Online cognitive behavioural therapy for reducing distress in people whose loved one died during the pandemic

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

Summary

ID

NL-OMON54959

Source
ToetsingOnline

Brief title
Grief and corona

Condition

- Adjustment disorders (incl subtypes)

Synonym
Disturbed Grief, Persistent Complex Bereavment Disorder

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Fonds Slachtofferhulp

Intervention

Keyword: Grief, Online, Trauma, Treatment

Outcome measures

Primary outcome

PCBD, PTSD, and depression

PCBD: Traumatic Grief Inventory - Clinician Administered (TGI - CA; Boelen,

Smid, & Lenferink, 2019).

PTSD: PTSS Checklist for DSM-5PCL-5 (PCL-5; Weathers, et.al., 2013)

Depression: Patient Health Questionnaire (PHQ-9; Kroenke et al., 2001)

Secondary outcome

not applicable

Study description

Background summary

Losing a loved one in traumatic circumstances, for instance a sudden or violent death, increases the risk of developing symptoms of persistent complex bereavement disorder (PCBD), posttraumatic stress disorder (PTSD), and depression. The death of a loved one during the COVID-19 pandemic could be considered a potentially traumatic loss, that likely results in high rates of PCBD, PTSD, and depression compared with the natural loss of a loved one. The interplay between the increase in deaths and corona-related stressors likely leads to an elevated risk for difficulties in the grieving process and thus an increase in number of people seeking professional grief support. Grief-specific cognitive-behavioural therapy (CBT) is considered the most effective treatment option for bereaved people. CBT for bereaved people aims to change maladaptive thoughts and to reduce avoidance behaviour. To date, CBT has mostly been

delivered through individual face-to-face formats, while treatment studies have shown that online treatment also yields promising results. Offering treatment online is now more than ever relevant during the pandemic and may offer important benefits compared with face-to-face CBT, such as lower costs and higher accessibility. In part 1 of the current study, our first hypothesis is that people allocated to a condition with unguided online CBT will show lower PCBD, PTSD, and depression symptom-levels post-treatment than people allocated to a waitlist (prior to obtaining this online treatment). Our second hypothesis is that treatment effects on PCBD, PTSD and depression symptom levels will persist from pre-treatment through six months post-treatment. In part 2 of the current study, our first hypothesis is that both guided and unguided online CBT lead to a decrease in the severity of PCBD, PTSD and depression symptom levels. Our second hypothesis is that participants allocated to a condition with therapist guided online CBT will show a stronger decrease in PCBD, PTSD and depression symptom levels post-treatment and at six months post-treatment than participants allocated to a condition with unguided online CBT.

Study objective

The primary aim in part 1 of this study is to evaluate the effectiveness of unguided online CBT (vs. waitlist controls), in terms of reductions in PCBD, PTSD, and depression symptom-levels, for people who lost a loved one during the COVID-19 pandemic.

The primary aim in part 2 of this study is to evaluate the effectiveness of guided online CBT (vs. unguided online CBT), in terms of reductions in PCBD, PTSD and depression symptom-levels, for people who lost a loved one during the COVID-19 pandemic.

Study design

In part 1 of the study, a two-arm (unguided online CBT vs. waitlist controls) open label parallel monocentre randomized controlled trial will be conducted. Pre-treatment/pre-waiting period, post-treatment or post-waiting period and six months post-treatment symptom-levels of PCBD, PTSD, and depression will be assessed by clinical telephone interviews. For participants allocated to the waitlist control condition, an additional assessment will take place post-treatment after the waiting period. All participants in part 1 of the study will serve as a control group (unguided online CBT) in part 2 of the study.

In part 2 of the study, a two-arm (guided online CBT vs. unguided online CBT) open label multicentre controlled trial will be conducted. All participants in part 2 of this study will be allocated to a guided online CBT condition. Self-rated symptom-levels of PCBD, PTSD and depression will be assessed at pre-treatment, post-treatment and six months post-treatment by telephone

interviews.

Intervention

In part 1 of the study, the intervention consists of an unguided online CBT for disturbed grief. In part 2 of this study, the intervention consists of a guided online CBT for disturbed grief. The starting point for this intervention is CBT for PCBD (Boelen & van den Bout, 2017). Reviews show that CBT is the most effective treatment for people who experience difficulties during the grieving process (Boelen & Smid, 2017; Doering & Eisma, 2016).

The online intervention consists of the following parts:

• Psycho-education contributes to the normalization of grief reactions. The surviving relative understands that certain reactions
to the loss, although often new to themselves, are normal.

• Exposure helps to break through fearful avoidance. Identifying and changing non-helping thoughts contributes to a better interpretation of grief reactions and more positive thinking about their own possibilities for processing the loss and cope with the future.

• Picking up and continuing meaningful activities helps to counter inactivity and depressive avoidance of activities. All components together strengthen the elaboration and thus the integration of the loss in the autobiographical memory and thereby reduce PCBD symptom levels.

All participants receive the same information; the content of the intervention is therefore not dependent on the input from the user.

Study burden and risks

Answering the interview questions 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 does not lead to increase of psychological distress after treatment (Currier, Holland, & Neimeyer, 2010)

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- be a family member, spouse, or friend of a person who died (whether or not due to corona) in the COVID-19 pandemic (period March 2020 till current);
- the death occurred at least three months earlier (this is in line with prior research, see Litz et al., 2014);
- be >=18 years of age;
- report clinically relevant symptom-levels of PCBD, PTSD, and/or depression based on interviews.

Exclusion criteria

- does not master the Dutch language;
- does not have access to Internet;
- suffers from a psychotic disorder or is suicidal.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2021
Enrollment:	128
Type:	Anticipated

Ethics review

Approved WMO Date:	07-10-2020
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	27-01-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	22-04-2021
Application type:	Amendment
Review commission:	METC NedMec

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	NL74518.041.20
Other	NL8993