Cognitive behavioural therapy for relatives of missing persons: study protocol for a pilot randomized controlled trial.

Gepubliceerd: 12-08-2014 Laatst bijgewerkt: 13-12-2022

The main aim of this project is to conduct a pilot randomized controlled trail (RCT) to evaluate the preliminary effectiveness and feasibility of cognitive behavioral therapy (CBT) as an intervention for relatives of long-term missing persons. The...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21442

Bron
NTR

Aandoening

Vermiste personen, missing persons, distress, trauma, grief, rouw, interventie, intervention

Ondersteuning

Primaire sponsor: University of Groningen, the Netherlands
Overige ondersteuning: Victim Support Fund (Fonds Slachtofferhulp)
University of Groningen
Promotion fund Bereavement Foundation (Stichting Stimuleringsfonds Rouw)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Differences in mean score of depression (assessed by the IDS-SR), PTSD (assessed by the PCL-5) and complicated grief (assessed by the ITG) at pre-, post and follow-up measurements after 12 and 24 weeks.

Toelichting onderzoek

Achtergrond van het onderzoek

The preliminary effectiveness and feasibility of cognitive behavioral therapy (CBT) as an intervention for relatives of long-term missing persons will be evaluated in a pilot randomized controlled trial. An intervention group will be compared to a wait-list control group. It is hypothesized that participants of the intervention group will show lower levels of psychological complaints by reducing repetitive negative thinking and intrusive memories and enhancing self-compassion in comparison to the participants of the wait-list control group at post-treatment measurement. Follow-up measurements at three and six months post-treatment will show the short- and long-term effects of the intervention.

Doel van het onderzoek

The main aim of this project is to conduct a pilot randomized controlled trail (RCT) to evaluate the preliminary effectiveness and feasibility of cognitive behavioral therapy (CBT) as an intervention for relatives of long-term missing persons. The effectiveness of CBT will be compared to a wait-list control group. Relatives of missing persons with clinically elevated levels of depression, PTSD and/or complicated grief are eligible for the individual CBT that aims to learn the individuals to deal with the unresolved loss of a loved one.

It is hypothesized that participants of the intervention group will show lower levels of psychological complaints by reducing repetitive negative thinking and intrusive memories and enhancing self-compassion in comparison to the participants of the wait-list control group at post-treatment measurement. Follow-up measurements at three and six months post-treatment will show the short- and long-term effects of the intervention.

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. Experimental condition
2. Wait-list control condition.

Experimental condition

Participants in the experimental condition are referred to a trained psychologist in their region. Approximately 15 psychologists are trained to conduct the CBT according to the treatment-protocol. The CBT consists of eight sessions divided over 12 weeks. The rationale for the treatment is based on previous studies that showed the effectiveness of CBT for reducing depression, PTSD and complicated grief. Due to the ongoing uncertainty and lack of closure for the relatives of missing persons, the therapy is not only focused on reducing psychological complaints, but also focused on enhancing coping strategies to deal with the painful situation by integrating mindfulness exercises. The treatment protocol is as follows: Session 1 - identification of psychological complaints, diagnosis, psycho-education. Session 2- invite a friend of family member, social support Session 3 - introduction of mindfulness Session 4 - 7 Recognition and changing maladaptive thoughts. Session 8 - evaluation of the therapy and relapse prevention During the therapy the participant is recommended to read chapters from the workbook (psycho-education) and to do home exercises (e.g. mindfulness exercises and recognition of changing maladaptive thoughts exercises). The exercises are based on previous literature from CBT and mindfulness. Before each session the participant is asked to answer a short questionnaire, in order to evaluate the progress during the therapy.

Wait-list control condition
Participants who are randomized to the wait-list control will start the intervention after 12 weeks. The intervention is the same as the intervention for the experimental condition.

Contactpersonen

Publiek

-
L.I.M. Lenferink
Grote Kruisstraat 2/1
Groningen 9712 TS
The Netherlands
0503639189

Wetenschappelijk

-
L.I.M. Lenferink
Grote Kruisstraat 2/1
Groningen 9712 TS
The Netherlands
0503639189

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Relatives of persons whom are missing for at least three months. Relatives are defined as family members (including (adoption- or step family), partner and friends;

- Clinically elevated levels of:

depression (score of > 13 on the IDS-SR) and/or complicated grief (score of >25 on the ITG) and/or PTSD (A provisional PTSD diagnosis can be made by treating each item on the PTSD Checklist for the DSM5 (PCL-5) rated as 2 = "Moderately" or higher as a symptom endorsed, then following the DSM-5 diagnostic rule which requires at least: 1 B item (questions 1-5), 1 C item (questions 6-7), 2 D items (questions 8-14), 2 E items (questions 15-20)), or a totalscore score of > 38

A clinical interview conducted by a trained professional has to confirm a diagnosis of depression, PTSD and/or complicated grief.

- > 18 years of age;

- written informed consent;

- mastering the Dutch language.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Relatives with high suicidal risk;

- or substance use disorder (based on questionnaire and/or interview).

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2014
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	12-08-2014
Soort:	Eerste indiening

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	NL4564
NTR-old	NTR4732
Ander register	METc UMCG : M14.158652

Resultaten