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

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Primary Objective: To evaluate the feasibility and acceptability of the culturally and contextually adapted WHO*s PM+ intervention for Arabic, Tigrinya and Ukrainian speaking refugee youth living in the Netherlands.Secondary Objective:1. To evaluate...

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON56254

**Source**
ToetsingOnline

**Brief title**
Implementation of PM+ in refugee adolescents

### Condition

- Other condition
- Mood disorders and disturbances NEC

**Synonym**
anxiety, depression, distress, Psychological symptoms

**Health condition**

Psychological symptoms of anxiety, (posttraumatic) stress and depression

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Vrije Universiteit
**Source(s) of monetary or material Support:** Swedish Research Council

## Intervention

**Keyword:** Implementation and evaluation, Mental health, Psychological distress, Scaling-up psychosocial interventions

## Outcome measures

### Primary outcome

The primary study parameter for the pilot study 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.

### Secondary outcome

Secondary parameters will be the reduction in self-reported psychological distress scores, measured with the Hopkins Symptom Checklist (HSCL-25). Assessments of participants will take place before PM+, 1-week post-PM+ and 3 months follow-up for all groups.

# Study description

### Background summary

Common mental health problems are prevalent among refugee minors and impair their daily functioning. Due to various barriers such as lack of culturally appropriate treatments, waiting lists, and stigma they have limited access to care. Problem Management Plus (PM+) was developed by the World Health Organization to address these barriers. PM+ is transdiagnostic, is delivered by

non-professional helpers, and consists of 5 sessions of problem-solving skills, behavioural activation and stress management. Currently, PM+ does not consist of a trauma processing module specifically targeting symptoms of PTSD. PM+ is effective in reducing adults* distress and improve functioning. We aimed to adapt PM+ for refugee minors and add an emotional processing module to target symptoms of posttraumatic stress disorder.

## Study objective

Primary Objective:
To evaluate the feasibility and acceptability of the culturally and contextually adapted WHO*s PM+ intervention for Arabic, Tigrinya and Ukrainian speaking refugee youth living in the Netherlands.

Secondary Objective:
1. To evaluate the feasibility and acceptability of PM+ with a newly developed Emotional Processing module (PM+ EP) among refugee minors in the Netherlands.
2. To assess the feasibility of the outcome measures in preparation of a future larger RCT evaluating the effectiveness of the adapted versions of PM+.

## Study design

Phase 1: A qualitative study for adaptation of PM+ manual to refugee adolescents living in the Netherlands (discussed in a seperate protocol, reference number: 2019.441).
Phase 2: An exploratory, single-blind pilot randomized controlled trial (RCT).
Phase 3: A qualitative study to evaluate the process following the pilot RCT.

## Intervention

There will be two treatment groups and one care as usual (CAU) comparison group in the pilot RCT phase. 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.

## Study burden and risks

Participants enrolled in the PM+ treatment group will receive six seventy-five-minute PM+ sessions, which will be audiotaped for supervision and monitoring. Participants enrolled in the PM+ EP group will also receive six seventy-five-minute adapted PM+ sessions that include emotional processing. Additionally, interested participants will be invited for a total of three assessment interviews including screening and post-assessments. These assessment interviews will be carried out by trained assessors and participants

will be asked to fill in questionnaires on daily functioning, psychological complaints, adverse experiences, and daily problems. These interviews will take approximately 2,5 hours.

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adolescents (16-17 years)
Adults (18-64 years)

## Inclusion criteria

- 16 to 25 years old
- Arabic, Tigrinya or Ukrainian speaking
- Elevated levels of psychological distress (K10>15) and reduced psychosocial functioning (WHODAS 2.0 (minor adaptations for adolescents)>16)

## Exclusion criteria

- 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 [Specialistische jeugdhulp or specialistische GGZ]
- In case of current psychotropic medication use: change in dosage during the past 2 months.
- Diagnosis of PTSD directly related to severe and repeated neglect, physical abuse,
and/or sexual abuse in childhood, identified by CAPS-V interview during the baseline
assessment.

# Study design

## Design

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| Study phase: | 3 |
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Active |
| Primary purpose: | Treatment |

## Recruitment

NL

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| Recruitment status: | Recruiting |
| Start date (anticipated): | 18-01-2022 |
| Enrollment: | 105 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 01-07-2020 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 22-09-2021 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 25-04-2022 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 07-12-2022 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 03-08-2023 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 31-07-2024 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
| --- | --- |
| CCMO | NL72668.029.20 |