Online cognitive behavioral therapy for traumatically bereaved people: A randomized waitlist-controlled trial

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

Summary

ID

NL-OMON20115

Source
Nationaal Trial Register

Brief title
TrafVic

Health condition

Persistent Complex Bereavement Disorder, Post traumatic stress disorder, major depressive disorder

Sponsors and support

Primary sponsor: 1.University of Groningen 2 Utrecht University
Source(s) of monetary or material Support: Fonds Slachtofferhulp (Victim Support Fund, The Netherlands) Stichting Stimuleringsfonds Rouw (Promotion Fund Bereavement Foundation)

Intervention

Outcome measures

Primary outcome

PCBD, depression, and PTSD symptom levels. PCBD: Traumatic Grief Inventory - Self Report (TGI - SR) (Boelen & Smid, 2017b). Depressive disorder: depression subscale of the Hospital Anxiety and Depression Scale (HADS-D; Zigmond & Snaith, 1983) PTSD: PTSD Checklist for DSM-5PCL-5 (Weathers, et.al., 2013)

Secondary outcome

Secondary study parameters are negative cognitions, avoidance behaviours, state anger, a sense of unrealness, therapeutic alliance, and accident-related stressors - Negative grief-related cognitions are assessed with the Grief Cognitions Questionnaire (GCQ; Boelen and Lensvelt-Mulders, 2005). - Self-efficacy is assessed with the General Self-Efficacy Scale (GSES; Schwarzer & Jerusalem, 1995). - Avoidance is measured with the Depressive and Anxious Avoidance in Prolonged Grief Questionnaire (DAAPGQ; Boelen & van den Bout, 2010). - State anger is assessed with the 15-item state anger subscale of the State-Trait Anger Expression Inventory-2 (STAXI-2; Spielberger, 1999; Dutch version: Lievaart, Franken, & Hovens, 2016). - Quality of the therapeutic alliance is measured with the 12-item Work Alliance Inventory-Short Form, Client Version (WAI-SF; Horvath & Greenberg, 1982; Dutch version: Vertommen & Vervaeke, 1990). - Accident-related stressors are assessed with an instrument developed by the researchers.

Study description

Background summary

The primary aim of this study is to evaluate the effectiveness of an online CBT (vs. waitlist controls), in terms of reductions in PCBD, PTSD, and depression symptom-levels, for people who lost significant others due to traffic accidents. Our primary hypothesis is that people in the online CBT condition will show larger reductions in PCBD, PTSD, and depression symptom levels post-treatment than people in the waiting list control condition. The second aim is to explore to what extent treatment reductions in symptom levels during treatment are associated with reductions of negative cognitions and avoidance behaviors and the experience of fewer accident-related stressors. Lastly the effect of the quality of the therapeutic alliance as perceived by the participant and therapist on treatment effects and drop-out rates will be explored. A two-arm (online CBT and waiting list) open label parallel randomized controlled trial will be conducted. Participants are asked to fill in questionnaires pre-treatment, and 12 and 20 weeks after enrollment in the study. Eligible for participation are people who lost a family member, spouse, or friend at least one year earlier due to a traffic accident and report clinically relevant levels of PCBD, PTSD, and/or depression.

Study objective

We expect that people allocated to the online CBT condition will show larger reduction at post-treatment assessments in symptom-levels PCBD, PTSD, and depression compared to waitlist controls (Hypothesis 1). We expect that greater reductions in symptom-levels of PCBD, PTSD, and depression for online CBT compared with waitlist controls will be related to reductions in negative cognitions (i.e., negative grief-related thoughts and self-efficacy), avoidance behaviour (i.e., depressive and anxious avoidance), state anger, and a sense of unrealness (Hypothesis 2a). In addition, we expect that accident-related stressors negatively impact symptom reductions of PCBD, PTSD, and depression for online CBT compared with waitlist controls (Hypothesis 2b). We expect that higher levels of therapeutic alliance are associated with better treatment outcomes and that higher dropout rates are related to lower therapeutic alliance (Hypothesis 3).

Study design

Pretreatment and 12 weeks and 20 weeks post-allocation

Intervention

The online intervention is based on the cognitive behavioral model of complicated grief (Boelen, van den Hout, & van den Bout, 2006). This model states that disturbed grief, even after a long period of time, persists because of three modifiable interacting processes, namely 1) problems with elaborating and integrating the loss; 2) negative cognitions and catastrophic misinterpretations of one's own grieving reactions; 3) anxious and depressive avoidance behavior. Recent reviews (Boelen & Smid, 2017; Doering & Eisma, 2016) show that cognitive behavioral therapy (CBT) is an effective form of treatment. Online CBT (Eisma et al., 2015), in which a client is accompanied by a therapist via the internet, also appears to be effective. CBT consists of the following parts: • Psycho-education about common grief reactions and processes that might foster or hamper recovery in bereavement. • Exposure to counter avoidance. • Cognitive restructuring to identify and change unhelpful thoughts. • Behavioral activation, which consists of reengaging in previously valued activities (e.g., social or recreational activities). Picking up and continuing meaningful activities helps to break down inactivity and depressive avoidance of activities. All components together strengthen the elaboration and thus the integration of the loss in the autobiographical memory and thereby reduce PCBD.

Contacts

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Eligibility criteria

Inclusion criteria

First, second and third degree (adoption- or step) family members, and spouses or friends of persons who died at a traffic accident - ≥ 18 years of age - meet the criteria for Persistent Complex Bereavement Disorder (PCBD), Posttraumatic Stress Disorder (PTSD) and/or Major Depressive Disorder (MDD) based on questionnaire scores.

Exclusion criteria

Participants will be excluded when they do not have Internet access or do not master Dutch language.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2020
Enrollment:	55

Type: Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion
Date: 01-02-2019

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47955
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7497
Other	METC Universitair Medisch Centrum Groningen (UMCG) NL : 2019/233
CCMO	NL69035.042.19
OMON	NL-OMON47955

Study results