Research Consent Form

Minneapolis VA Health Care System

Study Title: InCreasing Activity & REcovery for Veterans with PTSD (I CARE for Vets)	
Principal Investigator: Wei (Denise) Duan-Porter, MD, PhD	
Protocol #: VAM- 20-00562	**ICF Version Date: 10/20/2021**

INTRODUCTION

You are being asked to participate in a research study. The box below highlights some key information that you should know about the project, and more detailed information is provided on the following pages. Before you decide whether to participate, please ask questions about any of the information you do not understand.

Key Information for You to Consider

- **Voluntary Consent**. You are being asked to volunteer for a research study. Whether or not you decide to participate, treatment at the VA for which you are eligible will not be affected.
- **Purpose**. The goal of this small research study is to test a new program to help Veterans with PTSD be more physically active. We want to see if Veterans will be interested and engaged in the program.
- **Duration.** The program lasts 2 months. After the program is completed, there will be 2 months of follow-up, during which you will continue to track your physical activity.
- **Procedures and Activities.** During the first month, there will be 4 group sessions with a physical therapist, done virtually via videoconferencing. In these sessions, we will discuss barriers to increasing physical activity, set personal activity goals, and do 20-30 mins of exercise. During months 1-2, there will also be individual follow-up sessions with the physical therapist; these will occur via telephone or video-conferencing. Throughout the program, you will be asked to track your physical activity using a wearable fitness device (*eg*, Fitbit) and activity logs. At the beginning and end of the program, you will be asked to complete in-person study assessments, including simple physical tests (such as walking and balance) and some survey questions (on your functioning, symptoms, and sleep). These will done by the physical therapist at the Minneapolis VA. Finally, during this program, we will invite you to provide feedback on the different parts of the program.
- **Risks.** Some of foreseeable discomfort from your participation include expected symptoms associated with increasing physical activity, such as some muscle soreness. These risks are no greater than what may occur in routine clinical care. You may experience skin irritation from wearing the fitness device. To avoid this, we will remind you to keep your device clean and dry, and to avoid wearing it too tightly. For in person visits, we'll take precautions to prevent the spread of COVID-19; however, as with any public space, there are risks in coming into the Minneapolis VA.
- **Benefits**. Veterans participating in this study have the potential to increase their physical activity and improve their physical functioning. This may have additional significant health benefits, including reducing their risk for cardiovascular events. The knowledge gained from this study may also benefit other Veterans with PTSD in the future.
- **Alternatives.** Participation is voluntary. Other alternatives to increasing your physical activity are available at the Minneapolis VA (please contact your primary care clinic to see if these are appropriate for you).

Subject last name & Last 4 of SSN:	

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Detailed Information about this Research Study

What is research?
One purpose of this informed consent document is to provide clear information about the activities involved with this study. There are important differences between research and treatment plans:

- The goal of *clinical care* is to help you get better or to improve your quality of life. Doctors can make changes to your clinical care plan as needed.
- The goal of *research* is to learn new things that may help groups of people in the future. Research teams learn things by following the same plan with many study participants, sothey do not usually make changes to the plan for one person. You may or may not be helped by volunteering for a research study.

How many people will be studied?
We expect 18-24 people to participate in the study at the Minneapolis VA.

What happens if I say "*Yes, I want to be in this research*"?
You will participate in a program to help you increase your physical activity. As part of this new program, you will attend group and individual sessions with a physical therapist (PT), and be provided a wearable fitness device (e.g., Fitbit), to help you track your physical activity.

Study assessments with physical therapist (PT)
At the beginning and completion of the study, you will have an individual study assessment visit with a PT. Assessments will include simple physical tests (like walking and balance) and some survey questions (on your functioning, symptoms, and sleep). During the first visit, we will work with you to identify challenges to increasing your physical activity and discuss preferences for types of activity. Both visits will be in person at the Minneapolis VA Medical Center, and last 60-90 minutes.

Technology prep session
Before the group sessions, you will have a mock meeting using the videoconferencing platform, to make sure your equipment is working and that you don't have difficulties with this process. This will be with the study coordinator, and it should last about 30 minutes.

Group sessions
During the first month, you will have 4 weekly group sessions led by PT. These sessions will last 90 minutes and include 20-30 minutes of exercise. We will discuss personal barriers to physical activity and ways to increase activity in a safe and healthy manner. We will also set personal activity goals. The group will consist of 6-8 Veterans, including yourself, and all sessions will be done virtually via videoconferencing. We will audio record some of these sessions so we can evaluate how well the program is going. These recordings will only be used by the study team to help improve the program.

Individual sessions
During months 1-2, you will also follow-up individually with PT once per week. They will work with you to address your unique needs and concerns, help with goal setting, and follow up on your progress in meeting your physical activity goals. Each session will last 10-15 minutes, and will be done via telephone or videoconferencing.

Subject last name & Last 4 of SSN:	

Tracking daily activity (wearable fitness device and activity logs):
You will be asked to track your physical activity throughout the study (months 1-4). You will complete daily activity logs, and also receive a wearable fitness device that you will be able to keep after the study ends. We will collect information on your physical activity (such as step counts and minutes of vigorous activity) and sleep from the wearable device. We will work with a VA-approved contractor to obtain these limited data from your device. Other information may be collected by the wearable device company (such as your location), but it is up to you whether to share that additional information. In any case, the I CARE Study team will only access physical activity & sleep data. We will also guide you through the device setup, to help you understand and decide what other types of information you share with the device company. You will be assigned a study-specific email address to register your device. You will be asked to wear the device daily and charge it as needed.

Feedback on the program
After month 2, we will invite you to participate in an interview to provide feedback on the program, and what may be improved to provide a better experience for other Veterans. We plan to audio record these interviews, so that we can best capture all of your feedback. The audio recordings will be converted into a written form (transcribed) by VA researchers.

What are my responsibilities if I take part in this research?
If you take part in this research, you will be responsible for attending program sessions, completing and mailing back daily activity logs, and completing the study assessments at the beginning of the study and 4 months. You are also responsible for wearing and maintaining your device. We also ask that you let us know if you decide to participate in another research project or if you want to withdraw from this study.

What happens if I say "Yes" but change my mind later?
You can end your study participation at any time without penalty or loss of VA benefits or other benefits to which you are entitled. Please contact the study coordinator, Brittany Majeski, at 612- 629-7663 to let us know.

What if my test results show something unexpected?
There are several assessments in this study, including simple physical tests (such as walking and balance) and some survey questions (on your functioning, symptoms, and sleep). There is a possibility that the study tests and procedures may discover that you have a potential abnormality that we did not expect to see. This is what is called an "incidental finding." Study assessments are done for research purposes only. They are designed to answer research questions, not to medically examine you or provide a clinical diagnosis. If we see something unusual, we will inform you so you can obtain appropriate follow-up evaluation by your physician. The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility.

Are other procedures or treatments available if I don't participate in this study?
There are several programs at the Minneapolis VA that may help you increase your physical activity. If you are interested in this information, please contact your primary care clinic to see if any of these are appropriate for you.

Will I be paid for being in the study?
If you agree to take part in this study, we will pay you $2 for each day that you meet your daily activity goal, starting the week of the group session 1. This means that you can earn a maximum of $224 over

Subject last name & Last 4 of SSN:	

16 weeks of the program, if you meet your goal every day. Prior to group session 1, you will also receive $2 for each day that you wear your wearable device. We will also pay you $25 for completing the final study assessment at 4 months. You will have the option to receive these payments via direct deposit or Direct Express Debit Card. Compensation for participation in research is considered taxable income.

Will it cost me anything to participate in this research study?
There is no cost to you for taking part in this study. All the study costs will be paid for by VA Rehabilitation Research & Development (the sponsor of the study) or the Minneapolis VA. Veterans who must make a co-payment for their usual medications or treatments will continue to be required to make such a co-payment for non-study related care. There should be no additional medical costs to you for taking part in this study. However, frequent clinic visits may result in transportation costs and possible wages lost due to time missed from work.

Use of Identifiable Private Information
We are committed to respecting your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us permission to use your information, including health information in your medical records that can identify you. If all identifiers are removed from your private information that are collected during this research, that information could be used for future research studies without your additional informed consent.

We are also requesting access to your physical activity and sleep data as recorded by wearable fitness devices. Although the device company may seek permission to collect other types of data, this study will not seek access nor obtain any other data.

What happens to the information collected for the research?
Efforts will be made to limit the use and disclosure of your personal information to people who have a need to review this information. The results of this study may be published or presented, but your identity and records will not be revealed unless required by Federal Law. Organizations that are required by law to provide oversight of research projects may review your records. This includes several federal agencies, the VA's Research & Development Committee, and the Institutional Review Board. The sponsor of this research project, VA Rehabilitation Research & Development (RR&D), will also be allowed to review your medical records. Because of the need for these inspections, absolute confidentiality cannot be guaranteed.

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

Employees as Research Subjects
If you are a VA employee, you are considered a class of research subjects with special protections. Your decision to participate in this study should be free from pressure or coercion to participate. The research team will secure your information according to VA data security and privacy policies. Every effort will be made to prevent access by your supervisor and co-workers, but accidental disclosure or release of your private information could potentially occur.

Will I receive research test results?
If the research with your identifiable information gives results that do have meaning for your health, the investigators will contact you to let you know what they have found. Most tests done in research studies are only for research and have no clear meaning for health care. If the investigators notify you, then you

Subject last name & Last 4 of SSN:	

may want to get consult your own doctor. You may have to pay for those additional services yourself.

What happens if I am injured while participating in this research?
If you are injured from this research study, treatment will be available, including first aid, emergency treatment and follow-up care, as needed, by the VA Medical Center. In the event you cannot reach a VA facility, the VA will pay for necessary medical care for any injury or illness directly related to your participation in this research study.

You should immediately report any injuries resulting from your participation in this study to Dr. Wei Duan-Porter at (612) 467-5845 during the day and by calling the VA operator at (612) 725-2000 on evenings and weekends. If you do not live in the metropolitan area, you may call the toll-free number: 1- 866-414-5058.

VA will cover reasonable medical expenses for necessary treatment if you are injured by properly performed study procedures and have not caused the injury by failing to follow the directions of the study doctor or study staff.

Whom do I contact if I have questions, concerns or feedback about my experience?
You are encouraged to contact the Patient Representative at (612) 725-2106 if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

If you wish to verify the validity of the study and its authorized contacts, call the Patient Representative or contact the IRB office at (612) 629-7387.

I CARE Study Contacts
Study Coordinator, Brittany Majeski: 612-629-7663
Principal Investigator, Wei Duan-Porter: 612-467-5845

Urgent Matters:
Veterans' Crisis Line: 1-800-273-8255
Minneapolis VA Patient Contact Center: 612-467-1100

I have reviewed the information provided in this document. My questions have been answered and I voluntarily consent to participate in this study. I understand that I have not given away any of my legal rights by signing this form.

Subject's Signature:_____ Date: _____

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