

Targeting Negative Flashforward Imagery Using EMDR in Children and Adolescents with Social Anxiety Disorder: a Randomized Controlled Trial

No registrations found.

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

Summary

ID

NL-OMON24410

Source

NTR

Brief title

N/A

Health condition

Social anxiety disorder (SAD)

Sponsors and support

Primary sponsor: University of Groningen

Source(s) of monetary or material Support: Opleidingsinstituut PPO and University of Groningen

Intervention

Outcome measures

Primary outcome

- Primary outcome variables:

- Social anxiety and avoidance related to youths' most feared social situations (ratings of social anxiety and avoidance related to their top 3 selected situations, based on the list of situations from the Liebowitz Social Anxiety Scale for Children and Adolescents (LSAS-CA))

Secondary outcome

- Secondary outcome variables:

Vividness, distress and appraisal of youths' FF imagery (i.e., ratings of vividness, distress, and appraisal of imagery of feared future catastrophe related to their top 3 most feared social situations, assessed using an imagery interview); Social anxiety and avoidance in general (LSAS-CA; youth and parent)

- Other outcome variables:

Other avoidance measures (subtle avoidance and willingness to follow exposure treatment related to youths' most feared social situations (top 3)); Other characteristics of FF imagery related to youths' top 3 most feared social situations (e.g., perspective, occurrence, relatedness to memories, vividness and distress of related memories, assessed using an imagery interview); Other relevant imagery; Information on the amount of received social anxiety treatment and other treatments

- Baseline descriptives:

Social anxiety disorder diagnosis and (absence of) PTSD (Anxiety disorders interview schedule for DSM-IV (ADIS-IV-C/P) or Structured clinical interview for DSM-5-junior (SCID-5-junior); youth and parent), Depressive symptoms (Children's Depression Inventory 2 (CDI-2); youth and parent), Comorbid diagnoses, and information on previous and current treatment; Imagery ability (Vividness of Visual Imagery Questionnaire (VVIQ)); Demographic information

- Treatment expectations and satisfaction, and treatment process measures for the EMDR FF group:

Treatment expectations (Credibility and expectancy questionnaire (CEQ); youth and parent); Satisfaction with treatment (youth and parent); Treatment adherence (therapist); Treatment of FF (i.e., targeted FF and associated cognitions, and subjective units of distress (SUDs) and validity of the positive cognition (VOC) at the start and end of the session)

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, leaving room for improvement of current SAD treatments. One factor that may provide a fruitful pathway to intervene is mental imagery. Negative imagery (e.g., imagining looking odd, performing badly or being negatively evaluated) has been found to play an important role in the maintenance of social anxiety by increasing anxiety and avoidance behaviours. To date, however, most studies on imagery considered adults and few studies

examined imagery in youths with social anxiety. Similarly, treatments incorporating imagery have not been extensively evaluated in youths with social anxiety. By targeting negative imagery (i.e., by decreasing its vividness, emotionality, and negative (re)appraisal), its detrimental effects on anxiety and avoidance could possibly be dampened. In Dutch routine clinical care, eye movement desensitization and reprocessing (EMDR) targeting negative 'flashforward' (FF) imagery of feared catastrophes is used as part of the treatment of anxiety disorders, and the use of EMDR has been recommended in the treatment of anxiety disorders by influential EMDR handbooks. However, while EMDR targeting disturbing 'flashbacks' is considered an evidence-based treatment for posttraumatic stress disorder, a structured evaluation of EMDR FF effectiveness in SAD is lacking.

The main objective of this randomized controlled trial (RCT) is to evaluate the efficacy 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. As a secondary objective, we examine whether changes in FF imagery characteristics (lowering FF vividness and distress, and negative imagery appraisal) can explain treatment effects (mediation). Exploratory, we examine the longer term effectiveness in treating social anxiety and changing FF imagery characteristics (while taking into account subsequent care consumption). In addition, it is examined whether the treatment conditions differ in subsequent care consumption. The current study contributes to knowledge on the specific characteristics of mental imagery in children and adolescents with SAD, how (changes in) imagery characteristics relate to anxiety and avoidance, and the potential value of using EMDR FF in treating social anxiety in youth with SAD. The feasibility and preliminary outcomes of an imagery interview, protocol for EMDR FF, and associated measures in youths with SAD have been examined in a small pilot study as part of routine care (NTR Trial: NL8974). Feedback from this pilot study has been incorporated in the current study.

The results of this study will be submitted to international peer-reviewed journals.

Study objective

We hypothesize that the EMDR FF intervention (compared to a no-contact control group) results in a decrease in levels of social anxiety and avoidance related to individually relevant feared social situations (from the pre-intervention assessment at week 1 to the post-intervention assessments at week 4 and 8). Moreover, we hypothesize that this decrease can be explained by a decrease in FF image vividness, distress, and negative appraisal (mediation).

Study design

Pre-intervention assessment (week 1)

Post-intervention assessment (week 4)

Follow-up assessment 1 (week 8)

Follow-up assessment 2 (week 20; for exploring longer term effectiveness)

(4 time points + within session assessments for the EMDR FF group)

Intervention

Youths in the EMDR FF group receive three 45-minute EMDR FF sessions over the course of two weeks. The EMDR FF intervention is conducted using the Flashforward procedure or technique in the Dutch EMDR protocol, tailored to the current target population and research questions. During an EMDR FF session, negative FF imagery related to youth's top 3 most feared social situations is recalled and targeted as specified in the protocol (1 FF image for each of those 3 situations has previously been established in the imagery interview). The protocol includes a short introduction and explanation of the procedure, followed by determining the target image, as well as the associated negative cognition and emotions, subjective units of distress, and bodily sensations. Then, the steps of desensitization (holding the target image in mind while engaging in sets of eye movements) and installation of the positive cognition (linking a positive cognition to the target image) are followed. During each session, 1 (new) FF image is targeted, so that all 3 selected FF images are targeted in the three sessions.

Participants in the control group do not follow these sessions (no-contact control group). To be able to assess the effects of the EMDR FF sessions on our main study endpoints, in both groups, youths do not start with regular active treatment for SAD during the intervention period.

Contacts

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Eligibility criteria

Inclusion criteria

- Aged between 10-18 years old
- Sufficient knowledge of and proficiency in the Dutch language
- Meeting the DSM 5 criteria of social anxiety disorder, and social anxiety disorder is the current 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 cognitive behavioral therapy (CBT) or other previous treatments such as EMDR are no exclusion criteria, nor is continuation of medication with a stable dosage.

Exclusion criteria

- 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)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	07-10-2021
Enrollment:	50
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description

N/A

Ethics review

Positive opinion

Date: 07-10-2021

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50877

Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9779
CCMO	NL77137.042.21
OMON	NL-OMON50877

Study results

Summary results

N/A