

Targeting Negative *Flashforward* Imagery Using EMDR in Children and Adolescents with Social Anxiety Disorder: a Proof-of-Principle RCT

Published: 10-09-2021

Last updated: 15-05-2024

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

Summary

ID

NL-OMON50877

Source

ToetsingOnline

Brief title

Targeting negative flashforward imagery

Condition

- Anxiety disorders and symptoms

Synonym

social anxiety disorder, social phobia

Research involving

Human

Sponsors and support

Primary sponsor: Rijksuniversiteit Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: EMDR flashforward, mental imagery, Social anxiety disorder, youth

Outcome measures

Primary outcome

Main study endpoints are (average) social anxiety and avoidance, based on the ratings of social anxiety and avoidance related to the 3 most personally relevant socially anxious situations selected from a list of situations.

Secondary outcome

Secondary study endpoints are (average) FF image vividness and average FF image distress, and average FF imagery appraisal as assessed by the imagery interview.

Study description

Background summary

Social anxiety disorder (SAD) is a prevalent disorder in children and adolescents, characterized by an increased fear of negative evaluation and significant impairments in functioning. Treatment for SAD is currently less effective than treatment for other anxiety disorders, pointing to room for improvement of current SAD treatments. One factor that may provide a fruitful pathway to intervene is mental imagery. It has been found that individuals with SAD experience spontaneous negative images reflecting their main fears, which have a negative impact on emotions and behaviour. Although children and adolescents with (social) anxiety also mention experiencing imagery that is upsetting, most studies on examining and targeting imagery have been conducted in adults. As it is suggested that children are more prone to use imagery(-based processing) and to experience (distressing) imagery than adults, the potential value of identifying problematic imagery and incorporating imagery in treatment with youths increases. In current study, we are interested in further examining treatment components that target such negative *flashforward* (FF) images of impending (or future) social catastrophes in

youth with SAD, thereby aiming to dampen their detrimental effects. One way to target negative imagery is by using eye movement desensitization and reprocessing (EMDR). After EMDR, imagery of (trauma) memories has repeatedly been found to become less vivid and emotional, and possibly also (re)appraised less negatively, leading to less anxiety and avoidance in daily life in both adults and youths. The potential of using EMDR with imagery of future catastrophic outcomes is demonstrated by a series of analogue intervention studies in adults that found reductions in the vividness and emotionality of FF images. To date, however, there are no studies on the use of EMDR with FF in clinical samples with SAD. Nevertheless, the use of EMDR has been recommended in the treatment of anxiety disorders by influential handbooks. In the Dutch national multidisciplinary guidelines (i.e., Zorgstandaard Angstklachten en angststoornissen), it is noticed that *EMDR is frequently used in the treatment of anxiety disorders in routine clinical care*, but the treatment is not recommended as an intervention of choice, given the relatively limited evidence for its effectiveness for anxiety disorders. A structured evaluation of the value of examining and targeting negative FF images in youths with SAD seems very welcome and relevant.

Study objective

The main objective is to evaluate the effectiveness of three sessions of EMDR FF (targeting negative FF imagery related to youth*s most feared social situations) in treating social anxiety (lowering anxiety and avoidance related to those feared social situations) in children and adolescents with SAD. The secondary objective is to examine whether changes in FF imagery characteristics (lowering FF vividness and distress, and negative imagery appraisal) can explain treatment effects (mediation).

Study design

The present study design is a parallel-group Randomized Controlled Trial (RCT) with two conditions (EMDR FF versus a control group with no active treatment). The study is intended as a *proof-of-principle*-study of the effects of EMDR FF on anxiety and avoidance, and potential mediation of these effects by FF image vividness, distress, and appraisal. After the first, assessment, participants will be randomly assigned to one of the two conditions, with each condition consisting of 25 participants. Participants in the EMDR FF group receive three 45-minute EMDR FF sessions, participants in the control group do not follow these sessions. After the post-intervention assessment, youths continue to receive regular treatment for their social anxiety, when applicable (e.g. cognitive behavioural therapy (CBT), when they are next on the waitlist) and complete the final follow-up assessments during further regular care. The assessments consist of questionnaires for both youths and parents, and an imagery interview for youths.

Intervention

The EMDR FF treatment consists of three 45-minute sessions, conducted over the time of two weeks. The therapist follows a slightly adapted version of the EMDR *flashforward procedure* each session, which also refers to the standard Dutch EMDR protocol (de Jongh & ten Broeke, 2019). In each EMDR FF session, participants are asked to recall and rate an image of feared future catastrophe (i.e., FF) related to an anxious situation, as established previously in the imagery interview at the pre-intervention assessment. The FF is *desensitized* using EMDR following the flashforward procedure.

Study burden and risks

Treatment for SAD in youths is currently less effective than treatment for other anxiety disorders. As late childhood and early adolescence have been pointed out as the typical age of onset for social anxiety, improving treatment in youths by incorporating mental imagery might improve further outcome and costs. In the current research, we include children and adolescents as participants, since research on imagery and imagery-based treatment in adults might not be fully generalizable to youths. A potential risk of participation could be the time burden (i.e., a total of 180 minutes for youths of completing measures). Part of the questionnaires are administered during regular care, and may therefore not be considered as additional burden. Completing the measures may also involve distress experienced by the youths related to imagery about negative events. However, asking about anxiety and future catastrophes is common during both intake and regular treatment for anxiety disorders, and to decrease potential risks, deliberate positive imagery and guidance by trained EMDR therapists is included. Furthermore, the intervention that participants in the EMDR-FF group receive (three 45-minute sessions of EMDR FF) is hypothesized to be beneficial based on empirical and theoretical review, as well as frequent use in clinical practice as an add-on to (social) anxiety and trauma treatment. The participants in the no-contact control group have no intervention during these two weeks. As, often, there is a waiting time for treatment at Accare of around 4 weeks, this means that for most participants the first part of the study is conducted during waiting time for regular treatment. Participation in the current study entails no further impact on receiving regular care, since all youths continue to receive regular treatment for their social anxiety after the post-intervention assessment in Week 4, when applicable. It is thereby made clear to youths and their parents that they can stop participation in the study at any time, without consequences. Also, as all participants are in care at Accare, when youths or parents are concerned about their functioning, participants in both groups can contact their own therapist by regular means and receive the care that is necessary. Some potential benefits can be anticipated. First, by participating in the study, participants are able to get insight in their own imagery, which may not only be useful for their own further CBT treatment (when applicable), but also for increasing insight in

imagery of socially anxious youth in general. Also, participating in the study provides preliminary information on the value of using EMDR with negative FF imagery. This is an important first step that could potentially improve participants' own treatment outcome (for participants in the EMDR-FF group), and eventually treatment of social anxiety in youth in general (by contributing to research on this topic).

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Children (2-11 years)

Inclusion criteria

In order to be eligible to participate in this study, a potential participant must meet all of the following criteria:

- Aged between 10-17 years old

- Sufficient knowledge of and proficiency in the Dutch language
- Meeting the DSM 5 criteria of social anxiety disorder (based on child and parent semi-structured interviews), and social anxiety disorder is the focus of care (also in case of comorbidity, such as comorbid other anxiety disorders, ASD, AD(H)D, and depression)
- Currently not receiving active treatment for social anxiety disorder (e.g., after diagnostic process or when on the waitlist for active treatment). Note that previous CBT or other previous treatments such as EMDR are no exclusion criteria, nor is continuation of medication with a stable dosage.

Exclusion criteria

A potential participant who meets any of the following criteria will be excluded from participation in this study:

- Absence of permission of legal guardian(s) for youths aged 10-15 years
- Serious concerns that warrant current attention such as suicidality, psychosis or domestic violence
- Comorbid post-traumatic stress disorder (PTSD) or partial PTSD after exposure to DSM 5 criterion A traumatic event(s)
- Not reporting to experience FF imagery during the pre-intervention assessment (i.e., exclusion from participation in the rest of the treatment study)
- A medical condition that is considered a contra-indication for EMDR with eye movements such as a form of epilepsy

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	25-11-2021
Enrollment:	50

Type:

Actual

Ethics review

Approved WMO

Date: 10-09-2021

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date: 09-06-2022

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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: 24410

Source: NTR

Title:

In other registers

Register	ID
CCMO	NL77137.042.21
OMON	NL-OMON24410