STRENGTHS: Fostering responsive mental health systems in the Syrian refugee crisis

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Primary Objective:To evaluate feasibility, acceptability, effectiveness and cost-effectiveness of the culturally adapted PM+ intervention forSyrian refugees in The Netherlands.Secondary Objective(s):1. To translate and (culturally) adapt PM+ for use...

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

Summary

ID

NL-OMON53148

Source
ToetsingOnline

Brief title
Implementation of Problem Management Plus in Syrian refugees

Condition

- Other condition
- Mood disorders and disturbances NEC

Synonym
anxiety, depression, distress, Psychological symptoms

Health condition

Psychological symptoms of anxiety, (posttraumatic) stress and depression, anger, hair biomarkers

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Horizon2020 (European Union);SNTR (alleen voor studiefase 2)

Intervention

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

Outcome measures

Primary outcome

The main study parameter will be the decrease in psychological distress from

baseline to three-month follow-up, measured through the Hopkins Symptoms

Checklist (HSCL-25), a self-report measure for symptoms of psychological

distress. We expect a difference of Cohen*s d effect size of .4 between the PM+

group and controls.

Secondary outcome

Secondary parameters include functional impairment (WHODAS 2.0), posttraumatic

stress reactions (PCL-5), self-identified problems (PSYCHLOPS), cost of care

(CSRI schedule), anger (STAS-T), and hair biomarkers

Study description

Background summary

The current refugee crisis across the Middle East and Europe has large effects on individual refugees* psychological wellbeing, as well as on the healthcare systems of countries housing refugees. The WHO have developed Problem Management Plus (PM+), a brief (five-sessions), low-intensity psychological intervention, delivered by paraprofessionals, that addresses common mental

disorders in people in communities affected by adversity.

Study objective

Primary Objective:
To evaluate feasibility, acceptability, effectiveness and cost-effectiveness of the culturally adapted PM+ intervention for
Syrian refugees in The Netherlands.

Secondary Objective(s):
1. To translate and (culturally) adapt PM+ for use among Syrian refugees in The Netherlands (Study Phase 1, described in a separate protocol)
2. To obtain estimates of drop-out rates to inform a full-scale, definitive randomized controlled trial (Study Phase 2)
3. To understand the perceptions of key stakeholders with regards to PM+ intervention (Study Phases 3A and 5B)
4. To identify barriers and facilitators to accessing mental health care for Syrian refugees (Study Phase 3B)
5. To test effectiveness and cost-effectiveness of the PM+ intervention (Study Phase 4)

Study design

Study Phase 1, 3 and 5: Qualitative study
Study Phase 2: Exploratory, single-blind randomized controlled trial (RCT)
Study Phase 4: Definitive single-blind RCT

Intervention

Participants in the treatment group will receive five sessions of Problem Management Plus (PM+), and treatment as usual (TAU). PM+ is an evidence-based, low-intensity, psychological intervention and will be delivered by trained peer-refugees. The control group will receive TAU only.

Study burden and risks

Interested participants will be invited for a total of four interviews over a period of one year. The interviews include questionnaires on daily functioning and psychological complaints, adverse experiences, daily hassles and cost of care. The interview will take approximately 1.5hrs. Participants in the treatment group will receive five sessions PM+, which will be audiotaped for the purpose of supervision and monitoring.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

(Phase 2 and 4B, Exploratory randomized controlled trial (RCT) and Definite RCT)
- 18 years or above
- refugee
- Arabic-speaking
- Elevated levels of psychological distress (K10 >15.9) and reduced psychosocial functioning (WHODAS 2.0 >16)

Exclusion criteria

(for participants in phase 2 and 4B)
- Acute medical conditions
- Imminent suicide risk or with expressed acute needs/protection risks (e.g., a

young woman who expresses that she is at acute risk of being assaulted or killed)
- Severe mental disorder (psychotic disorders, substance-dependence)
- Severe cognitive impairment (e.g., severe intellectual disability or dementia)
- Currently enrolled in a specialized psychological treatment program (e.g., EMDR, CBT)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2018
Enrollment:	510
Type:	Actual

Ethics review

Approved WMO Date:	05-09-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-03-2018
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-12-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-05-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-07-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-05-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-02-2022
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	NL61361.029.17