Early Intervention and Treatment Prediction in Childhood Specific Phobias: Combining One-Session-Treatment with App-based Technology

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The main objective of this study is to evaluate what a newly developed, theory-driven, personalized app, adds to the short- and long-term effectiveness of the existing OST intervention in terms of anxiety symptom reduction and relapse.Three...

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

Summary

ID

NL-OMON55077

Source
ToetsingOnline

Brief title
KIBA - Kids Beat Anxiety

Condition

- Anxiety disorders and symptoms

Synonym
anxiety, Specific phobia

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden

Source(s) of monetary or material Support: Ministerie van OC&W,ZonMW,Trifork B.V. draagt bij door de app gratis te ontwikkelen. Trifork geeft geen financiële bijdrage aan het project. Eigendom van de app blijft bij de hoofdonderzoeker.

Intervention

Keyword: Childhood Specific Phobia, Exposure, Mobile-application, One-session-treatment

Outcome measures

Primary outcome

The main study parameters will be the clinician severity rating of the specific phobia, an assessment of behavioral avoidance of the feared stimulus with the Behavioral Avoidance Task, the Sheehan Disiability questionnaire to assess interference with daily life and a form on which the specific fear(s) are listed with a rating of how afraid the child is of this object/situation and how often he/she avoids this.

Secondary outcome

In addition to the primary measures several secondary measures will be administered in order to describe the population and investigate possible underlying mechanisms and predictors of treatment:

Child

- Interpretation bias will be assessed wit an Ambiguous Scenarios Task (AST)

- Sensation seeking will be assessed with the Sensation Seeking Scale for Children

- Habituation is assessed with a 0-8 subjective units of distress scale (SUDS) about how scared the child is, is administered multiple times

- Expectation violation/harm beliefs are assessed by asking the child several

questions throughout treatment regarding his/her beliefs about what might happen and what did actually happen

- Emotional problems will be assessed with the Short Mood and Feelings Questionnaire (SMFQ)

- ambivalent and avoidant reactions to attachment situations assessed with the Experiences in close relationships-Child Questionnaire

- Imagery or flash forwards will be assessed with a short interview and a short questionnaire

Child and Parent

- Parent and child self-efficacy will be assessed with the General Self Efficacy Questionnaire (GSE) and an adapted version for children

- Comorbidity will be assessed with a structured clinical diagnostic interview at intake

- Comorbid anxiety will be assessed with the Spence Children's Anxiety Scale (SCAS)

- Motivation for treatment will be assessed using the Motivation Questionnaire

- Credibility and expectancy of the treatment will be assessed with the Credibility and Expectancy Questionnaire (CEQ-C/P)

- Treatment compliance/time practiced; parents and children are asked how often they have practiced

- Treatment satisfaction will be assessed with three self and parent report items

- usability of and satisfaction with the app assessed with a short questionnaire (only in app condition)

- Parental coping with negative emotion assessed with an adapted version of the Child Development Questionnaire (CDQ)

-Positive mental health assessed with the Positive Mental Health Scale (PMH)

Parent

- Comorbid autism spectrum symptoms will be assessed with the Autism Spectrum Quotient (AQ)

- parental mentalization about their own functioning and the functioning of their child assessed with the Reflective (Parental) Functioning Questionnaire

- Parental mental health problems will be assessed using the Depression Anxiety Stress Scales (DASS) and a form on which specific fear(s) an be listed with a rating of how afraid the parent is of this object/situation and how often he/she avoids this.

- Demographic information will be gathered through a questionnaire

- Fear of Negative Child evaluation will be assessed with the Fear of Negative Child Evaluation Questionnaire (FNCE-Q)

Researcher

- Parental coping with the child's negative and positive emotions will be assessed by rating video clips of the homework session in which children and parents discuss how they will keep practicing exposure at home and what rewards

the child can earn.

- Treatment integrity will be assessed by scoring recorded therapy sessions

Researcher, parent and child

The (Clinical) Global impression and improvement scale will be used to assess

perceived improvement by therapist, parent and child

Study description

Background summary

Specific phobia is de most common mental disorder in children and can interfere greatly with daily life. Many children with a specific phobia do not receive the treatment they need. In addition, not all children that do get treatment profit enough from the treatment. The aim of the current study is to study how we can offer a treatment that is effective, easily accessible for everyone and does not stigmatize.

Study objective

The main objective of this study is to evaluate what a newly developed, theory-driven, personalized app, adds to the short- and long-term effectiveness of the existing OST intervention in terms of anxiety symptom reduction and relapse.

Three secondary objectives of this study are:
1) Replication of the effectiveness of standard OST for childhood specific phobias in a Dutch and German sample.
2) Investigating underlying mechanisms of OST, including self-efficacy, interpretation bias, and habituation and expectation violation.
3) Exploring possible predictors of treatment outcome, by examining child and family factors.

Study design

This study employs a multicenter pragmatic randomized controlled trial with 2 active treatments, and a 3-week waiting baseline control period. Accessors will be blind to treatment condition.

Intervention

The OST will be a 3-hour session in which the child is gradually exposed to the feared object or situation. After the OST, one group will receive an app that helps the child to complete exposure exercises for 4 weeks following treatment, the other group is instructed by the therapist to keep practicing at home but will not receive the app to assist them with this (Treatment as Usual).

Study burden and risks

A direct benefit for the children participating in this study, is that they will receive an effective intervention (the OST) to treat their specific phobia. Additionally, a potential indirect benefit of participating is that in case the specific phobia has not reduced enough after the intervention or if children experience different mental problems, they will be offered additional care either by a booster session, re-intake in the current or redirection to another mental health care center. In this way the current study may lower the threshold to seek help for any additional problems as well.

A burden for the participating children and their parents is that they have to visit the clinic six times during the study. However, five out of six visits are part of care as usual. The burden of participation in this study is comparable to other treatment studies in childhood psychiatry. The burden of the treatment received in this study is less then with treatment as usual, since the intervention that will be used consists of only one massed exposure session, a preparation session and homework instructions instead of the usual 12 session interventions. This leads to improvements in a shorter period of time and in this way likely prevents more distress in daily life sooner than without this treatment.

The only risk of participation is brief distress during the exposure exercises. The level of distress during these exercises will not exceed the distress children experience when they encounter the phobic stimuli in daily life or the distress experienced in regular treatment (in which exposure exercises are also an important component). To the best of our knowledge, using an online platform to deliver the maintenance program of an intervention doesn*t bring any risks. In addition, a recent pilot study in the United States showed that an exposure focused app was an acceptable addition to standard anxiety treatment for children, parents and therapists. No adverse effects were reported.

Because of the reasons stated above we are of the opinion that the benefits of participating outweigh the burden and risks of participation. Additionally, we think the current research question is most relevant in children, as opposed to adults, since specific phobias usually develop in early childhood. Therefore, we are restricted to the use of the proposed age group.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adults (18-64 years)
Children (2-11 years)

Inclusion criteria

(a) Meet DSM-IV criteria for a specific phobia with a severity score of 4 or higher determined with the anxiety disorders interview schedule (ADIS-IV-C/P)
(b) At least one parent/caregiver is willing to be involved in the study and active consent is obtained from both legal guardians and of the child if 12 years or older
(c) Fluent in German (Bochum site), Dutch (sites in the Netherlands) or English (all sites)
(d) 7 - 14 years of age

Exclusion criteria

(a) A comorbid problem that requires attention/treatment more immediate than the specific phobia (e.g. severe depressive symptoms, suicidal ideation, psychosis, trauma)
(b) Child hazard (e.g. suspected child maltreatment)
(c) Problems with understanding the procedure (e.g. being intellectually unable or nonverbal)
(d) Changes in anxiety medication during the treatment
(e) Other treatment targeting anxiety complaints at the time of the study

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-02-2021
Enrollment:	137
Type:	Actual

Ethics review

Approved WMO

Date:	24-03-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	01-10-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-10-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-01-2024
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

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: 22841
Source: NTR
Title:

In other registers

Register	ID
Other	NL 9216
CCMO	NL72697.018.20

Register	ID
OMON	NL-OMON22841