Transcutaneous vagus nerve stimulation to enhance exposure efficacy in public speaking anxiety

No registrations found.

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

Summary

ID

NL-OMON20935

Source
Nationaal Trial Register

Brief title
PRESENT!

Health condition

Social anxiety disorder

Sponsors and support

Primary sponsor: Leiden University Behandel en Expertise Centrum
Source(s) of monetary or material Support: Leiden University Behandel en Expertise Centrum

Intervention

Outcome measures

Primary outcome

Facilitation of extinction, as expressed by steeper slopes of SUDs decline during the first session in the tVNS condition.

Secondary outcome

Enhanced retention of extinction memory, as expressed by lower mean SUD ratings during session 2 in the tVNS condition.

Study description

Background summary

Rationale: Social Anxiety Disorder (SAD) is a common and debilitating anxiety disorder. Exposure Therapy is a proven effective treatment strategy for SAD. Notwithstanding its efficacy, many patients remain symptomatic after treatment and remission rates tend to be low. Extinction learning is thought to be the most important mechanism of action of ET. Preclinical studies recently demonstrated that vagus nerve stimulation promotes extinction learning, compared to sham. As such, vagus nerve stimulation seems a promising enhancement strategy for exposure therapy. Here, we aim to examine for the first time if transcutaneous stimulation of the auricular branch of the vagus nerve (tVNS) enhances exposure in patients suffering from SAD, compared to sham.

Objective: To investigate whether augmentation of one standardized exposure session for SAD with tVNS results in lower fear compared to sham. We also aim to test if tVNS yields enhanced retention of extinction memory, during a second exposure session compared to sham. Secondary, we aim to test the effects of tVNS + exposure vs. sham + exposure on levels of self-reported social anxiety and cardiac activity, and explore if individual characteristics are related to changes in the primary outcome.

Study design: A single-blind placebo controlled intervention study

Study population: Fifty-two individuals (18-70 years) satisfying DSM-5 criteria for SAD

Intervention: All participants receive two standardized sessions of exposure for SAD, 26 randomly allocated participants will receive tVNS during the first session, 26 will receive sham stimulation during the first session.

Main study parameters/endpoints: Subjective Units of Distress (SUDs): participants will provide fear ratings (ranging from 0; no fear to 100 most anxiety imaginable) prior, during and after both exposure sessions. Main outcome is the change of the SUDs during the first exposure session.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Participants will visit the Leiden Universiteit Behandel en Expertise Centrum for two visits: 1) the baseline assessment and first exposure; 2) the second exposure session. After these sessions, follow-up assessments will be conducted online. Participation will take approximately 4 hours in total. Concerning the tVNS and sham stimulation: The stimulation frequency, intensity and duration are within safety limits established from prior work in

humans (Kreuzer et al., 2012). Previous studies have used comparable or higher tVNS stimulation frequency, intensity and duration without reporting adverse side-effects (e.g. Dietrich et al., 2008; Kraus et al., 2007). The stimulation is not painful, only a typical short-lasting skin sensation (i.e., itching and/or tingling) can be experienced.

Study objective

To investigate whether augmentation of one standardized exposure session for SAD with tVNS has beneficial effects compared to sham enhanced exposure by examining subjective anxiety during exposure. Subjective anxiety will be measured with 'subjective units of distress' (SUDs), which are commonly used to gauge extinction success (Lonsdorf et al., 2017. Specifically, we will examine:

Study design

Baseline, multiple assessments of SUDs during exposure

Intervention

Transcutaneous vagus nerve stimulation at the cymbals concha with exposure; placebo stimulation of the earlobe with exposure

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

A. Between 18-70 years old
B. Social Anxiety Disorder (SAD) as established with a structured interview (MINI), and with speech anxiety as primary fear.
C. Self-reported SAD symptoms above clinical cut-off (score > 30 on the LSAS)

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
A. 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.
B. Prior participation in tVNS research
C. 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.
D. Psychosis or delusion disorders (current or in the past)
E. 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.
F. Mental retardation
G. Substance or alcohol dependence
H. Somatic illness (neurological and cardiac conditions)
I. Pregnancy or lactation
J. Antipsychotic medication
K. 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.
L. Insufficient ability to speak and write Dutch

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	04-03-2020
Enrollment:	52
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	04-03-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49420
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8436
CCMO	NL66143.058.18
OMON	NL-OMON49420

Study results