SPECIFIC AIMS

There is accumulating evidence that older adults with chronic low back pain (cLBP) have significant lower extremity functional limitations, resulting in difficulty performing necessary daily tasks (i.e., walking, standing, putting on clothing, climbing steps, conducting housework). Moreover, older adults with cLBP suffer from declining lower extremity physical function over time. A recent review by the Centers for Medicare Services reported cLBP as a condition commonly resulting in physical decline among older adults and emphasized the need for interventions to mitigate these effects. Physical Activity (PA) is known to improve functional outcomes among older adults. However, studies to date have not evaluated the effects of PA on physical function among older adults (65+) with cLBP. Therefore, we lack an evidence base for the feasibility and effectiveness of PA interventions in this functionally vulnerable group. Another area of limited investigation among older adults with cLBP is the incorporation of cognitive behavioral therapy for pain (CBT-P) to support and complement a PA program. For example, cognitive restructuring may help patients to modify overly negative thoughts about possible activity-related pain, and activity pacing can be important for helping patients with cLBP learn to plan and structure their PA to avoid pain exacerbations. However, the combination of PA and CBT-P has not been evaluated in older adults with cLBP.

To address these gaps, our proposed study will examine the feasibility and efficacy of home-based PA only and PA + CBT-P programs, compared to a wait-list control group; both programs can be disseminated widely in the VA health care system among older veterans with cLBP. In accordance with general recommendations for PA among patients with LBP, the PA program will be comprehensive, including stretching, strengthening, and aerobic endurance activities. However, the specific types and intensities of the PA will be specifically geared toward older adults. CBT-P will also be based on standard principles but tailored to specific issues for older adults with cLBP, including the challenge of adopting and maintaining a PA program in the context of chronic pain.

Another novel aspect of this project will be the evaluation of baseline pain sensitivity, measured with field-based techniques, as a potential predictor of response to the interventions. Some patients with cLBP have a lower threshold for pain, due to an augmented central pain processing mechanism. As such, measures of pain sensitivity may prove useful in understanding an ongoing refractory pain-process; it is possible that patients who have a lower threshold for pain may respond differentially to behavioral interventions. In particular, these patients may experience greater improvement when CBT-P is offered as an additional program component (compared to PA alone), since these cognitive skills have been shown to influence pain processing. This pilot study will be an important step, ultimately leading to guidance regarding whether some older adults with cLBP should be offered a PA only vs. PA + CBT-P.

To our knowledge this will be the first study to examine the home-based PA only and PA + CBT-P programs among older adults with cLBP, as well as the first to evaluate central pain sensitivity as a predictor of response to these interventions. Therefore preliminary data are needed to support a larger project. Our specific aims are:

Specific Aim 1: Examine the feasibility of conducting 12-week home-based, telephone-supported programs of: 1.) PA only and 2.) Combined PA+CBT-P, among older veterans (65+ years) with cLBP. Quantitative measures of feasibility will include the proportions of patients who initiate and complete the programs and adherence to in-home PA recommendations and cognitive behavioral skills practice. We will also collect in-depth qualitative information to assess aspects of the interventions that may need to be modified prior to a larger study.

Specific Aim 2: Collect preliminary data to evaluate the efficacy of the PA only and PA + CBT-P programs among older veterans with cLBP. Main outcomes will be an objective test of general physical function (timed up-and-go (TUG)) and self-reported physical function (PROMIS Health Assessment Questionnaire (PROMIS-HAQ)). Secondary outcomes will include: Patient Specific Functional Scale (PSFS), Satisfaction with Physical Function Scale, LBP-specific disability (Roland-Morris Low Back Pain and Disability Questionnaire (R-MDQ)), and the Coping Strategies Questionnaire.

Specific Aim 3: Examine whether baseline distal Pressure-Pain Threshold, an established biological marker of pain sensitization, and the Central Sensitivity Inventory, which measures health-related symptoms common to central pain sensitization, predict differential response to the PA only and / or PA + CBT-P programs among older veterans with cLBP.

There is a need to develop and disseminate effective programs to improve PA and ultimately physical function in this patient subgroup. This project will be a key first step in evaluating a home-based PA and PA + CBT-P programs that could be widely disseminated in the VA at relatively low cost and reach many functionally vulnerable older veterans with cLBP.

BACKGROUND AND SIGNIFICANCE

Low Back Pain is Highly Prevalent in Veterans and Older Adults

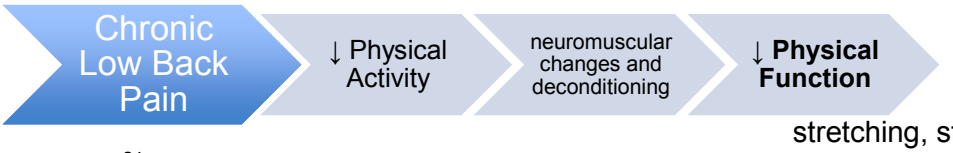
Low back pain (LBP) is a complex and a multidimensional condition resulting in approximately $100-$200 billion per year in costs for the U.S.[1] LBP is the second most common cause of disability[2] and a common reason to seek primary care. [3-5] LBP is particularly common among U.S. veterans. Sixty-percent of VA primary care patients report having chronic pain that significantly impacts self-rated health, functional status and self-reported quality of healthcare; of these, about 60% specifically report having LBP.[6] Similar to the civilian population[7] the prevalence of chronic low back pain (cLBP), defined as pain lasting >3 months, is rising steadily among veterans, with a 4.8% annual increase from 2000-2007[8]; this rate of increase is higher than those for diabetes, hypertension and depression. Among older adults, LBP is also very common, with prevalence estimates in the general community ranging from 13 to 49%.[9,10] The wide range is likely due to methodological differences in the definition of LBP and age range of included participants. Research on interventions to treat cLBP in older adults has been very limited.[10,11] This is an important consideration as the proportion of people over 65 years of age is expected to increase over the next 25 years, and the prevalence of musculoskeletal problems is expected to increase as well.[10]

Older Adults with cLBP are Particularly Susceptible to Functional Decline

A number of studies have shown that cLBP is associated with functional limitations and decline among older adults, independent of other health conditions.[12] Among older adults in the Health ABC study, for example, functional capacity scores worsened with increasing frequency and intensity of LBP.[13] Edmond and Felson[14] found that among older adults in the Framingham Heart Study, 18% to 34% of all functional limitations were attributable to back symptoms. In terms of ongoing functional decline, Reid and colleagues[15] found that participants with 4 months of LBP at baseline had declining gait speed, chair stands and foot tapping over the subsequent 18 months.[15] The impact of LBP on physical function in older adults is particularly important because functional decline is associated with many deleterious effects, including changes in cognitive function and mortality.[16,17] **We have chosen to focus on physical function as a primary outcome since LBP does not have to be completely eliminated to avoid adverse consequences of functional decline.[15]**

Physical Activity Can Improve Functional Outcomes, But Older Adults with cLBP Are Understudied

The relationship between cLBP and physical function is primarily based upon a model where cLBP leads to decreased PA, subsequent deconditioning and neuromuscular changes, followed by decreased physical function (See Figure).[18-23]



Guidelines state that a PA program for individuals with cLBP should be comprehensive and include stretching, strengthening, and endurance activities.[24] A recent meta-analysis also found that a combination of stretching, strengthening and endurance activity significantly improved physical function among older adults (OR=2.14 (95% CI 1.42 to 3.24)).[25] Despite this evidence and guidance, only 38% of veterans with chronic pain, including cLBP, use exercise to treat their pain.[6] Although there is evidence to support the use of PA for older adults in general, there is a lack of high quality RCT's[26] regarding PA interventions for older adults with cLBP. **Older adults with cLBP may be more likely to have comorbidities and greater functional limitations than middle aged adults with cLBP;[9] therefore there is a need to specifically evaluate the acceptability and effectiveness of PA programs in this subgroup of patients with cLBP.**

Cognitive Behavioral Therapy Can Improve Pain Perception for cLBP

Cognitive behavioral therapy comprises techniques that aim to influence maladaptive emotions, behaviors and cognitions through a goal-oriented, systematic procedure. Cognitive behavioral approaches have been applied to many health conditions and health behaviors [27] and can be flexibly adapted to a wide range clinical settings, including telemedicine. Cognitive behavioral therapy for pain (CBT-P) is associated with improved outcomes among individuals with cLBP[28], as well as other pain-related conditions.[29-31] Previous studies also show that older adults are willing to engage in self-management programs for pain that include both cognitive and PA components.[32,33] There is growing evidence that CBT-P alone or combined with PA can improve pain and function. However, the effectiveness of PA + CBT-P compared to PA alone has not been evaluated among older adults with cLBP.

Central Pain Sensitivity May Predict Differential Response to PA for Low Back Pain

To date it has been challenging to understand why some individuals with cLBP respond favorably to evidence based interventions, such as PA, and others do not.[34] One factor that may underlie this differential treatment response is central pain sensitivity.[35] Findings from cLBP studies suggest that some patients have an augmented pain sensitivity, in which the pain experience results from or is exacerbated by abnormal pain processing rather than damaged or inflamed peripheral structures.[36] As such, pain sensitivity may prove useful in understanding an ongoing refractory pain-process and particularly why some patients do not respond to a PA intervention alone.[37] There is evidence that psychosocial characteristics such as pain catastrophizing and depression contribute to pain sensitization,[38] and CBT-P can improve these psychological processes and outcomes.[39,40] Therefore older adults with cLBP who have higher baseline pain sensitivity may respond better when PA is combined with CBT-P versus a PA program alone. However, this has not been investigated, and this pilot study will be an important step in this area of research.

Summary of the Significance of the Proposed Study

Although there have been other studies of PA for patients with cLBP, including a walking program among veterans[41], our study makes novel and significant contributions: 1.) It will be specific to older adults, who are more susceptible to comorbid conditions and functional deficits, whereas previous studies have been conducted primarily among middle-aged samples.[41] 2.) It will incorporate a combination of stretching, strengthening, and aerobic activity in a semi-structured approach, conducted primarily in the home environment; these types of physical activity programs have been effective for improving functional status among older adults in general, and they can be disseminated widely in the VA healthcare system.[42] 3.) It will compare the effectiveness of PA + CBT-P vs. PA alone, which has not been investigated among older adults with cLBP. 4.) It will evaluate the potential role of central pain processing as a predictor of response to the PA alone and PA+CBT-P interventions, which has implications for downstream tailoring of care for patients.

PRELIMINARY STUDIES and STUDY TEAM COLLABORATION

The study team demonstrates both independent and collaborative research efforts that provide a foundation for a successful outcome for this proposal. Dr. Allen is Principal Investigator (PI) on three currently or recently funded clinical trials focused on behavioral interventions for patients with chronic musculoskeletal conditions, primarily osteoarthritis.[43,44] Two of these trials involve telephone-based interventions that include PA counseling and CBT-P.[44] Dr. Goode and Dr. Allen have recently collaborated on research showing that among adults with osteoarthritis, back pain was self-reported by 75% and associated with worse self-reported physical function and satisfaction with function.[45] Dr. Goode is a physical therapist with ample experience in treating patients with cLBP. His research focuses on epidemiology and health services related to LBP. Most relevant to this project, he has submitted several papers and abstracts that focus on predictors of LBP and the role of PA and physical function among older adults. First, in longitudinal analyses, the only significant predictor of future LBP was lower baseline functional status (risk ratio=1.75 (95% CI 1.42, 2.16)), measured by the Health Assessment Questionnaire (HAQ).[46] Second, among older adults, the presence of functional limitations was significantly more common among those with LBP, and moderate PA was lower among those with LBP.[47] Dr. Goode has also completed several studies determining the associations of central pain sensitivity with knee and hip osteoarthritis,[48,49] LBP and spine degeneration.[50] This experience has given Dr.

Goode knowledge of measurement and analysis-related issues regarding pressure pain threshold (PPT), one of our proposed measures. Dr. Hastings is a Geriatrician with research interests in improving transitions of care for older adults, in part through optimizing physical activity and function. She is Project Director for a Clinical Demonstration Program that aims to improve functional status among hospitalized older adults through a supervised walking program. She is also currently PI of a clinical trial examining telephone support for older veterans who are discharged from the emergency department. Dr. Carey is an epidemiologist and internal medicine physician. He is an internationally recognized leader in epidemiology and health services research related to LBP and has worked closely with Dr. Goode in these areas.[51-54]

RESEARCH DESIGN AND METHODS

Study Design: This project will be a randomized controlled pilot trial of 12-week programs of PA only and PA + CBT-P, both supported by telephone, among 60 older adults with cLBP at the Durham VA Medical Center (VAMC). Participants will be randomly assigned with equal allocation to the two intervention groups or a wait-list control (WL) group. Participants will complete assessments at baseline, then approximately 12-weeks later. Participants in the WL group may choose to participate in the PA only or PA + CBT-P program following 12-week assessments. The 12-week follow-up was chosen because this is a reasonable time frame for older adults to experience neuromuscular adaptations and changes in general physical function.[55] We chose a home-based exercise program because of its feasibility for widespread dissemination in the VA and because prior work has shown that home-based PA programs are safe and effective for improving physical function among older adults.[42] We have chosen telephone-based approach because we expect this method of communication will be well received by older veterans, based on our prior and ongoing work in telephone-based PA support for osteoarthritis.[44,56] We have chosen to include a control group in this pilot trial to account for any general improvement or changes in primary care intervention that may be observed in the course of cLBP. Participants will be paid $30 for each assessment visit for time and travel.

Participants and Recruitment: The target sample for this study will include older veterans (65+ years) with cLBP at the Durham VAMC. We may over-sample women to ensure this important demographic group of Veterans is adequately represented in the study. In particular, we may prioritize contacting women Veterans who meet study entry criteria so that they comprise at least 30% of the study sample. We will have three recruitment mechanisms:

1. Using VistA, we will first identify potential participants, age 65+ who have an ICD-9 code for low back pain or an indication of low back pain on the problem list and no exclusionary diagnoses. Because the study involves two in-person sessions, we may restrict this data pull to patients who live relatively close to the Durham VAMC. For example, we may initially restrict mileage to 60 miles from the Durham VAMC and based on our experience with this radius, we may expand or narrow this mileage. Next, we will review electronic medical records to confirm a physician diagnosis of chronic low back pain and further assess exclusion criteria. We will then mail introductory letters to these patients, providing a brief description of the study and informing patients that a study team member will be calling them to assess their eligibility and interest in participating. The letter will also include a telephone number patients may call if they are not interested in participating and do not wish to receive a follow-up call.

During the telephone call, a study team member will administer a screening questionnaire to assess additional eligibility criteria, including verification of cLBP symptoms. If veterans meet screening criteria and are interested in participating in the study, they will be asked to meet the Research Assistant at the VAMC for a baseline study visit.

2. We will work with Hospital Informatics to set up the CPRS consult option for referral of potential research participants into this study. We will provide information to health care providers in ambulatory care, geriatric services (Dr. Hastings is Director of the Geriatrics Clinic), and other services as necessary, to inform them about the study and availability of the consult. This may include information distributed by email, flyers, and in-person visits to clinic team meetings. We will designate two study team members to receive the consult as a View Alert. These staff will review the electronic medical record to assess whether the patient is eligible. If the patient is eligible based on medical record review, an introductory letter will be mailed, and the remaining screening and baseline appointment scheduling procedures will follow those described above. The staff will

then respond to the provider who issued the consult to let them know if the patient is eligible and will / will not be contacted for further screening procedures We have successfully utilized these strategies in other research projects.[43,44,56]

3. We will create a brochure that includes the study description and contact numbers for the project coordinator and research assistant. We will provide the brochure to physical therapists and potentially other providers at the Durham VAMC so that they can place them in clinic areas where they can be visible to veterans. If a veteran is interested and calls the study team, we will review the medical record to see if the veteran is eligible. If eligible by medical record review, the veteran will be screened using the same telephone screening method explained in the other recruitment methods listed previously.

The baseline visit will include administration of consent, baseline questionnaires and functional assessments, and an examination by a physical therapist (Dr. Goode). During the physical therapist exam a Well Straight Leg Raise physical examination test will be used to determine the presence of ongoing sciatica, which may be exacerbated with physical activity. This test is conducted with the participant in supine position and the examiner supporting the non-involved leg. The examiner then raises the leg. A positive test is indicated if the participant reports concordant leg pain. This test is commonly used in clinical practice and is highly specific for sciatica (specificity=97%).[57] Results of the physical therapist examination will be used to determine physical appropriateness for participation in the home-based PA program, based on the clinical expertise of the physical therapist and the criteria described below. If the physical therapist determines that the patient is not appropriate for participation in a home exercise program, the patient's primary care provider will be notified via response to the consult if the patient was referred by the provider, and that provider may refer the patient for more supervised physical therapy. All other non-qualified patients will have a progress note entered into CPRS stating that they may benefit from supervised physical therapy. During the baseline visit the participants will also receive a packet with several self-administered measures to fill out either at that time, or they can complete the questionnaires at home and then mail them back to the study team using a pre-addressed stamped envelope. We will monitor the return of these items and may need to do telephone follow-up calls to ensure that all measures are returned.

Randomization: Following the completion of all baseline assessments and the physical therapist examination, participants will be randomly assigned to one of the two intervention arms or to the wait list control group via an envelope selection procedure or by use of a randomization table programmed into the study tracking database. Randomization will be stratified by Central Sensitization Inventory (CSI) score (described below under *Measures of Central Pain Sensitization*), categorized by >40 vs. ≤40; this to ensure individuals with high vs. low pain sensitivity will be equally distributed across study groups.

The principal investigator, project coordinator, or physical therapist will select an envelope from one of two batches. One batch of envelopes will be for participants who have a CSI score of >40. The other batch of envelopes will be for those with CSI ≤40. Following randomization, participants assigned to the PA or PA + CBT-P intervention will receive their first intervention visit from the physical therapist, unless they need to complete this at another time for scheduling reasons.

Inclusion / Exclusion Criteria: Based on previous studies,[58] we will **include participants who**:

1) Self-report having had lower back pain on most days for greater than three months.
3) Can complete a 10 second semi-tandem stand and walk 8' in 6.0 seconds.
4) Report they are not satisfied with their current state of functional ability, based on reporting "dissatisfied" with at least one aspect of physical function on the Satisfaction with Physical Function Scale.[59]
5) Can safely participate in the intervention based upon the physical therapist baseline examination and clinical expertise.

Veterans will be **excluded if they have**:

1) acute unilateral or bilateral sciatica (based on Physical Therapist exam at baseline); isolated coccyx pain (based on self-report at screener);
2) dementia or other significant cognitive impairment;
3) movement or motor neuron disorders (e.g., Parkinson's Disease, Multiple Sclerosis, Amyotrophic Lateral Sclerosis);
4) rheumatoid arthritis, fibromyalgia, or other systemic rheumatic disease;

5) hospitalization for a stroke, myocardial infarction, heart failure, or coronary artery revascularization in the past 3 months;
6) significant hearing impairment (must be able to talk on the telephone);
7) psychosis or current, uncontrolled substance abuse disorder;
8) legally blind;
9) any other health conditions determined by the study team to be contraindications to performing mild to moderate home exercises.
Based on our prior and ongoing studies at the Durham VAMC that have similar recruitment and procedural methods, we are confident we can enroll n=60 older veterans with cLBP within the proposed recruitment period for this study. Study participants excluded after consent due to the presence of sciatica or other functional limitations or health problems as determined by the physical therapist at baseline will not be randomized and thus not included in our total enrollment goal, i.e. we plan to consent enough participants such that a total of n=60 are eligible to participate, having met the eligibility criteria assessed following consent.

Physical Activity Program: The PA program for this study is based on three general principles[60]: 1.) Feasibility to disseminate widely within the VA healthcare system. 2.) Recommendations for PA among older adults (e.g. mild to moderate intensity). 3.) Recommendations for PA programs for individuals with cLBP.[26] This PA program will include 12 weeks of home-based exercise, including stretching, strengthening, and aerobic activities, and will follow Department of Health and Human Services recommendations for PA for older adults.[61] At the baseline visit, the physical therapist will provide participants with basic information on appropriate PA techniques and an individualized PA program, guided by baseline assessments. PA programs will be based on a core set of strengthening and stretching exercises (in addition to regular aerobic activity), which cover major muscle groups and functional tasks. The physical therapist will provide personalized recommendations from within this set, including specification of the specific exercises assigned (e.g., starting with a smaller number of exercises at the beginning of the program, easier options for those with more limited function) and duration / number of repetitions for each exercise; the therapist may also add other exercises to address specific deficits and progression. Following this, the physical therapist will conduct approximately 30-minute phone calls at weeks 1, 4, and 9, and an exercise counselor will conduct phone calls at weeks 1-3, 5-8, and 10-12. We have chosen this "joint delivery" model to combine the clinical expertise of the physical therapist (e.g., addressing specific functional and clinical issues and recommending appropriate modifications and progression of activity) and the motivational interviewing expertise of the exercise counselor, to foster adherence. If participants report any pain increases or other clinical issues during a telephone call with the exercise counselor, the physical therapist may follow up with a telephone call to address these problems. The exercise counselor may recommend that participants decrease their overall activity level or discontinue any specific pain-inducing exercises until the physical therapist gives the participant further instructions. We will document these situations, and this will be important information for development of a larger clinical trials (e.g., whether more frequent calls from the physical therapist during a particular phase of the program may be advantageous). Although specific PA recommendations will be given by the physical therapist, the exercise counselor will help participants to identify and problem-solve general barriers to achieving PA goals, such as lack of time, lack of motivation, etc. The exercise counselor will ask participants about their PA during the prior week, and based on this information will help them to refine action plans for achieving PA goals for the upcoming week. All calls will use a semi-structured approach, where the overall content will be standardized across participants, but the physical therapist and exercise counselor will have flexibility to address patient-specific concerns

We will also provide participants with resources for facilitating PA. First, we will give participants a handout containing instructions for general strengthening and stretching exercises appropriate for older adults with cLBP. These exercises will not focus only on the low back, since recommendations indicate that more general exercise is appropriate for this patient group. However, these exercises will avoid positions and activities that tend to be painful or difficult for individuals with LBP and those with extremely low functional abilities. These booklets will contain both simple written instructions and high quality photographs for each exercise, similar to those Dr. Allen and colleagues have developed for other studies.[44,56] Second, we will provide participants with a copy of an exercise video called *Take Control With Exercise*, created by the Arthritis Foundation. Although

developed for individuals with various types of arthritis, this exercise video is very appropriate for older adults with cLBP and shows patients with various functional abilities completing the exercises.

One challenge in the area of PA is that of adherence. We will employ several strategies for fostering adherence to PA goals. First, we will ask participants to develop and document specific plans for when they will complete their PA. Second, we will help participants to develop PA action plans that are reasonable for them to achieve. Specifically, the exercise counselor will ask participants to rate their self-efficacy for completing action plans with a standardized question (i.e., How confident are you that you can complete these action plans, on a scale of 0-10, with 0 being not at all confident and 10 being very confident?). If participants rate their self-efficacy lower than 7, the exercise counselor will recommend they revise their plans so they are more confident they will be able to carry them out. Prior research has shown that a self-efficacy rating of 7 or above is associated with a greater likelihood of accomplishing a goal or plan, [62] and this strategy has proven successful in our prior and ongoing studies.[44,56] Third, during each telephone call the exercise counselor will ask about any barriers participants encountered since the last phone call. This will be in the form of an open-ended question "What barriers did you face to completing your physical activity action plans since we spoke last?". The exercise counselor will then guide participants in a process of problem-solving any barriers noted, which will be incorporated into action plans for the next week.

CBT-P Intervention

Participants in this group will additionally receive instruction in CBT-P skills, woven into each telephone-based session and with specific application to PA (e.g., overcoming pain-related barriers and managing pain associated with activity). This intervention will be delivered by the exercise counselor, who will be cross-trained to deliver CBT-P, as we have successfully done in prior studies.[44] We will utilize modules we have previously developed for teaching these skills in a behavioral intervention for osteoarthritis.[44] Participants will receive written materials for instruction in each skill, as well as an audio recording to facilitate progressive muscle relaxation. The specific topics included will be: activity pacing, breathing relaxation, distraction, progressive muscle relaxation, and cognitive restructuring. Consistent with a cognitive-behavioral approach, initial strategies will stress behavioral strategies whereas cognitive strategies are introduced later in treatment.[27] The exercise counselor will discuss each skill described below at two telephone calls. The first call will begin with education about the specific strategy, including a rationale for its application to the management of cLBP-related pain. Participants will then briefly rehearse the new skill with the counselor. The counselor will next discuss potential facilitators and barriers to practicing and applying the new skill. Finally, the counselor will help participants to develop a plan for independent practice and application of these strategies to manage symptoms. Participants will be provided with a log to record their practice of these skills. During the second call for each skill, the participant and counselor will work collaboratively to review progress towards mastering, adapting, and applying these new skills to meet the participant's individual goals.

The following are brief descriptions of each topic addressed in this portion of the intervention:

Activity Pacing: Activity pacing is a simple but essential principal for managing cLBP. Strategies for pacing activities include: going slower through normal daily activities, taking periodic rest periods, and breaking up activities into smaller tasks. When instructed in activity pacing, participants will be asked to identify regular tasks that sometimes result in increased pain. Then participants will be guided in a process of choosing a strategy to pace that activity to reduce the load on the body.

Breathing Relaxation: cLBP can be physically and emotionally taxing, and both physical and emotional tension can increase pain perception. Relaxation exercises are a well-documented method for reducing bodily tension, arousal, and anxiety, and for increasing a sense of control and well-being. Breathing relaxation entails slow, deep, rhythmic breathing, inhaling through the nose and exhaling through the mouth. We will provide participants with audio instructions on CD for relaxation exercises.

Distraction: Distraction involves changing the focus of attention when pain is experienced, or in anticipation of a painful experience. This skill is most useful during short, discrete tasks, such as walking up stairs. Participants will be asked to identify activities that sometimes result in increased pain and to think of something pleasant or engage their mind in another task during this activity.

Progressive Muscle Relaxation: Progressive muscle relaxation involves systematically tensing and relaxing each muscle group and can be effective in producing deep relaxation and reducing muscle tension. We will provide participants with audio instructions on CD for relaxation exercises.

Cognitive Restructuring ("Positive Self-Talk"): Cognitive restructuring is a technique for identifying and correcting negative thought patterns, which may be associated with maladaptive behaviors and emotional responses, as well as greater pain. This technique involves identifying "automatic thoughts", examining and challenging the assumptions behind those thoughts, and replacing them with more rational beliefs. Through repeated practice, participants learn to recognize and modify negative thinking and to create more adaptive and rational perceptions of situations, others, and themselves.

Measures and Data Collection: Outcomes will be measured in person at the Durham VAMC at baseline and 12-week follow up. Our primary outcomes consist of general physical function measures, assessed both objectively and via patient self-report:

Primary Physical Function Outcomes: *Timed Get Up-and-Go* [63]: This test requires the participants to stand from a standard arm chair, walk 3 meters and then return to sitting in the same chair.[64] The timed get up-and-go test has demonstrated excellent reliability and correlates well with other standard measures such as gait speed, self-report and clinical report indices of function, and is predictive of who can safely ambulate [65].
PROMIS Health Assessment Questionnaire (PROMIS-HAQ): The PROMIS HAQ is a self-reported physical function/disability measure that captures both activities of daily living and instrumental activities of daily living. It consists of 20-items scored on a 0-3 scale with a summed 0-100-unit scale.[66]

Secondary Outcomes: Our secondary outcomes will measure disease specific symptoms and disability:
Patient Specific Functional Scale (PSFS): This measure captures items that are specific functional tasks that may be missed on standardized questionnaires. The measure consists of 5 items specifically provided by the patient. Each item provided by the patient is score from a 0 (Unable to perform task) to 10 (able to complete the activity without difficulty) scale.[67] The PSFS is reliable, valid, and sensitive to change over time.[67,68]

Roland-Morris Disease Specific Disability Questionnaire (R-MDQ): We will measure the impact of patients LBP specific disability with the 24-item R-MDQ.[69] The R-MDQ is reliable and valid[69] and a responsive to for LBP.[70]

Satisfaction with Physical Function Scale: This is a validated 5-item questionnaire that assesses patients' satisfaction with their ability to complete basic functional tasks that are often affected by lower extremity OA, including stair-climbing, walking, doing housework (light and heavy), and lifting and carrying.[59] All items are rated on a 7-point scale ranging from Very Dissatisfied (-3) Very Satisfied (+3).

Physical Activity Scale for the Elderly (PASE): The PASE is a brief self-report, 12-item scale that measures level occupational, household and leisure activity during a one-week period. This scale has good reliability (r=0.68) and test-re-test reliability (r=0.75).[71] It has also been validated for telephone administration.

Short Physical Performance Battery (SPPB): The SPPB is an objective assessment of physical function. This series of functional tests has been shown to predict hospitalization, disability, nursing home placement, and declines in health and function. This test battery is relevant to the study because it assesses aspects of daily function that require lower extremity strength and are often impacted by low back pain. Specifically, this battery examines participants' balance (3 tests), gait speed (8-foot walk), and time to rise from a chair and return to the seated position five times. We will follow previously established protocols for administering and scoring each of these tests. For each test, the possible range if scores is 0-4, for a total range of 0-20 for all five tests. We will also administer the 2-minute step test. These assessments will be conducted at baseline and 12-week follow-up.

Measures of Central Pain Sensitization: There are a several methods for measuring central pain sensitivity.[35] For this study we have chosen field-based tests and a self-report measure because of their potential utility for use in clinical practice:
Pressure-Pain Threshold (PPT): PPT is a safe, easily administered, low cost, and validated biological marker of pain sensitivity that has been commonly used in musculoskeletal conditions.[72] This test involves using a digital device to measure the amount of pressure experienced by a participant. Consistent with established

protocols, PPT measurements will be collected from both the left and right upper trapezius muscle and lumbar spine erector spinae musculature at the level of L5 in a systematic fashion, with the first being a practice trial. Beginning with the left side, pressure will be applied to the muscle at approximately 1Kg per second until the participants indicate self-reported pain. Trials will continue until two consecutive readings were within +/-0.4 Kg's for a maximum of four trials. The same procedure will be repeated for the right side.

Central Sensitization Inventory (CSI): The CSI assesses 25 health-related symptoms common to central pain sensitization (Part A), as well as ten specific diagnoses related to central pain sensitization (Part B).[73,74] It is easy to administer and was developed specifically for use in medical settings, to help identify patients with central pain sensitivity and guide treatment approaches. Part A items (which will be the focus for this study) assess the frequency of symptoms on a Likert scale of 0 (never) to 4 (always). The CSI has demonstrated strong psychometric properties (test-retest reliability=0.817, Cronbach's alpha=0.879), and CSI Part A scores differed in the expected manner among healthy patients and those with different conditions associated with central pain sensitization (fibromyalgia, chronic widespread pain, and cLBP).[73] Recent data have also identified a clinically relevant cutoff value of 40 for CSI Part A (out of a maximum score of 100).[74]

Temporal pain summation and Wind-up ratio: Testing is conducted according to previous research and protocols.[75-77] On the participant's forearm, the researcher applies a 180-gram von Frey filament once or twice to familiarize with the sensation. Then it is applied 11 times within a 1 cm diameter circle. After one touch, the participant is asked to rate the pain on a 0-100 verbal pain scale. Then ten consecutive touches are applied at random locations with a 1 second interstimulus interval and the participant is asked to rate the pain of the 10th application. The participant is also asked to provide an estimated mean over the whole series of 10 stimuli using the 0-100 verbal pain scale. The whole procedure is repeated five times. Mechanical temporal summation is calculated by subtracting the pain rating after the 1st touch from the pain rating after the 10th touch from the first round of the testing. Wind up ratio is calculated as a ratio: mean rating of the five series divided by the mean rating of the five single stimuli. These measures provide an indication if some participants perceive more pain due to enhanced nociceptive responses from repeated neural firing.

Adherence and Feasibility Measures: An important part of this pilot study will be collection of data regarding the interventions' feasibility and acceptability to patients. We will collect the following information:
PA and CBT-P Logs and Telephone Call Completion: One important measure of feasibility will be to assess patients' adherence to the PA and PA + CBT-P programs. This will be assessed via the number of telephone calls completed, as well as performance of PA and practice of CBT-P skills. The latter will be evaluated by logs, which we will ask participants to return to the study team at the follow-up visit (or via a pre-addressed and stamped envelope if needed). We acknowledge that there are limitations to the reliability and accuracy of self-report logs. However, we believe that in this type of feasibility study it is useful to assess the degree to which participants are engaging in PA and CBT-P skills practice.
*Participant Feedback: W*e will ask participants a series of open-ended questions at the end of the program to obtain information on all aspects of the PA and CBT-P programs.

Duke-UNC Functional Social Support Questionnaire: The Duke-UNC Functional Social Support Questionnaire is an 8-item, self-reported, two-scale instrument assessing functional social support. Five items assess confidant support and three items assess affective support. The scales are computed by averaging the items, which are measured on a 6-point continuum.

Revenson: Four self-report items, used originally by Revenson and colleagues (1991), and used in further studies will assess problematic support for pain among the participant's close social relations. The items are measured on a 1-5 scale and averaged to create a composite score.

CSQ: The Coping Strategies Questionnaire was developed to assess coping skills in a chronic pain population. Two items assessing perceived control over pain were selected to assess this construct, consistent with the literature. The items are measured on a 1-5 scale and averaged to create a composite score.

CES: The Coping Efficacy Scale is a three-item, self-report scale designed to measure an individual's perceived efficacy in coping with pain. The items are measured on a 1-5 scale and averaged to create a composite score.

ECR-R: The Experiences in Close Relationships Scale-Revised is a self-reported measure of adult attachment, which captures both attachment avoidance and attachment anxiety. Each subscale is computed by taking the mean of 18 unique items, which are measured on a 1-5 scale.

BFI: The Big Five Inventory is a self-reported assessment of personality. Two subscales from the BFI were selected: neuroticism and extraversion. Subscales are computed by averaging the scores from 8 unique items, which are measured on a 1-5 scale.

Participant Demographic and Clinical Characteristics: These data will be collected at baseline to characterize the sample. Demographic characteristics will include self-reported age, gender, race/ethnicity, education level, income level, working status, and marital status. Clinical and health-related variables will include: BMI (calculated based on measured height and weight), duration and intensity of LBP symptoms, general self-rated health, and depressive symptoms (Patient Health Questionnaire-8[78]). Comorbid medical conditions will be assessed using the Self-Administered Comorbidity Questionnaire.[70,79] We will also administer the Coping Strategies Questionnaire and Pain Catastrophizing Scale. All clinical and health-related variables except height and weight will be self-reported.

Analyses: We will compare outcomes across study groups with analysis of covariance (ANCOVA) models (or non-parametric alternatives such as the Kruskal-Wallis test, when indicated), controlling for baseline values. Since this is a pilot study with small sample size, even clinically relevant differences may not be reflected as statistically significant differences (e.g. $p<0.05$). Therefore we will focus on effect sizes for the two intervention groups and evaluation of whether between-group difference reflects a threshold of clinical relevance. These data, along with means and standard deviations of baseline scores, correlations between baseline and follow-up scores, and attrition rate will also be used to calculate the appropriate sample size for a larger clinical trial. To address Aim 3, we will first plot baseline PPT and CSI values vs. changes in outcomes for each intervention group; we will also calculate correlations for these same associations. This will allow us to evaluate whether associations between baseline pain sensitivity measures and changes in outcomes may differ between the two intervention groups. Based on our previous experience with analyzing PPT data, we will also dichotomize these baseline scores at a <4kg vs. >=4kg to represent low and high pain sensitivity.[80] We will then add an interaction term to our ANCOVA models (study group * dichotomous PPT variable) to evaluate whether intervention effects vary by this indicator. If a significant interaction term is found, we will stratify the sample by this variable and explore the nature of the interaction. A similar analysis will be conducted with the established cutpoint on CSI scale or 40 out of 100.[81]

Privacy and Confidentiality and Information Security

The following measures will be taken to protect participants' privacy / confidentiality:

- The study involves sending recruitment letters; these will not contain the name of the study or any reference to the condition being studied.
- When leaving telephone messages regarding study activities, team members will not leave information about the study or condition, just the name of the study team member calling from the Durham VAMC.
- This study involves telephone calls to administer a screening interview and conduct parts of the intervention. These will be conducted in a manner that minimizes the possibility that any person not associated with the study can hear the participant's name or any other identifiable information.
- The study involves in-person consent, interviews, and physical function assessments. The consent process and interviews will be conducted in a private room in the VA. Some physical function assessments may need to be conducted in an appropriate area, such as a VA physical therapy clinic that has a therapy mat. For these assessments, we will use a private therapy room if available; if unavailable we will minimize interactions with non-study personnel and not verbally utilize any

identifiable information in the interaction. We will also let the participant know that they may choose not to participate in those assessments and still continue in the study.

- Use of paper documents will be minimized, and all of these documents (e.g., consent forms) will be stored in a locked file cabinet in the office of a study team member located on the 6th floor of the NC Mutual Building.
- All electronic study data will be stored on a secure VA server accessible only to study team members.

Information Security

The following addresses practices related to information security:

- The study requires use of some individually identifiable data, including participant names, street address, city, county, zip code, telephone number, and Social Security number to complete telephone screening, send recruitment letters, and appointment reminder letters. We will collect the minimum amount of study data required to complete study aims involving recruitment, outcome assessment and reimbursement. These data will we stored in the study tracking database (\\vhadurhsrdfile1\Distributed Apps\HSRDTrackingApp). This database will also be used to keep track of study related telephone calls to participants, opt-out calls, study payment dates, and study appointments.
- Some data will collected prior to consent, as outline in our HIPAA waiver request, and on page 4 "Participants and Recruitment" above. We will collect the minimum amount of data to be able to identify potentially eligible patients and contact them about the study. These data will come from VA medical records (see section above on Participants and Recruitment), as well as a brief telephone-based screening questionnaire to capture information not reliably included in the medical record.
- For patients who enroll in the study, other information will be collected via questionnaires (and results of functional tests), completed in person at the VA.
- Screening and outcome measures will be recorded using DatStat Illume™, provided per VA enterprise license and funded by HSR&D. Illume is a web-based survey tool. Data will be stored on a secure VA server. However, we will have consent forms and a form on which we will record results of functional tests (the latter will not include PHI; study ID only). All hard copies of data will be stored in a locked filing cabinet in the office of a study team member located on the 6th floor of the NC Mutual Building. All electronic data will be stored on a secure VA server (\\vhadurshrdfile1\$projects\PACe_LBP), managed by Durham VA HSR&D personnel, in a folder accessible only to study team members on the IRB approved staff listing.
- Consent forms with patient names will be transported from the VA interview rooms to the study team's offices in Legacy Tower by an approved study team member; these documents will remain in direct possession of the study team member in a locked courier bag throughout transport. VA clinicians may refer patients to the study team, with patients' permission; this will be via a consult option within the medical record.
- Only individuals on the IRB approved staff listing will have access to study data. This will be housed on a VA secure server, with folder access given by HSR&D IT personnel only to individuals on the staff listing. Access to the study data will be removed for staff members that are no longer part of the study team.
- Dr. Adam Goode is a co-investigator from Duke. He will obtain a VA WOC appointment (and complete human subjects training) and VA credentialing prior to any study involvement. His human subjects' activities on this project will all be confined to the VA; no clinical involvement will take place at Duke.
- We will share a de-identified data set with study investigators at Duke for the purpose of conducting some secondary data analyses at that site. This data will contain no elements of PHI per the HIPAA list, and there will be no ID provided to Duke OR retained by the VA that would allow re-linkage of the Duke data set back to any personal health information in the VA data set. The data will be transferred to Duke using an encrypted CD, encrypted thumb drive or other VA approved method, and stored on a secured, password protected server in the Department of Orthopedic Surgery at Duke where Dr. Goode has his primary appointment. The data will be accessible only to study personnel on the Duke IRB study staff listing.
- Information will be accounted for by regular checks and reports generated from the tracking database (e.g., information on participant stages within the study); this will be approximately biweekly. In addition the study team will maintain a check sheet associated with tasks and data collected for the baseline

and follow up assessments; this will help to ensure that all required tasks are completed (e.g., providing participant with copy of the signed consent form) and that all data collected and stored will be in accordance with the VA records control schedule.

- Security measures to protect individually identifiable data will include storage of electronic data only on a VA secure server and storage of paper documents only in locked filing cabinets in study team offices.

Any suspected or confirmed security or privacy incident will be reported to the Information Security Officer and Privacy Officer immediately. Once study data are no longer needed, paper files will be shredded in accordance with VA records control requirements for destruction of sensitive information. Information in electronic format will be deleted or purged from data files in accordance with VA records control requirements. AND: Should any incident such as theft or loss of data, unauthorized access of sensitive data or non-compliance with security controls occur it will be immediately reported according to VA policy. All incidents regarding information security/privacy incidents will be reported to the ISO and PO within 1 hour of acknowledgement of issue and done so using the VHADUR Research Events Report e-mail group (VHADURResearchEventReport@va.gov).

Participant Safety and Quality Control: The physical therapist and exercise counselor will follow all VA patient safety standards. Because of the variable and exacerbating / remitting nature of chronic LBP, we expect that some participants may experience increases (or decreases) in their pain during the course of the study, regardless of treatment group. Drs. Allen and Goode will train the exercise counselor in delivering the PA and CBT-P programs. The exercise counselor will perform practice calls with study team members, with feedback provided by Drs. Allen and Goode. In addition, a subset of intervention telephone calls will be audio recorded (approximately the first ten of these sessions and 10% of calls thereafter) and Drs. Allen and Goode will listen to these to ensure adherence to the intervention protocol. When these telephone calls are audio recorded, the participant will be notified verbally, and the consent form will also notify participants that these calls may be recorded. The audio recordings for fidelity checks of intervention calls will be digitally recorded using a VA approved USB recorder, currently a Sparky device. The recordings are made directly to a VA server (\\vhadurshrdfile1.v06.med.va.gov\$projects\PACe_LBP) and are only accessible to study team members. Dr. Goode will train the research assistant to administer the PPT measurement, following an a priori protocol; reliability of the PPT measurement will be established through practice trials prior to enrollment of participants. Brief training in PPT measurement has been shown to produce highly reliable results in trained observers.[82] In the event of any adverse events, Dr. Hastings will provide consultation regarding whether it is appropriate for the participant to remain involved in the study.

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