Follow the Dot to Beat your Anxiety - Using EMDR in Virtual Reality at home to diminish trauma and anxiety in youth

Published: 21-06-2021
Last updated: 15-05-2024

The main aim of the current study is to evaluate the effectiveness of the MVC and FT additives of regular EMDR treatment a) in the therapeutic context and b) with the use of VR-based EMDR in the own living environment of children and adolescents...

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

Summary

ID

NL-OMON52058

Source
ToetsingOnline

Brief title
Follow the Dot

Condition

- Anxiety disorders and symptoms

Synonym
Post-traumatic stress disorder, Trauma-related anxiety

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: Ministerie van OC&W,Publiek-Private Samenwerking toeslag (PPS-toeslag);Health Holland Top Sector Life Sciences & Health

Intervention

Keyword: Eye Movement Desensitisation and Reprocessing (EMDR), Mental Video Check, Trauma-related anxiety, Virtual Reality

Outcome measures

Primary outcome

Main study points are the changes in anxiety symptoms, post-traumatic stress symptoms, and avoidance behaviour after intervention.

Effectivity is defined as decreased anxiety, less relapse of posttraumatic stress symptoms and longer-lasting extinction of avoidance behaviors.

Secondary outcome

Secondary study parameters are changes in depressive symptoms, quality of life and parental distress. Moreover, treatment satisfaction and treatment characteristics will be assessed as secondary study parameters, including the following: Number of face-to-face sessions needed; number of VR-based sessions needed; duration per VR-based session; early termination yes/no; intensity settings of VR-based EMDR; description of the FT; all VoC (validity of cognition) scoring of the FT.

Furthermore, emotions and emotion regulation will be measured using the experience sampling method (ESM).

Study description

Background summary

Around 30% of trauma-exposed children and adolescents develop post-traumatic stress disorder (PTSD) symptoms. A frequently used therapy to reduce acute and long-term effects of trauma exposure is Eye Movement Desensitisation and

Reprocessing (EMDR). While EMDR is effective, children and adolescents often experience symptom recurrence when exposed to the feared situation outside the therapeutic context. This maintenance of fear could be due to avoidance behavior or context-dependent learning. The Mental Video Check (MVC) and Future Template (FT), which are included as optional additives to the standard EMDR-protocol, target avoidance and safety behaviors. The MVC and the FT are diversely used in clinical practice, but these additives are not scientifically evaluated yet as component of EMDR.
Moreover, as a solution for relapse from context dependent learning, the start-up company Psylaris will develop a Virtual Reality (VR) application targeting avoidance and safety behaviors with the MVC and the FT (VR-based EMDR), making it possible to intensify treatment by transferring this part from the therapeutic context to the own living environment.

Study objective

The main aim of the current study is to evaluate the effectiveness of the MVC and FT additives of regular EMDR treatment a) in the therapeutic context and b) with the use of VR-based EMDR in the own living environment of children and adolescents with avoidance behaviour (a core symptom of both anxiety disorders and PTSD). .
In addition, to understand how VR-based EMDR works and for whom, participant characteristics will be identified, and mechanisms of emotion regulation will be examined.
Children who receive the MVC and FT in the therapeutic context are expected to have less anxiety symptoms and avoidance behaviors than those who only receive regular EMDR (without these additives). VR-based EMDR will result in longer-lasting extinction of trauma-related stress and anxiety because of the possibility to intensify and relocate EMDR treatment to the home environment. Furthermore, VR-based EMDR stimulates self-care in the family setting and is expected to reduce symptom recurrence, enhance patient satisfaction and improve quality of life.

Study design

The MVC and FT will be scientifically evaluated in a multicenter Randomized Clinical Trial (RCT), with three conditions: a) EMDR-treatment as usual (EMDR-TAU), b) EMDR-TAU + additives c) EMDR-TAU + VR-based EMDR. Questionnaires are administered repeatedly (baseline, during intervention, post-intervention and 1, 3, and 12 months after intervention). Experience Sampling Methodology (ESM) is used before and during intervention to collect in-the-moment data of emotions and emotion regulation.

Intervention

MVC and FT: These optional steps are applicable for all situations which are

still avoided or endured with anxiety after standard EMDR treatment. It starts with assessment of such situation(s). The MVC consists of the patient mentally walking through the situation as a movie and whenever the patient feels anxiety or stress, a desensitisation set is given by the therapist until the patient can walk through the movie without tension. The FT follows the MVC with a mental image of the desired situation and behaviour, installing the positive cognition *I can do it*, until the patient believes it fully.
VR-based EMDR: VR-based EMDR consists of the MVC and FT exactly as described in the EMDR protocol appendix, but then provided through smart software which acts on the input of the patient. It will be used first with the presence of the therapist, and afterwards the patient can follow the steps again at home to relocate and intensify the treatment.

Study burden and risks

The risk profile is low, considering all children and adolescents in all groups will receive standard EMDR (TAU), which has been proven effective and is the current standard in clinical practice. Moreover, all children will be able to follow the optional MVC and FT. In the EMDR-TAU + additives and + VR-based EMDR groups, the optional steps are part of their treatment. Children in the EMDR-TAU group will be given the opportunity to follow these additives after the post-intervention assessment.

VR-based EMDR is a CE-certified product with class 1 risk. Children in the VR-based EMDR group will already profit from the possibility to practice with the FT and the MVC in their own environment. The MVC an FT focus on the future and both include a mental video (MVC) or image (FT) of a desired, positive situation of the previously avoided situation. Due to this positive approach, this part of the treatment is appropriate for practice at home. Secondly, the use of VR-based EMDR will be practiced first in the therapeutic context. Thirdly, parents are aware of the use and can help children in case is necessary. A safe home-environment is therefore part of the inclusion criteria of the present study.

Contacts

Public
Universiteit van Tilburg

Warandelaan 2
Tilburg 5037AB
NL
Scientific
Universiteit van Tilburg

Warandelaan 2
Tilburg 5037AB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

1. Aged 8-17 years.
2. Able to read/write and communicate in the Dutch language.
3. Indication for EMDR linked to a traumatic event or life-event causing symptoms of anxiety or PTSD, resulting in clinically significant distress or impairment.
4. Experiencing >1 symptoms of avoidance or safety behavior (either avoiding or making efforts to avoid distressing memories, thoughts or feelings and/or avoiding or making efforts to avoid external reminders).
5. Supporting family system

Exclusion criteria

1. Complex Trauma (cumulative poly-victimization that is typically interpersonal in nature and involves direct harm, exploitation or neglect/abandonment by caregivers.
2. The presence of symptoms in more urgent need of treatment (e.g. suicidal intent/acts, acute psychosis).
3. Starting (new) psychotropic medication three months prior to the start of the trial, OR during the EMDR treatment.
4. An IQ<80 as estimated by the therapist or based on information contained in the clinical record.
5. Following other psychological treatment simultaneously with the EMDR

treatment (starting from baseline to post-test).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-11-2021
Enrollment:	208
Type:	Actual

Medical products/devices used

Generic name:	VR-based EMDR
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	21-06-2021
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	02-11-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Approved WMO Date:	07-12-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	11-01-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	16-05-2022
Application type:	Amendment
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

ID: 28574
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL76375.028.21
Other	NL9614
OMON	NL-OMON28574