

# Facing fears together - a pilot study on peer-mentored cognitive behavioral therapy for adolescents with mild intellectual disability and anxiety

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Primary Objective: Is the intervention model feasible and acceptable for clients, parents/caregivers, peers and therapists? Secondary Objective(s): 1) Establishing first evidence of efficacy of peer-mentored CBT in reducing anxiety in adolescents...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Anxiety disorders and symptoms
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON56512

### Source

ToetsingOnline

### Brief title

Facing Fears Together

### Condition

- Anxiety disorders and symptoms

### Synonym

Fear and anxiety problems

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Jeugd

**Source(s) of monetary or material Support:** ZonMW

## **Intervention**

**Keyword:** Adolescents, Anxiety disorder, Cognitive behavioral therapy, Peer-mentor

## **Outcome measures**

### **Primary outcome**

Semi-structured interviews with clients, parents/caregivers, peer-mentors and therapists about feasibility and tolerability of the intervention. Interviews will be coded using deductive and inductive coding. Deductive codes will be based on the acceptability framework. Inductive codes will be organized in overarching themes.

In addition information regarding inclusion rate, compliance with measurements and adherence to therapy sessions will be used to assess other aspect of feasibility.

### **Secondary outcome**

- 1) Anxiety symptoms, anxiety diagnosis and percentage of steps taken in behavioral approach test
- 2) Anxiety symptoms and self-efficacy of peer-mentors
- 3) A semi-structured interview with therapists about usefulness of receiving an individualized strength/weakness profile.

## **Study description**

### **Background summary**

Anxiety disorders are one of the most prevalent clinical disorders in adolescents, and even more in adolescents with mild to borderline intellectual disability (MBID, i.e., IQ<85 and limitations in adaptive functioning). Exposure based CBT is currently viewed as the most effective form of treatment, however, with response rates of 30% for adolescents with MBID there is still much to be gained by boosting efficacy. Given the risks of long-term negative outcomes associated with anxiety disorders, the need for an (even more) effective intervention is clear. Adolescence is known as a period in which peers are an important social influence that greatly impacts the behaviour of adolescents, even more so for adolescents with MBID. Based on this making use of social learning during treatment might be a powerful port-of-entry for adolescents with MBID and anxiety disorders.

## **Study objective**

Primary Objective:

Is the intervention model feasible and acceptable for clients, parents/caregivers, peers and therapists?

Secondary Objective(s):

- 1) Establishing first evidence of efficacy of peer-mentored CBT in reducing anxiety in adolescents with MBID.
- 2) Do the peer-mentors themselves also experience further anxiety reduction and increase in self-confidence ?
- 3) Is it beneficial for treatment effect to include pre-treatment assessment with a strengths and weaknesses profile for clients with MBID?

## **Study design**

Embedded mixed methods design where the quantitative part consists of a single case experimental design with daily measurements during a baseline and treatment phase. Participants are randomized over two baseline lengths (2 and 4 weeks) and clients and peer-mentors keep a daily diary. In addition, questionnaires and behavioral measures are used to assess anxiety and self-efficacy at pre-baseline, pre-treatment, mid-treatment, post-treatment and follow-up. Finally, clients report on client satisfaction after each session. Measures are taken from clients, parents, therapists and peer-mentors.

## **Intervention**

In this study we will use the intensive exposure therapy model, which includes longer exposure sessions of three hours during which clients practise with their feared subject. The intervention starts with an anxiety analysis session, followed by three exposure sessions, a home-work session, 4 weeks of independent practice and an evaluation session. The new element to the intervention in this study is that a peer-mentor with lived experience will be

present during exposure session 1 and 2. Their role is that of model, information source and supporter. The therapist is present during all sessions.

For participants with MBID, guidelines recommend tailoring treatment to individual cognitive strengths and weaknesses. To gather information on the usefulness of establishing individual strength/weakness profiles prior to treatment, we will request information on strengths/weakness profiles from the organisation who assessed the client. For participants who have a strength/weakness profile we will make individualised recommendations for the therapist. For participants who do not have a strength/weakness profile, the therapist will receive general recommendations for providing therapy for adolescents with MBID.

### **Study burden and risks**

All clients sought out mental healthcare for help with anxiety problems and the core of the intervention is exposure therapy, which is the first choice treatment for anxiety disorders. All clients receive treatment, there is no waitlist or placebo group. The burden to participants mainly lies in time investment in the study measurements and keeping a daily diary. We believe to be the burden to be reasonable and have limited the number of time spent on measurements as much as possible.

## **Contacts**

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## **Trial sites**

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Adults (18-64 years)

### Inclusion criteria

Clients: 12-21 years old • An anxiety disorder diagnosis, which will be confirmed using the SCID-5-Junior interview • A support system should be in place to help the adolescent during the treatment. • IQ 55-85 • Significant limitations in adaptive functioning, ABAS-3 score <85

Peer-mentors:

- 12-21 years old
- Has received a MBID diagnosis in the past
- Has finished treatment for at least one anxiety disorder

### Exclusion criteria

• IQ < 55 • Other anxiety focused psychological treatment concurrent with the study. Concurrent psychopharmacological treatment is not an exclusion criterion, but participants should be on the correct dosage at the start of the study baseline period. Dosage changes during participation are an exclusion criterion. • Severe language or communication problems that would interfere with treatment

Peer-mentors:

- severe communication or language problems that would interfere with the role of peer-mentor
- peer-mentors will not be matched to an intended client if they know each other
- peer-mentors will not be matched to an intended client if they experience a clinical level of anxiety on the same topic as the client.

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 01-04-2024

Enrollment: 40

Type: Actual

## Ethics review

Approved WMO

Date: 26-01-2024

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

## 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	NL84418.058.23