# 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

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Parental modelling behaviours

Parental fear

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 guestionable 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).

#### 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