Study Title: **Patient-Centered Versus Imaging-Directed Care for Older Veterans With Chronic LBP**

NCT02697435

July 11, 2019

NOTE: **The manuscript that starts on the following page has been accepted for publication in Pain Medicine.**

Aging Back Clinics - A Geriatric Syndrome Approach to Treating Chronic Low Back Pain in Older Adults: Results of a Preliminary Randomized Controlled Trial

(Running Title: Chronic Low Back Pain Syndrome Treatment)

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ABSTRACT

Objective: Treating chronic low back pain (CLBP) with spine-focused interventions is common, potentially dangerous, and often ineffective. This preliminary trial tests the feasibility and efficacy of caring for CLBP in older adults as a geriatric syndrome in Aging Back Clinics (ABC).

Design: Randomized controlled trial

Setting: Outpatient clinics of two VA Medical Centers

Subjects: Fifty-five English-speaking Veterans age 60-89 with CLBP and no red flags for serious underlying illness, prior back surgery, dementia, impaired communication, or uncontrolled psychiatric illness.

Methods: Participants were randomized to ABC care or usual care (UC) and followed for 6 months. ABC care included: 1) a structured history and physical examination to identify pain contributors, 2) structured participant education, 3) collaborative decision making, and 4) care guided by condition-specific algorithms. Primary outcomes were *low back pain severity* (0 to 10 current, and 7-day average/worst pain) and *pain-related disability* (Roland Morris). Secondary outcomes included the SF-12 and health care utilization.

Results: ABC participants experienced significantly greater reduction in 7-day average (-1.22 points; p=0.023) and worst pain (-1.70 points; p=0.003), and SF-12 interference with social activities (50.0 vs 11.5%; p=0.0030) at 6 months. ABC participants were less likely to take muscle relaxants (16.7 vs. 42.3%, p=0.0481). Descriptively, UC participants were more likely to experience pain-related emergency room visits (45.8 vs 30.8%) and be exposed to non-COX2 nonsteroidal anti-inflammatory drugs (73.1% vs. 54.2).

Conclusion: These preliminary data suggest that ABC care for older Veterans with CLBP is feasible and may reduce pain and exposure to other potential morbidity.

KEY WORDS: chronic low back pain, function, disability, treatment, aging

ClinicalTrials.gov ID: NCT02697435; unique protocol ID: F2021-P

INTRODUCTION

Low back pain is the most common cause of pain in older adults (1). Providers are advised to approach low back pain as a non-specific condition, one that is associated with sciatica, or one caused by a specific disorder such as vertebral compression fractures, infection, or malignancy (2). More than 85% of patients that present to their primary care provider with low back pain are said to have non-specific causes (2). When low back pain becomes chronic (i.e., pain at least half the days for at least 6 months (3)) in older adults, a number of deleterious consequences may result including falls and fractures (4); impaired physical function (1, 5, 6); depression/anxiety and suicide (7-9); social isolation (10); impaired sleep, appetite, and cognitive functioning (11-14); and caregiver stress (15).

Rundell and colleagues recently demonstrated that greater than 75% of older adults with low back pain in the primary care setting suffer from the chronic variety (16). Nearly two-thirds of these patients continue to experience significant pain-related functional impairment a year after initial onset (16). Further, non-invasive treatments for chronic low back pain (CLBP) recommended by the American College of Physicians have typically been associated with only modest efficacy (17). These data suggest that alternative approaches to treatment are needed.

We posit that CLBP in older adults is a geriatric syndrome, that is, a final common pathway for the expression of multiple contributors (18). In this model, degenerative disease of the lumbar spine is the weakest link rather than the sole treatment target (19). This notion is supported by several observations. First, degenerative pathology is

nearly as common and severe in older adults who are pain-free as compared with those that have CLBP (20). Second, extra-spinal disorders such as hip osteoarthritis (OA), fibromyalgia and depression often co-exist in older adults with CLBP (21-24) and may be associated with pain-associated disability (25-27). Third, exclusively spine-focused treatments often are ineffective (28).

We recently validated the prevalence and functional correlates of a number of these disorders in community-dwelling older Veterans with CLBP (26). We also have published a series of clinical algorithms that resulted from modified Delphi interactions between a panel of interdisciplinary pain experts and PCPs (29-40). The purpose of these algorithms is to guide the evaluation and treatment of common contributors to pain and disability in older adults with CLBP.

The algorithms guide evaluation and treatment of the following conditions: 1) hip OA (29), 2) myofascial pain (30), 3) fibromyalgia (31), 4) depression (32), 5) maladaptive coping (33), 6) lumbar spinal stenosis (34), 7) insomnia (35), 8) lateral hip and thigh pain (36), 9) anxiety (37), 10) sacroiliac joint syndrome (38), 11) dementia (39), and 12) leg length inequality (40). All algorithms have the following common elements: 1) supportive literature evidence and when lacking, expert panel consensus; 2) imaging only to confirm pathology suspected based on history and physical examination (e.g., patient must have American College of Rheumatology clinical criteria for hip OA 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 (41), prescribing a walker instead of pain medications or an invasive procedure for the frail older adult with neurogenic claudication). Although these algorithms were carefully developed from evidence and expert consensus, their effects, when used collectively in practice, have not been tested.

We now conduct a randomized controlled pilot clinical trial evaluating the feasibility and preliminary evidence of the efficacy of implementing care guided by these algorithms. We hypothesize that older adults with CLBP that undergo comprehensive structured evaluation and algorithms-guided treatment in Aging Back Clinics (ABCs) will experience significantly greater reduction of pain and improvement in function after 6 months as compared with those randomized to usual care (UC).

METHODS

Participants and Setting

The study protocol was approved by the Institutional Review Boards (IRBs) and the Research and Development (R&D) Offices of the two participating sites - Veterans Administration (VA) Pittsburgh Healthcare System (Pittsburgh, PA) and the Hunter Holmes McGuire VA Medical Center (Richmond, VA). Participants were initially identified through the VA's data warehouse. Using an IRB-approved waiver of consent, research coordinators (RCs) at each site screened the electronic medical records of Veterans age 60 and older who carried a diagnosis of low back pain and were actively receiving care from a VA PCP. Records were screened for potential study eligibility. Those eligible were mailed a study brochure via US mail and a letter signed by the chief

of Primary Care. Those interested in participating telephoned the RC who performed additional eligibility screening. Those found to be eligible after the telephone screening procedure were then invited to come on site at the VA for additional study participation.

Inclusion/exclusion criteria were: 1) CLBP, defined as pain in the lower back of at least moderate severity (assessed with a verbal rating scale (42)), every day or almost every day, for at least 3 months; 2) lumbar MRI within the past 30 days that is without evidence of infection, malignancy, or acute fracture; 3) no 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); 4) no prior lumbar surgery; 5) pain in other body locations must be less severe than CLBP; 6) cognitively intact (based on Mini-Mental State Examination [MMSE] score, as described below); 7) no psychotic symptoms; 8) no acute illness; 9) no prohibitive communication impairment (e.g., severe hearing or visual impairment); and 10) able to commit to 6 months of study participation. We required a recent MRI because the literature indicates that advanced spinal imaging is the start of a slippery slope of potentially unnecessary and ineffective healthcare utilization (43). By starting with a recent MRI, and limiting participants to those with negative findings, we targeted patients whom were at risk for unnecessary care and could, therefore, benefit from the algorithm-based care being tested in this intervention.

After providing written informed consent, participants underwent the MMSE and those scoring < 24 were excluded.

Baseline Data

All participants were administered the following measures by the research coordinator (RC) at each site:

1. Outcome measures – Primary outcomes were *low back pain severity* (0 to 10 current, and 7-day average/worst pain) and *pain-related disability* (Roland Morris (42). Secondary outcomes were measured with the SF-12® Health Survey (44) and health care utilization.
2. Key participant characteristics :
    a. The *Minimum Dataset (MD)* recommended by the NIH Task Force on Research Standards for CLBP was administered (3). In addition to measuring pain severity and interference with daily activities, the MD assesses 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.
    b. *Medical comorbidity* was measured with the Duke comorbidity index (45).
    c. *Pain medications* (regularly scheduled and as-needed) were 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, and g) adjunctive agents (e.g., corticosteroids,

capsaicin). Regularly scheduled opioid analgesics were converted to daily oral morphine equivalents (46).

d. *Treatment expectancy/credibility* (47) was assessed using validated methods of Borkovec (48).
e. *Social support* was measured with the MOS Social Support Scale (49).
f. *Mild Cognitive Impairment (MCI)* was assessed (for participants not already excluded based on the MMSE) using the Quick MCI Questionnaire (50).

Randomization and Blinding

Following baseline data collection, participants were randomized to Aging Back Clinic Care (ABC) or UC. Within each site, we used a blocked randomization scheme to force continued approximate balance between the numbers of subjects in each arm during recruitment. The block size was randomly chosen to be 2 or 4 to prevent personnel from predicting treatment arm. The study statistician created separate randomization schedules for the two sites that contained a randomization sequence number (different from a participant's study identification number) and assigned arm. Then he created 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, research personnel opened the next available envelope, and record the randomization sequence number, subject identification number and group assignment in a dedicated database, different from the main study database. Personnel assessing follow-up outcomes were blinded to intervention assignment (see Follow-Up Data below), and the technical details of the randomization scheme described here were not revealed to the research staff.

Interventions

Those participants randomized to UC underwent no further baseline data collection or additional intervention beyond standard clinical care. They were not allowed to be seen by ABC providers during their study participation. Participants randomized to ABC care were administered the following questionnaires in addition to the baseline assessment described above, as they constitute additional evaluations required for ABC care:

1. *PHQ-4*, that combines the PHQ-2 screening for depression and the GAD-2 screening for anxiety (51).
2. *Insomnia Severity Index*, that screens for insomnia. A score of 11 was used as the criterion as a positive screen (52).
3. *Fibromyalgia Survey*, that screens for fibromyalgia (53).

A geriatrician trained by the PI in structured history and physical examination procedures described elsewhere (26) reviewed the results of the above screening questionnaires and tailored their history-taking accordingly. For example, if the participant screened positive for anxiety, the provider asked additional questions to determine the next step(s) as outlined in the anxiety algorithm. If (s)he screened positive for insomnia, the provider asked a variety of questions to hone in on the cause of the insomnia (e.g., restless legs, urinary frequency, sleep apnea) and determine the appropriate path to follow within the insomnia algorithm. Symptoms of neurogenic claudication also were queried to identify possible lumbar spinal stenosis. A structured physical examination also was performed to evaluate for key conditions that included

hip OA, sacroiliac joint syndrome, myofascial pain, leg length discrepancy, and lateral hip/thigh pain syndrome.

After completing the assessment, the provider educated the participant about their CLBP contributors, gave them a booklet summarizing their findings, and discussed a multifaceted approach to treatment that was guided by our published algorithms (29-40). ABC providers collaborated with patient participants in devising a treatment plan and patients were permitted to refuse treatments that were recommended without being withdrawn from the study. Additional appointments with the ABC research clinic provider were scheduled as needed.

Follow-up Data: Quantitative

Monthly telephone calls were made for 6 months during the intervention phase to collect data on the main outcome measures of pain severity and pain disability, as well as SF-12®. Pain medication use and pain provider/other health care utilization (e.g., emergency room visits, hospitalizations) also were collected at each time point using established methods (54). To ensure the research coordinator (RC) collecting these measures was masked to randomization group, the RC at the Pittsburgh site collected data on participants from the Richmond site and vice versa.

Follow-up Data: Qualitative

Qualitative data were collected to gain a deeper understanding of patient and provider perspectives on ABC care, including feasibility and acceptability. ABC patient participant perspectives were collected through telephone calls made at the time of 6-

months follow-up. Calls were made by two RCs (trained by the experienced qualitative researcher on the study team, KLR) and 23 study subjects were queried through audio recorded semi-structured one-on-one telephone interviews. One participant could not be reached. The patient interview guide was developed by the study PI tor and the multidisciplinary study team, including experts in geriatrics and management of CLBP. Interviews included open-ended questions and probes designed to elicit patient feedback on the ABC process, with an emphasis on identifying elements that were particularly useful or burdensome. For the providers' perspectives, calls were made within 2 months after all participant 6-month calls had been completed. KR conducted 1-on-1 interviews with the 3 ABC providers. All interviews were telephone-based, audio recorded, and semi-structured. The provider interview guide was also developed by the PI and multidisciplinary study team. Interviews included open-ended questions and probes designed to elucidate ways to improve the delivery of ABC care to maximize benefits to patients and minimize burden to both patients and providers.

Statistical Analysis (Quantitative): In this pilot trial, we descriptively interpreted magnitudes of intervention effects in addition to their statistical significance. We also employed graphical techniques such as needle to depict individual-level changes in addition to average changes, as done in other pilot studies (55, 56). All analyses were performed as intention-to-treat and using SAS® version 9.3 (SAS Institute, Inc., Cary, North Carolina). First, appropriate descriptive statistics were computed for all variables for each treatment group for each time point as well as change scores from baseline to follow-up. Second, the pre-intervention values of the variables and participant characteristics were compared between the treatments using independent samples *t*-,

Wilcoxon rank sum, chi-square or Fisher's exact tests, as appropriate. Third, for continuous variables such as pain, disability and scored SF-12® domains, we fitted a series of linear mixed models using the SAS® MIXED procedure with baseline to follow-up change in each outcome as the dependent variable; intervention group (ABC/UC), month of follow-up (1/2/3/4/5/6) and their interaction as fixed effects of interest; with and without baseline value of the dependent variable as a fixed effect covariate; and a Toeplitz correlation structure to account for multiple measurements from the same participants and allow for greater correlations between proximal measurements in time. Appropriately constructed means contrasts were used to compare intervention effect at each month. For dichotomized outcomes such as any improvement (yes/no) in interference with social activities rating and utilization of services or medications, we performed chi square and Fisher's exact tests but base our interpretations mostly on descriptive comparisons of proportions due to small sample size. Within each group, we correlated (*r*) baseline treatment expectations with change in outcomes.

Qualitative Analysis: Interviewers and the coder knew that each participant interviewed had been randomized to ABC care but were otherwise blinded to participant data. All data were analyzed using rapid identification of themes from audio recordings (RITA) that allows for data analysis and coding without transcribing the interviews (57). Because the traditional RITA methodology does not account for the use of qualitative data analysis computer software (i.e., NVivo), we replaced the original "coding form" with a supplemental coding document (see below).

Participant interview data were coded using deductive and inductive approaches. The

deductive approach started with reviewing specific foci from the qualitative study aims to guide preliminary codebook development, including elements of the ABC process that were particularly useful (e.g., in terms of pain management) or burdensome (from patient interviews), and potential ways to improve the delivery of ABC care to maximize benefits to patients and minimize burden on both patients and providers (from provider interviews). The deductive approach also included pre-identified codes based on the interview guide topics regarding 11 contributors to CLBP (i.e., the algorithm conditions listed in the Introduction, except dementia, as those with dementia were excluded from the study). The interview guide questions included: whether each contributor was discussed with their doctor; whether they were aware of each contributor to CLBP prior to seeing their doctor; what other things (besides the aforementioned 11 contributors to CLBP) contribute to their CLBP; what treatments they received; did they find that treatment helpful, and whether they engaged in pain self-management. An inductive approach was also used during the codebook development and coding phases in the event of identification of sub-codes for each of the aforementioned codes, as well as contributors to CLBP not included in the pre-identified deductive codes.

The finalized patient and provider codebooks were entered in NVivo 11 Pro for Windows (QSR International, Doncaster, Australia) used for audio coding. To record more detailed information about the coded audio segments throughout the coding process, a supplementary coding document was created in Microsoft Excel. The codebook and coding form were tested and subsequently refined using a small subset of interview audio files before formal coding began. An experienced qualitative researcher (KLR) ensured consistency during codebook development and coding by

assisting in resolution of coder uncertainties. She also reviewed the codebook prior to the completion of the coding process as well as a 20% (i.e., 5 patient audio files, 1 provider audio file) sample of coded audio files to ensure the transparency and comprehensibility in code application.

RESULTS

Quantitative

The CONSORT diagram for this pilot randomized controlled trial is shown in Figure 1 and participant characteristics in Table 2. No adverse effects were reported.

In the ABC group, participants were on average approximately 4 years older and more often had diabetes mellitus and lung disease than those randomized to UC. The two groups otherwise were comparable in other demographic characteristics and medical comorbidities. Similarly, there were no significant between-groups differences in parameters recommended by the NIH task force on research standards for chronic low back pain (i.e., Minimal Data Set (3)) that include pain duration/frequency/intensity, leg symptoms, pain in other locations, pain interference, physical functioning, prior treatments for CLBP, sleep quality, depressive symptoms, coping self-statements, and ethanol use. Descriptively, there were between-group differences in smoking history, with 8 (32.0%) never smokers in the ABC group versus 4 (13.3%) in UC, and 1 (4.0%) current smoker in the ABC group versus 7 (23.3%) in UC. There was a statistically significant difference in MMSE scores, although the one-point difference (28 vs. 29) is not clinically meaningful. Fewer veterans in ABC than UC group were on gabapentin

(8.0 vs 30.0%; p=0.0423), but there was no between-groups difference in the use of other pain medications, baseline physical function or treatment expectancy.

Of the various conditions only evaluated in the ABC group, insomnia was the most common central nervous system condition, with 14 (56%) participants screening positive. Myofascial pain (n=20; 80%) and sacroiliac joint pain (n=13; 52%) were the most common physical conditions identified.

Participants' CLBP contributors and further evaluations/treatments recommended are listed in Table 2.

Table 3 shows the change in continuous outcomes variables by month following baseline. All pain intensity measures (current pain, average pain over prior week, worst pain over prior week) improved in the ABC group as compared to UC at 6 months, with the greatest magnitude of improvement and statistical significance in worst pain. A 30% pain reduction over 6 months was seen in 21% and 15% of ABC and UC participants, respectively, in average pain during prior week; and 29% and 8% in worst pain prior week. Roland Morris and SF-12® physical component summary improvement was greater in the ABC based on descriptive statistics and magnitudes of estimates, but these differences did not reach statistical significance. Sensitivity analysis additionally controlling for age slightly reduced magnitudes of adjusted differences for pain but not materially (<15%).

In addition to the results based on averages and model-based estimates in Table 3, Figures 2 and 3 shows the changes experienced in participants at the individual level. We note that a greater number of participants in ABC care experienced a reduction in 7-day average pain than those in UC group, and in greater magnitudes. Moreover, there is a suggestion that those with the highest baseline levels of pain experienced the greatest benefit. Findings for the worst pain is similar but more pronounced. Interference with social activities also reduced in more participants in ABC care (50.0 vs 11.5%; p=0.0030).

Based on descriptive statistics, there was greater improvement in some of the other dichotomous outcomes (data not shown in tables or figures) in the ABC group as compared with UC. Specifically, during the 6-month follow up period, there were more pain-related emergency room visits in the UC group as compared with the ABC group (45.8 vs 30.8%; p=0.5136), and fewer ABC participants took non-COX2 non-steroidal anti-inflammatory drugs (54.2 vs. 73.1%; p=0.1640), opioids (20.8 vs. 38.5%; p=0.1742) and skeletal muscle relaxants (16.7 vs. 42.3%; p=0.0481). While fewer participants randomized to ABC care were exposed to opioids, this difference also was apparent at baseline.

Regarding treatment expectations at baseline, there were no significant associations with pain reduction.

Qualitative

Patient participants mostly said they already knew about the majority of their conditions contributing to their low back pain and creating difficulty doing the things they would like to do before they saw the MD. Also, they said that they discussed almost all of these conditions with their MD. For those currently receiving treatment, they identified the most common as physical therapy, self-management, acupuncture, and medications. Of all the treatment strategies pursued since their initial visit with the MD, those perceived as most helpful were the combination of all the treatments they received, as well as physical therapy and independent exercises, acupuncture, back injections, transcutaneous electrical nerve stimulation (TENS) unit, and medications. Other participants said the least helpful treatments were physical therapy, independent exercises, acupuncture, and epidural. Most participants said that all aspects of their pain and functioning had been adequately addressed since their initial visit with the MD; a few noted that they had upper leg or iliotibial (IT) band pain, knee pain, and spinal stenosis that were not adequately addressed. Patient participant suggestions for improving VA management of CLBP included more check-ins or follow ups with more consistent/frequent treatment, listening to the patient, treatment closer to the patient's home, consulting with private doctors, explaining management versus eliminating pain, not pushing for surgery, more communication between departments, staying up-to-date on research, stop prescribing pain medications, VA gym or gym access, and continuing programs and research for pain.

Provider participants said they liked that ABC care provided holistic and individualized patient care and that Veterans appreciated ABC care. Some were concerned that ABC care required a large time commitment (e.g., provider training, long clinic visits and follow ups) and felt that it could be difficult to institute more broadly across the VA.

They identified a number of processes and factors that facilitate the implementation of ABC care including provider training in screening exam techniques, having patient educational materials, the straightforward structure of ABC care steps, having additional support staff, Veterans being open to ABC care, and resources being available to Veterans (e.g., VA pays for chiropractor and acupuncture). Perceived barriers to implementing ABC care for CLBP noted by providers included patients living far from the VA, time required to train providers, lack of patient follow through (e.g., patients do not continue PT), and patients with maladaptive coping. Provider participants stated that ABC care could be improved by educating other healthcare providers about the contributors to CLBP (including those who do not deliver PCCET, such as primary care providers), training specialists about PCCET for CLBP (e.g., physical therapists, psychologists), integrating patients' self-report data into their electronic medical record, excluding patients who live an hour or more away from the VA, and broadening the list of possible contributors to CLBP.

DISCUSSION

This pilot randomized controlled trial suggests that a comprehensive patient-centered approach for the treatment of CLBP in older Veterans is feasible, well-tolerated, and associated with preliminary evidence of greater pain reduction and lesser exposure to potentially harmful medications as compared with UC. The greatest magnitude of improvement was in worst pain intensity over the past 7 days. Participants in ABC had significantly less exposure to skeletal muscle relaxants (medications on Beers' list) and reported reduced frequency of interference with social activities. Participants randomized to ABC on average descriptively experienced less exposure to nonsteroidal

anti-inflammatory drugs (also on Beer' list), fewer emergency room visits and more improvement in low back pain associated disability (i.e. Roland Morris score), although these differences were not statistically significant.

We deemed our intervention as feasible according to the feasibility domains outlined by Bowen and colleagues (58). These include: 1) acceptability – Our qualitative data support the acceptability of the intervention to providers and participants, and the fact that we had only one dropout with complete data collection on all other participants further supports acceptability; 2) demand (for the intervention) – Our ease of recruiting patients support the demand for alternate strategies to treat chronic low back pain in older veterans; 3) implementation – Our intervention utilizes resources that are routinely available in VA settings; 4) practicality – Our qualitative data support that ABC care is practical when delivered in specialty clinics but perhaps not in primary care clinics; we used this feedback in the design of our ongoing RCT in which the ABC clinics is a specialty clinic that is not embedded in primary care; 5) adaptation – Our pilot study did not highlight any areas that required adaptation; 6) integration – No organizational change was required to implement our intervention; 7) expansion – If we determine that the intervention is efficacious in the context of the RCT, we plan a large comparative effectiveness study; 8) limited-efficacy testing – This was accomplished and the results are presented in this manuscript.

We tested our hypotheses by examining the between-groups mean change in outcomes, an analytical approach that is traditionally used to evaluate intervention efficacy. Additional insight can be gained by examining participant level data.

Examining individual-level change revealed that 50% more people in ABC as compared with UC experienced a reduction in average pain intensity. Moreover, there was more than a twofold reduction in the number of people in the ABC group as compared with UC who experienced worse pain during the 6-months study period. Between-groups differences in 7-day worst pain intensity was even more striking. Our pain intensity data suggest that most people who receive ABC care may benefit. We are in the process of testing this hypothesis in the context of a recently funded, ongoing, full scale clinical trial to more definitively establish the efficacy of our *Aging Back Clinics* approach.

Our clinical experience in caring for older adults with CLBP resonates with several of our study findings, specifically those related to pain intensity, social function, and the trends in reduction of emergency room visits and certain analgesics. There was no significant between-groups difference in current pain intensity, although magnitudes tended to favor ABC care. We find that asking patients with CLBP to rate their current pain on a scale of 0 to 10 is not likely to be clinically useful, as symptoms are most often precipitated during standing-associated activities, not when sitting during typical clinic check-in procedures. Consistent with the observed reduction in 7-day worst pain intensity, one of the first things that clinic patients report after starting effective treatments is a significant reduction in the frequency and intensity of pain flares, and, therefore, a lesser need for emergency treatment seeking and analgesic use. Further, the observed reduction of interference with social function reflects our clinical experience that engagement in social activities is highly valued by older adults and is one of the first functional improvements to return after severe pain flares have been ameliorated.

It has been demonstrated that contextual factors that occur between the patient and provider are associated with significant placebo effects in patients with musculoskeletal pain (59). Several of the contextual components of ABC care may have contributed to improvement. First, participants received a thorough hands-on assessment designed to identify the physical contributors to the CLBP, and the touch-intensive aspect of the evaluation may have in and of itself been therapeutic. Second, participants received positive communication from the healthcare provider designed to educate the participant about the multi-faceted nature of CLBP and the multiple potential interventions that can reduce pain interference and improve quality of life. Third, the ABC provider and participant engaged in respectful and collaborative decision making about how to approach treatment.

It is worth highlighting that the three ABC providers in this preliminary study were geriatricians, and none had received official training in pain medicine. They only had been trained in the structured physical examination procedures and used the published treatment algorithms to guide their discussions with participants. Qualitative findings indicate that providers found the physical exam training to be both a benefit and at the same time a barrier to broad dissemination. Given the limited education that medical trainees receive on pain management in general (60) and for CLBP in particular (61), it would be a daunting task to teach all PCPs the requisite advanced knowledge and skills used in ABCs. Restructuring PCP visits to afford the time to spend with these complex patients would also be a challenge. Clinical settings that focus on older adults and/or pain management may be more appropriate targets than primary care for future

dissemination of ABCs.

In contrast to clinical trials that require adherence to a strict intervention protocol, the interventions for the participants' CLBP contributors were guided by collaborative decision making, as noted earlier. As highlighted by our qualitative data, the very same treatments that some patients valued highly were those that others found least helpful, reinforcing the importance of patient-centered care. The magnitude of pain reduction we observed is comparable to that found in trials that have tested single intensive interventions (62). If we replicate and expand our findings in the context of a full-scale trial, we will be well-positioned to propose broad dissemination of ABC as a model of care.

That ABC care did not result in a statistically significant reduction in pain-associated disability as compared with UC warrants reflection. Foremost, we did find greater magnitudes of improvements based on estimates and descriptive statistics, and statistical power to reach significance was low in our pilot study with a small sample size. But also, as noted above, participants were not required to engage in a rigorous intervention such as weekly physical therapy, yoga, cognitive behavioral therapy, or meditation. Studies that have tested these types of interventions typically have shown more modest reduction in pain-associated disability than in pain intensity (62). Further, we followed participants for only 6 months. Most participants reported having experienced low back pain for at least 5 years, thus 6 months may be inadequate to afford the intensive provider-participant interaction and educational reinforcement needed to change behavior. Our large clinical trial includes 12 months follow up.

The reduction in exposure to nonsteroidal anti-inflammatory drugs and muscle relaxants is noteworthy. Both of these medication classes are included in Beers' list of inappropriate medications for older adults because of the potential for these medications to cause significant morbidity either due to direct adverse effects or drug-disease interactions (63). Muscle relaxants are associated with potential anticholinergic side effects, sedation, risk of falls and fractures (63). Nonsteroidal anti-inflammatory drugs have a host of potential adverse consequences including gastrointestinal bleeding, renal insufficiency and exacerbation of hypertension and congestive heart failure (63). Thus, ABC care may have important benefits above and beyond pain reduction.

Pain at the present moment is a more dynamic and volatile outcome with day-to-day variability which happened to be somewhat less at baseline in the ABC group. That may have played a role in our ability to find significant differences with respect to current pain, although a pattern appears to be emerging in the later months signaling a greater benefit at later months.

While our study had a number of strengths, its limitations should be highlighted. First, ABC care was not conducted according to a stringent protocol. The baseline history and physical examination were structured, as was the education provided about each participant's pain contributors, but the treatments provided were not. Thus, we cannot be definitive about the most effective components of ABC care. Now that we have established feasibility and preliminary evidence of efficacy in the context of this pilot

study, we will track all interventions administered and ABC providers' perceived participant compliance in the context of our ongoing large randomized controlled clinical trial, enabling us to ascertain the most effective ABC components. Another study limitation is that all participants in our study were Veterans and they received care in the Veterans healthcare system. Thus, our findings may not be broadly applicable. If our larger ongoing clinical trial corroborates and extends the findings, a similar model of care should be examined in other settings.

CONCLUSIONS

This preliminary trial demonstrates that treating older adults with CLBP using a comprehensive geriatric syndrome approach is feasible, received positively by patients and providers, and may be efficacious. If supported by a larger randomized controlled trial, the proposed approach could improve quality of life and reduce morbidity and misdirected health care utilization for millions of older adults.

ACKNOWLEDGEMENTS

This material is based on work supported by the Department of Veterans Affairs, Veterans Health Administration, Office of Research and Development, grant # RX002021-01. The contents of this report do not represent the views of the Department of Veterans Affairs or the United States government.

The authors wish to thank Kimberly Clemens for her conscientious oversight of the study. They also wish to thank Dave Newman, Rachel Samuels, and Christopher Godschalk for their efforts in participant recruitment and data collection.

CONFLICTS OF INTEREST

None of the authors has any conflicts of interest to report.

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Table 1: Participant characteristics at baseline [mean ± standard deviation or N (%)]

	ABC N=25	UC N=30	p-Value
Age	71.3±7.5	67.2±5.5	0.0227
Gender			1.0000
Female	1 (4.0)	1 (3.3)	
Male	24 (96.0)	29 (96.7)	
Ethnicity			0.2424
Hispanic/Latino	0 (0.0)	0 (0.0)	
Not Hispanic/Latino	25 (100)	26 (86.7)	
Unknown	0 (0.0)	1 (3.3)	
Not reported	0 (0.0)	3 (10.0)	
Race			1.0000
Black	8 (32.0)	9 (30.0)	
White	17 (68.0)	20 (66.7)	
Unknown	0 (0.0)	1 (3.3)	
Employment status			0.7919
Working now	2 (8.0)	2 (6.7)	
Looking for work	1 (4.0)	1 (3.3)	
Disabled due to back pain	2 (8.0)	6 (20.0)	
Disabled for other reason	1 (4.0)	2 (6.7)	
Retired	18 (72.0)	19 (63.3)	
Other	1 (4.0)	0 (0.0)	
Education			0.5274
No high school diploma	3 (12.0)	1 (3.3)	
High school/GED	9 (36.0)	8 (26.7)	
Some college no degree	6 (24.0)	8 (26.7)	
Occupational/technical/vocational	1 (4.0)	3 (10.0)	

Associate degree	2 (8.0)	4 (13.3)	
Bachelor's degree	2 (8.0)	6 (20.0)	
Professional school degree	1 (4.0)	0 (0.0)	
Doctoral degree	1 (4.0)	0 (0.0)	
Height (cm)	176.3±5.4	178.1±6.0	0.2579
Weight (kg)	96.2±24.8	94.5±22.1	0.7923
Comorbidities			
Cardiovascular	9 (36.0)	6 (20.0)	0.1846
Neurological	4 (16.0)	2 (6.7)	0.3943
Musculoskeletal	25 (100)	30 (100)	NE
General	19 (76.0)	19 (63.3)	0.3115
Visual/hearing	16 (64.0)	22 (73.3)	0.4558
Diabetes	11 (44.0)	5 (16.7)	0.0263
Cancer	3 (12.0)	7 (23.3)	0.3184
Lung	11 (44.4)	5 (16.7)	0.0263
Duke comorbidity index	3.9±1.4	3.2±1.5	0.0689
Pain			
Current pain	4.5±2.8	5.3±2.4	0.2482
Average pain prior week	6.6±1.7	6.5±1.4	0.8725
Worst pain prior week	8.8±1.5	8.5±1.9	0.5132
Cognitive Function			
MMSE	28.1±1.6	29.0±1.1	0.0159
QMCI	72.2±8.5	72.7±9.9	0.8556
Medications			
Salicylate	1 (4.0)	0 (0.0)	0.4545

Non-aspirin, non-COX2 selective NSAID	9 (36.0)	10 (33.3)	0.8359
COX2 selective NSAID	0 (0.0)	3 (10.0)	0.2424
Acetaminophen	3 (12.0)	4 (13.3)	1.0000
Opioid analgesic	5 (20.0)	10 (33.3)	0.2689
Skeletal muscle relaxant	2 (8.0)	5 (16.7)	0.4363
Topical	2 (8.0)	1 (33.3)	0.5855
Corticosteroid	0 (0.0)	0 (0.0)	NE
Gabapentin	2 (8.0)	9 (30.0)	0.0423
Pregabalin	0 (0.0)	0 (0.0)	NE
Antidepressant, non-tricyclic	1 (4.0)	0 (0.0)	0.4545
Antidepressant, tricyclic	0 (0.0)	1 (3.3)	1.0000
Other	1 (4.0)	1 (3.3)	1.0000
Roland-Morris Disability Index	14.8±5.1	15.1±5.3	0.7912
Treatment Credibility & Expectations			
How logical	6.1±2.7	6.2±2.6	0.8683
Expectation of success	4.8±2.4	5.0±2.7	0.8135
Confidence in recommending to others	4.4±3.1	5.4±2.8	0.2158
Expected percent improvement	50.4±30.3	45.7±32.6	0.5822
Feeling of expected symptom reduction	5.4±2.8	5.4±2.5	0.9178
Feeling of percent symptom reduction	55.6±33.9	50.0±31.9	0.5318
History & Physical Exam (n=25)			
Fibromyalgia	4 (16.0)	NA	NE
Insomnia	14 (56.0)	NA	NE
Anxiety	2 (8.0)	NA	NE
Depression	4 (16.0)	NA	NE

Maladaptive Coping: Fear Avoidance Beliefs	5 (20.0)	NA	NE
Maladaptive Coping: Catastrophizing	5 (20.0)	NA	NE
Mild Cognitive Impairment	1 (4.0)	NA	NE
Myofascial Pain	20 (80.0)	NA	NE
Erector Spinae	10 (40.0)	NA	NE
Quadratus Lumborum	8 (32.0)	NA	NE
Gluteus Medius	4 (16.0)	NA	NE
Piriformis	10 (40.0)	NA	NE
Perpetuating factors: Scoliosis	14 (56.0)	NA	NE
Kyphosis	4 (16.0)	NA	NE
Mood disorder	4 (16.0)	NA	NE
Maladaptive coping	6 (24.0)	NA	NE
Abnormal gait	6 (24.0)	NA	NE
Leg length discrepancy	3 (12.0)	NA	NE
Other	6 (24.0)	NA	NE
Leg Length Discrepancy	5 (20.0)	NA	NE
Hip Osteoarthritis	8 (32.0)	NA	NE
Sacroiliac Joint Pain	13 (52.0)	NA	NE
IT Band Pain	6 (24.0)	NA	NE
Greater Trochanteric Pain	1 (4.0)	NA	NE
Lumbar spinal stenosis	5 (20.0)	NA	NE
Radiculopathy	3 (12.0)	NA	NE
MOS Social Support			
Emotional	67.9±21.7	68.1±30.3	0.9726
Tangible	70.5±26.2	68.1±32.1	0.7681
Affectionate	79.0±26.1	77.2±31.5	0.8229
Interaction	75.0±23.1	75.6±30.6	0.9407

Overall	71.5±20.3	71.0±26.1	0.9304
SF-12® Health Survey			
Physical component summary	31.2±8.1	32.5±9.4	0.5998
Mental component summary	51.7±11.4	51.3±10.8	0.8874
Frequency of physical health/emotional problems interfering with social activities			0.4635
All of the time	2 (8.0)	2 (6.7)	
Most of the time	6 (24.0)	4 (13.3)	
A good bit of the time	0 (0.0)	1 (3.3)	
Some of the time	3 (12.0)	6 (20.0)	
A little of the time	7 (28.0)	6 (16.7)	
None of the time	7 (28.0)	12 (40.0)	

ABC=Aging Back Clinic; COX = cyclooxygenase; IT = iliotibial band; MMSE = Mini Mental State Examination; NSAID = nonsteroidal anti-inflammatory; QMCI = Quick Mild Cognitive Impairment screen; NE = not estimable; NA = not applicable; UC = usual care

Table 2. CLBP Syndrome Conditions and Interventions Recommended for Participants Randomized to ABC Care

Participant	**CLBP Syndrome Conditions**	**Intervention(s) Recommended**
1	• Insomnia • Hip osteoarthritis (OA) • Lumbar spinal stenosis	• Physical therapy (PT) • Lumbar brace • Hip x-ray
2	• Insomnia • Depression • Hip OA • Sacroiliac joint (SIJ) pain	• Insomnia clinic referral • Chiropractic • Acupuncture • Hip x-ray
3	• Insomnia • Myofascial pain • SIJ pain • IT band pain	• Insomnia clinic referral • Acupuncture • Chiropractic
4	• Fibromyalgia • Insomnia • Anxiety • Depression • Maladaptive Coping • Hip OA	• Insomnia clinic referral • Interdisciplinary Pain Management Program referral • Hip x-ray
5	• Insomnia • Myofascial pain • Lumbar spinal stenosis	• PT • Epidural corticosteroid • Acupuncture

6	• Myofascial pain • Leg length Inequality • SIJ pain	• PT
7	• Depression • Myofascial pain • Hip OA • SIJ pain	• Titrate sertraline • Hip x-ray
8	• Myofascial pain • Leg length inequality • Lumbar spinal stenosis	• PT • Acupuncture • Statin holiday
9	• Myofascial pain • SIJ pain • IT band pain	• Titrate acetaminophen • PT
10	• Maladaptive coping • Myofascial pain • Leg length inequality • SIJ pain • IT band pain • Lumbar spinal stenosis	• PT • Chiropractic • Massage • Maintain spiritual support for coping; consider psychology in future
11	• Depression • Maladaptive coping • Myofascial pain	• Regularly scheduled acetaminophen • PT • Epidural corticosteroid

	• Lumbar spinal stenosis	• Psychology referral
12	• Insomnia • Anxiety • Maladaptive coping • Myofascial pain • Leg length inequality • SIJ pain	• Chiropractic • Lidocaine patch • Regularly scheduled acetaminophen • Discontinue muscle relaxant • PT
13	• Myofascial pain • SIJ pain	• Lidocaine ointment • PT
14	• Myofascial pain • Hip OA • SIJ pain • IT band pain • Lumbar spinal stenosis	• PT • Lidocaine patch • Discontinue muscle relaxant • Hip x-ray
15	• Myofascial pain • SIJ pain	• Regularly scheduled acetaminophen • PT
16	• Myofascial pain	• PT • Referred to MOVE program (for obesity management)
17	• Myofascial pain • Maladaptive coping	• PT • Acupuncture

		• Yoga for self-management • CBT (participant declined)
18	• Myofascial pain • SIJ pain • Lumbar spinal stenosis • Insomnia	• PT • Tramadol prn • SIJ injection • Follow up with sleep clinic for management of sleep apnea
19	• Insomnia • Myofascial pain	• PT • Sleep clinic (participant declined) • Sleep hygiene education
20	• Myofascial pain • IT band pain • Insomnia	• PT • “Acupuncture” (dry needling and gua sha) • Sleep clinic (participant declined) • Sleep hygiene education
21	• Insomnia • Depression • Maladaptive coping • Myofascial pain • SIJ pain • IT band pain	• PT • Psychology for cognitive behavioral therapy • Switch bupropion to duloxetine (approved by Psychiatry) • Sleep hygiene education
22	• Fibromyalgia • Insomnia • Anxiety	• Rheumatology referral • Psychology referral • PT

	• Maladaptive coping • Myofascial pain • Hip OA • Lateral thigh pain (IT band pain and greater trochanteric pain) • SIJ pain	• Acupuncture • Aquatherapy • Acetaminophen • Sleep clinic referral with diagnosis and treatment of sleep apnea • Continue T'ai Chi for self-management • Continue Psychiatry follow up • D/C methacarbamol (participant refused)
23	• Myofascial pain • Hip OA • Insomnia	• Hip x-ray • PT • Acupuncture • MOVE referral (participant refused) • Sleep hygiene education
24	• Myofascial pain • Hip osteoarthritis	• PT • Single point cane • Acupuncture • MOVE referral (participant refused) • Reduce cyclobenzaprine dose (participant refused discontinuation)
25	• Fibromyalgia • Insomnia • Maladaptive coping • Hip OA	• PT • Sleep hygiene education • Continue psychotherapy • Aquatherapy

	• SIJ pain	

Table 3: Changes in main outcomes in the two intervention arms

	Baseline to Follow-up Change Mean ± Standard Deviation		ABC vs UC Difference ± Standard Error [p-Value*]	
	ABC	UC	Unadjusted	Adjusted for Baseline
Current pain at the moment after:				
1 Month	0.76±2.73	0.38±1.83	0.38±0.72 [0.6015]	-0.23±0.59 [0.6938]
2 Months	0.13±2.56	0.12±1.90	0.06±0.72 [0.9315]	-0.53±0.59 [0.3743]
3 Months	0.41±2.63	0.28±2.37	0.07±0.73 [0.9225]	-0.49±0.60 [0.4110]
4 Months	-0.13±3.13	0.56±2.14	-0.80±0.72 [0.2709]	-1.38±0.59 [0.0202]
5 Months	0.09±3.36	0.19±2.81	-0.14±0.72 [0.8432]	-0.76±0.59 [0.2000]
6 Months	0.46±2.99	0.96±2.18	-0.46±0.72 [0.5261]	-1.07±0.59 [0.0702]
Average pain over prior week after:				
1 Month	-0.68±2.27	-0.27±1.76	-0.41±0.61 [0.5046]	-0.39±0.53 [0.4597]
2 Months	-1.13±2.33	-0.80±1.78	-0.25±0.62 [0.6820]	-0.22±0.54 [0.6759]
3 Months	-1.05±2.13	-0.32±1.93	-0.97±0.62 [0.1199]	-0.95±0.54 [0.0822]
4 Months	-1.33±2.06	-0.44±1.85	-1.21±0.62 [0.0525]	-1.18±0.54 [0.0283]
5 Months	-1.61±2.59	-1.00±2.26	-0.58±0.62 [0.3466]	-0.57±0.54 [0.2903]
6 Months	-1.38±2.46	-0.08±2.02	-1.24±0.62 [0.0456]	-1.22±0.54 [0.0230]
Worst pain over prior week after:				
1 Month	-1.12±2.45	-0.50±1.63	-0.62±0.60 [0.2992]	-0.59±0.57 [0.3015]

2 Months	-1.42±2.26	-0.84±1.99	-0.51±0.60 [0.3935]	-0.47±0.57 [0.4093]
3 Months	-1.55±2.86	-0.60±1.53	-1.15±0.61 [0.0586]	-1.11±0.58 [0.0562]
4 Months	-1.79±1.84	-0.48±1.42	-1.64±0.60 [0.0069]	-1.60±0.57 [0.0054]
5 Months	-2.35±2.55	-1.08±1.67	-1.19±0.60 [0.0484]	-1.15±0.57 [0.0453]
6 Months	-2.25±2.44	-0.42±1.42	-1.74±0.60 [0.0040]	-1.70±0.57 [0.0032]
Roland-Morris Disability Index after:				
1 Month	-1.12±4.96	-0.58±2.77	-0.54±1.28 [0.6711]	-0.72±1.25 [0.5665]
2 Months	-1.46±5.40	-0.40±3.79	-1.12±1.28 [0.3856]	-1.28±1.25 [0.3069]
3 Months	-1.27±3.18	-0.36±3.33	-1.50±1.29 [0.2452]	-1.68±1.26 [0.1851]
4 Months	-1.80±5.42	0.16±4.25	-1.96±1.28 [0.1266]	-2.13±1.25 [0.0894]
5 Months	-2.30±5.23	-0.69±3.95	-1.44±1.28 [0.2635]	-1.62±1.26 [0.1994]
6 Months	-1.29±6.05	0.08±4.12	-1.24±1.28 [0.3336]	-1.42±1.25 [0.2581]
SF-12® Physical Component Summary:				
1 Month	1.09±7.58	1.05±8.02	-0.11±2.22 [0.9615]	-0.30±2.12 [0.8886]
2 Months	0.81±6.74	0.70±7.36	0.04±2.23 [0.9858]	-0.19±2.13 [0.9286]
3 Months	3.77±7.44	0.89±8.20	2.93±2.27 [0.1983]	2.71±2.17 [0.2125]
4 Months	3.39±7.71	1.09±7.93	2.45±2.22 [0.2720]	2.23±2.12 [0.2935]
5 Months	2.47±8.22	-0.03±7.93	2.37±2.24 [0.2894]	2.18±2.13 [0.3084]
6 Months	1.46±8.38	-1.08±8.84	2.36±2.23 [0.2906]	2.17±2.12 [0.3068]

SF-12® Mental Component Summary:				
1 Month	-2.09±9.05	-3.98±9.53	2.05±2.60 [0.4325]	2.39±2.46 [0.3325]
2 Months	-0.64±8.31	-3.61±9.80	2.79±2.61 [0.2876]	3.05±2.47 [0.2191]
3 Months	-1.73±7.97	-1.54±9.23	0.01±2.65 [0.9958]	0.34±2.52 [0.8927]
4 Months	-1.09±7.49	-2.57±8.48	1.45±2.60 [0.5781]	1.75±2.46 [0.4779]
5 Months	-1.65±8.97	-2.11±10.47	0.76±2.62 [0.7718]	1.11±2.48 [0.6556]
6 Months	-1.14±9.55	-3.12±10.59	2.12±2.60 [0.4161]	2.47±2.46 [0.3182]

* Using a linear mixed model

Figure Legends

Figure 1. CONSORT diagram

Figure 2. Six months of individual participant level data in Aging Back Clinic care (ABC) and Usual Care (UC) for 7-day average 0 to 10 pain score (top diagram) and 7-day worst pain score (bottom diagram)

Figure 3. Six months of individual participant level data in Aging Back Clinic care (ABC) and Usual Care (UC) for SF-12® frequency of health/emotional problems interference with social activities item.

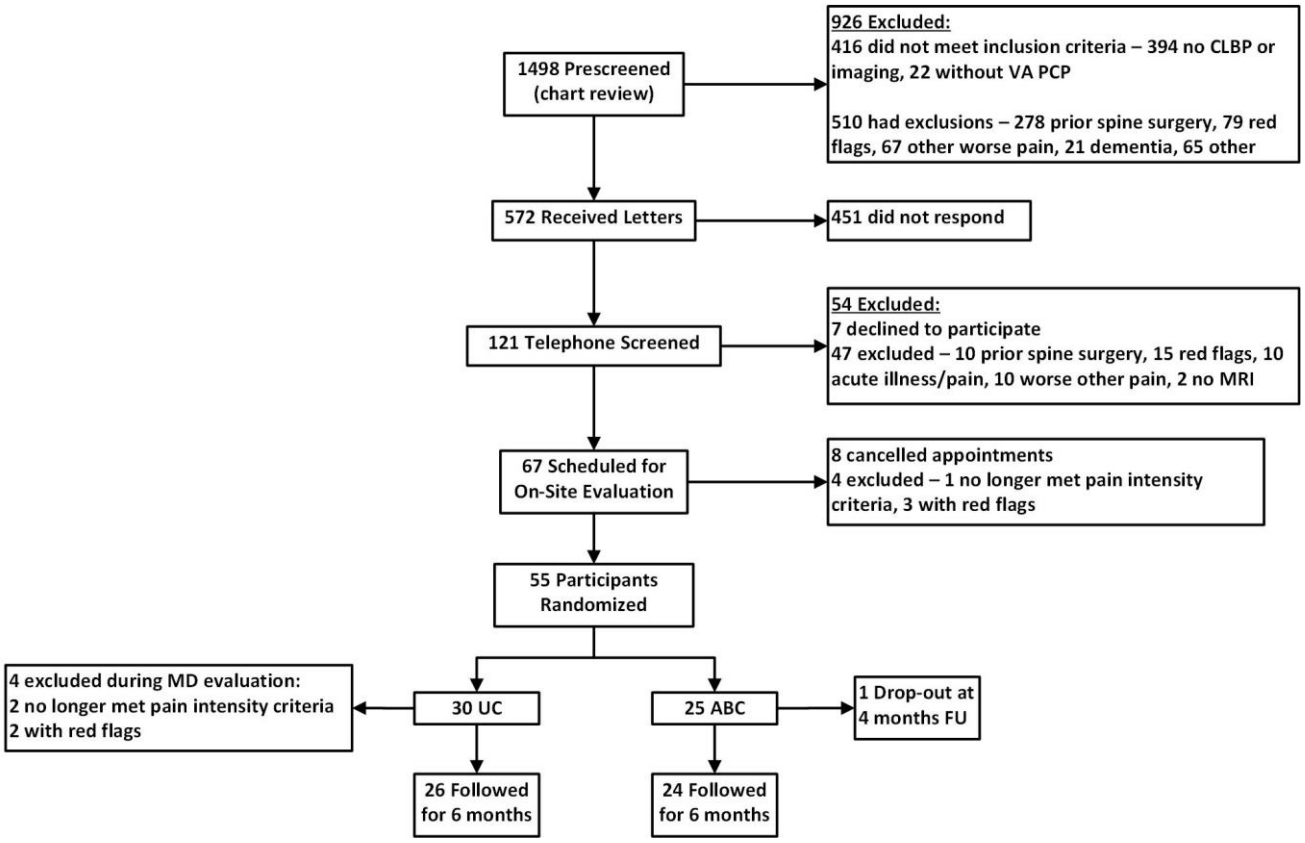

1498 Prescreened (chart review)
926 Excluded:
416 did not meet inclusion criteria – 394 no CLBP or imaging, 22 without VA PCP
510 had exclusions – 278 prior spine surgery, 79 red flags, 67 other worse pain, 21 dementia, 65 other
572 Received Letters
451 did not respond
121 Telephone Screened
54 Excluded:
7 declined to participate
47 excluded – 10 prior spine surgery, 15 red flags, 10 acute illness/pain, 10 worse other pain, 2 no MRI
67 Scheduled for On-Site Evaluation
8 cancelled appointments
4 excluded – 1 no longer met pain intensity criteria, 3 with red flags
55 Participants Randomized
4 excluded during MD evaluation:
2 no longer met pain intensity criteria
2 with red flags
30 UC
25 ABC
1 Drop-out at 4 months FU
26 Followed for 6 months
24 Followed for 6 months

Figure 1.

Figure 2.

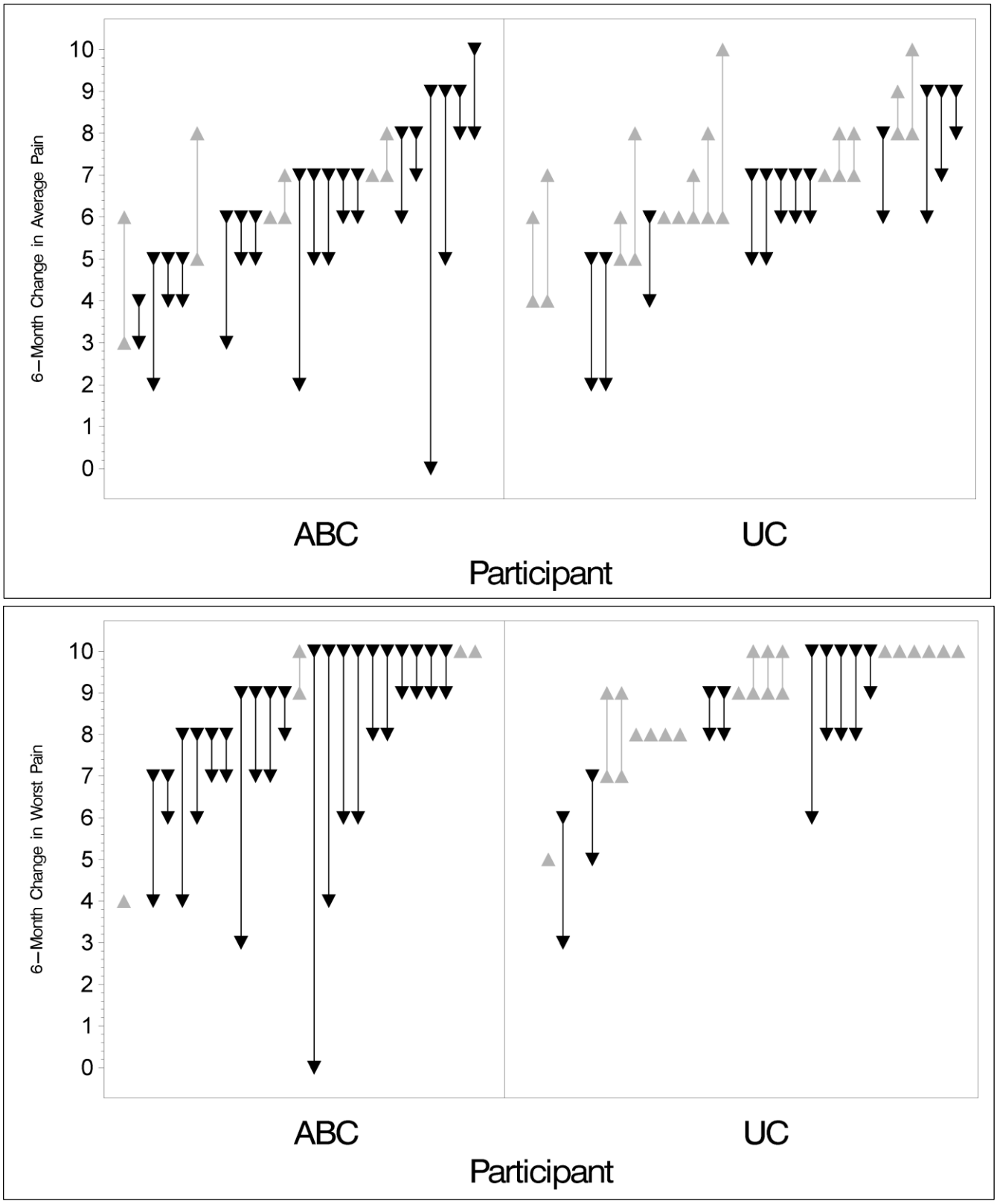
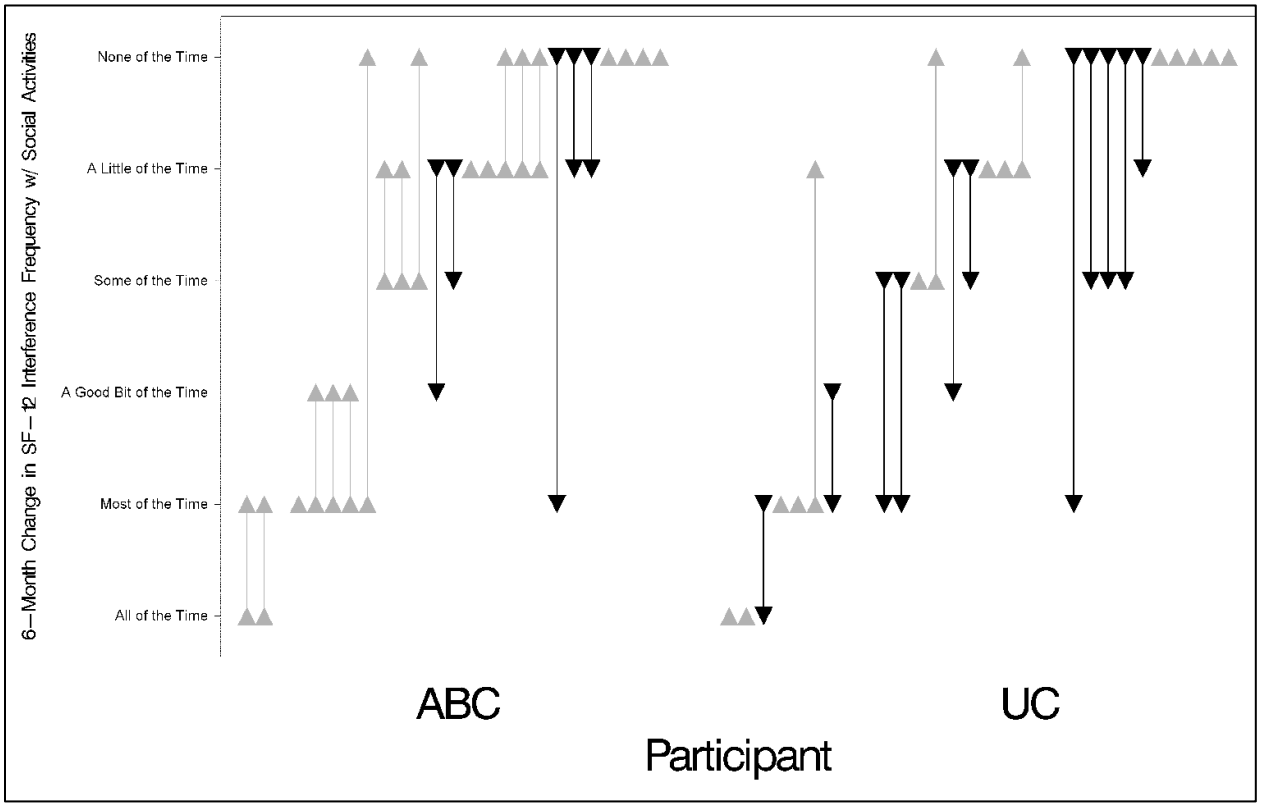

6–Month Change in Average Pain
10
9
8
7
6
5
4
3
2
1
0
ABC
UC
Participant
6–Month Change in Worst Pain
10
9
8
7
6
5
4
3
2
1
0
ABC
UC
Participant

Figure 3.


6-Month Change in SF-12 Interference Frequency w/ Social Activities
None of the Time
A Little of the Time
Some of the Time
A Good Bit of the Time
Most of the Time
All of the Time
ABC
UC
Participant

APPENDIX: NIH Minimal Data Set Participant Baseline Characteristics [mean ± standard deviation or N (%)]

Characteristic	ABC N=25	UC N=30	p-Value
Pain duration			0.2366
3-6 Months	1 (4.0)	1 (3.3)	
6 Months-1 Year	2 (8.0)	0 (0.0)	
1-5 Years	6 (24.0)	4 (13.3)	
>5 Years	16 (64.0)	25 (83.3)	
Pain frequency			1.0000
Every/nearly every day	23 (92.0)	27 (90.0)	
At least half the days	2 (8.0)	2 (6.7)	
Less than half the days	0 (0.0)	1 (3.3)	
Average pain prior week	6.5±1.4	6.4±1.8	0.8582
Pain spread to legs prior 2 weeks			0.5039
No	11 (44.0)	10 (33.3)	
Yes	14 (56.0)	18 (60.0)	
Not sure	0 (0.0)	2 (6.7)	
Bothered prior month by			
Stomach pain			0.2236
Not at all	18 (72.0)	18 (60.0)	
A little	6 (24.0)	6 (20.0)	
A lot	1 (4.0)	6 (20.0)	
Other joints			0.3986
Missing	0 (0.0)	1 (3.3)	

Not at all	6 (24.0)	3 (10.0)	
A little	10 (40.0)	11 (36.7)	
A lot	9 (36.0)	15 (50.0)	
Headaches			0.2060
Not at all	13 (52.0)	22 (73.3)	
A little	8 (32.0)	4 (13.3)	
A lot	4 (16.0)	4 (13.3)	
Widespread pain			0.5347
Not at all	13 (52.0)	15 (50.0)	
A little	5 (20.0)	3 (10.0)	
A lot	7 (28.0)	12 (40.0)	
Had surgery	0 (0.0)	0 (0.0)	NE
In the prior week pain interference with			
Day-to-day activities			0.6827
Not at all	1 (4.0)	2 (6.7)	
A little bit	4 (16.0)	3 (10.0)	
Somewhat	10 (40.0)	12 (40.0)	
Quite a bit	5 (20.0)	10 (33.3)	
Very much	5 (20.0)	3 (10.0)	
Work around the home			0.4029
Not at all	1 (4.0)	5 (16.7)	
A little bit	3 (12.0)	5 (16.7)	
Somewhat	11 (44.0)	7 (23.3)	
Quite a bit	7 (28.0)	10 (33.3)	

Very much	3 (12.0)	3 (10.0)	
Social activities			0.9924
Not at all	5 (20.0)	8 (26.7)	
A little bit	6 (24.0)	5 (16.7)	
Somewhat	6 (24.0)	7 (23.3)	
Quite a bit	6 (24.0)	7 (23.3)	
Very much	2 (8.0)	3 (10.0)	
Household chores			0.9929
Not at all	3 (12.0)	4 (13.3)	
A little bit	5 (20.0)	7 (23.3)	
Somewhat	7 (28.0)	8 (26.7)	
Quite a bit	7 (28.0)	7 (23.3)	
Very much	3 (12.0)	4 (13.3)	
Opioid painkillers (ever)			0.6788
No	11 (44.0)	13 (43.3)	
Yes	13 (52.0)	17 (56.7)	
Not sure	1 (4.0)	0 (0.0)	
Current use			0.4148
Missing	4 (16.0)	6 (20.0)	
No	16 (64.0)	14 (46.7)	
Yes	5 (20.0)	10 (33.3)	
Injections			0.3962
No	13 (52.0)	19 (63.3)	
Yes	12 (48.0)	11 (36.7)	
Exercise therapy			0.1568

Missing	0 (0.0)	1 (3.3)	
No	7 (28.0)	5 (16.7)	
Yes	16 (64.0)	24 (80.0)	
Not sure	2 (8.0)	0 (0.0)	
Psychological counseling			0.1075
No	22 (88.0)	21 (70.0)	
Yes	3 (12.0)	9 (30.0)	
Off work prior month			0.6504
Disagree	5 (20.0)	6 (20.0)	
Agree	0 (0.0)	2 (6.7)	
Not applicable	20 (80.0)	22 (73.3)	
Workers' Comp/Disability			0.1364
Disagree	5 (20.0)	3 (10.0)	
Agree	0 (0.0)	4 (13.3)	
Not applicable	20 (80.0)	23 (76.7)	
Physical function			
Chores			0.1912
W/o any difficulty	0 (0.0)	2 (6.7)	
W/ a little difficulty	3 (12.0)	8 (26.7)	
W/ some difficulty	11 (44.0)	14 (46.7)	
W/ much difficulty	5 (20.0)	4 (13.3)	
Unable to do	6 (24.0)	2 (6.7)	
Up/down stairs			0.3416
W/o any difficulty	1 (4.0)	3 (10.0)	
W/ a little difficulty	9 (36.0)	4 (13.3)	

W/ some difficulty	6 (24.0)	7 (23.3)	
W/ much difficulty	1 (4.0)	3 (10.0)	
Unable to do	8 (32.0)	13 (43.3)	
Walk 15 minutes			0.6610
W/o any difficulty	3 (12.0)	6 (20.0)	
W/ a little difficulty	6 (24.0)	4 (13.3)	
W/ some difficulty	5 (20.0)	5 (16.7)	
W/ much difficulty	5 (20.0)	4 (13.3)	
Unable to do	6 (24.0)	11 (36.7)	
Run errands			0.2460
W/o any difficulty	7 (28.0)	5 (16.7)	
W/ a little difficulty	5 (20.0)	5 (16.7)	
W/ some difficulty	8 (32.0)	11 (36.7)	
W/ much difficulty	5 (20.0)	4 (13.3)	
Unable to do	0 (0.0)	5 (16.7)	
Prior week felt			
Worthless			0.3717
Never	14 (56.0)	18 (60.0)	
Rarely	2 (8.0)	3 (10.0)	
Sometimes	8 (32.0)	4 (13.3)	
Often	1 (4.0)	4 (13.3)	
Always	0 (0.0)	1 (3.33)	
Helpless			0.8443
Never	17 (68.0)	21 (70.0)	
Rarely	2 (8.0)	3 (10.0)	

Sometimes	5 (20.0)	3 (10.0)	
Often	1 (4.0)	2 (6.7)	
Always	0 (0.0)	1 (3.3)	
Depressed			0.4410
Never	16 (64.0)	17 (56.7)	
Rarely	2 (8.0)	2 (6.7)	
Sometimes	3 (12.0)	9 (30.0)	
Often	3 (12.0)	1 (3.3)	
Always	1 (4.0)	1 (3.3)	
Hopeless			1.0000
Never	18 (72.0)	21 (70.0)	
Rarely	3 (12.0)	4 (13.3)	
Sometimes	2 (8.0)	3 (10.0)	
Often	1 (4.0)	1 (3.3)	
Always	1 (4.0)	1 (3.3)	
Sleep quality prior week			0.9842
Very poor	4 (16.0)	6 (20.0)	
Poor	7 (28.0)	8 (26.7)	
Fair	9 (36.0)	10 (33.3)	
Good	5 (20.0)	6 (20.0)	
Prior week sleep was			
Refreshing			0.5904
Not at all	5 (20.0)	8 (26.7)	
A little bit	7 (28.0)	4 (13.3)	
Somewhat	9 (36.0)	10 (33.3)	

Quite a bit	3 (12.0)	4 (13.3)	
Very much	1 (4.0)	4 (13.3)	
Had problems			0.7678
Not at all	5 (20.0)	4 (13.3)	
A little bit	4 (16.0)	6 (20.0)	
Somewhat	8 (32.0)	6 (20.0)	
Quite a bit	3 (12.0)	6 (20.0)	
Very much	5 (20.0)	8 (26.7)	
Difficulty falling asleep			0.7590
Not at all	8 (32.0)	11 (36.7)	
A little bit	6 (24.0)	3 (10.0)	
Somewhat	4 (16.0)	7 (23.3)	
Quite a bit	2 (8.0)	3 (10.0)	
Very much	5 (20.0)	6 (20.0)	
Not safe to be physically active			0.1039
Disagree	14 (56.0)	23 (76.7)	
Agree	11 (44.0)	7 (23.3)	
Terrible and not going to get better			0.1039
Disagree	14 (56.0)	23 (76.7)	
Agree	11 (44.0)	7 (23.3)	
Involved in lawsuit			0.3942
No	22 (88.0)	29 (96.7)	
Yes	2 (8.0)	1 (3.3)	
Unsure	1 (4.0)	0 (0.0)	
Past year			

Drunk/used drugs			0.3124
Never	22 (88.0)	24 (80.0)	
Rarely	3 (12.0)	2 (6.7)	
Sometimes	0 (0.0)	3 (10.0)	
Often	0 (0.0)	1 (3.3)	
Wanted to cut down			0.2015
Never	24 (96.0)	26 (86.7)	
Rarely	0 (0.0)	3 (10.0)	
Sometimes	1 (4.0)	0 (0.0)	
Often	0 (0.0)	1 (3.3)	
Smoking status			0.0536
Missing	1 (4.0)	0 (0.0)	
Never smoked	8 (32.0)	4 (13.3)	
Current smoker	1 (4.0)	7 (23.3)	
Former smoker	15 (60.0)	19 (63.3)	