

Internet-delivered cognitive behavioral therapy for posttraumatic stress disorder in international humanitarian aid workers: Study protocol



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ABSTRACT

Background: 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 investigate the participants' experiences and progress with the treatment, in order to determine whether TELLUS is acceptable for humanitarian aid workers.

Methods and design: 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.

1. Introduction

Humanitarian aid workers may often be exposed to or witness complex emergencies. These are relatively acute situations that involve a combination of war and civil strife, food shortages, natural disasters and the displacement of people (IASC, 2007; Toole and Waldman, 1990). Humanitarian aid workers may work extended periods of time in such settings around the world, where they may often be confronted with emotionally demanding situations and be routinely exposed to both physical and psychological stressors (Haugen et al., 2012; IASC, 2007).

When emergency situations are considered, posttraumatic stress disorder (PTSD) is one of the most commonly studied mental health problems following adversities and trauma (Alexander and Klein, 2001; Fullerton et al., 2004). PTSD may occur in up to 42% of emergency responders (Strohmeier and Scholte, 2015; Thormar et al., 2010). However, these estimates depend on the responders' duty, location of

assignment, past professional experience, the type of emergency they have been exposed to and other factors that influence the impact of traumatic events (e.g. Thormar et al., 2010). Previous studies have assessed persons after exposure to natural and man-made disasters, who have been directly exposed to events or have been indirectly exposed to emergencies because they were members of national and international organizations providing humanitarian assistance (e.g. Ager et al., 2012; Ehrling et al., 2011; Razik et al., 2013; Wang et al., 2013). For example, Ager et al. (2012) examined the mental health status of national humanitarian aid workers from 21 humanitarian agencies after the civil strife in Northern Uganda and found that 26% of the respondents experienced PTSD. On the other hand, Ehrling et al. (2011) assessed the prevalence of emotional disorders in emergency responders after an earthquake in Northern Pakistan and found that 42% of respondents showed clinically relevant levels of PTSD.

Characteristic symptoms of PTSD, as defined by the DSM-5 (APA, 2013), include intrusions (e.g. re-experiencing trauma-related

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memories), avoidance (e.g. avoiding trauma-related memories), negative alterations in cognitions and mood (e.g. fear, anger, guilt), and alterations in arousal and reactivity (e.g. irritability or sleep problems). Furthermore, PTSD is regarded as a debilitating condition that is often associated with psychiatric comorbidity, diminished quality of life, and typically follows a chronic life course (Hofmann et al., 2003; Rauch et al., 2010; Solomon and Davidson, 1997). It is also known to lead to significant occupational and social impairment, as well as considerable personal and societal costs (Hidalgo and Davidson, 2000; Kessler, 2000). With the increasing research in the mental health consequences of humanitarian aid work, the provision of effective staff care has become an important concern for the international community (Curling and Simmons, 2010).

1.1. Background and rationales

Internet-delivered CBT (iCBT) is a treatment strategy with the potential to improve the access to evidence-based care (Andersson, 2016; Andersson and Titov, 2014). It has been suggested that Internet-delivered interventions may be more accessible for persons living in areas with longer travel distances from mental health professionals, as well as for persons with restricted mobility and fear of stigmatization (Andersson, 2016). Compared to face-to-face treatments, it has been proposed that these interventions are more flexible, cost-effective and may reduce waiting lists, since they can be accessed at any period of the day and can be used by more people at the same time (Andersson and Titov, 2014).

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. The effectiveness of the program has been tested in a RCT, including 62 Swedish participants with chronic PTSD (Ivarsson et al., 2014). The results indicated significant reductions in PTSD symptoms in the TELLUS group compared to the delayed treatment group, showing a between-group effect on the IES-R (Weiss and Marmar, 1997) of Cohen's $d = 1.25$, and $d = 1.24$ on the Posttraumatic Stress Diagnostic Scale (PDS; Foa, 1995). There were also larger reductions in self-reported depression ($d = 0.55$) and anxiety ($d = 0.60$) symptoms, and an increase in quality of life ($d = 0.53$) in the TELLUS group compared to the delayed treatment group. Treatment gains were maintained up to one year follow-up (Ivarsson et al., 2014).

No studies have yet evaluated the effectiveness of iCBT for PTSD in humanitarian aid workers. This population is different from many other trauma-exposed populations in that it may involve people from various nationalities and cultural backgrounds. Furthermore, they may be located all over the world and usually in challenging contexts with ongoing conflict and lack of adequate resources. It is yet unclear whether iCBT is feasible, acceptable, and safe to administer in this population.

The aim of the current study is to evaluate the feasibility of TELLUS in international humanitarian aid workers with PTSD. We will examine the participants' experiences and progress with the treatment, in order to determine whether TELLUS is acceptable for humanitarian aid workers.

1.2. Theoretical underpinnings

For PTSD treatment, trauma-focused cognitive behavioral therapy (CBT) has been recommended across guidelines worldwide (Bisson et al., 2005; WHO, 2013). However, face-to-face CBT may be limited in resource-constrained settings, such as the ones humanitarian aid workers operate in (WHO, 2013). Recent staff mental healthcare evaluations of the United Nations High Commissioner for Refugees (UNHCR) have also recommended that adversities within staff members

should be adequately addressed and options for treatment utilization in- and outside UNHCR should be available (PDES, 2013). Accordingly, it has been suggested that options should be provided and promoted for the utilization of remote care, such as the application of Internet-delivered services (PDES, 2013).

With iCBT's potential to improve access to mental healthcare, recent meta-analyses indicate that therapist-assisted iCBT is comparably effective to face-to-face CBT in the treatment of depression (Andersson et al., 2014; Andersson and Cuijpers, 2009), anxiety disorders such as panic disorder and phobia (Andersson et al., 2014; Cuijpers et al., 2009), and other health problems such as pain and headaches (Cuijpers et al., 2008). A meta-analysis of twelve randomized controlled trials (RCTs) comparing iCBT to waitlist-control has shown promising results in the reduction of PTSD symptoms (Sijbrandij et al., 2016b). Similar findings have been reported in a subgroup analysis of fifteen RCTs on iCBT within a larger meta-analysis on Internet-delivered interventions (Kuester et al., 2016). However, the number of studies examining iCBT included in the meta-analyses was low, which hampers the generalization of results. Therefore, more RCTs in relevant trauma-exposed populations are needed.

2. Methods and design

2.1. Aim

This study aims to use the TELLUS program in international humanitarian aid workers and evaluate its feasibility by investigating the participants' experiences and progress with the treatment, in order to adapt and improve the program for use in humanitarian aid workers. For this purpose, we will conduct a pre-post pilot feasibility study with 20 humanitarian aid workers.

2.2. Participants

A sample of 20 humanitarian aid workers will be recruited by email through international humanitarian organizations.

The inclusion criteria are: 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.

The exclusion criteria are: 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.

2.3. Informed consent

A researcher will provide information about the study during a scheduled telephone or Skype meeting. If an individual is interested in participating, they will receive an information letter with a consent form through email. The potential participant will have at least 24 h to determine whether they wish to participate, and if so, they will be required to print, sign and send a scanned copy of the consent form by email. If the signed informed consent form cannot be scanned and returned by email, the individual can also return it by regular mail.

2.4. Procedure

An information leaflet will be distributed by email through international humanitarian organizations to their staff members. Individuals

interested in participating may then contact a designated researcher from the Department of Clinical Psychology at VU University Amsterdam, the Netherlands. The researcher will make a telephone or Skype appointment with the potential participants, in order to provide more information about the study and the informed consent procedure. After providing informed consent, the participant will again be contacted by the researcher, who will deliver the required items of the MINI (Sheehan et al., 1998).

If eligible, the individual will receive an invitation to register at the online portal of the project, where they may create their own username and password. The participant will then be asked to complete demographic questions and the following self-report measures: Life Event Checklist (LEC; Blake et al., 1995), Impact of Events Scale – Revised (IES-R; Weiss and Marmar, 1997), Hospital Anxiety and Depression Scale (HADS; Zigmond and Snaith, 1983), Credibility and Expectancy Questionnaire (CEQ; Borkovec and Nau, 1972), 12-item World Health Organization Disability Assessment Schedule (WHO-DAS II; WHO, 2000), and the Suicide Ideation Attributes Scale (SIDAS; Van Spijker et al., 2014). The participant will then be provided access to the first module of the TELLUS program. The participant is presented with the subsequent module only after feedback has been provided by a psychologist to the homework assignments of the current module. Each homework assignment is expected to be returned by the end of the same week. The participant cannot skip modules forward, but he/she may go back to the already completed modules if needed. A mid-treatment assessment will be performed after the fourth module, which includes the following self-report measures: IES-R, CEQ, HADS, WHO-DAS II, and SIDAS. If a participant indicates any symptom increase from the baseline to mid-treatment assessments, he/she will be contacted for follow-up and possible referral to other health services through their organization.

After the completion of the program, the following post-treatment assessments will be required: MINI for PTSD and suicidal ideation, IES-R, HADS, WHO-DAS II, SIDAS, CEQ, Working Alliance Inventory – Short Revised (WAI-SR; Hatcher and Gillaspay, 2006) and Psychological Outcome Profiles (PSYCHLOPS; Ashworth et al., 2013). All assessments and data-analyses will be carried out at the Department of Clinical Psychology at VU University Amsterdam, the Netherlands. Fig. 1 (see Appendix) gives an overview of the study procedure.

2.5. Sample size

Since this is an observational pilot study, no power calculations were conducted. The study will include a sample size of 20 participants.

2.6. Intervention

TELLUS is a therapist-assisted Internet-delivered CBT program that consists of components that have been validated and commonly used in face-to-face CBT treatment of PTSD, including psychoeducation, in-vivo and imaginal exposure, cognitive restructuring and stress management (Bisson et al., 2005; Harvey et al., 2003). When Internet-delivered treatment protocols are considered, the meta-analysis conducted by Sijbrandij et al. (2016b) indicates that the majority of iCBT protocols for PTSD are comparable with respect to their constitutive elements to protocols of face-to-face CBT. The iCBT protocols are also shown to be more effective when they are therapist-assisted and contain eight or more treatment sessions (Sijbrandij et al., 2016b).

The first module offers psychoeducation about PTSD and the treatment program. The participant is introduced to cognitive, emotional and behavioral responses to traumatic experiences. It further explains the characteristics of PTSD and factors influencing persistence of PTSD symptoms. The module discusses the functioning of the treatment program and provides reading and working instructions. The participant also has an opportunity to create a contract with him/herself for motivational purposes. Further, the information provided in the

first module helps the participants decide whether they would wish to proceed with the treatment. According to Wessely et al. (2008), psychoeducation in CBT legitimizes the trauma reaction, helps the client to formulate their symptoms and aids to understand the reasoning behind the treatment.

The second module provides stress management training in the form of breathing retraining and conditioned relaxation. The participant is provided with instructions and exercises on how to practice deep breathing with the use of the stomach. It also provides information on how the participant can learn to associate this deep breathing with relaxation. The aim of the stress management technique is to assist the participant during the upcoming modules, with which they may gain control in the exposure exercises and reduce their levels of arousal. Research has shown that the learning of stress management techniques equips clients with coping skills, in order for them to gain a sense of control and management of their own fear (Bisson et al., 2005).

Modules three to six provide information on imaginal and in-vivo exposure. Module five is a continuation of module three (imaginal exposure) and module six is a continuation of module four (in-vivo exposure). During the imaginal exposure modules, participants are instructed how to write about trauma-related experiences in first person and then read their narratives out loud. In the in-vivo exposure modules, participants are instructed how to identify unpleasant triggers, evaluate their level of discomfort, create their own hierarchies and confront situations that are avoided. The exposure to triggers is gradual, by exposing from moderately to increasingly distressing triggers and the process is done repeatedly. Imaginal and in-vivo exposure allow for emotional and informational recounting of traumatic memories and triggers, until they are no longer experienced as highly distressing (Bisson et al., 2005). It is also assumed that through the process of extinction, the incorporation of corrective non-fearful information in the trauma memory is promoted (McLean and Foa, 2011).

The seventh module focuses on cognitive restructuring as an important factor in the maintenance and reduction of PTSD symptoms (Harvey et al., 2003). It helps the participant in recognizing and evaluating negative automatic thoughts and appraisals about oneself and the world. As alternative appraisals are identified, the client disconfirms their perceptions of the trauma and incorporates new information about the course of the event. Research has emphasized the importance of appraisals in the development and maintenance of PTSD and the integration of corrective information that deter the existent fear structures (Ehlers et al., 2005).

Lastly, the eighth module of the program intends to assist the participant in maintaining and stabilizing the acquired skills gained throughout the modules. It provides a summary of what has been learned during the treatment, as well as practical tips for maintaining the acquired progress in the future.

Throughout the treatment program, a master-level psychologist will contact the participants at the end of each module. The task of the psychologist is to provide written feedback through the online platform on the assignments of each module and to clarify questions about the content of the modules and their assignments. A participant may also be asked to revise answers that seem insufficient or unclear to the person providing feedback before continuing to the following module. In addition, the psychologist offers guidance, support and encouragement as part of the feedback given for each module. The psychologist will be supervised by three experienced psychologists involved in the study before the feedback is given to the participant. Contact between the psychologist and the participant is done through the online correspondence within the program.

2.7. Primary outcome measures

The PSYCHLOPS (Ashworth et al., 2013) assesses the progress on problems for which a client seeks help and their understanding of change throughout the treatment. It consists of four questions that

cover three domains: two questions about problems, one question about functioning and one question about well-being. In addition, participants are asked to provide five textual answers to the domains on problems and functioning, as well as an overall evaluation item ranging from ‘much better’ to ‘much worse’. Items are scored on a 6-point scale per domain, with a maximum score of 18. The measure has been validated in the general population (Heoinsson et al., 2013) and has been used in studies on individuals exposed to adversities in humanitarian settings (Sijbrandij et al., 2015; Sijbrandij et al., 2016a, 2016b).

The WAI-SR (Hatcher and Gillaspay, 2006) is a 12-item self-report measure that assesses three aspects of the therapeutic alliance: agreement on the therapeutic tasks between the participant and therapist, agreement on goals and the quality of the affective bond. Each item is rated on a scale from 1 (seldom) to 5 (always), where higher scores indicate a stronger alliance. The WAI-SR has demonstrated good validity and reliability (Hatcher and Gillaspay, 2006; Munder et al., 2010).

The CEQ (Borkovec and Nau, 1972) is a 6-item self-report measure that assesses treatment credibility and client expectancy for improvement. The first four items of the scale are rated based on cognitive appraisals about the treatment, while the last two items are rated based on feelings about the treatment. The CEQ has demonstrated good validity and reliability (Deville and Borkovec, 2000).

2.8. Secondary outcome measures

The MINI (Sheehan et al., 1998) is a brief structured diagnostic interview that is compatible with DSM-IV (APA, 1994) psychiatric disorders. It is used to diagnose mood disorders, anxiety disorders, substance use disorders, and psychotic disorders. Each module has a screening question that, if positive, leads to further examination of the criteria for the specific disorder. For the purpose of this study, the MINI will be administered through the telephone for the assessment of PTSD, suicidal ideation, substance dependence, and psychotic disorders. The MINI has demonstrated good validity and reliability (Sheehan et al., 1998), and has previously been administered over the telephone in studies evaluating iCBT programs for PTSD (e.g. Klein et al., 2009; Spence et al., 2011).

The IES-R (Weiss and Marmar, 1997) is a well-established 22-item self-report measure assessing the presence and severity of PTSD symptoms. The items are divided into three subscales: intrusion (8 items), avoidance (8 items), and hyperarousal (6 items). The frequency of each symptom is scored using a 5-point scale with equal intervals, ranging from 0 (not at all) to 4 (extremely). The scores can be summed to produce a total IES-R score (range 0–110), where a higher score indicates a greater level of PTSD symptoms. The IES-R has demonstrated good validity and reliability (Creamer et al., 2003; Weiss and Marmar, 1997).

The HADS (Zigmond and Snaith, 1983) is a 14-item self-report measure for emotional distress with subscales for depression and anxiety. Each subscale has 7 items. The responses are scored on a scale of 0–3, where higher scores indicate higher symptom severity. The scores for each subscale range from 0 to 21, and the total scores for the entire scale range from 0 to 42. Higher scores indicate more emotional distress. The HADS had demonstrated good validity and reliability (Bjelland et al., 2002; Mykletun et al., 2001).

The WHO-DAS II (WHO, 2000) is a brief version of the 36-item self-report measure that assesses functioning and disability over the past 30 days. The scale covers six domains and the two most significant items of each domain are selected for the 12-item version: understanding and communicating (items 3 and 6), getting around (items 1 and 7), self-care (items 8 and 9), getting along with others (items 10 and 11), life activities (items 2 and 12), and participation in society (items 4 and 5). Rating options are on a scale from 1 (no difficulty) to 5 (extreme difficulty), with scores that range 0–100. Higher scores indicate higher levels of disability. The 12-item version of the WHO-DAS 2.0 has demonstrated good validity and reliability (Luciano et al.,

2010).

The SIDAS (Van Spijker et al., 2014) is a 5-item self-report measure that assesses the severity of suicidal ideation. Each item can be rated on a scale from 0 to 10, which is later reverse-scored and the total scores are calculated as the sum of all five items. The total score can range from 0 to 50, where higher scores indicate greater severity of suicidal ideation. The scale has shown to have good internal consistency and validity with other measures on suicidal ideation (Batterham et al., 2015; Van Spijker et al., 2014).

2.9. Other outcome measures

Completion rates will be assessed by a researcher during treatment and at post-treatment. A completion rate of 60% would be considered acceptable, considering the study of Ivarsson et al. (2014) and other studies on Internet interventions for PTSD (e.g. Klein et al., 2010; Knaevelsrud et al., 2015). Data on socio-demographic information (age, sex, marital status, education, country of origin) will also be collected.

The LEC (Blake et al., 1995) is a 17-item self-report measure assessing the experiences of 16 different potentially traumatic events known to result in PTSD. One item assesses any other potentially traumatic experience that is not captured in the other 16 items. The respondents rate their experiences on a 5-point nominal scale (1 = happened to me, 2 = witnessed it, 3 = learned about it, 4 = not sure, and 5 = does not apply). The measure is designed to be administered prior to the administration of a diagnostic interview to evaluate the respondent's experience. The LEC has demonstrated good validity and reliability (Gray et al., 2004).

2.10. Analysis

All self-report outcome measures will be treated as continuous outcomes. Changes in symptoms of PTSD, depression, anxiety suicidality, and functional disability between baseline and post-treatment will be evaluated by two-tailed *t*-tests. The MINI will be treated as a categorical outcome measure, and changes between baseline and post-treatment will be evaluated by chi-squared tests. A *p*-value < 0.05 will be considered to indicate statistical significance.

Descriptive statistics (means and standard deviations) will also be computed at baseline, while treatment credibility/expectancy, treatment progress and working alliance will be computed at post-treatment. Both continuous data (e.g. age) and categorical/dichotomous data (e.g. sex) will be used to compute descriptive statistics.

All analyses will be conducted on an intention-to-treat basis, where pre-treatment scores will be carried forward and used as post-treatment scores for missing data.

3. Discussion

By evaluating the feasibility of iCBT for PTSD in humanitarian aid workers, we seek to determine whether this form of treatment would be acceptable for humanitarian aid workers suffering from PTSD worldwide. If proven feasible, TELLUS may set the ground for a large-scale RCT that would test the effectiveness and cost-effectiveness of the program compared to a valid control such as treatment-as-usual. The ultimate goal of this research would be to provide both a feasible and evidence-based treatment for PTSD in humanitarian aid workers. Using TELLUS for humanitarian aid workers may expand the reach of an already effective form of treatment provision. Accordingly, this study may contribute to the better understanding of PTSD treatment and it may increase the availability of evidence-based treatments in resource-constrained settings (WHO, 2013). Depending on the outcomes, the TELLUS protocol may also be adapted and scaled-up to better suit humanitarian aid workers. For future research, the feasibility and effectiveness of TELLUS may be a stepping stone for further exploration of the program for different populations affected by trauma and

adversities, such as youth and families of different socio-cultural and economic backgrounds (Tol et al., 2011a; Tol et al., 2011b).

Conflicts of interest

None.

Appendix A

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This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

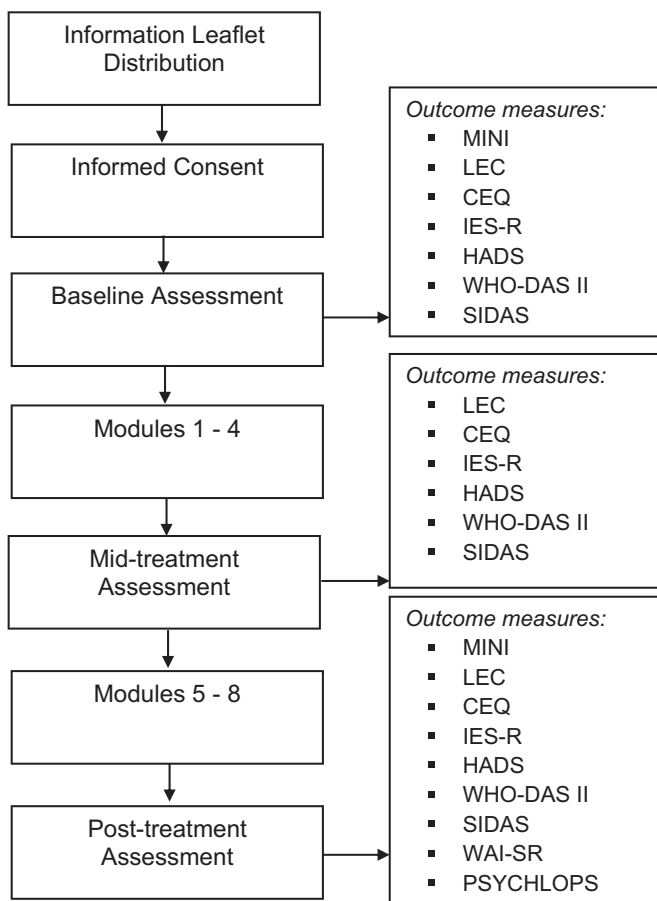


Fig. 1. Flowchart of study procedures.

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