Title: Optimizing Outcomes for Older Veterans with Chronic Low Back Pain Syndrome: Aging Back Clinics

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Abstract

Degenerative disease of the lumbar spine is ubiquitous in older adults, but low back pain is not. Treatments that focus exclusively on degenerative spine disease, such as spinal injection and surgery, have resulted in rising costs and exposure to potentially life-threatening morbidity but outcomes have not improved. We posit that to improve treatment outcomes for older adults with chronic low back pain (CLBP – back pain that has been present on at least half the days for at least 6 months), the condition should be approached as a syndrome, that is, a final common pathway for the expression of many contributors, in the same way that geriatricians approach the evaluation and treatment of delirium and falls. Using this model, the lumbar spine is considered a weak link, but is rarely the sole treatment target. Conditions that commonly contribute to pain and disability in older adults with CLBP include hip osteoarthritis, fibromyalgia, anxiety, maladaptive coping, and myofascial pain, each of which is associated with specific evidence-based treatments. Because such conditions are not routinely evaluated in patients with CLBP, it is perhaps not surprising that first line treatments that do not specifically target multiple contributors (e.g. spine-focused physical therapy and analgesics) often provide suboptimal treatment outcomes. This often results in continued treatment-seeking including potentially toxic medications and invasive, expensive, and potentially life-threatening procedures such as complex spinal fusion.

The central question that the proposed randomized trial is designed to answer is: What is the efficacy of caring for older adults with CLBP in Aging Back Clinics (ABC), where the patient is first treated as an older adult, and second as a patient with CLBP, compared with usual care (UC)? We have developed evidence and expert-opinion based guidelines for the evaluation and treatment of 12 key contributors to pain and disability in older adults with CLBP. Our prior work also supports the commonplace nature of multiple contributors to CLBP in older Veterans and the feasibility of delivering patient-centered comprehensive care that follows our published guidelines. We now wish to implement these guidelines in our ABC clinics and compare this approach to that of UC in older Veterans. Proof of the hypotheses could significantly impact patient care by reducing pain and disability and identifying key conditions whose treatment could prevent the pursuit of invasive treatments and their associated potential morbidity and cost.

About 450 Veterans age 65-89 with CLBP will be recruited from primary care provider practices at 3 VAs – VA Pittsburgh Healthcare System, VA Greater Los Angeles, and Richmond VA to meet a target randomization of 310. Individuals will be randomized to receive either ABC care or UC and they will be followed for one year. Those in ABC care will be referred to a generalist (e.g., geriatrician, physiatrist, rheumatologist) that has been identified and trained in a structured assessment to identify the conditions for which evidence and expert opinion-based algorithms have been created. Usual care will not be constrained. Outcomes will be assessed at baseline and over the telephone at up to three later time points: 3 months, 6 months, 9 months and 12 months. Health Care Utilization will be assessed monthly. Gait speed, a strong predictor of morbidity and mortality in older adults, will be measured at baseline. The proposed clinical trial has the potential not only to improve pain-related disability, but also to reduce morbidity, increase quality of life, and limit healthcare utilization.

List of Abbreviations

ABC- Aging Backs Clinic
ACP- American College of Physicians
CARF- Commission for Accreditation of Rehabilitation Facilities
CBT- cognitive behavioral therapy
cIRB- central Institutional Review Board
CLBP- chronic low back pain
co-I - co-Investigator
COX2- cyclooxygenase-2
CPRS- computerized patient record system
CTC- Clinical Trial Center
CVS- Concurrent Versions System
Dr.- Doctor
e.g.- exempli gratia or for example
EP- Expert Panel
FAB- Fear Avoidance Beliefs
FES- Falls Efficacy Short Form
FIPS- Federal Information Process Standards
FMS- fibromyalgia syndrome
G&EC- Geriatrics and Extended Care
GAD-7 -General Anxiety Disorder-7
GEM- Geriatric Evaluation and Management
GH- Global Health
GRECC- Geriatric Research, Education and Clinic Center
i.e.- for example
IRB- Institutional Review Board
LA- Los Angeles
LHP- lateral hip/thigh pain
LLD- leg length discrepancy
LSS- lumbar spinal stenosis
LVCF- least-value-carried-forward
MAR- missing at random
MCI- mild cognitive impairment
MCID- minimal clinically important difference
M.D.- Medical Doctor
MDS- Minimum Data Set
MH-PH- Mental Health Physical Health
MMSE- Mini Mental Status Exam
MOS Social Support Survey- Medical Outcomes Study Social Support Survey
MP- myofascial pain
MR- multidisciplinary rehabilitation
MRI- magnetic resonance imaging
NIH- National Institutes of Health
NNT- number needed to treat
NSAID- nonsteroidal anti-inflammatory drugs

OA- osteoarthritis
ODI- Oswestry Disability Index
OEF- Operation Enduring Freedom
OIF- Operation Iraqi Freedom
PACT- Patient Aligned Care Team
PCP- primary care provider
PhD- Doctor of Philosophy
PHQ-4 - Patient Health Questionnaire for Depression and Anxiety-4
PHQ-9 - Patient Health Questionnaire-9
PI- Principal Investigator
PT- Physical therapist
QMCI- Quick Mild Cognitive Impairment
R&D- Research and Development
RC- Research Coordinator
Richmond, VA- Richmond Virginia
RR&D- Rehab Research and Development
Rx- medical prescription
SAS- Statistical Analysis Machine
SIJS- sacroiliac joint syndrome
SPiRE- Small Projects in Rehabilitation Research
SSN- Social Security Number
SUD- Substance Use Disorders
TBB- Take Back Your Back
UC- Usual Care
VA- Veterans Administration
VAPHS- Veterans Administration of Pittsburgh Healthcare System
VHA- Veterans Health Administration

Contents

Protocol Title: Optimizing Outcomes for Older Veterans with Chronic Low Back Pain Syndrome: Aging Back Clinics

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2.0 Introduction

BACKGROUND AND SIGNIFICANCE

Statement of the Problem. Back and other musculoskeletal pains are the most common reasons that United States Veterans seek medical care,[18] and approximately half of these patients are age 65 and older.[19] The prevalence of low back pain in those 85+, the most vulnerable and fastest growing segment of society, is estimated at 44%.[20] Chronic low back pain (CLBP, i.e., exists on at least half the days for at least 6 months[4]) is associated with the overwhelming majority of low back pain-associated healthcare resource utilization and personal suffering, including physical disability, depression, anxiety, insomnia, cognitive dysfunction, loss of sleep and appetite, and social isolation.[21-23] In older Veterans (i.e., ≥ age 65), physical and emotional suffering may be compounded by a heightened risk of iatrogenic adversity associated with commonly employed interventions such as spinal injections, surgery, and potentially toxic medications (e.g., gastrointestinal bleeding and renal failure with nonsteroidal anti-inflammatory drugs, falls and hip fractures with opioids[24]). And, while substantial resources continue to target treating patients with back pain, treatment outcomes have remained stagnant.[3] What accounts for this healthcare crisis?

Lumbar Spine-Targeted CLBP Treatment. When evaluating patients with CLBP, spinal imaging such as x-rays and magnetic resonance imaging (MRI) are not recommended because they have not improved care.[25,26] But the utilization of spinal imaging and procedures guided by this imaging (e.g., epidural corticosteroids, spinal surgery) for patients with CLBP has continued to skyrocket.[3] This approach often is not helpful for older Veterans because degenerative disease of the lumbar spine (e.g., degenerative disc and facet disease, bulging discs) identified with imaging is nearly ubiquitous in people age 65 and older, even in those who are pain-free.[1] An estimated 1 in 5 pain-free older adults also has moderate to severe lumbar spinal stenosis on MRI.[2]

If we attempt to manage the older adult with CLBP solely using spinal imaging, there may be one of three results: 1) In the best-case scenario, the physical cause of pain is identified and the appropriately targeted treatment is prescribed (e.g., severe central canal stenosis is identified and decompressive laminectomy results in reduction of pain and disability); 2) Pathology is identified that may be incidental (e.g., asymptomatic central canal stenosis, bulging discs, degenerative disc disease) but the cause(s) of pain and disability lies outside of the lumbar spine (e.g., sacroiliac joint syndrome [SIJS], myofascial pain of the erector spinae or quadratus lumborum, hip OA), thus treatment may be misdirected; 3) Spinal pathology is identified that, when combined with biopsychosocial factors outside of the lumbar spine (e.g., anxiety, depression, fear avoidance beliefs, insomnia, fibromyalgia syndrome [FMS], hip OA), adds to CLBP and further disability results. If our treatment targets only degenerative spine disease in these patients, suboptimal outcomes are likely. That is, imaging-directed treatment failures in older Veterans with CLBP may relate to the treatments being **spine-centered rather than patient-centered.**

Non-specific CLBP Treatment. Some providers practice at the opposite end of the spectrum. Instead of prescribing treatment that targets spinal pathology, they approach CLBP as a generic condition. As previously mentioned, "non-specific low back pain" is a commonly used term defined as low back pain that is not attributable to a recognizable, known specific spinal pathology (e.g., infection, tumor, spinal fracture, structural deformity, inflammatory disorder) or associated with radiculopathy/spinal stenosis.[25,27] First line treatment

involves physical therapy and/or oral analgesics, an approach that typically results in modest improvement in pain and function.[28] This approach fails to acknowledge the commonly occurring specific contributors to CLBP and back pain-related disability in older adults that **cannot be detected on spinal imaging and respond to a variety of evidence-based treatments** such as hip osteoarthritis[29], fibromyalgia[30], and depression.[31]

The 2017 Clinical Practice Guideline on Acute, Subacute and Chronic Low Back Pain from the American College of Physicians (ACP) approach CLBP as a non-specific condition and recommend "treatment with nonsteroidal anti-inflammatory drugs (NSAIDs) as first-line therapy" for patients "who have had an inadequate response to nonpharmacologic therapy."[28] Even these recent guidelines fail to acknowledge that NSAIDs are very cautiously recommended for chronic use in older adults because these drugs risk causing renal insufficiency, gastrointestinal bleeding, and other adverse events.[24] The guidelines also recommend initial treatment of CLBP with multidisciplinary rehabilitation (MR) as one non-pharmacological option based on moderate quality evidence[28], even though these programs are characterized by high participant burden, making them inaccessible to many older Veterans, especially those who are physically and/or cognitively frail. Evidence indicates that **while MR improves function, it is only modestly effective in reducing pain intensity [32], one of the key outcomes that our patients value.** As noted above, older adults with CLBP can have many physical contributors to their pain[33] that have specific evidence-based pain treatments and may not be included in MR programs, as these programs tend to be group based, not individualized. Thus, approaching CLBP as a non-specific condition is fraught with limitations that result in suboptimal outcomes for many older adults.

How can we redirect the evaluation and treatment of older adults with CLBP to result in better outcomes? To answer this question, we started by convening an expert panel of three physical therapists (PTs) and a geriatrician/ rheumatologist whose practices focused on chronic pain management. The panel's task was to **identify common categories of physical pathology in older adults with CLBP that were not being treated because they were overlooked or misdiagnosed** by referring providers. Four categories were identified: myofascial pain (MP), fibromyalgia, sacroiliac joint syndrome (SIJS), and hip disease.[33] We developed protocols to identify these conditions and established the feasibility of training providers in their recognition.[33] We found that MP exists in 96% of older adults with CLBP, SIJS in 84%, hip disease in 24%, and fibromyalgia in 19%. Eighty-two percent had multiple conditions [33], none diagnosed with spinal imaging, but all detectable during a thorough history and physical exam.

This work validated our clinical observations of the multiple physical contributors to CLBP in older adults that were being missed with spinal imaging. We then took the next step toward facilitating practice change, recognizing the need to **break down specialty silos**. We collaborated with 42 providers (9 PCPs and 33 pain/pain-related experts [chiropractic, geriatric medicine, neuropsychology, occupational therapy, pain medicine, pharmacology, physiatry, physical therapy, psychiatry, psychology, rheumatology, sleep medicine]), to gather and evaluate the wealth of evidence scattered within specialty literature, often inaccessible to many providers. The 42-member panel used a modified Delphi process to **synthesize existing evidence** and develop a set of 12 algorithms that guide the systematic evaluation and safe treatment of key physical and non-physical contributors to pain and disability in older adults with CLBP. The 12 conditions are: a) those that cause CLBP directly (i.e., hip osteoarthritis[66], fibromyalgia[30], myofascial pain[67], SIJS[68], leg length discrepancy[54], lumbar spinal stenosis [LSS][69]); b) those that impair an individual's ability to modulate pain and compound CLBP-associated disability (i.e., anxiety and/or depression[21], insomnia[23], maladaptive coping [i.e., fear avoidance beliefs[70] and pain catastrophizing[71]], dementia[72]); and c) those associated with leg pain not caused by degenerative spine disease and can mimic radiculopathy (i.e., greater trochanteric pain syndrome[73], myofascial pain[74]). Each of these conditions, except LSS, **cannot be detected on spinal imaging and respond to a variety of evidence-based treatments**, per Table 1**.** Thus, evaluating and treating these conditions can **prevent unnecessary and ineffective care**. The protocols we developed are the foundation of the Aging Backs Clinic (ABC) arm of the proposed trial (Appendix 5). **ABC care approaches the older adult with CLBP, first as an older adult, and second as a patient with chronic pain.** CLBP is approached as a geriatric syndrome, i.e., a final common pathway for the expression of multiple contributors[5] rather than a disease isolated to the spine or a non-specific condition. That is, we conceptualize the lumbar spine as an area of vulnerability, but not the sole treatment target.

ABCs and the VA Stepped Pain Care Model. In 1998 the Veterans Health Administration launched their Pain Management Strategy in response to the growing number of Veterans with pain and the associated personal and financial burden. The overarching objective of the Strategy was to develop a "comprehensive, multicultural, integrated, systemwide approach to pain management that reduces pain and suffering for Veterans experiencing acute and chronic pain associated with a wide range of illnesses including pain at the end of life."[75] To guide implementation of the Strategy, in 2009 the VA Stepped Pain Care model was published, shown in Figure 1.[75] This model calls for "assessment and management of health problems via low intensity interventions followed by the introduction of more intensive, specialized, and individually tailored approaches if persons do not maximally benefit from less intensive efforts."[75] ABC care aligns with the VA Stepped Pain Care model and is guided by our published stepped care algorithms targeting the Veteran's individual pain contributors. It conceptually straddles Step 1 and Step 2 in Figure 1, and incorporates comprehensive screening, assessment and management of important conditions contributing to CLBP and disability, with as needed referrals to other specialists, depending on the patient's individual pain contributors. Depending on the Veteran's response to initial treatments and their physical/cognitive stamina, interdisciplinary pain clinic referral (Step 3) also may be offered. **The flexibility of the ABC approach affords truly patient-centered care.** Additional details about ABC operations are provided in the Research Design and Methods section.

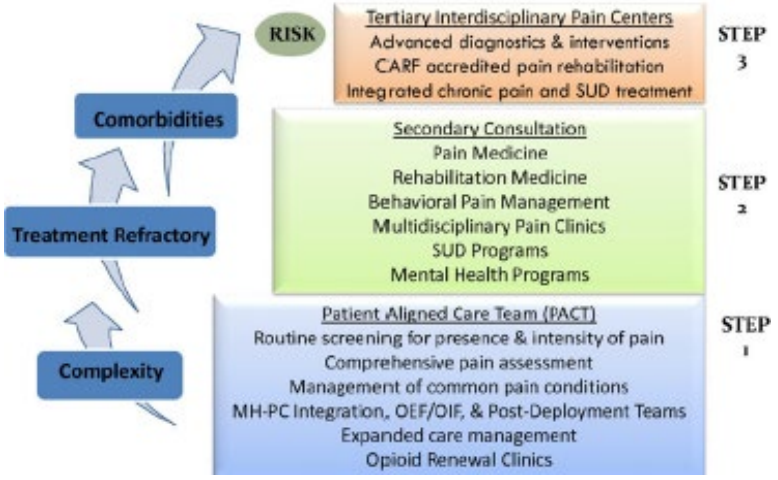


Figure 1. VA Stepped Pain Care[75]

The Proposed Study. The goal of the proposed clinical trial is to evaluate the efficacy of ABC care as compared with that of Usual Care (UC) for older Veterans with CLBP. The preparatory work that we have conducted to establish the foundation for this trial is presented in the Preliminary Studies section below.

PRELIMINARY STUDIES

Standardization of ABC Clinic Treatments. Our first pilot study funded by VA Rehabilitation Research & Development (Pilot Study #1) resulted in the creation of the 12 CLBP algorithms referenced in the Background and Significance section. An interdisciplinary expert panel (EP) created each algorithm and accompanying materials (i.e., tables outlining stepped care medication management and rationale for individual components of the algorithm with supportive references). A 9-member panel of experienced PCPs, including VA providers, reviewed the materials, focusing on feasibility of implementation in the VA. The EP modified the algorithms based on PCP feedback and the process continued until no revisions were recommended.

All algorithms have these common elements: 1) supportive literature evidence and, when lacking, EP consensus; 2) imaging only to confirm pathology suspected on history and physical examination (e.g., American College of Rheumatology clinical criteria for hip OA required before ordering hip x-rays); 3) emphasis on self-management; 4) patient-provider collaborative decision making; 5) stepped-care management that acknowledges specific vulnerabilities in older adults (e.g., avoiding medications in Beers' criteria for potentially inappropriate medications in older adults[24], prescribing a walker instead of pain medications or an invasive procedure for the frail older adult with neurogenic claudication). As shown in Table 1, most of the conditions are associated with strong evidence-based treatments that have been incorporated into each of the algorithms. Dr. Rollin Gallagher, former Director of Pain Management for the Veterans Health Administration, endorsed the importance of our work (see letter of support); each algorithm has been published along with an illustrative case in Pain Medicine, the official journal of the American Academy of Pain Medicine (Appendix 5).

Feasibility of Training Providers in Evaluating CLBP Conditions. In Pilot Study #1, four providers (2 at VAPHS and 2 at Richmond VA - 3 geriatricians and one general internist with a large older adult patient panel) were trained in the structured physical assessment (Appendix 6) to ascertain the presence of hip OA, leg length discrepancy (LLD), myofascial pain (MP), sacroiliac joint syndrome (SIJS), and lateral hip/thigh pain (LHP – e.g., greater trochanteric pain syndrome), and a structured history to screen for lumbar spinal stenosis. After two training sessions (separated in time by ~ 1 month), all providers were confident in their ability to perform the physical assessment for the conditions listed above (hip OA, LLD, MP, SIJS, LHP) and immediately began incorporating their newfound skills into the care of their own patients. Providers uniformly felt empowered in their ability to educate their patients about the contributors to their CLBP and felt that patients were more satisfied with their encounter than they had been previously. Specific provider comments included, "I find seeing these patients fun now!" "I was so excited that I was able to identify the cause of the patient's pain!" "These protocols have given me a way to offer my patients options other than sending them for potentially harmful procedures…Many of them are getting better!" These data, although associated with a small sample size, underscore the feasibility and potential value of training providers in the structured CLBP physical exam that helps to guide ABC care.

Table 2. Prevalence of CLBP Contributors (n=51)

Condition	Prevalence n (%)
Hip OA	15 (29)
Myofascial pain	38 (74.5)
Sacroiliac joint syndrome	34 (67)
Lumbar spinal stenosis	16 (31)
Leg length discrepancy	13 (25.5)
Lateral hip/thigh pain	8 (15.7)
Fibromyalgia	12 (23.5)
Depression	17 (34)
Anxiety	14 (28)
Maladaptive coping	33 (61)
Insomnia	30 (63.8)
Only 1 CLBP contributor	1 (2)
>1 physical contributor	45 (88)
>1 non-physical contributor	30 (60)
≥1 physical AND ≥1 non-physical contributor	44 (86.3)

Clinical Profile of Older Veterans with CLBP. In Pilot Study #1, a research coordinator at each site administered questionnaires to screen for non-musculoskeletal CLBP contributors, specifically, the PHQ-9 for depression [76], the GAD-7 for anxiety [77], the Insomnia Severity Index for insomnia [78], the catastrophizing scale of the cognitive strategies questionnaire [79], and the fear avoidance beliefs questionnaire.[80] The prevalence of conditions among participants is summarized in Table 2. Most participants, 88%, had at least one physical contributor; 60% had at least one non-physical contributor (i.e., depression, anxiety, maladaptive coping [either catastrophizing or fear avoidance beliefs], or insomnia); and the majority (86.3%) had both physical and non-physical contributors. These data highlight the validity of the comprehensive approach that will be applied in the ABC arm of the proposed trial.

Feasibility of Recruitment and Implementation of ABC Care: Pilot Study #2 funded by VA Rehabilitation Research & Development is being conducted to evaluate the feasibility of recruitment and implementation of ABC care. Electronic medical records of Veterans age 65-89 who had undergone a lumbar MRI during the prior 30 days or were scheduled to have an MRI within 30 days, were reviewed for eligibility (absence of red flags/need for urgent and specialized treatment; no prior lumbar surgery; cognitively intact) at VAPHS and the Richmond VA. The results are summarized in Figure 2. All 50 participants have been enrolled. They are 96% male, age 68.7 ± 8.2, 28% black, with an average back pain intensity 6.4 ± 1.6 and average pain duration 5.7 ± 0.7 years. The follow up time points that have been collected thus far are shown in Figure 2. There have been no dropouts and no adverse events. Data on CLBP contributors were collected using methods identical to that of Pilot Study #1. The clinical profile of participants was: 4.2% had only one contributor to their CLBP, 79.2% had two or more physical contributors, 20.8% had two or more non-physical contributors, and 66.7% had at least one physical and at least one non-physical contributor. In this Pilot, we recruited Veterans with a recent lumbar MRI because such imaging can lead to a cascade of events that do not result in improved outcomes.[81] As per Figure 2, this strategy resulted in excluding the majority of potential older Veteran participants with CLBP. To optimize the generalizability of findings associated with the proposed clinical trial, we do not require imaging as a prerequisite to participating. This revised strategy is also consistent with clinical guidelines, as highlighted in Background and Significance.

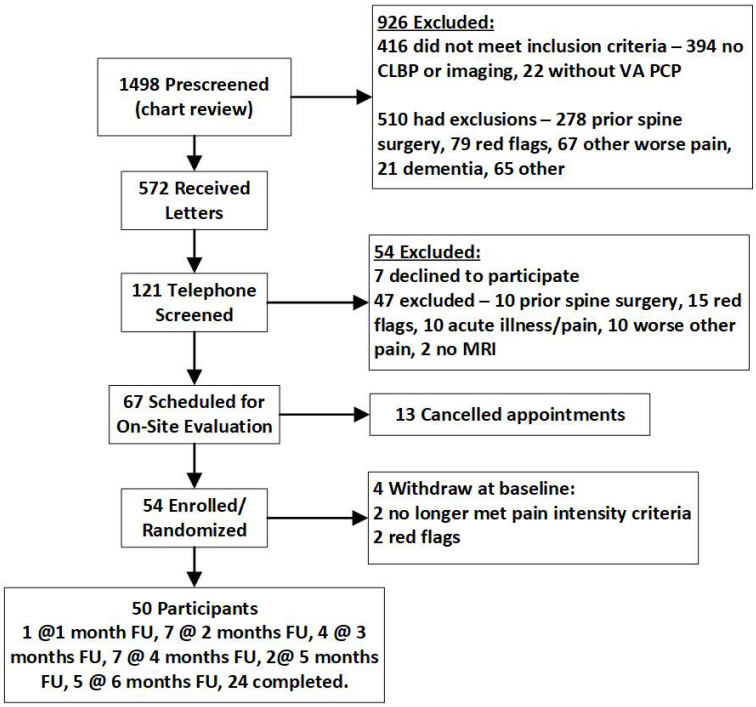


Figure 2. Status of Pilot Study #2

To ascertain the feasibility of the revised (no imaging required) recruitment strategy, we reviewed 100 randomly selected charts at each site from among the total available pool (i.e., those available for pre-screening). As shown in Table 3, data pulled from our 3 participating sites over the past 12 months revealed 17,235 Veterans age 65-89 with a diagnosis of low back pain and who had seen their PCP within the prior 6 months (7,486 from Los Angeles, 4,739 from Pittsburgh and 5,010 from Richmond). Pre-screening excluded 40% at Los Angeles, 50% at Richmond, and 39% at VAPHS. The most common reason for ineligibility across sites was prior spine surgery (60% of those excluded at Los Angeles, 34% of those excluded at Richmond, and 38% of those excluded at VAPHS). Total numbers available for on-site assessment following telephone screening and those eligible following on-site assessment were calculated based on Pilot Study #2 (Figure 2) and the results are shown in Table 3. Thus, we expect to easily meet our recruitment goals of 55 participants per site per year.

Table 3. Annual Recruitment: Potential Enrollees

Number of Veterans…	VAPHS	Los Angeles	Richmond
Available for pre-screening	4,739	7,486	5,010
Eligible for telephone screening	2,890	4,491	2,505
Eligible for on-site assessment	1,600	2,470	1,387
Eligible after on-site assessment	1,194	1,828	1,035

Table 4. Value of ABC Care: Veteran Quotes

- I am sleeping better, having less pain, and able to do things I couldn't do before, like cut the grass.
- My pain is tolerable now.
- Before the study I was getting one hour of sleep; now I am doing much better.
- I can stand longer and the pain is not as intense. Before the study I could only walk 20 yards and my back felt like it was on fire. I no longer feel that.
- I wouldn't trade [being in the study] for a million dollars. I am fortunate to be a veteran and to be able to get this kind of care. I'm sincere about it.

Perceived Value of ABC Care. Pilot Study #2 is ongoing

thus we have not broken the study blind. As per our study protocol, an unmasked research coordinator has conducted exit interviews at study completion (6 months follow up) for participants that were randomized to PCC care. Noteworthy feedback is in Table 4.

Educating and Screening Older Veterans for CLBP Contributors. Pilot Study #3 was funded by an award from the VA Pittsburgh Healthcare System (VAPHS) Geriatric Research, Education and Clinical Center. This funding supported the development of Take Back Your Back (TBB), an interactive tablet-based tool for older adults with CLBP. This tool takes ~7-10 minutes to complete and is designed to be self-administered prior to the patient undergoing CLBP evaluation by their healthcare provider (e.g., in the waiting room or waiting in the physical exam room). Specifically, the tool:

1) **Educates patients** about realistic treatment expectations; the multifactorial biopsychosocial nature of CLBP; the role of imaging, injections, and analgesics in managing CLBP; and the risks associated with opioids, muscle relaxants and NSAIDs.[24]

2) **Screens for key CLBP contributors** – Anxiety and depression are screened with the PHQ4[82] and insomnia is screened with a single item: In the past 7 days, my sleep quality was: very poor/ poor/ fair/ good/very good.[4] Fibromyalgia is screened with the fibromyalgia survey[83]; fear avoidance beliefs (FAB) and/or catastrophizing[4], as indicators of maladaptive coping, by asking the following questions from the NIH Minimal Data Set: Do you agree with the following statements? – 'I feel that my back pain is terrible and it's never going to get any better (an affirmative response suggests catastrophizing);' 'It's not really safe for a person with my back problem to be physically active (an affirmative response suggests FAB). We screen for possible hip OA with the question, 'Do you have pain in one or both of your hips?' The presence of leg symptoms precipitated by walking and relieved by rest as a possible indicator of lumbar spinal stenosis also is included in TBB.

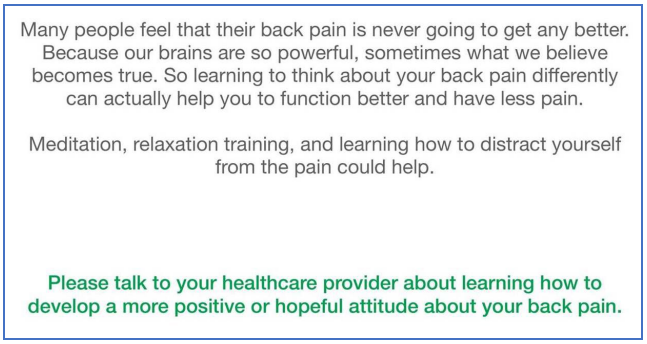


Figure 3. *Take Back Your Back:* Catastrophizing pop-up

3) **Encourages the patient to communicate** with their healthcare provider. For example, if the patient screens positive for fear-avoidance beliefs by responding "yes" to the question: Do you agree with the following statement? - 'I feel that my back pain is terrible and it's never going to get any better,' a pop-up will appear, per Figure 3, encouraging the patient to discuss this concern with their healthcare provider. As described in the Research Design and Methods section, a summary screen of the Veteran's responses will be given to the healthcare provider and this will facilitate targeting of their history and physical examination. That is, while TBB will screen for key conditions, its purpose is not to diagnose. Additional details about TBB that relate to its incorporation into the proposed trial are provided in the Research Design and Methods section.

Table 5. Participant Feedback on "Take Back Your Back"

Veteran Quotes
• Starts you thinking what you can and can't do • Very straightforward • Helpful because it's a "holistic approach; included a wide variety of problems" • Liked the ipad over a booklet [like a pamphlet in the doctor's office]; more fun! • Helped me realize things I already knew but forgot • Opened my mind to different options • It was helpful that the questions were even asked • It tries to get to the source of the problems (and it gets to the point!) • I feel empowered by the app (from an 88 y.o. participant) • Better prepared to talk to my doctor. • Good starting point; something to build on
Non-Veteran Quotes
• Would have been really helpful to have (wish I would have had this) when I first started seeking treatment for my low back pain • Great refresher

We have conducted three rounds of usability testing with TBB in 15 older adults (mean age 71.7, range 60-88 ± 7.9) with CLBP (81% Veterans). Each round had 5 or more participants. In rounds 2 and 3, one to two participants from the prior round participated, as per standard iterative usability testing methods.[84] The reading level of TBB is at a Flesch-Kincaid Grade level of 6.9. All participants voiced that the material was

presented in a clear manner. In the third round of testing, no suggestions for modifications were recommended. A round of beta-testing (mean age 75.1, range 60-86) was performed on an additional 30 participants, 14 Veterans and 16 non-Veterans. Noteworthy feedback from participants is shown in Table 5. Thus, this tool was very well received by Veterans. Further, by removing the need for dedicated staff (e.g., the research coordinator in Pilot Study #1) to screen for non-musculoskeletal CLBP contributors, it has the potential to efficiently facilitate translation of our research findings into clinical practice.

Summary of Preliminary Studies. The studies described above lay the essential foundation for the proposed clinical trial. We have: 1) used a rigorous process to develop and publish 12 evaluation and treatment protocols for key conditions that contribute to CLBP and disability in older adults and these will be implemented in the ABC arm; 2) established the feasibility of training providers in the evaluation of musculoskeletal contributors; 3) validated the importance of comprehensive biopsychosocial assessment in older Veterans; 4) developed an interactive patient self-report and education tool usable in the clinical setting; 5) examined the feasibility of conducting the trial (i.e., participant recruitment and intervention implementation). These studies have prepared us to take the next important step, that is, to conduct a randomized controlled clinical trial to test the efficacy of a new approach to CLBP care for older Veterans – Aging Back Clinics (ABCs).

Inclusion of Vulnerable Subjects and Special Populations. Vulnerable subjects will not be enrolled. Neither pregnant subjects nor women of childbearing potential will be included because we are targeting older adults with low back pain. Neither children nor prisoners will be included.

3.0 Objectives

SPECIFIC AIMS

Degenerative disease of the lumbar spine (e.g., degenerative discs and facets, bulging discs) is ubiquitous in older adults, but low back pain is not.[1,2] Treatment that focuses exclusively on degenerative spine disease such as spinal injection and surgery, therefore, has resulted in rising costs and exposure to potentially life-threatening morbidity but not improved outcomes.[3] We posit that to improve treatment outcomes for older adults with chronic low back pain (CLBP – back pain that has been present on at least half the days for at least 6 months[4]), the condition should be approached as a syndrome, that is, a final common pathway for the expression of many contributors. Geriatricians evaluate and treat other syndromes, such as delirium and falls similarly, with good outcomes.[5] When an older patient experiences delirium, a geriatrician doesn't recommend brain surgery. Using this model, the lumbar spine is considered a weak link, but is rarely the sole treatment target. Conditions that commonly contribute to pain and disability in older adults with CLBP such as hip osteoarthritis (OA), fibromyalgia, and depression, are associated with specific evidence-based treatments.

PURPOSE AND HYPOTHESES

The central question that the proposed randomized trial is designed to answer is: **What is the efficacy of comprehensive patient-centered care of CLBP as a syndrome that is delivered in Aging Back Clinics (ABC), compared with usual care (UC)?** Through prior VA Rehabilitation Research & Development support, we have developed and published evidence and expert-opinion based guidelines for the evaluation and treatment of 12 key contributors to pain and disability in older adults with CLBP – hip OA, fibromyalgia, myofascial pain, lumbar spinal stenosis, sacroiliac joint syndrome (SIJS), leg length discrepancy, lateral hip/thigh pain, insomnia, depression, anxiety, maladaptive coping, and dementia.[6-11] Our prior work also supports the commonplace nature of multiple contributors to CLBP in older Veterans and the feasibility of delivering ABC care that follows our published guidelines. We now wish to compare this approach to that of UC in older Veterans. Proof of the hypotheses that we will test could significantly

impact patient care by reducing pain and disability and avoiding costly and potentially morbid treatments. The proposed trial is designed to address the following aims:

Aim 1: Establish the efficacy of ABC care compared to usual care.
We hypothesize that those randomized to ABC care will have:
H1.1: Greater 6-month reductions in pain-related disability as measured by Oswestry Disability Index (ODI; primary outcome and endpoint);
H1.2: Greater 12-month reductions in ODI; and greater 6- and 12-month reductions in pain severity (by PROMIS 29), quality of life (by PROMIS Global Health [GH]); depressive and anxiety symptoms (by PROMIS 29); and greater improvement in falls efficacy (by Falls Efficacy Scale-International short form);
H1.3: Less healthcare utilization between 6 and 12 months with respect to emergency room visits, hospitalizations, opioids prescribed, and invasive procedures performed (secondary outcomes and endpoints).

Aim 2: Explore the heterogeneity of treatment efficacy of ABC care.
H2.1: Those with greater baseline CLBP-associated disability, anxiety/depression, mild cognitive impairment, and/or obesity will reap greater benefits from ABC compared to UC (exploratory subgroup discovery).

Four hundred fifty Veterans age 65-89 with CLBP, (for a targeted enrollment of 310), will be recruited from primary care provider (PCP) practices at 3 VAs – VA Pittsburgh Healthcare System, VA Greater Los Angeles, and Hunter Holmes McGuire (Richmond) VA. Individuals will be randomized to receive either ABC care or UC, and they will be followed for one year. Aging Back Clinics will be staffed by consultants (e.g., geriatrics, pain medicine, rheumatology) that have been trained in evaluating and treating key CLBP conditions associated with our published evidence-based algorithms. Usual care will not be constrained. Baseline measures will be assessed on site or on the telephone and include: Minimal Data Set recommended by the NIH Task Force on research standards for CLBP[4]; Oswestry Disability Index (ODI; main outcome)[12]; cognitive function (QMCI)[13]; PROMIS-29 that includes pain severity, pain-related activity interference, physical function, sleep disturbance, depressive symptoms, leg symptoms[14]; quality of life with the PROMIS-GH scale[15], participant opioids-related concerns with the Prescribed Opioids Difficulties Scale[16], gait speed, balance confidence with the Falls Efficacy Scale-International short form[17]; healthcare utilization over the prior month (e.g., pain medications, emergency room visits, hospitalizations) will be assessed on site. We will also be utilizing the Life Space Assessment[106] to measure the spatial extent of a participant's mobility. Three, 6-, up to 9-, and 12-months outcomes (ODI, PROMIS 29 and GH, balance confidence, healthcare utilization, life space assessment and VR-12) will be assessed over the telephone by individuals masked to group assignment. While monthly, the 0-10 Numerical Pain Rating Scale, Medications (pain medications monthly and all medications at baseline and final follow-up), and Health Care Utilization will be measured. The Global Impression of Change data measure will be administered only at the final phone follow up. The proposed clinical trial has the potential not only to improve pain-related disability, but also to reduce morbidity, increase quality of life, and limit healthcare utilization.

4.0 Resources and Personnel

The Overall PI (Dr. Debra Kaye Weiner) and the Overall RC (Kimberly Hayes Clemens) will oversee all study related activities to ensure the protocol is followed.

This research study will be conducted at three VA facilities.

Site One: VA Pittsburgh Healthcare System (VAPHS; Pittsburgh, PA)
Pittsburgh LSI: Dr. Edward Garay
Pittsburgh Local Site RC: David Newman

Site Two: VA Greater Los Angeles Healthcare System
Dallas LSI: Dr. Meika Fang
Dallas Local Site RC: David Segovia

Site Three: Hunter Holmes McGuire VA Medical Center (Richmond, VA)
Richmond LSI: Dr. Angela Gentili
Richmond Local Site RC: Judy Pulliam

The Local Site Investigator and Research Coordinator at each of the three sites will be responsible for site specific daily operations. They will have access to PHI.

All RCs will be responsible for recruiting subjects, obtaining informed consent, administering survey/interview procedures, among other responsibilities.

The study Statistician, Dr. Subashan Perera will be in charge of data analysis along with the PI. He will remain at the University of Pittsburgh to analyze data and will do so on time allocated for the VA grant through his IPA. They will work together along with LSIs in writing papers and manuscripts that are a result of this study.

Dr. Wei Duan Porter will serve as a co-Investigator on the overall study analysis. She works out of the Minneapolis VAMC. She will not have access to identifiable data nor any patient interaction. She will work with the PI in data interpretation and preparation of manuscripts that result from this research.

Contractor:
All patients in the intervention group will be provided with a copy of the pain self-management workbook ("Learning about Chronic Pain") developed by consultant and pain psychologist Dr. Beverly Thorn.[95] The workbook, "Learning About My Pain (LAMP)," has been successfully implemented in the context of a trial that specifically targets patients of low literacy and was funded by the Patient-Centered Outcomes Research Institute. The workbook was developed to be used in a group setting and will be modified during the startup phase of the proposed trial for use by individuals not in a group setting, under the guidance of Dr. Thorn.

5.0 Study Procedures

5.1 Study Design

RESEARCH DESIGN AND METHODS

The proposed clinical trial is designed to evaluate the efficacy of Aging Back Clinics (ABCs) that approach CLBP in older Veterans as a geriatric syndrome, that is, a final common pathway for the expression of multiple contributors, as compared with Usual Care (UC). In the context of the research proposed, **ABCs are virtual interdisciplinary clinics** that are inserted within the stepped care model shown in Figure 4. Veterans without red flags requiring urgent attention are referred for ABC care that will be **delivered by a specialist provider** that has been trained in use of the algorithms. Both ABC care and UC will be provided for up to12 months. Those with refractory symptoms may be referred for intensive interdisciplinary pain rehabilitation, depending on their availability and the Veteran's capacity to participate. Interventions for ABC care participants are numerous and vary depending on participants' needs. These interventions include but are not limited to CBT, pharmacotherapy, physical therapy (PT), exercise therapy, analgesia, orthotics, injections, and acupuncture. One of the primary goals of ABC care is to avoid unnecessary and costly imaging and the risks associate with it, including unnecessary, ineffective, and potentially morbid surgeries.

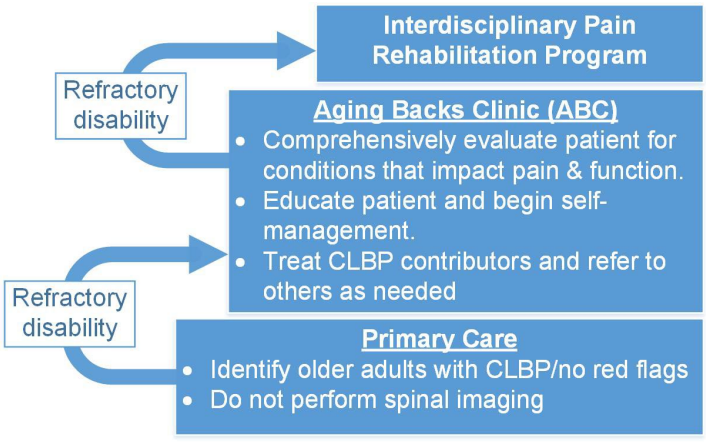


Figure 4. The ABC Stepped Care Approach

The conditions targeted by ABCs include those that cause CLBP directly (hip OA[66], SIJS[68], myofascial pain[67], lumbar spinal stenosis[69], leg length discrepancy[54]); those that impair pain modulation, compound CLBP-associated disability and that themselves can cause disability (fibromyalgia[30], depression[21], anxiety[21], maladaptive coping [i.e., pain catastrophizing[71] and/or fear avoidance beliefs[70]], insomnia[23], dementia[72]); and those that can mimic radiculopathy (greater trochanteric pain syndrome[73], myofascial pain[74]). While our screening procedures exclude Veterans with possible dementia (based on the Mini Mental State Examination), those with possible mild cognitive impairment (MCI) will be included. As MCI and dementia are on a continuum, providers may wish to apply elements of the published Dementia protocol to those that screened positive for MCI.

Participants:
About 450 Veterans (150 from each site), age 65-89 with chronic low back pain (CLBP) will be recruited, (to target randomizing 310 participants), from the VA Pittsburgh Healthcare System (VAPHS), the VA Greater Los Angeles Healthcare System (Los Angeles, CA), and the Hunter Holmes McGuire VA Medical Center (Richmond VA). We anticipate the need to telephone screen ~1050 (i.e., ~175 per site per year) to obtain 450 participants who meet all inclusion and exclusion criteria. No one will be excluded on the basis of race, gender or ethnicity. Based upon the data from each of the three sites, we anticipate that our overall participant sample will be 97% male, 3% female, 2% Hispanic or Latino, 98% Not Hispanic or Latino, 1% American Indian/Alaskan Native, 0% Asian, 2% Native Hawaiian or Pacific Islander, 18% Black or African American, and 79% White or Caucasian. Non-Veterans will not be recruited to participate. Vulnerable subjects will not be enrolled, including children and prisoners. Neither pregnant subjects nor women of childbearing potential will be included because we are targeting older adults with chronic LBP.

Costs and Payment:
In order to compensate participants for their time, they will be paid $100 in total, with payments spaced out over 12 months. They will be paid $40 for their baseline visit and $30 for their final follow-up visit. An additional $30 will be paid after their 6-month follow-up call.
Participants will be paid by check or electronic bank deposit, $100 in total, with payments spaced out over up to 12 months. They will be paid $40 for their baseline visit and $30 for their final follow-up visit. An additional $30 will be paid after their 6-month follow-up call. Participants may drop out of the study at any time without forfeiting the payments they have already received. Payments typically take between 10 days and two weeks to reach Veterans.

5.2 Recruitment Methods

Recruitment Procedures: We will recruit 450 participants with methods that we have used successfully for other VA clinical trials:

1. We will request a waiver of informed consent to review the CPRS records of Veterans age 65-89 with a documented diagnosis of low back pain. The research coordinator (RC) at each site will review records of potentially eligible Veterans to ensure the veteran has a primary care provider within the VA system and that they have seen their PCP within the past 6 months for low back pain. This pull of potential eligible participants will initially be extracted from the Corporate Data Warehouse by a study staff member. Potentially eligible Veterans will be mailed a letter signed by the site PI and a flyer or brochure describing the study (both of which will be IRB-approved). If (s)he is interested in participating, (s)he will call the study research coordinator (RC), whose name and contact information will be provided in the brochure. In addition, 14 days after we have mailed letters, if we have not been contacted, we will call potential participants to ascertain their interest in participation. We have successfully adopted this strategy in the context of our ongoing pilot study.
2. We will recruit directly from clinics, at each local VA site, using the following approaches: a) Site PIs will send email to the Providers in clinics at their site to introduce the study. b) Brochures will be delivered to clinic waiting rooms and to the Providers themselves including those associated with Women's Health Clinics. We will suggest that Providers keep brochures in their exam rooms for distribution to potentially eligible Veterans. c) IRB-approved posters will be placed in exam rooms. d) Site PIs will deliver an educational presentation on CLBP for PCPs and/or Providers in the context of an existing conference, and study information with be provided at that time.
3. The IRB-approved brochures will also be placed in waiting rooms of specialty clinics that commonly care for Veterans with CLBP (e.g., orthopedics, neurosurgery, neurology, pain medicine). Interested Veterans will call the RC to complete screening procedures.

5.3 Informed Consent Procedures

In order to meet the timeline demands of this extremely low-risk study, we will request both a waiver of HIPAA authorization and a waiver of Informed Consent so Research Coordinators (RC) may review CPRS records for potentially eligible participants. The information collected will have no PHI attached to it.

At baseline, the RC at each site will administer the Informed Consent and HIPAA prior to study procedures. Ample time will be provided for questions and discussion. Subjects will be considered enrolled once they have provided written informed consent, and a copy of the signed Informed Consent document will be provided to the participant. Before data collection begins, the RC will screen the participant for cognitive impairment with

the Mini Mental State Examination (MMSE). Participants who score less than 24 will be excluded, and their PCP will be alerted. Excluded participants will still be paid $40. Baseline data collection will begin at this time for eligible participants. Baseline data beyond the screening for cognitive impairment and gait speed test may be collected over the phone or on site.

A progress note documenting consent will be placed in CPRS after completion of baseline. The signed Informed Consent will be kept under double lock and key in the research staff members' office and only the research staff will have access to these documents.

Local site study personnel will be required to maintain active training in CITI for their Human Subjects Protections training courses. They will also be required to be listed as administers of informed consent at their local site.

5.4 Inclusion/Exclusion Criteria

We are targeting older Veterans with CLBP, defined as pain in the lower back of at least moderate severity (assessed with a verbal rating scale), on ≥ half the days for ≥ 6 months. Veterans must be age 65-89 and English speaking. They must be able to commit to up to 12 months of study participation. The Quick Mild Cognitive Impairment Screen (QMCI) will be administered on site to screen for mild cognitive impairment (MCI). Those with MCI will not be excluded, but their PCP will be alerted.

Exclusion Criteria include:

- Positive screen for dementia (score ≤23 on the MMSE)
- Pain in other body locations that is more severe than their low back pain
- Red flags indicative of serious underlying illness requiring urgent care (e.g., fever, change in bowel/bladder function, sudden severe change in pain, unintentional weight loss, new lower extremity weakness)
- Previous lumbar surgery
- Acute illness
- Psychotic symptoms
- Prohibitive communication impairment (e.g., severe hearing or visual impairment)
- Evidence of illicit substance abuse on urine drug screen at anytime in the past 6 months or active drug abuse documented by provider
- Other (e.g. have moved out of state, are homebound, terminal illness, etc.)

Neither pregnant subjects nor women of childbearing potential will be included due to the age requirements of the study. Vulnerable subjects will not be enrolled, nor children and prisoners.

Research staff will recruit all participants. They will not use coercion of any kind.

5.5 Study Evaluations

Screening Procedures (Appendix 7)**:** Telephone screening by the RC (approved via a waiver of consent) using a structured questionnaire will determine participant eligibility, i.e., CLBP, ability to participate for up to 12 months, no red flags or prohibitive communication impairment, and no acute medical or psychiatric illness. If the screening procedures indicate that the Veteran is eligible, (s)he will be invited to come in for on-site baseline testing. After the participant has signed the HIPAA and Informed Consent documents they are considered enrolled. Then, the RC will administer the MMSE and those who fail (i.e., screen positive for dementia with a score <24) will be excluded and their PCP notified. We use the MMSE because it has been

studied extensively, has good diagnostic accuracy (sensitivity 0.85, specificity 0.9) and it takes only 5 to 7 min to administer.[85] Then a doctor who is part of this study will perform a Red Flags Screening. After this is complete, participants will be considered active participants in this study. Beyond the data measures that must be collected on site (MMSE, gait speed, and Red Flags Screening by provider), the remaining may be collected over the telephone or on site.

Baseline Testing (Appendix 8) - On all enrolled participants, RCs will collect a set of established measures that assess constructs relevant to older adults and have low participant burden, as shown in Table 6.

1. The **Oswestry Disability Index (ODI):** Our main outcomes measure, the ODI assesses interference of pain with function.[12]
2. The **Minimal Data Set (MDS),** recommended by the NIH Task Force on research standards for CLBP, measures pain severity and interference with daily activities, widespread pain, prior CLBP treatments, overall physical function, depressive symptoms, sleep, psychological maladaptation (i.e., fear-avoidance beliefs and catastrophizing), alcohol/drug use, cigarette smoking, demographics (age, race, ethnicity, gender, education, marital status), height and weight.[4]
3. The **PROMIS 29** collects items not already included in the MDS - anxiety symptoms, fatigue, and participation in social roles and activities.[14] The full PROMIS 29 will be administered during follow-up.
4. **Other key cofactors** that may impact outcomes, and are relevant to older Veterans:
   a. Medical comorbidity will be measured by self-report with the Duke comorbidity index.[86]
   b. Pain medications (regularly scheduled and as-needed) will be categorized into sub-classes: a) salicylates (aspirin > 1200 mg/day, salsalate), b) non-aspirin, non-COX2 selective non-steroidal anti-inflammatory drugs (NSAIDs), c) COX2 selective NSAIDs, d) acetaminophen, e) opioids, f) skeletal muscle relaxants, g) adjunctive agents (e.g., corticosteroids, capsaicin). Regularly scheduled opioid analgesics will be converted to daily oral morphine equivalents.[87]
   c. Medications other than pain will be collected as well.
   d. Social support will be measured with the well-validated MOS Social Support Scale.[88]
   e. Opioid difficulties will be measured (in those taking opioids) with the Prescribed Opioids Difficulties Scale, a patient-centric instrument that assesses patient problems and concerns attributed to use of opioids.[16]
   f. Suicidality will be measured with a question from the PHQ 9: "Over the last 2 weeks, have you had thoughts that you would be better off dead or of hurting yourself?" If the veteran responds affirmatively and the assessment is being conducted in person, the RC will immediately notify the site's PI who will contact the Veteran's primary care provider and proceed with the VA suicide hotline protocol that includes a warm transfer to a VA mental health provider. If the assessment is being conducted over the telephone, the RC will ask the Veteran to hold on and (s)he will immediately contact the site PI using another telephone and the facilitiy's Suicide Threat Call Protocol will be followed.
5. **Quality of life** will be measured with the PROMIS-Global Health scale (36) and the Veterans Rand 12 Item Health Survey (VR-12) [ref].
6. **Balance confidence** (i.e., confidence in avoiding falling) will be measured because of data supporting the relationship between pain and falls in older adults.[89] We will measure this with the Falls Efficacy Scale-International short form.[17]
7. **Falls** during the prior 3 months will be queried because of the relationship between pain and falls in older adults.[89] We also will collect data on falls history during the quarterly follow-up calls (see below).
8. **Quick Mild Cognitive Impairment (QMCI)** screen, a validated measure that screens for the presence of mild cognitive impairment, will be administered.[13,90] Evidence supports the impact of MCI on physical functioning in older adults in general and specifically in those with pain.[91] The RC will upload the results of the QMCI to CPRS.
9. **Gait speed**, a well-validated measure of physical frailty in older adults, will be measured over 4 meters using standard methods.[92] That is, participants will be asked to walk at their usual pace and from a standing start. This will be measured twice and results expressed as the average over two trials.
10. **Life Space Assessment[106]** will be utilized to measure the spatial extent of a participant's mobility.
11. **0-10 Numerical Pain Rating Scale** will be utilized to measure pain at the moment, on average during the last week and the worst pain of the last week.
12. **Treatment History** will be collected on all patients using the Treatment History form to gain an understanding of treatments participants have already received or are receiving to try and aid their CLBP.

13. The **Pain Self Efficacy Questionnaire (PSEQ)** will measure participants' confidence in their ability to do things despite their pain.

Randomization and Blinding: Following baseline testing, we will use the high quality pseudo-random deviate generator in SAS® (SAS Institute, Inc., Cary, North Carolina) to randomize participants to ABC care or UC in a 1:1 ratio, stratified by recruitment site. Within each site, we plan a blocked randomization scheme to force continued approximate balance between the numbers of subjects in each arm during recruitment. The block size will be randomly chosen to be one of two small even numbers to prevent personnel from predicting treatment arm, and exact block sizes will be revealed at the study conclusion. The study statistician will create separate randomization schedules for the 3 strata that contains a randomization sequence number (different from a participant's study identification number) and assigned arm. Then he will create a series of sealed envelopes for each of the sites containing the treatment assignment but conspicuously labeled on the outside with only the randomization sequence number. At the time of randomization, the overall RC based at the coordinating site will open the next available envelope specific for the participant's site, and record the randomization sequence number, subject identification number and group assignment in a dedicated database, different from the main study database. She will then inform the RC at the participant's site of their randomization group and the local RC will inform the participant of next steps. Personnel assessing follow-up outcomes will be masked to intervention assignment (see Follow-Up below). The study statistician has successfully employed the same process in other clinical trials.

Intervention

UC will not be constrained. As a courtesy, participants who are randomized to UC will be offered the ability to see an ABC provider at their site (in person or virtually) after their completion of all study related procedures and the end of their up to12 month participation. The RCs will track the components and location of care with monthly telephone calls using methods that we and others have used successfully in older adults (see below). We considered other control group designs, but chose not to for the following reasons: 1) Our clinical experience in delivering care to older Veterans with CLBP in our pain clinics highlights that most patients with CLBP already have had and failed a trial of physical therapy; thus, while we considered a control condition of physical therapy and analgesics, patients' prior participation in physical therapy would threaten recruitment feasibility. 2) We considered physical therapy and analgesics for the control group, and altering our inclusion criteria; specifically, we considered including only Veterans with "new onset" CLBP, e.g., back pain on most days for no more than the prior 12 months to reduce the likelihood of prior physical therapy; had we used these criteria in our previously described pilot work, however, only 4 of 50 participants would have qualified. 3) We considered recruiting patients from pain clinics, i.e., randomizing participants to either ABC care or Pain Clinic care, but the numbers of Veterans referred to Pain Clinics is considerably smaller than those available with our strategy. Comparing ABC care to standard Pain Clinic care could be the focus of a much larger, future trial.

ABCs will be staffed by a minimum of 3 non-surgical consultants at each site who have been trained in the published evaluation and treatment protocols. The PI will train providers at VAPHS and the Greater Los Angeles VA on site. Those at the Richmond VA site will be trained by co-I Dr. Gentili (Richmond site PI) who has been trained in the context of the VA Rehab R&D-funded pilot studies that form the foundation of the proposed clinical trial. Training at all sites will occur over one day and will use effective adult learning principles that we have successfully employed in our pilot studies (see Preliminary Studies). Learning will be interactive and characterized by goal-directed practice coupled with targeted feedback[93,94] as follows:

1. The trainers (Drs. Weiner and Gentili) will teach the structured examination (Appendix 6) to providers on 3-4 patients. They will demonstrate the examination on the first patient, then observe the provider perform the exam on 2 to 3 additional patients, provide immediate feedback and answer any questions. This will occur during the first half of the day.
2. During the second half of the day, the trainers and the providers will perform the structured exam on a separate group of 5-6 patients using the same goal-directed model with targeted feedback.
3. Because of the importance of content reinforcement for adult learners[94], the PI also will conduct a weekly teleconference during the start-up period with all participating providers to review the algorithms and accompanying materials using illustrative case examples, and to answer any questions. Two to three algorithms will be reviewed once a week for 4-5 weeks.

4. The materials will be housed on a SharePoint site dedicated specifically to this study and to which the participating providers will have ready access for the duration of the study period.
5. Reinforcement training sessions will be scheduled as needed prior to the start of participant enrollment.

As in the UC group, RCs will track the components and location of care with monthly telephone calls.

Care in the ABCs will proceed as follows:

1. Usual clinical staff will check the Veteran into the clinic using standard procedures (i.e., confirm his/her name and SSN, and purpose of the visit).
2. The Veteran will complete Take Back Your Back, an interactive tablet-based questionnaire described in Preliminary Studies (Appendix 9). This will take ~7-10 minutes. As noted previously, the purpose of this tool is to educate the Veteran, screen him/her for key component conditions (e.g., fibromyalgia, depression, anxiety, maladaptive coping [i.e., fear avoidance believes and catastrophizing], and insomnia), and encourage the Veteran to discuss these potential contributors with the ABC provider. This can all be administered via verbally by research staff, over the phone.

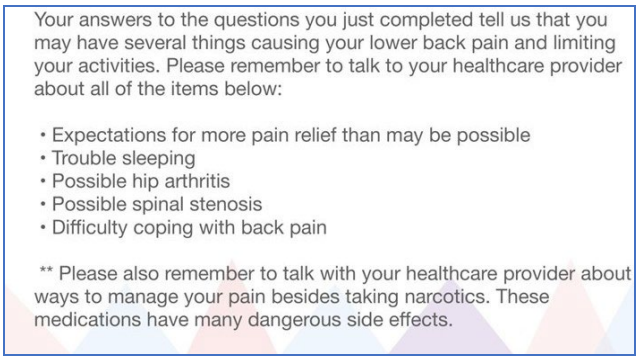


Figure 5. *Take Back Your Back:* Summary Screen

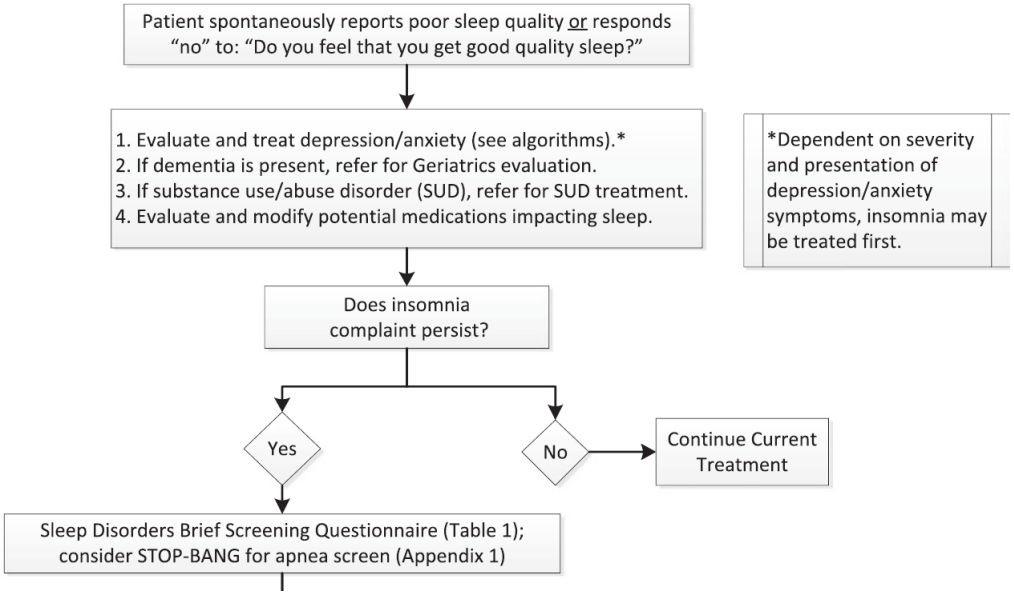
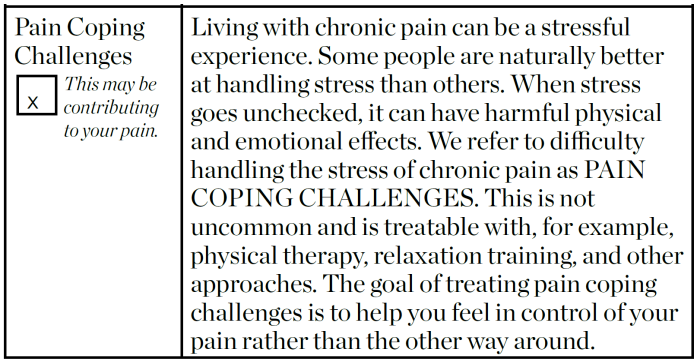


Figure 6. Portion of Insomnia algorithm

3. The Summary Screen from Take Back Your Back (example shown in Figure 5) will be revealed to the provider in the ABC clinic who will review it with the Veteran and tailor their history-taking accordingly. This can be done virtually. Also, the history can be attained virtually, or in person, by the Provider. The participant whose results are shown in Figure 5 screened positive for unrealistic treatment expectations, insomnia, possible hip arthritis and spinal stenosis, and maladaptive coping. Armed with this knowledge, the ABC provider will tailor his history accordingly. As per the first portion of the Insomnia algorithm shown in Figure 6, the provider would want to evaluate this Veteran's mood, even though his PHQ4 was negative. The provider also will want to evaluate this Veteran's history of substance use, and review the medication list to determine if there are any that can negatively impact sleep.
4. The ABC provider also will check the results of the QMCI so that the pace and implementation of treatment can be modified accordingly. As MCI and dementia are part of a continuum, the published Dementia algorithm can be applied to those with MCI.
5. The provider will perform the previously learned structured physical examination to identify the other CLBP contributors listed in Table 1 (hip OA, SI joint syndrome, myofascial pain, leg length discrepancy, lateral hip/thigh pain syndrome).

6. The provider will educate the Veteran about the contributors to their CLBP and functional impairment. This will be facilitated by a brief educational booklet that will be given to the Veteran to take home and keep. The booklet, "Making Better Lives: Patient-Focused Care for Low Back Pain (Appendix 10)," was created for our ongoing SPiRE trial (Pilot Study #2) and provides a brief overview of the Veteran's contributing conditions, using simple language, as shown in Figure 7. In this Figure, the ABC provider determined, based on their evaluation, that the Veteran has maladaptive coping (i.e., fear avoidance beliefs and/or catastrophizing) as one potential contributor to CLBP/disability.

7. The provider will use the algorithms (Appendix 5) to direct next steps (e.g., referral for insomnia consultation to consider behavioral treatment[50]; obtaining an x-ray of the hip to confirm a diagnosis of hip OA; referral to physical therapy for treatment of lumbar spinal stenosis). All patients, regardless of pain contributors, will be provided with a copy of the pain self-management workbook developed by consultant and pain psychologist Dr. Beverly Thorn (Appendix 11).[95] The workbook, "Learning About My Pain (LAMP)," has been successfully implemented in the context of a trial that specifically targets patients of low literacy and was funded by the Patient-Centered Outcomes Research Institute. The workbook was developed to be used in a group setting and will be modified during the startup phase of the proposed trial for use by individuals not in a group setting, under the guidance of Dr. Thorn (see letter of support). We will refer to it as "Learning About Chronic Pain" book. Participants will be encouraged to revisit Learning About Chronic Pain book periodically to determine how they perceive themselves to be coping.



Pain Coping Challenges [X] *This may be contributing to your pain.*	Living with chronic pain can be a stressful experience. Some people are naturally better at handling stress than others. When stress goes unchecked, it can have harmful physical and emotional effects. We refer to difficulty handling the stress of chronic pain as PAIN COPING CHALLENGES. This is not uncommon and is treatable with, for example, physical therapy, relaxation training, and other approaches. The goal of treating pain coping challenges is to help you feel in control of your pain rather than the other way around.

Figure 7. Excerpt from "Making Better Lives: Patient-Focused Care for Low Back Pain"

8. To facilitate communication with other providers involved in the algorithms-guided care, the ABC provider will document their baseline assessment results using a standardized template in CPRS. This assessment will include a list of the participant's contributing conditions and the treatments recommended (See Appendix 12) in a data measure called the Post H&P Rx. The ABC provider also will complete templated follow-up visits notes (Appendix 12).

9. The frequency of ABC care visits will not be constrained. Suggestions for frequency of patient monitoring are provided within the algorithms. At follow-up visits (which can be in person or virtual), the ABC Provider will collect data measures to capture the participant's main conditions. This study focuses on 11 main conditions related to CLBP, and a data measure will be provided for each condition so that the ABC Provider may capture all the necessary data. For each of the participant's contributing conditions, the provider will record current treatment, perceived compliance (full, partial, none), treatment response (complete, partial, none, did not tolerate), method of

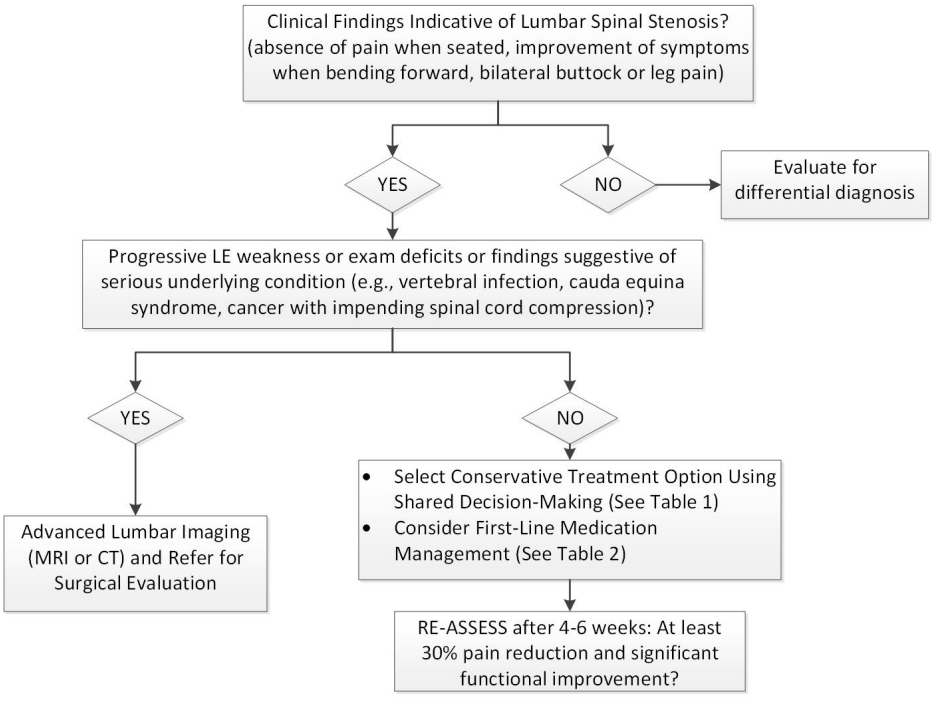


Figure 8. Portion of Lumbar Spinal Stenosis algorithm

response assessment, and plan. The 3 Question Follow Up Data Measure will be administered at each follow up visit. As shown in Figure 8, for example, if the provider's evaluation reveals symptoms consistent with lumbar spinal stenosis and the patient is neurologically stable, conservative treatment is recommended for 4-6 weeks followed by reassessment. Each algorithm has multiple steps and recommendations conditional upon response. The goal of treatment across all algorithms is reduction of pain-associated functional interference/disability.

10. The participants randomized to the ABC Care group will be contacted either by phone, or if they would like to come on site, by an ABC Provider at their local site. No data measures will be collected. The purpose of this interaction would be to help discuss and guide the participant on care after study completion.

11. ABC Providers will complete a " Final MD ABC Participant Assessment" for each of the participants upon completion of their finalmonth of participation.

Rationale for Specialists Delivering ABC Care: The investigative team discussed whether ABC care should be delivered by PCPs or specialists. The study proposed is an **explanatory clinical trial**, thus we chose specialists because: 1) CLBP is a complex multifaceted condition that requires time to evaluate thoroughly. Patients typically are referred to specialty consultants to evaluate and recommend management for a single condition. Primary care providers, on the other hand, must manage a host of conditions in each patient and their appointment duration is brief (e.g., 15 minutes for a follow-up patient), thus pragmatism played a significant role in our decision for specialist consultants to provide ABC care. 2) The background and training of many pain medicine consultants (i.e., anesthesiology[96]) and the desire of many patients for a "quick fix" often leads to pain clinics delivering spine-focused, procedure-oriented care (i.e., spinal injections). Such care often is not associated with salient functional improvement, the outcome of critical relevance for older adults. Since PCPs often do not have time to address chronic pain adequately, pain specialist referral occurs commonly, as recommended by the VA stepped care model (see Figure 1 in the Background and Significance section). Thus, expanding the expertise of consultants to address the needs of frail older adults has the potential not only to reduce pain and improve function, but to avoid unnecessary care and morbidity.

Follow-up (Appendix 13): Quarterly telephone calls for up to12 months following randomization will collect data on the main outcomes measure (the ODI) as well as the PROMIS 29, PROMIS-GH, VR-12, falls and falls efficacy (Falls Efficacy Scale-international short form), and the Life Space Assessment.[106] Health care utilization that includes pain medication use (oral morphine equivalents[87]), emergency room visits, hospitalizations, and pain provider/other health care utilization as well as the 0-10 Numerical Pain Rating Scale will be collected monthly using established methods.[97] Monthly collection of data on health care utilization will facilitate comparison of key components of ABC care and Usual Care. During the final call at 12 months, the Perceived Intervention Value data measure will be administered as well as the Global Impression of Change data measure. Also, during the final call, all medications will be collected. To ensure the RC collecting these measures is masked to randomization group we will employ methodology that we have used successfully with other VA trials. For Example: the RC at the Pittsburgh site will collect follow up data on participants from the Los Angeles site, the RC from the Richmond site will collect follow up data on participants from the Pittsburgh site, and the RC from the Los Angeles VA will collect follow up data on participants from the Richmond site. Participants who were randomized to the UC group will be made aware that they may see an ABC provider at their site, outside of the context of this study, for one visit after completion of participation. Participants who were randomized to the ABC Care group will be contacted at their final month of particpiation, whether by phone, or if they choose on site, to discuss care after their participation. No data measures will be collected and no study related procedures performed. The ABC Providers will fill out a Final MD ABC Participant Assessment for each ABC Participant upon completion of their up to 12-month participation. The purpose of this data measure is for the provider to comment on each condition for which the participant was treated, and if the condition was in fact treated, and if not the rationale for not treating the condition. If during telephone-based follow up data collection (for a participant based at the sister site) the Veteran expresses suicidal ideations, the RC will ask the Veteran to hold on and (s)he will immediately call the site PI at the sister site (i.e., the site of the Veteran's home VA) who will call the Veteran and follow the facility's Suicide Threat Call Protocol. If the sister site PI is not immediately available, the RC will call the PI at their own site who will

talk with the Veteran, assess risk and follow procedures according the Veteran's home VA's Suicide Threat Call Protocol.

Retention Strategies: We will employ methods to minimize dropout that we have used successfully for our other VA clinical trials. Specifically, we will: 1) Provide $40 compensation following the completion of baseline data collection, and $30 each following the completion of 6 and final month of data collection. Thus, each participant can receive up to $100 for their participation. 2) If we are unable to reach participants during the quarterly telephone calls (3 X over 2 weeks), we will send a reminder letter requesting that they call the RC for data collection. 3) Those randomized to the UC group will be offered ABC care after they have completed final month data collection.

Tracking Intervention Adherence: Following their baseline visits, participants from both the ABC and UC groups will be followed for adherence to their treatment plans. An RC will query CPRS records beginning 30 days following baseline testing to determine whether participants have attended their scheduled visits. Results will be recorded in a secure tracker. All RCs will query CPRS records a minimum of every 30 days for the duration of the study. Participants in the Choice program will be asked to confirm their appointments with check-in calls.

5.6 Data Analysis

Data Management: A summary of the baseline and follow-up data is provided in Table 7. Data will be collected using paper forms. Completed data forms will be entered into a secure electronic database on a VA network server with regular server backup. The PI will work with the VAPHS research team to oversee all aspects of data management in accordance with policies and procedures outlined in VHA Handbook 1200.12. Only research team members at participating sites will have access to personal information needed for conducting informed consent procedures and participant tracking. Data collected on paper forms and any identifiable information will be stored in the Research Coordinator's office at each site, under double lock and key. All participants will be assigned unique synthetic identifiers that will appear on forms, files and serve as a non-identifiable index in database tables. Only de-identified data will be entered into the secure electronic database. There will be no data fields in which to enter individually identifiable information electronically, except the synthetic participant study IDs. Data entry will include double data entry checks. All research desktop computers will be encrypted. The encryption software will be Federal Information Process Standards (FIPS) 140-1,2 compliant. Data collected for this study will be kept in compliance with VHA regulations forbidding the destruction of research records.

Table 7. Baseline and Follow-up Data

Measure	Timepoint		
	Baseline	Q3 month*	Q month
Oswestry Disability Index (Primary Outcome)	X	X	
NIH Task Force Minimum Data Set	X		
Quick Mild Cognitive Impairment (QMCI) screen	X		
Medical Comorbidity (Duke Comorbidity Index)	X		
Social Support (MOS Social Support Scale)	X		
Prescribed Opioids Difficulties Scale	X		
Pain Self Efficacy Questionnaire	x		
Gait Speed	X		
Life Space Assessment	X	X	
0-10 Numerical Rating Pain Scale	X	X	X
PROMIS-29	X	X	
Falls Efficacy Scale-international Short Form	X	X	
PROMIS Global Health Scale	X	X	
Veterans RAND 12 Item Health Survey (VR-12)	X	X	
Treatment History	X		
Healthcare Utilization (pain medication, emergency room use, hospitalization)	X	X	X
Medications	X		final month
Perceived Intervention Value			final month
Global Impression of Change			final month

*Collected at 3 months, 6 months, 9 months, 12 months follow up

Data Analysis:

Overview:
The study Statistician, Dr. Subashan Perera will be in charge of data analysis along with the PI. Dr. Perera will be sent only de-identified data as described above. We will perform all main analysis based on **intention-to-treat** following the a priori plans outlined

below. All statistical analyses will be performed using SAS® version 9 (SAS Institute, Inc., Cary, North Carolina) by the study statistician Dr. Perera. Participant flow will be summarized using a CONSORT diagram.[98] Data will be summarized by intervention arm and time point as well as baseline to follow-up change using appropriate descriptive statistics. First, the baseline participant characteristics will be compared between the two arms. Any significant differences will be noted and accounted for as covariates in the sensitivity analyses. Second, primary and secondary analyses to address the aims will be performed as outlined below using multiple imputation for missing data. The primary analysis will be performed to test the primary hypotheses H1.1 about the ODI. Secondary analyses will be performed for remaining hypotheses, secondary outcomes and other exploratory analyses. Third, we describe below our primary approach to missing data and a set of sensitivity analyses by including additional covariates, ignoring missing data, and reasonable alternative statistical modeling strategies to assess the robustness of our findings.

Baseline Comparison:
Due to the large sample size and the randomization scheme balanced with respect to site, it is highly unlikely that baseline participant characteristics will be significantly different between the arms. If we do find any, they will be included as covariates in the sensitivity analyses. We will not alter the primary analysis to preserve its a priori nature and predictability. We will use independent samples t- or Wilcoxon rank sum tests, as appropriate based on distributional properties, to compare continuous baseline characteristics between the intervention arms. For categorical baseline participant characteristics, we will use chi-square and Fisher's exact tests, as appropriate. Statistical significance of the intervention term will be interpreted as indicating the need to include them as covariates in sensitivity analyses.

Aim 1 Primary Analysis:
We will fit a linear mixed model with baseline to follow-up change in ODI score as the dependent variable; intervention arm (ABC/UC), follow-up time point (6/12 months) and their interaction as fixed effect of main interest; baseline ODI as a fixed effect covariate; and a participant random effect to account for multiple repeated assessments of the same participant over time. The statistical significance at $\alpha=0.05$ of the ABC vs UC means contrast at the 6-month point will serve as the formal test of the primary hypothesis H1.1. Upon confirming the H1.1 primary hypothesis, we will compute the number-needed-to-treat (NNT) as the reciprocal of the between-intervention difference in percentages of those showing a meaningful ODI improvement above its MCID.

Aim 1 Secondary Analyses:
To characterize the intervention actually received under ABC care, we will describe the conditions identified, further evaluations/initiated treatments and their responses recorded in the form that tracks response to treatment and additional management plans (see Appendix 12). We will employ the same analytic strategy described above for ODI (under primary analysis) for our secondary continuous outcomes pain severity, quality of life and falls efficacy. The statistical significance of the ABC vs UC means contrast at the 6- and 12-month points will serve as the formal tests of the secondary hypotheses H1.2.

Measures of healthcare utilization between 6 and 12 months in H1.3 (prescriptions/refills of opioids and inappropriate medications for elderly, invasive procedures, emergency room/hospital visits) are mostly in the form of counts. As such, we will fit a series of generalized linear models with each count utilization outcome as the dependent variable, a negative binomial distribution to account for any over dispersion and a logarithmic link function for the count outcome, actual person-time of exposure with opportunity for reporting utilization outcome as an offset, and intervention arm (ABC/UC) as the independent factor of interest. Intervention arm incident rate ratios and their statistical significances will constitute tests of H1.3.

Aim 2 Analyses:
The goal is to explore whether ABC vs UC differences in improvement vary across participant subgroups of interest (effect modification). We will add each of the subgroups (based on baseline CLBP-associated disability, anxiety/ depression, mild cognitive impairment and obesity) and associated subgroup × intervention group interaction effects as additional fixed effects in the above statistical models. Rigorous methodological guidelines for subgroup analyses require significant interaction effects for making conclusions of differential intervention effects in subgroups.[99] As such, we will first construct difference-in-difference type means contrasts representing the difference in ABC vs UC effects in different subgroups at each of the follow-up time points. If and only if the said interaction contrast is significant, we will estimate ABC vs UC differences and

their statistical significance within those subgroups.

Missing Data:
The best approach for handling missing data is to prevent it. We will use the methods described earlier to retain participants and prevent missing data. Despite our best efforts, missing data will occur. We will clearly document those with missing data and reasons in the CONSORT diagram, and compare those with missing data to complete data with respect to available data. Statistical guidelines for handling missing data recommend methods such as multiple imputation, which considers the uncertainty involved in imputing missing data.[100] Multiple imputation is arguably the best available objective method to analytically account for missing data under the ignorable or missing-at-random (MAR) assumption. Specifically, we will generate M=5 imputed values for each missing value, analyze the 5 datasets as though complete, and finally combine the results appropriately so that they reflect the uncertainty involved in imputation. SAS® MI and MIANALYZE procedures will be used. Other approaches to missing data, including the naïve approaches of ignoring the missing values and last-value-carried-forward (LVCF) will also be considered in sensitivity analyses and robustness of the results to using these approaches will be examined.

Sensitivity Analyses:
We will perform a series of sensitivity analyses to ensure the robustness of our results against various assumptions. One such analysis will involve inclusions of baseline participant characteristics significantly different between groups as additional covariates in the linear mixed and generalized linear models above. Another will involve sensitivity of results to missing data handling techniques. In addition, if analyses of residuals from the models show violations of statistical assumptions, we will consider fitting models after Box-Cox transforming[101] the continuous variables. Finally, a reasonable alternative to the proposed negative binomial models for count data representing healthcare utilization measures is the zero-inflated Poisson model.[102] We will examine the sensitivity of our findings for utilization outcomes against this alternative modeling strategy.

Sample Size Justification and Statistical Power:
Planned sample size is 310 participants. Prior data and assumptions include a between-subject standard deviation of 18 points for pre- to post-intervention change in the primary outcome ODI[103]; a conservative estimate of a minimally clinically important difference (MCID) of 7 points[104]; a conservative dropout rate of 15% from other back pain trials[105]; using published methods implemented in commercial software (PASS 2012®, Number Cruncher Statistical Systems, Kaysville, Utah), with 310 patients and 280 anticipated completers, we will be able to detect an observed primary outcome difference as small as 7 points with 90% power in a 2-tailed test at the $\alpha=0.05$ level.

5.7 Withdrawal of Subjects

After participants sign both the HIPAA and Informed Consent documents, officially enrolling them in the study, they will be screened for cognitive impairment with the MMSE questionnaire before starting baseline data collection. Those who score $\leq$23 will immediately be withdrawn from the study, and their PCPs will be alerted.

Participants are able to withdrawal at any time without consequence by either alerting the RC or the investigator. They will be able to keep the payment(s) they have already received but will not receive additional payment. UC participants can continue or discontinue care at their discretion. ABC care participants will no longer be treated as part of the study but can be referred to an ABC clinic by their PCP to re-engage treatment. Follow-up calls will be terminated, discontinuing data collection. Previously collected data will still be analyzed.

6 Reporting

The overall PI and the overall RC will be available on a daily basis to take calls and emails from all study-site personnel. In addition, teleconferences will be scheduled at the site PI's discretion to discuss goals, progress, modifications, documentation, recruitment, retention, data analysis, and confidentiality. Any instances of adverse events, protocol deviations, or other problems identified during the meetings

will be reported as soon as possible within the required reporting timeframes using the standard forms and/or procedures set forth by the IRB. In addition, clinical coordinators may review study documentation and/or consent forms to ensure that subject's confidentiality is maintained.

7 Privacy and Confidentiality

Protected Health Information (PHI) will be used for the purposes of contacting the subject via telephone and mail, as well as to screen their CPRS records. PHI will not be used outside of these few functions, nor will it be disclosed or used on any data collection measures.

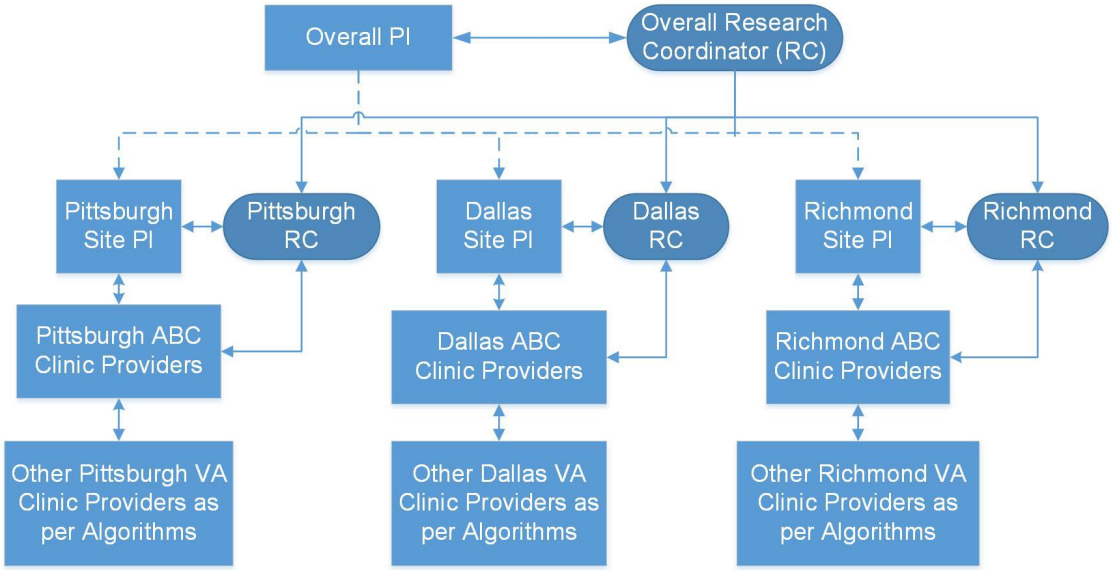
All data will be collected on hard copies and stored under double lock and key in the research team members' office and/or file cabinets. No members outside of the research team will have access to this information. Data will be entered into an electronic database created in Microsoft Access, specifically for the purposes of this study. No PHI will be kept in this database. All electronic data and information will be kept on a protected VA shared drive that only research team members will have access to. Also, a master list of all subjects who have signed Informed Consent documents will be kept electronically on the VA Shared Drive.

Study subjects will be assigned unique identifiers that will appear on all files used in the statistical analyses; all data will be de-identified. Only limited team members at participating VAs will have access to personal information needed for tracking and informed consent. Several steps will be taken to ensure data quality and data integrity: 1) use of standard methods of data collection and recording specified in a manual of operations 2) required viewing of a webcast staff workshop on research integrity and data entry at the beginning of the study and when new personnel are hired, and 3) audits on a random sample of participants to verify completion of interviews and data accuracy. A code number will be the only identifier on the electronic data that is stored on a protected VA Shared Drive. There will be no data fields in which to enter PHI electronically.

All research desktop computers will be encrypted. The encryption software will be Federal Information Processing Standards (FIPS) 140-1,2 compliant. Data will be kept on the protected VA Shared Drive at least 3 years following completion of the study and will be archived to ensure compliance with VHA regulations forbidding the destruction of research records.

8 Communication Plan

The within and between site communication structure is shown in the diagram below.



Within and Between Sites Communication Structure

The Overall PI and Overall RC, located at VAPHS, will have ongoing communication throughout the duration of the study. The Overall PI and the Local Site PIs also will maintain an open line of communication for the duration of the study, as will the Overall RC and the Local Site RCs, and the Local Site PIs and the Local Site RCs. We expect site personnel to respond to each other within 24 hours, preferably with the same day.

The ABC Clinic operations will be overseen by the Local Site PI and the Local Site RC. The RC will be responsible for maintaining the clinic schedule (i.e., scheduling all appointments and any changes to the schedule). The Local Site PI will be the ABC Clinic Director. The RC will schedule appointments with the ABC clinic providers and ensure that those assigned to UC do not have appointments with the ABC providers for the duration of the study. Day to day procedures for operationalizing this process will be finalized during the study start-up period at each site.

Communication also will occur between ABC Clinic Providers and other relevant clinic providers that are consulted in the context of the algorithms. This will occur in the same manner as per standard VA care. That is, consultations will be ordered through CPRS and all patient-related communications will occur securely through CPRS.

Recurring Meetings

The Overall PI and the Overall RC will meet weekly to discuss overall and site-specific activities, including recruitment, enrollment, retention, and any additional study activities or concerns. Additional meetings will be conducted as the need arises. The RC will take notes and keep those records for the duration of the study.

The Overall PI, Overall RC, Local Site PIs and RCs will meet weekly via teleconference during project start-up and the first six weeks of recruitment. Then, meeting frequency will be monthly or as needed for the duration of the project. During the first three months of recruitment, they will discuss recruitment strategies, progress, and ensure adherence to the protocol. For the duration of the study, the calls will focus on responding to local site PI/RC questions, discussing recruitment goals and actual recruitment, as well as retention, enrollment, and follow-up progress. Notes will be taken by the Overall RC and kept for the duration of the study.

The Overall PI, the Local Site PIs, and all ABC clinic providers will communicate during regularly scheduled meetings. During project start-up, the Overall PI will meet with the Local Site PIs and ABC clinical providers to review 2-3 algorithms per week. During the first 6 weeks of participant enrollment, weekly meetings will continue, and specific participant cases will be discussed. Providers will present cases which allow for discussion on adherence to and reinforcement of the published algorithms. Subsequently these meetings will occur monthly or on an ad hoc basis.

Local Site PI, the local site ABC Clinic Providers, and the Site RC will meet weekly or as needed to ensure that the procedures discussed during the meetings with the Overall PI and Overall RC are followed. They will discuss any site-specific clinical and administrative issues that arise, including but not limited to recruitment, enrollment, retention, follow up, flow of the study, and adherence to the protocol. Local RCs will take notes and keep them for the duration of the study.

Any instances of adverse events, protocol deviations, or other problems identified during the above meetings will be reported as soon as possible within the required reporting timeframes using the standard forms and/or procedures set forth by the IRB.

A summary of the project meetings is provided in the table below.

Within and Between Site Communication

Communication Level and Participating Staff	**Communication Frequency**		**Meeting Focus**
	Start-up period	**Post-startup and following**	
Overall: PI and RC	Weekly	Weekly	Track overall study progress and procedures
Overall with Local Sites: Overall PI/RC, site PIs and site RCs	Weekly	Monthly or as needed	Track site-specific study progress and procedures
Overall with Local Sites: Overall PI, Site PIs, and ABC clinic providers	Weekly	Monthly or as needed	Discuss active cases in ABC arm
Within Site: Site PI/RC and ABC Clinic Providers	Weekly	Weekly or as needed	Team discusses site-specific study activities, both clinical and administrative

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