

Effectiveness of childhood social anxiety interventions

Submission date 16/01/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/01/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/04/2023	Condition category Mental and Behavioural Disorders	<input checked="" type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Social anxiety is characterized by a fear of negative evaluation by peers, distress in social situations and the avoidance of social situations that might provoke anxiety. Social anxiety in childhood and adolescents has been related to various negative wellbeing outcomes (such as fewer friendships and impaired social skills). To prevent and treat social anxiety, many interventions have been developed. Two dominant intervention components are generally included in these programs: exposure and cognitive restructuring. Currently, little evidence is available for the separate effectiveness of these intervention components.

To better understand the effectiveness of interventions aimed at reducing social anxiety in children, this study aims to assess the separate and combined effects of two dominant intervention components: exposure and cognitive restructuring. These two components are generally included side by side in interventions aimed at reducing (social) anxiety.

Who can participate?

Eight- to twelve-year-old children with emerging social anxiety symptoms as measured using the Social Anxiety Scale for Adolescents.

What does the study involve?

Schools are randomized into a condition (i.e., exposure condition, cognitive restructuring condition, or combination condition) and children from grades four to six that report experiencing more social anxiety than the class average will be invited to participate in an intervention. The interventions consist of four one-hour sessions, which are provided by certified professionals. Participants complete four measurement occasions: approximately five weeks before the start of the intervention, one week before the start of the intervention, one week after the intervention has ended and three months after the intervention has ended.

What are the possible benefits and risks of participating?

There are no risks for children's participation in this study. Participation in this study's interventions is free to schools and their students. The intervention modules implemented and

evaluated in this study teach children how to (better) manage anxiety provoking situations. This may reduce their experience of anxiety in social situations, and in turn may improve their self-esteem and may lead to more positive peer interactions.

Where is the study run from?

University of Amsterdam, Department of Child Development and Education, Netherlands

When is the study starting and how long is it expected to run for?

May 2017 to March 2019

Who is funding the study?

ZonMw (Netherlands Organisation for Health Research and Development)

Who is the main contact?

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Contact information

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

2017-CDE-8033

Study information

Scientific Title

Effective components of social anxiety interventions for children with emerging social anxiety symptoms

Study objectives

This study intends to gain insight into the effectiveness of separate intervention components (i. e., exposure and cognitive restructuring), which are generally combined in multifaceted intervention programs to reduce children's social anxiety symptoms.

This study aims to answer two questions:

1. Is a brief group intervention using exposure, cognitive restructuring, or a combination of both, effective in reducing social anxiety symptoms in children?
2. Is there a difference in effectiveness between the brief group interventions using exposure, cognitive restructuring, or a combination of both components?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 26/07/2017, Ethics Review Board of the Faculty of Social and Behavioral Sciences (Nieuwe Achtergracht 129B, 1018WS Amsterdam, the Netherlands; +31(0)205256686; w.p.m. vandenwildenberg@uva.nl), ref: 2017-CDE-8033

Study design

Randomized three-arm micro-trial with four measurement occasions

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Emerging social anxiety

Interventions

Schools are randomized into a condition (i.e., exposure condition, cognitive restructuring condition, or combination condition) and children from grades four to six that report experiencing more social anxiety than the class average will be invited to participate in an intervention.

Schools were matched based on their size and the level of education children generally continue to (a schools' average standardized test score). Using a random number generator, schools were assigned a number between 1 and 3, which indicated which condition they would be assigned to.

The interventions consist of four one-hour sessions, which are provided by certified professionals. Participants complete four measurement occasions: approximately five weeks before the start of the intervention, one week before the start of the intervention, one week after the intervention has ended and three months after the intervention has ended.

Three intervention modules will be assessed:

1. A module with exposure exercises
2. A module with cognitive restructuring exercises
3. A module combining exposure and cognitive restructuring exercises

The modules were developed for the purpose of this study and were inspired by evidence-based anxiety interventions, such as Cool Kids.

The exposure module will consist of exposure exercises only, using social situations that are common in the school context (i.e., answering a question, giving an oral presentation. The cognitive restructuring module will consist of cognitive restructuring exercises only and will use the same social situations in a hypothetical manner. The combination module will include both cognitive restructuring exercises and exposure exercises.

All modules will consist of four one-hour sessions and will be provided by certified professionals.

Intervention Type

Behavioural

Primary outcome measure

Approximately five weeks before the start of the intervention, one week before the start of the intervention, one week after the intervention has ended and three months after the intervention has ended.

1. Social anxiety symptoms measured using the self-reported Social Anxiety Scale for Adolescents
2. Distress measured using a self-report measure developed for the purpose of this study

3. Avoidant and approach behavior measured using a self-report measure developed for the purpose of this study
4. Automatic thoughts measured using the Children's Automatic Thoughts Scale – Positive /Negative

Secondary outcome measures

Approximately five weeks before the start of the intervention, one week before the start of the intervention, one week after the intervention has ended and three months after the intervention has ended.

1. Internalizing behavior measured using the subscale Internalizing behavior from the self-report version of the Social Skills Improvement System – Rating Scales
2. Social skills measured using multiple subscales from the self-report version of the Social Skills Improvement System – Rating Scales
3. Self-efficacy measured using a self-report measure developed for the purpose of this study
4. Self-perceived competence measured using the Dutch translation of the Self-perception Scale for Children

Overall study start date

01/01/2017

Completion date

31/03/2019

Eligibility

Key inclusion criteria

Eight- to twelve-year-old children with emerging social anxiety symptoms as measured using the Social Anxiety Scale for Adolescents.

Participant type(s)

Other

Age group

Child

Lower age limit

8 Years

Upper age limit

12 Years

Sex

Both

Target number of participants

156 split between three arms

Total final enrolment

191

Key exclusion criteria

1. No signs of social anxiety
2. Participation in another social anxiety intervention
3. Insufficient mastery of Dutch language

Date of first enrolment

01/05/2017

Date of final enrolment

31/08/2018

Locations**Countries of recruitment**

Netherlands

Study participating centre**University of Amsterdam**

Department of Child Development and Education

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Sponsor type

University/education

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ROR

<https://ror.org/04dkp9463>

Funder(s)

Funder type

Charity

Funder Name

ZonMw

Alternative Name(s)

Netherlands Organisation for Health Research and Development

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Netherlands

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact-factor journal. This manuscript will also be part of a dissertation on the effective components of social skills training programs for children. A second publication might assess the mediation of intervention effects.

Intention to publish date

01/06/2020

Individual participant data (IPD) sharing plan

Current IPD sharing statement as of 04/10/2022:

The anonymized data for this study is publicly available in the repository Open Science Framework.

The link to the data is <https://osf.io/3kv2x/>

Previous IPD sharing statement:

The datasets generated during and/or analysed during the current study are not expected to be made available due to a lack of consent to share the data.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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Thesis results	22/04/2021	28/09/2022	No	No
Dataset	24/08/2021	04/10/2022	No	No
Results article	13/01/2023	05/04/2023	Yes	No