Feasibility and efficacy of cognitive behavioural therapy for youths with parental support: a pilotstudy with a multiple baseline design.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON31798

Source
ToetsingOnline

Brief title
CBT for grieving youths: a multiple baseline study

Condition

- Other condition

Synonym
complicated grief, Problematic grief

Health condition

rouwgerelateerde klachten

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: Zon-MW programma Zorg voor Jeugd (1e ronde: vroegtijdige signalering en interventies)

Intervention

Keyword: Cognitive behavioural therapy, Grief, Prevention, Youth

Outcome measures

Primary outcome

The study will yield a first impression of the efficacy of the treatment by

examining these outcome measures; lessening of grief related complaints,

behavioural problems, depressive symptoms and post-traumatic stress reactions.

Also, a particular set of questions is aimed at measuring the feasibility of

the intervention for children, parents and therapists.

Secondary outcome

nvt

Study description

Background summary

In the Netherlands, every year thousands of children lose a family member in the first degree (parent, brother or sister). Research has shown that these children run a greater risk of subsequent psychological problems. Therefore, early identification and treatment of children that are likely to get stuck in processing their grief is desirable. Studies in children and adults show that problematic grief can be distinguished from depression and anxiety. Also, in adults it has been demonstrated that problematic grief calls for specific (grief-oriented) interventions. Similar research has not yet been performed in children. As a consequence it is likely that their problematic grief will not be detected and treated timely and adequately. The present proposed research

project is aimed at bridging this gap.

Study objective

The prime objective of this research project is to assess the feasibility of a low-threshold, accessible, preventive cognitive-behavioural therapeutic intervention with parental support for grieving children and their parents, and to get a first impression of its efficacy.

Study design

A multiple baseline will be used. The study will start with a pre-measurement, followed by baseline measurements, measurements at the end of every session and a final post-measurement. Baseline measurements are done to determine the baseline level of grief reactions and to exclude any changes in these reactions before the intervention starts. Children will be randomly assigned to one of three different baseline conditions with a duration of either 3,5 or 7 weeks, during which they are asked to complete a short Grief Checklist assessing the intensity of certain grief reactions. These grief reactions correspond to the proposed (DSM V-) criteria for Complicated Grief (Prigerson et al, 2007) Because the start of the intervention is not dependent on the baseline period, alternative explanations for changes in experienced grief (like cyclic influences and regression towards the mean) are less likely. The intervention starts after the baseline period. During the intervention the child will complete the Grief Checklist after each session. Also, at the end of every session clients (i.e., child and parent(s)) and the therapist will complete a number of questions regarding the feasibility of the session. The therapist will complete this for both the sessions with the child and those with the parent(s), whereas the child and parent will only complete these questions after each of their own sessions. At the end of the complete intervention there is one post-measurement (measurement 3).

Intervention

The children will receive 8 sessions of individual cognitive behavioural therapy; parents will receive 5 sessions of parental support.

Study burden and risks

The questionnaires ask only little time and effort from the participants and do not pose any risk to them. Many of the instruments are used routinely in everyday practice. Other instruments have been used extensively in research. Moreover, the completion of questionnaires will be guided by specially trained research assistants and special attention will be given to specific needs of the participants. The named burdens and risks do not outweigh the benefits of researching and developing an intervention aimed specifically at youths that

run a heightened risk of developing severe psychopathologies.

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 in the age of 8 to 18 years; suffered the loss of mother, father, sister or brother within the 6 to 12 months before entering the study; minimal score of 40 on the RVL-K or RVL-J questionnaire; presence of a specific need related to the experience of grief .

Exclusion criteria

Severe suicidal ideation with child or parent(s); being the recipient of other coincidental psychosocial help; alcohol- or drug abuse with parent(s) or children; the child having mental retardation, autism, behavioural disorders (ODD, CD) or substantial ADHD.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-09-2008
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO

Date:	19-02-2008
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL20025.041.07