

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON27612

### Source

Nationaal Trial Register

### Brief title

STRENGTHS

### Health condition

Common mental disorders

Depression

Anxiety

Posttraumatic stress disorder

Low-intensity interventions

Refugees

## Sponsors and support

**Primary sponsor:** Vrije Universiteit Amsterdam

**Source(s) of monetary or material Support:** EU Horizon 2020

## Intervention

## Outcome measures

### Primary outcome

Psychological distress: HSCL-25

### Secondary outcome

PTSD symptoms: PCL-5

Self-identified problems: PSYCHLOPS

Cost of care: CSRI schedule

Access to health care: own questionnaire

## 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 World Health Organization (WHO) has developed Problem Management Plus (PM+), a brief (5 sessions), low-intensity psychological intervention, delivered by trained non-specialized workers, that addresses common mental disorders in persons affected by adversity.

The primary objective of STRENGTHS is to evaluate the feasibility, acceptability, effectiveness and cost-effectiveness of the culturally adapted PM+ intervention for Syrian refugees in The Netherlands. The current trial registration is for the pilot trial to investigate the feasibility and acceptability (e.g., obtain estimates of drop-out rates), to inform a full-scale, definitive randomized controlled trial.

Study participants include adult Syrian refugees (18 years and older) in The Netherlands with self-reported functional impairment (WHODAS 2.0 >16) and elevated psychological distress (K10 >15.9). Participants in the treatment group will receive five sessions of PM+ and care-as-usual (CAU). Participants in the comparison group will receive CAU only.

The main study parameter will be the decrease in psychological distress from baseline to three-month post-intervention assessment, measured through the Hopkins Symptoms

Checklist (HSCL-25).

## **Study objective**

The pilot RCT has a pre-post study design with the objective to inform the definitive RCT about drop-out rates and estimated effect sizes. We expect a decrease in psychological distress (HSCL-25).

## **Study design**

- Baseline
- 1 week post-intervention assessment (6 weeks after baseline)
- 3 month post-intervention assessment (4-4.5 months after baseline)

## **Intervention**

There are two arms in this study:

1. Comparison group: Care as usual (CAU) only
2. Treatment group: CAU with Problem Management Plus (PM+)

Care as usual (CAU):

CAU ranges from community care (e.g., social work, POH-GGZ, NGO buddy systems) to specialized psychological treatment programs.

Currently, waitlists for mental health services hamper access for Syrian refugees who do not master the Dutch language, due to a lack of Arabic speaking mental health care professionals.

Problem Management Plus (PM+):

The World Health Organization (WHO) has developed the low-intensity PM+ programs, a new generation of shorter, less expensive and trans-diagnostic (i.e., not condition-specific, but targeted at a broader set of symptoms of common mental disorders) programs to reduce common mental health symptoms and improve psychosocial functioning. It is based on the WHO treatment guidelines for conditions related to stress (WHO, 2013).

PM+ is a 5-sessions intervention (Dawson et al., 2015) that reduces symptoms of depression, anxiety, PTSD, and related conditions. It is delivered by trained non-specialized workers or lay people, and is available in individual and group delivery formats for both children and adults. It comprises evidence-based techniques, such as (a) problem solving, (b) stress management, (c) behavioral activation, and (d) accessing social support.

PM+ has been proven to be effective in two randomized controlled trials (RCTs) in Kenya and Pakistan (Bryant, Dawson, Schafer, Sijbrandij, & van Ommeren, 2016; Rahman, Hamdani, Awan, Bryant, Dawson, Khan, Mukhtar-ul-Haq Azeemi, et al., 2016).

## Contacts

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## Eligibility criteria

### **Inclusion criteria**

- Adults of 18 years or above
- Syrian refugee status
- Arabic-speaking
- Elevated levels of psychological distress (K10 >15.9) and reduced psychosocial functioning (WHODAS 2.0 >16)

### **Exclusion criteria**

- Acute medical conditions
- Imminent suicide risk or 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)

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	23-04-2018
Enrollment:	60
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	20-11-2017
Application type:	First submission

## 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
NTR-new	NL6665
NTR-old	NTR6842
Other	: METC protocol no NL61361.029.17 (phase 2)

## Study results

### Summary results

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>

Dawson, K. S., Schafer, A., Anjuri, D., Ndogoni, L., Musyoki, C., Sijbrandij, M., ... Bryant, R. A. (2016). Feasibility trial of a scalable psychological intervention for women affected by urban adversity and gender-based violence in Nairobi. *BMC Psychiatry*, 16(1), 410. <https://doi.org/10.1186/s12888-016-1117-x>

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>