I CARE for Vets: InCreasing Activity & RECovery for Veterans with PTSD

Study Protocol Version 2.6, 10/20/21

Funding Agency: VA RR&D

Principal Investigator: Wei (Denise) Duan-Porter, MD, PhD

ABSTRACT

Impacts: This project will be a key step forward in fulfilling the mission of VA RR&D to restore function and enable social reintegration for Veterans. Development of an intervention to increase physical activity may improve physical functioning for Veterans with posttraumatic stress disorder (PTSD), thus addressing an important gap in existing care. If demonstrated to be efficacious in a future randomized trial, this intervention could be implemented throughout VHA to improve quality of life and enable a full recovery for many Veterans with PTSD. Results from this study may also advance our understanding of how to optimally incorporate mobile health technology (mHealth) with more traditional types of patient contacts, such as in-person visits and telephone calls. Effective use of mHealth may offer greater flexibility for VHA clinics looking to implement new programs. Incorporation of mHealth may also increase access to clinical services for Veterans who reside far from VHA facilities.

Background: One in ten Veterans seen in Veterans Health Administration (VHA) primary care clinics has PTSD. Individuals with PTSD are more likely to report impairments in physical functioning, including health-related limitations in climbing stairs or performing common household tasks. As an essential component of overall functioning and quality of life, physical functioning is an independent predictor of risk for adverse health outcomes, including mortality. Mechanisms underlying the association of PTSD and poor physical functioning are multifactorial, but a key contributing factor is likely persistent low levels of physical activity. Barriers to engaging in physical activity may include low perceived behavioral control for making positive long-term lifestyle changes and personal attitudes about the harms (vs. benefits) of physical activity. Those with PTSD have reduced self-efficacy for behavioral change and less ability to cope with setbacks, leading to greater difficulty with initiating and maintaining new health behaviors. Individuals with PTSD are also more likely to have ongoing pain and fatigue, which may contribute to beliefs about harmful effects of physical activity and lead to avoidance of activity. Current VHA outpatient programs are primarily focused on addressing physical activity in the context of specific medical conditions (eg, obesity or cardiovascular disease), and there is a paucity of programs specifically tailored to the unique needs of Veterans with PTSD. Development of effective programs to increase physical activity for Veterans with PTSD may therefore improve their physical functioning and represent an important contribution to VHA efforts to enhance health and recovery for this population.

Objectives/Aims: The overall objectives of this study are to develop and pilot test a novel intervention aimed at initiating and maintaining higher levels of physical activity for Veterans with PTSD.
Aim 1: Adapt graded exercise therapy (GET) and incorporate motivational interviewing and mHealth to increase physical activity and improve physical functioning for Veterans with PTSD.
Aim 2: Conduct a pilot study to examine feasibility and acceptability of the intervention for a future randomized controlled trial.

Methods. To increase physical activity for Veterans with PTSD, this project will combine GET, motivational interviewing, and mobile health technology (mHealth) to address attitudinal and behavioral barriers particularly relevant for this group. First, we will work collaboratively with our Veteran Engagement Panel to adapt GET protocols effective for non-PTSD populations (eg, adults with chronic pain or fatigue), and incorporate motivational interviewing and mHealth. We will then pilot test the intervention in 3 consecutive groups of 6-8 participants (total n=18-24) and use concurrent mixed-methods to examine feasibility and acceptability. Quantitative measures will include recruitment (proportion enrolled out of total eligible); attendance (proportion who attend 75% of in-person visits); and retention (proportion who complete data collection post-intervention). Qualitative assessments will involve semi-structured interviews on acceptability of

intervention components (eg, session formats and topics, usability of mHealth), and barriers and facilitators to attendance. At baseline, during and post-intervention, we will also assess overall and physical functioning using Veterans RAND 36-item, 6-minute walk, and 30-second sit to stand, and collect additional data (PTSD symptoms, depression, pain,fatigue, and sleep quality) to inform a future randomized trial.

List of Abbreviations

CCDOR	Center for Care Delivery & Outcomes Research
CBT	Cognitive Behavioral Therapy
Co-I	Co-Investigator
ED	Emergency Department
GET	Graded Exercise Therapy
HSRD	Health Services Research and Development
IRB	Institutional Review Board
mHealth	Mobile Health Technology
MVAHCS	Minneapolis VA Health Care System
NIH	National Institutes of Health
PACT	Patient Aligned Care Team (VA primary care staff)
PCMHI	Primary Care Mental Health Integration
PCL-5	PTSD symptom checklist for the DSM-5
PC-PTSD-5	Primary Care Screen for PTSD for DSM-5
PEG	Brief 3-item Scale on Pain Intensity & Interference
PHQ-9	Patient Health Questionnaire-9
PI	Principal Investigator
PSQI	Pittsburgh Sleep Quality Index
PTSD	Posttraumatic Stress Disorder
PT	Physical Therapist
RR&D	Rehabilitation Research and Development
UMN	University of Minnesota
VA	Department of Veterans Affairs
VHA	Veterans Health Administration
VINCI	VA Informatics and Computing Infrastructure
VR-36	Veterans RAND 36-item Health Questionnaire
WRAP	Wearables Research and Analytics Platform

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1.0 STUDY PERSONNEL

Principal Investigator/Study Chair:

1. Wei (Denise) Duan-Porter, MD, PhD; wei.duanporter@va.gov, 612-467-5845

2.0 INTRODUCTION

One in ten Veterans seen in VHA primary care clinics has posttraumatic stress disorder PTSD.[1, 2] Individuals with PTSD are more likely to report impairments in physical functioning, including health-related limitations in climbing stairs or performing common household tasks.[1, 3, 4] As an essential component of overall functioning and quality of life,[5, 6] physical functioning is an independent predictor of risk for adverse health outcomes, including mortality.[7, 8] Although those with PTSD have higher prevalence of chronic medical conditions (eg, diabetes and heart disease) that may lead to limitations in physical functioning, these comorbidities do not account for the association between PTSD and poor physical functioning.[1, 3, 4] Mechanisms underlying the association of PTSD and poor physical functioning are multifactorial, but a key contributing factor is likely persistent **low levels of physical activity**.[9-11] Development of effective programs to increase physical activity for Veterans with PTSD may therefore improve their physical functioning and represent an important contribution to VHA efforts to enhance health and recovery for this population.

Individuals with PTSD have low levels of physical activity,[9-11] and face unique and substantial barriers to increasing physical activity, compared to those without PTSD. Lack of physical activity leads to deconditioning and risk for further declines in physical functioning.[12, 13] In applying the **Theory of Planned Behavior,**[14, 15] we posit that barriers to engaging in physical activity for those with PTSD include **low perceived behavioral control** for making positive long-term lifestyle changes and **personal attitudes** about the harms (vs. benefits) of physical activity. Those with PTSD have reduced self-efficacy for behavioral change and less ability to cope with setbacks,[16, 17] leading to greater difficulty with initiating and maintaining new health behaviors. Individuals with PTSD are also more likely to have ongoing pain and fatigue,[18-21] which may contribute to beliefs about harmful effects of physical activity and lead to avoidance of activity. Current VHA outpatient programs are primarily focused on addressing physical activity in the context of specific medical conditions (eg, obesity or cardiovascular disease). These programs were not designed for the particular challenges faced by those with PTSD and participation rates are lower for this group. For example, Veterans with PTSD were 20% less likely to participate in VHA MOVE program (for weight loss) at recommended levels.[22] Among participants who attended sessions as recommended, achieving 6-month goals was less likely for Veterans with vs. without PTSD.[23] Despite these findings, a paucity of programs targeting physical activity have been specifically tailored to the unique needs of Veterans with PTSD. The few existing pilot studies of physical activity interventions for PTSD utilized mostly group exercises and did not show increased activity levels at home or improved functioning.[24-26] Therefore, our long-term goal is to develop and implement effective interventions to increase physical activity, improve physical functioning, and reduce risk for adverse health outcomes for Veterans with PTSD.

A. Overview & Conceptual Model

We will adapt GET and incorporate motivational interviewing and mHealth in a new intervention to increase physical activity (Aim 1), and conduct a pilot study to evaluate intervention feasibility and acceptability (Aim 2). The intervention applies GET to enhance **perceived behavioral control,** and motivational interviewing and mHealth components to address unhelpful **personal attitudes** that are barriers to physical activity (Figure 1). **GET** provides individualized assessments and instructions to build knowledge, and emphasizes setting small achievable increases in activity goals to boost confidence in ability to engage in physical activity. Together, these elements of GET lead to increased behavioral control for physical activity. **Motivational interviewing** in a small group setting helps participants examine attitudinal barriers to engaging in activity and provides social support. **mHealth** components include wearable devices to reinforce positive attitudes about physical activity through real-time feedback on meeting individualized goals.

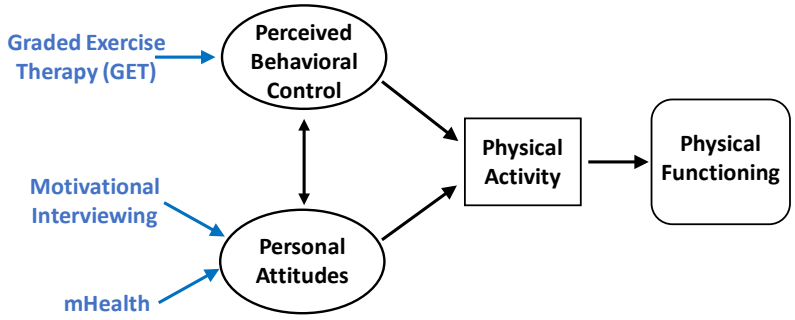


Figure 1. Conceptual Model of Intervention Components and Effects on Physical Activity and Physical Functioning.

B. Rationale for Intervention Components

1. Graded exercise therapy (GET)

Randomized trials of GET have demonstrated efficacy for improving physical functioning for adults with chronic pain and/or fatigue symptoms.[27, 28] Often delivered by physical therapists (PT), GET protocols involve individualized assessment of exercise capacity; coaching about appropriate types of physical activity; and collaborative decision-making between therapists and participants to set achievable goals for increasing activity (usually 10-20% per week, focusing first on longer duration). Some interventions have included cognitive behavioral therapy (CBT) to directly address negative cognitions about physical activity (*eg*, pain after exercise means damage is occurring to the body) and problematic behavioral patterns (*eg*, cycles of intense activity followed by long periods of inactivity in response to increased symptoms).[29-32] CBT sessions often focused on time-based pacing, appropriate responses to bodily symptoms, and coping skills.

Some elements of existing GET interventions will be directly applicable to Veterans with PTSD, due to the high prevalence of pain and fatigue symptoms among those with PTSD. However, there may be certain barriers particularly relevant to individuals with PTSD (eg, avoidance of outdoor activities due to hypervigilance) that are not addressed by current GET protocols. Additionally, past protocols required substantial clinic resources for weekly (or more frequent) in-person visits over several months, which limit feasibility for broad implementation. Extended duration of in-person visits may also reduce acceptability and uptake among those with PTSD. Therefore, GET protocols need to be adapted for Veterans with PTSD and modified to improve feasibility for implementation in outpatient settings.

2. Motivational interviewing and mobile health technology (mHealth)

Motivational interviewing has been used to address a variety of health behaviors and can be effectively delivered both in-person (individually and in groups) and by telephone.[33-37] It focuses on eliciting personal reasons and motivations for behavioral change and engages with participants' ambivalence about change using a nonjudgmental stance. Recent studies have also shown that

mHealth (eg, wearable devices and smart-phone applications), combined with financial incentives, is effective for increasing physical activity.[38, 39] Wearable devices enable remote collection of physical activity data, asynchronous follow-up by staff (via text messages or telephone calls), and individualized goal-setting. Thus, mHealth components may improve acceptability among participants and feasibility for implementation in busy outpatient clinical settings, due to decreased need for in-person visits. mHealth and financial incentives to increase physical activity are realistic for implementation by VHA clinical services, as they would build on existing VHA investments in mHealth (eg, for mental health treatment and smoking cessation[40, 41]) and recent nationwide efforts to incorporate financial incentives in support of treatment for substance use disorders (ie, contingency management with financial rewards for abstinence and attendance of treatment sessions[42, 43]).

C. Significance & Innovation

Successful completion of this study will result in a tailored intervention to **increase physical activity, and thereby improve physical functioning**, for Veterans with PTSD. If demonstrated to be effective, this intervention may also reduce risk for adverse health outcomes, including cardiovascular events and mortality. Thus, this project will be highly significant for advancing VHA clinical care by contributing to development of effective outpatient programs that improve health and quality of life for Veterans with PTSD. This will be a critical next step towards fulfilling VA RR&D's mission to restore function and enable recovery for Veterans.

Results from this project will also advance our understanding of how to optimally incorporate mHealth components with traditional patient contacts (in-person visits and telephone calls). Effective use of mHealth may offer greater flexibility for VHA clinics to implement new programs and increase access to these services for Veterans. Thus, this work will expand the applicability of VHA's current investments in mHealth for clinical care.

This novel program may also help participants build confidence about their general ability to make positive changes related to health, thus increasing the likelihood they will engage in (and adhere to) mental health treatments. If such synergy is ultimately demonstrated, it will open a new direction for VA RR&D and VHA clinical care by indicating that interventions focusing on physical activity need to be more closely integrated with mental health services.

To address potential challenges with recruitment, acceptability and/or retention (often encountered by randomized trials evaluating new interventions[44, 45]), this study incorporates a novel patient engagement model. Stakeholder engagement can improve the relevance of research to end-users and uptake of findings.[46, 47] Patient engagement is also thought to increase the quality of assessment instruments and effectiveness of recruitment strategies.[48] We adapted an existing model of patient engagement[49, 50] to address several noted barriers to effective stakeholder engagement.[51] Our panel consists of Veterans with lived-experience of PTSD who participate in project-focused meetings. A core group of experienced investigators and research staff at CCDOR organize and facilitate meetings to ensure they are focused and effective for both project investigators and Veteran stakeholders. Completion of this project will help establish the utility of our model of Veteran engagement for rapidly developing effective interventions with improved feasibility and acceptability.

3.0 OBJECTIVES

The overall objectives of this study are to develop and pilot test a novel intervention aimed at initiating and maintaining higher levels of physical activity for Veterans with PTSD.

Aim 1: Adapt GET and incorporate motivational interviewing and mHealth to increase physical activity and improve physical functioning for Veterans with PTSD. We will develop treatment manuals, training procedures for physical therapists (as interventionists), and processes for fidelity assessment.

Aim 2: Conduct a pilot study to examine feasibility and acceptability of the intervention for a future randomized controlled trial. We will pilot test the intervention in 3 consecutive groups of 6-8 participants (total n=18-24) and use concurrent mixed-methods to examine feasibility and acceptability. We expect 75% attendance and retention, based on results from pilot studies of group exercise interventions for PTSD (*eg*, retention of 76-82%).[25, 26]

4.0 RESOURCES AND PERSONNEL

A. Research Site: Minneapolis VA Health Care System (MVAHCS)

Center for Chronic Disease Outcomes Research, MVAHCS, Minneapolis, MN. Activities that take place at this site include the following:

1. Data extraction
2. Recruitment, obtaining informed consent, and data collection, including interviews by trained staff, who are the study coordinator and co-investigators
3. Intervention administration/delivery
4. Data analysis

B. Principal Investigator

Wei Duan-Porter, MD, PhD

a. Will have access to protected health information
b. Will be involved in recruiting subjects; obtaining informed consent; supervising and administering interview procedures/conduct of interviews, training and supervising providers in intervention delivery, and performing data analysis

5.0 STUDY PROCEDURES

A. Study Design

This will be a 2-year study. During the first 6 months, we will develop the intervention by adapting GET and incorporating motivational interview and mHealth components. In the next 18 months, we will conduct a single-arm pilot with 3 groups (6-8 participants per group) to evaluate feasibility and acceptability.

Table 1. Project Timeline

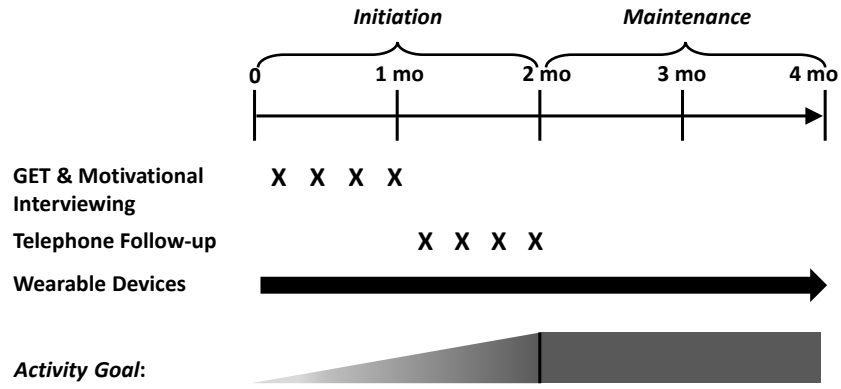
	Year 1				Year 2			
Planned Activities	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**
Aim 1: Adapt GET and incorporate motivational interviewing & mHealth								
Develop session formats, topics, and materials	X	X	X					
Work with CCDOR Veteran Engagement Panel to refine treatment manual, materials, and recruitment procedures		X						
Develop training procedures and fidelity assessments			X					
Establish processes for mHealth components and data			X					
Aim 2: Conduct pilot study to examine feasibility and acceptability								
Develop recruitment procedures with primary care and PCMHI staff	X	X	X					
Conduct groups 1-3 (6-8 participants per group)				X	X	X	X	X
Examine recruitment, attendance, retention, and acceptability				X	X	X	X	X
Collect data on physical activity, physical functioning, PTSD symptoms, depression, pain, fatigue, and sleep quality				X	X	X	X	X

B. Development of Physical Activity Intervention

1. Development of intervention manual and training procedures

The investigators will develop treatment manuals, training procedures for interventionists, and processes for fidelity assessment. During months 1-3 of the project, we will elaborate session content and format. We will then present topics, formats, and communications materials to the Minneapolis VA Center for Care Delivery & Outcomes Research (CCDOR) Veteran Engagement Panel for PTSD research (see below). In months 4-6, we will incorporate Engagement Panel input, and develop protocols for training PT to deliver the intervention. Training procedures may include didactic sessions, role playing and mock video-conferencing sessions.

Figure 2. Timeline of Intervention Components and Activity Goals.



The proposed 4-month intervention will focus on initiation (months 1-2) and maintenance (months 3-4) of higher physical activity levels (Figure 2). In month 1, sessions will employ GET and motivational inter-viewing to provide intensive, personalized counseling, thereby over-coming barriers to initiation. In month 2, further gains in physical activity will be supported by weekly telephone contacts. Wearable devices will be incorporated to reinforce benefits of achieving activity goals, and in months 3-4, support maintenance of higher physical activity levels.

2. CCDOR Veteran Engagement Panel for PTSD research

Our Engagement Panel is adapted from a previously developed model of patient engagement,[49, 50] and is comprised of 12 Veterans who have lived-experience with PTSD, including 6 men and 6 women of diverse race and ethnicity, 25-67 years old. The panel meets quarterly and more often, as requested to support ongoing projects. Meetings of 2-3 hours are organized by the CCDOR Engagement Workgroup, with input from project teams on topics and goals. Meetings begin with a brief investigator presentation on overall project goals and 2-3 key questions for panel members to address. Workgroup staff facilitate meetings, take detailed notes during meetings and review themes with project teams immediately afterwards. Investigators are also provided written summaries of key feedback. Co-Investigator Meis will lead collaboration with the Veteran Engagement Panel on session formats and topics (eg, additional barriers to address), communication materials (eg, brochures and worksheets for activity planning), and recruitment procedures.

3. Adaptation of GET and integration with motivational interviewing

We will combine GET and motivational interviewing in individual meetings and group sessions to be delivered by a trained PT.

At the first individual meeting, participants will complete in-person baseline assessments, learn about intervention rationale and components, discuss their values and goals, describe preferences for types of physical activity (*eg*, walking), and be introduced to mHealth components. Weekly group sessions in month 1 will involve closed cohorts of 6-8 participants and be conducted by video-conferencing (see Section 4b below). Based on our experience with motivational interviewing, chronic pain rehabilitation, and PTSD psychotherapies, the group format should optimize development of relationships and support between participants, while also permitting personalized attention to motivations and barriers. Additionally, groups may be particularly beneficial for individuals with PTSD, who are often isolated and have greater difficulty making

use of existing social supports.[52] Group sessions have been effective in previous studies of GET interventions for non-PTSD populations.[31] Each session will have 2 main discussion topics, and incorporate approximately 30 minutes of group exercises. Proposed group session topics include time-based pacing, attitudes related to pain and/or fatigue after activity, improvement of sleep, and strategies to address other personal barriers. At the end of group sessions, participants will develop individualized plans for physical activity at home. Physical activity goals will take into account participants' baseline levels of activity and exercise capacity, with gradual increases of 10-20% per week, focusing first on extending duration and then increasing intensity.

Additional individual follow-up will occur between weeks 1 and 2; between weeks 2 and 3; and after week 4. By video-conferencing or telephone, PT will assess progress with increasing activity, apply motivational interviewing techniques and tools (*eg*, amplifying change talk and readiness rulers), and provide personalized troubleshooting as needed. PT will continue to use motivational interviewing in weekly follow-up telephone calls during month 2.

Table 2. Goals and Content of Individual Meetings and Group Sessions

Week	Individual Meetings	Group Sessions	Goals & Content
0	X		Assess baseline activity & functioning; introduce intervention rationale & components; identify personal values & goals
0.5	X		Mock session to introduce videoconference platform and troubleshoot issues
1		X	Explore reasons for increasing activity; elicit change talk; rating of perceived exertion; group exercise; time-based pacing & endurance
1.5	X		Individual assessment, amplify change talk, troubleshooting (as needed)
2		X	Review experiences & challenges; discuss beliefs about pain & fatigue; group exercise; brainstorm strategies to address challenges
2.5	X		Individual assessment, amplify change talk, troubleshooting (as needed)
3		X	Review experiences & challenges; discuss benefits of activity for sleep; group exercise; review strategies to address challenges
4		X	Review experiences with activity & sleep; group exercise; develop activity plans
4.5	X		Individual assessment, amplify change talk, troubleshooting (as needed)

4. Mobile health technology (mHealth)

a. Wearable fitness devices

Wearable devices will provide daily feedback to participants on their physical activity and help improve personal attitudes about activity (Figure 1). Principal Investigator Duan-Porter and Co-Investigator Erbes will lead the incorporation of wearable fitness devices (*ie*, Garmin Vivosmart 4) and financial incentives. Wearable devices will be introduced to participants at the first individual meeting with PT, providing time for participants to troubleshoot technical issues before the first group session. We will encourage participants to consistently wear the device on either right or left wrists (per their preference), and calibrate stride lengths.

Participants will receive financial incentives to support their engagement with the wearable device and to add motivation for increasing their physical activity (see section below on incentives). During month 1, participants will determine their physical activity goals at the end of group sessions and we will assist them with setting these goals in their devices. In month 2, goals will be set during weekly telephone calls. In months 3-4, wearable devices (and financial incentives) will continue with no scheduled participant contacts or further increases in activity levels (Figure 2).

To access physical activity and sleep data from wearable devices, we will work with a VA-approved contractor (RTI International, Inc). Device companies routinely obtain and store these data in their databases, as part of standard service to users. RTI will use dummy email identifiers to create and maintain online accounts through the device company (*eg*, "icare001@gowrap.org"). Participants will use the dummy email address to register their devices with the company. Cross-referencing with identifying information is known only to VA study staff. Participant data will be accessed through these accounts, and after the study concludes, participants will disconnect their devices from the study accounts and no further data will be collected or accessed. Participants may choose to share other data through their devices, but RTI will only access physical activity (*eg*, step counts and minutes of moderate intensity activity) and sleep data. No other data (*eg*, participant name or location) will be obtained by RTI. All RTI staff with data access have been trained in HIPAA security and ethics of human subjects research.

RTI will provide weekly data to the VA study team, and once obtained, these data will be stored behind the VA firewall (see section below on protection of participant privacy for full description of information security procedures). VA study staff may review participants' physical activity and sleep data via the company website, in order to provide feedback to participants on their progress. RTI will also assist with generating weekly activity summary progress reports for participants. These will include physical activity data to provide updates on participants' progress towards their activity goals (*eg*, minutes of walking or biking per day). The reports may display physical activity data using graphs and other figures available through the device company accounts (see Appendix 1). Additionally, reports will include messages of encouragement that are tailored to the participants' progress that week (Table 3). Finally, we will provide a short summary statement of financial incentives they should expect (*eg*, "You met your goals on 3 days during this past week. This means you will receive $6."). In all communications with RTI (and materials sent by them), participants will be referred to by their dummy email & device identifier. RTI will not have access to any identifiable participant information.

Table 3. Examples of Tailored Messages

Group 1: Meeting daily activity goals ≥ 5 days per week	Group 2: Meeting daily activity goals 3-4 days per week	Group 3: Meeting daily activity goals 0-2 days per week
You are on the right track!	. You will be on your way to a healthier new you!	New activities can be challenging to do. Take it one day at a time!
You are on your way to a healthier new you!	We know this is tough but keep at it!	We know it is not easy, but it is worth it! Tell a friend what you look forward to most!

b. Video-conferencing

Due to the COVID-19 pandemic and higher risk for group activities, we will conduct all group sessions and some individual meetings (see Appendix 2) via videoconferencing on Zoom, a VA and HIPAA compliant videoconferencing platform. VA ORD permits group meetings via platforms that are approved by the ISSO. Zoom is included in the VA Technical Reference Model (TRM), a list of VA-approved technologies. We will audio-record some sessions to assess intervention fidelity.

We will generate unique Zoom meeting links for each participant's individual sessions and for group sessions. Participants will be required to log into the videoconferencing platform with the unique link. Meeting invitations will be sent from a study-specific VA email address. The

waiting room feature will be enabled for all meetings, so each participant will be let into a meeting by a study team member with host capabilities. No PHI will be included in the subject line and recipents will only see their own email address.

c. Financial incentives

Financial incentives for participants are tied to physical activity data from their wearable devices. After their baseline visit and before group session 1, they will receive $2 for each day that their devices record at least 500 steps. This is to help participants develop the routine of consistently wearing their devices, syncing data, charging and other maintenance. After participants begin setting activity goals (*eg*, group sessions 1-4), they will receive $2 for each day that they meet their daily activity goal, giving a maxium of $14 each week. Participants may need to record the activity on their wearable device to obtain the incentives. However, if an unforeseen device problem arises that prevents the participant from using the device, the participant will receive the incentives during the period of the device issue. Participants will have the option to receive incentives via direct deposit or debit card.

C. Pilot Study to Evaluate Feasbility & Acceptability

We propose to conduct a pilot study of 3 groups with 6-8 participants each (total n=18-24). Based on our clinical and research experience with piloting group interventions, and number of participants in the active arm of recent pilot studies of group exercise interventions for PTSD,[25, 26] we expect that 3 groups will provide sufficient data on feasibility and acceptability to inform a larger study. A control group will not be enrolled as examining efficacy is not appropriate at this stage,[53, 54] and our main goal is to evaluate feasibility and acceptability of the active intervention. Co-Investigator Vogsland will be the PT interventionist conducting in-person assessments, video-conferencing sessions, and telephone calls. We will use a concurrent mixed-methods approach to assess feasibility and acceptability, and anticipate making protocol modifications as appropriate. Data on physical activity, functioning, and symptoms will also be collected, to determine feasibility of outcomes assessments for a future randomized trial.

1. Human Subjects Involvement & Characteristics.

We will screen Veterans being seen in-person or having virtual care appointments at MVAHCS primary care clinics for PTSD (*ie*, ≥3 on Primary Care Screen for PTSD-5) and self-reported health-related limitations in mobility (*ie*, climbing several flights of stairs or walking several blocks). Exclusion criteria include ongoing suicidal ideation or psychosis; medical contraindications to exercise (*eg*, complete paraplegia); high degree of disability (*ie*, impairments in ≥2 basic activities of daily living); plans to move out of the area permanently within 4 months; major neurocognitive impairment (*eg*, dementia), schizophrenia; acute mental health crisis within the past 3 months (requiring an ED visit or hospitalization); and routinely completing 150 minutes or more of moderate to vigorous activity per week. We will not recruit prisoners, institutionalized individuals, or children. Our goal is to conduct 3 groups of 6-8 participants each (18-24 total).

Study participants will be asked to attend group and individual sessions during the first month, to address attitudinal and behavioral barriers to increasing physical activity. Most of these will occur by video-conferencing (see Section B). Participants will be encouraged to safely and gradually increase their daily physical activity. At the baseline in-person visit, participants will be interviewed about personal goals and motivations for increasing physical activity, beliefs about pain and fatigue related to activity, and specific barriers they have encountered in attempting to increase activity. Participants will also undergo assessments of physical functioning, PTSD and depressive symptoms, pain, fatigue, and sleep. During and after the intervention, participants will be interviewed to evaluate feasibility and acceptability of intervention components.

a. Data sources

There will be 3 sources of data for this study: 1) existing VA electronic medical record (EMR) data (from the VA Corporate Data Warehouse [CDW]) to confirm lack of medical contraindications to exercise and to capture baseline health status; 2) physical activity and sleep data collected by wearable devices and accessed via RTI's Wearables Research and Analytics Platofrm (WRAP); and 3) participant assessments, including interviews on acceptability, self-reported data (on physical activity, functioning, mental health symptoms, pain, fatigue, and sleep), 6-minute walking distance, and 30-second sit to stand test. No biological specimens will be involved. To obtain EMR information from CDW for potential participants, we will use social security numbers (SSN) and full names. Participant interviews will be audiorecorded and transcribed by the VA Health Services Research & Development (HSR&D) Transcription Core at the Salt Lake City VA. No protected health information will be shared with non-VA entities.

b. Potential risk to participants

The pilot study proposed in Aim 2 will pose minimal risk to subjects, as the therapeutic risks are no greater than what may occur in routine clinical care. Individual attitudinal and behavioral barriers discussed during intervention sessions are less likely to be of a sensitive nature, compared with therapy sessions for mental health conditions. There is a small risk of injury for participants as they increase their physical activity, but we anticipate recommendations will mainly be for low-intensity activity (*eg*, walking) that are well within the range of normal functioning. Some participants may experience skin irritation related to wearing the fitness device. The main research risks are breach of confidentiality, lost time, and inconvenience associated with participating in a research study. There are no economic risks and minimal social or psychological risks of participating. Participants could potentially feel some stress or discomfort during interviews or responding to surveys, but most questions are not of an especially sensitive nature.

c. Adequacy of protection from risks

The risk of psychological harm is minimal, as described above. Participants will be informed that they do not have to answer any question that makes them uncomfortable. Should participants report moderate to severe symptoms of depression or PTSD, we will discuss these results with participants and if they are not engaged in treatment, we will refer them to mental health resources at the Minneapolis VA. Intervention sessions will be conducted by an experienced PT who will also be trained in motivational interviewing techniques and tools. Risks associated with physical activity will be minimized, beginning with a thorough assessment of baseline activity levels and exercise capacity conducted by PT. The PT interventionist will also instruct participants on proper form and technique for physical activity, to help prevent injuries. Additionally, Veterans with clear medical contraindications to exercise will be excluded from participation. We will teach and reinforce good practices for cleaning the wearable device and protecting skin (*eg*, do not wear too tightly, dry devices as soon as possible after exercise). We will also follow all Minneapolis VA Research protocols related to COVID-19 precautions, including screening of participants via telephone before in-person assessments.

d. Confidentiality and protection of participant privacy

All study data will be stored behind the VA firewall on Minneapolis VA servers and on the VA Informatics and Computing Infrastructure (VINCI) in accordance with VA-approved data security standards. The servers are accessible only to designated, security-cleared, and trained personnel, and data are limited in terms of protected health information to the greatest extent possible. Data on both VINCI and CCDOR specific servers are organized by projects within designated folders for each principle investigator. Only personnel on the study team for a given

project have access to a specific project folder. Approved study personnel must use Windows authentication or Personal Identity Verification (PIV) card to access project data. Thus, all data housed on these servers are secure, and access by unauthorized persons is highly unlikely.

All participants will be assigned randomly generated unique study identifiers that do not contain names or other personal identifying information. The crosswalk linking participants to their identifiers will be stored on secure VA servers (behind the VA firewall), and restricted to approved analysts who are part of the CCDOR Data Team and study team. Electronic data (*eg*, CDW data, scanned surveys, interview transcripts) will be stored on secure VA servers and de-identified as quickly as is feasible.

Physical activity and sleep data will be collected remotely from wearable devices (*eg*, number of steps taken, number of minutes of physical activity, and number of minutes of sleep per day for each participant). These data are transmitted to databases maintained by the wearable device company, per their established protocols for all device users. We will work with a VA-approved contractor, RTI, to access only the data specified above. No other data (*eg*, participant name or location) will be obtained by the contractor or stored in their databases. Also contractor staff with access to data have been trained in HIPAA security and ethics of human subjects research. Physical activity data will be linked via dummy email identifiers, and cross-referencing with identifying information is known only to VA study staff. Data for each participant will be retrieved weekly by RTI and sent to VA study staff. Once obtained, activity data will be stored on secure VA servers behind the VA firewall, using the same procedures as noted above for other participant data.

Emails with meeting information will be sent from a study-specific VA email address. Recipients will not see other email addresses and will be asked not to reply to invitation emails. Encrypted emails with activity summary reports will be sent to each participant separately. In all communications with RTI, participants will be referred to by their dummy email or device identifier.

e. Potential benefits of research to subjects and others

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. If this intervention is subsequently found to be effective, it will lead to improved functioning for many Veterans enrolled in VHA who have PTSD and limitations in functioning. Veterans participating in the pilot study will also have the potential to receive up to a total of $277 for financial incentives tied to meeting daily physical activity goals and for completing the final post-intervention assessments.

The proposed work will be an important step forward in fulfilling the mission of VA RR&D to restore function and enable social reintegration for Veterans. Development of an intervention to improve physical functioning for Veterans with PTSD will address an important gap in existing care. If eventually shown to be effective, this new intervention could be implemented throughout VHA to improve quality of life and enable a full recovery for many Veterans with PTSD. Results from the proposed work may also advance our understanding of how to optimally incorporate mHealth with more traditional types of patient contacts (ie, in-person visits and telephone calls). Effective use of mHealth may offer greater flexibility for VHA clinics looking to implement new programs. Incorporation of mHealth may also increase access to clinical services for Veterans who reside far from VHA facilities.

f. Data and safety monitoring plan

Safety Monitoring: We do not expect any injuries or safety events to occur during the pilot study, as we will be encouraging increased physical activity after a thorough evaluation by an experienced PT interventionist. However, as safeguards, study staff will inquire about any new injury or health problem that may affect participants' ability to engage safely in physical activity,

at regular intervals during the intervention. Participants will also be instructed to contact study staff if any change in health status occurs in between scheduled study follow-ups. The investigative team includes general internal medicine physicians, in addition to the PT interventionist, who will help assess the full range of concerns regarding any changes in participant health status. If an injury is thought to be potentially related to the study, we will follow appropriate MVAHCS IRB policy for reporting and care of participants.

Accuracy and Integrity of Data—Secure Data Infrastructure: VINCI is an HSR&D Resource Center that provides researchers a national view of VA patient data. VINCI is a research and development partnership and operational platform for health services research, epidemiology, decision support, and business intelligence. Partners include VA Office of Informatics and Analysis, and Office of Information and Technology (OIT) Business Intelligence Service Line. VINCI brings together data sources and the analytical environment for performing studies, along with the expertise of data stewards such as VHA National Data Systems (NDS) and VA Information Resource Center (VIReC). New research projects are granted access to dynamic views or data snapshots that can be updated as needed. In addition to data storage, VINCI includes a cluster of servers with dedicated software for analysis, data processing, and extracting information from text. VINCI is accessible from the VA intranet, providing VA researchers with a central, secure location to access data and the applications they need to select, transform, and analyze patient data.

CCDOR also maintains several of its own secure virtual data servers that are protected behind the VA firewall. All individuals with administrative access privileges to the CCDOR servers have been screened and assigned a security clearance to work with patient level data. OIT Administrative access to the data is strictly limited to backing up server data, which prevents catastrophic loss of data. Backups of these servers occur regularly and are stored in a secure location.

2. Recruitment Procedures

Data collection and recruitment will take place at MVAHCS. We will rely primarily on 2 methods of identifying potentially eligible Veterans: 1) primary care staff referral and 2) self-referral.

Staff Referral: Referrals from primary care staff, including Primary Care Mental Health Integration (PCMHI), will provide our first-line recruitment source, as this will closely model how the patients would receive referrals in typical clinic care. We will make announcements about the study in multiple settings and forums (*eg*, announcements at team meetings, presentations at grand rounds). We will provide flyers and brochures to staff and discuss the study with them. We will ask primary care staff to provide potentially eligible Veterans (ie, positive on PTSD screen and without suicidal ideation, see detailed inclusion and exclusion criteria below) with brochures about the pilot study. If a Veteran demonstrates interest, primary care staff will either encourage Veteran to directly call study coordinator (information in brochure) or ask for permission to share their name and telephone number with the coordinator.

Self-Referral: To facilitate self-referral, we will use study fliers and brochures strategically placed in appropriate clinic locations and make announcements to inform primary care staff about the study. Individuals who are self-referred to the study will reach out to study staff to express their interest directly.

Active Outreach: Due to decreased in-person visits during the COVID pandemic (which limit opportunities for staff and self-referrals), we will identify potentially eligible Veterans who have a positive screen for PTSD in the past 2 months through an administrative data pull and recruit these Veterans through mailed letters and telephone calls. We will send out letters introducing the study and providing contact information for individuals to opt out of further contacts. Starting 10 days after the letter is sent, we will make up to 3 calls (on at least 2

different days) to provide more information about the study and conduct eligibility screening, for those who are interested.

3. Inclusion/Exclusion Criteria

To identify Veterans with PTSD symptoms and poor physical functioning who may benefit from the intervention, eligibility criteria are as follows (**Error! Reference source not found.**):

Inclusion: 1) ≥18 years old; 2) patient in primary care at MVAHCS; 3) score ≥3 on Primary Care PTSD Screen (PC-PTSD-5), which is routinely administered during primary care appointments (95% sensitivity and 85% specificity for PTSD diagnosis[55]); 4) "yes" to any of 3 questions about health-related limitations from the Veterans RAND 36-Item Health Survey (VR-36),[56, 57] as an indicator of impaired functioning; 5) has access to device (smart phone, tablet, or computer) that enables participation in videoconferencing; 6) has a smartphone or tablet that can support Garmin application; 7) has internet access for videoconferencing.

Exclusion: 1) active suicidal ideation or psychosis; 2) medical contraindication to participation (eg, complete paraplegia); 3) self-reported impairments in 2 or more activities of daily living (ADLs); 4) plans to move out of area permanently within next 4 months; 5) major neurocognitive impairment (e.g., dementia); 6) schizophrenia; 7) acute mental health crisis within the past 3 months (requiring an ED visit or hospitalization); and 8) routinely completing 150 minutes or more of moderate to vigorous activity per week. Individuals meeting these criteria may be unable to safely increase physical activity at home or not have a need for this program.

For Veterans referred by primary care and PCMHI staff, the study coordinator and/or principal investigator will conduct further eligibility screening using the following sources: 1) review of medical records for exclusion criteria (recent episodes of psychosis and medical contraindications to physical activity); 2) discussion with primary care provider for clarification about potential contraindications, as needed; and 3) telephone call to administer questions on mobility limitations, other health problems, and ADL impairments. For Veterans who self-refer, the study coordinator will first complete the PC-PTSD-5 and screening questions for suicidal ideation. After completing screening for eligibility, the study coordinator will schedule Veterans for a phone call to obtain informed consent and provide additional information on the intervention.

4. Informed Consent Procedures

The study coordinator will schedule a telephone call with Veterans to go over the informed consent form, HIPAA authorization form, and enrollment forms for financial incentives. We will also include other materials to describe the study (*eg*, FAQ document, expectations for confidentiality and privacy during group meetings, and troubleshooting Zoom). We will mail potential participants these materials ahead of the phone call, instructing them not to sign any forms until the call. During the call, the study coordinator will provide a thorough overview of study participation, risks, benefits, alternatives, protections, and IRB and study staff contact information. We will emphasize the voluntary nature of study participation and provide the opportunity for questions about the study. The consent process will be conducted by the study coordinator, who is trained in the ethics of human subject research. Those who agree to participate will mail back signed informed consent and HIPAA authorization forms via prepaid stamped envelopes. Signed informed consent and HIPAA authorization forms will be received by the study team before collection of any participant data.

5. Quantitative Data & Analyses (Table 4)

Feasibility will be quantitatively assessed as **recruitment** (proportion enrolled out of total identified as eligible), **attendance** (proportion who attend ≥ 75% of in-person visits), and **retention** (proportion who complete post-intervention assessments). To determine feasibility, we will first evaluate recruitment and time needed to enroll participants. We anticipate approximately

20 Veterans per month may be eligible (based on preliminary data noted above), and with 20% recruitment, we expect to complete enrollment for each group in 4-6 weeks. We have set attendance and retention benchmarks at 75%, which are realistic estimates based on recent pilot studies of group exercise interventions for PTSD (participants attended an average of 78-82% of sessions and overall retention were 76-82%).[25, 26]

Data on participant **physical activity** will be collected using both wearable devices and self-reported activity dairies. **Physical functioning** will be measured at baseline and post-intervention using VR-36, 6-minute walk,[58, 59] and 30-second sit to stand.[59, 60] Based on our clinical experience, these latter 2 tests can be feasibly administered to detect small but clinically relevant improvements in endurance and lower body strength. We will also assess **PTSD symptoms** (PTSD Checklist for DSM-5 [PCL-5])[61, 62]; **depression** (Patient Health Questionnaire-9 [PHQ-9])[63]; **pain** (brief 3-item scale on intensity and interference [PEG])[64], **fatigue** (PROMIS 4-item short form)[65]; **sleep quality** (PROMIS sleep disturbance and impairment)[66, 67]; **self-efficacy** (PROMIS general 4-item[68] and one item specific to physical activity); and **social support** for physical activity (1 item). We will compare physical activity data from wearable devices and self-reported diaries, for consistency and data quality for these different methods. For measures of physical functioning, PTSD and other symptoms, we will refine procedures for administering assessments and also confirm consistency and data quality.

Table 4. Assessments during Pilot Study.

	Baseline	During Intervention	Post-intervention
Feasibility & Acceptability			
Recruitment, Attendance & Retention		X	X
Acceptability of intervention components (semi-structured interviews)		X	X
Barriers & facilitators to attendance (semi-structured interviews)		X	
Physical Activity & Functioning			
Wearable device physical activity & sleep data		X	
Self-reported physical activity diaries	X	X	X
VR-36, 6-minute walk, 30-second sit to stand	X		X
Medical Conditions & Symptoms			
Medical diagnoses, medications (EMR)	X		
PTSD symptoms (PCL-5)	X		X
Depressive symptoms (PHQ-8)			
Pain (PEG)	X		X
Fatigue (PROMIS 4-item)	X		X
Sleep Disturbance & Impairment (PROMIS)	X		X
Self-efficacy	X		X
Social support for physical activity	X		X

EMR=Electronic Medical Record; PCL-5=PTSD Checklist for DSM-5; PEG=3-item scale on pain intensity and interference; PHQ-9=Patient Health Questionnaire-9; PROMIS=Patient Reported Outcomes Measurement Information System; PSQI=Pittsburgh Sleep Quality Index; VR-36=Veterans RAND 36 Item Health Survey

6. Qualitative Data & Analyses (Table 4)

Qualitative assessments will involve semi-structured interviews at the end of month 2 and post-intervention, to address **acceptability** of intervention components, including session formats and topics and usability of wearable devices. Month 2 interviews will also elicit **barriers and facilitators** to attendance. Interviews will be audiorecorded and transcribed. We will use triangulation to integrate qualitative interview data with quantitative measures of attendance and retention. First, Drs. Duan-Porter and Spoont will apply an established rapid approach for qualitative analysis to identify key themes.[69] This involves reviewing transcripts for the initial 3-4 interviews to develop templates that are then applied to summarizing subsequent transcripts. Summary information will be further reviewed and analyzed using matrices to identify major themes for each main topic (*eg*, acceptability of mHealth components). Then, a matrix will be

developed to compare themes for those who attended 75% of in-person visits with those who did not. A similar matrix will compare themes for those who completed post-intervention assessments and those who did not.

7. Withdrawal of Subjects

Participants can withdraw from the study at any point in time and for any reason by contacting study personnel in person, by telephone, or by mail, and requesting to withdraw. We anticipate termination of participation if:

1. The participant becomes ineligible to participate
2. The participant does not follow instructions from the researchers
3. The study is unexpectedly suspended or canceled.

6.0 REPORTING

Any change in a participant's ability to engage in the physical activity program will be immediately reported by the PT interventionist to Dr. Duan-Porter, the Principle Investigator and communicated to the participant's primary care team. If suicidal ideation is found upon initial eligibility screening by the study staff, they will immediately notify Dr. Duan-Porter, who will undertake appropriate evaluations and clinical referrals. If participants are noted to have severe or worsening PTSD and/or depression symptoms, they will be offered referrals for mental health treatment at MVAHCS. Notably, given the additional clinical expertise of Co-Investigators in rehabilitation medicine and mental health, this study team is well prepared to handle any potential health concerns that may arise.

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APPENDICES

Appendix 1: Example I CARE Participant weekly activity summary report

CARE

Weekly Activity Summary

Activity Log 9/14 – 9/20

Goals -- 10 minutes walking

All activities entered

Sep 19	Walking	1.33 mi	27:52	20:58 min/mi	113 bpm	118 C
Sep 19	Running	1.81 mi	18:52	10:25 min/mi	--	163 bpm
Sep 18	Walking	2.82 mi	52:01	18:27 min/mi	107 bpm	219 C
Sep 17	Running	1.91 mi	15:56	8:21 min/mi	--	173 bpm
Sep 16	Walking	0.39 mi	6:31.0	16:39 min/mi	114 bpm	31 C
Sep 15	Walking	1.50 mi	27:09	18:07 min/mi	107 bpm	118 C
Sep 14	Walking	0.50 mi	12:24	24:42 min/mi	108 bpm	60 C

Reminder—For meeting your daily activity goal, only activities for which your average heart rate is at least 90 beats per minute are counted.
You will receive $8 for meeting your activity goal on 4 days during the past week.
Stay focused. You're making progress!

Appendix 2: Detailed Outline of Topics and Goals for Sessions

Week	Content and Goals

0	**Baseline In-Person Visit (95 min)**
	• **Assessments (30 min)**
	  o Survey—Functioning, mental health symptoms, sleep, pain, & fatigue*
	  o Physical Performance—6-minute walk, 30-second sit to stand, range of motion screen, strength screen, & 4-stage balance test
	• **Introduction to rationale & I CARE schedule (20 min)**
	  o Rating of perceived exertion (handout)
	• **Motivational interviewing (20 min)**
	  o Identify values & beliefs about physical activity
	  o Develop discrepancy between current behavior and values
	  o Readiness rulers—confidence & importance
	• **Introduction to device, activity logs & financial incentives (20 min)**
	  o Set up Garmin Vivosmart 4 & Garmin Connect Application
	  o Instruct on completing activity logs & mailing back
	• **Closing (5 min)**

0.5	**Tech Prep Call (Virtual via Zoom, 30 min)** • Mock session to introduce and troubleshoot Zoom platform issues

1	**Group Session #1 (Virtual via Zoom, 90 min)**
	• **Discussion #1 (30 min)**
	  o Introductions, establish ground rules for group meetings (Expectations & Guidelines Handout)
	  o Elicit participant goals for physical activity & health (Readiness Rulers)
	• **Group exercise (25 min)**
	• **Discussion #2 (15 min)**
	  o Participant experiences with group exercise, rating of perceived exertion
	  o Graded steps to increase activity, time-based pacing (Graded Steps Handout)
	  o I CARE video playlist, elicit other exercise options
	• **Home exercise plan (15 min)**
	  o Plan for week #1 (Home Exercise Worksheet; Readiness Rulers)
	  o Share goals with group
	  o **Closing (5 min)**

1.5	**Individual Session #1 (Virtual via Phone, 10-15 min)**
	• MI:
	  o Readiness ruler
	  o Self-efficacy, develop discrepancy
	  o Amplify change talk, roll with resistance
	• Troubleshooting home activity plan
	  o Review safe space in home
	  o Address level of activity, correct positions, etc.

2	**Group Session #2 (Virtual via Zoom, 90 min)**
	• **Discussion #1 (30 min)**
	  o Elicit experiences with home activity goals (Self-Reflection Worksheet)
	  o Physical activity, pain & fatigue (Activity, Pain & Fatigue Handout)
	• **Group exercise (25 min)**
	• **Discussion #2 (15 min)**
	  o Participant experiences with group exercise
	  o Brainstorm strategies to address challenges, emphasize change talk

	• **Home exercise plan (15 min)**
	  o Plan for week #2 (Home Exercise Worksheet; Readiness Rulers)
	  o Share goals with group
	  o **Closing (5 min)**

2.5	**Individual Session #2 (Virtual via Phone, 10-15 min)** • Troubleshooting home plan • MI: Self-efficacy, amplify change talk, roll with resistance

3	**Group Session #3 (Virtual via Zoom, 90 min)**
	• **Discussion #1 (15 min)**
	  o Elicit experiences with home activity goals (Self-Reflection Worksheet)
	• **Group exercise (25 min)**
	• **Discussion #2 (30 min)**
	  o Participant experiences with group exercise
	  o Physical activity and sleep (Better Sleep Guidelines and Worksheet)
	• **Home exercise plan (15 min)**
	  o Plan for week #3 (Home Exercise Worksheet; Readiness Rulers)
	  o Share goals with group
	  o **Closing (5 min)**

4	**Group Session #4 (Virtual via Zoom, 90 min)**
	• **Discussion #1 (20 min)**
	  o Elicit experiences with home activity goals (Self-Reflection Worksheet)
	  o Elicit experiences with sleep changes (Better Sleep Worksheet)
	• **Group exercise (25 min)**
	• **Discussion #2 (20 min)**
	  o Participant experiences with group exercise
	  o Review physical activity, pain, fatigue, and sleep concepts
	• **Home exercise plan (15 min)**
	  o Plan for next 4 weeks (Home Exercise Worksheet; Readiness Rulers)
	  o Share goals with group
	• **Closing statements (10 min)**

4.5	**Individual Session #3 (Virtual via Phone, 10-15 min)** • Troubleshooting home activity plan for next month • MI: Self-efficacy, amplify change talk, roll with resistance
5-8	**Individual Sessions #4-7 (Virtual via Phone, 10-15 min, weekly)** • Troubleshooting home activity plan • Gradually increase activity goals • MI: Self-efficacy, amplify change talk, roll with resistance

16	**Final In-Person Assessment (60 min)**
	• Post-intervention Assessments:
	  o Physical functioning (VR-36,[56,57] 6-minute walk,[58,59] and 30-second sit to stand[59,60])
	  o Other study measures*
	• **Disconnect Garmin Vivosmart 4 device from I CARE Study account**

**PTSD symptoms (PTSD Checklist for DSM-5 [PCL-5][61,62]); depressive symptoms (Patient Health Questionnaire-8 [PHQ-8][63]); pain (brief 3-item scale on intensity and interference [PEG][64]); fatigue (PROMIS 4-item fatigue short form[65]); sleep quality (PROMIS sleep disturbance and impairment)[66, 67]; self-efficacy (PROMIS general 4-item[68] and one item specific to physical activity); and social support for physical activity (1 item).*