Testosterone enhancement of exposure therapy in social anxiety disorder

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20251

Bron
NTR

Verkorte titel
Testosterone enhancement of exposure therapy in SAD

Aandoening

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

Ondersteuning

Primaire sponsor: Prof. dr. Karin Roelofs
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Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

- 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)

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-06-2017
Aantal proefpersonen:	52
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	01-05-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44812
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten