

Online CBT for bereaved youth due to a traffic accident

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

Summary

ID

NL-OMON53448

Source

ToetsingOnline

Brief title

Online CBT for bereaved youth

Condition

- Adjustment disorders (incl subtypes)

Synonym

Disturbed Grief, Prolonged Grief Disorder

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Utrecht

Source(s) of monetary or material Support: Fonds Slachtofferhulp, Universiteit Utrecht

Intervention

Keyword: Children and adolescents, Grief, Online, Treatment

Outcome measures

Primary outcome

The main study parameter is the decline in PGD symptoms within individuals.

Secondary outcome

The secondary study parameters are the changes in symptoms of PTSD and depression before and after a baseline period, before and after treatment.

Furthermore, completed numbers of lessons, number of times logging in per week, and total amount of time spent on each lesson will be monitored.

Study description

Background summary

Children and adolescents who lose a loved one are at risk of developing symptoms of Prolonged Grief Disorder (PGD), posttraumatic stress disorder (PTSD), and depression. Deaths due to a traffic accident involve unique features that might impose more traumatic stress on bereaved youths next to the experience of the death itself, such as attention from the media and dealing with authorities. Consequently, detection and adequate intervention of psychological symptoms for this at-risk group of bereaved youths is important. An intervention that has shown to be effective in reducing symptom-levels of PGD, PTSD, and depression for bereaved children is Grief-Help; a face-to-face grief-specific cognitive-behavioral therapy (CBT). CBT aims to change three core processes considered to be crucial in the development and persistence of PGD: 1) the insufficient integration of the separation in the autobiographical memory, 2) maladaptive beliefs and misinterpretations of grief, and 3) avoidance behavior. For non-grief related psychological symptoms, there is evidence that online formats of CBT can be effective for youth, which have important benefits compared to face-to-face formats, such as lower costs and higher accessibility. In the current study, the potential effectiveness of online grief-specific CBT (i.e., an online format of Grief-Help) will be studied in children and adolescents bereaved due to a traffic accident. The primary hypothesis is that undergoing the online CBT co-occurs with stronger

changes in symptom-levels of PGD when compared to a baseline-period with no treatment. Furthermore, we expect that the children and adolescents will have similar symptom-levels of PTSD and depression before and after the baseline-period, and lower symptom-levels of PTSD and depression after treatment than before treatment (i.e., after the baseline-period).

Study objective

The primary aim of the current study is to evaluate the potential effectiveness of online grief-specific CBT, in terms of reductions in symptom-levels of PGD, PTSD, and depression, for children and adolescents who lost a loved one due to a traffic accident.

Study design

A sequential replicated and randomized A-B-phase design will be conducted. This design will consist of a baseline and a treatment phase. The baseline phase will consist of at minimum three and at maximum seven weekly measurement occasions. The treatment phase, in which the online CBT will be followed, will include nine weekly measurement occasions. During the weekly measurements in the baseline and treatment phase, PGD symptoms will be assessed. Before the baseline phase, after the baseline phase and after treatment, PGD, PTSD and depressive symptoms will be measured in an online interview.

Intervention

The intervention consists of online individual grief-specific CBT.

Study burden and risks

Completing the instruments could evoke painful thoughts or feelings related to the loss. The treatment could lead to a temporary increase in grief. However, previous research gives no indication that CBT or participation in bereavement research results in an unacceptable risk of exacerbation of complaints for bereaved children and adolescents.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Adults (18-64 years)

Children (2-11 years)

Inclusion criteria

- has experienced the death of a loved one (i.e., family member or friend) to a traffic accident at least 6 months earlier;
- be ≥ 8 years of age, but ≤ 18 years of age;
- report clinically relevant symptom-levels of PGD, PTSD, and/or depressive disorder based on the screening interview.

Exclusion criteria

- Does not master the Dutch language
- Does not have access to Internet
- Is suicidal

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-06-2023
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO	
Date:	10-05-2023
Application type:	First submission
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

CCMO

ID

NL83136.041.22