Testosterone enhancement of exposure therapy in social anxiety disorder

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20251

Source
Nationaal Trial Register

Brief title
Testosterone enhancement of exposure therapy in SAD

Health condition

Social anxiety disorder
Speach anxiety
Exposure therapy
Sociale angststoornis
Spreekangst
Exposure behandeling

Sponsors and support

Primary sponsor: Prof. dr. Karin Roelofs
-Radboud University Nijmegen, Behavioural Science Institute (BSI) & Donders Institute for Brain, Cognition and Behaviour, Radboud University Nijmegen, Postbus 9101, 6500 HB Nijmegen
-Leiden University, Faculty of Social and Behavioural
Sciences, Institute of Psychology
Wassenaarseweg 52, 2333 AK Leiden
K.roelofs@donders.ru.nl
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

Our main outcome is subjective anxiety, as assessed by Subjective Units of Distress (SUDs). participants will provide fear ratings (ranging from 0; no fear to 100 most anxiety imaginable) prior and during both exposure sessions.

Secondary outcome

- Fear of scrutiny at post-treatment (assessed by the Social Phobia Scale (SPS). (Time points: baseline, post-assessment and follow-up)

- Implicit avoidance of angry/happy/neutral faces will be assessed with an Approach Avoidance Task. (Time points: Baseline and post-assessment)

- Feelings of submissiveness and dominance will be assessed exploratory via the Social Comparison scale (SCS). (Time points: baseline, prior and after exposure sessions, post-assessment, follow-up)

- Harm Expectancy (HE) ratings will be assessed exploratory (Time points: prior and after both exposure sessions)

- Video-tapes of participants' performance during each exposure session will be rated with the Social Performance Rating Scale (SPRS), which is an evaluation of behavioral indicators of anxiety.

- In addition some predictor variables will be assessed exploratory: fear learning and low cost avoidance (via two brief computer tasks; time points: baseline). Personality traits (assessed via a short version of the NEO-FFI, time point: baseline), Salivary testosterone and cortisol levels (time points: baseline, prior to testosterone intake, prior and directly after both speech exposures and 30 minutes after speech exposure) , and a proxy of fetal testosterone assessed via a 2D:4D digit ratio (Time point: baseline)

Study description

Background summary

In this randomized placebo controlled trial we will investigate the effects of testosterone on exposure for social anxiety disorder in women. Fifty-two women (age 18-45 years) will be recruited. Eligible participants will i) have a social anxiety disorder as established by a

structured interview; ii) have SAD symptoms of at least moderate severity (LSAS >30); iii) be naive to exposure therapy. Participants will be randomly allocated to receive brief standardized exposure plus testosterone (sublingual, 0.50 mg) or exposure plus identical looking placebo. Testosterone/Placebo will be administered 4 hours prior to the first exposure session. Our main outcome is subjective anxiety as assessed with subjective units of distress (SUDs) ratings. In addition, we will assess self-reported social anxiety symptoms (SPS), automatic socio-anxiolytic behavior tendencies by means of implicit measures, fear learning and avoidance behavior by brief computer tasks.

Study objective

We expect to detect testosterone effects on response to exposure in terms of subjective anxiety and self reported social anxiety symptoms. Additionally we expect testosterone effects on implicit avoidance tendencies. Lastly, Personality traits, feelings of submissiveness/dominance, avoidance behavior on fear learning task, extinction capacity and a proxy of fetal testosterone will be examined exploratory. As such, no hypotheses were formed regarding these possible predictors.

Study design

- Baseline assessment

- Exposure session 1 (one week after baseline assessment)

- Exposure session 2 + post exposure assessment (one week after exposure 1)

- Follow-up assessment (four weeks after exposure session 2, online assessment)

Intervention

Participants will be randomly allocated to receive exposure therapy plus testosterone (sublingual, 0.50 mg) or exposure therapy plus identical looking placebo. Participants will receive two 60 minutes exposure sessions, targeting speech anxiety.

During the first exposure session participants will receive testosterone/Placebo. Testosterone/Placebo will be administered four hours prior to the first exposure session. During the second session participants will receive exposure therapy without testosterone/placebo.

Contacts

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Eligibility criteria

Inclusion criteria

- Woman, 18-45 years old

- Social Anxiety Disorder (SAD) as established with a structured interview (MINI), and with speech anxiety as primary fear

- Self reported SAD symptoms above clinical cut-off (score > 30 on the Liebowitz Social Anxiety Scale)

Exclusion criteria

- Prior non response to exposure therapy (i.c. speech exposure) for SAD symptoms, as defined by the patient’s report of receiving specific and regular exposure assignments as part of previous therapy.

- Entry of patients with other mood or anxiety disorders will be permitted in order to increase accrual of a clinically relevant sample; however in cases where SAD is not judged to be the predominant disorder, participants will not be eligible.

- Psychosis or delusion disorders (current or in the past)

- Patients with significant suicidal ideations or who have enacted suicidal behaviors within 6 months prior to intake will be excluded from participation and referred for appropriate clinical intervention.

- Mental retardation

- Substance or alcohol dependence

- Somatic illness

- Women of childbearing potential that are not willing to use an active form of birth-control during the trial

- Pregnancy or lactation

- Infertility

- Antipsychotic medication

- Participants that use antidepressants or benzodiazepines will not be excluded, but have to be on a stable dose for at least 6 weeks prior to enrollment.

- Insufficient ability to speak and write Dutch

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2017
Enrollment:	52
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	01-05-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44812
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6238
NTR-old	NTR6418
CCMO	NL47410.091.14
OMON	NL-OMON44812

Study results