

# A controlled study examining CBT for bereaved children.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON25798

### Source

NTR

### Health condition

The death of a loved one in childhood and adolescence is a risk factor for distress and dysfunction. This event has been associated with increased emotional problems including elevated depression, anxiety, and posttraumatic stress, as well as somatic complaints and behavioural problems (Dowdney, 2008; Kaplow, Layne, & Pynoos, 2012). An estimated 5% to 10% of children, experience clinically significant psychiatric problems following loss, including major depression, posttraumatic stress-disorder (PTSD), and Prolonged Grief Disorder (PGD) (Melhem, Moritz, Walker, Shear, & Brent, 2007; Melhem, Porta, Shamseddeen, Walker, & Brent, 2011).

PGD encompasses several symptoms including separation distress, preoccupation with thoughts about the lost person, a sense of purposelessness about the future, numbness, bitterness, difficulties accepting the loss and difficulty moving on with life without the lost person (Prigerson et al., 2009; Shear et al., 2011). Although PGD has mostly been studied among adults, a growing body of empirical studies has shown that children and adolescents can develop PGD symptoms, that can be reliably assessed, are distinct from normal grief, depression and anxiety, including PTSD, and are predictive of significant concomitant internalizing and externalizing problems (Brown & Goodman, 2005; Dillen, Fontaine, & Verhofstadt-Denève, 2008; Spuij, Prinzie et al., 2012; Spuij, Reitz et al., 2012).

Evidence that, in a small percentage of people, acute grief reactions turn into chronic debilitating distress, blocking reestablishment of normal routines, will likely lead to the inclusion of two bereavement-related disorders in the DSM-5, namely Adjustment Disorder Related to Bereavement, located in its main text, and Persistent Complex Bereavement-Related Disorder, located in its appendix (APA, 2000; APA, 2012; for discussions see Boelen &

Prigerson, 2012; Kaplow et al., 2012; Wakefield, 2012).

## Sponsors and support

**Primary sponsor:** Universiteit Utrecht

Faculteit Sociale Wetenschappen

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## Intervention

## Outcome measures

### Primary outcome

The primary goal is to examine the (preventive) effects of the two treatments on symptoms of prolonged grief disorder (PGD). Accordingly, the primary dependent variable is the intensity of PGD symptoms, as assessed by the Dutch version of the Inventory of Prolonged Grief (IPG). This measure will be administered at 5 assessment moments (i.e., before the first treatment session, after the last treatment session, and 3, 6, and 12 months after the last treatment session).

### Secondary outcome

Apart from the effects of the treatment on symptoms of Prolonged Grief Disorder, we will also examine the effects of treatments on conduct problems, 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 from loss have an increased chance of developing psychosocial problems. It is useful to develop interventions that are aimed at the reduction and prevention of such problems. Thus far, no such interventions are available.

This proposed randomised controlled trial (RCT) seeks to examine the effect of "Grief-Help", 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 "Grief-Help" 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.

We aim to include 160 children and their parents, aged 8-18 years, who all have suffered the loss of a loved one at least 6 months prior to inclusion into the study.

### **Study objective**

In the past years there is growing recognition of a syndrome of disturbed grief referred to as Prolonged Grief Disorder (PGD). Although mostly studied in adults, clinically significant PGD symptoms have also been observed in children and adolescents. To date, no effective treatment for childhood PGD yet exists. We want to investigate a cognitive behavioural therapy (CBT) treatment for bereaved children in a randomised controlled trial.

### **Study design**

The primary goal is to examine the (preventive) effects of the two treatments on symptoms of Prolonged Grief Disorder (PGD), assessed with the Dutch version of the Inventory of Prolonged Grief (IPG). This measure will be administered at all 5 assessment moments.

T1: Prior to treatment;

T2: After treatment;

T3: 3 months after treatment;

T4: 6 months after treatment;

T5: 12 months after treatment.

### **Intervention**

This proposed randomised controlled trial seeks to examine the effect of "Grief-Help", 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 ("Grief-Help" combined with parental support);
2. A control treatment consisting of supportive counseling combined with parental support.

## Cognitive behavioural therapy:

Cognitive behavioural therapy (CBT) for childhood PGD is based on a cognitive behavioural framework that postulates that symptoms of acute grief persist and exacerbate to the point of impairment in people with PGD. The treatment consists of nine individual sessions with the children combined with five counseling sessions with the (surviving) parent(s) or other caretaker(s).

The treatment is divided into five main parts, all described in a workbook the child uses throughout treatment. In the first part of treatment (titled "Who died?"), the child is invited to talk about facts of the loss and things she misses and wished she could still share with the lost person. An important aim of this part is to encourage confrontation with the reality and pain of the loss for the client, and for the therapist to gather information about maladaptive thinking and behavioural patterns that are to be addressed later on in treatment. In the second part of the treatment (titled "What is grief?") a task-model (comparable to Worden's task-model of grief (e.g., Worden, 1996)) is introduced. The model explains four tasks bereaved children are faced with in coming to terms with loss and the processes that may block achievement of these tasks (i.e., Task 1: Facing the reality and pain of the loss; Task 2: Regaining confidence in yourself, other people, life, and the future; Task 3: Focusing on your own problems and not only those of others; Task 4: Continuing activities that you used to enjoy). The model provides a framework for interventions applied in the next stages of the treatment. For instance, in the third part ("Cognitive Restructuring") cognitive restructuring is used to work on Task 2. The fourth part of the treatment (titled "Maladaptive Behaviours") targets maladaptive coping behaviours. Furthermore, graded exposure interventions are used to work on Task 1, problem solving skills are taught to address Task 3, and behavioural activation is used to help achievement of Task 4. In the fifth and final part of treatment ("Moving Forward after Loss") the skills that are learned during the treatment are reviewed, summarized, and written down. Additionally, a plan is discussed for continued practice of learned skills. Specific attention is paid to what the child could do, should his or her emotional problems exacerbate. Moreover, the child writes three letters to an imaginary or real friend as a means to facilitate consolidation of the learning process and that form a document of learned skills that can be consulted after treatment.

The aim of these parent sessions is to support them in coaching their child during her therapeutic process. To this end, the therapist and parent(s) review the workbook that guides treatment and any maladaptive thinking and behavioural patterns are discussed that may block the child's grieving process. In addition, parents are given assignments focused on spending more quality time with their child, improving communication skills, and sharing thoughts and feelings about the loss, in order to improve the parent-child relation.

## Supportive counseling:

Supportive counseling for childhood PGD is based on non-directive treatments for bereaved children (Bluestone, 1999; Ryan & Needham, 2001; Webb, 2002), bereaved adults (Boelen et al., 2007; De Keijser & Schut, 1991) and treatments for children with PTSD (Cohen &

Mannarino, 1996). Children are encouraged to express all their feelings and thoughts about the loss in a way that fits the child. The idea is that a bereaved child is confronted with a lot of feelings and thoughts about the loss and that it can learn to cope with those feelings by expressing them. Expressing can take the form of talking and playing. It is important that the therapist encourages the child to express their feelings in their own manner (e.g. playing or making a memory-book) and that the therapist facilitates the ways of expression of the child's choice.

As in the GriefHelp treatment, here too are nine individual sessions with the child, and five counseling sessions with the (surviving) parent(s) or other caretaker(s). The treatment is divided in 3 parts. First, the therapist will investigate which feelings and thoughts the child has about the loss and any maladaptive behaviours that the child expresses. As a second step, the therapist and child will have a closer look at all themes that have been identified in the first phase of the therapy. The child decides if she prefers to talk, play or express their feelings in any other possible way. In the last phase the therapist and child speak or play about saying goodbye to each other. There are no homework assignments given by the therapist.

Parents will talk to the therapist every two weeks. In the first session a plan is made about which themes parent(s) want to discuss and in what order that should happen. The therapist helps the parents to think about solutions for problems that they experience in supporting their child. There are no homework assignments for the parents in this treatment condition.

## Contacts

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## Eligibility criteria

### Inclusion criteria

1. Children aged 8-18 years;
2. Suffered the loss of a loved one at least six months ago;
3. Minimal score of 40 on the Dutch version of the Inventory of Prolonged Grief (IPG);
4. Presence of a specific need for help in coping to terms with their loss.

### Exclusion criteria

1. Severe suicide ideation with child or parent(s);
2. Receiving concurrent psychosocial help;
3. Alcohol or drug abuse with child or parent(s);
4. The child having mental retardation;
5. 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

## Recruitment

NL  
Recruitment status: Recruiting  
Start date (anticipated): 01-02-2010  
Enrollment: 160  
Type: Anticipated

## Ethics review

Positive opinion  
Date: 05-02-2013  
Application type: First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 35013  
Bron: ToetsingOnline  
Titel:

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

No registrations found.

### In other registers

Register	ID
NTR-new	NL3684
NTR-old	NTR3854
CCMO	NL30528.041.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35013

## Study results

## **Summary results**

N/A