

The Effect of Virtual Reality Homework Exercises as an Add-On to Behavioural Therapy for Children with Selective Mutism

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Primary Objective:- To investigate the effectiveness of the combined treatment *Speaking at school, a matter of doing* with the addition of the VR homework exercises. Secondary Objectives:- To identify factors that predict adherence to the VR...

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

Summary

ID

NL-OMON57163

Source

ToetsingOnline

Brief title

VR homework for Children with Selective Mutism

Condition

- Anxiety disorders and symptoms

Synonym

elective mutism, speaking anxiety

Research involving

Human

Sponsors and support

Primary sponsor: Kinder- en Jeugdpsychiatrie

Source(s) of monetary or material Support: Financiering door de Vereniging Nederlandse Gemeenten; zij hebben geld beschikbaar gesteld aan het Amsterdam UMC. Amsterdam UMC heeft besloten dit geld in te zetten voor het huidige project.

Intervention

Keyword: Anxiety disorder, Children, Selective Mutism, Virtual Reality

Outcome measures

Primary outcome

SM symptoms

Change in SM symptoms

Secondary outcome

Adherence to the VR homework exercises

Psychosocial functioning child

Family functioning

Study description

Background summary

Selective mutism (SM) is a rare anxiety disorder that first manifests itself in early childhood. Children with selective mutism do not speak in certain situations where this is expected of them. For example, a child may talk at home, but is afraid to speak at school. Selective mutism is treated with a behavioural therapy protocol in which the child is gradually stimulated to speak at school. The treatment usually takes place at school. During the COVID-19 lockdown, therapists had to switch to digital solutions to treat children with SM. Virtual reality exposure (VRE) therapy is proven to be an effective method for treating anxiety disorders. This led to the development of a VR homework exercises as an add-on to the behavioral treatment.

Study objective

Primary Objective:

- To investigate the effectiveness of the combined treatment *Speaking at school, a matter of doing* with the addition of the VR homework exercises.

Secondary Objectives:

- To identify factors that predict adherence to the VR homework exercises.
- To identify factors that predict the treatment outcome of the combined treatment *Speaking at school, a matter of doing* with the addition of the VR homework exercises.
- Compare the level of anxiety induced by the VR homework exercises compared to the level of anxiety induced during individual therapy.
- To explore the underlying principles that contribute to the therapeutic effect of the VR homework exercises
- To evaluate the use of the VR homework exercises in young children with SM.

Study design

Single Case Experimental Design (SCED). SCED can provide a detailed examination of the effect of the treatment on SM symptoms over time; it provides more detailed insight into within-person effects; it is suitable for innovative interventions and for small and more rare populations. Parents and teacher asked to fill out a micro assessment thrice a week. The assessment consists of 9 short yes/no questions on the child's speaking behaviour.

There are 6 moments of assessment*:

- 1) A comprehensive baseline assessment (T0) will be conducted with the child, parents and the teacher after receiving informed consent.
- 2) Short assessment (T1) At the start of the treatment.
- 3) Short assessment (T2) After the child has finished step 5 of individual therapy.
- 4) Short assessment (T3) After the child has finished step 10 of individual therapy.
- 5) Post treatment assessment (T4) At the end of treatment.
- 6) Follow-up assessment (T5) 3 months after the end of treatment.

In the comprehensive assessments (T0, T4, and T5), parents and the teacher are asked to report on the psychosocial functioning of the client. The client also fills out one questionnaire. At these times, a clinical interview takes place with parents, and they fill out questionnaires about family functioning. At the short assessments (T1, T2, and T3), contains only the primary study variable (SM symptoms).

Intervention

The treatment in this study consists of behavioural therapy for selective mutism (with the protocol 'Talking at school, a matter of doing') with the addition of the VR homework exercises. The protocol consists of 10 steps that help the child to gain confidence while speaking at school. For every treatment step there are VR homework exercises available. Families receive a VR headset for the duration of the study. Parents are instructed to work on the VR

homework exercises at least once a week and encouraged to work on the VR homework exercises several times a week.

Study burden and risks

The risks associated with participation are negligible, and the burden is minimal.

Risks: Children might experience some anxiety when completing the VR homework exercises. However, it is necessary to simulate a stressful situation to break the pattern of not speaking. Parents receive guidance from the therapist on how to support their child in this process. Children might experience motion sickness while using the VR headset. In case the child experiences motion sickness, the VR headset can be removed. Motion sickness is temporary and does not have any lasting effects.

Burden: Parents and children do not have any additional visits for the extra assessments. The majority of the questionnaires used in this study are part of standard care. Therefore the study burden on parents and children is minimal. Children will be asked to fill out questionnaire (together with their parents) at 3 different times. During the individual therapy sessions, children asked to indicate how they are feeling (using pictures). After individual therapy and the VR homework exercises, children rate their level on Visual Analogue Scale (VAS). Parents and the child are asked to do the VR homework exercises at least once a week for a short time. The exercises are playful, and positive reinforcement is used.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adults (18-64 years)

Children (2-11 years)

Inclusion criteria

Children, attending primary education, aged 4 - 13 with SM as a primary DSM-5 diagnosis.

Exclusion criteria

No participating parents, insufficient mastery of the Dutch language, parents or child have an estimated IQ below 75, the child needs inpatient treatment, children with a (medical) condition that is a contraindication for the use of VR (epilepsy, claustrophobia, facial condition, panick attacks, sensitive vestibular system); additional parent training that is not part of the intervention; having received protocolled behavioural therapy for SM in the previous 12 months

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-12-2024
Enrollment:	16
Type:	Anticipated

Ethics review

Approved WMO	
Date:	04-12-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL86645.018.24