

Follow the Dot to Beat your Anxiety

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28574

Source

NTR

Brief title

Follow the Dot

Health condition

Posttraumatic Stress Disorder, Posttraumatic Stress Symptoms, Anxiety Disorders, Anxiety Symptoms

Sponsors and support

Primary sponsor: Tilburg University

Source(s) of monetary or material Support: The collaboration project is co-funded by the PPP Allowance made available by Health~Holland, Top Sector Life Sciences & Health, to stimulate public-private partnerships.

Intervention

Outcome measures

Primary outcome

PTSD symptoms (Dutch version of the Child and Adolescent Trauma Screen; CATS)

Anxiety symptoms (Youth Anxiety Measure for DSM-5; YAM-5)

Avoidance behavior (The Child Avoidance Measure – Self Report/Parent report; CAMS/P)

Secondary outcome

Depression (Childhood Depression Inventory, CDI)

Parental distress (distress thermometer for parents, DT-P)

Quality of Life (PedsQL 3.0 General Wellbeing Scale)

Treatment satisfaction

Treatment characteristics (e.g., diminished SUD scores and higher VoC scores)

Emotions and emotion regulation strategies measured in daily life using 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 Desensitization 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 develops a Virtual Reality (VR) application 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.

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 aged 8-17 years, with an indication of EMDR treatment.

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.

Study objective

The study will randomly allocate participants to one of three groups in order to assess the components of the additives MVC and FT and of VR-based EMDR in the home environment separately, creating the following three groups:

1. EMDR-TAU (standard protocol without the additives)
2. EMDR-TAU + additives (mental video check and future templates)

3. EMDR-TAU + VR-based EMDR

1. EMDR-TAU + additives will result in better extinction of avoidance behaviors as compared to EMDR-TAU, resulting in less trauma-related stress and anxiety (short and long-term).
2. EMDR-TAU + VR-based EMDR, compared to EMDR-TAU and EMDR TAU + additives, will result in faster and more sustained improvement in terms of diminished anxiety, post-traumatic stress symptoms and improved quality of life.
3. EMDR-TAU + VR-based EMDR is expected to show larger effects across age and time since the traumatic event took place. Effects are expected to be independent of type of trauma, number of sessions needed to desensitize the traumatic event, and gender. Other trauma, child, and parent characteristics related to better treatment outcomes after VR-based EMDR will be examined in an explorative fashion.
4. The treatment effects of EMDR-TAU + VR-based EMDR on diminished anxiety and post-traumatic stress symptoms, are expected to be associated with and strengthened by a decreased use of maladaptive emotion regulation strategies (i.e., catastrophizing, expressive suppression, rumination and distraction).

Study design

Baseline (T0), post-EMDR-TAU (T1), post-additives (MVC and FT/ VR-based EMDR/waitlist, T2), and follow-up assessments 1, 3 and 12 months (T3 - T5).

Intervention

All groups receive EMDR, The Dutch translation of the most recent EMDR protocol for children and adolescents will be used (developed in 2021). Participants will follow the 6 standard steps (introduction, assessment, desensitization, installation of the positive cognition, body scan and positive closure). These steps are empirically supported by earlier studies, and can be used for all three prongs (either focusing on past memories, present triggers or flashforwards).

1. The EMDR-TAU group will follow EMDR-TAU treatment described above. After EMDR-TAU, they will pause their treatment for two weeks until after T2 assessment (waitlist). After T2, they will be randomly allocated to either + additives (face to face) or + VR-based EMDR.
2. The EMDR-TAU + additives group will receive the optional steps mental video check and future template as described in the most recent version of the Dutch EMDR protocol (2021) for children and adolescents in one face-to-face session.
3. The EMDR-TAU + VR-based EMDR group will also receive the optional steps mental video check and future template as described in the protocol, but they will receive them using the VR-application. First, they will learn and walk through the mental video check and future template within the therapeutic context. After this face-to-face session using VR-based EMDR, the participant will take the VR-headset home and will repeat the mental video check

and future template several times during the week. With the VR-headset, they also receive a homework sheet on paper, describing the situation of the mental video check and future template as reminders.

Contacts

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Eligibility criteria

Inclusion criteria

- Aged 8-17 years.
- Able to read/write and communicate in the Dutch language.
- Indication for EMDR linked to a traumatic event or life-event causing symptoms of trauma-related stress and anxiety, resulting in clinically significant distress or impairment.
- 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).
- Supporting family system.

Exclusion criteria

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

from baseline to post-test).
- Having epilepsy

Study design

Design

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

Recruitment

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

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion	
Date:	16-07-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52058

Bron: ToetsingOnline

Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9614
CCMO	NL76375.028.21
OMON	NL-OMON52058

Study results