Permission to Take Part in a Human Research Study

Title of Study: Combating Alzheimer's through Sleep and Exercise (CASE*)*
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Sponsor: The Shipley Foundation

A person who takes part in a research study is called a study participant. In this consent form, "you" always refers to the study participant.

Key Information about This Research Study

We are asking you to join a research study. You may have been in another research study with us and have consented to being contacted for future research. The purpose of this research is to see how sleep and/or exercise affect dementia risk over time.

If you choose to participate, the study will last approximately nine weeks and will include an initial screening period to determine eligibility. Participants will be randomly assigned to one of three groups focused on improving sleep, increasing physical activity, or improving both sleep and physical activity. Throughout the study, participants will be asked to wear monitoring devices, complete questionnaires and cognitive assessments, and follow guidance related to sleep and/or exercise, depending on group assignment. Some in-person visits will be required, and blood samples will be collected.

A more detailed description of study procedures, visits, devices, and assessments is provided later in this consent form. Participation is voluntary, and you may choose not to take part or to withdraw at any time.

Here are some reasons you may want to take part in this research:

- Taking part will help us understand how sleep and/or exercise may help prevent dementia and how we can help people before they develop dementia.

Permission to Take Part in a Human Research Study

- You may benefit in terms of cardiovascular/aerobic and resistance training health, sleep health, and your cognitive health.

Here are some reasons you may not want to take part in this research:

- There are general risks that are involved with this study. These include the risks of the moderate exercise program, from wearing the study devices, the blood draw, and the possibility of being uncomfortable with the obtainment of a weight measurement and/or answering survey questions. These risks are described in detail later in this form.

Taking part in this study is voluntary. You do not have to take part if you do not want to, and you can leave the study at any time. Whatever you decide, you will not be penalized or lose benefits.

What if I have Questions?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 305-243-1298 or at CASE@miami.edu.

An Institutional Review Board ("IRB") reviewed and allowed this research to move forward. An IRB is a group of people who consider the risks and benefits of research to determine whether the research should happen. The Human Subject Research Office (HSRO) is the team that supports the University of Miami's IRBs.

Please call the HSRO at 305-243-3195 if:

- The research team has not answered your questions, concerns, or complaints.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Permission to Take Part in a Human Research Study

What happens if I say yes, I want to be in this research?

In this study, we want to see if exercise and/or sleep improve your brain, cardiovascular, and metabolic health, cognitive (mental) abilities, and reduce your dementia risk over an 8-week period. Therefore, you will be assigned randomly (like a flip of a coin) to one of three groups: 1) exercise only, 2) sleep only, or 3) combined exercise and sleep.

- Group 1: Exercise Only
  - You will wear a Fitbit device continuously while you continue your daily living activities for an onboarding "data collection" period of 7 days of physical activity levels.
  - You will receive a Fitbit device to be worn at all times. You will also wear the Fitbit during these biweekly exercise sessions.
  - During your first and follow-up study visits, you will complete a six-minute walking test to assess your aerobic fitness.
  - You will take part in an in-person, supervised, moderate-intensity workouts twice per week for sixty (60) minutes each time, which will consist of 10 minutes of warm-up stretching, 20 minutes of moderate-intensity aerobic activity, 20 minutes of resistance training, and 10 minutes of after-exercise stretching. This will total 16 exercise sessions throughout the 8-week period.
  - On the remaining five (5) days each week when you are not coming on-site to participate in exercise sessions, you will be asked to walk for 30 minutes at a brisk pace.
- Group 2: Sleep Only
  - You will wear an Elemind headband (see **Figure 1**) while you sleep for an onboarding "data collection" period of 7 days.
  - Then, for at least 3–4 nights a week for 8 weeks, you will wear the Elemind headband; this headband is designed to collect information about your sleep quality and help you fall asleep faster through sound stimulation.
  - You will wear a LYS device at all times, which can be strapped onto clothing, a purse, or a backpack; this device captures information about light exposure.

- Because you will be wearing a sleep intervention in your own home throughout the study without the need to come to the research site after your first in-person visit until your final in-person visit 8 weeks later, our research team will contact you at least once a week throughout the 8-week study after the first in-person visit for brief, 10–15-minute discussions by phone or secure video conferences to ensure there are no issues with using the Lys, Fitbit, or Elemind headband devices and to provide reinstruction on using the devices, as needed.

- Group 3: Exercise and Sleep
  - You will wear the Fitbit device continuously and the Elemind Neuromodulation headband nightly for an onboarding "data collection" period of 7 days.
  - During your first and follow-up study visits, you will complete a six-minute walking test to assess your aerobic fitness.
  - You will take part in the guided, in-person exercise program as described above in addition to wearing the Elemind headband 3–4 nights a week as well as the LYS and Fitbit devices at all times, as described above.
  - On the remaining five (5) days each week when you are not coming on-site to participate in exercise sessions, you will be asked to walk for 30 minutes at a brisk pace.

At the first study visit, we will collect your weight and height. Two height measurements and two weight measurements will be collected at the first visit and averaged from both readings to ensure that the height and weight measurements are accurate. When you return for your last study visit 8 weeks later, only weight will be measured again, with two readings again obtained and averaged. If there is a significant difference between the two measurements obtained for either height and/or weight, a third measurement will be collected and incorporated into the average to determine the final visit height/weight.

All participants provide two (2) blood samples throughout the study, which will analyze samples of cardiovascular disease risk, inflammation, and insulin resistance. Your blood sample will also be analyzed to assess your brain health. You will also fill out multiple questionnaires and use the Altoida, a digital device used for testing your cognitive (mental) abilities.

Permission to Take Part in a Human Research Study

Figure 1. Elemind Neuromodulation headband



(a)

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(**b**)

The wearable Elemind Neuromodulation headband (**a**) when worn (**b**). Images copyright 2024 (**a**) and 2025 (**b**) by Eleming Technologies, Inc.

Exercise Program

The exercise sessions are low-risk, moderate-intensity, aerobic and resistance training exercises that will be conducted in person, totaling 60 minutes twice per week, with at least one research assistant present at all times during the exercise sessions to direct and supervise the exercise sessions. These exercise sessions will be scheduled according to your flexibility over the next 8 weeks, but morning sessions will be strongly encouraged. These exercises are designed to be performed by people at any age and level of fitness. Exercise sessions will involve 10 minutes of an initial warm-up, 20 minutes of aerobic exercise, 20 minutes of resistance training, and 10 minutes of recovery stretching.

Permission to Take Part in a Human Research Study

What happens if I want to leave the study?

If you leave the research, we will keep the information about you that we obtained or created. Tell the study team if you want us to destroy the blood and other tissue samples that we collected while you were in the study. If the blood and other samples are not linked to your identity, the study team cannot destroy them.

Can anyone remove me from the research without my OK?

The researchers may take you out of the study, even if you want to continue, if:

- Your health changes and staying on the study are no longer in your best interest;
- Your cognitive assessment results indicate you are already have early-onset Alzheimer's disease/dementia;
- You do not follow the study rules;
- You no longer meet the requirements to be in the study; or
- The sponsor or the study doctor stops the study.

What are my other choices if I do not take part in this study?

This is not a treatment study. Because of this, your only option is not to take part in this study. There is no known cure for mild cognitive impairment to date.

Is there any way that being in this study could be bad for me?

There may be risks if you take part in this research. The study doctor and study team will monitor you to see if you are experiencing any harm related to this research. Inform the study team as soon as possible if you experience any pain or discomfort.

The general risks that are involved in this study are related to moderate-intensity exercise. Specifically, moderate-intensity exercise may cause muscle soreness, dizziness, or shortness of breath. In rare instances, exercise tests may cause chest pain, tightness, or a change in vital signs (heart rate and blood pressure). For this reason, you will not be able to participate in this study if you have an unstable or uncontrolled medical conditions (e.g., recent serious health incidents related to the heart (cardio) and metabolism (metabolic), such as heart attacks, strokes, and heart failure within the past 6 months or uncontrolled diabetes). During the study, there will be lab members with experience in exercise and fitness training available during the in-person exercise sessions if you would like to talk to them about

how you are feeling. You are also welcome to contact the Primary Investigator for this study, Dr. Azizi Seixas, at 305-243-3797 for questions about your health.

If you don't feel well after completing the in-person exercising sessions, please call your primary physician or medical professional.

We will collect information about you, but we will not link the information to your name, so the risk to your privacy is minimal.

There may also be mild discomfort of wearing devices, but no more so than a normal headband or wristband.

The obtainment of a weight measurement as part of the visit may be upsetting or uncomfortable for you. You may also feel mild discomfort when having your blood drawn by Quest Diagnostics. Drawing blood may cause brief pain from the needle stick, bruising or swelling at the site. Rarely, people faint during a blood draw or develop an infection.

Some of the questions the researchers ask you may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you can skip it and go to the next question.

What if new information becomes available?

We will tell you if we have any new information that may affect your willingness to stay in the study.

Will being in this study help me in any way?

You may benefit from being in the study by experiencing better sleep from using the headband, if applicable, and/or better fitness levels as a result of the exercise regimen, if applicable. Furthermore, your participation in the study may help other people in the future by helping us learn more about how exercise and sleep can affect cognitive, brain, cardiovascular, and metabolic health. However, it should be noted that this study is not a substitute for your regular medical care. You should continue to see your regular medical providers.

Will being in this study cost me anything?

There will be no cost to you for the procedures in the study that are done for research purposes only and are not part of your regular care. For all in-person visits, if you drive your own car on-site to attend the

visit, your parking fees will be paid for by the study. If you instead choose to arrive by the Metro, you will be provided with complementary Metro passes to pay for your travel to and from the study site.

Will I be paid or receive anything for being in this study?

You will be compensated a total of $100 if you complete the following: $50 for completing the baseline surveys, assessment, brief exercise test (if applicable), and blood collection at beginning of the study and $50 for completing all of the study at week 8.

We may ask you for your social security number for payment purposes. We will not use it for any other purpose without your permission.

If you receive $600 or more during a calendar year from the University for taking part in this research, you may receive an IRS 1099 form for tax purposes. Reimbursements for travel and other expenses are not included in this amount.

After you enter the study, the study team will give you a Greenphire ClinCard. This is a debit card that you will use while you are in this study. The study team will show you how to use the card. As you progress through the study, they will load funds on the card according to the payment schedule. Greenphire is the company providing the card. Greenphire requires the team to enter your name, address, and birth date on a website. If you want to receive messages about the study, the study team can also include your cellphone number and/or your email address. Greenphire will use this information only for payment and messaging purposes. Greenphire will not give your information to another company or link it to any of your study data.

What happens if I am injured or get sick because of this study?

Although risks are unlikely, if you are injured, treatment will be available in most cases. If you have insurance, your insurance company may or may not pay these costs. If you do not have insurance, or if your insurance company refuses to pay, you will need to pay. Funds to compensate you for pain, expenses, lost wages, and other damages caused by the injury are not available. This policy does not prevent you from trying to obtain compensation through the legal system.

Permission to Take Part in a Human Research Study

Our study MD will review all test results. You may be asked to follow-up with your primary care physician if the doctor notices (a) clinically significant result(s).

What happens to the information collected for the research?

We will do our best to protect your personal information (data). Data includes data from this research study and from your medical records. We have strict rules to protect your data.

We will limit access to people who have a need to review your data. We will also limit who has access to your name, address, phone number, and other data that can identify you. The study doctor and his/her collaborators will consider your data confidential to the full extent permitted by laws and regulations.

Data will be stored on protected computers at the University of Miami offices. De-identified data (data that cannot be tied to you) will be stored on each of the device companies' platforms and will be securely communicated and stored.

Clinical monitoring guidelines will be in place. Our study physician, a medical doctor, will monitor participants who may experience medical problems while enrolled in the study. Participants will be encouraged to seek treatment from their primary healthcare providers while in the study. Clinical site monitoring is conducted to ensure that the rights and well-being of human subjects are protected, that the reported trial data are accurate, complete, and verifiable, and that the conduct of the trial is in compliance with the currently approved protocol/amendment(s), Good Clinical Practices, and applicable regulatory requirement(s).

We cannot promise complete confidentiality. Some groups may have to inspect and copy your data, such as the Institutional Review Board and other University of Miami representatives who are responsible for managing and overseeing the study. Some data will be processed and stored by external companies, including FitBit, Elemind headband, LYS, and Quest Diagnostics.

If you are assigned to an intervention that involves exercise, in order to collect your blood for analysis, we will ask you to attend an appointment at Quest Diagnostics 1-7 days before the exercise intervention and 1-2 days after the last exercise intervention. Quest Diagnostics will request your name, mailing address, and date of birth. Your results can be viewed via a secure email from the study team. However,

please note that these test results are not intended to diagnose or treat any health conditions. By consenting to this study, you are also consenting to share your Quest results with the study team.

We will remove identifiers from the data we collect about you. After we remove all the identifiers, we will place a code on the data. We will link the code to your identity and keep the link in a location separate from your study data. We will keep your study data on encrypted computers.

We may publish and present what we learn from this study, but none of this information will identify you directly.

The following is a list of people who may access your records:

- Members of the research team for this study
- People in departments or on committees responsible for overseeing the research
- People who do tasks for the study, such as scheduling tests, performing procedures, and dealing with billing.
- The U.S. Office for Human Research Protections
- Companies or groups performing services for the study, such as Quest Diagnostics, FitBit, Elemind, and LYS Technologies. They will only access the data collected from their respective device or service.
- The U.S. Food and Drug Administration (FDA)
- Regulatory Authorities from other countries

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Federal law provides more protections for your medical records and related health information. The second part of this consent form, the University of Miami HIPAA Authorization for Research, describes these safeguards.

Permission to Take Part in a Human Research Study

May we contact you by email?

We are requesting your email address so we can communicate with you. Email is generally not a secure way to communicate about your health, as there are many ways for unauthorized users to access email. For this reason, we will not send sensitive, detailed personal information by email. You should not send this type of information either. You also should not use email to convey information of an urgent nature. If you need to talk to someone immediately, please contact Dr. Azizi Seixas at (972) 849-0862. You do not have to provide your email address to participate in this study. Please initial one of the lines below.

_____ Yes, you may use email to contact me for this study. My email address is: _____

_____ No, I do not want to be contacted by email.

PARTICIPANT'S STATEMENT/SIGNATURE

You will receive a signed and dated copy of this consent form if you agree to take part in this study and sign the form.

- *I have read this form and a member of the study team explained this research study to me.*
- *I had a chance to ask questions, and a research team member answered my questions.*
- *The research team told me whom to contact if I have more questions.*
- *I agree to be in the research study described above.*

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent

Permission to Take Part in a Human Research Study

ADDENDUM 1: UNIVERSITY OF MIAMI

RESEARCH AUTHORIZATION

What is the purpose of this part of the form?

State and federal privacy laws protect the use and disclosure of your Protected Health Information "PHI". Under these laws, your health care providers generally cannot disclose your health information for the research listed above unless you give your permission. You will use this form to give your permission. By signing this form, you authorize the University of Miami, the Principal Investigator and his/her/their/its collaborators and staff to obtain, use, and disclose your health information, as described below. We call these people and institutions "Providers" in this form.

What Protected Health Information will be used or shared?

You are authorizing the use and sharing of all the information collected or created during this research as described in the first part of this document, including information in your medical records that is relevant to this research study. Information that may be relevant includes:

- Your past medical history
- All other medical information relating to your participation in the study listed at the top of this document

Who may receive my Protected Health Information?

The Providers may use and share your health information with:

- The Principal Investigator and his/her/their research staff
- Representatives of government agencies that have oversight of the study or who the law permits to access the information, such as the U.S. Food and Drug Administration, the Department of Health and Human Services, and the Florida Department of Health
- Groups that collaborate and sponsor research (Cooperative Groups)
- Institutional Review Boards (groups of people who oversee research)
- Other persons who watch over the safety, effectiveness, and conduct of research

Permission to Take Part in a Human Research Study

- The Sponsor of the research, its agents, monitors, and contractors
- Other participating researchers; and
- Independent data and safety monitoring boards

Authorized staff, such as doctors and nurses who are taking care of you but are not involved in this research, may be aware that you are participating in a research study and may have access to research information about you. If the study is related to your medical care, we may include the study-related information in your permanent hospital, clinic, or physician's office records.

Why will my Protected Health Information be used and disclosed?

- Researchers (those individuals in charge of the study) and research team members will use your information to conduct the research study described in this informed consent document and other activities related to the research, such as evaluating the safety of the study.
- The research sponsor, its authorized representatives, business partners, clinical research organizations and affiliates will use your information for the purposes described in the first part of this document and for other activities related to the research. These activities include assessing the safety or effectiveness of the drug, device or treatment that we are studying, improving designs of future studies or obtaining approval for new drugs, devices or health care products.
- The University of Miami's clinical trial organizations will use your information to review and support clinical trials at the University.
- Other University of Miami offices involved in regulatory compliance, including the Institutional Review Board (IRB), Offices of General Counsel, and Compliance, may use your information to ensure the study teams are performing the research correctly.
- U.S. government agencies, such as the Food and Drug Administration and the Office for Human Research Protections, government agencies from other countries, and others who must use your information to review or oversee this research and to review the data so they can decide whether to approve a new drug, device or other health care product for marketing.

What other information should I know?

Permission to Take Part in a Human Research Study

1. Once the study team has disclosed your information to a third party, the federal privacy law may no longer protect the information from further disclosure.
2. You do not have to sign this Authorization, but if you do not sign it, you may not participate in the research and receive the research treatment; however, your decision will not affect your right to other medical care.
3. You may change your mind and revoke (take back) this Authorization at any time and for any reason. To revoke this Authorization, you must write to the study doctor, Dr. Alberto Ramos, at 900 Northwest 17th Street, Floor 5, Miami, FL 33136 or to the Human Subjects Research Office at 1531 Brescia Avenue, Casa Bacardi, Coral Gables, Fl. 33146.
4. If you revoke this Authorization, you will not be able to continue taking part in the research.
5. While the research is in progress, you cannot access and read your health information that is created or collected by the institutions and people listed above. After the research is finished, you may see your health information.
6. This Authorization does not have an expiration date. There is no set date at which your information will be destroyed or no longer used because the research will need to analyze the information for many years, and it is not possible to know when they will complete the analysis.
7. A study team member will give you a copy of this authorization after you sign it.

_____ _____

Signature of participant Date

_____

Printed name of participant