Enhancement of exposure therapy for social anxiety disorder with testosterone: A randomized placebo controlled clinical trial

Published: 08-12-2014
Last updated: 15-05-2024

To investigate the efficacy of testosterone enhanced exposure therapy for social anxiety disorder.

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

Summary

ID

NL-OMON44812

Source
ToetsingOnline

Brief title
Testosterone enhancement of exposure therapy in SAD

Condition

- Anxiety disorders and symptoms

Synonym
performance anxiety, social anxiety disorder, social phobia, speech anxiety

Research involving
Human

Sponsors and support

Primary sponsor: ProPersona (Nijmegen)
Source(s) of monetary or material Support: Europese Subsidie en Pro Persona

Intervention

Keyword: Enhancement, Exposure therapy, Social Anxiety Disorder, Testosterone

Outcome measures

Primary outcome

Our main outcome is reduction of social anxiety disorder symptoms, 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

- Subsequently, outcome will be assessed by other self-report questionnaires (Liebowitz Social Anxiety Scale (LSAS), Social Phobia Scale (SPS), Social Phobia Anxiety Inventory (SPAI), Beck Depression Inventory (BDI), Visual Analogue Scales (SUDs) and Harm Expectancy (HE) ratings.
- 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.
- Both exposure sessions will be audio-recorded and transcribed, speech will be rated and analyzed by the Linguistic Inquiry and Word count (LIWC).
-In addition, we will assess automatic socio-anxiolytic behavior tendencies by means of implicit measures, e.g. approach/aviodance and risktaking behaviour.

Study description

Background summary

Social anxiety disorder (SAD) is the most common anxiety disorder and among the most common psychiatric disorders. If untreated, the disorder typically follows a chronic, unremitting course leading to substantial impairments in vocational and social functioning. Exposure therapy is a proven effective treatment for SAD, but remission rates tend to be low, underscoring the need for new treatment strategies that enhance remission rates. A novel line of research has shown that pairing exposure therapy with a pharmacological agent, aimed at the enhancement of underlying mechanisms of action of exposure therapy, augments treatment effects. Testosterone plays an important role in social motivational behavior, and administration of a single dose has been shown to diminish social fear symptoms and avoidance behavior. As exposure therapy is aimed at reduction of avoidance behavior, we argue that testosterone administration could enhance this process. In this first efficacy study, we aim to investigate the augmentation effects testosterone by conducting a randomized placebo-controlled clinical trial comparing four sessions of exposure therapy plus testosterone (0.50 mg) with exposure therapy plus placebo. We expect testosterone enhanced exposure therapy to lead to superior outcome.

Study objective

To investigate the efficacy of testosterone enhanced exposure therapy for social anxiety disorder.

Study design

The planned study is a double-blind randomized placebo controlled trial.

Intervention

Participants will be randomly allocated to receive exposure therapy plus testosterone (sublingual, 0.50 mg) or exposure therapy plus identical looking placebo. Testosterone/Placebo will be administered four hours prior to two 60 minutes exposure sessions, during the first exposure session the participants will receive testosterone/placebo and during the second session they will receive exposure therapy without testosterone/placebo.

Study burden and risks

We believe the risk of the current study to be very limited. The possible side effects of single doses of 0.5 mg testosterone cyclodextrin are negligible.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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 abuse 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 phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2017
Enrollment:	52
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	n/a

Generic name:	testosterone
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	08-12-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-10-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-04-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-07-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	20-12-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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: 20251

Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2014-004475-23-NL
CCMO	NL47410.091.14
OMON	NL-OMON20251

Study results

Date completed:	20-08-2019
Actual enrolment:	54