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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26682

Source
Nationaal Trial Register

Brief title
STRENGTHS

Health condition

Common mental disorders; Depression; Anxiety; Posttraumatic stress disorder

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

Functional impairment: WHODAS 2.0
PTSD symptoms: PCL-5
Self-identified problems: PSYCHLOPS
Cost of care: CSRI schedule (adapted)
Access to health care: health access questionnaire developed by STRENGTHS consortium
Anger: STAS
Cortisol: hair cortisol concentrations
Impact of COVID-19

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), scalable psychological intervention, delivered by trained non-specialized helpers, 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 definite, single-blind randomized controlled trial (RCT) to investigate the effectiveness and cost-effectiveness of PM+ in reducing symptoms of psychological distress. This trial follows a pilot RCT (N=60) that evaluated the feasibility and acceptability of PM+ (Trial NL6665 (NTR6842)).

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). 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 main hypothesis is that PM+/care-as-usual (CAU) will decrease psychological distress as compared to CAU alone.

Study design

- Baseline

- 1 week post-intervention assessment (6 weeks after baseline)
- 3 month post-intervention assessment (4.5 months after baseline)
- 12 month follow-up (12 months after baseline)

Contacts

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Eligibility criteria

Inclusion criteria

- Adults of 18 years or above
- Syrian refugee
- Arabic-speaking
- Elevated levels of psychological distress (K10 >15) 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)
- Currently enrolled in a specialized psychological treatment program (e.g., EMDR, CBT)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2019
Enrollment:	184
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
This dataset will be merged with similar data collected in the larger STRENGTHS project to perform IPD meta-analyses that are planned as part of the work of STRENGTHS. After completion of the STRENGTHS project, datasets can be made available to external parties upon requests.

Ethics review

Positive opinion

Date:	01-03-2019
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	NL7552
Other	METC VUMC : METC protocol no NL61361.029.17 (phase 4)

Study results

Summary results

Sijbrandij, M., Acarturk, C., Bird, M., Bryant, R. A., Burchert, S., Carswell, K., … Cuijpers, P. (2017). Strengthening mental health care systems for Syrian refugees in Europe and the Middle East: integrating scalable psychological interventions in eight countries. European Journal of Psychotraumatology, 8, 1388102. https://doi.org/10.1080/20008198.2017.1388102

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