

Exploring the Effects of Exercise Training on PTSD
Symptoms and Physical Health in Older Veterans with
PTSD

NCT04199182

June 8, 2021



Research Informed Consent Form

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Participant Name:

Date:

Study Title:

Exploring the effects of exercise training on PTSD symptoms and physical health in older Veterans with PTSD.

DVAHCS Principal Investigator:

Katherine Hall, PhD

VAHCS: Durham VAMC

OVERVIEW AND KEY INFORMATION

Please read this form carefully. You are being asked to participate in this research study because you are a Veteran, over the age of 65, who might have PTSD. This study is voluntary and will include only people who choose to take part. Ask your study doctor or study staff to discuss this consent with you, please ask him/her to explain any words or information that you do not understand. It is important that you understand the information on this form.

The purpose of this study is to test whether exercise impacts mental health or functional ability in older Veterans with PTSD.

Your participation in this study will involve 3 appointments with Durham VAMC research staff over the next 9 months to complete some questionnaires and do low-impact tests of daily activities (like walking, getting up/sitting down in a chair). In addition, you will be asked to participate in group wellness sessions held in close proximity to the Durham VAMC or conducted over video session.

The greatest risks of this study include temporary emotional distress to some of the survey questions, muscle soreness following physical activities, and potential loss of confidentiality.

WHY IS THIS STUDY BEING DONE?

The study is being done to explore if regular exercise has any effect on the physical or psychological health of older Veterans with PTSD. To do this, we have designed two different groups: an exercise group, and a Healthy Aging education group.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY

Approximately 188 people will be randomized in this study at the Durham VA Health Care System.

HOW LONG WILL I BE IN THIS STUDY?

Your participation in this study will last 9 months.

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WHAT IS INVOLVED IN THIS STUDY?

If you agree to participate in this research study, you will be asked to sign and date this consent form. Next, we need to ask you some questions about your trauma history and PTSD symptoms that you may be experiencing. At this session we will also have you fill out some questionnaires about your health, psychological well-being, and lifestyle habits, and will measure your height, weight, heart rate, blood pressure, and waist size. We guide you through a series of general physical function assessments: how far you can walk in six minutes, getting up/sitting down in a chair, balancing on one leg, and walking speed over a short distance. These functional assessments are not designed to be strenuous, and reflect activities you likely do in a typical day. Finally, we ask that you wear an activity monitor for up to 7 days following each assessment.

After completing all of these assessments, we randomize you to a study group. Using a procedure like flipping a coin, you will have a 50% chance of being assigned to a Healthy Aging group or an Exercise group. Both programs are group-based and will be delivered face-to-face (at or near the Durham VA) and/or via remote video technology to your home. In total, today's session will take about 2.5 hours.

If you are assigned to the Healthy Aging Group, you will be asked to participate in 16 group sessions over the next 6 months, either at the DVAMC or remotely via video technology. These sessions will be held weekly for the first 2 months, and then will alternate every other week for the remaining 4 months of the study period. We expect each session to last approximately 2 hours, though this may vary depending on level of participation and content. In this group we will discuss the "keys" to improving health as we age, covering topics such as blood pressure, nutrition, smoking, creativity and learning, regulating blood glucose, cancer screening, immunizations, finances and future planning, and maintaining healthy bones, joints, and muscles. We ask that you attend as many sessions as you are able during the 6 months. Travel reimbursement will not be provided for your travel to/from the DVAMC for these sessions. Table 1 is a summary of study procedures for the Healthy Aging Group (in addition to the group sessions):

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Table 1. Healthy Aging Group Study Procedures

Session	Tasks	Time	Payment
1 (DVAMC/Video)	<ul style="list-style-type: none"> Consent Screening (CAPS-5 clinical interview, questionnaires) Height, weight, BP, waist-to-hip ratio Physical performance tests Randomization 	2.5 hrs	\$50
2 (6-months, DVAMC/Video)	<ul style="list-style-type: none"> Questionnaires & CAPS-5 clinical interview Weight, BP, waist-to-hip ratio Physical performance tests 	2 hrs	\$50
3 (9 months/end of study, DVAMC/Video)	<ul style="list-style-type: none"> Questionnaires Assessments (CAPS-5 clinical interview, questionnaires) Weight, BP, waist-to-hip ratio Physical performance tests 	2 hrs	\$75
		TOTAL	Up to \$175

If you are assigned to the Exercise Group, you will be asked to participate in a supervised exercise program 3 times per week for the next 6 months either at a facility located near the DVAMC or remotely via video technology. This program targets strength, flexibility, balance and cardiovascular fitness, and is designed to meet the individual needs and limitations of each individual. These exercise sessions are supervised by an exercise specialist, and last approximately one hour. We ask that you attend as many sessions as you are able during the 6 months. Travel reimbursement will not be provided for your travel to/from the exercise facility. Table 2 is a summary of study procedures for the Exercise Group (in addition to the 3 times/week exercise sessions):

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Table 2. Exercise Group Study Procedures

Session	Tasks	Time	Payment
1 (DVAMC/Video)	<ul style="list-style-type: none"> • Consent • Screening (clinical interview, questionnaires) • Height, weight, BP, waist-to-hip ratio • Physical performance tests • Randomization 	2.5 hrs	\$50
2 (6 months/end of study, DVAMC/Video)	<ul style="list-style-type: none"> • Questionnaires • Assessments (clinical interview, questionnaires) • Weight, BP, waist-to-hip ratio • Physical performance tests 	2 hrs	\$50
3 (9 months/study follow-up; DVAMC/Video)	<ul style="list-style-type: none"> • Questionnaires • Assessments (clinical interview, questionnaires) • Weight, BP, waist-to-hip ratio • Physical performance tests 	2 hrs	\$75
		TOTAL	Up to \$175

PHOTOGRAPHS AND RECORDINGS

Throughout the study we may take photographs, video, and/or audio recordings for research purposes. For example, to measure fidelity of the Healthy Aging group content across leaders and discussant groups. These photographs, video, and/or audio recordings may also be used outside of the VA for promotional purposes, including media publications, promotional brochures/flyers, and presentations about the study.



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WHAT ARE THE RISKS AND DISCOMFORTS OF PARTICIPATING IN THIS RESEARCH STUDY?

There are some risks to participating in the study. First, there is a small risk that you may fall or experience muscle soreness with the physical performance testing and/or exercise training. The risk of doing these activities is similar to the risk of doing moderate-intensity physical activity. To minimize this risk, we follow standardized testing procedures and have well-trained research staff supervise these activities. We ask that let us know if you experience any unusual shortness of breath, dizziness, tightness or pain in the chest or arms, skipping heart beats, numbness, loss of balance, nausea, or blurred vision during your time in the study. The risk of death from participating in moderate-intensity exercise is very low (1 death per 656,000 hours of activity). We will minimize these risks by developing an exercise routine appropriate for your fitness level, gradually increasing the intensity of your exercise program over the course of the study and monitoring individual responses to exercise.

There is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. While it is not possible to keep your identity confidential in the group setting, all participants will be asked to sign a confidentiality agreement stating that disclosure of group member identities to anyone outside the group is not permissible. Some questions asked as part of this study may make you feel uncomfortable or increase distress. This discomfort or increased distress is usually temporary and well tolerated. You do not have to answer questions and you can take a break at any time. You can call the study team at any time if you experience any discomfort related to the research.

WILL I BENEFIT FROM TAKING PART IN THIS RESEARCH STUDY?

You may not personally benefit from taking part in this study, but your participation may lead to knowledge that will help other Veterans in the future. We hope that participation in this study may improve your health and well-being, by participating in exercise or learning about strategies for healthy aging.

WHAT OTHER OPTIONS OR ALTERNATIVES DO I HAVE?

Taking part in this study is your choice. You may choose to not participate. Other VA programs that you may participate in include the MOVE! program, Gerofit, or trauma-focused psychotherapy at the Durham VA.

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VAHCS: Durham VAMC**HOW WILL MY RESEARCH DATA BE PROTECTED AND SECURED?**

Your information used for this study will be kept confidential as required by law. The results of this study may be used for scientific purposes or for publication, but these results will not include any information that would identify you. Your identity will not be disclosed without your consent, or unless required by law. Your research records will be maintained and destroyed according to VHA records retention requirements. Your data will not be stored and used for future studies even if identifiable information, such as your name or medical record number, are removed.

Hard copy paper records (that is, any forms you sign or questionnaires you complete) will be stored in a locked filing cabinet in the study coordinator's locked office, within the Durham Veterans Affairs Medical Center. Much of these data will also be entered into an electronic database which is password-protected and stored behind the VA firewall. Access to both paper and electronic research records data will be limited to a small number of study team members who have been trained to preserve participant confidentiality. To protect individual confidentiality, we will assign you a randomly generated Study ID number that will be used on all study materials, instead of your name. The key linking Study ID numbers and identifying information will be kept in the study coordinator's locked office at the Durham VAMC and will be maintained on password-protected computers behind the VA firewall.

As part of this study, coded/de-identified data (that is, data that includes no individual identifiers) collected from you may be moved to a secured server at Duke University Medical Center. This includes information collected from the activity monitor. This information will be encrypted while being moved (e.g. encrypted email) and while stored and will only be available to Dr. Hall and/or her study staff. Data will be securely transferred to Duke for the purpose of data analysis only.

Your research records may be reviewed by Durham VA staff who are responsible for the safe conduct of this research. We may also provide your research records to federal agencies such as the Office for Human Research Protections (OHRP), the VA Office of the Inspector General (OIG), and the Office of Research Oversight (ORO). We may also disclose your information to the VA Office of Research and Development, or VA Financial Services employees who process participant reimbursement. We will not share any information with these groups outside the VHA unless they agree to keep the information confidential and use it only for the purposes related to the study. Any information shared with these outside groups may no longer be protected under federal law. These groups may disclose



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your information to other groups. If the sponsor receives identified information, it is then the sponsor, and not the VA, who is responsible for the security of the information.

DOES PARTICIPATION IN THIS RESEARCH STUDY COST ANYTHING?

There will be no costs to you for any of the research treatment or research testing done as part of this research study. Some Veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

WILL I RECEIVE ANY COMPENSATION (MONEY OR OTHER) FOR TAKING PART IN THIS RESEARCH STUDY?

You may be reimbursed up to \$175 for your participation in this study (see Tables 1 and 2 above).

WHAT WILL HAPPEN IF I AM INJURED WHILE PARTICIPATING IN THE RESEARCH STUDY?

The VA will provide necessary medical treatment should you be injured by being in this study. You will be treated for the injury at no cost to you. This care may be provided by the Durham VAHCS or arrangements may be made for contracted care at another facility. Every reasonable safety measure will be taken to protect your well-being. You have not released this institution from liability for negligence. In case of research related injury resulting from this study, you should contact your study team. If you have questions about compensation and medical treatment for any study related injuries, you can call the medical administration service at this VA Medical Center at 919-286-6957.

WHAT ARE MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You can choose to not be in this study, or, if you agree to be in the study, you can withdraw at any time. If you withdraw from the study, no new data about you will be collected for study purposes. We will keep and use the data that we already collected before you withdrew your consent.

If you choose to not be in the study or if you withdraw from the study, there will be no penalty or loss of any benefits to which you are otherwise entitled. This will not affect your relationship with or treatment by the Veterans Health Administration (VHA) or your rights as a VHA patient. You will still receive all the medical care and benefits for which you are otherwise eligible.

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ARE THERE REASONS THAT MY RESEARCH PARTICIPATION MAY END EARLY?

Dr. Hall may take you out of the study without your consent for one or more of the following reasons: failure to follow instructions of investigator and/or study staff, inability to complete the study requirements, behavioral disruptions, or other administrative reasons. We will tell you about new information that may affect your health, condition, welfare, or willingness to participate in this study.

WILL THE RESULTS OF THIS RESEARCH STUDY BE SHARED WITH ME?

Participants who complete all of the study assessments will receive a full report of their physical performance tests. These results will not be made available until after the study is complete, and the data has been analyzed. If you would like to receive copies of any journal articles that are written using the data we gather during this study, please tell the study coordinator. He/she will make note and send you a copy of any article about this study.

DO ANY OF THE RESEARCHERS HAVE A FINANCIAL INTEREST RELATED TO THIS RESEARCH STUDY?

This study is funded by the Department of Veterans Affairs, and portions of the study staff members' salaries are paid by this study.

WHERE CAN I FIND OTHER INFORMATION ABOUT THIS RESEARCH STUDY?

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.

WHO DO I CONTACT IF I HAVE QUESTIONS OR CONCERNS ABOUT THE RESEARCH STUDY?

If you have questions about the research or need to talk to the study team, you can contact Dr. Hall at [REDACTED] during the day, and at [REDACTED] after hours. If you have questions about the research or your rights as a research participant, would like to obtain information, offer input, or have other concerns or complaints, you may contact the administrative officer of the research service at (919) 286-0411, extension 177632. If you would like to check that this study is approved by the Durham VAHCS's Institutional Review Board, please call the research office at (919) 286-6926 or (888) 878-6890, extension 176926.



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AFFIRMATION FROM PARTICIPANT

I have read this form, or it has been read to me. My rights as a research participant have been explained to me, and I voluntarily consent to participate in this study. I have received an explanation of what the study is about and how and why it is being done. I authorize the use and disclosure of my identifiable information as described in this form. I will receive a signed copy of this consent form.

Signature of Participant

Date

Signature of Person Obtaining Consent

Date