A Feasibility Study of Behavioral Activation in the Rehabilitation of Veterans With Post-TBI Depression

NCT04976621

December 27, 2023

Participant's Name: _____ Date: _____

Title of Study: ACTIVE: Activity Therapy to Increase Veteran Engagement

Principal Investigator's Name: Helene Moriarty, PhD, RN, FAAN

SUMMARY OF STUDY

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

We are asking you to choose whether or not to volunteer for a research study being funded by the VA Rehabilitation Research and Development (RR&D) Service. The study will assess an approach to improve mood and activity in persons with traumatic brain injury (TBI). This initial material is to give you key information to help you decide whether to participate. We have included detailed information about this study later in the document. Ask the research team questions. Taking part in this study is completely voluntary.

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

The purpose of this study is to learn whether the ACTIVE approach is acceptable and helpful in improving your mood and activity.

ACTIVE is a brief behavioral therapy that aims to improve mood and engagement in meaningful activities. It is widely used in patients with other medical conditions, but not yet with people with TBI.

By doing this study, we hope to learn if the ACTIVE approach improves mood, participation in meaningful activities, and quality of life in veterans with TBI. Your participation in this research will last about 3 months.

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

You might choose to volunteer for this study to help us see if the ACTIVE approach helps to improve your mood and increase activity that is meaningful to you. You might also participate to help us learn more about whether ACTIVE helps other veterans with TBI and mood problems. **For a complete description of benefits, please refer to** the Research Details section of this document.

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

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You might choose not to volunteer for this study because it takes some of your time and you may or may not receive any benefit. **For a complete description of risks, refer to the** Research Details section of this document.

You will randomly be assigned (like the flip of a coin) either to the group that receives the ACTIVE approach (in addition to your usual care) or to the group that receives their usual care alone. Thus, all participants will receive their usual care from the Corporal Michael J. Crescenz (CMC VAMC) Rehabilitation Medicine Service and other VA providers.

DO YOU HAVE TO TAKE PART IN THE STUDY?

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

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Helene Moriarty, PhD, RN, FAAN of the Corporal Michael J. Crescenz VA Medical Center (CMC VAMC). If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, her contact information is**:** 3900 Woodland Ave., Mail code 118, Philadelphia, PA 19104, [redacted] or Laraine Winter, PhD, the Project Manager and Co-Investigator, at the same address and phone number.

If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

RESEARCH DETAILS

WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

The purpose of this research study is to see if ACTIVE is acceptable and helpful to you and other veterans with TBI**.** We hope to learn whether ACTIVE is helpful in improving your mood and your quality of life. We also hope to learn if ACTIVE helps other veterans with TBI and depression. You are being invited to participate because you have mild to moderate TBI and you are feeling, blue, sad, or depressed. In addition, you are a patient at the Polytrauma Program in the Rehabilitation Service of the Corporal Michael J. Crescenz VA Medical Center (CMC VAMC).

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This ACTIVE approach is a type of Behavioral Activation (BA) treatment that has been shown to be effective in improving mood and wellbeing in people with other medical conditions. But, it has not been studied sufficiently in those with TBI. ACTIVE is a brief behavioral treatment that helps people define goals, create and carry plans to reach them, and engage in meaningful activities - especially those that are part of social roles and activities that TBI may disrupt. ACTIVE aims to help people engage in activities that improve their mood.

HOW LONG WILL I BE IN THE STUDY? HOW MANY PEOPLE WILL BE IN THE STUDY?

Your individual participation in this this study will take about three months. This research study is expected to take approximately 2 years.

We plan to enroll at least 40 veterans from CMC VAMC**.**

WHAT IS EXPECTED IF I TAKE PART IN THIS STUDY?

If you agree to take part in this study, the following will happen:

First Visit and Interview

At the first visit, we explain the study, answer your questions, and obtain your consent. If you consent to participate, we conduct the first interview. We will begin by asking you questions about your thinking, your mood, and your TBI to see if you qualify to continue in this study. If you can continue in the study, we will then ask you questions about your:

- background (such as age, education, race, and occupation)
- physical health (including health services you use)
- everyday functioning
- mood
- overall well-being
- activities in the community (e.g., in your family, work, school, neighborhood, social life with friends)

The first interview will take about 1-1/2 hours.

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Assignment to group

You will then be assigned to one of two groups:

- the group that will receive Treatment as Usual (TAU)
- the group that will receive ACTIVE (in addition to TAU)

This assignment is random (like the flip of a coin), and we cannot change your group assignment once it is made.

The Treatment as Usual group will continue to see and receive care from their VA Polytrauma team health care providers and other providers as usual at the VA.

ACTIVE Group

The ACTIVE intervention will be delivered in 6 sessions over 3 months by an Occupational Therapist (OT). During these sessions, you and the OT will focus on your goals, values, and activities that are meaningful to you. The OT will work with you to design strategies that help you engage in these activities. Each ACTIVE session will last about 1 ½ hours. Sessions take place in the CMC VAMC outpatient Rehabilitation Medicine clinic. They can also be delivered online using the VA's televideo system, VA Video Connect (VVC), if necessary..

The OT may also ask your permission to audiotape a session. No identifiable information would be asked during the recording. Only authorized investigators on the study team would listen to the tape. This is done for ensure that the OT is following the program. Please check Agree or Do Not Agree to indicate your willingness for digital voice recording. Please note that you can still participate in the study if you do not agree to the voice recording.

☐ I AGREE to the digital voice recording.

☐ I DO NOT agree to the digital voice recording.

3 Month Follow-Up Interview (both groups):

In three to four months, we will conduct a follow-up interview with you at the clinic or by phone, regardless of which group you are in. It will be very similar to the first interview and take about the same length of time (1-1/2 hours).

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If you are in the Treatment-as-Usual group, this will be the end of your study participation. If you are in the ACTIVE group, a study team member may call you to ask about your experience in ACTIVE (see next, Final Optional Phone Interview).

Final Optional Phone Interview for ACTIVE group only

You may also be asked to take part in a phone call with a member of the research team. This call would take place at a time convenient for you and would last up to 45 minutes. The research team member would ask you about your experience with the ACTIVE program. There are no right or wrong answers to the questions. We are interested in learning from you and hearing about your experience. These phone discussions will be recorded and transcribed. Transcripts of the discussions will not contain any names or other potentially identifiable information. Please check Agree or Do Not Agree to indicate your willingness for this digital voice recording. Please note that you can still participate in the study if you do not agree to the voice recording.

☐ I AGREE to the digital voice recording.

☐ I DO NOT agree to the digital voice recording.

Compensation

As a small token of our appreciation for your participation, you will receive $40 after your completion of the First Interview and $50 after completion of the 3 Month Follow-Up Interview. You will receive the money directly deposited to your bank account or added to a special Direct Express® MasterCard, depending on what you set up.

Study Staff

Our Interviewers and Occupational Therapists (OT) are highly trained members of our study team. The study Principal Investigator (PI) or a Co-Investigator may accompany our Interviewers or OTs on study visits, with your permission. This is to ensure consistency throughout the study.

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

There are no known physical or other risks involved in this study. You may feel some emotional discomfort when discussing sensitive issues related to your TBI and mood. You have the right to

refuse to answer any questions that make you feel uncomfortable for any reason, or you may request to stop the session. Our trained interviewer will also be able to help you if you feel upset or uncomfortable. We may also refer you to appropriate resources within the medical center. If you indicate an intention to harm yourself or others, we are obligated to notify the appropriate medical and mental health professionals immediately. We are always concerned for your safety and the safety of those around you. If you mention that there is child abuse or elder abuse going on, we are required by law to report this to the proper authorities.

For your privacy and comfort, discussions will take place in a private area. It is possible that you may feel fatigue during the interviews. You will be given opportunity to take breaks or complete the interview or visit on another day if you wish.

A breach of confidentiality is a potential risk in this or any study. Plans to avoid this risk and protect your identity are described later in this form.

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. In the researchers' past studies with study participants with TBI who received occupational therapy (OT), the participants did not experience any problems from being in the study.

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.

WHAT ARE THE POSSIBLE BENEFITS OF THE STUDY?

You may not benefit directly from participating in this research study. However, you may acquire skills that improve your mood and increase your participation in activities with your family, community, friends, and other situations that are meaningful and important to you. In addition, your participation may help other veterans by increasing our understanding of how to assist veterans with TBI cope with mood problems.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

During this study, we will collect personal information such as:

- name, address, phone number
- age

- past medical history related to your TBI
- your physical health and everyday functioning
- your mood
- your psychiatric history
- medications you may be taking

We will collect dates to be able to schedule interviews with you, but we will not keep any dates for later analysis.

Your name and the last 4 digits of your social security number will be used only as necessary within the CMC VAMC, but other private information may be disclosed to the:

- CMC VAMC Institutional Review Board (IRB)
- Office of Human Research Protections (OHRP)
- VA Office of Research Oversight (ORO)
- Government Accountability Office (GAO)

If you have an accident or reaction during your time in the study, your medical record may be used and disclosed as clinically necessary.

This informed consent document will be added to your medical record.

The results of this study may be published; however, you will not be identified by name or other personal identifiers. Further, your medical records will not be revealed unless required or authorized by law. The investigators will take special precautions to maintain your confidentially throughout the study. The information you provide will be assigned a code number that will be used in place of your name on study materials. Study materials include:

- your interview data
- data from your medical record
- data held by the occupational therapists (if you are in the group receiving services from OTs)
- audio recordings (if you are audio recorded)

Only the Principal Investigator (PI) and Co-Investigator, Dr. Winters, will have access to the list linking codes to individual names. This list will be kept in a locked file cabinet in the investigator's locked office, Room B910 in the North Building of CMC VAMC. Electronic data will be kept on the secure VA server.

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The interviewer for the study will ask you questions and record your answers on paper questionnaires. Authorized study team members will enter this information into locked files on secure CMC VA servers. Only authorized members of the research team can gain access into the study files on the computer. The paper questionnaires will be stored in the PI's locked office in a locked cabinet.

If home visits are necessary, the data will be kept in locked cases during transport. The paper data with your contact information and visit date will be kept in a locked briefcase, separate from the completed questionnaire data. If the OT is not able to go directly from your home to the CMC VAMC, the locked briefcases will be taken to Jefferson University's Occupational Therapy Department, Edison Building, 130 South 9th Street, Philadelphia, PA. They will be stored in a locked cabinet in a locked office (Suite 500). It will be transported to CMC VAMC, again in locked briefcases, when you have completed ACTIVE sessions.

All research records, including the investigator's research records, must be retained according to the National Archives and Records Administration VHA's Records Control Schedule.

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA 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 HIPAA 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. They may also collect other information including your name, address, and information from your medical records such as:

- current medications for mood
- mental health treatments
- other relevant health conditions

They will also ask you to give the name and phone number of a family member or friend whom the study team may call if they have trouble reaching you. You are not required to provide this extra contact information.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the CMCVAMC Institutional Review Board, Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability Office (GAO).

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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.

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, Helene Moriarty, PhD, RN, 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 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.

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

The VA will provide treatment for research related injury in accordance with applicable federal regulations (38 CFR 17.85).

It is important that you tell your study doctor, Helene Moriarty, PhD, RN or Laraine Winter, PhD if you feel that you have been injured because of taking part in this study. You can tell them in person or call them.

If you should have a medical concern or get hurt or sick because of taking part in this study, call:

DURING THE DAY:

Participant's Name: _____ Date: _____

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Principal Investigator's Name: Helene Moriarty, PhD, RN, FAAN

Dr. Helene Moriarty at [redacted] or [redacted].

AFTER HOURS:
Dr. Winter or Dr. Moriarty at [redacted] or [redacted]

Emergency and ongoing medical treatment will be provided as needed.

DO I HAVE TO TAKE PART IN THE STUDY?

Your participation in this study is voluntary, and refusal to take part will involve no penalty or loss of benefits to which you are otherwise entitled.

If you are a VA employee, your refusal to take part in this study will in no way influence your employment, ratings, or subsequent recommendations, as applicable.

You may discontinue taking part in the study at any time without any penalty or loss of benefits and without impacting the standard of care that you would otherwise have received.

If you discontinue participation, any data that has already been collected will still be used by the investigators, but no new data about you will be collected.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

The study investigators may end your participation in the study:

- if they are unable to reach you after many attempts to contact you
- if you become unavailable for study visits,
- if the investigator feels that you would benefit more from a treatment that the study cannot provide
- if the investigator feels that continued participation in the study might be harmful to you

If this happens, the study team will want to meet with you for an end-of-study visit to assist you in obtaining other treatment and/or using other resources.

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

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 Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study.

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You should contact the Research Compliance Officer at 215-823-7847 or the Patient Representative at 215-823-5803 from 8:00 AM to 4:30 PM, Monday through Friday if you have questions, complaints, or concerns about the study, or if you would like to obtain information or offer input.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

We will share the study results with you at the end of the study. We will contact you in a timely manner if significant new findings emerge during your time in the study which may influence your willingness to continue in the study.

FUTURE USE OF DATA AND RE-CONTACT

Your de-identified data (meaning that it has nothing that would link the data to you) may be used in future studies or distributed to another investigator for future research studies without additional informed consent from you.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

A member of the study team 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 for 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. A copy of this signed consent will also be put in your medical record.

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

Individual Obtaining Consent (required)		

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Print Individual's Name Obtaining Consent	**Signature of Individual Obtaining Consent**	**Date Signed**