

Taking Action to Reduce Pain

Funding Agency: VA HSR&D

Principal Investigator/Study Chair: Diana Burgess, PhD

June 9, 2020

Abstract

Our long-term goal is to improve the quality and equity of pain treatment in order to improve pain outcomes for all Veterans. The objective of this application is to test the effectiveness of a multi-component intervention that specifically targets known barriers to effective pain care among black Veterans with chronic MSK pain. This project will result in a non-pharmacological intervention to reduce pain and improve functioning among Veterans in VA care suffering from chronic musculoskeletal (MSK) pain, by increasing walking. This intervention is specifically designed to address factors that contribute to MSK pain among black Veterans; however, we expect that it will also benefit non-black Veterans.

The primary aim of this four-year project is to test the effectiveness of a non-pharmacological, self-regulatory intervention administered proactively by telephone, at improving pain outcomes and increasing walking among black Veterans. We will explore whether the intervention reduces service utilization and opioid analgesics and conduct a process evaluation. These aims will be pursued in three phases: intervention content refinement (Phase 1, year 1); intervention recruitment, implementation, and baseline data collection (Phase 2, years 2-3); and post-intervention process and outcome data collection and evaluation (Phase 3, years 2-4).

Our central hypothesis is that an intervention that uses Action Planning, motivational techniques, and a pedometer-based program to increase walking will improve chronic pain outcomes for black VA patients with MSK pain. We will also test the effectiveness of the intervention on Veterans with MSK pain who are not black, many of whom also experience suboptimal pain treatment and have similar contributors to pain as black Veterans.

Our hypothesis is based on several lines of supporting research evidence. First, physical activity can reduce chronic musculoskeletal pain and improve function. Second, research demonstrates that proactive telephone outreach (in which a counselor reaches out to patients to offer them the intervention, rather than requiring the patients to seek out care) can address utilization-related and provider-related barriers that black Veterans experience. Third, pedometer-based walking programs are effective at increasing walking for various groups. Fourth, making an Action Plan (specifying when, where, and how the behavior will be performed) increases the likelihood that individuals will perform intended behaviors and overcome psychological and environmental barriers. Finally, black patients desire non-pharmacological approaches to pain treatment, such as including exercise.

List of Abbreviations

CCDOR: Center for Chronic Disease Outcomes Research

CDW: Corporate Data Warehouse

COT: Chronic opiate therapy

EMR: Electronic Medical Record

HSR&D: Health Services Research & Development

IC: Intervention Condition

IMMPACT: Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials

MED: Morphine equivalent dose

MI: Motivational Interviewing

MSK: Chronic musculoskeletal

NEPEC: North East Program Evaluation Center

OA: osteoarthritis

OST: opioid substitution therapy

PEG: brief pain intensity and interference scale

PHQ: Patient Health Questionnaire

PSEQ: Pain Self-Efficacy Questionnaire

PTSD: Post Traumatic Stress Disorder

RMD: Roland and Morris Disability Questionnaire

TSK-R: Tampa Scale of Kinesiophobia

UC: Usual Care VA: Veterans Affairs

WOC: worker without compensation

VINCI: VA Informatics and Computing Infrastructure

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Protocol Title: Taking Action to Reduce Pain

1.0 Study Personnel

Principal Investigator:

Diana Burgess, PhD; diana.burgess@va.gov, 612-467-1591; VA employee
Minneapolis VAHS

Co-Investigators:

- Brent Taylor, PhD; Brent.Taylor2@va.gov; 612-467-4941; VA employee
Minneapolis VAHS
- Erin Krebs, MD, MPH. Erin.Krebs@va.gov; 612-467-7558; VA employee
Minneapolis VAHS
- Steven Fu, MD, MSCE. Steven.Fu@va.gov; 612-467-2582; VA employee
Minneapolis VAHS
- Laura Meis, PhD. Laura.Meis@va.gov; 612-467-4516; VA employee
Minneapolis VAHS
- Robert Kerns, PhD. Robert.Kerns@va.gov; 203-932-5711 x3841; VA employee
VA Connecticut Healthcare System
- Alicia Heapy, PhD. Alicia.heapy@va.gov; 203-932-5711 x2299; VA employee VA
Connecticut Healthcare System
- Joseph Goulet, PhD. Joseph.Goulet@va.gov; 203-932-5711 x5325; VA
employee VA Connecticut Healthcare System
- Kelli Allen, PhD. Kelli.Allen@va.gov; 919.286.0411 Ext:7090; VA employee;
Durham VAMC
- Sarah Krein, PhD. Sarah.Krein@va.gov; 734-845-3621; VA employee; Ann Arbor
VAMC
- Patrick Hammett, PhD, Patrick.hammett@va.gov; VA employee; Minneapolis VAHS
- Elizabeth Goldsmith, MD, MS, elizabeth.goldsmith2@va.gov; VA employee; Minneapolis
VAHS

Collaborators:

- a. Emily Hagel Campbell; Emily.HagelCampbell@va.gov; VA employee; Minneapolis
VAHS
- b. Ann Bangerter; ann.bangerter@va.gov; VA employee; Minneapolis VAHS
- c. Sean Nugent; sean.nugent@va.gov; VA employee; Minneapolis VAHS
- d. Andrea Cutting; andrea.cutting@va.gov; 612-467-1881; VA employee; Minneapolis
VAHS
- e. Tam Do, tam.do3@va.gov; VA employee; Minneapolis VAHS
- f. Lee Cross, MPH; lee.cross@va.gov; VA employee; Minneapolis VAHS

- g. Mark Ackerman, PhD. Mark.ackerman1@va.gov. 404-321-6111; VA employee; Atlanta VA
- h. Michael Saenger, PhD. Micahel.saegner@va.gov. 404-321-6111; VA employee; Atlanta VA

2.0 Introduction

Rationale for the proposed study

Chronic musculoskeletal (MSK) pain is one of the most common conditions among Veterans, affecting approximately 60% of those seen in VA primary care.³¹ As in the greater population, pain among Veterans is most often located in the back, hip, or knee.³¹ Since 2000, the prevalence of low back pain has been increasing at an annual rate of 4.8% among VA users.³² This is particularly worrisome because chronic pain is associated with poorer self-reported health status, worse mental health, and lower levels of employment.³³ Importantly, chronic pain is associated with lower satisfaction with VA care. Only 28% of patients receiving VA pain treatment report very good or excellent pain treatment effectiveness.³¹

Numerous studies conducted over the past two decades, including studies conducted in the VA, have documented racial and ethnic disparities in pain and pain treatment.^{1,2,8,33}

Racial and ethnic minority groups report greater pain-related disability, physical and emotional impairment, and pain severity when compared to whites.^{1,2} In the VA, for instance, black male Veterans who reported receiving treatment for chronic pain perceived their pain treatment as less effective than white male Veterans and reported higher levels of pain interference (the extent to which pain interfered with their normal work over the past 4 weeks).⁸

Contributors to racial and ethnic disparities in pain are complex and multi-level. One set of barriers involves utilization of healthcare. Minority patients are more likely than whites to have unmet medical needs due to myriad factors, including discrimination and mistrust of healthcare (associated with avoiding and delaying care), poorly coordinated care, lack of a primary care provider, and logistical barriers (e.g., lack of childcare and transportation).^{2,14} Many minority patients report experiencing pain for many years before receiving appropriate pain treatment.² A second set of barriers (provider-related) involves how patients are treated by their providers within the healthcare system. Minorities are more likely to have their pain discounted and underestimated,⁴ to have poor quality communication with their providers,¹⁵ and are less likely to be screened for and given pain medication (including opioids) compared with whites.⁵⁻⁷ A third set of barriers (psychological) involves patient beliefs and attitudes that contribute to poor pain outcomes (e.g., pain-related fear of movement, low perceived control over pain), which members of minority groups are more likely to hold.^{3,10-12} A fourth set of barriers (environmental) involves factors outside of healthcare in the patient's "life space."³⁴ These include life stressors disproportionately experienced by minorities that are associated with pain, such as racial/ethnic discrimination,¹³ and environmental barriers to engaging in physical activity (e.g., lack of time to walk, unsafe neighborhoods).^{12,35}

Although the VA is a leader in pain management, minority Veterans continue to experience greater barriers to high quality pain care than white Veterans. For example, black VA patients are less likely to be screened for pain than white patients⁵ and are less likely to perceive their chronic pain treatment to be effective.⁸ There is also evidence of racial differences in prescription of pain medication in VA,^{7,36} suggesting that providers are using race in clinical decisions about pain treatment. Minority VA patients also report utilization barriers, such as dissatisfaction with the VA (which patients identified as a barrier to utilizing VA care),¹⁵ provider-level barriers such as poorer quality communication with healthcare providers and greater dissatisfaction with interpersonal care compared with whites,¹⁵ environmental barriers, such as racial discrimination (which was associated with higher levels of pain among older black Veterans),¹³ and psychological barriers, such as lower levels of pain/exercise self-efficacy.^{3,10,11}

The proposed intervention addresses contributors to pain among Black Veterans that exist at multiple levels. This intervention takes a biopsychosocial approach to chronic pain, which acknowledges not only the physiological basis of pain but also the importance of psychological and environmental factors in contributing to and relieving pain.⁹ It consists of 6 telephone-based coaching sessions over 10-12 weeks in which: 1) Motivational Interviewing (MI) and Cognitive/Motivational techniques will be used to increase patients' motivation to walk and address anticipated barriers to walking (e.g., fear of movement, low self-efficacy), and 2) Action Planning will be used to help translate patients' motivation and intention to walk into walking behavior. Below we describe how different classes of barriers will be addressed through specific components of the intervention.

-Barriers related to utilization of VA care will be addressed through the use of proactive telephone outreach in which the counselor initiates the call to Veterans, who have been identified as having a diagnosis of chronic hip, back, or knee pain in their medical record, as compared to "reactive care," in which the individual Veteran must initiate treatment. Additionally, the use of proactive, telephone-based care addresses barriers such as lack of transportation and negative healthcare experiences which have been associated with lower levels of healthcare utilization and unmet medical needs among blacks.¹⁴

-Provider-related barriers will be addressed through the use of counselors trained in MI techniques, which emphasizes supportive and respectful care, reflective listening, and patient-driven decision making. This addresses communication barriers that minority patients often experience within the VA healthcare system.¹⁵ These communication barriers are likely to be compounded for minority patients with chronic pain, as many providers view chronic pain patients as a major source of frustration³⁷ and many chronic pain patients express feeling disrespected, distrusted, and dismissed by their providers.¹⁶

-Psychological and environmental barriers. The intervention is specifically designed to address psychological barriers to effective self-management (e.g., lower levels of self-efficacy in coping with pain and greater levels of pain-related fear),^{3,10,11} and environmental barriers to engaging in physical activity (e.g., unsafe neighborhoods)¹² that are greater among minority patients. This is important, as a large number of primary care providers do not feel adequately trained to treat

the non-biomedical aspects of chronic pain, and therefore do not address psychological and environmental barriers. A key component of the intervention is ---Action Planning (also called “Implementation Intentions”), a specific volitional technique (distinct from goal setting), which has been shown to increase the likelihood that individuals will translate their intentions into actions, and overcome psychological and environmental barriers to enacting the behavior. Action Planning works by creating “if-then” contingencies, so that cues in the environment trigger the desired behavior (e.g., “if it is nighttime and I haven’t walked, and I feel unsafe walking outside, I will walk inside my apartment before I go to bed”). Although there have been a number of studies that have used Action Planning to increase physical activity,²⁶ we could locate only one study that used Action Planning to promote physical activity in chronic pain patients,³⁸ and could find no studies targeting black or minority patients.

There is growing consensus that chronic pain treatment should involve more than pharmacotherapy, and strong evidence to support the effectiveness of physical activity for MSK pain.^{17,18} Although studies have documented racial disparities in pain pharmacotherapy, especially in use of opioid analgesics,⁶ simply increasing the use of opioid analgesics to treat minority individuals with MSK pain would be a less than ideal solution. There is a lack of data on the long-term effectiveness and safety of opioids for this purpose and evidence of serious risks associated with opioids.³⁹ Federal reports document rising incidence of emergency department visits, hospitalizations, and deaths related to opioid analgesic use that have paralleled the increasing use of opioids for chronic pain management. Moreover, our own research found that 84% of black and 79% of white MSK patients with opioid prescriptions reported substantial functional interference due to pain, pointing to the need for additional pain treatment modalities.⁷

Physical activity has been shown to prevent recurrence or reduce pain, improve functional status, and decrease sick leave and disability for back pain and osteoarthritis pain.^{17,18,40} Overall, members of racial/ethnic minority groups, including those with chronic pain,⁴¹ are more likely to be sedentary and less likely to engage in physical activity than whites.⁴² Moreover, many individuals are unaware of the beneficial effects of physical activity on MSK pain, and levels of physical activity among people with MSK pain are low.³¹ The documented challenges of increasing physical activity among the sedentary are compounded for patients with MSK pain, who often anticipate pain related to physical activity and so avoid it (“fear-avoidance behavior”) and who often do not believe that they will be able to engage in exercise (“low exercise self-efficacy”).⁴³ These challenges are greater among minority patients with MSK pain, who are more likely to experience these psychological barriers than whites.^{3,10-12} Nonetheless, despite these barriers to exercise, many minority patients desire non-pharmacological approaches to pain treatment, including the use of exercise,²⁸ and prefer walking to other forms of exercise.⁴⁴ This gap between minority patients’ desire to exercise and actual exercise behavior represents an opportunity for our intervention to capitalize upon.

Research and theory underlying the proposed project

The conceptual framework shown in Figure 1 summarizes the key components of the proposed intervention and how they are expected to improve pain outcomes. The

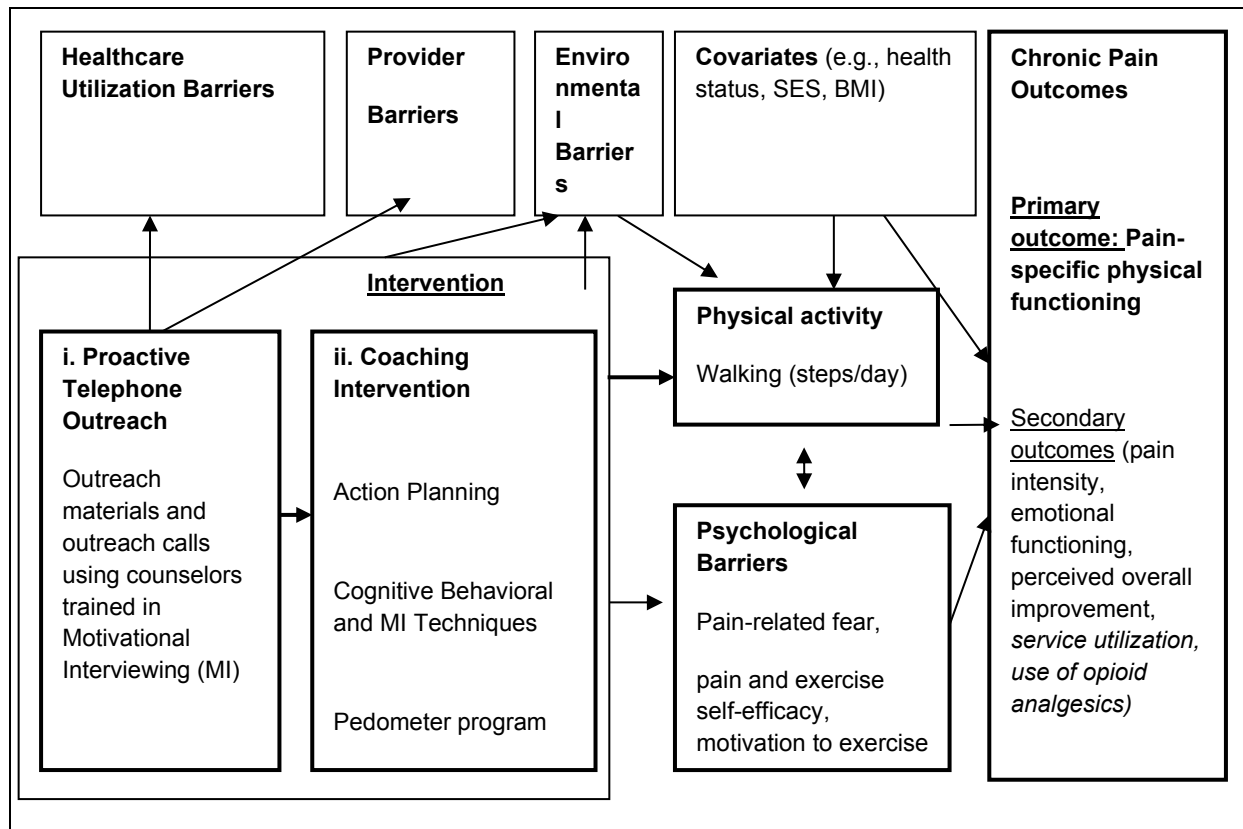
intervention is based on the chronic pain and exercise literature and studies of physical activity and health behavior; it incorporates constructs from different theories of behavior change, most notably theories of self-regulation and Action Planning, and the Theory of Planned Behavior.⁴⁵⁻⁴⁸

- Proactive Telephone Outreach and Motivational Interviewing (MI) techniques will be used to engage patients in the intervention and overcome barriers related to utilization of care and provider-related barriers (e.g., communication).
- Action Planning will be used to translate intentions to walk into actual walking behavior (i.e., volition).⁴⁵⁻⁴⁸
- Two Master's level counselors will also use MI, Motivational/Cognitive techniques and Action Planning to help participants overcome environmental barriers to exercise through problem-solving, coping skills coaching, and plan-making using the techniques of coping planning (i.e., making plans to overcome barriers),⁴⁹ supportive/ facilitative planning (i.e., making plans to increase and strengthen helpful factors),⁴⁵ and collaborative planning (i.e., making plans that involve friends and family members).⁵⁰ Motivational and Cognitive techniques will be used to overcome psychological barriers to exercise (pain-related fear, low self-efficacy for exercise and coping with pain). Self-efficacy is particularly important, as a recent review identified self-efficacy as the strongest predictor of intentions to walk more.⁴⁵
- Pedometers will be used as a tool to promote walking through feedback, goal setting, and monitoring.^{20,51}

The intervention is expected to improve *pain outcomes* through multiple mechanisms:

Increased physical activity is expected to lead to improved emotional functioning, decreased sedentary time, reduced pain-related fear and self-protective behaviors associated with reduced muscle tone, and increased pain perceptions and functional disability. Reductions in pain-related fear and improved self-efficacy are also expected to improve pain directly.¹⁰ Evidence for the key intervention components is discussed below *and in Table 1, which summarizes prior studies that demonstrate the acceptability, feasibility, and potency of the proposed intervention in the target population.*

Figure 1: Conceptual Model



Description and Justification for the Key Intervention Components

I. Proactive Telephone Outreach

The proposed study will use Proactive Telephone Outreach to offer the intervention to patients. Specifically, the intervention will be offered “proactively” to patients from the Atlanta VA Medical Center with diagnoses of hip, knee, and back pain by counselors trained in MI. MI is a patient-centered method whose main purpose is to help the participant explore and resolve ambivalence about a particular behavior change. The counselor avoids confrontation and takes advantage of opportunities to enhance self-efficacy by pointing out and reinforcing the patient’s strengths and successes. This approach addresses several contributors to racial/ethnic pain disparities. Proactive telephone outreach addresses barriers to healthcare utilization as the program does not require a medical care encounter and is delivered in the patient’s own home. The use of counselors trained in MI, which emphasizes collaboration with and respect for the patient also addresses provider barriers related to expectations of poor interpersonal treatment that prevent chronic pain patients and minority patients from seeking help from their usual provider. Importantly, a recent trial found a smoking cessation intervention that incorporated proactive outreach and MI (led by Co-I Dr. Steven Fu (VA HSR&D #05-303)) to be effective at reducing smoking among VA patients across several racial/ethnic groups, including black patients. Similarly, a telephone-based osteoarthritis (OA) self-management program (VA HSR&D IIR #04-016), conducted by Co-I Dr. Kelli Allen, in which a health educator delivered

treatment proactively to patients with OA, improved chronic pain outcomes among black OA patients in the VA system⁵² and was viewed by black Veterans as helpful for improving their OA symptoms.⁵³

II. Pedometer-Facilitated Walking Intervention with Action Planning

Pedometer-Facilitated Walking. The pedometer-facilitated walking program used in conjunction with Action Planning (described below) will be used to promote walking directly through goal setting, monitoring, and feedback. As in Dr. Sarah Krein's and Dr. Alicia Heapy's walking interventions, participants will be asked to increase their daily walking 10% over the previous week's daily average. Walking is considered an ideal exercise as it is something that most people can do regardless of their health condition and does not involve the use of specialized equipment. The feasibility and safety of home-based walking programs for individuals with chronic health conditions, including chronic musculoskeletal pain conditions, have been previously demonstrated.^{54,55} Additionally, studies suggest that a majority of middle-aged and older adults, including racial and ethnic minorities, prefer physical activity outside a formal setting,⁵⁶ and that participation rates and maintenance of physical activity are generally better in home-based programs.⁵⁷ Pedometer-based walking programs have been shown to increase walking across different patient populations.²⁰ Moreover, a recent systematic review of pedometer interventions found significant decreases in systolic blood pressure and body mass index.²⁰ This same systematic review found that setting a step goal and using a step diary were key components underlying the success of pedometer programs.²⁰ *Most pertinent to the current study is a recent trial conducted by Co-I Dr. Krein, in which a pedometer-mediated walking program improved pain outcomes among VA patients with chronic low back pain.* Although the majority of individuals in pedometer trials are white, three recent trials found pedometer interventions to be effective at increasing walking and improving objective measures of health among blacks²¹⁻²³ and a predominantly minority sample of low-income mothers,²⁴ although these studies did not target patients with pain.

Action Planning. Forming an Action Plan—a tailored strategy that specifies when, where, and how the person will perform a specific behavior—has been shown to be a very effective self-regulatory tool for translating intentions into action. Hundreds of studies have shown that forming an action plan increases the likelihood that one will engage in an intended behavior, compared with simply forming an intention to achieve a goal.^{25,26} A 2006 meta-analysis of 94 independent trials, which included numerous studies of health-related behaviors, found medium-to-large effects of implementation intentions on goal implementation.²⁵ Action Planning has been successfully used to promote exercise (including walking) in clinical and nonclinical populations (including chronic pain patients), and has been shown to be more effective than motivational interventions consisting of goal-setting alone (see *meta-analysis #7 in Table 1*).^{26,38,45-47} For example, in one study with chronic low back pain patients, those who participated in an intervention using Action Planning and motivational and cognitive techniques to increase physical activity had increased their physical capacity relative to controls.³⁸

Action Planning works by using situational cues to automatically trigger an intended behavior (e.g., “After I eat dinner, I will go for a walk with my wife”) so that, over time, the behavior becomes a habit that is enacted in the presence of those cues (e.g., after dinner, with one’s wife). Action Planning has been shown to be particularly effective among patients with impaired self-regulatory capacity and for individuals in situations in which self-regulatory capacity is temporarily diminished, because it automates desired behaviors so that individuals do not have to exert conscious effort (or “willpower”) to engage in the behavior.^{58,59} Because pain has been shown to reduce self-regulatory capacity, Action Planning should be particularly beneficial for pain patients.⁴⁸ Members of negatively stereotyped groups such as blacks also experience many situations that temporarily diminish regulatory capacity, such as social exclusion, racial discrimination, and stereotype threat (feeling that one is at risk of being negatively stereotyped).^{60,61} For this reason, Action Planning should be especially beneficial for black patients. Moreover, certain types of action plans-- Coping Planning⁴⁹ and Facilitative Planning⁴⁵ --can help individuals overcome barriers and leverage supportive factors in their environment (e.g., “if I have a very busy day, I will walk around the block for 5 minutes after breakfast, lunch, and dinner,” “if the weather is bad, I will walk in the mall,” “if I am afraid of hurting myself, then I will remember that walking will help me with my pain”³⁸). Friends and family members have been shown to be important supportive factors that increase the likelihood that an Action Plan will be successful, and our intervention will explicitly guide participants to develop at least one Action Plan that incorporates friends or family members as part of the plan (i.e., Collaborative Planning).⁵⁰

Given that Black veterans with MSK pain are more likely to report lower self-efficacy for coping with pain and greater pain-based fear of movement, intervention counselors will be trained to address these barriers during Action Planning with specific cognitive techniques. Counselors will inquire about beliefs and thoughts that support fear of movement and diminish self-efficacy and challenge these thoughts using accepted cognitive/motivational methods such as Socratic questioning and reframing of negative thoughts with more realistic and positive ones. These techniques have been used successfully in combination with Action Planning in an intervention with chronic low back pain patients.³⁸ *Self-management approaches to chronic pain, which include self-efficacy building, goal-setting and action-planning, problem-solving, and partnership have been shown to be effective at improving pain among patients with arthritis.*

3.0 Objectives

Primary Aim: To test the hypothesis that the intervention will improve chronic pain-specific physical functioning—the primary outcome, improve emotional functioning, pain intensity and ratings of overall improvement and increase walking, compared to UC for black patients with chronic hip, back, and knee pain.

Secondary Aim 1: To investigate whether key contributors to racial/ethnic disparities targeted by the intervention (motivation to exercise, pain/exercise efficacy, reduction of pain-related fear) mediate improvement in chronic pain outcomes and increases in walking.

Secondary Aim 2: To explore whether the intervention reduces service utilization and use of opioid analgesics.

Secondary Aim 3: To determine if the intervention is effective for non-black VA patients and other subgroups of patients who may experience barriers to effective pain treatment.

Secondary Aim 4: To explore whether the intervention reduces racial disparities in pain outcomes.

4.0 Resources and Personnel

Research Sites

1. Center for Chronic Disease Outcomes Research, Minneapolis VA, Minneapolis, MN.
 - a. Data extraction will take place at the MPLS VA
 - b. Intervention will be administered by counselors here, to participants over the telephone.
 - c. The study coordinator, research assistant, and support staff at the MPLS VA, all trained interviewers, will collect survey data via phone and mail at the MPLS VA
 - d. Data will be analyzed here
2. Atlanta VA (not considered an engaged site requiring an LSI)
 - a. Focus groups (Phase 1) will be conducted here

Principal Investigator: Diana Burgess, PhD; diana.burgess@va.gov, 612-467-1591; VA employee Minneapolis VAHS;

- a. Will have access to protected health information (in the course of interviewing participants)
- b. Will be involved in recruiting subjects; obtaining informed consent; administering interview procedures/conducting interviews; and performing data analysis of de-identified qualitative data.

Co-Investigators:

1. Brent Taylor, PhD; Brent.Taylor2@va.gov; 612-467-4941; VA employee Minneapolis VAHS;
 - a. Role: lead statistician
 - b. Will not have access to protected health information
 - c. Will be involved in performing data analysis of de-identified quantitative data. Will participate in manuscript writing.
2. Erin Krebs, MD, MPH. Erin.Krebs@va.gov; 612-467-7558; VA employee Minneapolis VAHS

- a. Role: Co-Investigator
 - b. Will be a part of the Intervention & Measures Subgroup, and will contribute her research expertise on chronic pain measurement and her clinical expertise in chronic pain management. Will participate in manuscript writing. Will not have access to protected health information.

3. Steven Fu, MD, MSCE. Steven.Fu@va.gov; 612-467-2582; VA employee
Minneapolis VAHS;
 - a. Role: Co-Investigator
 - b. Will serve as a member of the Intervention & Measures and the Implementation/Dissemination subgroups. Will participate in manuscript writing. Will not have access to protected health information.

4. Laura Meis, PhD. Laura.Meis@va.gov; 612-467-4516; VA employee
Minneapolis VAHS;
 - a. Role: Co-Investigator
 - b. Will help train and supervise the counselors and participate as a member of the Intervention & Measures Subgroup. Will participate in manuscript writing. Will have access to protected health information only if a mental health crisis with a participant requires it. Will perform data analysis of de-identified qualitative data (for quality assurance checks).

5. Robert Kerns
 - a. Role: Co-Investigator
 - b. Will play a key role in dissemination and implementation activities, within and outside the VA, as a member of the Dissemination/Implementation Subgroup, and provide consultation throughout the course of the project. Will participate in manuscript writing. Will not have access to protected health information.

6. Alicia Heapy
 - a. Role: Co-Investigator
 - b. Will lead the intervention component of this project, and a member of the Intervention & Measures Subgroup. Will not have access to protected health information. Will perform data analysis of de-identified qualitative data (for quality assurance checks).

7. Joseph Goulet
 - a. Role: Co-Investigator
 - b. Will provide guidance on use of ICD pain code measures by assisting our local programmer, Ann Bangerter Dr. Goulet will serve as a member of the Intervention & Measures Subgroup. Will not have access to protected health information or any of our data. We do not consider New Haven to be an engaged site because they will not have access to the data.

8. Kelli Allen
 - a. Role: Co-Investigator
 - b. Will serve as a member of the Intervention and Measures Subgroup, where she will help refine intervention content and recruitment and retention strategies based on her extensive expertise in this area. Will participate in manuscript writing. Will not have access to protected health information

9. Sarah Krein
 - a. Role: Co-Investigator
 - b. Will serve as a member of the Intervention and Measures Subgroup. Dr. Krein's role will also be to provide implementation expertise and to participate in the Dissemination/Implementation Subgroup. Will participate in manuscript writing. Will not have access to protected health information.

10. Patrick Hammett, Patrick.hammett@va.gov; VA employee; Minneapolis VAHCS
 - a. Role: Co-Investigator
 - b. Will not have contact with research participants
 - c. Will have access to protected health information
 - d. Will help with data analysis and manuscript writing.

11. Elizabeth (Lizzy) Goldsmith; elizabeth.goldsmith2@va.gov; VA employee; Minneapolis VAHCS
 - a. Role: Co-Investigator
 - b. Will not have contact with research participants
 - c. Will have access to protected health information
 - d. Will help with data analysis and manuscript writing.

Collaborators:

1. Emily Hagel Campbell; Emily.HagelCampbell@va.gov; VA employee; Minneapolis VAHS
 - a. Role: statistician
 - b. Will only have access to protected health information when creating a de-identified quantitative dataset
 - c. Will not have contact with research participants
 - d. Will be involved in performing data analysis of de-identified quantitative data
2. Ann Bangerter; ann.bangerter@va.gov; VA employee; Minneapolis VAHS
 - a. Role: programmer
 - b. Will have access to protected health information
 - c. Will not have contact with research participants
3. Sean Nugent; sean.nugent@va.gov; VA employee; Minneapolis VAHS
 - a. Role: programmer
 - b. Will have access to protected health information
 - c. Will not have contact with research participants
4. Andrea Cutting, andrea.cutting@va.gov; VA employee; Minneapolis VAHS
 - a. Role: programmer
 - b. Will have access to protected health information
 - c. Will not have contact with research participants
5. Tam Do, tam.do3@va.gov; VA employee; Minneapolis VAHS
 - a. Role: Study Supervisor
 - b. Will have access to protected health information
 - c. Will be involved in recruiting subjects and obtaining consent, and conducting counseling sessions over the telephone
6. Lee Cross, MPH, lee.cross@va.gov; VA employee; Minneapolis VAHS
 - a. Role: Study Coordinator
 - b. Will have access to protected health information
 - c. Will be involved in recruiting subjects, obtaining consent, and conducting surveys over the telephone
7. Mark Ackerman, mark.ackerman@va.gov; VA employee; Atlanta VA
 - a. Role: consultant
 - b. Will NOT have contact with patients or see any kind of data

- c. Will help schedule rooms at Atlanta VA for phase 1 focus groups
 - d. Will help with manuscript writing
8. Michael Saegner, Michael.saegner@va.gov; VA employee; Atlanta VA
- a. Role: consultant
 - b. Will NOT have contact with patients or see any kind of data
 - c. will help with manuscript writing

5.0 Study Procedures

5.1 Study Design

Phase 1 Focus Groups: This is a 4-year study. **In study month 2**, we will conduct focus groups with black patients with hip, back and knee pain at the Atlanta VAMC, using algorithms derived from 14 ICD9 codes that capture the most commonly used chronic pain codes. ICD codes are grouped (e.g. connective tissue disorder) using AHRQ groupings.

- We will use a brief telephone screener to select patients that meet the following criteria: 1) presence of pain (using the three-item PEG, a brief pain inventory that measures average pain intensity, interference with enjoyment of life, and interference with general activity,^{80,81} 2) lack of cognitive impairment (using the six-item Callahan screener that identifies cognitive impairment for potential research subjects)⁷⁷.
- We will use these focus groups to refine the recruitment materials (recruitment letter, brochure, and recruitment scripts), counselor communication strategies and pedometer instructions, and collect additional information on barriers to walking.
- Veteran tips will also be sought for increasing likelihood of phone contact with potential candidates for the intervention and control groups.
- We will use Rapid Assessment Process (RAP) methods to obtain the insights needed to modify these materials in a timely way.

In study month 4, we will conduct two additional patient focus groups to obtain feedback on modified versions of these materials, based on input from the first two focus groups.

This use of focus groups to refine intervention content is modeled on a process successfully used by Drs. Fu and Burgess in Dr. Fu's Veterans Victory study. The moderator will use a semi-structured interview guide, modified from one developed for the Veterans Victory study by nationally recognized focus group experts Dr. Mary Anne Casey and Dr. Richard Krueger. Veteran expectations of the counselor regarding communication will be elicited by prompting Veterans to recall past experiences with their health care providers, particularly during visits in which they sought treatment for pain and during visits in which they had negative experiences (as negative experiences have been shown to have outside influence on individuals).

Phase 2 Pilot: We will recruit three African American Veterans from the Atlanta VAMC using the same methods for Phase 2 in order to pilot the counseling portion of Phase 2. (These will not be any participants from Phase 1 and these participants will be excluded from Phase 2.)

Participants will receive the information sheet along with the recruitment letter. The participant will be called 7-14 days after the letter has been mailed and the interviewer will assess interest and conduct the phone screener to see if the participant fits eligibility criteria. If the participant meets eligibility criteria and is interested, research staff will confirm the mailing address and mail out a pedometer with the with the accompanying cover letter and information sheet, pedometer instructions and pedometer Q&A. While recruiting participants, study staff will be sure to emphasize to read the information sheet carefully, and that they are voluntarily choosing to consent by being willing to participate. The first counseling session will be 60-75 minutes. This allows 30-45 minutes for the counseling portion and 15-30 minutes for feedback following the intervention. The following session will be 45-60 minutes, allowing 30 minutes for counseling and up to 30 for feedback. Any questions regarding feedback will be asked by research staff other than the interviewer to allow the participant to give their full and honest opinion of the session.

Phase 2: Intervention recruitment, implementation, baseline data collection, 3 month outcome data collection, 6 month follow-up outcome data collection, (Phase 2) and post-intervention evaluation (Phase 3). We will identify 500 black and 500 non-black patients with diagnoses of hip, back, and knee pain from the Atlanta VAMC, using algorithms derived from the 14 ICD9 (and ICD10 code conversions) that capture the most commonly used chronic pain codes (data will be extracted at the Minneapolis VA and will not leave this site). We have chosen the Atlanta VAMC because it has a high percentage of black patients (43%). We have elected to focus on chronic hip, back, and knee pain as the literature supports the efficacy of walking for these conditions, and these are the most common chronic pain conditions in VA. After participants receive the recruitment letters, which provide an opt-out option, the interviewer (study coordinator/RAs) will call the veterans from a private office and state that all answers are kept private and confidential and remind them the study is completely voluntary before conducting the screening survey. If the participant fits the eligibility criteria and is interested in the study, the interviewer will explain the study again and the consent process by going over the information sheet that was mailed along with the recruitment letter. Study staff will be sure to read the information sheet carefully, and to emphasize that they are voluntarily choosing to consent by being willing to participate in the study. If the participant consents, the interviewer will confirm the mailing address and obtain height and weight (in order to setup their pedometer prior to mailing to the participant). The participant will be mailed a Baseline Survey, accompanying cover letter, pedometer, and pedometer Q&A. On day 14 after the initial mailing of the baseline, we will mail a reminder postcard. About 2 weeks later, we will make 1 final contact attempt via phone. Two or three weeks prior to the 3- and 6-month follow-up time points, a postcard reminder will be mailed to all participants. This postcard will remind participants to wear their pedometer so that step count data can be collected on the 3- and 6-month surveys. The 3- and 6-month cover letters and surveys will be mailed to participants about a week prior to the 3 or 6

month date. A reminder post card to return the survey will then be sent to non-responders at about 14 days after the survey was mailed. At the 6-month time point, a second cover letter and survey will be mailed to non-responders about 3 weeks after the initial mailing. Study staff (study coordinator and/or RAs) will follow-up with phone calls to answer any questions and offer to do the survey over the phone if the participant prefers. The participant's surveys (screening, baseline, 3 & 6 month) will only be identified by a subject ID number. Data from non-enrolled patients will be immediately stripped of personal identifiers and will not be used in any other analyses. (The screening data will allow for comparison of enrollees with those patients who were ineligible or refused participation, and will enable the detection of inclusion biases.)

If randomization is delayed after receipt of completed baseline survey (e.g., due to staffing issues), participants may no longer be eligible (e.g., their pain has diminished beyond the eligibility threshold), so these particular participants will be called again. Trained interviewers will use a script to 1) remind the participant about the study and review the purpose and what is involved; 2) ask if they are still interested in participating; 3) go through the eligibility questions again if they are interested. If they are no longer interested, these people will not be contacted again. If they are interested and eligible so far, they will be mailed another baseline survey and will receive another \$20 for completion. Upon baseline return, if originally contacted prior to Amendment 8 approval, which added a chart review step to determine eligibility, they will be randomized and treated the same as all other participants from pre-Amendment 8 approval for the duration of the study. Upon baseline return, if originally contacted after Amendment 8 approval, a medical chart review will determine whether they are eligible, and they will be treated the same as all other participants from post-Amendment 8 approval for the duration of the study. If they are interested but no longer eligible based on their answers to the screening questions, study staff will apologize and explain the situation. These people will not be contacted again.

After completing the baseline survey, study staff will conduct a chart review to determine eligibility (see 5.4 Inclusion/Exclusion criteria for more details), and eligible patients will be randomly assigned to the Usual Care (UC) or Intervention Condition (IC). We will continue to contact patients until we have our required sample of 500 eligible patients (250 in each arm); we are aware that we may need to contact more black than non-black patients due to the likelihood of lower response rates among blacks. Intervention participants will be invited to participate in the 6-session intervention, a pedometer-mediated walking intervention that incorporates Action Planning and MI and Motivational and Cognitive techniques. Patients in the UC condition will receive an informational brochure and a pedometer. The Primary Outcome, pain-related physical functioning, and other pain domains recommended by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT), psychological mediators, and measures of utilization, provider, and environmental factors, and current treatment for pain (pain related services and use of opioid analgesics) will be measured at baseline survey. Baseline data on utilization of health care services, prescription for pain medications, medical comorbidities, and demographic information will be obtained from the Corporate Data Warehouse (CDW) data. We will survey patients by mail (at 3 months and 6 months post-baseline) to assess the same pain measures and psychological mediators that we assessed at

baseline, and assess walking, in the form of daily step counts measured through patient logs of pedometer readings. We will also assess service utilization and opioid analgesics, using data from the CDW and survey data. Data analysis of primary aims will follow intent-to-treat methodology. During Phase 3, we will also conduct analyses of intervention processes using the RE-AIM framework.

- **Study Setting.** The sample will be drawn from the Atlanta VAMC (the main facility and satellite clinics) which has about 19,146 black and 17,657 non-black patients (16,580 of whom are white) who have received a musculoskeletal diagnosis over the past 12 months. Race data will be collected on the brief screening survey. Recruitment (via the administration of a brief telephone screening questionnaire) and telephone coaching will be conducted at the Center for Chronic Disease Outcomes Research (CCDOR), at the Minneapolis VAMC. Participants randomized to the Usual Care control condition will receive pedometers and an informational brochure. They will be instructed to wear the pedometer throughout the study period and instructed (via a mailed postcard) to record their pedometer readings on logs over 7 days at the 3-month and 6-month follow-up periods. They will report these step counts during the subsequent surveys, a procedure which has been used successfully in previous studies with similar populations. Although the pedometer is an enhancement beyond what is received in usual care, we decided to provide pedometers to the control condition because it is the only way to determine whether the intervention increases walking (as self-reported measures have not been shown to be reliable), and because past studies suggest that pedometers in isolation are unlikely to result in a sustained increase in walking among generally sedentary individual and that the use of pedometer self-monitoring in research does not lead to increased physical activity.
- **Intervention Condition.** Participants assigned to the intervention group will receive personalized recruitment materials including a brochure describing the program and the benefits of walking for pain. Materials will include targeted messages to enhance persuasive appeal among this population and will be developed and modified using 4-6 focus groups among VA patients at the Atlanta VA in phase 1. This approach to developing recruitment materials was successfully used by Fu et al. in the Veterans Victory study. The pedometer component of this intervention is based on the work of French et al. and Co-Investigators Krein and Heapy, in which patients will set modest goals to gradually increase their step count. Intervention participants will wear the pedometer and maintain a pedometer diary for the duration of the 6-month study using weekly pedometer diaries, a protocol that was demonstrated to be feasible in the “Fit for Life” and H.U.B. City Steps studies. The structure and intensity of our intervention was chosen to balance practical concerns about future dissemination while accommodating our intervention components and providing a sufficient dose of counselor time based on comparable prior interventions that successfully increased walking and improved pain. The intervention will be tailored to the specific population we are targeting through the Phase 1 focus groups and Phase 2 pilot.

- Telephone Sessions.** Intervention participants will complete six sessions of telephone coaching over a 10-12 week period (maximum of 14 weeks will be allowed). Participants are expected to receive approximately 180 minutes of total therapist time during the study. Sessions #1-4 occur weekly and sessions #5-6 occur with longer breaks in between. The Action Planning component of this intervention is based on a protocol and structured curriculum developed by French et al, which was effective at increased walking in several trials in a non-clinical population (healthy volunteers) and also incorporates techniques developed in an intervention that used Action Planning to promote physical activity among patients with chronic low back pain. Participants will be coached to create and write action plans for their proposed walking activity during the week(s) between coaching sessions, using a template, which prompts them to indicate when, where, and with whom they will walk. We have adapted this component for our target population, so that counselors will be trained to coach patients in developing plans to overcome common environmental barriers to walking experienced by members of racial minority groups (e.g., lack of time, neighborhood safety, lack of motivation to exercise during leisure time, and health concerns). We will specifically address fear of movement and promote self-efficacy for walking during the Action Planning process by incorporating these topics into the Action Planning sessions and, based on the pilot work of Allen, will design the materials for lower literacy levels.

Evaluation of Intervention (Phase 2)

Data Sources and Data Collection Data collection will occur by mail and telephone at baseline and at 3 and 6 months post-randomization. We will also include administrative data extracted from the CDW at these three timepoints (see Table 3).

Description of the MSD. Gender, birthdate, race, and zip code of residence will be gathered from the CDW. Medical and psychiatric diagnoses will be based on ICD-9 codes (and ICD-10 code conversions). Only conditions noted in the year prior to cohort entry will be counted as baseline conditions, as they were likely to be active at the time of the incident musculoskeletal diagnosis encounter. Service utilization encounters will be defined using stop codes. Non-VA service paid for by VA will be assessed using fee-for-services data.

Table 3: Table of Evaluation for Phase 2 (Data Sources, Constructs and Measures)

Construct	Measure	0 mo	3 m o	6 m o
Baseline screening questions				
Race/ethnicity	Standard measures of race and ethnicity	X		
Pain intensity/interference	Brief pain intensity and interference scale (PEG)	X		

Ability to walk a block	Single-item screening question	X		
Cognitive screener	Callahan Measure	X		
Anticipated back, knee or hip or other major surgery in next 12 mo.	Single-item question	X		
Primary Outcome				
Disease-specific functioning	Revised Roland and Morris Disability Questionnaire (RMD)	X	X	X
Secondary Chronic Pain Outcomes				
Pain intensity/interference	Brief pain intensity and interference scale (PEG)	X	X	X
Emotional functioning	Personal Health Questionnaire Depression Scale (PHQ-8)	X	X	X
Emotional functioning	Generalized Anxiety Disorder 7 item (GAD-7)	X	X	X
Overall improvement	Patient Global Impression of Change scale		X	X
Average daily total steps	<u>Pedometer data</u> recorded over past 7 days on patient logs	X	X	X
Utilization and pain medication				
<i>Service utilization</i>	<i>Number of outpatient visits, emergency room visits, referrals for specialty care, and hospitalizations. (from CDW)</i>	X	X	X
	<i>Survey items</i>	X	X	X
<i>Use of opioid analgesics</i>	<i>CDW – Pharmacy files (RXOutpatFill, RxOutpat, RxOutpatSig), Non-VA Meds (From CDW)</i>	X	X	X
	<i>Survey items</i>	X	X	X
Psychological mediators				
Exercise self-efficacy	Exercise Regularly Scale	X	X	X
Pain management self-efficacy	Pain Self-Efficacy Questionnaire-8 item version (PSEQ-8).	X	X	X
Pain-related fear avoidance	Fear-Avoidance Beliefs Questionnaire (FABQ) Scale 1: Fear-avoidance beliefs about physical activity	X	X	X
Social support	Social Support for Exercise: Marcus Social Support Questions	X		
Social support	Life Stressors Inventory (LISRES-A)	X		
Environmental factors	Neighborhood Environment Walkability Scale (NEWS)	X		
Utilization factors				

Experiences of discrimination	Perceived Discrimination in Healthcare	X		
Mistrust of medical Care	Evaluation of VA Care scale	X		
Demographic factors	Standard measures of education, income, employment, height, weight, service connection	X		
Walking Aid Question		X		
RE-AIM Measures (open-ended) *	Open-ended questions assessing participants' experience with the intervention and recommendations for improvement. *RE-AIM measures will only be assessed for intervention participants.			X

Note: Unless otherwise indicated, items are collected by survey self-report

Patient telephone survey If participants do not return a paper mailed survey, data will be collected by phone by trained interviewers, (the study coordinator and research assistants located at CCDOR in MPLS), who are blinded to treatment condition. Patients will be assured that reports will not be shared with their counselor or healthcare provider, without their verbal permission, unless they indicate their safety or the safety of others is at risk.

Description of measures

- **Screening Items:** Patients will be screened using: 1) two items assessing race and ethnicity, 2) the three-item PEG, a brief pain inventory that measures average pain intensity (P), interference with enjoyment of life (E), and interference with general activity (G),^{80,81} 3) a single question asking them if they are able to walk a block, 4) the six-item Callahan screener that identifies cognitive impairment for potential research subjects,⁷⁷ and 5) a question asking them if they anticipate back, knee, or hip surgery or other major surgery within the next 6 months.
- **Chronic Pain Outcomes.** We will assess the following core chronic pain outcome domains and measures recommended by IMMPACT:²⁹ 1) **The primary outcome will be a pain-specific measure of functioning**, the revised version of the **Roland and Morris Disability Questionnaire (RMD)**, widely used in studies of chronic musculoskeletal pain and included in the IMMPACT recommendations. Although the original version focused on low back pain,⁸² the revised version has been adapted for MSK pain more broadly, and has been validated with MSK patients.³⁰ The scale has good internal consistency, discriminative validity and is sensitive to change.⁸³ 2) Emotional functioning will be assessed by items on Personal Health Questionnaire Depression Scale (PHQ-8)^{90, 99} and Generalized Anxiety Disorder 7 item (GAD-7).¹⁰⁵ 3) Pain intensity/interference will be assessed by the brief pain intensity and interference scale (PEG).^{80,81} 4) Participant ratings of overall improvement will be assessed by the Patient Global Impression of

Change scale, a single item measure assessing patients' views of improvement/worsening in their pain.⁸⁵

- **Average Daily Total Steps.** Walking will be measured as the number of average daily steps using pedometer readings recorded in walking logs at three and six months, based on seven consecutive days of data. We will use the Omron HJ-321 pedometer, used in prior studies (including the Krein pedometer study). This pedometer can be worn in a pocket, around the neck, or on a belt clip (orientation does not matter) and has been shown to be highly accurate, including in obese populations.⁸⁶ Patients will be instructed on how to use the pedometers, and we will conduct pilot tests (as part of the Atlanta focus groups) to assess whether these instructions are accurately understood. Participants in the intervention arm will have additional support for ongoing pedometer use as part of the intervention, but the walking outcome assessment protocol will be identical in both arms.
- **Psychological Factors (Mediators).** Pain-related fear will be measured using the Fear-Avoidance Beliefs Questionnaire (FABQ) Scale 1: Fear-avoidance beliefs about physical activity.¹⁰⁶ Self-efficacy for exercise will be measured using the Exercise Regularly Scale, which includes questions asking respondents how confident they can do aerobic exercise such as walking three to four times each week and how confident they are they can exercise without making symptoms worse.⁸⁷ Pain management self-efficacy will be measured using the Pain Self-Efficacy Questionnaire (PSEQ),⁸⁸ which has been used in numerous studies of chronic pain patients. **Service Utilization.** We will assess use VA services using administrative data from the CDW, which we will supplement with survey measures to assess health care utilization outside the VA. Categories of VA service utilization will include the number of outpatient visits, emergency room visits, referrals for specialty care, and hospitalizations. These variables are defined using stop codes and encounter dates. Mental health visits are determined from stop codes devised using the VA North East Program Evaluation Center (NEPEC) algorithms. Because we have found that Veterans frequently receive care at multiple VA facilities and even multiple VISNs, site of care will be recorded for each encounter.
- **Use of Opioid Medication.** We will assess use of opioid medication using administrative data from the CDW which we will supplement with survey measures to capture medication received outside the VA. Receipt of opioid medication will be defined as any dispense of VA formulary category CN101 drug. Because most methadone for opioid substitution therapy (OST) is in a separate VA table, we will assess OST by stop code 523. Chronic opiate therapy (COT) will be defined as >90 consecutive days of medication dispensed. We will calculate average daily morphine equivalent dose (MED). A recent non-VA cohort study found that patients receiving medically prescribed opioids of 100mg or more per day MED had a 9-fold increase in overdose risk, that most overdoses were medically serious, and 12% were fatal.²⁸ We will create indicator variables for average MED of 1-20, 21-49, 50-99, 100-124, and > 125mg.
- **Environmental Factors:** The baseline survey will include the Neighborhood Environment Walkability Scale (NEWS) in order to elicit information about access to and the use of equipment, facilities, and places where they can walk as well as

environmental barriers (e.g., safety concerns). Seasonal effects will be taken into account based on date of survey completion. Social influence/encouragement to exercise will be measured by the Social Support Exercise: Marcus Social Support Questions and the Life Stressors Inventory (LISRES-A).

- **Utilization Factors** will include experiences of discrimination (associated with delay of healthcare and unmet medical needs), assessed using the Perceived Discrimination in Healthcare scale¹⁰⁷, and the experiences with VA care, assessed by the Evaluation of VA Care scale, an 8-item scale measuring patient satisfaction with and perceptions of quality of VA healthcare.⁹³
- **Socio-demographic characteristics**: Participants will be asked to provide basic socio-demographic information that is not available from the CDW, such as education level and income.
- **RE-AIM Measures Collected from Intervention Participants**. Our process analysis will use the RE-AIM model⁷³ and will include information about the participants' experience of the intervention. We will collect this information as part of the 6-month survey, by asking intervention participants about their experience with the intervention and asking them for recommendations for improvement using open-ended questions.

Power and sample size

Our sample size calculation was based using the Roland Morris Disability Questionnaire (RMDQ) score as the primary endpoint. For our primary analysis we use a responder analysis, in which we define clinical significant changes as a 30% reduction in pain disability from baseline, using the RMDQ, and have powered the study to be able to detect this change. This is the accepted threshold for clinically significant improvement in clinical trials and recommended by the IMMPACT guidelines and studies demonstrate that a 30% reduction on the RMDQ is a clinically important difference.^{96,97} Prior studies have shown that 15-20% of usual care patients will demonstrate a 30% reduction in pain function score (using the RMDQ and similar measures) from baseline to follow-up, so in order to detect an absolute difference to 20% in the primary outcome measure between treatment groups (i.e. 15-20% in the usual care group compared with 35-40% in the intervention group), we estimate that we will need between 86-97 people in each group with complete data. This estimate takes into account that we are setting the alpha error rate to look separately at both black and non-black patients. We will use the between-group change on the RMDQ as a secondary measure.

We also need to factor in that up to 50% of the study sample may be non-black, since we want to be able to have power to detect meaningful effects in the subgroup that only includes black patients (~100/50%=200). To allow for up to 20% attrition, we would need to randomize 250 patients for each arm of the study, for a total of 500 patients recruited, and 200 black patients with complete data for the final analyses. We estimate that in order to reach a total of 500 patients randomized, we will need to enroll (i.e. participants who are eligible after the phone screener is completed and are thus mailed a baseline survey packet) as many as 1500 patients. Once we reach the goal of randomizing 500 participants, we will stop enrollment.

Risk vs. Potential Benefit

The proposed research poses “minimal risk” to subjects. There are no experimental procedures involved in this study. The potential risks to study participants include loss of privacy and confidentiality. There are no economic and minimal social risks of participating in the study. The baseline survey will not ask very sensitive questions and subjects can refuse to answer any question(s). The potential risk associated with the focus group is psychosocial stress (any research project with direct contact with human subjects contains some risk of deleterious effects due to psychosocial stress). This is true for both usual care as well as intervention groups.

The intervention group is expected to benefit from this study. It is hypothesized that this group will experience improvements in chronic pain-specific physical functioning, emotional functioning, pain intensity and will report overall. This group is also expected to increase their walking which has been shown to have a beneficial effect on health.

5.2 Recruitment Methods

- **Phase 1 (Focus group):** Potential participants will be sent a letter from the MPLS VA explaining the project and providing an opt-out option. Within two weeks the study coordinator and/or the research assistant will attempt to contact them by phone and asked if they would be interested in participating in a 60-90minute group discussion on their opinions about a study on reducing pain through walking. The call will include reviewing information that will be contained in the consent form. The study coordinator and research assistant will attempt to call the participants for a maximum of 6 times at different times of the day. The recruitment sample focus groups will be restricted to black patients from the Atlanta VAMC, selected from the CDW (who will then be excluded from the study sample). At the time of the focus groups the participant will be presented with the consent form. The participant will be given time to read the form. Key aspects of the form will also be reviewed verbally, including that (1) the focus group is expected to last 60-90 minutes (2) they will be audiotaped (3) the information they provide will be de-identified prior to analysis (4) they may skip any questions or terminate the interview at any time if they wish 5) and it will not affect their care at the VA if they choose not to participate. Only participants signing an informed consent form will be interviewed. All focus groups will be conducted in the Atlanta VAMC by Dr. Burgess, PI.
- In month 2 of the study we will conduct two patient focus groups to refine the recruitment materials (recruitment letter, brochure, recruitment scripts), the instructions related to use of pedometers, and counselor communication strategies, and to collect additional information on barriers to walking. In study month 4, we will conduct two additional patient focus groups to obtain feedback on modified versions of these materials, based on input from the first two focus groups.

- Initially we used Olympus digital voice recorders, which had been approved by MPLS ISO for use. Once the Olympus voice recorders were no longer supported by VA OIT, encrypted Philips DCM Digital Voice Recorders were purchased and used for recording. The voice recorders are VA equipment tracked via bar code by the MPLS facility inventory specialist. The ISO has worked with the PI to establish local procedures for use of the recorders, which are kept in a locked safe when not in use and are logged in and out prior to and after interviews. Once the interview is complete and a recording has been made on the device, the interviewers will promptly transfer the recording to the established secured VA server space and the recordings will be erased from the device. At the end of their life cycle the digital recording devices will follow electronic media sanitation procedures under the guidance of the MPLS ISO. This same procedure is used in C-IRB #12-28.
- **Phase 2 Pilot:** Recruitment methods for the Phase 2 Pilot will be kept the same as Phase 2 recruitment methods, differing only in that we are recruiting and enrolling 3 participants for the Pilot.
- **Phase 2:** We will use the 14 ICD9 (and ICD10 code conversions) that capture the most commonly used chronic pain codes to identify 1,000 patients with Musculoskeletal Diagnoses within the past 12 months, who are identified as Atlanta VAMC patients. Potentially eligible patients will be mailed a letter from the Minneapolis VAMC describing the study, providing an opt-out option, and informing them that they will be contacted by phone. Along with the letter will be an information sheet containing elements of informed consent. All patients will then be called by a trained interviewer, who will be the study coordinator and/or the RAs (from the Minneapolis VA) approximately a week or two after the letter is sent out, who will ask if they received the letter about the study and will briefly tell them about the purpose and the opportunity to participate. We will use the same call protocol described in phase 1. If they are interested, the interviewer will ask them 12 screening questions. If eligible, they will be invited to participate in the study and the interviewer will review the information sheet and obtain verbal consent. Eligible patients must meet the inclusion criteria.

Participants who were found eligible and completed the baseline but were not immediately randomized (due to coaching staffing issues, randomization was putting on hold at the end of 2016 and beginning of 2017), will be given an additional call to see if they are still interested in participating. Trained interviewers will use a script to 1) remind the participant of about the study and review the purpose and what is involved; 2) ask if they are still interested in participating; 3) go through the eligibility questions again if they are interested. If they are interested and found eligible, they will be mailed a baseline survey and will receive another \$20 for completion. Upon baseline return, they will be

randomized and be treated the same as all other randomized participants for the duration of the study.

- If eligible, the participant will receive the baseline survey in the mail. Once they return the baseline survey, a chart review will determine if they are eligible, and if so, the subject will be randomly assigned to the Usual Care (UC) or Intervention condition. We will continue to contact patients until we have our required sample of 500 eligible patients (250 to each arm). Intervention participants will be mailed an introductory letter, informational brochure, and Veteran's Workbook (to be used during coaching sessions) shortly before being called to schedule their first counseling session. Patients in the UC condition will receive an informational brochure. Recruitment (via the administration of a brief telephone screening questionnaire), baseline, 3 and 6-month surveys, and telephone coaching will be conducted at the Minneapolis VA. The study coordinator and/or research assistants will attempt to call the participants for a maximum of 3 times at different times of the day at each of the recruitment and data collection timepoints (eligibility, baseline, 3-month, and 6-month).
- **Describe materials that will be used to recruit subjects, e.g., advertisements. Include materials as an appendix or separate attachment.**

See IRB supporting documents

Subject payments:

- Survey participants will be compensated for their time with \$20 for each outcome assessment (baseline, 3 and 6 month) completed (for a total of \$60, or potential \$80 total if the participant is asked to complete the baseline a second time). Focus group participants will be compensated for their time with \$50. Phase 2 Pilot participants will be compensated \$20 for session 1 and 6, and \$15 for sessions 2, 3, 4 and 5. This payment amount is similar to those used in other studies, and is provided for the time and inconvenience of participating in research. The amount is not so much that subjects would feel coerced into participation.
- The study coordinator will dispense payments for survey participants for all phases.
- Phase 1 will consist of a onetime payment of a \$50 check mailed 8-10 weeks after participation in the focus group.
- In Phase 2, participants will receive a \$20 check within 8-10 weeks of completing the baseline, 3 and 6-month follow-up survey.

5.3 Informed Consent Procedures

Phase 1 & 2: We are seeking a waiver for screening pain participants at the Atlanta VA so that we can identify our population and conduct future analyses for non-

respondents. This waiver would only apply toward secondary data (i.e. data that has been collected and provided in VA records).

Phase 1 (Focus group): We will provide a full written informed consent and HIPAA authorization form.

Phase 2 Pilot: We will mail participants the recruitment letter and information sheet explaining that they can voluntarily consent by agreeing to participate in the study.

Phase 2 (Intervention): We are requesting a waiver of documentation of informed consent as recruitment and consent will be obtained verbally over the phone. We will conduct a 12-question screening phone survey to determine eligibility status for recruitment with potential subjects, and once eligible and agree to participate, all contacts are done over the phone or by mail (screening survey, baseline, 3- and 6-month follow-up survey).

- **Documentation:**
 - **Phase 1:** We will provide a full written informed consent and HIPAA authorization form.
 - **Phase 2 Pilot:** We have a waiver of documentation of informed consent, and a waiver of HIPAA authorization for the duration of the study
 - **Phase 2:** We have a waiver of documentation of informed consent, and a waiver of HIPAA authorization for the duration of the study. The study and consent will be explained over the phone after the subject meets eligibility and is interested in participation.
- Dr. Burgess will conduct the focus groups at the Atlanta VA. She will review the informed consent and HIPAA with participants and obtain consent at the time of the focus group.

5.4 Inclusion/Exclusion Criteria

- **Phase 1 (Focus group participants):** The recruitment sample for focus groups will be restricted to black patients from the Atlanta VAMC, with diagnoses of hip, knee, or back pain, using algorithms derived from 14 ICD9 codes (and ICD10 code conversions) that capture the most commonly used chronic pain codes. They will then be excluded from the study intervention sample. Focus groups are restricted to black patients because the study is designed to increase walking among this population and we want to make sure that our materials are culturally appropriate. Additionally, these veterans will help us refine the recruitment materials (recruitment letter, brochure, and recruitment scripts), counselor communication strategies and pedometer instructions, and identify additional information on barriers to walking.

- **Phase 2 Pilot:** The recruitment sample will be restricted to African American patients from the Atlanta VAMC with hip, knee, or back pain (using algorithms derived from 14 ICD9 codes and ICD10 code conversions), have pain duration of ≥ 6 months, moderate-severe pain intensity and interference with function (defined as a PEG score of ≥ 5), self-reported ability to walk at least 1 block, and must be able to communicate effectively by telephone (no cognitive disability). We will not exclude patients who are on medication or receiving interventions to treat their chronic pain. We will exclude those who cannot obtain the threshold level of steps (400 steps per day) in 2 days of data collection. We will exclude Phase 2 pilot participants from the Phase 2 study.
- **Phase 2:** The recruitment sample will include all patients from the Atlanta VAMC, regardless of race/ethnicity, with hip, knee, or back pain (using algorithms derived from 14 ICD9 codes and ICD10 code conversions), have pain duration of ≥ 6 months, moderate-severe pain intensity and interference with function (defined as a PEG score of ≥ 5), self-reported ability to walk at least 1 block, and must be able to communicate effectively by telephone (e.g., no cognitive disability). We will not exclude patients who are on medication or receiving interventions to treat their chronic pain. We have chosen the Atlanta VAMC because it has a high percentage of black patients (43%).
- We will include the approximately 10% of patients who have no race data; race data will be collected on the brief screening survey.

We will not include any vulnerable populations or those who meet any of the following exclusion criteria that may interfere with the outcome assessment: a) moderately severe cognitive impairment defined as > 2 errors on a brief cognitive screener; b) anticipated back, knee, hip, or other major surgery within the next 6 months; c) patients who say they are unable to walk at least a block; d) patients who say they would be unavailable to participate in a 6 month study; e) patients with active psychotic symptoms, suicidality, severe depression, and/or active manic episode or poorly controlled bipolar disorder, as determined by chart review.

5.5 Study Evaluations

- **Describe all evaluations to be conducted (including screening; tests/questionnaires that will be administered; any procedures that subjects will be required to complete) and data collection methods. Include materials as an appendix or separate attachment.**
- See IRB supporting documents

5.6. Data Analysis

Phase 1

- **Analysis of focus group data.** Our short timeline for refining the intervention content will require us to identify key insights from our focus groups quickly so that we can use them to guide our revisions on the materials. We will therefore employ rapid assessment process (RAP) methodology to analyze the data collected in this study. RAP is a team-based method that can be used to obtain rich qualitative results in a brief amount of time. A key feature of this method is iterative data collection and analysis where investigators analyze data after each interview. For our study, use of RAP methods will involve scheduling time immediately following each focus group for the investigators participating in data collection (Dr. Burgess and RAs) to identify and discuss key findings. The list of key findings will be updated and expanded with each subsequent focus group session. Investigator notes from each interview session will be amended to this list of key findings to create a running log of key interview data. The log will be periodically distributed to investigators and discussed during ongoing project meetings.
- **Phase 2 Pilot Data:** There will be no data analysis for Phase 2 Pilot. Although we will be audio-recording the counseling sessions, we plan to use these recordings ONLY to accurately capture the Veteran's reactions to the materials and counseling. We may refer back to the feedback from the Veteran in order to improve our training materials for our counselors, but will not be analyzing the recordings.

Phase 2

- The overall design of the study is a two-arm patient-level randomized trial. All analyses will take this design structure into account and will primarily follow an intent-to-treat analysis where patients are analyzed based on the group they were randomized to regardless of whether or not they actually receive the assigned intervention. Secondary analyses will assess the impact of the intensity of intervention compliance on outcomes and to test study outcomes among patients.
- **Primary Aim.** To test the hypothesis that the intervention will improve chronic pain-specific physical functioning—the primary outcome (H1a), improve emotional functioning, pain intensity and ratings of overall improvement (H1b), and increase walking (H1c), compared to UC for black patients with chronic hip, back, and knee pain.
- The primary analyses for these aims will be conducted in the sample of black patients, so the focus of much of the methods speaks to this primary sample. However, it needs to be clear that the study is designed to be adequately powered to detect effects separately in both the black and non-black groups. This is important from an implementation standpoint since if this intervention is successful it will be important to know whether the effects generalize to a non-black population.

- General Analytic Approach.** These analyses will proceed in three phases. In the first phase (data verification), we will examine the distribution of all study variables to assess extreme values, missing data, variances, skewness, and type of distribution. Frequency distributions and descriptive statistics for all study variables will be computed prior to conducting any analyses. Should normality tests indicate evidence of non-normality for any of our variables (e.g., pain severity ratings) we will compute necessary data transformations. In the second phase, we will evaluate bivariate associations between patients' experimental condition and the outcomes, as well as between each covariate and the outcomes and between each covariate and intervention. These analyses will be done to determine unadjusted measures of effect and assess possible confounders. In the final phase, we will use generalized regression models to estimate the main effects of the intervention. Because of randomization of treatment assignment, we do not anticipate any imbalances in baseline characteristics between groups, but any differences between experimental arms in baseline characteristics will be included as covariates. Likewise, if we find differences in missing data, multiple imputation methods will be used to explore the impact of the missing data and attempt to adjust for its effects on the intervention's effectiveness.
- Aims 1a) and 1b)** To compare the effects of the intervention to UC on the IMMEDIATE measures of pain outcomes. The primary measure for these aims is the RMDQ score (i.e. primarily a 30% reduction from baseline and secondarily mean change from baseline), and the other secondary measures are pain intensity, the Profile of Mood States, and the global rating of change scale. Analytic approaches for all of these measures will be similar with the exception that some of the measures are dichotomous (i.e. did the participant have a 30% reduction in RMDQ) while other outcomes are assessed on a continuous scale. For all of these outcomes we will use generalized linear regression fit using appropriate distribution and link functions (i.e. for the primary outcome of whether the patient's RMDQ improved by 30% or more we will fit a binomial distribution and logit links, whereas for the comparison of mean differences between treatment groups we might fit a normal distribution). We expect the RMDQ score to decrease (indicating improvement) in the short term (3-month) as well as over the longer term (6-month) in the intervention group, while improving only slightly from baseline in the control group. For continuous outcomes in this model, for example the RMDQ, scores from both 6 months and baseline will be used as the dependent variable, and the independent variables will include the indicator for the intervention group and an interaction term of 6-month time by intervention group indicator. Each participant will be modeled as a random intercept to allow within-patient correlation of the repeated measures. The model can also include other baseline covariates such as age and pain intensity. The use of a mixed-effects model, rather than using multiple linear regression or analysis of

covariance with change-scores or the 6-month values as the dependent variable, will allow us to use data from participants who may be missing either baseline or the 6-month data while giving an unbiased estimate of the outcome comparisons as long as missing-ness is approximately random. The 3-month effect will be similarly assessed.

- We will assess the time-averaged effect of the intervention on pain-related functional interference and the outcome trends over time using the outcome measures at all three times (including the baseline) as repeated measures nested within patients and using a mixed-effects model. Prior to fitting the mixed-effects model, we will explore the trends graphically by plotting the cross-sectional means of the outcome measures at each measurement time separately by the two study groups. We will also graph the outcome measures by individual participants to assess the participant specific longitudinal pattern over time. The mixed-effects model will be guided by the results of the graphical analyses. For instance, we expect decreasing trends in the outcome measures over time in the intervention group and no particular trends in the control group. If such a pattern is indicated, linear time and an interaction of linear time by intervention group will be included in the model. In this model, if the time variable is not significant and the interaction is estimated with a significant negative coefficient, it would provide evidence for linearly decreasing outcomes (i.e., improvement in function) in the intervention group over the one follow-up period. If, on the other hand, the graphical analyses suggest that the outcomes in the intervention group decrease at 3 months with no noticeable change between 3 to 6 months, we will model this by including time as dummy categorical variables and interaction terms of intervention group by time dummy categorical variables. An appropriate contrast for the covariate adjusted difference in outcome means at 3 months and 6 months between groups will be constructed to estimate and test for the intervention effect. Using this model, mean changes from baseline can also be estimated and tested for each group. If we find no difference in the intervention effect between 3 and 6 months using this model, we will model the post-intervention time together to obtain a time-averaged intervention effect. The mixed-effects models will also include the baseline values of the outcome measure and other baseline covariates to adjust for potential baseline differences between the groups.
- **Aim 1c)** To compare the effects of the intervention to UC on increasing walking behavior. Walking will be measured by step counts, which are reported based on readings from the Omron HJ-720 ITC pedometer. The effect of the intervention on step counts will be assessed by comparing average daily step counts (or appropriately transformed scores, if the distribution is shown to be skewed) measured over 7 days. We will use a mixed-effects model with the average daily step counts as reported on the baseline survey, during the last week of the 3 month and 6 month measurement points as the dependent variables, with a similar analytic plan as described for Aim 1a.

- **Secondary Aim 1:** To investigate whether key contributors to racial/ethnic disparities targeted by the intervention (motivation to exercise, pain/exercise efficacy, reduction of pain-related fear) mediate improvement in chronic pain outcomes and increases in walking. The key measures for this aim include the Exercise Regularly Scale, the PSEQ-8, and the FABQ Scale 1. Each of these will be measured at baseline, 3- and 6-month, and each has continuous distribution, and therefore, analytic approaches for each of these measures will be identical to that of Primary Aim 1 with the primary objective of assessing the long-term (6-month) effect of the intervention on these outcomes and secondary objective of exploring outcome trends over time. Indirect effects will be directly tested using the bootstrap approach to obtaining confidence intervals to avoid the often-violated assumption underlying Sobel's (1982) method that the sampling distribution of the indirect effect be normal.¹⁰³
- **Secondary Aim 2:** To explore whether the intervention reduces service utilization and use of opioid analgesics. Using similar analytical methods as described for the Primary Aims, we will use generalized linear models to explore whether service utilization and use of opioid analgesics measures are reduced in the intervention group compared to the UC group.
- **Secondary Aim 3:** To determine if the intervention is effective for non-black VA patients and other subgroups of patients who may experience barriers to effective pain treatment. We will conduct the same analyses as for the Primary Aims and Secondary Aims 1-2 on the sample of non-black patients (most of whom are expected to be white) and subgroups based on key demographic factors (age, gender, education, and income) and psychological, environmental, and utilization, measured at the baseline survey, that we included because they were expected to constitute barriers to effective pain treatment, based on our theoretical framework. We will also explore whether treatment effects will be moderated by common psychiatric conditions (PTSD, anxiety, depression) and receipt of other forms of pain treatment, in order to see whether our intervention is effective for Veterans with these common psychiatric conditions and/or who are involved in other pain treatment.
- **Secondary Aim 4:** To explore whether the intervention reduces racial disparities in pain outcomes, generalized linear regression models described above do allow for the incorporation of a race by intervention variable into the models to explore whether there might be evidence that the intervention is more or less in effective in black Veterans as compared with non-black Veterans. We expect that the intervention will be effective across racial groups and assume that the differences between racial groups receiving the intervention will be substantially smaller than the differences between the intervention and UC groups. Since the study is powered to detect the main effects that are assumed to be larger than

the interaction effects, this study may not be able to detect clinically important differences in the intervention's effectiveness between racial groups. We will however explore tests of interaction for the key study outcomes and use any information to help craft a future study, if we find evidence that there might potentially be important race-specific treatment effects.

- **Describe how, where and by whom the data will be analyzed.**

The data will be analyzed at CCDOR by statisticians and Co-Investigators, including Dr. Brent Taylor, Emily Hagel Campbell, Elizabeth Goldsmith, and Patrick Hammett at the Minneapolis HCS.

5.7 Withdrawal of Subjects

Phase 1 (focus groups): Participants can withdrawal from the study (i.e. the one-time focus group) at any time they feel uncomfortable. We anticipate termination of participation if:

1. The participant displays abusive behavior toward other participants in the focus group and/or the study staff
2. The study is suspended or canceled.

Phase 2 Pilot: Participants can withdraw or be terminated from the study at any point. We anticipate termination of participation if:

1. The participant displays hostile or aggressive behavior to the counselor.
2. The study is suspended or canceled.
3. The participant chooses to withdraw consent.

Phase 2: Participants can withdraw or be terminated from the study at any point for any reason. We anticipate termination of participation if:

1. The study team believes that it is not in the participant's best interest to stay in the study
2. The participant becomes ineligible to participate
3. The participant does not follow instructions from the researchers
4. The participant loses three pedometers
5. The study is suspended or canceled
6. The participant displays hostile or aggressive behavior to the counselor or study staff
7. The study team believes the participant cannot meaningfully participate in the study
8. The participant chooses to withdraw consent

6.0 Reporting

- We will follow the VA Central IRB Table of Reporting Requirements for all issues that must be reported (i.e. summary of adverse events, unexpected problems and any actions or changes with respect to the protocol). The research assistant (RA) and the counselors will meet weekly by phone with the project coordinator to discuss study processes, progress, and any problems encountered. The local RA and project

coordinator will also report directly to the local site PI regarding any problems with data collection. Data will be reviewed regularly to insure accuracy and data safety. In the case of problems, the project coordinator immediately discusses with the study PI. The PI in turn will report any problems to the central IRB.

- Once learned of any SAEs, UAP, compliance issues, RCO, and/or protocol deviation the study PI will report these events as defined by the VA Central IRB Table of Reporting Requirements to the VA Central IRB. The study PI will complete the appropriate forms (i.e., 119 or 129) as listed on the VA Central IRB Table within 5 business days of learning of its occurrence. If there are modifications or amendments to the study the study PI will also complete the appropriate Central IRB form (i.e. 116) and wait for approval prior to implementation.

7.0 Privacy and Confidentiality

- We will employ rigorous procedures to guard against loss of confidentiality and loss of privacy. The CCDOR data group will manage all data collected during the study.
- We will link data to a specific subject by a code rather than a direct identifier. CCDOR programmers Ann Bangerter and Sean Nugent, will maintain the code and have access to the link. All crosswalk files that link the study ID to other participant identifiable data will be kept securely within the VA firewall.
- To prevent improper use of any data collected for research projects conducted at the Minneapolis COIN we will use a combination of local Minneapolis VA secure servers as well as the national secure VA Informatics and Computing Infrastructure (VINCI). The local VA secure servers facilitate data collection and provide a platform for the customized research tracking application, while the VINCI platform provides a robust environment for pooling the primary research collected data with direct connections to daily or weekly updated mirrors of nearly the entire VHA EMR. VINCI also provides access to extensive storage area networks, drives, file shares, databases, SharePoint for collaboration and correspondence sites, SAS/Grid, and servers containing virtual machines with an extensive collection of software called the VINCI Workspace.
- VINCI allows individual researchers and their staff the means to securely conduct their research projects within a secure and well controlled technical environment. All of these VA systems undergo backups of the servers nightly and servers are updated when new security patches become available. All individuals with administrative privileges to the VHA servers have been screened and have been assigned security clearance putting them in trusted positions to work with patient-level data.

8.0 Communication Plan

P.I. Dr. Diana Burgess will meet regularly with the project coordinator. At these meetings, Dr. Burgess will check in with the project coordinator to ensure that the following key communications occur:

1. Ensure that required local site approvals are obtained

2. Notify the Director of any facility where the research is being conducted, but the facility is not engaged.
3. Keep engaged sites informed of changes to the protocol, informed consent, and HIPAA authorization
4. Inform local sites of any Serious Adverse Events, Unanticipated Problems, or interim results that may impact conduct of the study.
5. Notify all local facility directors and LSIs when the study reaches the point that it no longer requires engagement of the local facility

The study team will also review relevant sections of the protocol periodically, so that we can make sure that the different phases of the study are conducted according to the IRB-approved protocol.

9.0 References

1. Anderson KO, Green CR, Payne R. Racial and ethnic disparities in pain: causes and consequences of unequal care. *J Pain* 2009;10:1187-204.
2. Meghani SH, Polomano RC, Tait RC, Vallerand AH, Anderson KO, Gallagher RM. Advancing a national agenda to eliminate disparities in pain care: directions for health policy, education, practice, and research. *Pain Med* 2012;13:5-28.
3. Shavers VL, Bakos A, Sheppard VB. Race, ethnicity, and pain among the U.S. adult population. *J Health Care Poor Underserved* 2010;21:177-220.
4. Staton LJ, Panda M, Chen I, et al. When race matters: disagreement in pain perception between patients and their physicians in primary care. *J Natl Med Assoc* 2007;99:532-8.
5. Burgess D, Gravely A, Nelson D, et al. A National Study of Racial Differences in Pain Screening Rates in the VA Health Care System. *Clinical Journal of Pain* Accepted.
6. Meghani SH, Byun E, Gallagher RM. Time to take stock: a meta-analysis and systematic review of analgesic treatment disparities for pain in the United States. *Pain Med* 2012;13:150-74.
7. Burgess DJ. Unpublished data. In; 2012.
8. Dobscha SK, Soleck GD, Dickinson KC, et al. Associations between race and ethnicity and treatment for chronic pain in the VA. *J Pain* 2009;10:1078-87.
9. Gatchel RJ, Peng YB, Peters ML, Fuchs PN, Turk DC, eds. *The biopsychosocial approach to chronic pain: scientific advances and future directions*; 2007.
10. Allen KD, Oddone EZ, Coffman CJ, Keefe FJ, Lindquist JH, Bosworth HB. Racial differences in osteoarthritis pain and function: potential explanatory factors. *Osteoarthritis Cartilage* 2010;18:160-7.
11. McCracken LM, Matthews AK, Tang TS, Cuba SL. A comparison of blacks and whites seeking treatment for chronic pain. *Clin J Pain* 2001;17:249-55.
12. King AC, Castro C, Wilcox S, Eyler AA, Sallis JF, Brownson RC. Personal and environmental factors associated with physical inactivity among different racial-ethnic groups of U.S. middle-aged and older-aged women. *Health Psychol* 2000;19:354-64.
13. Burgess DJ, Grill J, Noorbaloochi S, et al. The effect of perceived racial discrimination on bodily pain among older African American men. *Pain Med* 2009;10:1341-52.

14. Burgess DJ, Hargreaves M, Ding M, Phelan S, van Ryn M. Relationship between perceived discrimination and unmet physical and mental healthcare needs in a multi-ethnic community sample. *Journal of Health Care for the Poor and Underserved* 2008;18.
15. Saha S, Freeman M, Toure J, Tippens KM, Weeks C, Ibrahim S. Racial and Ethnic Disparities in the VA Health Care System: A Systematic Review. *J Gen Intern Med* 2008.
16. Upshur CC, Bacigalupe G, Luckmann R. "They don't want anything to do with you": patient views of primary care management of chronic pain. *Pain Med* 2010;11:1791-8.
17. Hayden JA, van Tulder MW, Malmivaara AV, Koes BW. Meta-analysis: exercise therapy for nonspecific low back pain. *Ann Intern Med* 2005;142:765-75.
18. Chou R, Huffman LH. Nonpharmacologic therapies for acute and chronic low back pain: a review of the evidence for an American Pain Society/American College of Physicians clinical practice guideline. *Ann Intern Med* 2007;147:492-504.
19. Fu SS, van Ryn M, Sherman SE, et al. Population-based tobacco treatment: study design of a randomized controlled trial. *BMC Public Health* 2012;12:159.
20. Bravata DM, Smith-Spangler C, Sundaram V, et al. Using pedometers to increase physical activity and improve health: a systematic review. *JAMA* 2007;298:2296-304.
21. Zoellner J, Connell C, Powers A, Avis-Williams A, Yadrack K, Bogle ML. Does a six-month pedometer intervention improve physical activity and health among vulnerable African Americans? A feasibility study. *J Phys Act Health* 2010;7:224-31.
22. Zoellner J, Powers A, Avis-Williams A, Ndirangu M, Strickland E, Yadrack K. Compliance and acceptability of maintaining a 6-month pedometer diary in a rural, African American community-based walking intervention. *J Phys Act Health* 2009;6:475-82.
23. Zoellner JM, Connell CC, Madson MB, et al. H.U.B city steps: methods and early findings from a community-based participatory research trial to reduce blood pressure among African Americans. *Int J Behav Nutr Phys Act* 2011;8:59.
24. Clarke KK, Freeland-Graves J, Klohe-Lehman DM, Milani TJ, Nuss HJ, Laffrey S. Promotion of physical activity in low-income mothers using pedometers. *J Am Diet Assoc* 2007;107:962-7.
25. Gollwitzer PM, Sheeran P. Implementation intentions and goal achievement: A meta-analysis of effects and processes. *Advances in Experimental Social Psychology* 2006;38:69-119.
26. Belanger-Gravel A, Godin G, Amireault S. A meta-analytic review of the effect of implementation intentions on physical activity. *Health Psychology Review* 2011:1-32.
27. Hoffman BM, Papas RK, Chatkoff DK, Kerns RD. Meta-analysis of psychological interventions for chronic low back pain. *Health Psychol* 2007;26:1-9.
28. Beissner K, Parker SJ, Henderson CR, et al. A cognitive-behavioral plus exercise intervention for older adults with chronic back pain: race/ethnicity effect? *J Aging Phys Act* 2012;20:246-65.
29. Dworkin RH, Turk DC, Wyrwich KW, et al. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. *J Pain* 2008;9:105-21.
30. Stroud MW, McKnight PE, Jensen MP. Assessment of self-reported physical activity in patients with chronic pain: development of an abbreviated Roland-Morris disability scale. *J Pain* 2004;5:257-63.
31. Butchart A, Kerr EA, Heisler M, Piette JD, Krein SL. Experience and management of chronic pain among patients with other complex chronic conditions. *Clin J Pain* 2009;25:293-8.
32. Sinnott P, Wagner TH. Low back pain in VA users. *Archives of internal medicine* 2009;169:1338-9.
33. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*. Washington, DC: National Academy of Sciences; 2011.

34. Crowley-Matoka M, Saha S, Dobscha SK, Burgess DJ. Problems of quality and equity in pain management: exploring the role of biomedical culture. *Pain Med* 2009;10:1312-24.
35. Kelly CM, Schootman M, Baker EA, Barnidge EK, Lemes A. The association of sidewalk walkability and physical disorder with area-level race and poverty. *J Epidemiol Community Health* 2007;61:978-83.
36. Dominick KL, Bosworth HB, Jeffreys AS, Grambow SC, Oddone EZ, Horner RD. Racial/ethnic variations in non-steroidal anti-inflammatory drug (NSAID) use among patients with osteoarthritis. *Pharmacoepidemiol Drug Saf* 2004;13:683-94.
37. Upshur CC, Luckmann RS, Savageau JA. Primary care provider concerns about management of chronic pain in community clinic populations. *J Gen Intern Med* 2006;21:652-5.
38. Christiansen S, Oettingen G, Dahme B, Klinger R. A short goal-pursuit intervention to improve physical capacity: a randomized clinical trial in chronic back pain patients. *Pain* 2010;149:444-52.
39. Sjogren P, Gronbaek M, Peuckmann V, Ekholm O. A population-based cohort study on chronic pain: the role of opioids. *Clin J Pain* 2010;26:763-9.
40. Hayden JA, van Tulder MW, Tomlinson G. Systematic review: strategies for using exercise therapy to improve outcomes in chronic low back pain. *Ann Intern Med* 2005;142:776-85.
41. Jordan MS, Lumley MA, Leisen JC. The relationships of cognitive coping and pain control beliefs to pain and adjustment among African-American and Caucasian women with rheumatoid arthritis. *Arthritis Care Res* 1998;11:80-8.
42. August KJ, Sorkin DH. Racial/ethnic disparities in exercise and dietary behaviors of middle-aged and older adults. *J Gen Intern Med* 2011;26:245-50.
43. Rasmussen-Barr E, Campello M, Arvidsson I, et al. Factors predicting clinical outcome 12 and 36 months after an exercise intervention for recurrent low-back pain. *Disabil Rehabil* 2012;34:136-44.
44. Belza B, Walwick J, Shiu-Thornton S, Schwartz S, Taylor M, LoGerfo J. Older adult perspectives on physical activity and exercise: voices from multiple cultures. *Prev Chronic Dis* 2004;1:A09.
45. Darker CD, French DP, Eves FF, Sniehotta FF. An intervention to promote walking amongst the general population based on an 'extended' theory of planned behaviour: a waiting list randomised controlled trial. *Psychol Health* 2010;25:71-88.
46. French DP, Stevenson A, Michie S. An intervention to increase walking requires both motivational and volitional components: A replication and extension. *Psychol Health Med* 2011.
47. French DP, Williams SL, Michie S, et al. A cluster randomised controlled trial of the efficacy of a brief walking intervention delivered in primary care: study protocol. *BMC Fam Pract* 2011;12:56.
48. Broonen JP, Marty M, Legout V, Cedraschi C, Henrotin Y. Is volition the missing link in the management of low back pain? *Joint Bone Spine* 2011;78:364-7.
49. Sniehotta FF, Scholz U, Schwarzer R. Action plans and coping plans for physical exercise: A longitudinal intervention study in cardiac rehabilitation. *Br J Health Psychol* 2006;11:23-37.
50. Prestwich A, Conner MT, Lawton RJ, et al. Randomized controlled trial of collaborative implementation intentions targeting working adults' physical activity. *Health Psych* 2012;31:486-95.
51. Krein SL, Metreger T, Kadri R, et al. Veterans walk to beat back pain: study rationale, design and protocol of a randomized trial of a pedometer-based internet mediated intervention for patients with chronic low back pain. *BMC Musculoskelet Disord* 2010;11:205.
52. Allen KD, Oddone EZ, Coffman CJ, et al. Telephone-based self-management of osteoarthritis: A randomized trial. *Annals of internal medicine* 2010;153:570-9.

53. Sperber NR, Bosworth HB, Coffman CJ, et al. Participant evaluation of a telephone-based osteoarthritis self-management program, 2006-2009. *Prev Chronic Dis* 2012;9:E73.
54. Rhudy JL, Dubbert PM, Kirchner KA, Williams AE. Efficacy of a program to encourage walking in VA elderly primary care patients: the role of pain. *Psychol Health Med* 2007;12:289-98.
55. Morey MC, Ekelund C, Pearson M, et al. Project LIFE: a partnership to increase physical activity in elders with multiple chronic illnesses. *J Aging Phys Act* 2006;14:324-43.
56. King AC, Wilcox S. Exploring physical activity preferences. *Ann Behav Med* 2008;35:123-4.
57. King AC, Haskell WL, Taylor CB, Kraemer HC, DeBusk RF. Group- vs home-based exercise training in healthy older men and women. A community-based clinical trial. *JAMA* 1991;266:1535-42.
58. Ginis KAM, Bray SR. Application of the limited strength model of self-regulation to understanding exercise effort, planning and adherence. *Psychology & health* 2010 25 1147-60.
59. Baumeister RF, Tierney J. *Willpower*. New York: Penguin Books; 2011.
60. Schmader T, Johns M, Forbes C. An integrated process model of stereotype threat effects on performance. *Psychol Rev* 2008;115:336-56.
61. Jackson JS, Knight KM. *Race and self-regulatory health behaviors: the role of the stress response and the HPA axis in physical and mental health disparities. Social structures, aging, and self-regulation in the elderly* New York, NY: Springer 2006:189-207.
62. Sperber NR, Bosworth HB, Coffman CJ, et al. Differences in osteoarthritis self-management support intervention outcomes according to race and health literacy. *Health Educ Res* 2013.
63. Tse MM, Vong SK, Tang SK. Motivational interviewing and exercise programme for community-dwelling older persons with chronic pain: a randomised controlled study. *Journal of clinical nursing* 2013.
64. Carmody TP, Duncan CL, Huggins J, et al. Telephone-Delivered Cognitive-Behavioral Therapy for Pain Management Among Older Military Veterans: A Randomized Trial. *Psychological services* 2012.
65. McDonough SM, Tully MA, Boyd A, et al. Pedometer-driven Walking for Chronic Low Back Pain: A Feasibility Randomized Controlled Trial. *The Clinical journal of pain* 2013.
66. Fortney JC, Burgess JF, Jr., Bosworth HB, Booth BM, Kaboli PJ. A re-conceptualization of access for 21st century healthcare. *J Gen Intern Med* 2011;26 Suppl 2:639-47.
67. Darkins A, Ryan P, Kobb R, et al. Care Coordination/Home Telehealth: The Systematic Implementation of Health Informatics, Home Telehealth, and Disease Management to Support the Care of Veteran Patients with Chronic Conditions. *TELEMEDICINE and e-HEALTH* 2008;14:1118-26.
68. Wilkinson JR. PACT- Integrating Telehealth into the PACT Care Model. In: *Cyberseminar*; 2012.
69. Armitage CJ. A volitional help sheet to encourage smoking cessation: a randomized exploratory trial. *Health Psychol* 2008;27:557-66.
70. Armitage CJ, Arden MA. A volitional help sheet to reduce alcohol consumption in the general population: a field experiment. *Prevention science : the official journal of the Society for Prevention Research* 2012;13:635-43.
71. Armitage CJ, Arden MA. A volitional help sheet to increase physical activity in people with low socioeconomic status: A randomised exploratory trial. *Psychol Health* 2010;25:1129-45.
72. Burgess DJ. Unpublished data. Response rates of black and white Veterans on the SHEP. In; 2012.

73. Glasgow RE, McKay HG, Piette JD, Reynolds KD. The RE-AIM framework for evaluating interventions: what can it tell us about approaches to chronic illness management? *Patient education and counseling* 2001;44:119-27.
74. Beebe J. Basic concepts and techniques of rapid appraisal. *Human Organization* 1995;54:42-51.
75. Baumeister RF, Bratslavsky E, Finkenauer C, Vohs KD. Bad is stronger than good. *Review of General Psychology*, 2001;5:323-70.
76. Safman RM, Sobal J. Qualitative sample extensiveness in health education research. *Health Educ Behavior* 2004;31:9-21.
77. Callahan CM, Unverzagt FW, Hui SL, Perkins AJ, Hendrie HC. Six-item screener to identify cognitive impairment among potential subjects for clinical research. *Medical care* 2002;40:771-81.
78. Matevey C, Rogers LQ, Dawson E, Tudor-Locke C. Lack of Reactivity During Pedometer Self-Monitoring in Adults. *Measurement in physical education and exercise science* 2006;10:1–11.
79. Van Duyn MA, McCrae T, Wingrove BK, et al. Adapting evidence-based strategies to increase physical activity among African Americans, Hispanics, Hmong, and Native Hawaiians: a social marketing approach. *Prev Chronic Dis* 2007;4:A102.
80. Krebs EE, Bair MJ, Damush TM, Tu W, Wu J, Kroenke K. Comparative responsiveness of pain outcome measures among primary care patients with musculoskeletal pain. *Medical care* 2010;48:1007-14.
81. Krebs EE, Lorenz KA, Bair MJ, et al. Development and initial validation of the PEG, a three-item scale assessing pain intensity and interference. *J Gen Intern Med* 2009;24:733-8.
82. Roland M, Morris R. A study of the natural history of low-back pain. Part II: development of guidelines for trials of treatment in primary care. *Spine* 1983;8:145-50.
83. Riddle DL, Stratford PW, Binkley JM. Sensitivity to change of the Roland-Morris Back Pain Questionnaire: part 2. *Phys Ther* 1998;78:1197-207.
84. Curran SL AM, Studts JL. Short Form of the Profile of Mood States (POMS-SF). *Psychol Assess* 1995;7:80-3.
85. Fischer D, Stewart AL, Bloch DA, Lorig K, Laurent D, Holman H. Capturing the patient's view of change as a clinical outcome measure. *JAMA* 1999;282:1157-62.
86. Bassett DR, Jr., John D. Use of pedometers and accelerometers in clinical populations: validity and reliability issues. *Physical Therapy Reviews* 2010;15:135-42.
87. Lorig K, Stewart A, Ritter P, Gonzalez V, Laurent D, Lynch J. Outcome measures for health education and other health care interventions. Thousand Oaks, CA: Sage Publications; 1996.
88. Nicholas MK. The pain self-efficacy questionnaire: Taking pain into account. *Eur J Pain* 2007;11:153-63.
89. Kroenke K, Spitzer RL, Williams JB. The Patient Health Questionnaire-2: validity of a two-item depression screener. *Medical care* 2003;41:1284-92.
90. Kroenke K, Spitzer RL, Williams JB, Lowe B. The Patient Health Questionnaire Somatic, Anxiety, and Depressive Symptom Scales: a systematic review. *Gen Hosp Psychiatry* 2010;32:345-59.
91. Ouimette P, Wade M, Prins A, Schohn M. Identifying PTSD in primary care: comparison of the Primary Care-PTSD screen (PC-PTSD) and the General Health Questionnaire-12 (GHQ). *J Anxiety Disord* 2008;22:337-43.
92. Krieger N, Smith K, Naishadham D, Hartman C, Barbeau EM. Experiences of discrimination: validity and reliability of a self-report measure for population health research on racism and health. *Social science & medicine (1982)* 2005;61:1576-96.

93. Kressin NR, Clark JA, Whittle J, et al. Racial differences in health-related beliefs, attitudes, and experiences of VA cardiac patients: scale development and application. *Medical care* 2002;40:172-85.
94. Galassi J, Ware W, Schanberg R. The patient reactions assessment: A brief measure of the quality of patient-provider medical relationship. *Psychological Assessment* 1992;4:346-51.
95. Dworkin RH, Turk DC, McDermott MP, et al. Interpreting the clinical importance of group differences in chronic pain clinical trials: IMMPACT recommendations. *Pain* 2009;146:238-44.
96. Jordan K, Dunn KM, Lewis M, Croft P. A minimal clinically important difference was derived for the Roland-Morris Disability Questionnaire for low back pain. *Journal of clinical epidemiology* 2006;59:45-52.
97. Ostelo RW, Deyo RA, Stratford P, et al. Interpreting change scores for pain and functional status in low back pain: towards international consensus regarding minimal important change. *Spine* 2008;33:90-4.
98. Dobscha SK, Corson K, Perrin NA, et al. Collaborative care for chronic pain in primary care: a cluster randomized trial. *JAMA : the journal of the American Medical Association* 2009;301:1242-52.
99. Kroenke K, Bair MJ, Damush TM, et al. Optimized antidepressant therapy and pain self-management in primary care patients with depression and musculoskeletal pain: a randomized controlled trial. *JAMA : the journal of the American Medical Association* 2009;301:2099-110.
100. D'Agostino RB, Chase W, Belanger A. The Appropriateness of Some Common Procedures for Testing the Equality of Two Independent Binomial Populations. *The American Statistician* 1988;42 198-202.
101. Fleiss JL, Levin, B., Paik, M.C. . *Statistical Methods for Rates and Proportions*. 3rd ed. New York: John Wiley & Sons; 2003.
102. Preacher KJ, & Hayes, A. F. . SPSS and SAS procedures for estimating indirect effects in simple mediational models. *Behavior Research Methods, Instruments, & Computers* 2004;36:717-31.
103. Sobel ME. Asymptotic confidence intervals for indirect effects in structural equation models. In: Leinhardt S, ed. *Sociological methodology*. San Francisco: Jossey-Bass; 1982:290-312.
104. Houston TK, Allison JJ, Sussman M, et al. Culturally appropriate storytelling to improve blood pressure: a randomized trial. *Ann Intern Med* 2011;154:77-84.
105. Spitzer RL, Kroenke K, Williams JBW, et al. A Brief Measure for Assessing Generalized Anxiety Disorder: The GAD-7. *Arch Intern Med* 2006;166:1092-1097.
106. Waddell G, Newton M, Henderson I, et al. A Fear-Avoidance Beliefs Questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability. *Pain* 1993;52:157-168.
107. Hausmann LRM, Kressin NR, Hanusa BH, et al. Perceived Racial Discrimination in HealthCare and Its Association with Patients' Healthcare Experiences: Does the Measure Matter? *Ethnicity and Disease* 2010;20:40-47.