The effectiveness and underlying mechanisms of a psychological treatment for people who lost loved ones in the Plane Crash Ukraine

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Adjustment disorders (incl subtypes)
Study type	Interventional

Summary

ID

NL-OMON42503

Source
ToetsingOnline

Brief title
Grief after MH17 plane crash

Condition

- Adjustment disorders (incl subtypes)

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 en Stichting Stimuleringsfonds Rouw

Intervention

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

Outcome measures

Primary outcome

The primary study parameters are the difference in severity of

PCBD-complaints, depression and posttraumatic stress complaints of the

intervention after 18 months group compared to the intervention after 21 months

group (c.q. the waitlistgroup) at the post measurement.

Secondary outcome

The secondary study parameters are 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 at the post treatment assessment and the long-term effects of the

treatment in terms of reductions in PCBD, PTSD and MDD.

Study description

Background summary

Almost 300 people died after the Plane Crash in Ukraine on the 17th of July 2014. Acute grief complaints are the expected response to the loss of a loved one. Acute grief reactions decrease to an acceptable level after 6 months for the vast majority (Bonanno, et al., 2002; Bonanno, Wortman, & Nesse, 2004). When grief reactions persist or increase it can be defined as Persistent Complex Bereavement Disorder (PCBD) (Shear, et al., 2011). Approximately 5 to 10% of bereaved individuals develop PCBD (Middleton, Raphael, Burnett, & Martinek, 1998; Prigerson, et al., 2009). For those who lost a loved one due to

a disaster, estimated percentages of PCBD range from 40 to 70% (Ghaffari-Nejad, Ahmadi-Mousavi, Gandomkar, & Reihani-Kermani, 2007; Neria, et al., 2007). PCBD is associated with, yet distinct from Posttraumatic Stress Disorder (PTSD) and major depressive disorder (MDD) (Boelen, van de Schoot, van den Hout, de Keijser & van den Bout, 2010; Prigerson, et. al., 1996).
Various interventions are developed for those who experience a distorted grieving process. However, many intervention-studies lacked a strong design and results are unstable (Currier, Holland & Neimeyer, 2010). More robust research into the effectiveness of grief treatments is needed to adequately support bereaved persons who develop psychopathology.
The effectiveness of cognitive behavioral therapy (CBT) and eye movement desensitization and reprocessing (EMDR) in the treatment of PTSD and related disorders has been studied in diverse populations (see for example the review of Ponniah & Hollon, 2009). Preliminary results of an intervention study among homicidally bereaved persons with PCBD show the beneficial effect of CBT combined with EMDR (van Denderen, de Keijser, & Boelen, in preparation). The CBT-part of the latter study aims at changing maladaptive thoughts and diminishing avoidance behavior, while EMDR aims at integrating intrusive memories that are related to the loss. 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.

Study objective

The primary aim of this study is to evaluate the effectiveness of CBT and EMDR in reducing PCBD, depression and posttraumatic stress complaints 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.

Study design

By conducting a two-arm (intervention after 18 months versus intervention after 21 months) 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.

Intervention

The intervention consists of eight sessions: Session 1 is an introductory session, in session 2 mourning in the family is discussed. In session 3, 4, and 5 eye movement disensitization and reproccessing (EMDR) is applied, which take up to 90 minutes. In session 6, 7, and 8, cognitive behavioral therapy (CBT) is used. These sessions last up to 45 minutes.

By handing out a manual (based on the manual of the homicide-study) the

participant will receive psycho-education and learn how to handle maladaptive thoughts.

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).

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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 the Plane Crash Ukraine;
- >= 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 suffer from a substance use disorder, psychotic disorder or mental retardation and when they are suicidal.

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):	15-04-2016
Enrollment:	113
Type:	Actual

Ethics review

Approved WMO

Date:	18-01-2016
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL52722.042.15
Other	registratie under review bij Nederlands Trial Register

Study results