Internet-delivered cognitive behavioral therapy for posttraumatic stress disorder in humanitarian aid workers: a pilot study

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Primary objectives: 1. To translate and adapt the iCBT program TELLUS for use in IFRC humanitarian aid workers2. To determine feasibility of TELLUS in terms of: completion rates and self-reported treatment credibility/ expectancySecondary objective:…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON44333

Source
ToetsingOnline

Brief title
Internet-delivered CBT for PTSD

Condition

- Anxiety disorders and symptoms

Synonym
posttraumatic stress disorder (PTSD), psychological trauma

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cognitive behavioural therapy (CBT), humanitarian aid workers, internet, posttraumatic stress disorder (PTSD)

Outcome measures

Primary outcome

The main parameter will be the completion rate for the program and

self-reported treatment credibility/ expectancy.

Secondary outcome

Secondary outcomes measured at post-treatment will be symptoms of PTSD,

depression and anxiety, and functional disability.

Study description

Background summary

Humanitarian aid workers may often be exposed or witness complex emergencies. Posttraumatic stress disorder (PTSD) is one of the most widespread and most commonly studied mental health problems in such situations. However, face-to-face treatment has limited utilization in the resource-constrained settings, where humanitarian aid workers often operate. Therefore, the utilization of remote care, such as internet-based services, has been recommended. 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. However, no studies have yet explored the feasibility of iCBT for humanitarian aid workers with PTSD.

Study objective

Primary objectives:
1. To translate and adapt the iCBT program TELLUS for use in IFRC humanitarian aid workers
2. To determine feasibility of TELLUS in terms of: completion rates and self-reported treatment credibility/ expectancy

Secondary objective:
3. To evaluate reductions in symptoms of PTSD, anxiety and depression and functional disability to determine within Cohen*s d effect sizes to inform a future RCT in IFRC humanitarian aid workers.

Study design

A pre-post pilot feasibility study will be carried out in 20 IFRC humanitarian aid workers.

Intervention

TELLUS is a therapist-assisted internet-delivered treatment program based on trauma-focused CBT components for individuals with PTSD. The treatment program was developed by Prof. Dr. Gerhard Andersson (Linköping University, Sweden). The TELLUS program contains eight text-based modules. Each module is presented at the beginning of the week (Monday), and is expected to be completed by the end of the same week (Sunday). The modules include psychoeducation, breathing retraining, in-vivo exposure, exposure to memories, cognitive restructuring, and relapse prevention. Each module has a homework assignment related to the content of the module, which needs to be returned by email to the person providing feedback by the end of the week (Saturday).

Study burden and risks

The burden of participation consists of completing one primary telephone interview (duration: approximately 10 minutes), a secondary telephone interview (duration: approximately 25 minutes) and five self-report questionnaires and demographic questions (duration: approximately 27 minutes) at pre-treatment, following the eight TELLUS modules for eight weeks (duration: approximately 180 minutes per week), completing two self-report questionnaires after the forth module (duration: approximately 10 minutes), and completing one telephone interview (duration: approximately 20 minutes) and four self-report questionnaires (duration: approximately 20 minutes) at post-treatment. The risks associated with participation are considered minimal, since the TELLUS program has been shown to be an efficacious treatment option in a randomized controlled trial. Participants may benefit from their participation, since TELLUS has been shown to be helpful in reducing symptoms of posttraumatic stress disorder. Nevertheless, it cannot be excluded that some participants may become upset or experience distress during the interviews, self-report assessments, and/or intervention. In case a participant fulfills exclusion criteria, experiences strong emotional distress during the assessments or intervention, does not respond to emails in time, or reports symptom increase, the participant will be referred with his/her approval to the UNHCR Staff Welfare Section for support.

Contacts

Public
Vrije Universiteit

Van den Boechorststraat 1
Amsterdam 1081BT
NL
Scientific
Vrije Universiteit

Van den Boechorststraat 1
Amsterdam 1081BT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion criteria are: 1) currently an international staff member or international volunteer at IFRC, 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 internet and telephone/ Skype, 5) being on a current stable dose of medication or medication-free.

Exclusion criteria

Exclusion criteria are: 1) organic or psychotic disorders, substance dependence, or imminent suicide risk as established with the MINI, 2) presence of PTSD symptoms related to childhood

trauma, 3) receiving psychological treatment at the time of inclusion, 4) experiencing ongoing trauma or being under current threat.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-06-2016
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	11-03-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-06-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20069
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL49966.029.14
OMON	NL-OMON20069