

The effectiveness of a virtual reality intervention on trauma-related shame in sexually abused adolescents: A single-case experimental study.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Psychiatric disorders NEC
Study type	Interventional

Summary

ID

NL-OMON53968

Source

ToetsingOnline

Brief title

Decreasing shame with Virtual Reality: The effectiveness of SHINE-VR.

Condition

- Psychiatric disorders NEC

Synonym

Post-traumatic stress disorder

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Leiden

Source(s) of monetary or material Support: Stichting Universitas

Intervention

Keyword: post-traumatic stress disorder, self-compassion, trauma-related shame, Virtual Reality

Outcome measures

Primary outcome

Primary study parameters are trauma-related shame and self-compassion.

Secondary outcome

Secondary parameters are treatment motivation and PTSD symptoms. The exploratory objective is to evaluate SHINE-VR.

Study description

Background summary

Suffering from PTSD in childhood can have detrimental formative consequences. Researchers have been eager to develop effective interventions and to enhance treatment motivation since the introduction of the diagnosis of PTSD in the DSM. With evolving understanding of the disorder, its definition and criteria have changed over the course of time. The most recent change involves the addition of the criterium D of negative affects or emotions in relation to PTSD, the feeling of shame amongst others. Individuals experiencing interpersonal trauma, such as sexual abuse, are at high-risk developing trauma-related shame, which in turn can impact the course and effectiveness of PTSD treatment. Shame-inducing situations are typically being avoided, and the feelings are not disclosed to peers and other people. Hence, acknowledging and sharing feelings of shame as well as practicing self-compassion have been proposed to reduce the impact of that negative self-conscious emotion. These aspects get partially tackled in evidence-based trauma therapies, however, there appears to be a need for a more specific trauma-related shame intervention in addition to existing treatments. Recent research has focused on developing such interventions for adults and has reported positive effects. To our knowledge, there is no intervention specifically tackling trauma-related shame in adolescents. Virtual Reality (VR) is a promising tool for such an intervention. Findings suggest that including VR in a treatment results in high treatment satisfaction and that it is highly motivating for its users, which is

a crucial component for treatment success.

Study objective

The goal of this study is to test the effectiveness of a short-term VR shame intervention (SHINE-VR) for adolescents suffering from PTSD after having experienced sexual abuse. The primary objectives of this study are:

- 1) To assess the effect of SHINE-VR on trauma-related shame, self-compassion, PTSD symptom reduction and PTSD treatment motivation.
- 2) To investigate whether an increase in self-compassion and treatment motivation, and a decrease in trauma-related shame are associated with PTSD symptom reduction.
- 3) Evaluation SHINE-VR: Assessment of feasibility measures such as usability, acceptability, tolerability, and satisfaction

Study design

A single case experimental design will be used to evaluate the intervention. Participants will receive SHINE-VR additionally to the regular trauma treatment. SHINE-VR is administered by the therapist of the participant.

Intervention

The SHINE-VR takes place after trauma processing and consists of the following 3 VR sessions à 45min:

- Introduction: getting acquainted with VR, playing VR game developed for the feasibility study (Krupljanin et al., 2023), receiving psychoeducation about seeking help.
- Shame: virtual group therapy setting, psychoeducation about shame, virtual peers sharing thoughts of shame and their learnings/positive affirmations.
- Self-compassion: practicing self-compassion.

Study burden and risks

This study will be testing a short-term VR shame intervention and will as such be part of regular trauma treatment. Therefore, participants are considered to have minimal burden in terms of additional travels or other expenses of similar nature.

There is a minimal risk involved considering the technical nature of the VR module. Being in VR can lead to so called visually induced motion sickness. However, studies investigating this phenomenon in children aged 4 years or older have found no significant changes in subjective physical well-being. As a measure, all therapists will receive a briefing and a protocol (see document K6. Protocol for use in case of motion sickness 09-01-23) for symptoms of motion sickness. These symptoms typically resolve shortly after leaving the virtual environment. This risk is therefore considered to be minimal.

The participation in this study involves 3 VR sessions, regular trauma treatment and filling out questionnaires. The therapists themselves will receive sufficient VR training before delivering the module and regular meetings with the coordinating investigator. The time burden associated with filling in the questionnaires depends on the patient, we expect the total investment, including the VR sessions and filling out daily questionnaires during the multi-week VR intervention phase, to amount to 422 - 452 minutes (3 extra sessions à 45 minutes and daily questionnaires with an average duration of 6 minutes). The questionnaires will be programmed online, which has the advantage of being accessible from the phones or laptops of the participants. The participants are hypothesized to directly benefit from the intervention; however, the participants will also receive a gift voucher worth €25 and small gift in the end of the study. The caregivers and the participants are offered a short summary of the research project after completion of the data collection at T2. In summary, we believe that the commitment we are asking of the therapists and the participants is well balanced.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Inclusion criteria

- Between 12;0 and 17;11 years old at inclusion
- Indication for PTSD treatment
- Getting trauma treatment as usual
- Interpersonal trauma (sexual abuse); in case of multiple traumas the main trauma should be sexual abuse
- Adequate command of the Dutch language

Exclusion criteria

- Known mental disability
- Epilepsy

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-08-2024
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date: 07-08-2023

Application type: First submission

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

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Approved WMO

Date: 12-04-2024

Application type: Amendment

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

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Approved WMO

Date: 31-05-2024

Application type: Amendment

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

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Approved WMO

Date: 20-08-2024

Application type: Amendment

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

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Approved WMO

Date: 25-11-2024

Application type: Amendment

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

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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	NL83340.058.23