Title:IMOVE: A randomized, controlled trial of Improvisational MOVEment for people with memory loss and their caregivers
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Wake Forest®
School of Medicine

Section of Gerontology and Geriatric Medicine

COGNITIVE ASSESSMENT for the IMOVE STUDY

Informed Consent Form to Participate in Cognitive Assessment
Christina Hugenschmidt, PhD, Principal Investigator

SUMMARY

You are invited to participate in a screening for the IMOVE study for the purpose of determining your eligibility. You are invited to complete this visit because you have expressed interest in participating in the IMOVE study, but you do not have a recent assessment of your memory that can be used to determine your eligibility. Your participation in this visit will involve up to 3 hours of your time.

Participation in this screening will involve testing of your memory and thinking skills, a review of your medical history and current medications, and neurological and physical exams by one of our clinical staff. All research studies involve some risks. A risk to this visit that you should be aware of is the potential for emotional discomfort resulting from the memory testing. There is no expectation that you will benefit directly from this visit.

Your participation in this screening is voluntary. You do not have to participate if you do not want to. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this screening visit. Please read this description carefully. You can ask any questions if you need help deciding whether to continue. The person in charge of this screening visit is Christina Hugenschmidt, PhD. If you have questions, suggestions, or concerns regarding this visit, her contact information is: [redacted] or [redacted].

If you have any questions, suggestions, or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

INTRODUCTION

You are invited to complete a screening visit for the IMOVE Study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this visit because you have expressed interest in participating in the IMOVE study, but you do not have a recent assessment of your memory that can be used to determine your eligibility. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss these assessments with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this screening is to determine whether or not you are eligible to participate in the IMOVE study. The IMOVE study is for people experiencing memory loss. You have indicated that you have concerns about your memory, but either you have not had your memory formally tested, or that testing was not done recently enough to meet our study criteria.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Because the purpose of this screening visit is to participate in the IMOVE study, there is not a target number for people to be screened. We anticipate up to 150 people will take part in this screening visit. Screening visits will end once enrollment for the IMOVE study is filled and that may be less than 150 people.

WHAT IS INVOLVED IN THE STUDY?

You will be asked to complete one visit with your study partner at the Sticht Center for Healthy Aging and Alzheimer's Prevention. Your partner can be a spouse, other family member, or friend. During your visit, we will complete the following:

- Review your medical history and medications
- Physical and neurological exam
- Measurement of heart rate, blood pressure, height, and weight
- Tests of memory and thinking, which include answering questions about your feelings
- We will ask your study partner questions about your memory, daily activities and behavior

If you have previously completed full testing of your memory, but that testing was more than one year ago, we will begin with a single cognitive test. Depending on the result of that test, you may be deemed eligible or ineligible to continue in IMOVE, or you may be asked to complete the remainder of the visit in order to determine your eligibility for the study

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As part of this assessment, you will be audiotaped using a digital recorder while performing some of the cognitive tests. This is to assure accuracy as we record your answers. You will not be able to

inspect, review, or approve the content of the audiotapes. You may request the recording be stopped at any time, and you can withdraw your consent to use the audiotape before any information is transcribed. Recordings will not include identifying information and will be stored indefinitely.

We can send copies of your test results to your personal physician if you would like. If you do not wish to have any of your medical information sent to your physician, you can still participate in this research study. Do you request that we send important medical findings from your study tests/exams to your personal physician?

[ ] Yes [ ] No _____ Initials

WILL THIS RESEARCH DATA BE SHARED?

Data from this research visit will be shared with the Wake Forest Alzheimer's Disease Research Center (ADRC) and with researchers from the National Alzheimer's Coordinating Center (NACC) at University of Washington. All links with your identity will be removed from the data before it is shared Data sharing is important for further translation of research results into knowledge, products, and procedures to improve human health. Sharing data with these Alzheimer's Centers is an important way to contribute to national research about the development and progression of Alzheimer's disease and related dementias. We can share your identifying information at your request, for instance, if you are interested in participating in another study through the Wake Forest ADRC and you wish us to share the information.

This visit is considered to be part of the IMOVE study.

HOW LONG WILL I BE IN THE STUDY?

The screening visit will last approximately 3 hours. If you qualify for the IMOVE study, your participation will be extended up to 9 months.

You can stop participating at any time. If you decide to stop participating in the assessments, we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

WHAT ARE THE RISKS OF THE STUDY?

Completing this assessment involves some risk to you. You should discuss these risks with the study staff. The risk of harm or discomfort that may happen as a result of taking part in this research visit is not expected to be more than in daily life or from routine physical or psychological examinations or tests. Risks and side effects related to the procedures we are performing include:

- Stress and mood checklists. You will be asked to complete several questionnaires about stress, mood, and changes that may be happening in your life due to the diagnosis or feeling of memory loss. Sometimes talking about these changes can lead people to feel uncomfortable or distressed. Please talk with study staff and let them know if you experience distress.
- Cognitive tests. You will be asked to complete some tests of thinking and memory. The tests may be given orally or written on paper. Careful instructions will be given before the testing.

There is a risk that some people may feel frustrated or worried when taking these tests. Please talk with study staff and let them know if you experience distress.

- Body measurements. An automated sphygmomanometer will be used for blood pressure and heart rate. A recently calibrated scale and stadiometer will be used to determine your weight and height. The results from body measurements may also be distressing. Again, please inform the study staff if you experience distress.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other risks that we cannot predict. You should tell the research staff about all the medications, vitamins, and supplements you take and any medical conditions you have that may contribute to the risk of this screening visit for you.

Taking part in this research visit may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You are not expected to receive any direct benefit from taking part in this research visit. We hope the information learned from this study will benefit other people in the future.

WHAT OTHER CHOICES ARE THERE?

This is not a treatment study. Your alternative is to not participate in this study.

WHAT ARE THE COSTS?

All costs, including any procedures related directly to the study visit, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study visit may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

To help us protect your privacy, the National Institutes of Health provides a Certificate of Confidentiality for research funded by their agency. This Certificate applies to both data collected for the IMOVE Study and to the data shared with the Wake Forest Alzheimer's Disease Research Center (ADRC) and the National Alzheimer's Coordinating Center NACC). The Certificate of Confidentiality is needed because sensitive information will be collected during the course of these procedures. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally-funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research.

If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. The Certificate of Confidentiality does not prevent the investigator from notifying state or local authorities of North Carolina if he/she obtains evidence of abuse or if you threaten violence to yourself or others.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study visit.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by a grant awarded by the National Center for Complementary and Integrative Health (NCCIH), one of the National Institutes of Health. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT ABOUT MY HEALTH INFORMATION?

In this research assessment, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research includes: cognitive testing; checklists of stress and mood; information about your current medications and health diagnoses; demographic information; and vital signs.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after this study visit. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Monitors, auditors, IRB, or other regulatory agencies will be granted direct access to your original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study visit that is maintained in the research records will be kept for an indeterminate period of time. This authorization does not expire.

You can tell [redacted] that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record.

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

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study visit is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Christina Hugenschmidt, PhD at [redacted] normal business hours and at [redacted] after hours and ask for the geriatrician on call. Please identify yourself as an IMOVE study participant.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, you should contact the Chairman of the IRB at [redacted]

You will be given a signed copy of this consent form.

SIGNATURES

I agree to take part in this study visit. I authorize the use and disclosure of my health information as

WFU School of Medicine
Institutional Review Board
IRB Number:IRB00042460
Meeting Date Approved 1/4/2021
Version Valid Until: 1/3/2022

described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm

Study Partner Name (Print): _____

Relationship to the Subject:_____

Study Partner Signature: _____ Date:_____Time:_____am pm

Legally Authorized Representative Name (Print):_____

The above named Legally Authorized Representative has legal authority to act for the research subject based upon (specify health care power of attorney, spouse, parent, etc.)

Relationship to the Subject:_____

Legal Representative Signature: _____Date:_____Time:_____am pm

Christina Hugenschmidt, PhD, Principal Investigator

As a study partner, you have important tasks that need to be carried out in order for the study visit to be conducted in the safest and best manner possible. These responsibilities include:

- You must accompany the participant to the screening visit.
- You are an important source of information about the participant. You will be asked questions about the participant's health status, and memory and thinking abilities in order to find out whether there have been any changes
- You will be asked about your own medical history and medications. This will help avoid repeating this procedure with your partner should you be enrolled as a pair in the IMOVE study.

Your responses about your partner will be shared with the National Alzheimer's Coordinating Center, but your personal information will only be used for IMOVE study data if you are ultimately enrolled in the full study.

I agree to take part in this research study visit. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Study Partner Name(printed):_____

Study Partner signature: _____

Date: _____ Time: _____am/pm

Person Obtaining Consent(printed):_____

Person Obtaining Consent signature: _____

Date: _____ Time: _____am/pm