PRogram to Improve Stress-levels and Enhance Memory

NCT05845918

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STUDY00004811

You Are Being Asked to Be in a Research Study

Concise Presentation of Key Concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 45 people who are being studied at Emory.

Why is this study being done?

This study is being done to answer the question "Is a multi-component lifestyle intervention program effective in improving chronic stress, heart health, and brain health among older adults with mild cognitive impairment?" You are being asked to be in this research study because you have been identified as someone who may be at risk for developing Alzheimer's Disease and other dementias due to having a diagnosis of mild cognitive impairment.

Therefore, the goal of this study is to see if a multi-component lifestyle intervention program is effective in improving heart health, brain health, and stress levels among older adults with mild cognitive impairment in order to reduce the risk of developing Alzheimer's Disease and other dementias as well as other related diseases, such as obesity, diabetes, or high blood pressure.

Do you have to be in the study?

It is your choice to join this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you choose, take time to learn about the study.

What do you have to do if you choose to join this study?

If you qualify and choose to join the study, you will be asked to participate in PRISEM Remote, which is an online lifestyle intervention program. You will participate in this study for one year (3 study visits).

<u>The researchers will ask you to do the following</u>:

- Participate in online group sessions that focus on improving health education, nutrition, physical activity, cognitive health, stress levels, and overall well-being
- Fill out surveys and/or participate in interviews
- Complete clinical testing to assess your heart health
- Complete various tests to assess your brain functioning

All of these procedures will be paid for by the study.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question. Additionally, the study results may be used to help other patients in the future. You may also benefit from this study by learning more about your health and having free heart health and physical assessments.

What are the risks or discomforts you should know about before deciding to participate?

The study will take time. The procedure that is being tested may not work any better than regular care and may even cause harm. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious. Risks for this study include:

- risks of the procedure, some of which include:
    - discomfort
    - anxiety
    - fatigue
- loss of privacy
- breach of confidentiality

You can find a full list of expected risks, their frequency and severity in the section titled "*What are the possible risks and discomforts?*"

Alternatives to Joining This Study

Since this is not a treatment study, the alternative is not to participate.

Costs

There will be no cost to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

There is more information in the "*Costs*" section further below.

What Should You Do Next?

Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions such as how much time you will have to spend on the study, any words you do not understand and more details about study procedures. Make sure you understand which parts of the study are research and which are standard care that you would have even if you did not join the study. Take time to think about this and talk about it with your family and friends.

Emory University
Consent to be a Research Subject / HIPAA Authorization

Title: PRogram to Improve Stress-levels and Enhance Memory (PRISEM)- PRISEM Remote

IRB #: STUDY00004811

Principal Investigator: [redacted], MD, PhD

Emory University School of Medicine

Department of Preventative and Family Medicine

Sponsor: National Institute of Aging

Introduction

You are being asked to be in a medical research study. This form tells you what you need to think about before you choose if you want to join the study. It is your choice. If you choose to join, you can change

your mind later and leave the study. Your choice will not cause you to lose any medical benefits. If you choose not to join this study, your doctor will still treat you.

Before you decide:

- Read this form or have it read to you
- Listen to the study doctor or study staff explain the study to you
- Ask questions about anything that is not clear

You will get a copy of this form. Take your time to think about joining the study. You may wish to discuss it with family or friends. Do not sign this form if you still have questions or something does not make sense to you. By signing this form, you will not give up any legal rights.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

What is the purpose of this study?

The purpose of this study is to improve prevention and treatment intervention programs that are feasible and designed for patients with mild cognitive impairment and have real potential to reduce negative health outcomes associated with mild cognitive impairment.

You have been approached to participate in this study because you have been identified as someone who might be at risk for developing Alzheimer's Disease and other dementias due to having a diagnosis of mild cognitive impairment, which is a transitional state between normal aging and dementia.

Several studies have shown that a greater percentage of people with mild cognitive impairment will develop dementia within five years. These health effects are likely to be even worse in elderly or minority populations, like African Americans, due to chronic stress (such as perceived discrimination and daily environmental stress) and among those who participate in unhealthy behaviors, such as smoking, improper diet, and physical inactivity.

Therefore, this study will focus on determining if a remote multi-component lifestyle intervention that addresses nutrition, physical activity, stress, and other health behaviors is successful in improving heart health, brain health, and stress levels in older adults with mild cognitive impairment.

What will you be asked to do?

You will be asked to participate in PRISEM Remote, which is a remote-based lifestyle intervention program. You will participate in this study for one year, which includes 3 study visits.

The researchers will ask you to do the following:

- Participate in **online group sessions** that focus on health education, nutrition, physical activity, cognitive health, ways to cope with stress, and improving overall well-being for the **duration of 6 months**. You are strongly encouraged to invite your caretaker/household support person to attend these sessions with you throughout the entire program.
- Attend study visits
    - The 1st visit will be completed at the beginning of the study (baseline).

- The 2nd visit will be completed after 6 months of being in the study, which will be the end of the study.
- The 3rd visit will be completed after one year of being in the study, which will be the follow-up period after completing the study intervention.

During each study visit, you will be asked to complete the following:

1. Fill out surveys and/or participate in interviews that ask questions about your mental health, stress, and lifestyle habits, such as your level of physical activity and eating habits.
2. Complete clinical testing to assess your heart health, which includes heart rate variability and pulse wave analysis testing. (Disclaimer: These tests will only be completed during the 1st and 2nd study visits.)
    a. **Heart rate variability measures the changes in time between the beats of your heart**. This is a non-invasive test and a chest strap monitor will be placed on you. This monitor will not require any skin preparation, patches, or gels.
    b. **Pulse wave analysis measures the stiffness of the main artery in your heart, which is your aorta**. This is a non-invasive test and a blood pressure cuff will be put on your thigh and a pressure probe will be applied to your neck to complete this test.
3. Complete testing to assess your brain functioning
    a. You will be asked to complete tasks that stimulate your brain's response to different stimuli, such as matching images to a target image and determining the direction of arrows.

To track your physical activity improvements during this study, you will be asked to wear a **non-invasive activity monitor** for **1 week** at the **beginning** of the study intervention and at the end of the study intervention. You will also be asked to participate in a focus group interview after completing the lifestyle intervention program, which will be at the one year period of the study. During the focus group interview, you and other intervention participants will be asked to provide your experiences, attitudes, and further needs concerning the study.

Who owns your study data and samples?

If you join this study, you will be donating your samples and data. You will not be paid if your samples or data are used to make a new product. If you leave the study, the data and samples that were already collected may still be used for this study. However, you may request to destroy your samples and data or discontinue its use.

What are the possible risks and discomforts?

We will take the necessary precautions to ensure the research data is not connected to you in any way, but there is still a possibility of risk of loss of confidential data collected for this study. You may also experience a loss of privacy due to being asked to provide personal information about your health.

There may be side effects from the study procedures that are not known at this time. However, this study will utilize widely used procedures and highly qualified healthcare professionals and staff will carry out study procedures to minimize risks.

The most common risks and discomforts expected in this study are:

- anxiety, frustration, and overall fatigue due to completing the mental health assessments
- mild discomfort and tingling due to the use of a blood pressure cuff and pressure probe to assess heart health

The probability of any of the risks listed above is less than 1%.

Researchers may learn something new during the study that may affect your choice to be in the study. If this happens, they will tell you about it. Then you can choose if you want to stay in this study. You may be asked to sign a new form if you choose to stay in the study.

Will you benefit from the study?

You may benefit from this study by learning more about your health and having free heart and physical assessments. You may also expect to receive a significant benefit related to improvement in stress and potentially other lifestyle habits, such as physical activity and diet. This in return could reduce the negative health effects of other related diseases, such as obesity, diabetes, or high blood pressure.

Will you be paid for your time and effort?

You will get a $200 gift card upon completing the 6-month follow-up visit, and a $50 gift card for the study visit at one year for your participation and time in the study. Therefore, you will receive a total of $250 if you attend every study visit. Following each study session surveys will be issued for participant feedback; you will be compensated an additional $5 for each one of these surveys you complete.

What are your other options?

If you choose not to join this study, you can get care outside of this study. Emory Healthcare is a large healthcare system, and you can receive standard care at any of their health facilities located in Atlanta and the metropolitan Atlanta area, such as Emory Brain Health Center or Emory at Dunwoody. The study doctor will discuss these with you. You do not have to be in this study to be treated for your condition.

How will your private information be protected?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research

information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases
- Giving law officials information about abuse of a child, elderly person or disabled person
- Giving out information to prevent harm to you or others
- Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

We will store all the data and specimens that you provide using a code. We need this code so that we can keep track of your data over time. This code will not include information that can identify you (identifiers). Specifically, it will not include your name, initials, date of birth, or medical record number. We will keep a file that links this code to your identifiers in a secure location separate from the data.

We will not allow your name and any other fact that might point to you to appear when we present or publish the results of this study.

Your data and specimens may be useful for other research being done by investigators at Emory or elsewhere. We may share the data or specimens, linked by the study code, with other researchers at Emory, or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory. We will not share the link between the study code and your identity.

We may also place data in public databases accessible to researchers who agree to maintain data confidentiality, if we remove the study code and make sure the data are anonymized to a level that we believe that it is highly unlikely that anyone could identify you. Despite these measures, we cannot guarantee anonymity of your personal data.

Medical Record

If you have been an Emory patient before, then you already have an Emory medical record. If you have never been an Emory patient, you do not have one. An Emory medical record will be made for you if an Emory Atlanta provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory medical record you have now or any time during the study.

In Case of Injury

If you believe you have become ill or injured from this research, you should contact [redacted] at telephone number [redacted]. You should also let any healthcare provider who treats you know that you are in a research study.

If you get ill or injured from being in the study, Emory will help you to get medical treatment. Neither Emory nor the sponsor have set aside money to pay for this medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

For Emory, the only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory employee. "Negligence" is the failure to follow a standard duty of care. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence.

Costs

There will be no cost to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

For your safety, however, you should consider the study doctor's advice about how to go off the study treatment. If you leave the study before the last planned study visit, the researchers may ask you to complete some of the final steps such as lab work or imaging as applicable.

The researchers also have the right to take you out of the study without your consent for any reason. They may do this if they believe it is in your best interest or if you do not agree to changes that may be made in the study

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. As part of this study, we will get your protected health information (PHI) from health care entities who are covered by the Health Insurance Portability and Accountability Act and regulations (HIPAA). Because the health care entities are covered by HIPAA, we must have your authorization to get your PHI from them. However, once we get your PHI from the health care entities, it changes from PHI to individually identifiable health information (IIHI) and is no longer covered by HIPAA. We will put your IIHI in a separate research record that is not a part of your medical record. IIHI placed in the separate research record is not covered by HIPAA.

Purpose of this Authorization:

By signing this form, you give us permission to get your PHI from health care entities and to use and disclose your IIHI as described in this document. You do not have to sign this form. If you do not sign this form, then you may not participate in the research study.

No Provision of Treatment

There is no research-related treatment involved in this study. You may receive any non-research related treatment whether or not you sign this form.

IIHI that Will be Used/Disclosed:

The IIHI that we will use or disclosed for the research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures, and tests you have before and during the study.

- Laboratory test results

Purposes for Which Your IIHI Will be Used/Disclosed:

We will use and disclose your IIHI for the conduct and oversight of the research study. Once we have your IIHI we will keep it in a separate research record that will be used for the conduct of the study. If you leave the study, we may use your IIHI to determine your vital status or contact information.

Use and Disclosure of Your IIHI That is Required by Law:
We will use and disclose your IIHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults.

People Who will Use/Disclose Your IIHI:

The following people and groups will use and disclose your IIHI in connection with the research study:

- Emory may use and disclose your IIHI to get payment for conducting the study and to run normal business operations.
- The Principal Investigator and research staff will disclose your IIHI with other people and groups to help conduct the study or to provide oversight for the study. This includes sharing your IIHI with people and groups at other sites who are helping conduct the study.
- National Institute of Aging is the Sponsor of the study. The Sponsor may use and disclose your IIHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your IIHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.

The following people and groups will use your IIHI to make sure the research is done correctly and safely:

- Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration. These include the Emory IRB, the Emory University and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
- Government agencies that regulate the research including: Office for Human Research Protections
- Public health agencies
- Research monitors and reviewer
- Accreditation agencies

Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your IIHI may be disclosed to the new institution and the institution's oversight offices.

Expiration of Your Authorization

Your HIPAA authorization will expire once no more PHI is needed from your medical records for this study.

Revoking Your Authorization

If you sign this form, at any time later you may revoke (take back) your permission to use your IIHI. If you want to do this, you must contact the study team at: [redacted] by email at [redacted] or telephone at [redacted].

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the IIHI already collected as described in this Authorization. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy

Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. HIPAA does not apply to the research records for this study because the study does not include treatment that is billed to insurers or government benefit programs. Your information collected for this study may be disclosed to others without your permission. The researchers and people and companies working on this study are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

To maintain the integrity of this research study, you generally will not have access to your IIHI related to this research until the study is complete. When the study ends, and at your request, you generally will only have access to your IIHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. You will not have a right of access to IIHI kept in a separate research record used only for research purposes. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your IIHI. Information without identifiers is not subject to HIPAA and may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

If you have questions about the study procedures, appointments, research-related injuries or bad reactions, or other questions or concerns about the research or your part in it, contact the principal investigator, [redacted] at [redacted].

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your rights as a research participant, or if you have complaints about the research or an issue you would rather discuss with someone outside the research team, contact the Emory Institutional Review Board at [redacted] or [redacted] or [redacted].

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at

[redacted]

Consent and Authorization

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TO BE FILLED OUT BY SUBJECT ONLY

Print your name, **sign**, and **date** below if you choose to be in this research study. You will not give up any of your legal rights by signing this form. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____

Signature of Subject (18 or older and able to consent) **Date** **Time**

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TO BE FILLED OUT BY STUDY TEAM ONLY

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Name of Person Conducting Informed Consent Discussion

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Signature of Person Conducting Informed Consent Discussion **Date** **Time**