ISRCTN14600708 https://doi.org/10.1186/ISRCTN14600708

Changing catastrophic scenarios in imagery in people with severe social anxiety

Submission date 14/02/2020	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 17/02/2020	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 16/03/2021	**Condition category** Mental and Behavioural Disorders	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims

Social anxiety disorder, also called social phobia, is a long-lasting and overwhelming fear of social situations. It's a common problem that usually starts during the teenage years. Social anxiety is more than shyness. It's an intense fear that does not go away and affects everyday activities, self-confidence, relationships and work or school life.

Patients with social anxiety disorder (SAD) do not only experience dysfunctional negative thoughts in anxiety-provoking social interactions but recent studies show that they also suffer from recurrent, intrusive, negative images. A study showed in most patients with social anxiety disorder these images were linked to past social traumatic memories. Recently a treatment technique 'imagery rescripting' is applied to update these traumatic memories. This resulted in a strong decrease in social anxiety complaints. However, rescripting of the intrusive, negative images itself, the future-oriented catastrophic scenarios or 'flashforwards' has not been studied yet. It is possible this is an even more direct way to treat anxiety in social situations.

The research question is whether imagery rescripting focused on flashforwards can reduce social anxiety symptoms in patients with social anxiety disorder.

Who can participate?

Patients with a diagnosis of social anxiety disorder, IQ above 80, and able to read and write in Dutch or English.

What does the study involve?

Patients with social anxiety disorder follow treatment with imagery rescripting focused on flashforwards: images of future

catastrophic scenarios of social interaction. The treatment consists of two sessions of 60 minutes per week with a total of 12 sessions. At waitlist, pre-treatment, post-treatment, 1-month follow-up and 6-month follow-up patients fill out various questionnaires to assess their symptom level. Prior to each session and twice a week during waiting-list patients fill out 2 short questionnaires on social anxiety complaints and 1 that comprised idiosyncratic social situations. Sessions were audio-recorded.

What are the possible benefits and risks of participating?

The possible benefits of participating of this study are that the treatment will reduce social

anxiety disorder complaints. There are no risks involved in participating in this study. The disadvantage of participating in this study is the time it requires to participate in the interviews and fill out the questionnaires.

Where is the study run from?
1. Virenze-Riagg Maastricht (Netherlands)
2. Vincent van Gogh Instituut (Netherlands)

When is the study starting and how long is it expected to run for?
December 2013 to September 2018

Who is funding the study?
Maastricht University (Netherlands)

Who is the main contact?
Prof Marleen Rijkeboer
marleen.rijkeboer@maastrichtuniversity.nl

Contact information

Type(s)
Scientific

Contact name
Prof Marleen Rijkeboer

ORCID ID
https://orcid.org/0000-0002-3083-6891

Contact details
Postbox 616
Maastricht
Netherlands
6200 MD
+31 433882222
marleen.rijkeboer@maastrichtuniversity.nl

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
ECP-134; 04_11_2013

Study information

Scientific Title
Flashforward Rescripting in Social Anxiety Disorder

Acronym
FFinSAD

Study objectives
A treatment regimen focused on flashforward rescripting can substantially change social anxiety symptoms in patients with Social Anxiety Disorder (SAD)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/09/2014, Maastricht University Ethics Committee Psychology (ECP) (Ethics Review Committee Psychology and Neuroscience (ERCPN), Maastricht University, Department of the Faculty of Psychology and Neuroscience, Postbox 616, 6200 MD Maastricht, Netherlands; +31 43 3884008; no email provided), ref: ECP-134; 04_11_2013

Study design
Interventional case series

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Social anxiety disorder

Interventions
This study has a case-study design, with a randomized waitlist between 2 and 7 weeks. Patients were randomised over the number of weeks of their waitlist period. The randomization list was provided by a computerized randomization program.

Patients with social anxiety disorder (n=6) followed treatment with imagery rescripting focused on flashforwards: images of future catastrophic scenarios of social interaction. The treatment consists of two sessions of 60 minutes per week with a total of 12 sessions. At waitlist, pre-treatment, post-treatment, 1-month follow-up and 6-month follow-up patients fill out various questionnaires to assess their symptom level. Prior to each session and twice a week during waiting-list patients fill out 2 short questionnaires on social anxiety complaints and 1 that comprised idiosyncratic social situations. Sessions were audio-recorded.

Flashforward Rescripting: 60 minutes sessions twice a week, with a total of 12 sessions depending on the progress of treatment. Three types of imagery exercises are provided, all focus on future catastrophic scenarios.

Intervention Type
Behavioural

Primary outcome(s)

At waitlist, pre-treatment, post-treatment, 1-month follow-up and 6-month follow-up:
1. The Social Interaction Anxiety Scale (SIAS)
2. The Social Performance Scale (SPS)
3. Situational anxiety severity and avoidance measured using the idiosyncratic rating scale

Key secondary outcome(s))

At waitlist, pre-treatment, post-treatment, 1-month follow-up and 6-month follow-up:
1. The shortened Social Phobia and Anxiety Inventory (SPAI-18)
2. Center for Epidemiologic Studies Depression scale (CES-D)
3. Self-focused Attention scale (SFA)
4. Social Phobic Beliefs (SPB)
5. Subtle Avoidance Frequency Examination (SAFE)
6. Remoralisation measured using the Remoralisation Questionnaire
7. Subjective Happiness Scale (SHS)
8. The avoidant personality items of the Personality Disorders Questionnaire (ADP-IV)

Completion date
01/09/2018

Eligibility

Key inclusion criteria
1. Diagnosis of Social Anxiety Disorder
2. IQ above 80
3. Able to read and write in Dutch or English

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
6

Key exclusion criteria
1. Diagnosis of substance abuse disorder
2. Diagnosis of Psychotic Disorder
3. Diagnosis of Bipolar Disorder
4. Acute Suicidality

Date of first enrolment
16/12/2013

Date of final enrolment

01/09/2018

Locations

Countries of recruitment

Netherlands

Study participating centre
Virenze-Riagg Maastricht

Parallelweg 45-47
Maastricht
Netherlands
6221 BD

Study participating centre
Vincent van Gogh Instituut

Stationsweg 46
Venray
Netherlands
5803 AC

Sponsor information

Organisation

Maastricht University

ROR

https://ror.org/02jz4aj89

Funder(s)

Funder type

University/education

Funder Name

Universiteit Maastricht

Alternative Name(s)

Maastricht University, UM

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date