Treatment of disturbed grief, posttraumatic stress, and depression in bereaved people after a traffic accident

Published: 16-09-2019
Last updated: 13-01-2025

The primary aim of this study is to evaluate the effectiveness of face-to-face and online CBT (vs. waitlist) in reducing PCBD, depression and posttraumatic stress complaints in people bereaved by a traffic accident. The second aim is to study to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON47955

Source
ToetsingOnline

Brief title
Trafvic-study

Condition

- Mood disorders and disturbances NEC

Synonym
Persistant Complex Bereavement Disorder; complicated grief

Research involving
Human

Sponsors and support

Primary sponsor: Rijksuniversiteit Groningen
Source(s) of monetary or material Support: Fonds Slachtofferhulp

Intervention

Keyword: Cognitive Behavioral Therapy, Persistent Complex Bereavement Disorder, Traffic incident, Treatment

Outcome measures

Primary outcome

PCBD, depression and PTSD.

PCBD: Traumatic Grief Inventory - Self Report (TGI - SR) (Boelen & Smid,

2017b).

PTSD: PTSS Checklist for DSM-5PCL-5 (Weathers, et.al., 2013)

depression: depression subscale of the Depression Hospital Anxiety and

Depression Scale (HADS-D; Zigmond & Snaith, 1983).

Secondary outcome

Secondary study parameters are the possibly mediating/moderating effect of

avoidance, maladaptive thoughts, anger, and accident-related stressors

Avoidance - Depressive and Anxious Avoidance in Prolonged Grief Questionnaire

(DAAGPQ; Boelen & van den Bout, 2010)

Maladaptive thoughts - Grief Cognitions questionnaire (Boelen &

Lensvelt-Mulders, 2005)

Anger - anger subscale of the State-Trait Anger Expression Inventory-2

(STAXI-2; Lievaart, Franken, & Hovens, 2016)

Accident-related stressors - Questions related to the accident (e.g.,

experiencing single or multiple loss(es))

Study description

Background summary

The Groningen-Utrecht research group of the applicants has been researching grief and loss for a long time. With the support of FSH, research has been conducted into the consequences of the loss for the left behind of various forms of loss. In these studies in relatives of murder and the MH17 disaster and relatives of missing persons, the nature and coping with problems is combined with a treatment study for those relatives with a lot of psychological problems and a need for help. The treatments are performed by a selected and trained network of BIG-registered therapists who are spread throughout the Netherlands. The so-called network therapists work locally together with the case manager of Slachtofferhulp NL under the supervision of the applicants. This creates a regional link that guarantees that the treatments can be offered adequately to help requesting surviving relatives at the end of the research.
Recent reports on the position of road casualties and survivors in the Netherlands (see: 1. Investigation report Criminal law response to traffic offenses, Van der Aa et al, 2017, 2. Zwartboek, VVS, 2016) clarifies which obstacles for traffic accident victims and NVD face. They have a lot of problems with additional stressors, such as long procedures with the police, justice, problems with insurers, (too) low compensation and penalties for offenders. NVD with a high level of complaints will be offered a face-to-face treatment or an online psychological treatment. These treatments effects are compared with a wait-list control condition.
Question: What is the effect of a face-to-face (vs. waitlist controls) and online treatment (vs. waitlist controls) in terms of reduction in symptom-levels of PCBD, depression, and PTSD in bereaved people after a traffic accident?
Based on intervention research at other groups of surviving relatives, we expect that a targeted psychological face-to-face and online treatment is more effective than no treatment (participation in the waiting list group, Boelen & Smid, 2017a).
Additional questions: To what extent is the effect of the treatments mediated/moderated by factors such as avoidance, negative thinking, anger, and accident-related stressors?

Study objective

The primary aim of this study is to evaluate the effectiveness of face-to-face and online CBT (vs. waitlist) in reducing PCBD, depression and posttraumatic stress complaints in people bereaved by a traffic accident. The second aim is to study to what extent the treatment effect is mediated/moderated by avoidance, negative thinking, anger, and accident-related stressors.

Study design

People bereaved by a traffic accident who meet the criteria of PCBD, depression and / or PTSD at least one year after death are eligible for participation. A psychological treatment focused on traumatic grief (face-to-face or online) will be offered and the effect of this treatment is investigated. The psychological treatment (face-to-face or online) will be compared with a waiting list control group (see below: interventions).

Earlier grief research shows that between 10-20% cooperates. It is expected that over the period of 5 years, (per year 600 x 7 years = 3000 x 4 bereaved people = 12,000, of this 15% cooperate =) potential 180 people can be included. Bereaved people with clinically significant scores on questionnaires for PTSD, PCBD and/or depression and a request for help (estimate: at least 10%) receive a treatment indication. Within this group of at least 180 bereaved people random allocation takes place a) face-to-face cognitive behavioral therapy b) an online cognitive behavioral therapy or c) a waiting list control group. For among others ethical reasons, persons from the waiting list control group will receive face-to-face or online treatment at random after a waiting period of 20 weeks. The intervention groups start immediately after a pre-measurement with the intervention. The required participation in the intervention groups to answer the key questions is at least 146 people. Based on prior work, we expect that this required number is achievable.

Measurement occasions face-to-face and online treatment conditions: T1 = baseline measurement; T2 = post-intervention measurement (12 weeks), T3: follow-up (20 weeks).
Measurement occasionswaitlist control condition: T1 = baseline measurement; T1a = 12 weeks post waiting period, T1b = 20 week post-waiting period, T2 = post-intervention (12 weeks after starting treatment), T3: follow-up (20 weeks after starting treatment).

Midtreatment one brief assessment (12 item questionnaire about therapeutic alliance) takes place.

Intervention

The starting point of both interventions offered is the cognitive behavioral model of PCBD (Boelen, van den Hout, & van den Bout, 2007). This model states that normal mourning, even after a long period of time persists through three influencing mechanisms, 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 review studies (Boelen & Smid, 2017a; 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 usually consists of the following parts:
* Psycho-education contributes to the normalization of grief reactions. The surviving relative understands that certain reactions to the loss, although often new to themselves, are normal.
* Exposure helps break through fearful avoidance. Identifying and changing non-helping thoughts contributes to a better interpretation of grief reactions and more positive thinking about their own possibilities for loss processing and about the future.
* 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 the PCBD.

Study burden and risks

Filling in the questionnaires could evoke painful thoughts or feelings related to the death of the loved one(s). The treatment could lead to a temporary increase in distress. Different studies with trauma victims and bereaved individuals showed that CBT and/or EMDR does not lead to increase of psychological distress after treatment (Currier, Holland, & Neimeyer, 2010; Ponniah & Hollon, 2009).

Contacts

Public
Rijksuniversiteit Groningen

Grote Kruisstraat 2 Grote Kruisstraat 2
Groningen 9712 TS
NL
Scientific
Rijksuniversiteit Groningen

Grote Kruisstraat 2 Grote Kruisstraat 2
Groningen 9712 TS
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

First, second and third degree (adoption- or step) familymembers, and spouses or friends of persons who died at a traffic accident
- * 18 years of age - meet the criteria for Persistant 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 master the Dutch language and do not have access to Internet.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2020
Enrollment:	146
Type:	Actual

Ethics review

Approved WMO Date:	16-09-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	29-04-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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: 20115
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL69035.042.19
Other	Trial NL7497
OMON	NL-OMON20115