The effects of transcutaneous vagus nerve stimulation on perseverative cognitions in daily life.

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The main objective of the current study is to assess whether tVNS affects perseverative cognition, especially worry, in the daily lives in chronic worriers.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43119

Source
ToetsingOnline

Brief title
tVNS and worry in daily life

Condition

- Other condition

Synonym
perseverative cognition; chronic worrying

Health condition

piekerklachten

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: NWO

Intervention

Keyword: ambulatory, perseverative cognition, vagus nerve stimulation

Outcome measures

Primary outcome

The daily ambulatory assessment of perseverative cognitions is the main study parameter of this study.

Secondary outcome

We are interested in the effects of tVNS on neurophysiological underpinnings of worry. These secondary study parameters will be tested during the psychophysiological assessments, which are scheduled four times over the course of the study.

Study description

Background summary

Perseverative cognition, such as worrying and rumination, lies at the heart of the pathogenesis and maintenance of stress-related disorders. The currently available psychological and pharmacological treatments for stress-related disorders are only moderately effective. The activity of the vagus nerve is chronically low in chronic worriers. In this exploratory study, we aim to test whether transcutaneous stimulation of the vagus nerve (tVNS) affects the frequency and duration of participant*s worries. Non-invasive stimulation of the vagus nerve seems a promising treatment as the vagus nerve projects onto emotional brain areas implicated in perseverative cognition.

Study objective

The main objective of the current study is to assess whether tVNS affects

perseverative cognition, especially worry, in the daily lives in chronic worriers.

Study design

A randomized single blinded controlled trial. Participants* worry behaviour is assessed over a two-day period using experience sampling methods, where participants provide ambulatory assessments of the frequency and duration of their daily worries using their smartphones. During this two-day period, participants receive either tVNS or sham stimulation.

Intervention

Stimulation of the auricular branch of the vagus nerve via the concha of the left ear, or stimulation of the earlobe in the control condition. The stimulation will consist of a constant current of 0.5mA delivered twice a day for 30 minutes with a stimulation frequency of 25 Hz and stimulus wavelength of 250µs, active for 30 seconds, followed by a break of 30 seconds.

Study burden and risks

Potential side-effects include itching and a local pain or burning sensation at the stimulation site. These side-effects often disappear rapidly after stopping the stimulation. tVNS is not associated with changes in heart rate, heart rate variability or respiratory rate.

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

Participants must be aged 18-65 years and score higher than 62 on the Penn State Worry Questionnaire (PSWQ), a questionnaire designed to assess worry as a behavioural trait. As described by Behar et al (2003), a cut-off score of 62 on the PSWQ will allow for a highly sensitive and selective selection of chronic worriers when assessing an advertised-for population.
Participants can only participate in this study if they have a smartphone on which they can download the app which will be used to prompt participants to answer the daily questions.

Exclusion criteria

Exclusion criteria for this study are based on the study by Kreuzer and colleagues (2012). As such, participants will be excluded from participating in the proposed study if they are diagnosed with a neurological or cardiac disease, and if the participant does not have a history of alcohol or drug abuse. Participants will be excluded from participating in this study if they use other psychological or pharmacological interventions at the start of or during the study.
Additionally, participants will be excluded if they can*t read and comprehend Dutch language, and if they are unable to give informed consent.
Finally, participants are excluded from participating in this study if they indicate that the stimulation is intolerable.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	04-06-2018
Enrollment:	96
Type:	Anticipated

Ethics review

Approved WMO

Date:	30-03-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL57229.058.16