UNIVERSITY OF JYVÄSKYLÄ

DEPARTMENT OF PSYCHOLOGY

2024-2027

RESEARCH NOTIFICATION

1. The effect of vagus nerve stimulation on learning, request to participate in the study

You are invited to participate in the "Effect of Vagus Nerve Stimulation on Learning" study. The vagus nerve, or vagus nerve, is a branch of the autonomic nervous system that carries information from the body to the brain and from the brain to the body. The vagus nerve is an important part of the parasympathetic nervous system, i.e. the nervous system that calms the body's functions, and its activity affects, for example, the heart rate, but possibly also the functioning of the brain. Branches of the vagus nerve extend throughout the body, including the ear. In this study, we find out how electrical stimulation of the vagus nerve through the left ear affects learning. The purpose is to find out whether learning can be improved by changing the balance state of the autonomic nervous system, i.e. by activating the parasympathetic nervous system. There is almost no previous similar research. Stimulation itself has been found to be harmless, and stimulation devices are sold to consumers for free use. We conduct research in collaboration with Parasym Ltd. company, and we use their device for stimulation. The connection between vagus nerve stimulation and learning is studied in the laboratory using a name-face learning task. During the experiment, brain activity is measured with MEG and EEG, as well as physiological functions (heart rate, breathing, electrical conductivity of the skin) to see what kind of differences or changes are brought about by stimulation. In total, the laboratory test lasts approx. 2.5 hours. After the laboratory visit, the learning is monitored at home with the help of memory tests performed via the internet, and well-being is inquired about with surveys. These follow-ups are done in the evening of the same day and the next morning, and they take a total of approx. 10–15 minutes.

You are being asked to participate in the study because you are a healthy adult aged 20–35.

This announcement describes the study and participation in it. The attachment describes the processing of your personal data.

Participation in the study requires that you do not have:
• a hairstyle that prevents the measurement of brain activity on the surface of the head (e.g. dreadlocks)
• diagnosed neurological diseases or (head) injuries
• a diagnosed attention or linguistic processing problem (e.g. dyslexia)
• a diagnosed degenerative brain disease or dementia
• significant hearing impairment or visual impairment
• disease of the cardiovascular system
• medication affecting the central nervous system
• metal implants in the head area

Approximately 60 adult volunteer subjects will participate in the study.

This is a one-off study, and you will not be contacted again later.

2. Voluntariness

Participation in this study is voluntary. You can refuse to participate in the study, suspend your participation or withdraw the consent you have already given without giving a reason at any time during the study. This will have no negative consequences for you.

When you stop your participation in the study or withdraw your consent, the personal data, samples and other information collected about you until then will be used as part of the research material when it is necessary to ensure the research results.

3. Experiment description

The research is carried out at the Department of Psychology, University of Jyväskylä, in a laboratory space, and there is one research visit. The visit takes about 2.5 hours in total. The address of the laboratory is:

Department of Psychology, University of Jyväskylä, Kärki property, Mattilanniemi 6, 40100 Jyväskylä

We will pick you up from the downstairs lobby at the agreed time. In the laboratory, you will first get to know the information about the research and if you decide to participate in the research, you will sign the consent form.

Preliminary preparation

The research begins by attaching electrodes needed to measure the functions of the brain and body. During this, you sit in your place on a chair. To measure the electroencephalogram, or EEG, a cap is placed on your head, where the measuring electrodes that come onto the surface of the skin are located. In addition, you will be attached the electrodes needed to measure eye movement (electrodes around the eye), skin electrical conductivity (electrodes in the palm) and heart rate (on the side, upper chest and neck), as well as a flexible belt (over the clothes) needed to measure body movement produced by breathing. To measure the electroencephalogram, or MEG, positioning coils are placed on your head. While the researcher makes the above-mentioned preparations, you fill out a short background information survey inquiring about your sleeping habits. Next, you get to test the vagus nerve stimulation, which means that together we will find the stimulation strength that suits you. The device is placed in the left ear after the skin is first cleaned. The device produces a weak electric current that stimulates the nerve pathways running under the electrode. When the appropriate intensity has been found, the device is removed from the ear. All in all, these initial preparations take approx. 60 minutes.

Face-name task

Next, the actual test begins, and you walk to the MEG device to be measured. In the MEG device, you sit still with your head inside the device and look at the screen in front of you. First, the baseline level of physiological signals is measured for 5 minutes. After that, you will be shown people's faces and written names, and your task is to learn who each one is. The task is repeated for 4 rounds, and at the end of each round you do a test (which name of the four options belongs to the presented faces?) and you get feedback on your performance (what percentage got it right?). There is a short break between rounds. The task takes a maximum of 40 minutes. Finally, the baseline level of physiological signals is measured again for 5 minutes.

Vagus nerve stimulation

After the memory task, you move away from the MEG device and undergo vagus nerve stimulation with previously determined values. The stimulation lasts approx. 20 minutes, and

during that time you sit still. At the end of the stimulation, you fill out a short questionnaire regarding the sensations related to the stimulation. Finally, you sit in the MEG machine again for 5 minutes, and we measure the baseline level of physiological signals. When the measurement is finished, you move to the chair in the preparation room and the measuring devices are removed.

Memory tests and surveys remotely
After leaving the lab, you can continue your day as usual. We remind you to do the memory test (approx. 10 min, one round of face photos and name selection) remotely at 8 pm the same day and at 8 am the next morning. You will receive more detailed instructions with you when you visit the laboratory, and if necessary, you can ask for instructions after receiving a reminder message.

4. Possible benefit from the research

There is no individual feedback from the research and there is no direct benefit to the researched person.

The results of the study deepen the understanding of the mechanisms of learning and may open opportunities to develop interventions for memory problems.

5. Risks, disadvantages and inconveniences that may arise from the study and preparation for them

The methods used in the study have no known significant side effects. Putting the EEG cap in place may feel a little uncomfortable, as the scalp must be cleaned by gently rubbing. When measuring the electroencephalogram, we use gel, which is why you may want to wash your hair afterwards. In the measurements of heart rate, muscle activity and electrical conductivity of the skin, electrodes placed on the surface of the skin are used, for which the skin is cleaned. Slight irritation of the skin may occur from the electrodes. For vagus nerve stimulation, we are looking for the intensity of stimulation that is just right for you, and at this stage you will probably experience short-term (less than 5 s) uncomfortable irritation of the stimulated ear. The known possible side effects of the device used in vagus nerve stimulation are discomfort at the stimulation site, for example numbness or other strange sensation on the skin at the point of use of the electrode. Skin irritation, pain or burning at the stimulation site is also possible if the device is used continuously at a high intensity. Stimulation may cause dizziness. Side effects are rare and usually disappear soon after the stimulation is stopped.

6. Research costs and compensation for the research subject

There is no cost, and no reward paid for the participants.

7. Communication of research results

The material collected in the research is put into such a form that the individual subject cannot be identified. This material is analyzed, and the results are published in international peer-reviewed scientific journals. In addition, preliminary results are presented at scientific congresses. An openly accessible version of all research reports is published in the JYX archive of the University of Jyväskylä. Theses are also being prepared from the material, which will also be openly published in the JYX archive. Depending on the interest (journalists contact us based on press releases), we also tell a wider audience about our research through media such as newspapers. If they wish, the subjects can get information about the results of the study by later contacting the responsible leader of the study. As said, no information from the study will be published that could identify an individual subject. The data protection notice tells you about the use of your personal data as part of the research.

It is not possible to give personal feedback about the research.

8. Insurance for participants

The operations and subjects of the University of Jyväskylä are insured.

The insurance policies of the University of Jyväskylä cover only those damages that are directly related to the given research task and which have occurred during the actual instructed research task. The insurance does not cover damages that occur during breaks.

The insurance policies of the University of Jyväskylä are not valid for studies carried out remotely if the subject's domicile is not in Finland.

The insurance includes patient insurance, liability insurance and voluntary accident insurance. The research subjects (test subjects) are insured against accidents, damages and injuries caused by an external cause during the research. Accident insurance is valid during the measurements and the trips immediately related to them.

9. More information from

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