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

Submission date
22/08/2022

Recruitment status
No longer recruiting

Registration date
23/08/2022

Overall study status
Completed

Last Edited
31/01/2023

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Syrian refugees are at risk for common mental disorders (CMDs), such as depression, anxiety and post-traumatic stress disorder (PTSD). However, access to mental health care can be limited due to barriers such as long waitlists and communication difficulties. The World Health Organization (WHO) developed a brief, transdiagnostic psychological intervention (Problem Management Plus; PM+) for communities affected by adversity.

We aim to investigate the effectiveness of PM+ in reducing symptoms of CMDs among Syrian refugees in the Netherlands.

Who can participate?
Syrian refugees (18 years and above) living in the Netherlands with self-reported distress (K10 >15) and functional impairment (WHODAS 2.0 >16) are invited to participate. Participants with acute medical conditions, imminent suicide risk/acute needs/protection risks, a severe mental disorder, or severe cognitive impairment are excluded and referred to appropriate services. Participants currently enrolled in a specialized psychological treatment program are also excluded.

What does the study involve?
Included participants complete a baseline assessment with questionnaires on mental health, psychosocial functioning, severe stressors and health care use. After baseline, participants are randomized into the PM+ treatment group (PM+/CAU) or into the CAU control group. After the intervention period, participants are re-assessed at 1-week post-assessment (i.e., 6 weeks after baseline), 3-month follow-up (i.e., 4.5 months after baseline), and 12-month follow-up (i.e., 12-months after baseline).

What are the possible benefits and risks of participating?
Problem Management Plus (PM+) may reduce psychological distress, but it is not certain. If you are allocated to the CAU control group, you will not benefit from participating in this study. However, your participation can contribute to a better understanding of the effect of short-term psychological interventions for Syrian refugees in reducing psychological distress.

A potential risk of participating int he study is that you may experience (temporary) distress or anxiety because you are asked about your feelings. You can always skip questions if you prefer. In case you will be allocated to the PM+/CAU treatment group, you may temporarily experience distress or anxiety during the PM+ sessions. Our PM+ helpers are well-trained to support you, and may also refer you to specialist care.

Where is the study run from?
The study is conducted by the Vrije Universiteit Amsterdam and I-psy mental health care (Almere).

When is the study starting and how long is it expected to run for?
March 2019 to December 2022.

Who is funding the study?
Horizon 2020 Framework Programme for Research and Innovation (2014-2020).

Who is the main contact?
Ms. Anne de Graaff (a.m.de.graaff@vu.nl)
Prof. dr. Marit Sijbrandij (e.m.sijbrandij@vu.nl)

Study website
http://strengths-project.eu/en/strengths-home/

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NL7552

Study information

Scientific Title
Implementation of Problem Management Plus in Syrian refugees: a randomized controlled trial RCT

Acronym
STRENGTHS

Study objectives
Problem Management Plus (PM+) will reduce psychological distress among Syrian refugees in the Netherlands three months after receipt of the intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/09/2017, Research Ethics Review Committee at VU Medical Center (BS7, kamer H-565, Amsterdam, Netherlands; +31 (0)20 -4445585; metc@vumc.nl), ref: NL61361.029.17

Study design
Single-blind two-arm randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
http://strengths-project.eu/en/participants/

Health condition(s) or problem(s) studied
Common mental disorders; Depression; Anxiety; Posttraumatic stress disorder

Interventions
Problem Management Plus (PM+):
PM+ consists of five weekly in-person sessions of 90 minutes each with a non-specialist helper. The intervention is based on cognitive-behavioral therapy and problem solving, and incudes four evidence-based strategies: stress management (slow breathing exercise; session 1), problem-solving (session 2), behavioural activation (re-engaging with pleasant and task-oriented activities; session 3), and accessing social support (session 4). Homework practice is scheduled following each session and discussed in the next session. Psychoeducation is delivered in session 1 and relapse prevention discussed in session 5. In the current trial, the non-specialist helpers were Arabic (and Dutch or English) speaking. The non-specialist helpers received 8-day training on common mental disorders, basic counselling skills, delivery of intervention strategies, and self-care, followed by a practice-case. Helpers met weekly for group-supervision by a PM+ supervisor. PM+ trainers and supervisors were mental health professionals who had received 5-day training covering elements of training of helpers, and training and supervision skills.

Care as usual (CAU):
CAU includes all (mental) health services that individuals with a refugee background may access in the Netherlands, ranging from primary care services to specialist mental health care.

A randomization list with permuted block sizes (4-6-8) was generated in R by an independent researcher not involved in the rest of the study. Allocation concealment involved sealed opaque envelopes.

Intervention Type
Behavioural

Primary outcome measure
Psychological distress (Hopkins Symptom Checklist; HSCL-25) at screening/baseline, 1-week post-assessment, 3-month follow-up, 12-month follow-up

Secondary outcome measures
Measured at screening/baseline, 1-week post-assessment, 3-month follow-up, 12-month follow-up unless noted:
1. Depression (HSCL-25 subscale)
2. Anxiety (HSCL-25 subscale)
3. Symptoms of post traumatic stress disorder (PTSD Checklist DSM-5; PCL-5)
4. Functional impairment (WHO Disability Assessment Schedule; WHODAS 2.0)
5. Self-identified problems (Psychological Outcomes Profiles; PSYCHLOPS)
6. Cost of care (Client Service Receipt Inventory; adapted CSRI)

7. Anger (Trait Anger Scale; STAS) at baseline and 1-week post assessment
8. Cortisol (hair cortisol concentrations) at baseline and 3-month follow up

Overall study start date
01/03/2019

Completion date
12/12/2022

Eligibility

Key inclusion criteria
1. Adults of 18 years or above
2. Syrian refugee
3. Arabic-speaking
4. Elevated levels of psychological distress (K10 >15) and reduced psychosocial functioning (WHODAS 2.0 >16)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
184

Total final enrolment
206

Key exclusion criteria
1. Acute medical conditions
2. 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)
3. Severe mental disorder (psychotic disorders, substance-dependence)
4. Severe cognitive impairment (e.g., severe intellectual disability or dementia)
5. Currently enrolled in a specialized psychological treatment program (e.g., EMDR, CBT)

Date of first enrolment
07/03/2019

Date of final enrolment
23/12/2021

Locations

Countries of recruitment
Netherlands

Study participating centre
Vrije Universiteit Amsterdam
Van der Boechorststraat 7
Amsterdam
Netherlands
1081BT

Study participating centre
i-Pys mental health care
Metropolestraat 1c
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Sponsor information

Organisation
VU Amsterdam

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Sponsor type
University/education

Website
https://vu.nl/en

ROR
https://ror.org/008xxew50

Funder(s)

Funder type
Government

Funder Name
Horizon 2020 Framework Programme

Alternative Name(s)
EU Framework Programme for Research and Innovation H2020, Horizon 2020, Rahmenprogramm Horizont 2020, Programa Marco Horizonte 2020, Programme-cadre Horizon 2020, Programma quadro Orizzonte 2020, Program ramowy Horyzont 2020, Horizont 2020, Horizonte 2020, Orizzonte 2020, Horyzont 2020, Horizon 2020 Framework Programme (H2020), H2020

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
The Vrije Universiteit Amsterdam (VU) will keep a central data repository of all data collected in the STRENGTHS project. The data will be available upon reasonable request to the STRENGTHS consortium. Data access might not be granted to third parties when this would interfere with relevant data protection and legislation in the countries participating in this project and any applicable EU legislation regarding data protection. Interested researchers can contact Dr Marit Sijbrandij at e.m.sijbrandij@vu.nl to initiate the process.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		20/01/2020	22/08/2022	Yes	No