Optimizing exposure in the treatment of anxiety in youth: Facing fears in-session or out-session?

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

Summary

ID

NL-OMON45412

Source
ToetsingOnline

Brief title
Facing Fears

Condition

- Anxiety disorders and symptoms

Synonym
specific fear, Specific phobia

Research involving
Human

Sponsors and support

Primary sponsor: Rijksuniversiteit Groningen
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Anxiety, Children, Effectiveness, Exposure

Outcome measures

Primary outcome

The main study parameter is specific phobia diagnosis of the animal/situational

subtype.

Secondary outcome

Secondary:

Subjective level of fear

Fearful cognitions

Bodily tension

Avoidance

Coping

Approach behaviour

Self-efficacy

Other:

Healthcare costs

Quality of life

Specific phobia severity

General comorbidity

Comorbid anxiety and depression

Parental fear

Parental modelling behaviours

Demographic variables

Credibility and expectancy of the treatment

Treatment compliance

Treatment satisfaction

Treatment integrity

Therapeutic alliance

Study description

Background summary

Anxiety problems are a major concern of youth mental health given that the prevalence of anxiety disorders in Dutch children aged up to 12 is approximately 4 to 8 percent (Nederlands Jeugd Instituut, 2016). In this group, specific phobias are among the most common. Cognitive Behavioral Therapy (CBT) with exposure as its key ingredient, takes a prominent place in national guidelines for the treatment of anxiety disorders. These guidelines are based on empirical support that exposure is effective in the treatment of specific phobia (Wolitzky-Taylor et. al. 2008; Craske, 1999). Yet, despite the empirical evidence of its efficacy, a gap between theory and practice remains, with exposure-based interventions CBT being underused in clinical practice. For example, a recent Dutch survey found that exposure was mostly practiced outside the formal therapy sessions as homework assignment (Sars & van Minnen, 2015). It is questionable whether this is effective, given that it might be hard for children to do these assignments independently (e.g., without the help of a therapist or their parents). This study therefore proposes to evaluate the effectiveness of different degrees of therapist and parent involvement during exposure, from comparing therapist supported exposure to with self-supported exposure with or and without the use of parents as co-therapists.

Study objective

The primary goal of this study is to evaluate whether therapist supported in-session exposure exercises are more effective than individual out-session exposure exercises, or parent supported out-session exposure exercises. The secondary goal is to find child, parent and therapist factors that possibly relate to the effectiveness of the exposure exercises.

Study design

Single-blind parallel randomized controlled trial (RCT) with three parallel groups (intervention versus intervention versus intervention).

Intervention

Three conditions receiving each three sessions:
A. 1 Psycho-education session (PE) + 2 exposure sessions with the therapist (EXP)
B. 1 PE + 2 EXP sessions in which the homework exercises for the child are prepared and evaluated
C. 1 PE + 2 EXP sessions in which the homework exercises for the child together with the parent are prepared and evaluated

Study burden and risks

The potential value of the current study is that we gain insight in the most optimal degree of therapist and parent involvement during exposure in the treatment of anxiety in youth. Regarding this insight we can provide therapists with evidence-based recommendations for optimizing their treatment of children with anxiety disorders. A possible direct benefit of participating in this study, is that we offer children with a specific phobia an effective intervention to treat their anxiety disorder. A possible indirect benefit of participation is that in case the provided intervention was not sufficient in reducing the specific phobia, participants will be invited for a re-intake and provided with additional care at the current or another mental health care center. A burden for the participating children and their parents is that they have to visit the mental health care center seven times during participation in this study. However, given that four out of the seven visits are part of care as usual, we consider this burden justifiable. It*s the intake, treatment sessions and a number of questionnaires in the assessments, like the RCADS, SCAS and SEQ, that are part of care as usual. In addition, the used intervention is less of a burden than care as usual, given that the current intervention exists of three sessions, whereas the care as usual intervention consists of twelve sessions. Therefore, we only consider the additional interviews, questionnaires and behavioral test during the assessments as a direct burden for participation. However, the duration of the assessments is limited to 80 minutes, with a number of questionnaires shortened to Visuals Analogue Scales (VAS). Therefore the burden for participating in this study is comparable to other studies in the child- and adolescent psychiatry. In addition, the only risk of participation is short-lived distress during the exposure exercises. This level of distress will not exceed stress as experienced when encountering the feared object or situation in daily life or in regular treatment. Therefore, we are of opinion that this burden and risk outweigh the potential benefits of less anxious children. Moreover, we consider the research question most relevant to children, and less relevant to adolescents or adults, who generally do not involve their parents in treatment.

This means that for answering this question we are restricted to group relatedness.

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

* Aged between 8-12 years old and in primary school
* Sufficient knowledge of the Dutch language
* Meeting the criteria of a specific phobia of the situational or animal subtype

Exclusion criteria

* Absence of permission of legal guardian(s)
* Currently in treatment or receiving medication for anxiety
* Received Cognitive Behavioural Therapy for anxiety in the past 12 months
* Specific phobia that do not fall under the situational or animal subtype
* Different and more urgent request for help
* (Risk of) suicidality, psychosis or domestic violence

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-08-2017
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	28-06-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	30-04-2019

Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL59889.042.16
Other	wordt aangemeld bij NTR