One-session treatment for children with a specific phobia

Published: 25-01-2021
Last updated: 15-05-2024

1) the OST is superior to the 3-weeks waiting period 2) the OST+app is superior to the OST-only at post-treatment and at follow-up

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

Summary

ID

NL-OMON22841

Source
NTR

Brief title
OST-kids

Condition

- Anxiety disorders and symptoms

Health condition

specific phobia

Research involving
Human

Sponsors and support

Primary sponsor:	ZonMw
Secondary sponsors:	Universiteit Leiden
Source(s) of monetary or	Trifork B.V.

material Support:

Intervention

- Psychosocial intervention

Explanation

Outcome measures

Primary outcome

- ADIS diagnosis specific phobia

- Severity rating of ADIS for specific phobia

- questionnaire that measures self-reported fear, avoidance and severity of specific phobia

- Adapted Sheehan Disability scale, self-reported burden of specific phobia

- Behavioral Approach Task

Secondary outcome

- Spence Anxiety Scale (SCAS)

- Fear Survey Short form (FSSC-R-SF)

- Short mood and feelings questionnaire (SMFQ)

- Clinical Global Impression Scale (CGI)

Study description

Background summary
Background: With estimated prevalence greater than 10%, specific phobia is the most common and also one of the earliest onset mental disorders in children. Specific phobia is characterized by an excessive and persistent fear of a specific object or situation (APA, 2013) and is a strong predictor for the onset of a range of other disorders. For example, children with a specific phobia have over four-times greater chance of developing other anxiety disorders, including panic disorder and generalised anxiety disorder and over two-times more chance of developing affective disorders including bipolar disorder, and depression. Early recognition and intervention is thus very important in this at-risk group of children, but

unfortunately, very few children with phobias receive adequate treatment. Furthermore, there is limited research on predictors of treatment or on underlying active ingredients of anxiety that can help personalize treatment, and the few existing studies examined these factors in relative isolation (Klein et al., 2011, 2012, 2014, 2017; in press). What we need is an easily accessible, evidence-based early intervention for children that does not stigmatize and contributes to the strengthening of self-control of children and parents.

Goals: To improve early recognition and intervention for specific phobias and to personalize their treatment among children. More specifically, we will test: 1) the efficacy of a low-cost evidence-based early intervention (One-Session Treatment, OST) for specific phobias in a population of Dutch and German children, 2) whether a newly developed, theory-driven personalised app, supporting the intervention, adds to the short- and long-term effectiveness of the intervention in term of anxiety symptoms reduction and functioning, 3) what active underlying mechanisms of OST can by identified, including biased cognitive processes.

Methods and Study Type: This study employs a multicenter pragmatic randomised controlled trial with 2 active treatments, and a 3-week waiting baseline control period. In total, 173 children will be included who have a clinical specific phobia with a request for help between the ages of 7 and 14 years. The two active treatments will either be 1) a combination of the face-to-face OST supported by an app that helps children to complete exposure exercises for 4 weeks following OST, or 2) face-to-face OST only without the personalized app. The interactive app will be therapist-supported, personalized to, for example, age, gender, subtype of fear of the child and contain movie fragments of the child's own OST session. Additionally, the study includes cognitive and behavioral measures and follows a multi-informant approach including reports from children, parents, and therapists.

Innovation and Significance: This project will be the first study worldwide to test an early intervention One-Session Treatment for children supplemented by a therapist-supported personalised app. It is the next step to develop short, low-cost, efficient and effective early interventions for high-risk children. By combining clinical studies with fundamental research on childhood specific phobias, we can further develop the efficacy of treatments. Earlier and more successful treatment of childhood specific phobias will reduce the suffering of children and their families, and may also prevent the development of mental health problems and improve functioning later in life.

Study objective
1) the OST is superior to the 3-weeks waiting period

2) the OST+app is superior to the OST-only at post-treatment and at follow-up

Study design
Randomized controlled trial, Active, Parallel

Intervention
The one session treatment is an individualised intensive form of CBT and consists of one 3-hour exposure session. The app consists of individualised daily exposure exercises to be used during the 4-weeks of home practice under supervision of the parents and therapist.

Study burden and risks

Time investment of families. No expected risks

Contacts

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Eligibility criteria

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

Inclusion criteria

1) A primary diagnoses of specific phobia according to the DSM-5 2) one or both parents are willing to be actively involved in the study, and active consent is obtained of both legal guardians 3) age 7-14 years 4) good command of Dutch or German

Exclusion criteria

1) currently co-morbid problem that requires immediate attention/treatment 2) child hazard 3) problems with understanding the procedure (e.g., be intellectually unable) 4) changes in anxiety medication during treatment 5) other treatment targeting anxiety complaints during the treatment

Study design

Design

Study phase:	N/A
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:	173
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Plan description
n/a

Ethics review

Approved WMO

Date:	24-03-2020
Application type:	First submission
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

ID: 55077
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9216
CCMO	NL72697.018.20
OMON	NL-OMON55077

Study results

Summary results
n/a