

Cool Little Kids: Effectiveness of an early intervention program for anxiety-prone toddlers in the Netherlands

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23178

Source

Nationaal Trial Register

Brief title

CLK

Health condition

Prevention of anxiety disorders

Sponsors and support

Primary sponsor: None

Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Child anxiety

Secondary outcome

Study description

Background summary

Rationale: The high prevalence, adverse outcomes, and continuity of childhood anxiety disorders emphasize the importance of early, effective treatment programs. Research has indicated that behavioral inhibition (BI), the tendency to react with caution and hesitation to new stimuli, can be identified at a fairly young age and is a useful construct for detecting vulnerable, anxiety-prone children at an early point during their development. Australian studies indicated that a parent-education intervention for young behaviorally inhibited children called 'Cool Little Kids' (CLK) is very effective in reducing anxiety; however, this promising treatment has not yet been evaluated in The Netherlands.

Objective: To examine the (i) (cost)effectiveness of the CLK intervention on the reduction of anxiety symptoms and prevent anxiety disorders in young, anxiety-prone Dutch children compared to a book with general parenting advice, (ii) whether parental factors influence treatment outcomes, and (iii) parents' satisfaction and treatment integrity of this intervention.

Study design: The study uses a randomized controlled trial: parents of anxiety-prone children will be randomly allocated to either the Cool Little Kids parent-education intervention condition or they will receive a book with general parenting advice.

Study population: Participants are parents and teachers of anxiety-prone (inhibited) children between the ages of 2 and 6 years. Participants will be recruited via the GGD and professionals of other organizations that see (parents of) children aged 2-6 years within the municipality of Amsterdam, The Hague and possibly other municipalities as well.

Intervention: The intervention condition CLK consists of a six-session parent-education program. This program will be conducted in groups of approximately six sets of parents and focuses on educating parents about the nature of BI and anxiety and teaching them techniques to reduce these behaviors in their children. Each session lasts approximately 90 minutes. The active control condition consists of a book with general parenting advice that parents will receive at home.

Main study parameters/endpoints: Main study outcome is child anxiety. This is measured by a clinical interview and several parent and teacher questionnaires at pre-intervention, post-intervention, and 6- and 12-months follow-up. In addition, children themselves will be asked to fill out an easy and age-appropriate self-report interview instrument measuring anxiety symptoms.

Study objective

Given the results of previous studies, we predict that children in the CLK intervention condition will exhibit a significant reduction in anxiety symptoms compared to children in the monitoring condition. Secondly, we predict that treatment outcomes will be mediated through effects of the intervention on parent anxiety and overprotection. Thirdly, we predict that parents will be satisfied with the program and that there will be high levels of treatment integrity. Finally, we predict that the CLK intervention is cost-effective.

Study design

pre-intervention, post-intervention, 6 months follow-up, 12 months follow-up

Intervention

The intervention condition consists of a six-session parent-education program, which is the Dutch translation of the Cool Little Kids program of Rapee et al. (2005; 2010). The sessions will be conducted in groups of approximately six to eight sets of parents and aims to teach parents to reduce inhibited and anxious behaviors in their children. More specifically, the program focuses on psychoeducation about behavioral inhibition and anxiety (session 1), parent management strategies (session 2), and cognitive restructuring and exposure techniques (sessions 3 to 6). The first four sessions are held weekly, with the fifth session two weeks later, and the final session after one month after that. Each session lasts approximately 90 minutes.

Participants in the active control condition will receive the book 'How2talk2kids' (Faber & Mazlish, 2007). This book offers parents practical effective communication skills, based on theory developed by psychologist Dr. Haim Ginott. Amongst other things, the book discusses the handling of negative emotions, setting boundaries, effective praise and gaining more self-confidence as a parent.

Contacts

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Eligibility criteria

Inclusion criteria

Parents of children are included in the study if the following inclusion criteria are met:

- a) Their child is between 2 and 6 years old.
- b) Their child scores above the BIQ-SF cut-off score of 42.
- c) Written informed consent by the parents is given.
- d) The parent has a sufficient command of the Dutch language.

Exclusion criteria

Parents of children are excluded when:

- a) When their child is currently being treated for anxiety disorders.
- b) When the parents are in acute psychiatric care.
- c) When the screening indicates that the child suffers from other child psychiatric diagnoses such as trauma related disorders.

These children will be further referred to specialistic mental health care.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-09-2021
Enrollment:	170
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date: 26-07-2021

Application type: First submission

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

NTR-new NL9633

Other METC LDD and the Psychology Research Ethics Committee of Leiden University :
N21.079 (METC) & 2021-07-08-L.J. Vreeke-V2-3346 (Psychology Research Ethics
Committee)

Study results