Tigrinya (Jesuthasan et al., 2018) translations of the instrument are available.

Potential trauma exposure will be assessed using checklist of 23 types of traumatic events, which has been developed and used with refugee populations (de Graaff et al., 2020; Nickerson et al., 2015). The Arabic version is available (de Graaff et al., 2020) and it will be translated into Tigrinya for this study.

Table 2. Feasibility measures.

Outcome Measure	Explanation	Time point	Criteria
Recruitment and the consent rates	Percentage of acceptance rate and number of youth recruited	Baseline	At least 70% of the target
Attendance to the sessions & follow-up assessments	Attendance of study participants in each arm to sessions and assessments throughout the trial and drop-out rates	During the trial	At least 70% of the participants completes all sessions and assessments
Fidelity to the protocols	Through fidelity checklists, research team will assess the rate of adherence to the intervention protocol	During the trial	At least 75% or greater
Presence of adverse or serious adverse events	Number of adverse events and serious adverse events will be compared across the three groups	During the trial	AE fewer than 10% of the participants and no SAE
The feasibility and acceptability of intervention outcome measures	Evaluation of outcome measures, completion rates and estimation of differences across the three groups	During the trial	Fewer than 15% missing items on outcome measures in all assessments
Views of participants, families, helpers, supervisors and stakeholders about the implementation	Semi-structured interview data from the process evaluation will be used	After the trial ended	Qualitative data will be coded for themes

PTSD symptom severity and diagnosis will be established with the Clinician Administered PTSD Scale for DSM-5 (CAPS-5) (Weathers et al., 2013). The CAPS-5 can be used with people older than 16 years old. The CAPS-5 is composed of seven clusters (from A to G) corresponding to the PTSD diagnostic criteria in the DSM-5 (American Psychiatric Association, 2013). Each diagnostic criterion is rated from 0 to 4 (0 = absent to 4 = extreme/incapacity). Total symptom severity (range: 0–80) is calculated by summing up the first 20 PTSD symptoms. When the symptom severity score is rated 2 (moderate/threshold) or higher, a symptom is considered as present. The presence of at least one Criterion B (intrusion), Criterion C (avoidance), Criterion D (cognitions and mood), and two Criterion E (arousal and reactivity) symptoms are needed for a diagnosis. In addition, Criterion F (duration of the disturbance) and Criterion G (distress or impairment) must be met (cf. DSM-5; American Psychiatric Association, 2013). A Dutch version of CAPS-5 is available (Boeschoten et al., 2014). CAPS-5 will be translated to Arabic and Tigrinya for this study.

The Psychological Outcomes Profiles (PSYCHLOPS) will be used to indicate the client's perspective of change in their psychological distress level after therapy (Ashworth et al., 2004). The PSYCHLOPS has four questions measuring three domains; the problem(s) bothering the individual (two questions), how these problem(s) affect the daily functioning and wellbeing of the individual. Scores range from 0 to 5 and higher scores represent more psychological difficulty (range = 0–20). An Arabic version is available (de Graaff et al., 2020) and Dutch and Tigrinya translations will be made.

To measure social support, a 1-item question of 'bonding social capital', from the Stockholm Public Health Cohort (Svensson et al., 2013) will be used (Johnson, Rostila, Svensson, & Engström, 2017). Participants will be asked: 'Do you know any people who can provide you with personal support for personal problems or crises in your life?'. The response will

be categorized as 'high social support' or 'low social support'. The item will be translated to Arabic, Tigrinya and Dutch.

Post-Migration Living Difficulties Checklist (PMLD; Steel, Silove, Bird, McGorry, & Mohan, 1999) will be used to measure the level of post-migration challenges during the last 12 months. Items are rated on a five-point scale (0: not a problem to 4: a very serious problem). Items scored at least 3 (a serious problem) are considered positive responses, yielding a total count of living difficulties. For this study, three new items were added ('Bullying or being rejected by peers', 'Worries about future education and/or work', and 'Arguments with parents over new friends and/or hobbies') which makes the total item number 20. Additionally, the item 'Difficulties with employment' is changed into 'Difficulties with education/employment' and 'teachers' were added to the item 'Conflicts with social workers/other authorities'. The Arabic version is available (de Graaff et al., 2020). It will be translated into Tigrinya for this study.

A modified version of Client Service Receipt Inventory (CSRI) (Beecham & Knapp, 1992) will be used to track all the health care services the participants received. CSRI will be administered in the baseline and in the follow-up assessment. The number of contacts with different types of community health services and psychotropic medication use in the last 3 months will be assessed. It will be translated to Dutch, Arabic and Tigrinya for the study.

2.6.4. Translation and adaptation of the measures

The WHO guidelines on the translations and adaptation of research instruments will be followed (WHO, 2018). In case there is no available translations and back-translations will be carried out by native speakers. Conflicting items will be discussed individually. Through cognitive interviews, the measures will be pilot-tested.

2.7. Interventions

The generic PM+ manual (WHO, 2016) was adapted according to a cultural adaptation framework (Bernal, Bonilla, & Bellido, 1995). Qualitative interviews with Eritrean ($n = 16$), Syrian ($n = 10$) and Afghan ($n = 8$) refugee youth, policymakers ($n = 5$), professionals ($n = 9$), and key people from the communities (4 Eritreans, 3 Syrians and 3 Afghans) were conducted. Two separate focus group discussions with Eritrean ($n = 6$) and Syrian ($n = 5$) youth were carried out (cf. Applied Mental Health Research Group, 2013). Following this work, the research team decided to change one of the target groups from Afghans to Iraqis since there are more Iraqi youth in the Netherlands than Afghan youth for this age range. Culture- and age-specific changes to the language, examples, illustrations, and structure were made. The adapted versions (PM+ and PM+EP) consist of six face-to-face, individual PM+ or PM+EP sessions, each 75 minutes. Details of the formative work will be published elsewhere.

2.7.1. Problem Management Plus (PM±/CAU)

Participants in the PM+/CAU group will receive sessions including: 1) Managing Stress (sessions 1 to 5), 2) Managing Problems (sessions 2 to 5), 3) Get Going Keep Doing (sessions 4 and 5), 4) Strengthening Social Support (session 5) and 5) Staying Well (session 6) modules from the generic PM+ with minor reductions in the duration (see Table 3). In sessions 3, 4 and 5 there will be non-directive supportive counselling (NDSC) equal to the time the other group received the 'Emotional Processing' module. NDSC can be defined as an unstructured part of the session where the helpers do not aim to teach any new strategies, do not discuss distressing or traumatic events, but just empathically listen to the client (Areán et al., 2010). The helpers will follow the protocol for NDSC and just listen the participant, reframe what they are saying, and reflect emotions in a non-directive way. The helpers will ask questions only about daily issues and will not talk about prior difficult life events. In all sessions, the time spent on each module will be kept equal across two groups.

2.7.2. Problem Management Plus with Emotional Processing Module (PM±EP/CAU)

The second treatment group will receive PM+ with a newly developed emotional processing module combined with CAU (PM+EP/CAU). The novelty of PM+EP is the 'Emotional Processing' module which will be introduced in session 3. This module is named 'Managing Emotions and Memories'. In this module,

participants will be asked to imagine significant memories as pieces of a jigsaw puzzle. Every participant will choose three memories, two pleasurable memories and one distressing memory. Through talking about the significant life events (puzzle pieces), the thoughts, the emotions, and the future perspectives, this module aims to process these memories. Participants will be asked to rate the intensity of emotions before and after they talk about their memories each time.

Participants assigned to the PM+EP will receive; 1) Managing Stress (session 1 to 5), 2) Managing Problems (sessions 2 to 5), 3) Emotional Processing (sessions 3 to 5), 4) Get Going Keep Doing (sessions 4 and 5), 5) Strengthening Social Support (session 5) and 6) Staying Well (session 6) modules. In all sessions, in addition to the new modules, the previously introduced modules will also be reviewed.

2.7.3. Care-as-Usual

Care-as-Usual (CAU) refers to all health and mental health services available to refugee youth in the Netherlands. These may include basic mental health care or referral to specialized mental health care services by general practitioners, or health care delivered in the asylum centres.

2.8. Helpers and PM+ trainers/supervisors

The PM+ and PM+EP interventions will be delivered by helpers who are Syrian, Eritrean or Iraqi refugees with at least a high school degree, matched to the participants according to their cultural backgrounds. They will be native speakers of either Arabic or Tigrinya, and have sufficient speaking ability in Dutch or English. The helpers will receive a 9-day training that focuses on PM+ strategies as well as on the common mental health problems, basic counselling skills and self-care strategies (Rahman et al., 2016), and the Emotional Processing module. Following training, helpers will be required to complete one practice case. They will receive weekly group supervision throughout the programme by a PM+ supervisor.

The PM+ trainers and supervisors will be mental health professionals who received a five-day training-of-trainers (ToT). The ToT will be provided by an experienced PM+ trainer and include information on PM+ strategies and supervision skills. The PM+ supervisors will receive regular supervision from a PM+ master trainer.

2.9. Fidelity check

Protocol adherence will be assessed in two ways. Firstly, helpers will be asked to fill in a session-by-session checklist after each session. In this checklist, they will indicate which of the main components of the PM+ (including NDSC) or PM+EP they have completed for that specific

Table 3. Session structures.

	PM+	PM+EP
Session 1	Introduction and what is PM+ (25 minutes) Understanding Adversity (25 minutes) Managing Stress (20 minutes) Closure (5 minutes)	Introduction and what is PM+ (25 minutes) Understanding Adversity (25 minutes) Managing Stress (20 minutes) Closure (5 minutes)
Session 2	General review (10 minutes) Managing Problems (55 minutes) Managing Stress and closure (10 minutes)	General review (10 minutes) Managing Problems (55 minutes) Managing Stress and closure (10 minutes)
Session 3	General review and introduction (5 minutes) Managing Problems (30 minutes) Non-Directive Supportive Counselling (30 minutes) Managing Stress and closure (10 minutes)	General review and introduction (5 minutes) Managing Problems (30 minutes) Managing Emotions and Memories (30 minutes) Managing Stress and closure (10 minutes)
Session 4	General review and introduction (5 minutes) Managing Problems (15 minutes) Non-Directive Supportive Counselling (15 minutes) Get Going, Keep Doing (30 minutes) Managing Stress and closure (10 minutes)	General review and introduction (5 minutes) Managing Problems (15 minutes) Managing Emotions and Memories (15 minutes) Get Going, Keep Doing (30 minutes) Managing Stress and closure (10 minutes)
Session 5	General review and introduction (5 minutes) Managing Problems (10 minutes) Non-Directive Supportive Counselling (15 minutes) Get Going, Keep Doing (10 minutes) Strengthening Social Support (25 minutes) Managing Stress and closure (10 minutes)	General review and introduction (5 minutes) Managing Problems (10 minutes) Managing Emotions and Memories (15 minutes) Get Going, Keep Doing (10 minutes) Strengthening Social Support (25 minutes) Managing Stress and closure (10 minutes)
Session 6	General review and introduction (5 minutes) Staying Well (30 minutes) Imagining How to Help Others (20 minutes) Looking to the future (15 minutes) Ending the programme (5 minutes)	General review and introduction (5 minutes) Staying Well (30 minutes) Imagining How to Help Others (20 minutes) Looking to the future (15 minutes) Ending the programme (5 minutes)

session. Second, audio-recordings of sessions will be taken if participants provide informed consent for recording. A random sample of 10% of recordings will be scored independently by two research assistants. The interrater-reliability for the audio recordings will be computed by using Cohen's kappa (κ).

2.10. Adverse event reporting

Adverse Events (AEs) can be defined as any undesirable experience occurred to a study participant during the trial, whether or not related to the PM+ or PM+EP interventions. A serious adverse event (SAE) is any medical occurrence that results in death; is life threatening; requires hospitalization or longer stay of existing inpatients' hospitalization; results in persistent or significant disability; or any other important medical event that is not necessarily related to the interventions. All AEs and SAEs will be recorded, and SAEs will be reported to the Medical Ethics Committee of the Amsterdam University Medical Center (UMC), location Vrije University Medical Center (VUmc). All AEs and SAEs will be followed until they are resolved and referrals to the relevant specialists will be done when necessary.

3. Analysis

To evaluate the feasibility and acceptability of the interventions, qualitative analysis will be used, and quantitative analysis will be used to inform the design of a possible future definitive RCT. To measure comparisons between the three groups, one-way ANOVAs

(continuous variables) or chi-squared tests (categorical variables) will be conducted for normally distributed data; Kruskal–Wallis tests will be conducted for continuous non-normally distributed data.

For the feasibility evaluation, intervention-specific analysis (fidelity, attendance of the sessions) will be carried out to compare the two intervention groups (PM+/CAU, PM+ EP/CAU), whereas the others will be carried out across all three groups. The qualitative process evaluation data will be analysed following thematic analysis by ATLAS.ti Scientific Software, version 8.4.

To estimate the possible effectiveness for a future trial, intention-to-treat (ITT) analysis will be employed. To estimate the effects of PM+/CAU, PM + EP/CAU and treatment effect, linear mixed model analyses will be employed comparing the three groups in terms of HSCL-25, PSYCHLOPS, PMLD, CAPS-5 (subscale scores and total scores), trauma experiences and social support. The linear mixed models will have treatment as fixed effects, baseline measurement of the endpoints as covariates, and subject as random effects. The mean differences between the three treatment arms at each visit/time together with its 95% confidence interval will be derived from the mixed model. SPSS will be used for the descriptive analysis and the linear mixed modelling analysis will be done in R version 3.6.0. No interim analyses will be carried out.

4. Ethics

This study was approved by the Medical Ethical Committee of the Amsterdam UMC, location VUmc

(Protocol ID: NL72668.029.20, 1 July 2020) and embedded in the Mental Health Program of the Amsterdam Public Health (APH) Research Institute. Additionally, a team of international researchers have reviewed the adapted PM+ and PM+ EP protocol.

5. Discussion

In this pilot RCT, we aim to evaluate the feasibility and acceptability of culturally and contextually adapted PM+ and PM+EP among Syrian, Eritrean and Iraqi refugee youth in the Netherlands, who are impaired by psychological distress and show decreased psychosocial functioning. Another aim is to assess the trial procedures in preparation for a larger RCT on the effectiveness of these interventions.

PM+ individual has already been tested with favourable outcomes among adults in LMICs including Kenya (Bryant et al., 2017) and Pakistan (Rahman et al., 2016). A pilot RCT showed positive outcomes in the Netherlands, with Syrian refugees above 18 years old (de Graaff et al., 2020). This study will be the first to focus on evaluating individual PM+ and the newly added emotional processing module to PM+ aimed to reduce PTSD in refugee youth between the ages of 16 to 25.

While mental health services are available for refugee youth in the Netherlands, there are certain barriers to accessing and engaging in such services (van der Boor & White, 2020). This intervention offers a potentially more acceptable service that can attract more refugee youth. The findings from this study would help us advocate for scaling up PM+ in the Netherlands if it is found to be a feasible and acceptable intervention. Further, the findings regarding the new emotional processing module would give us insight into the feasibility and acceptability of delivering exposure elements to refugee youth by non-specialized mental health workers.

Data availability statement

Since this is a manuscript describes a study protocol; currently, no data set is available. Due to privacy reasons, the data will be made available only on request to the Principal Investigator, Prof. Marit Sijbrandij (e.m.sijbrandij@vu.nl), after the trial begins.

Disclosure statement

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

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