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Anxiety in adolescents with mild intellectual disabilities

Submission date
23/03/2017

Recruitment status
No longer recruiting

Registration date
14/04/2017

Overall study status
Completed

Last Edited
07/06/2023

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Social anxiety disorder, also known as social phobia, is a common type of anxiety disorder, in which a person feels a persistent and overwhelming fear of social situations. The symptoms can range from very mild to so severe that it causes major problems in day-to-day life. Social anxiety disorder often starts during adolescence and is particularly common in this age group. Although the number of adolescents with social anxiety is similar to the number with Mild Intellectual Disabilities (MID), there is a lack of studies looking at adolescents with anxiety disorders. There is a general conclusion is that treatments for anxiety are even less effective in individuals with MID compared to individuals with an average IQ. The aim of this study is to develop a training program to help reduce social anxiety symptoms in adolescents with MID.

Who can participate?
Adolscents with MID who are suffering from social anxiety.

What does the study involve?
Participants are randomly allocated to one of two groups. Each group takes part in five 20-30 minute training sessions on a computer at their school. The training involves different scenarios for each group. In the first group, the scenarios are related to social situations and have a positive ending. In the second group, the scenarios are non-emotional and end in a neutral way that is irrelevant to anxiety. At the beginning of the study, directly following training, and 10 weeks later, participants in both groups preform a range of tasks and questionnaires in order to assess their social anxiety.

What are the possible benefits and risks of participating?
Adolescents may benefit from an improvement to their social anxiety symptoms. In addition, participants receive a voucher as a reward for completing each study procedure. There are no notable risks involved with participating.

Where is the study run from?
Eight secondary schools in the Netherlands (Netherlands)

When is the study starting and how long is it expected to run for?
April 2015 to September 2016

Who is funding the study?
1. 's HeerenLoo (Netherlands)
2. Antonia Wilhelmina Fonds (Netherlands)
3. VU Amsterdam (Netherlands)

Who is the main contact?
1. Dr Mariët van der Molen (scientific)
2. Dr Anke Klein (scientific)
3. Dr Elske Salemink (scientific)

Contact information

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Additional identifiers

Protocol serial number
KLEIN17MID

Study information

Scientific Title
In socially anxious adolescents with mild intellectual disabilities, does cognitive bias modification for interpretation (CBM-I) reduce interpretation biases and social anxiety?

Study objectives
Adolescents in the positive CBM-I training group would show significant reductions in interpretation biases and self-reported social anxiety after training, compared to adolescents in the neutral CBM-I training group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Faculty Ethics Review Board (FMG-UvA) of the University of Amsterdam, 17/08/2015, ref: 2015-DP-4592
(Amendment approved 20/10/2015)

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Social anxiety

Interventions
A sample of approx. 700 - 750 adolescents will be recruited from secondary schools for students with mild to borderline intellectual disabilities in the Netherlands. After passive consent is granted by the adolescents and their parents, adolescents will participate in the screening part of this study. Directly following screening, adolescents scoring above the clinical cut-off score on the social phobia subscale of the SCARED-NL-71 during the screening, will be selected to attend

the training. Selected adolescents (and their parents) will receive an information letter with an invitation to participate in the study. The letter explains the study in detail and both the adolescent and their parents give approval to participate in the training. After active consent is signed, adolescents will be randomly allocated to either the positive training or the neutral control-training. Participant numbers will be allocated before the screening phase started. Allocation to training type will be based on participant number; even numbers receive the neutral training, uneven numbers receive the positive training (simple randomization). The research assistants on the project will enroll the participants and assign the participants to the intervention.

After randomization, adolescents will be invited to an assessment session in which they perform the IREC-T, the AST and the SASC-R individually in a testing room at their own school. They will then receive five training sessions in three weeks time individually in a separate room at their own school. Each training session, performed on a school computer, will take about 20-30 minutes and participants will be able to take short breaks after every 10 scenarios. Directly following the last training session and during the 10-week-follow-up, the participants will perform the assessment session including the IREC-T, the AST and the SASC-R again. A trained Master's level student in Developmental Psychology accompanies all session.

To modify interpretation bias, adolescents will complete a training program of 5 sessions in a three-week period. Each session consists of 40 ambiguous scenarios. Each scenario consists of three short sentences, with one word in the last sentence missing. Two different versions of the training task will be created, a positive training and a neutral control-training. In the positive training (intervention), all ambiguous scenarios will be related to social situations and the word fragment will make the story end positively. In the control training, all ambiguous scenarios will be non-emotional and the word fragment will make the story end in a neutral non-emotional way that is irrelevant to anxiety.

All participants preform the baseline (approximately 3 days pre-training), 3 (post-training) and 10 weeks (follow up) assessments.

Intervention Type
Behavioural

Primary outcome(s)
1. Social anxiety symptoms (reported by children) are measured using the Social Anxiety Scale for Children – Revised and the the social phobia subscale of the SCARED-NL-71 at baseline (pre-training), 3 (post-training) and 10 weeks (follow up)
2. Social anxiety symptoms (reported by one of the parents and the teacher) are measured using the Social Anxiety Scale for Children – Revised and the social phobia subscale of the SCARED-NL-71 at baseline, 3 and 10 weeks
3. Interpretation bias is measured with the Ambiguous Scenarios Task (AST) and the Interpretation Recognition Task (IREC-T) at baseline, 3 and 10 weeks

Key secondary outcome(s))
1. State anxiety during the training as measured with a state anxiety list at baseline, 3 and 10 weeks
2. Interference and attention bias as measured with the original STROOP and an Emotional STROOP tests at baseline, 3 and 10 weeks
3. Total level of anxiety is measured with the SCARED 41 questionnaire at baseline, 3 and 10 weeks

4.Aggression is measured with the Reactive-Proactive aggression scale (RPQ) at baseline, 3 and 10 weeks
5. Attention control is measured with the Attention Control Scale (ACS) at baseline, 3 and 10 weeks
6. Motivation to partake in the training and to change social anxiety symptoms are measured using interview questions at baseline, 3 and 10 weeks

Completion date
30/09/2016

Eligibility

Key inclusion criteria
1. Aged 12-18 years
2. Mild intellectual disability (IQ 60-85)
3. Scoring above the clinical cut-off score on the social phobia subscale of the SCARED-NL-71

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
12 years

Upper age limit
18 years

Sex
All

Total final enrolment
69

Key exclusion criteria
No exclusion criteria

Date of first enrolment
01/09/2015

Date of final enrolment
01/05/2016

Locations

Countries of recruitment

Netherlands

Study participating centre
Scholengemeenschap W.J. Bladergroen
Flevostraat 257
Purmerend
Netherlands
1442 PX

Study participating centre
Praktijkschool Westfriesland
Gording 124
Hoorn
Netherlands
1628 HG

Study participating centre
Praktjikschool de Brug
Saenredamstraat 39
Assendelft
Netherlands
1566 KL

Study participating centre
Praktijkcollege De Atlant
Teilingen 4
Amsterdam
Netherlands
1082 JS

Study participating centre
Futura College
Abeellaan 2
Woerden
Netherlands
3442 JB

Study participating centre

Luca Praktijkschool
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Amsterdam
Netherlands
1095 CS

Study participating centre
Emaus College
Groene Allee 120
Ermelo
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3853 JW

Study participating centre
Oost ter Hout
Oosterhoutlaan 19
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2012 RA

Sponsor information

Organisation
VU University

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Charity

Funder Name
's HeerenLoo

Funder Name
Antonia Wilhelmina Fonds

Funder Name
VU Amsterdam

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Anke Klein (a.m.klein@uva.nl).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/09/2018	07/06/2023	Yes	No
Other publications	results	01/08/2017		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes