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

Published: 29-05-2019
Last updated: 15-05-2024

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

Summary

ID

NL-OMON49420

Source
ToetsingOnline

Brief title
tvNS and exposure for public speaking anxiety

Condition

- Anxiety disorders and symptoms

Synonym
public speaking anxiety; social anxiety disorder

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Exposure, Public Speaking Anxiety, Social Anxiety Disorder, tVNS

Outcome measures

Primary outcome

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.

Secondary outcome

Secondary outcome measures:

- SUDs ratings during the second exposure session, i.e. retention of extinction

memory

- Self-reported social anxiety (Social Phobia Scale)

- Cardiac activity (Heart Rate Variability; HRV)

- Harm Expectancies

Study description

Background summary

Social Anxiety Disorder (SAD) is a common and debilitating anxiety disorder, with fear of public speaking as one of the core symptoms. 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.

Study objective

To investigate whether augmentation of one standardized exposure session for SAD with tVNS results in lower fear compared to expsoure plus 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 if tVNS explore the effects on tVNS 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

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.

Study burden and risks

Participants will visit the Leiden Universiteit Behandel en Expertise Centrum for four visits: a baseline assessment, for two exposure sessions, and a post intervention assessment The follow-up assessment will be conducted online. Participation will take approximately 5 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). Participants will be screened for cardiac or neurological disorders, metal pieces in the body, pregnancy, migraine and medication or drug use. The presence of any of these conditions will preclude participation in the proposed study. Previous studies have used comparable or higher tVNS stimulation frequency, intensity and duration without reporting adverse side-effects (e.g. Kraus et al., 2007; Dietrich et al., 2008). The stimulation is not painful, only a typical short-lasting skin sensation (i.e., itching and/or tingling) can be experienced.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion 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. Prior non response to exposure therapy (i.e. 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. (History of) Substance or alcohol dependence
H. Somatic illness
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 phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2020
Enrollment:	52
Type:	Anticipated

Medical products/devices used

Generic name:	transcutaneous vagal nerve stimulator
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	29-05-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	21-12-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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: 20935
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL66143.058.18
OMON	NL-OMON20935