

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

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To investigate whether augmentation of one standardized exposure session for SAD with tvNS results in lower fear compared to exposure plus sham. We also aim to test if tvNS yields enhanced retention of extinction memory, during a second exposure...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Anxiety disorders and symptoms
<b>Study type</b>	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 exposure 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**

### **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**

- 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.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. (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)

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Approved WMO

Date: 21-12-2020

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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## 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: NTR

Title:

### In other registers

Register	ID
CCMO	NL66143.058.18
OMON	NL-OMON20935