Peripheral nerve stimulation to improve learning

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

Summary

ID

NL-OMON53198

Source
ToetsingOnline

Brief title
PNS & Learning

Condition

- Other condition

Synonym
Learning, memory

Health condition

menselijk presteren

Research involving
Human

Sponsors and support

Primary sponsor: TNO
Source(s) of monetary or material Support: TNO intern - risicodragen verkennend onderzoek

Intervention

Keyword: Learning, Neurostimulation, PNS, Vagus Nerve

Outcome measures

Primary outcome

Performance on the learned task, which includes accuracy and reaction times.

Secondary outcome

Performance on sustained attention and cognitive control tasks, sleep scores

and mood scores

Study description

Background summary

In a fast-changing world with rapid technological advancements there is a high pressure on people in the workforce to continually learn and adapt to keep up with changing demands. A promising method to support the learning process is peripheral nerve stimulation (PNS). This method involves applying a small electrical current non-invasively to the cervical branch of the Vagus nerve (e.g., in the neck) with a medically approved device which is normally used for treatment of cluster headaches at home. Although studies on the effect of PNS on learning are scarce, initial results are very promising showing PNS improving performance on the training task after 2 days, with higher retention performance at 30 and 60 days post-training. Here we propose to test how PNS can improve learning on a military-relevant task.

Study objective

The main objective of the proposed study is to investigate the effect of PNS as a means to support the learning process in order to accelerate learning and improve knowledge and competence retention. This will be tested by applying PNS stimulation during training, followed by retention tests at different times

post-training to investigate long-term benefits of stimulation.

Study design

The study design will be a single-blind, sham-controlled, between-subjects intervention study with two groups of 20 participants. Participants will be trained on a specialized visual detection task over the course of four days, spending approximately an hour each day. Participants will receive PNS stimulation before and after the training task. Retention tests will be performed 1, 30 and 60 days post-training.

Intervention

Both groups will undergo a 4-day training protocol, with one group receiving PNS and the second group receiving active sham stimulation. Electrical stimulation at 25 Hz is applied twice for 2 minutes in the neck using a handheld device (gammaCore® developed by electroCore®, FDA-approved and CE-marked to treat cluster headaches and treatment-resistant migraines at home), before and after each training session.

Study burden and risks

Participants will be invited for a total of 7 sessions of approximately 1-2 hours, 5 of which will be on consecutive days. There are small burden and risks associated with participation, and there is no risk for any serious (adverse) event. The burden consists of the following activities:
- Peripheral nerve stimulation: Stimulation will be done with a medically approved device (for at-home use) that applies a small current to the neck, targeting a cervical branch of the vagus nerve (i.e., in the neck). Stimulation will only be applied twice for 2 minutes, once on the left and once on the right side of the neck, with a 2 minute break in between. Some mild discomfort may occur locally, which stops when stimulation is stopped. Single session stimulation is associated with minimal side-effects, and use of the device is considered safe in healthy individuals.
- Behavioural testing: The participant is asked to participate in training sessions on a computer task, which tests perceptual detection and decision-making

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1. The potential subject has given informed and written consent and is able to comply with all study assessmentsscheduled in the protocol.
2. All subjects need to be between 18 and 55 years of age.
3. All subjects have computer skills.
4. All subjects declare to be in good health, and declare not to have any chronic diseases.
5. Subjects must be able to communicate, participate, and comply with the requirements of the entire study.
6. No signs of flue or viral infection in the last 5 days before the start.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
1. Pregnancy
2. Atherosclerosis
3. Other cardiovascular health issues

4. Epilepsy and a history of psychiatric illness (including sleeping disorders).
5. Having an active implantable (metallic) device.
6. Using another device at the same time of testing or any portable electronic device (e.g., mobile phone).
7. Used alcohol the day before the start of a test day.
8. Used drugs in the last 3 months.

Study design

Design

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	28-08-2023
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	gammaCore
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	14-08-2023
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Approved WMO Date:	30-01-2024
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL84460.028.23