

The Effectiveness of Virtual Reality Exposure Therapy in Adolescents with Social Anxiety - a Single Case Experimental Design

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The primary goal of this study is to evaluate the effectiveness of VR-exposure therapy (VRET) in diminishing anxiety and avoidance within adolescents with social anxiety. We expect that, compared to the within-person baseline and standard treatment...

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

Summary

ID

NL-OMON56509

Source

ToetsingOnline

Brief title

Researching VRET using SCED

Condition

- Anxiety disorders and symptoms

Synonym

Social anxiety; Social phobia

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg

Source(s) of monetary or material Support: Ministerie van OC&W, Family Supporters, Psylaris

Intervention

Keyword: Exposure Therapy, Single Case Experimental Design (SCED), Social Anxiety, Virtual Reality (VR)

Outcome measures

Primary outcome

Participants will complete daily dairies with 3 to 6 idiographic questions throughout all phases of the treatment. These will consist of the top problems and goals of the participant, and will be focused on the 1) anxiety feelings/emotion, 2) cognitions or negative expectations and 3) avoidance behavior or safety behavior. Parents will also rate the behaviors of the adolescents in a daily dairy. As these measures are idiographic, it will depend per participants how the questions are asked, and which questions will be included.

Secondary outcome

To explore participants' experiences, an interview will be conducted with all participants and parents at the end of the study to identify how they experienced VRET, what could be improved and what was already good. This interview will be semi-structured and conducted by the researchers.

Study description

Background summary

Social anxiety disorder (SAD) is most prevalent in adolescence, with a prevalence rate between 2.0% and 5.7% depending on the diagnostic criteria.

Most of the socially anxious situations that adolescents endure are within the school environment. Adolescents with higher social anxiety have higher odds of poorer school functioning and lower aspirations of higher education, and having SAD is related to more school refusal. First-line treatment for SAD is cognitive behavioral therapy (CBT), typically with an exposure component, which has been found to be effective in diminishing social anxious symptoms. Using virtual reality exposure therapy (VRET) can help to reduce attrition and open up possibilities for more exposure scenarios. However, there is a lack of studies in adolescents with SAD, or with anxiety in general, where VRET is assessed as possible treatment option. The purpose of the current study is to see whether VRET is effective in diminishing social anxiety in adolescents.

Study objective

The primary goal of this study is to evaluate the effectiveness of VR-exposure therapy (VRET) in diminishing anxiety and avoidance within adolescents with social anxiety. We expect that, compared to the within-person baseline and standard treatment phases, VRET further decreases anxiety and avoidance behavior. Moreover, we want to explore what changes come first and what changes will follow with regard to the following modalities that treatment can change. The secondary objective is to explore the experiences of the clients with VRET through an semi-structured interview.

Study design

The study is a multiple baseline (MB) single case experimental design (SCED). The baseline length will be randomly assigned to participants.

Intervention

All participants will follow all 5 phases of the study design: Baseline, Standard Treatment, VRET, Exposure in vivo and Follow-up. The VRET is the intervention of interest and trends of symptoms will be compared with the other phases of the treatment. VRET consists of making a hierarchy of anxious situations for the participant and selecting the appropriate videos that fit within the individual hierarchy. During the therapy session, participants will practice exposure in VR with these videos, going from least to most frightening.

Study burden and risks

The burden of participants is filling out a daily diary which would take approximately one minute to complete per day. Moreover, at the start of each phase there will be a short questionnaire regarding social anxiety and avoidance, which takes about 10 to 15 minutes to complete. As the VRET is already in use in practice and has been shown effective in adult population, we

are not expecting any additional risks in participating in the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Inclusion criteria

1. Aged 12 up to and including 16 years
2. Currently in high school
3. Experiencing social anxiety in the school setting
4. Able to understand, read, write and communicate sufficiently in the Dutch language

Exclusion criteria

1. Having epilepsy
2. The child has a severe physical impairment, such as deafness or blindness.
3. An IQ<80 as estimated by the therapist or based on information in the clinical record.
4. The presence of symptoms in more urgent need of treatment (e.g., suicidal intent/acts, acute psychosis).
5. Starting (new) psychotropic medication in the three months prior to the start of the study or during the study period.
6. Having received VRET before the start of the study
7. Following other psychological treatment simultaneously to the study (except for all treatments stated in the study design, such as CBT and systemic therapy).

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-01-2024

Enrollment: 8

Type: Anticipated

Medical products/devices used

Generic name: Virtual Reality Exposure Therapy (VRET)

Registration: Yes - CE intended use

Ethics review

Approved WMO

Date: 11-01-2024

Application type: First submission

Review commission: METC Brabant (Tilburg)

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	NL85347.028.23