

Core elements of Cognitive Behavioural Therapy in treating speech anxiety in youth: Facing fears by focussing on behaviour, body, or mind?

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

Summary

ID

NL-OMON45453

Source

ToetsingOnline

Brief title

Talk like that!

Condition

- Anxiety disorders and symptoms

Synonym

fear of public speaking, Social anxiety disorder

Research involving

Human

Sponsors and support

Primary sponsor: Rijksuniversiteit Groningen

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Anxiety, Cognitive restructuring, Exposure, Relaxation

Outcome measures

Primary outcome

The main study parameter is level of fear of performance/public speaking symptoms.

Secondary outcome

Secondary study parameters are subjective level of fear, fearful cognitions, bodily tension, avoidance, coping (possible mediator variables), social phobia diagnosis, approach behavior, and self-efficacy. Tertiary study parameters are healthcare costs and quality of life (cost-effectiveness). Other study parameters are social phobia severity, comorbid anxiety and depression, and demographic variables (possible moderator variables); and credibility and expectancy of the treatment, treatment satisfaction, treatment compliance, and treatment integrity (treatment characteristics).

Study description

Background summary

Anxiety problems are a major concern of youth mental health given that the prevalence of anxiety disorders in Dutch adolescents aged 12 to 18 is approximately 10 percent (Nederlands Jeugd Instituut, 2016). In this group, social phobia like speech or performance anxiety are among the most common. Intervention programs based on the principles of exposure-based Cognitive

Behavioral Therapy (CBT) have proven to be the most effective and most applied in therapy for social anxiety among adolescents. Thus far, research has mainly focused on effectiveness of *intervention packages* consisting of multiple CBT elements (i.e., exposure plus cognitive restructuring and relaxation exercises). The most common CBT element in current intervention packages for anxiety in youth is exposure, which is often only applied after providing the child with cognitive restructuring (CR) and relaxation exercises (RE). However, although most empirical evidence supports the value of the use of exposure, there is hardly empirical evidence for the additional value of CR or RE (Reynolds, Wilson, Austin, & Hooper, 2012). In addition, it is unclear whether the combination of these elements with exposure is counterproductive compared to the use of exposure only. After all, without lengthening the treatment, the addition of CR and/or RE will leave the therapist and child with less time to spend on exposure exercises. This study proposes to evaluate the effectiveness of these three different types of CBT-elements in the treatment of speech/performance anxiety among adolescents.

Study objective

The primary goal of this study is to evaluate which elements add to the effectiveness of current CBT programs. Second, it will be investigated whether the effect of exposure is reduced by the addition of cognitive restructuring and relaxation exercises. In addition, it will be explored how a given element is effective (i.e., mediation), by investigating which dimension of anxiety (approach/avoidance behavior, cognitions or bodily tension) is changed by which specific element, in a group of adolescents with the performance/public speaking subtype of social phobia.

Study design

Randomized Controlled Trial with each three parallel groups (intervention versus intervention versus intervention).

Intervention

Adolescents will be randomly assigned to one of the three conditions. All adolescents will be offered a psycho-education session on anxiety, social phobia and exposure. Following this session either four exposure sessions (condition A) or two exposure session and two additional sessions are offered. The additional session are either two cognitive restructuring sessions (condition B) or two relaxation sessions (condition C). Each session will be given in groups consisting of five to eight participants. Every session will take up to an hour and is implemented by a psychologist assisted by a master student in psychology, who will receive training and supervision by a certified CBT therapist.

Study burden and risks

The potential value of the current study is that we gain insight in the effectiveness of three most commonly used CBT elements in the treatment of social anxiety among adolescents. Regarding this insight we can provide therapists and teachers 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 speech or performance anxiety an effective intervention to treat their fear of public speaking.. A burden for the participating adolescents is that they have to attend the three assessments and five treatment sessions. However, we will try to schedule these meetings right after school, to keep this burden justifiable. In addition, given that five out of the eight meetings (i.e. the treatment sessions) and a number of questionnaires in the assessments (the RCADS and SEQ) are part of care as usual, we consider the burden of participation to be fair. Moreover, the used intervention is less of a burden than care as usual, given that the current intervention exists of five 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 burden for participation. However, the duration of the assessments is limited to 80 minutes, with a number of questionnaires shortened to Visual 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 a public speaking situation in daily life or in regular treatment. In addition, there is a common view that the marked stigma is one of the major drawbacks in conducting intervention studies at school. However, a recent study found that a similar program for depression at school was not associated with marked stigma in absolute terms (Rapee et al., 2006). We assume that the same holds for providing a program for speech anxiety at schools. In sum, we are of opinion that this burden and risk outweigh the potential benefits of less anxious adolescents. Moreover, we consider the research question most relevant to children and adolescents, since we cannot be sure whether findings in adults can be generalized to youth. 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)

Inclusion criteria

- * Adolescents are aged between 12-15 years old
- * Sufficient knowledge of the Dutch language
- * Subclinical or higher level of the fear of performance/public speaking subtype of social phobia (SPAI-C PPF score >6)

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
- * Past or current diagnosis of autism/ADHD
- * Different or more urgent request for help
- * (Risk of) suicidality or suicidal ideation

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:	Recruitment stopped
Start date (anticipated):	04-09-2017
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO	
Date:	27-07-2017
Application type:	First submission
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	NL60377.042.16
Other	wordt aangemeld bij NTR