Aging Well through Interactions and Scientific Education - Action Plan (AgeWISE-AP)

NCT06006962

Version Date: 2023 June 12

Combined Informed Consent and HIPAA Authorization Template

VA Central IRB
VA Institutional Review Board for Multisite Studies

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by VA Rehabilitation Research & Development Service. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn about the effects of AgeWISE-Action Plan (AgeWISE-AP), a 20-week program designed to provide education and individualized planning with a goal of improving brain health. If you agree to take part in the study, you will be randomly assigned to the AgeWISE-Action Plan program or a treatment as usual control group. If you are assigned to the treatment as usual control group, you can choose to take part in the AgeWISE-AP group after your participation in the study. If you are assigned to the AgeWISE-AP, you will participate in a 12-week class, designed to teach you about the aging brain, lifestyle factors related to successful brain aging, and tips and tricks to manage everyday problems with memory and thinking. You will also meet with a brain health interventionist for 8 individualized sessions to create and work on specific goals intended to improve your brain health.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

By participating in this research study, you will be helping the research team understand the effect of AgeWISE-AP intervention on brain health. Understanding how AgeWISE-AP is working will help improve care for future Veterans. No matter which group you are enrolled in, you will continue to receive your usual clinic-based care.

For a complete description of benefits, refer to the Detailed Information section of this consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You may not want to commit to 20 weeks of the intervention. You may not want to answer questions about your health. You may not want to be in a group setting.

For a complete description of risks, refer to the Detailed Consent.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you chose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Maureen K. O'Connor, PsyD at the Bedford VA Medical Center. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is [redacted].

Participant Name: _____ IRBNet ID: 1753578

Title of Study: Aging Well through Interactions and Scientific Education - Action Plan (AgeWISE-AP)

Principal Investigator: Maureen K. O'Connor, PsyD VA Facility: 518 – VA Bedford Healthcare System

Principal Investigator for Multisite Study: Maureen K. O'Connor, PsyD

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to learn about the effects of AgeWISE-Action Plan (AgeWISE-AP), a 20-week program designed to provide education and individualized planning with a goal of improving brain health.

HOW LONG WILL I BE IN THE STUDY?

Your individual participation in the project will take about 1 year. You will be actively involved in the intervention for 6 months, and there will follow-up interviews conducted 3 months and 6 months after intervention completion. We expect to enroll 128 Veterans over 4 years.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

- Screening
    - You will first be asked to complete a brief questionnaire, which would ask about your age, medical and psychiatric conditions, usage of alcohol and other substances, and your memory will be assessed. This questionnaire would take about 15 minutes to complete. You are free to skip any questions you would prefer not to answer, but doing so may compromise your eligibility to enroll in this study. This first portion of the study will establish your eligibility for the study. If you do not meet eligibility, then your participation in the study will end here.
- Baseline
    - If eligible, you will complete a baseline interview, which will last about 1.5 hours. The interviewer will ask questions about your health, lifestyle factors, psychological wellbeing, and self-reported memory.
- Randomization
    - After the baseline interview, you will be randomly assigned to receive the intervention or be part of the treatment as usual control group. There is essentially a 50/50 chance (like the flip of a coin) that you will be assigned to the intervention.
- Treatment
    - Intervention

        - If you are assigned to the AgeWISE-AP, you will participate in a 12-week class, designed to teach you about the aging brain, lifestyle factors related to successful brain aging, and tips and tricks to manage everyday problems with memory and thinking. You will also meet with a brain health interventionist for 8 individualized sessions to create and work on specific goals intended to improve your brain health.
    - Control Group
        - If you are assigned to the treatment as usual control group, you will continue to receive your usual clinic-based care.
- Follow-Ups
    - Additional interviews will be completed at 6 months, 9 months, and 1 year, each lasting about 1.5 hours.
- Optional
    - Brain Imaging (MRI)
        - Occurs at baseline and 1 year.

      Please check the box below if you are interested in receiving brain imaging (MRI)

      ☐ I am interested in receiving brain imaging (MRI)

If you are assigned to the treatment as usual control group, you will have the option to complete AgeWISE-AP at the conclusion of your participation in the study.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

AgeWISE-AP and control group participants will be expected to complete all 4 interviews.

Only participants in AgeWISE-AP will be expected to attend a 12-week class held once a week, complete some homework between class, and attend 8 individual sessions with a brain health interventionist.

Participants interested in brain imaging (MRI) may be given the option to do so at VA Boston in Jamaica Plain; those who decide to do so will be expected to complete brain imaging at the beginning of the study and after 1 year.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any study has possible risks and discomforts. You may be asked questions that you are unable to answer, and this may make you uncomfortable. You do not have to answer any questions that you don't want to.

You may be asked to set health related goals and if you have trouble meeting those goals you may feel disappointed. Study staff will be monitoring your goal progress and emotions around progress to help reduce any feelings related to lack of progress.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

There is also a small risk that a breach of confidentiality may occur. To minimize this risk, we have detailed our practices to protect the data we collect in the section below titled "HOW WILL MY PRIVATE INFORMATION BE PROTECTED?"

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. However, possible benefits may include:

- Increasing your knowledge about brain aging
- Increasing your feelings of control over brain aging
- Reducing anxiety about brain aging
- Improving personal health factors related to successful brain aging
- Learning memory tips and tricks to help you perform better in daily life
- Improving mood and well-being

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Taking part in this study will involve collecting private information about you. This information will be protected in the following ways:

- A participant code will be used for data to help protect your privacy. The code number will not be based on any information that could be used to identify you. The master list linking names to codes will be kept separately from the research data, in a secure and locked location.

- Data collected will be destroyed according to VA's Record Control Schedule, which is currently 6 years after research study is complete.
- Data collected will be stored in a locked cabinet in a locked room in the VA and/or will be stored on a password secure and encrypted VA computer.
- Access to collected data will be limited to the research team, including the Principal Investigator, study coordinator, and personnel responsible for the support or oversight of the study.

There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Institutional Review Board (IRB), our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you.

Information about your collected as part of this research, even if identifiers are removed, will not be used or distributed for future research studies.

Health Insurance Portability and Accountability Act (HIPAA)

There are rules to protect your private information. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. The study team may also collect other information including your name, address, date of birth, and information from your medical records.

The research team may also need to disclose the information to others as part of the study progress. Others may include the following: Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), the Government Accountability Office (GAO), the VA Institutional Review Board, and the local VA medical facility Human Research Protections Program (HRPP).

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

While this study is being conducted you will not have access to your research related health records.

This will not affect your VA healthcare, including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, Dr. Maureen K. O'Connor and her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment, or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

If you are eligible for the study and complete the study, you will be offered compensation for your time in the form of gift cards handed to you in-person immediately after the visits mentioned hereafter. You will be offered $50 after completing the intervention and subsequent interview. Further, you will be offered $75 for each of two follow-up interviews – 3 months and 6 months after completion of the intervention.

If you choose to participate in brain imaging, you will be offered $100 after completing the last imaging appointment 1 year after joining the study.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call the study coordinator, **Andrew,** at [redacted].

DO I HAVE TO TAKE PART IN THE STUDY?

Participation in this study is voluntary. Refusal to participate will involve no penalty or loss of rights to which you are otherwise entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled. Data already collected prior to withdrawal may be included in the research but no further data collection will be undertaken.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

This study is expected to end after you have completed all interviews and all information has been collected. This study may be stopped or your participation ended without your consent for the following reasons:

- The study team determines it is necessary for your health or safety.
- You have not followed study instructions.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you want to contact the primary research investigator, you can call Dr. Maureen K. O'Connor at the VA Bedford Healthcare System in Bedford, MA at [redacted]. If you have any questions, concerns, or complaints regarding your rights as a research subject at the Bedford VA, you may call the Administrative Officer for Research, Karen Smith, at [redacted].

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date: November 8, 2023

LSI Approval Date: NA

LSI Verification Date: NA

Participant Name: _____ IRBNet ID: 1753578

Title of Study: Aging Well through Interactions and Scientific Education - Action Plan (AgeWISE-AP)

Principal Investigator: Maureen K. O'Connor, PsyD VA Facility: 518 – VA Bedford Healthcare System

Principal Investigator for Multisite Study: Maureen K. O'Connor, PsyD

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms _____ has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

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PI/SC Approval Date: November 8, 2023

LSI Approval Date: NA

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