A randomised controlled trial examining the effects of a cognitive behavioural treatment for bereaved children combined with parental support

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This proposed randomised controlled trial seeks to examine the effect of "GriefHelp" - a cognitive behavioural treatment for children with emotional problems following the death of a loved one. Participants are randomly assigned to two...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON35013

Source
ToetsingOnline

Brief title
A controlled study examining CBT for bereaved children

Condition

- Other condition

Synonym
complicated grief, Problematic grief

Health condition

rouw, verliesgerelateerde emotionele problemen

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Cognitive Behavioural Therapy, Grief, Prevention, Youth

Outcome measures

Primary outcome

The primary goal is to examine the (preventive) effects of the two treatments on grief-reactions. Thus, the primairy dependent variable is the intensity of grief-reactions, as assessed by the Dutch version of the Inventory of Complicated Grief for children (RVL-K). This measure will be administered at all 5 assessment moments.

Secondary outcome

Apart from the effects of the treatment on grief-reactions, we will also examine the effects of treatments on conductproblems, posttraumatic stress symptoms, and symptoms of depression.

Study description

Background summary

The death of a loved one is one of the most distressing and prevalent events that children can experience. Children suffering loss have an increased chance of developing psycho-social problems. It is useful to develop interventions that are aimed at the prevention of such problems. Thus far, no such interventions are available.

Study objective

This proposed randomised controlled trial seeks to examine the effect of "GriefHelp" - a cognitive behavioural treatment for children with emotional problems following the death of a loved one. Participants are randomly assigned to two treatment conditions: (1) the experimental treatment ("GriefHelp" combined with parental support) or (2) a control treatment consisting of supportive counseling combined with parental support. Participants are asked to complete questionnaires before and after treatment, and at three follow-up assessment points.

Goals:
1) Comparing the (preventive) effects of "GriefHelp" with the effects of supportive counseling.
2) Generate knowledge about variables mediating the effects of "GriefHelp"
3) Generate knowledge about variables associated with the effectiveness of "GriefHelp"

Study design

This is a randomised controlled trial in which elible children are randomly assigned to one of two treatments:
1) the experimental cognitive behavioural treatment ("GriefHelp" combined with parental support) or
2) a control treatment consisting of supportive counseling combined with parental support.

Intervention

This proposed randomised controlled trial seeks to examine the effect of "GriefHelp" - a cognitive behavioural treatment for children with emotional problems following the death of a loved one. Participants are randomly assigned to two treatment conditions: (1) the experimental treatment ("GriefHelp" combined with parental support) or (2) a control treatment consisting of supportive counseling combined with parental support.

Study burden and risks

The proposed study can not be conducted without children and their parents. The costs for participants is limited. It is important to stress that participating children are included only when they themselves feel a need to undergo professional treatment. Thus, the extra time that is asked from them - apart from the time it takes for them to follow the treatment - is limited to the time necessary to complete the three follow-up assessments. The questionnaires that are administrered are all widely used in clinical practice. If participation in the study leads to an additional need for help, participants caretakers and - if so needed - the researchers will make sure that appropriate

help is provided.

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)
Elderly (65 years and older)

Inclusion criteria

Children aged 8-17 years; suffered the loss of a loved one at least six months ago; minimal score of 40 on the Dutch version of the Inventory of Complicated Grief for children (RVL-K); presence of a specific need for help in coming to terms with their loss.

Exclusion criteria

Severe suicide ideation with child or parent(s); receiving concurrent psychosocial help; alcohol- or drug abuse with child or parent(s); the child having mental retardation; child being diagnosed with autism, behavioural disorders (ODD, CD), or severe ADHD.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-05-2010
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO Date:	22-03-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-12-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 25798
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL30528.041.09
OMON	NL-OMON25798