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

Gepubliceerd: 20-11-2017 Laatst bijgewerkt: 18-08-2022

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).

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27612

Bron
Nationaal Trial Register

Verkorte titel
STRENGTHS

Aandoening

Common mental disorders
Depression
Anxiety
Posttraumatic stress disorder
Low-intensity interventions
Refugees

Ondersteuning

Primaire sponsor: Vrije Universiteit Amsterdam
Overige ondersteuning: EU Horizon 2020

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Psychological distress: HSCL-25

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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).

Onderzoeksopzet

- Baseline

- 1 week post-intervention assessment (6 weeks after baseline)

- 3 month post-intervention assessment (4-4.5 months after baseline)

Onderzoeksproduct en/of interventie

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).

Contactpersonen

Publiek

Department of Clinical Psychology, VU University Amsterdam

Marit Sijbrandij
Van der Boechorststraat 1

Amsterdam 1081 BT
The Netherlands
+31 20 598 8360

Wetenschappelijk

Department of Clinical Psychology, VU University Amsterdam

Marit Sijbrandij
Van der Boechorststraat 1

Amsterdam 1081 BT
The Netherlands
+31 20 598 8360

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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)

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

- 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)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	23-04-2018
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	20-11-2017
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	NL6665
NTR-old	NTR6842
Ander register	: METC protocol no NL61361.029.17 (phase 2)

Resultaten

Samenvatting resultaten

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