Optimizing exposure in the treatment of anxiety in youth: Facing fears in big or small steps?

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

Summary

ID

NL-OMON49153

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: Adolescents, Anxiety, Effectiveness, Exposure

Outcome measures

Primary outcome

The main study parameter is specific phobia diagnosis of the of the animal,

natural environment, medical, situational or other subtype.

Secondary outcome

Secondary:

Out-session fear

Fearful cognitions

Bodily tension

Avoidance

Coping

In-session fear

In-session harm expectancy

Approach behaviour

Self-efficacy

Other:

Healthcare costs

Quality of life

Specific phobia severity

General comorbidity

Comorbid anxiety and depression

Demographic variables

Credibility and expectancy of the treatment

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 ages 8 to 12 is 4-8 percent and in Dutch adolescents aged 12 to 18 is approximately 10 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-Taylora et al. 2008; Craske, 1999). Therapists help phobic adolescents to overcome their fear by gradually, step by step, working their way up from less scary situations to situations that cause a greater deal of anxiety (Olatunji, Deacon, & Abramowitz, 2009). Although it is clear that exposure is effective, the size of the steps to be taken in this process remains unclear. However, there are multiple reasons to assume that one or the other works best. Clinicians argue that On the one hand, adolescents will soon gain trust in their own abilities when taking small steps, which enlarges their feeling of self-control (e.g., self-efficacy). On the other hand there is the risk that these small steps might be experienced as safety behavior and avoidance, which is counterproductive to the essence of exposure (i.e., overcoming the fear) and undermines the potential effect (Hedtke, Kendall, & Tiwari, 2009). This might result in either a longer treatment or insufficient treatment benefits. Considering this risk, and the fact that confrontation with a feared object or situation in daily life is also not a step-by-step process, this study proposes to evaluate the optimal dosage of exposure, by studying whether exposure in big steps is more effective than exposure in small steps.

Study objective

The primary goal of this study is to evaluate whether exposure in big steps is more effective than a small step-by-step approach. The secondary goal is to

find child, parent and therapist factors that possibly relate to the effectiveness of the exposure exercises.

Study design

Singe Blind Randomized Controlled Trial (RCT) with two parallel groups (intervention versus intervention).

Intervention

Two conditions recieving each three sessions:
A. 1 Psycho-education session (PE) + 2 exposure sessions in big steps working towards treatment goal
B. 1 PE + 2 EXP sessions in small steps working towards treatment goal

Study burden and risks

The potential value of the current study is that we gain insight in the most optimal dosage of exposure in the treatment of anxiety in youth. Regarding this insight we can provide therapists with evidence-based recommendations for optimizing their treatment of adolescents with anxiety disorders. A possible direct benefit of participating in this study, is that we offer adolescents 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.

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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 8-17 years old and in primary or secondary school • Sufficient knowledge of the Dutch language • Meeting the criteria of a specific phobia of the situational or animal subtype either one of the following subtypes: o Animal: fear of pets, insects, spiders, small reptiles and amphibians, farm animals, birds o Natural environment: fear of heights, darkness, thunder, fire o Medical: fear of blood, needles, medical or dental care, injury, choking o

Situational: fear of enclosed places, elevators, escalators, using one specific type of transportation (cars, buses, trains, ships) o Other: fear of loud sounds, fireworks, costumed characters, amputated limbs, fruit etc

Exclusion criteria

• Absence of permission of legal guardian(s) • Currently in treatment or receiving medication for anxiety • Received CBT for anxiety in the past 12 months • Specific phobia that do not fall cannot be treated with either in-session or out-session exposure due to absence of available phobic stimuli, for example: o Animal: fear of zoo animals o Natural environment: fear of water, lightning, storms, fires o Medical: fear of invasive medical procedures, infection, vomiting o Situational: fear of using multiple types of transportation (cars, buses, trains, ships), plane flights o Other: fear of open spaces etc. • 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):	04-10-2017
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	21-08-2017
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)
Approved WMO Date:	10-12-2019
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	NL59986.042.16
Other	wordt aangemeld bij NTR