

# REMAIN: Feasibility and Acceptability of Problem Management Plus (PM+) for Refugee Youth Living in the Netherlands

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We expect to see that Problem Management Plus is a feasible and acceptable intervention for Syrian, Eritrean and Iraqi refugee youth.

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving nog niet gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON24354

### Bron

NTR

### Verkorte titel

REMAIN

### Aandoening

Common mental disorders  
Depression  
Anxiety  
Post-traumatic stress disorder  
Scalable interventions  
Refugee youth

### Ondersteuning

**Primaire sponsor:** Vrije Universiteit Amsterdam

**Overige ondersteuning:** Swedish Research Council

### Onderzoeksproduct en/of interventie

# Uitkomstmaten

## Primaire uitkomstmaten

The primary outcome of this study will be the feasibility and acceptability of PM+ interventions.

## Toelichting onderzoek

### Achtergrond van het onderzoek

In recent years, due to wars, conflicts, and natural disasters many people forcedly displaced from their countries of origin. According to the United Nations High Commissioner for Refugees (UNHCR), there are 68.5 million people forcibly displaced worldwide and almost half of the displaced people are minors under eighteen years old. This massive human movements not only affect individuals' psychological well-being but also created a need for new solutions for the responsiveness of health care systems of the hosting countries. With this need, World Health Organization (WHO) has developed Problem Management Plus (PM+), a brief, scalable, psychological intervention that can be delivered by trained non-professionals and addressing common mental health problems.

The main objective of this study is to evaluate the feasibility and acceptability of the culturally and contextually adapted WHO's PM+ intervention for Syrian, Eritrean, and Iraqi refugee youth living in the Netherlands. Additionally, this study aims to develop and incorporate a new Emotional Processing module (PM+ EP) to the adapted PM+. Another objective is to evaluate the feasibility and acceptability of PM+ with this new module.

Study participants (n= 90) include Syrian, Eritrean, and Iraqi refugee youth (age: 16 to 25) living in the Netherlands, with self-reported functional impairment (WHODAS 2.0>16) and elevated levels of psychological distress (K10>15). Participants will be randomized into one of the three study groups (PM+ intervention, PM+ intervention with emotional processing module, or Care-as-Usual). Participants in the first group (n= 30) will receive six sessions of Problem Management Plus (PM+) as well as care as usual (CAU). The second group (n= 30) will receive six-sessions of an adapted version of PM+, which includes an emotional processing module (PM+ EP) as well as CAU. The third group (n= 30) will receive CAU only.

The main study parameter will be the feasibility and acceptability of PM+ interventions. The feasibility criteria are composed of recruitment and consent rates, attendance, fidelity to the protocols, adverse events, and the perceptions about the PM+ interventions.

### Doel van het onderzoek

We expect to see that Problem Management Plus is a feasible and acceptable intervention for Syrian, Eritrean and Iraqi refugee youth.

## Onderzoeksopzet

- Baseline
- 1 week post-intervention assessment (7 weeks after baseline)
- 3 month post-intervention assessment (4.5-5 months after baseline)

## Onderzoeksproduct en/of interventie

There are three arms in this study.

### Treatment Group 1: Problem Management Plus (PM+) Program

The first treatment group will receive WHO's Problem Management Plus (PM+) program in addition to care-as-usual (CAU). PM+ is a brief, scalable psychological intervention developed by WHO and the University of New South Wales, Australia and delivered by trained non-professionals. It is based on cognitive behavioural therapy (CBT) techniques which are empirically supported and recommended by WHO (Dua et al., 2011). The manual involves the following techniques: stress management, problem-solving, behavioural activation, and accessing social support (WHO, 2016).

Up to today, different studies proved the effectiveness of PM+ in individual (Bryant et al., 2017; De Graaf et al., 2020; Rahman, Riaz, et al., 2016) and group format (Rahman et al., 2019). Even though the intervention mainly designed for LMIC, its feasibility has been evaluated for high resource countries as well (eg. De Graaf et al., 2020).

For this study, an adapted version of PM+ will be used and there will be six individual sessions.

### Treatment Group 2: Problem Management Plus (PM+) Program with an additional Emotional Processing Module

The second treatment group will receive CAU and PM+ with a newly developed Emotional Processing Module included. This new module will include psychoeducation about traumatic experiences, emotional processing of positive and negative life events and positive imagination about their future selves.

### The comparison group: Care-as-usual (CAU)

The comparison group will receive CAU only. CAU for refugee adolescents in the Netherlands corresponds to primary health care, education, social protection services, and specialized psychological treatment programs.

## Contactpersonen

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## **Wetenschappelijk**

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## **Deelname eisen**

### **Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)**

- 16 to 25 years old
- Syrian, Eritrean or Iraqi background
- Elevated levels of psychological distress (K10>15) and reduced psychosocial functioning (WHODAS 2.0>16)

### **Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)**

- Acute medical conditions
- Imminent suicide risk or expressed acute needs and protection risks.
- Severe mental disorder (psychotic disorders, substance-dependence)
- Severe cognitive impairment (e.g. severe intellectual disability)
- Currently receiving a psychological treatment within specialized mental health care
- In case of current psychotropic medication use: change in dosage during the past 2 months.

## **Onderzoeksopzet**

### **Opzet**

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

## Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2020
Aantal proefpersonen:	90
Type:	Verwachte startdatum

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

### Toelichting

N/A

## Ethische beoordeling

Positief advies	
Datum:	03-07-2020
Soort:	Eerste indiening

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

Register	ID
NTR-new	NL8750
Ander register	METc VUmc : METc Protocol No: NL 72668.029.20 (Phase 2)

## Resultaten

### Samenvatting resultaten

Bryant, R. A., Schafer, A., Dawson, K. S., Anjuri, D., Mulili, C., Ndogoni, L., . . . van Ommeren, M. (2017). Effectiveness of a brief behavioural intervention on psychological distress among women with a history of gender-based violence in urban Kenya: A randomised clinical trial. *PLOS Medicine*, 14(8), e1002371. doi:10.1371/journal.pmed.1002371

Dawson, K. S., Bryant, R. A., Harper, M., Kuowei Tay, A., Rahman, A., Schafer, A., & Van Ommeren, M. (2015). Problem Management Plus (PM+): A WHO transdiagnostic psychological intervention for common mental health problems. *World Psychiatry*, 14(3), 354–357. <https://doi.org/10.1002/wps.20255>

de Graaff, A. M., Cuijpers, P., Acarturk, C., Bryant, R., Burchert, S., Fuhr, D. C., . . . Sijbrandij, M. (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

Rahman, A., Hamdani, S. U., Awan, N. R., Bryant, R. A., Dawson, K. S., Khan, M. F., ... Van Ommeren, M. (2016). Effect of a multicomponent behavioral intervention in adults impaired by psychological distress in a conflict-affected area of Pakistan. A randomized clinical trial. *JAMA*, 316(24), 2609–2617. <https://doi.org/10.1001/jama.2016.17165>