ISRCTN76653370 https://doi.org/10.1186/ISRCTN76653370

Effectiveness of childhood social anxiety interventions

Submission date
16/01/2020

Recruitment status
No longer recruiting

Registration date
20/01/2020

Overall study status
Completed

Last Edited
05/04/2023

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[X] 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. Socially 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?
Brechtje de Mooij
L.S.deMooij@uva.nl
Minne Fekkes
minne.fekkes@tno.nl

Contact information

Type(s)
Scientific

Contact name
Ms Brechtje de Mooij

ORCID ID
https://orcid.org/0000-0002-0569-3913

Contact details
Nieuwe Achtergracht 127
Amsterdam
Netherlands
1018WS
+31 622915656
L.S.deMooij@uva.nl

Type(s)
Scientific

Contact name
Mr Minne Fekkes

Contact details
Schipholweg 77
Leiden
Netherlands
2316ZL
+31 634056595
minne.fekkes@tno.nl

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomized three-arm micro-trial with four measurement occasions

Study type(s)
Prevention

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(s)
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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
8 Years

Upper age limit
12 Years

Sex
All

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
Nieuwe Achtergracht 127
Amsterdam
Netherlands
1018WS

Sponsor information

Organisation
University of Amsterdam

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

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?
Results article		13/01/2023	05/04/2023	Yes	No
Dataset		24/08/2021	04/10/2022	No	No
Thesis results		22/04/2021	28/09/2022	No	No