Grief after MH17 Plane Crash

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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...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23105

Bron
NTR

Aandoening

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

Ondersteuning

Primaire sponsor: 1. University of Groningen
2. Utrecht University
4. Foundation Centrum ’45 Arq Psychotrauma Expert Group
Overige ondersteuning: 1. Fonds Slachtofferhulp Nederland (Victim Support Fund, the Netherlands)
2. Stichting Stimuleringsfonds Rouw (Promotion Fund Bereavement Foundation)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2015
Aantal proefpersonen:	113
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten