Grief after MH17 Plane Crash

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23105

Source
Nationaal Trial Register

Health condition

Persistent Complex Bereavement Disorder, Cognitive Behavioral Therapy, Eye Movement Desensitization and Reprocessing

Sponsors and support

Primary sponsor: 1. University of Groningen
2. Utrecht University
4. Foundation Centrum ’45 Arq Psychotrauma Expert Group
Source(s) of monetary or material Support: 1. Fonds Slachtofferhulp Nederland (Victim Support Fund, the Netherlands)
2. Stichting Stimuleringsfonds Rouw (Promotion Fund Bereavement Foundation)

Intervention

Outcome measures

Primary outcome

The primary study parameter is the difference in severity of PCBD-complaints of the immediate intervention group compared to the delayed intervention group.

Secondary outcome

The secondary study parameters are (1) the difference in severity of PTSD and MDD of the immediate intervention group compared to the delayed intervention group (2) the possibly mediating effect of reduction of maladaptive thoughts, avoidance behavior and intrusive memories in reducing PCBD of the immediate intervention group compared to the delayed intervention group

Study description

Background summary

We hypothesize, based on previous studies, that CBT and EMDR are effective in reducing PCBD as well as PTSD and MDD among bereaved persons who lost a relative due to the Plane Crash Ukraine.
The primary aim of this study is to evaluate the effectiveness of CBT and EMDR in reducing PCBD in relatives of the Plane Crash Ukraine victims. The second aim is to study to what extent the treatment effect is mediated by reduction of maladaptive thoughts, avoidance behavior and/or intrusive memories.

By conducting a two-arm (immediate intervention versus delayed intervention) randomized controlled trial, we aim to fulfill both study objectives. The participants are asked to fill in questionnaires prior to the treatment and within one week, 12 and 24 weeks post treatment.

Study objective

1. The immediate intervention group will show significantly larger reductions in PCBD, PTSD and MDD at the one week post treatment assessment compared to the one week pretreatment assessment of the delayed intervention group.

2. The treatment effect is mediated by a reduction in maladaptive thoughts, avoidance behavior and intrusive memories.

4. All participants will show significant reductions in severity of PCBD, PTSD and MDD when comparing the baseline assessments to the 12 and 24 weeks post treatment assessments.

Study design

Pretreatment, posttreatment, follow-up measure after 12 weeks and follow up measure after 24 weeks.

Intervention

Participants are randomized into

1. Immediate Intervention Group

2. Delayed Intervention Group

The treatment consists of eight sessions offered in a time period of maximum 12 weeks. In the first session, therapist and client introduce themselves, share expectations regarding the treatment and the participant is invited to share his story about his deceased loved one(s). Social support is the theme of the second session. The client is asked to invite a relative to join the client in the second session. During session 3, 4 and 5 eye movement desensitization and reprocessing (EMDR) is offered. Session 6, 7 and 8 consists of changing maladaptive thoughts by cognitive behavioral therapy (CBT). Each session has a duration of 45 minutes, except for the EMDR-sessions. Each EMDR-session has a duration of maximum 90 minutes.

Participants receive a manual with psycho-education and exercises for how to handle maladaptive thoughts.

Participants who are randomized to the delayed intervention group will start the intervention after 12 weeks. The intervention is the same as the intervention for the immediate intervention group.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
be a first, second, or third degree (adoption- or step) family member, spouse, colleague or friend of a person who died at the Plane Crash Ukraine;
be at least 18 years of age;

written informed consent;

meet the DSM-5 criteria for PCBD, PTSD and/or MDD based on questionnaire scores. PCBD will be assessed with the Traumatic Grief Inventory - Self Report. Participants meet research criteria for PCBD when they score a 3 (3 = sometimes) or higher on at least 1 B-cluster symptom (Item 1, item 2, item 3 and item 14), and at least 6 C-cluster symptoms (item 4 up to 11 and item 15 up to 18) and a score of 2 (2 = seldom) or higher on the D-cluster symptom (item 13). PTSD will be assessed with the PTSD Checklist for DSM-5, by treating each item rated as 2 = "Moderately" or higher as a symptom endorsed, then following the DSM-5 diagnostic rule which requires at least: 1 B item (items 1-5), 1 C item (items 6-7), 2 D items (items 8-14), 2 E items (items 15-20), or a totalscore of 39 or higher. Severity of MDD will be assessed with the Quick Inventory of Depressive Symptomatology Self report, by which an established cut-off score of at least 6 will be used.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study if he or she:

- does not master the Dutch language;

- suffers from a substance use disorder;

- suffers from a psychotic disorder;

- is mentally disabled;

- is highly suicidal.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2015
Enrollment:	113
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5031
NTR-old	NTR5260
Other	: 201500496 UMCG Research Register

Study results