IRB APPROVED
Apr 18, 2024

RESEARCH SUBJECT CONSENT FORM

TITLE: Cognitive Augmentation via Multimodal Sensing and Auricular Neurostimulation

PROTOCOL NO.: FA238423PB017

SPONSOR: OpenBCI, Inc.

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Your participation in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. More detailed information about this research can be found in the next section of this document.

How long will I be in this research?

We expect your role in this research will last for a total of six days over the course of one year. You will participate in three experimental phases, each lasting for two days, for a total of six days. Each test day will last no longer than three hours.

Why is this research being done?

The purpose of this research is to examine the potential of using electrical stimulation to enhance cognitive performance in a closed-loop system that measures brain activity and responds to detected changes in cognitive state with electrical stimulation.

What happens to me if I agree to take part in this research?

If you decide to take part in this research study, you will take part in a series of procedures while wearing a biosensing virtual reality (VR) headset. You may be asked to perform a number of tests that induce different cognitive effects, such as cognitive overload, cybersickness, and mental stress. The purpose of these tests is to gauge physiological responses to different stimuli and estimate cognitive state based on those physiological responses. In following tests, you may be asked to wear a neural stimulation earpiece alongside the biosensing headset in order to determine how controlled neural stimulation affects cognitive states and cognitive performance.

Could being in this research hurt me?

This testing involves relatively minimal risk. The most significant risk or discomfort that you may experience is cybersickness (also known as *VR sickness*). Cybersickness is similar to motion sickness, and may result in nausea, dizziness, headaches and disorientation. Cybersickness is not considered a serious concern, and symptoms tend to disappear after a few hours. You will be closely monitored for symptoms during the study, and you will be allowed to exit the VR simulator at any point due to cybersickness or discomfort.

Sparrow Link has not been cleared by the US Food and Drug Administration (FDA) for cognitive enhancement and is considered investigational for this protocol. The device is FDA cleared for treatment of opioid withdrawal symptoms. Most therapy-related side effects are reversible and corrected by reprogramming or turning the system OFF or removing the earpiece. Chronic, irreversible stimulation-related adverse events are expected to be rare.

Will being in this research benefit me?

It is not expected that you will personally benefit from this research.

Possible benefits to others include the development of a closed-loop neural interface capable of improving cognitive performance. This type of system is intended for use in training and classroom environments. Other parties may benefit from the development of a training system based on this research.

What other choices do I have besides taking part in this research?

This research is not designed to diagnose, treat, or prevent any disease. Instead of being in this research, you can choose not to participate in this study.

What else should I know about this research?

Participants will be asked to follow the instructions listed below:

1. Maintain a level of caffeine or xanthine (e.g., coffee, tea, energy drinks) consumption which is consistent with your normal routine over the two weeks prior to each experiment.
2. Abstain from alcohol usage for 24 hours before the start of each experimental phase.
3. Abstain from strenuous exercise for 8 hours before the start of each experimental phase.

4. Refrain from eating large meals in the 8 hours prior to the start of each experimental phase.
5. Minimize screen time (cell phones, PCs, etc.) the night before each experimental phase.
6. Avoid use of VR/XR head mounted displays altogether in the 24 hours prior to the start of each experimental phase.

If you do not believe you can follow this guidance, for the time periods described, then this study may not be for you. Note that these rules only apply to the six days when you will be asked to participate in experiments. These six days will be scheduled over the course of a year, and you will be provided with reminders of this guidance before each experiment.

Investigator Financial Interests
Dr. Mahmood has received stock options from the sponsor in the past 12 months. Please feel free to ask any further questions you might have about this matter.

DETAILED RESEARCH CONSENT

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

Why is this research being done?

The purpose of this research is to combine OpenBCI's existing virtual reality (VR) neurotechnology headset, *Galea*, with non-invasive neurostimulation technology, *Sparrow Link*, to enhance cognitive performance in commercial and defense applications. Transcutaneous auricular neurostimulation (tAN™; stimulating nerves around the ear and through the skin) is a promising technique that has been shown to improve cognitive performance in a variety of categories and the stimulation mechanism is compatible with Galea's biosensors. We have integrated a tAN system developed by Spark Biomedical, Inc. with the head-mounted Galea biosensor platform to create an automated closed-loop system for cognitive augmentation specifically targeting stress, attention, and cybersickness performance metrics. The combined use of the Galea headset with Sparrow Link stimulation technology is investigational in this study.

The system will be optimized to maintain attention to cognitively demanding tasks, improve performance under stress, and increase resistance to cybersickness in subjects.

About 50 subjects will take part in this research.

How long will I be in this research?

We expect your role in this research will last for a total of six days over the course of one year. You will participate in three experimental phases, each lasting for two days, for a total of six days. Each day will last no longer than three hours.

What happens to me if I agree to take part in this research?

You will attend a 30-minute online orientation session before any experiments begin. An investigator will reach out to you to schedule the first round of experiments. All experiments will take place on site at the Sponsor's (OpenBCI, Inc.) primary testing facility (67 West St. Ste 609, Brooklyn, NY, 11222).

After scheduling your study appointments, you will receive reminders 24 hours and 48 hours before each experiment. These reminders will provide guidance as to what you should and should not do in the lead-up to the experiment in order to maintain experimental validity.

For the first experimental phase, the experiments are split up over two days.

The following section details a typical timeline for the first day of experiments. Specific details about each experiment will be described after the timeline.

Timeline for Day 1 Activities (approx. 140 minutes total)

1. You will be briefed on the procedures for the day.
2. The *Galea* biosensing headset will be set up on your head with the assistance of a proctor.

During Phase II and Phase III experiments, a proctor will help attach a *Sparrow Link* device, which uses an earpiece to provide electrical stimulation.

3. We will record 10 minutes of baseline data, where you will relax and not perform any cognitive tasks.
4. You will perform the Flanker Task for approximately 20 minutes. See below for a description of the Flanker Task.
5. You will remove the Galea headset with the aid of a proctor.

During Phase II and Phase III experiments, the *Sparrow Link* should not be removed or altered in any way.

6. You will respond to survey questions relating to your cognitive state during the prior experiment.
7. The Galea biosensing headset will be set up on your head.
8. We record another 10 minutes of baseline data, where no cognitive tasks are performed, and you just relax.
9. You will perform the MATB Task for approximately 40 minutes. See below for a description for the MATB task.
10. You will remove the Galea headset with the aid of a proctor and respond to a survey regarding the task.

For Phase II and Phase III experiments, with the aid of a proctor, you will remove the Sparrow Link earpiece, and return the device.

Overview of Day 1 Tasks:
Flanker Task

The Flanker Task requires participants to respond to a central target (usually an arrow), which is surrounded by other targets that may or may not match the central target, as shown in Figure 1. These tasks become more challenging over time either by decreasing the time required to react to new stimuli or by introducing more contradictory information. This experimental task tests a participant's ability to maintain attention on relevant stimuli while ignoring irrelevant stimuli.

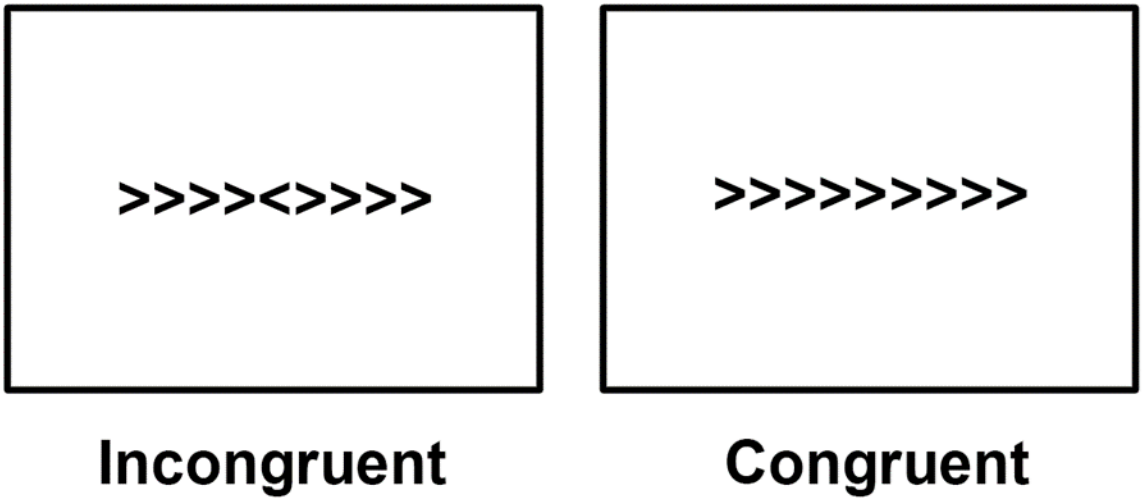

Figure 1. Examples of Incongruent and Congruent Stimuli in a Standard Flanker Task

MATB Task: Multi-attribute Task Battery

The Multi-Attribute Task Battery (MATB) is a computer-based task designed to evaluate operator performance and workload. MATB emulates the types of gauges and information clusters that aircraft crew would have to evaluate during flight. MATB requires participants to track a number of concurrent tasks and perform dynamic resource management (Figure 2). MATB is a commonly used research platform in organizations like NASA and the United States Air Force.

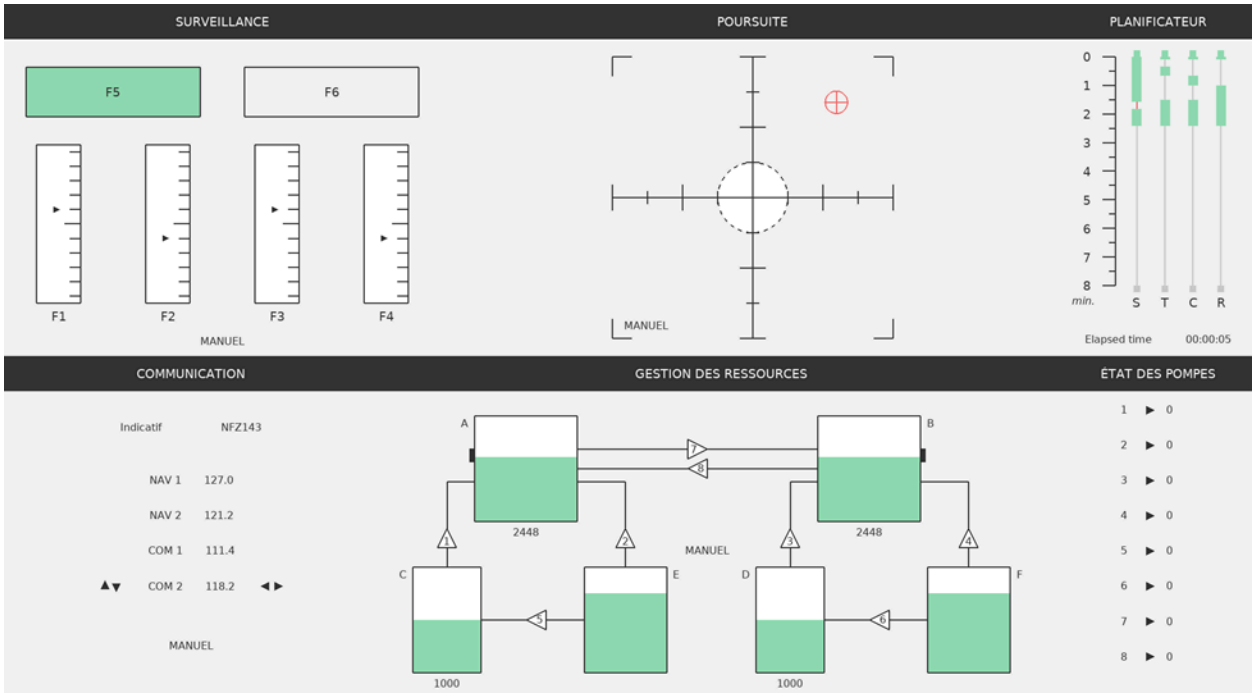

Figure 2: Sample Screenshot from OpenMATB User Interface

Timeline for Day 2 Activities (approx. 170 minutes total):

1. You will be briefed on the procedures for the day.
2. The Galea biosensing headset will be set up on your head with the assistance of a proctor.

During Phase II and Phase III experiments, a proctor will help attach a *Sparrow Link* device, which uses an earpiece to provide electrical stimulation.

3. We record 10 minutes of baseline data, where you will relax and not perform any cognitive tasks.
4. You will perform the GradCPT task for approximately 30 minutes. See below for a description of the GradCPT task.
5. You will remove the Galea headset with the aid of a proctor.

During Phase II and Phase III experiments, the *Sparrow Link* should not be removed or altered in any way at this point.

6. You will respond to survey questions relating to your cognitive state during the prior experiment.
7. With the aid of a proctor, you will once again place the *Galea* headset back on your head to continue the experiment.
8. We record another 10 minutes of baseline data, where you will relax and not perform any cognitive tasks.
9. You will perform the cybersickness task for no more than 30 minutes. See below for a description of the cybersickness task.
10. You will remove the Galea headset with the aid of a proctor.

For Phase II and Phase III experiments, with the aid of a proctor, you will remove the Sparrow Link earpiece, and return the device.

11. After a short cooldown period of up to 10 minutes, you will be asked to respond to survey questions relating to your cognitive state during the prior experiment, along with information about feelings of cybersickness.
12. There is a mandatory cooldown period of 30 minutes after removing the headset.

Overview of Day 2 Tasks:

GradCPT Task

GradCPT is a variant of a continuous performance task where participants are required to respond to frequent stimuli. Here, stimuli in the form of images are presented consecutively, with a majority of them sharing a similar description (i.e., non-target images). However, some of the images will not match this description (i.e., target images), and the subject is required to identify and not respond to these targets. Typically, subjects respond to targets by pressing a button. Figure 3 illustrates the gradual transition from a non-target city image to a target mountain range image. Participants are required to press a button each time a city scene is presented and withhold a response when the infrequent mountain scene is presented. Task difficulty can be set by reducing the time between images or reducing the frequency of target images.

Figure 3: *GradCPT Transition Between Non-Target City Image to Target Mountain Image*

Cybersickness Task

A required part of the experiment is to attempt to induce cybersickness (i.e., VR sickness) in participants, which results in symptoms similar to motion sickness (e.g., dizziness, nausea, and lightheadedness). Therefore, participants will be placed in a virtual 3D environment while different visual effects are displayed, including increasing latency, and loss of control.

Safety Monitoring
All procedures will be performed in the presence of an investigator, and all interactions with investigational devices are performed by a proctor. If you feel uncomfortable or ill, you may indicate this to the proctor and investigator, and they will help to resolve the issue. If you decide that you are feeling too unwell to continue, the research may be terminated.

Study Groups
There are two study groups, which only take effect during Phases II and III of this experiment. You will be put into a study group by chance (like a coin toss). You have a 50% chance of being placed in either group.

One group will receive active tAN using the *Sparrow Link*, and the other will receive sham tAN. If you are placed in the sham tAN group, the earpiece will be applied and the cable will be connected to the Patient Controller, but stimulation will not be turned on.

You cannot choose your study group. During the research, you and the study investigator will not know which group you are in.

Devices and Systems

The *Galea* headset is a commercially available FDA cleared device. The *Galea* headset is composed of two major components: the virtual reality (VR) head-mounted display (HMD) and the biosensing headgear. The *Galea* includes a number of sensors to gauge physiological state, by monitoring brain electrical activity, heart rate, and other physiological metrics.

Figure 4. Galea Biosensing Headset

Sparrow Link is investigational, which means that it is not approved by the Food and Drug Administration (FDA). The device is a system that consists of a Patient Controller, Cable, and a disposable flexible earpiece (see Figure 5). The Patient Controller produces the electrical stimulation which is delivered through the cable to the earpiece. The device is based on a different device called the Sparrow Ascent device, which is FDA cleared for treatment of opioid withdrawal symptoms (K230796).

Figure 5. Sparrow Ascent: (A) Earpiece, (B) Cable, and (C) Patient Controller

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to follow the instructions listed below:

1. Abstain from consuming products which contain caffeine or xanthine (e.g. coffee, tea, energy drinks) for 12 hours prior to the start of each experimental phase.
2. Abstain from alcohol usage for 24 hours before the start of each experimental phase.
3. Abstain from strenuous exercise for 8 hours before the start of each experimental phase.
4. Refrain from eating large meals in the 8 hours prior to the start of each experimental phase.
5. Minimize screen time (cell phones, PCs, etc.) the night before each experimental phase.
6. Avoid use of VR/XR head mounted displays altogether in the 24 hours prior to the start of each experimental phase.

If you do not believe you can follow this guidance, for the time periods described, then this study may not be for you. Note that these rules only apply to the six days where experiments will be run over the course of a year, and you will be provided with reminders of this guidance before each experiment.

Could being in this research hurt me?

Participating in this research is generally low risk and is unlikely to cause harm to you. There may be unknown risks which cannot be currently predicted. However, some potential risks are detailed below. You cannot participate in this study if you are pregnant. There may be risks to a developing baby that are unknown.

Risks related to VR/XR simulations

There are inherent risks related to usage of virtual reality. Extended usage of VR can cause eye strain, blurry vision or dry eyes. This risk is largely mitigated by the short length of each experiment and providing breaks in-between tasks.

Risks related to deliberately inducing cybersickness

Cybersickness is closely related to motion sickness or simulator sickness, and manifests as symptoms including nausea, dizziness, headaches, and disorientation. Cybersickness is not associated with any long-term risks, with symptoms fading over a few hours. During this part of the experiment, the participant will be allowed to stop the stimulus and remove the virtual reality display as soon as they feel like they are too unwell to continue. The experiment will be interrupted by the experiment investigator if you report that you feel seriously ill or feel like vomiting.

Risks related to the Galea Biosensing Headset

The Galea biosensing headset is a low-risk device that uses a cluster of electrodes and other sensors to measure biometric and electrophysiological data. The methods for measuring this data are non-invasive and well-established to be completely safe.

Risks related to the Sparrow Link tAN device

The most important risks or discomforts that you may expect from taking part in this research include:

- Dermal (skin) irritation
- Erythema (redness where device is touching the skin)
- Paresthesia (tingling, prickling, or numbness)
- Allergic contact dermatitis (red, itchy rash due to allergy)
- Dermal hypersensitivity (increased skin sensitivity)
- Transient (temporary) pain or discomfort due to stimulation
- Transient pain or discomfort due to device malfunction
- Otalgia/otodynia (earache)
- Muscle twitching during stimulation
- Failure of a device component resulting in loss or decrease of therapeutic effect

Most therapy-related side effects are reversible and corrected by reprogramming or turning the system OFF or removing the earpiece. Chronic, irreversible stimulation-related adverse events are expected to be rare.

Part of this experiment involves deliberately inducing cybersickness to the point of impairing cognitive performance to study how tAN stimulation can mitigate these symptoms.

Will it cost me money to take part in this research?
The only expense you may incur are travel expenses, which may be reimbursed up to $10 per travel event.

Will being in this research benefit me?
There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, development of a closed-loop cognitive enhancement platform may provide benefit to future students and trainees who utilize this technology for reduced training time and improved learning performance.

What other choices do I have besides taking part in this research?
This research is not designed to diagnose, treat, or prevent any disease. Your alternative is to not take part in the research.

What happens to the information collected for this research?
All identifiable information about you will be coded with a study identification number (study ID). Your private information and research data will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor (OpenBCI, Inc.)
- Research collaborators, including Spark Biomedical, Inc.
- U. S. Government agencies, such as the Air Force, Food and Drug Administration (FDA).
- WCG IRB, the Institutional Review Board (IRB) that reviewed this research

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

Data collected in this research might be deidentified and used for future research or distributed to another investigator for future research without your consent.

Who can answer my questions about this research?
If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number(s) listed in this document.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may contact them at 855-818-2289 or clientcare@wcgclinical.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

What if I am injured because of taking part in this research?

If you are injured or become sick because of being in this research, call the study coordinator immediately. The study coordinator will call for emergency medical treatment. Your insurance may be billed for this treatment. The sponsor will pay any charges that are not covered by insurance policy, provided the injury was not due to your underlying illness or condition and was not caused by you or some other third party.

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- You have a side effect that requires stopping the research
- The research is canceled by the sponsor
- You become pregnant during the experiment's duration
- You are unable to keep your scheduled appointments

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

What happens if I agree to be in this research, but I change my mind later?

If you decide to leave this research, contact the research team so that the investigator can remove you from the records and settle any outstanding payments owed to you.

There are no risks to you if you decide to leave at any time.

Will I be paid for taking part in this research?

For taking part in this research, you may be paid at least $437.50 for completing all parts of the study. Your compensation will be broken down as follows:

- For each hour of research participation, you will be compensated at minimum $25.
- Payments will be made electronically at the end of each two-day experimental phase.
- A bonus payment of at minimum $50 will be provided at the end of the third and final experimental phase.
- If you drop out or are removed for any reason, you will be compensated based on the rate of at minimum $25/hr for any outstanding unpaid participation.

Additionally, reimbursement is possible for travel.

Future research utilizing data collected from this study

The data information that have been collected from this study will be de-identified, which means any information that could be used to identify you will be removed. The de-identified data information may be used for future research studies or shared with other researchers. You will not be informed of or asked for additional consent to these future research studies. If any commercial products are developed from this data information, there are no plans to share any profits with you.

Do you agree to allow data information to be stored for future research studies?

€ YES
€ NO

Statement of Consent

Your signature documents your consent to take part in this research.

_____

Printed name of subject

_____ _____

Signature of subject Date

_____

Printed name of person obtaining consent

_____ _____

Signature of person obtaining consent Date