Optimizing online CBT-interventions for anxious children

Published: 16-05-2018
Last updated: 15-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON50712

Source
ToetsingOnline

Brief title
Optimizing online CBT-interventions for anxious children

Condition

- Anxiety disorders and symptoms

Synonym
being afraid, being scared

Research involving
Human

Sponsors and support

Primary sponsor: Open Universiteit
Source(s) of monetary or material Support: Fonds Psychische Gezondheid

Intervention

Keyword: anxiety, CBT, mediators of change, online

Outcome measures

Primary outcome

- Anxiety

- Cognitive developmental level

- Cognitions

- Coping skills

- Avoidance

Secondary outcome

n.a.

Study description

Background summary

Anxiety disorders have a high continuity and have the highest prevalence rate of psychiatric disorders in children. Cognitive Behavior Therapy (CBT) is an effective method for intervening in high levels of anxiety. However, children cannot profit optimally from CBT, because of three barriers . First, only 20 % of the children with anxiety disorders receive a training or treatment to treat the disorder. This is due to the accessibility and the availability of treatment. Second, the working mechanisms of CBT in children have not been identified. Based on the theoretical models of CBT in adults, children are offered strategies to change their cognitions (to have less dysfunctional cognitions) and to reduce avoidance behavior. However, empirical studies on the working mechanisms of cognitive and behavioral strategies in children are only limited and incomplete. Third, interventions are not been sufficiently adapted to suit the specific needs of children, because it is not clear in which children CBT works well, and in which children CBT works less well. Possibly, the developmental level of children strongly affects the amount to which children can profit from CBT.

Study objective

The current project aims to address the three barriers that obstruct children from profiting optimally from CBT. For this purpose, an easy accessible, online, CBT-based training for anxious children (aged 8-13 years) will be developed and assessed on its efficacy by performing a randomized controlled trial (barrier 1). It will be examined whether the training sorts its effect via reducing dysfunctional cognitions and via reducing avoidance behavior (barrier 2). Finally, the effect of the cognitive developmental level on the training*s working mechanisms will be stdueid (barrier 3). Both increasing CBT*s availability for anxious children by offering an online training, and providing insight into the working mechanisms and elements that affect CBT*s efficacy, will contribute to the optimalisation of CBT for anxious children.

Study design

A longitudinal randomized intervention study

Intervention

The online training *Learn to Dare!* is based on the paper version of *Learn to Dare!* (Simon & Bogels, 2014), which is an evidence based low-level intervention and includes common CBT-elements. The training will be developed for children aged 8-13 years with an increased level of anxiety, mild or severe specific phobias or other DSM-5 anxiety disorders of moderate severity. The entire training will be offered online via an online platform and there will be no face-to-face meetings. The exposure exercises will be offered via video examples and written instructions. Communication with the trainer will take place mainly via e-mail, but can also be offered via a (video) chat function. *Learn to Dare!* will be offered to individual children, but children can communicate via a forum if they want to. The training does not contain any parent sessions. Parents will, however, be informed about the content of the training and parent will play a role in stimulating the child to continue taking part in the training.
The therapists who provide the training, will work via standardized instructions that have been described in detail. They also received several basic instructions about performing cognitive restructuring and exposure in children in this age group and with these problems. Suitable trainers are bachelors or masters in psychology, orthopedagogy, social workers, or teacher mentors.
The training consists of eight weeks. The child will spend approximately 2 hours per week on this training. The children work on a weekly basis on exercises, together with their trainer, and also work in the online module independently. During session 1, the trainer and the child get to know each other, the child gets an overview of the training and the role of the parent will be explained in more concrete detail. During session 2, the child and the trainer decide together which two anxieties will be given attention during the training, based on the info from the diagnostic interview and questionnaires.

After this, via an automated randomization, it will be decided which anxiety will be the focus of the first part of the training (exposure) and which anxiety will be the focus of the second part of the training (cognitive restructuring). During session 3, the fearful expectations of the child (what does the child think will happen) of both anxieties will be made explicit. The trainer strongly supports and directs the child during this process in order to validly and safely test the child*s fearful expectations. During session 4 and 5, the child practices with its first fear by exposing himself to it. To promote generalization of what the child will learn, practicing will be done in different manners and in different contexts. After each exposure, consolidation of what was learned will be promoted by judging the extent to which the fearful expectation came true. During session 6 and 7, the child will learn cognitive restructuring. In session 6, the focus will be on learning general cognitive restructuring skills: the children will learn how to identify dysfunctional thoughts and adapt the dysfunctional thought into a functional one. In session 7, the cognitive restructuring techniques will be applied to the child*s second fear. During session 8 the child and the trainer focus on how to handle possible future anxieties and attention will be given to saying goodbye to each other.

Study burden and risks

Measurements only: 10 hours time investment
Measurements + intervention = 10 + 16 = 26 hours time investment

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Children from a community sample who have an increased level of anxiety, but have not been referred for their anxiety (non-clinical)

Exclusion criteria

Children with severe anxiety disorders: these children received an anxiety diagnosis with a high level of severity (on a severity scale from 0-8, these children score 7 or 8)

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):	05-12-2018
Enrollment:	240
Type:	Actual

Ethics review

Approved WMO Date:	16-05-2018
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL60801.068.17