Internet-Delivered Cognitive Behavioral Therapy for Posttraumatic Stress Disorder in International Humanitarian Aid Workers: Study Protocol

No registrations found.

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

Summary

ID

NL-OMON20069

Source
Nationaal Trial Register

Health condition

Post-traumatic stress disorder, PTSD, Cognitive Behavioral Therapy, CBT, Internet-delivered, iCBT, humanitarian aid workers, Cognitieve gedragstherapie, CGT, Posttraumatische-stressstoornis, PTSS, Hulpverleners.

Sponsors and support

Primary sponsor: Department of Clinical Psychology, VU University Amsterdam
Source(s) of monetary or material Support: This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Intervention

Outcome measures

Primary outcome

1) Credibility/ expectancy, 2) Significant reductions in symptoms of PTSD from pre- to post-

test.

Secondary outcome

1) Significant reductions in symptoms of comorbid depression, anxiety, suicidality, and functional disability from pre- to pos-test, 2) Treatment completion rates.

Study description

Background summary

Introduction: Humanitarian aid workers are likely to be exposed or witness complex emergencies. Posttraumatic stress disorder (PTSD) is one of the most widespread and most commonly studied mental health problems after exposure to adversities and trauma. However, face-to-face treatment has limited utilization in the resource-constrained settings where humanitarian aid workers often operate. Internet-delivered cognitive behavioral therapy (iCBT) is a treatment option with the potential to improve the access to evidence-based care for humanitarian aid workers. Until now, only a few studies have evaluated iCBT in the treatment of PTSD. No studies have yet explored the feasibility of iCBT for humanitarian aid workers with PTSD. The aim of this study is to determine completion rates, self-reported treatment credibility/expectancy, and decrease in symptoms (PTSD, anxiety, depression, and functional disability) of the TELLUS program in humanitarian aid workers with PTSD.
Methods: A pilot feasibility study will be conducted with 20 humanitarian aid workers with a full or subclinical PTSD diagnosis according to DSM-IV criteria. The intervention used is TELLUS, which is a therapist-assisted Internet-delivered treatment program based on trauma-focused CBT components for individuals with PTSD. It contains eight text-based modules, where each module is expected to be completed within one week.

Discussion: This study may set the ground for a large-scale randomized control trial that would test the effectiveness and cost-effectiveness of the program. The study may contribute to the better understanding of PTSD treatment and increase the availability of evidence-based treatments in resource-constrained settings.

Study objective

1) The intervention (TELLUS) is credible to international humanitarian aid workers, 2) the intervention is significantly reduces symptoms of PTSD from pre- to post-test, and 3) the intervention significantly reduces symptoms of comorbid depression, anxiety, suicidality, and functional disability from pre- to pos-test.

Study design

The treatment is expected to last eight weeks and assessments are done: 1) before

beginning of treatment (pre-treatment), 2) after four modules of the treatment (mid-treatment), 3) after completion of all eight modules of the treatment (post-treatment).

Intervention

TELLUS is an Internet-delivered program based on trauma-focused CBT components for PTSD (Ivarsson et al., 2014). The treatment program contains eight text-based modules, where each module is expected to be completed within one week. The modules have homework assignments related to their content, which are communicated online with a supervised psychologist on a weekly basis.

Contacts

Public
Department of Clinical Psychology, VU University Amsterdam

Marit Sijbrandij
Van der Boechorststraat 1

Amsterdam 1081 BT
The Netherlands
+31 20 598 8360
Scientific
Department of Clinical Psychology, VU University Amsterdam

Marit Sijbrandij
Van der Boechorststraat 1

Amsterdam 1081 BT
The Netherlands
+31 20 598 8360

Eligibility criteria

Inclusion criteria

1) currently a staff member of an international humanitarian organization, 2) a full diagnosis of PTSD according to DSM-IV (APA, 1994), or subclinical PTSD with one intrusion, one avoidance and one hyperarousal symptom according to DSM-IV (APA, 1994), as established with the Mini International Neuropsychiatric Interview (MINI; Sheehan et al., 1998), 3) fluency in the English language, 4) access to the Internet and telephone/ Skype, 5) being on a current

stable dose of psychiatric medication or medication-free.

Exclusion criteria

1) organic or psychotic disorders, substance dependence or imminent suicide risk as established with the MINI, 2) a diagnosis of PTSD as a result of childhood trauma, 3) receiving psychological treatment at the time of inclusion, 4) being under severe current threat.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2014
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	10-04-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44333
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6333
NTR-old	NTR6525
CCMO	NL49966.029.14
OMON	NL-OMON44333

Study results