Online guided vs. unguided cognitive behavioral therapy for distress in people who lost a loved one during the COVID-19 pandemic: A controlled trial

Gepubliceerd: 18-05-2021 Laatst bijgewerkt: 18-08-2022

Our first hypothesis is that both guided and unguided online CBT lead to a decrease in the severity of PCBD, PTSD, and depression symptoms. Our second hypothesis is that people allocated to the guided online CBT group will show a stronger decrease...

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

Samenvatting

ID

NL-OMON24026

Bron
NTR

Verkorte titel
Grief and Corona

Aandoening

Persistent Complex Bereavement Disorder, Posttraumatic Stress Disorder, depression.

Ondersteuning

Primaire sponsor: Utrecht University
Overige ondersteuning: Fonds Slachtofferhulp (Victim Support Fund, The Netherlands)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

PCBD symptoms will be assessed with the Traumatic Grief Inventory – Clinician-Administered (Lenferink et al., in prep.).

Toelichting onderzoek

Achtergrond van het onderzoek

This study consists of two parts. Part 1 of the study has already been registered in the Netherlands Trial Register (ID: NL8993). The primary objective of part 2 is to evaluate the short-term and long-term effectiveness of a therapist guided online Cognitive Behavioral Therapy (CBT) (vs. unguided online CBT) in reducing symptoms of persistent complex bereavement disorder (PCBD), posttraumatic stress disorder (PTSD), and depression in bereaved adults during the COVID-19 pandemic. Our first expectation is that both guided and unguided online CBT lead to a decrease in the severity of PCBD, PTSD, and depression symptoms. Our second expectation is that people allocated to the therapist-guided online CBT group will show a stronger decrease in PCBD, PTSD, and depression symptoms immediately after treatment and at six months post-treatment compared with people allocated to the unguided online CBT group. The following research question will be answered: What is the effectiveness of therapist guided online CBT in reducing symptom-levels of PCBD, PTSD and depression immediately after treatment and at six months post-treatment among people whose loved one died during the COVID-19 pandemic compared with unguided online CBT? A two-arm (guided online CBT versus unguided online CBT) open label multicenter controlled trial will be performed. Pre-treatment, one week post-treatment, and six months post-treatment symptom levels of PCBD, PTSD, and depression will be evaluated by clinical telephone interviews. Eligible participants are people who lost (a) loved one(s) (i.e., a family member, spouse or friend) at least three months earlier during the COVID-19 pandemic (i.e., March 2020 until present) and who experience clinically relevant symptoms of PCBD, PTSD, and/or depression.

Doel van het onderzoek

Our first hypothesis is that both guided and unguided online CBT lead to a decrease in the severity of PCBD, PTSD, and depression symptoms. Our second hypothesis is that people allocated to the guided online CBT group will show a stronger decrease in PCBD, PTSD, and depression symptoms immediately after treatment and at six months post-treatment compared with people allocated to the unguided online CBT group.

Onderzoeksopzet

Pre-treatment, one week post-treatment and six months post-treatment.

Onderzoeksproduct en/of interventie

The investigational treatment consists of a guided online grief-specific CBT aimed at people who report clinically relevant levels of PCBD, PTSD and/or depression, at least three months after the loss of (a) loved one(s) during the COVID-19 pandemic. Therefore, this treatment could be viewed as a secondary preventive treatment and not a primary preventive treatment (which includes self-help modules accessible for all bereaved people; Schut & Stroebe, 2005). The guided online CBT consists of eight weekly sessions tailored to this specific population. During treatment, participants will be supported by a trained psychologist through e-mail contact. According to the Dutch guidelines for the treatment of PCBD, central components of the online treatment are exposure, cognitive restructuring, and behavioral activation (Boelen & van den Bout, 2017). Session 1 consists of psychoeducation regarding possible emotional reactions to the loss of (a) loved one(s) during the COVID-19 pandemic that might facilitate or hamper recovery from the loss. In addition, information is offered about specific corona-related factors that could exacerbate grief symptoms in this specific population, such as the impact of the absence of traditional grief rituals, lack of physical social support, and fear of infection with COVID-19. Lastly, a rationale of the CBT treatment is offered. Session 2, 3 and 4 consist of exposure exercises; the circumstances and story of the loss are addressed in detail, and the participant is encouraged to face stimuli that are avoided. Further, a rationale of exposure is provided using examples of avoidance of stimuli relevant for this population (e.g. the hospital where the loved one passed). Session 5 and 6 are focused on cognitive restructuring; these sessions are aimed at identifying and changing negative cognitions that hinder the grieving process. Emphasis is put on cognitions related to responsibility/guilt and fear, which could be heightened after the death of (a) loved one(s) during the COVID-19 pandemic (Eisma et al., 2020). Session 7 and 8 are spent on behavioral activation, in which the participant is urged to reengage in previously valued occupational, social and recreational activities to facilitate the adjustment process.

Contactpersonen

Publiek

Utrecht University
Lyanne Reitsma

06-22299573

Wetenschappelijk

Utrecht University
Lyanne Reitsma

06-22299573

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria for participation in the study are as follows: 1) having lost a loved one (i.e., a family member, spouse or friend), 2) the death occurred at least three months earlier during the COVID-19 pandemic (period March 2020 until present), 3) at least 18 years of age and 4) report clinically relevant symptoms of PCBD, PTSD, and/or depression based on clinical telephone interviews.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria are the following: 1) no mastery of the Dutch language, 2) no Internet access and/or 3) suffering from a psychotic disorder or suicidality.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2021
Aantal proefpersonen:	102
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:	18-05-2021
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	NL9485
Ander register	Medical Ethics Committee – University Medical Centre Utrecht (UMCU) NL : METC 20-446

Resultaten