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PROTOCOL: THE IMPACT OF ACTIVITY GOAL SETTING ON PAIN/DISABILITY RATINGS OF OLDER VETERANS RECEIVING CHIROPRACTIC CARE FOR LOW BACK PAIN

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ABSTRACT

Objective: There is no literature addressing the impact chiropractic services have on older adults achieving individualized specific goals throughout a course of care for chronic low back pain. This study will explore the effect of setting a self-determined, "what matters most" activity/goal of rehabilitation care with relevant activities as part of standard chiropractic care on the self-rated pain and disability of older Veterans.

Methods: Participants will be randomized into 2 groups. The first is an experimental group where participants will identify a goal and receive standard chiropractic care. The second will be a control group that receives standard chiropractic care only. Participants will receive 6 sessions of care.

Results: Outcome assessment tools, including an individualized goal setting measurement tool will be utilized at pre, post, and 6-week follow-up for both groups as primary measures. Relationships between clinical and demographic patient characteristics such as age, sex, and comorbid conditions will be explored with correlation regression as secondary measures.

Conclusion: The results of this pilot may aid in recognizing the value of employing patient-priorities/"what matters most" goal-setting as a means of amplifying the effect of chiropractic services on return to self-identified goals or activities that impact the quality of life among older Veterans. *(J Contemporary Chiropr 2022;5:212-217)*

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INTRODUCTION

Chronic low back pain (cLBP) is a condition that will impact an estimated 80% of the population at some point during their lifetime. (1) cLBP affects populations ranging from adolescents to older adults. When people experience cLBP, they often develop fear of activities associated with these conditions because these activities can sometimes exacerbate their pain. (2) These psychological influences have demonstrated association with both self- reported and performance-based disability in older adults. (3) Previous studies have shown exercise and physical activity reduce this fear perception and increase gait, balance, and reduce the risk of falls. (4-5)

Spinal manipulative therapy (SMT) is a treatment for cLBP that is safe and effective. (6) SMT is a technique applied by manual therapy practitioners such as ostepaths, chiropractors, and physical therapists. According to the National Institute of Health (NIH), SMT is technique where practitioners use their hands or a device to apply a controlled thrust (that is, a force of a specific magnitude or degree in a specific direction) to a joint in the body. Spinal manipulation is a common complementary and integrative health approach used in the VA for the treatment of chronic pain in Veterans. (7)

Neurophysiological pain education is a means of talking to patients about their pain condition and providing education on the background, prevention, and self-care measures to help manage pain. There is some evidence supporting this technique, and prior research shows SMT has positive results in managing cLBP. (8) The combination of exercise, spinal manipulation, and patient education also has demonstrated positive results in managing cLBP. (9) In older adults, cLBP decreases physical activity and performance and increases fear avoidance behavior and depression symptoms. (10) This increase in depression symptoms may be associated with

reduced activities that the individual used to engage in and rates personally important. (11)

Personal importance ties in with Age Friendly Health Systems (AFHS) "4M's" of age-friendly care, specifically, "what matters most." AFHS "what matters most" is defined as "knowledge and aligned care with each older adult's specific health outcome goals and care preferences. (12) This is equally true in the older Veteran population, where cLBP results in reduced activities and increased disability despite desiring to return to regular function. (13) The use of goal setting is emerging topic of importance to healthcare providers for the treatment of cLBP. (14) Patient led goals can include, but are not limited to, increased physical activity, performance of activities of daily living (ADLs), or even to get a "full night sleep." There is extensive literature regarding low back pain, many of which identify patient goals within treatment. However, there is limited literature, especially with older adults, addressing patient led goals as an intervention and its association on outcomes for cLBP treatments as a primary measure. To this time, no specific study exists examining older Veterans with cLBP's ability to return to a self-identified "what matters most" individualized activity goal following a trial of chiropractic intervention. Our proposed study aims to explore the relationship between older Veterans and their own self-identified "what matters most" goal in combination with chiropractic care relative to standard care alone. This paper examines our proposed protocol.

PROTOCOL

Study Design

The design of the study is a randomized controlled trial including veterans, aged 55 years or older, seeking treatment for cLBP in the BVAHCS. Fifty participants will be randomized into either an experimental (n= 25) or control (n=25) group. After recruitment, informed consent, and randomization, all participating veterans' demographic and clinical characteristic information will be collected. Primary outcome measures will also be collected from each group. These outcome measures will be collected pre-treatment, post-treatment, and at a 6-week follow up.

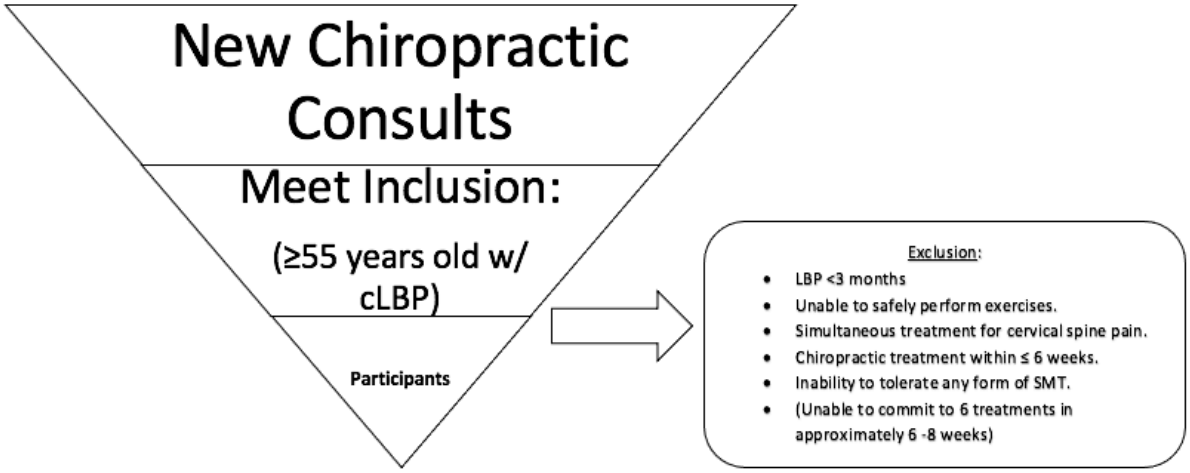
Study Objectives

Aim 1: To investigate the efficacy of using a standard tool for setting an individualized goal (Activity/Goal of rehabilitation Care- AGoC) in combination with standard chiropractic care (SoC) to reduce self-rated pain and disability of 50 older Veterans (55 years and older) suffering with chronic low back pain (cLBP). For the purposes of this study, SoC will consist of 3 therapeutic exercises, spinal manipulation/mobilization, and at least 10-15 minutes of "education" on chronic low back pain from a standardized education sheet.

We hypothesize that ratings on standardized metrics of pain and disability will be significantly improved (pre-post) among an intervention group of Veterans with cLBP receiving SoC Chiropractic care plus the individualized AGoC.

Aim 2: We will use correlation and linear regression to explore relationships between baseline clinical

Figure 1. *Inclusion/exclusion of study participants.*



and demographic patient characteristics (e.g. age, sex, comorbid conditions) and the primary pain and disability outcomes.

We hypothesize that secondary analysis will demonstrate that in individuals with multiple chronic comorbid conditions positive outcomes will be reduced. We predict that younger veterans would have better outcomes than older veterans. We will evaluate and compare clinical characteristics of participants who were able to achieve their individualized goal relative to those who were not.

DISCUSSION

Study setting

This study and interventions will take place exclusively in the chiropractic clinic at the Birmingham VA Healthcare System (BVAHCS) In Birmingham, Alabama, USA.

Eligibility

Eligible veterans will be aged 55 and older, have low back pain (persistent or recurrent) for greater than 3 months, and will be seeking treatment for cLBP at the BVAHCS chiropractic clinic. Participating veterans will be requested to commit to at least 6 treatment visits, and be willing to answer questions at baseline, end-of-care and at six-week follow-up assessment (phone). Veterans with no history of cLBP will be excluded as will those younger than 55 years.

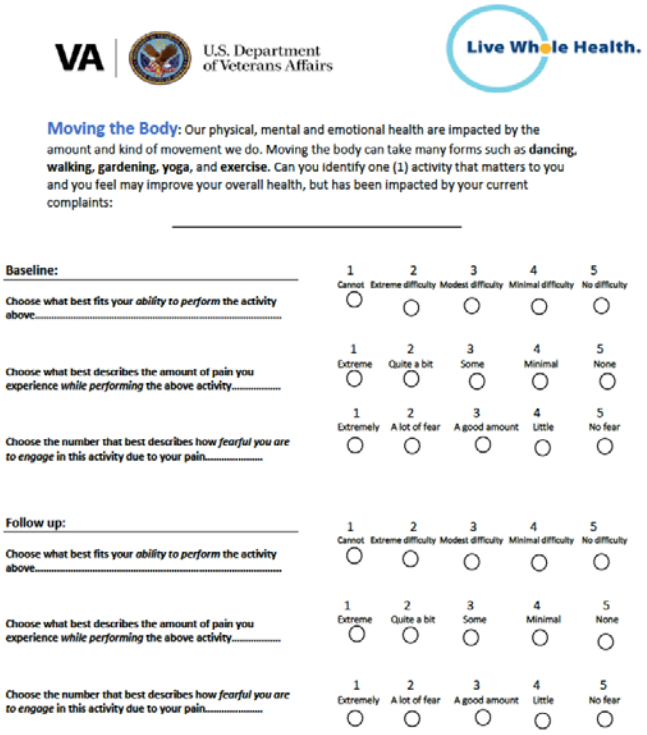
Inclusion criteria is being a veteran aged 55 or older, have a history of cLBP (LBP lasting greater than or equal to 3 months.) Exclusion criteria includes being less than 55 years old, LBP for less than 3 months, the inability to tolerate SMT or exercise, simultaneous treatment for cervical spine pain, or unable to commit to 6 treatments over approximately 6 weeks. (See Figure 1)

Interventions

All participating Veterans will receive chiropractic care. Care will follow a standardized plan that will include a combination of a standardized education pamphlet, a set of standardized exercises, and SMT. All participants will receive a series of 6 treatments.

In addition to SoC, participants in the experimental group will receive the "AGoC questionnaire" (AGoC) and be asked to identify a "what matters most" goal. (See Figure 2) This questionnaire will also be administered pre, post, and at 6 weeks of the chiropractic intervention. The AGoC was developed specifically for this study and it allows space for the participant to write a specific goal or activity of their choice. The goal or activity is something they no longer do or do less of due to their increase in cLBP. The AGoC also has three follow-up questions regarding the goal or activity selected. These questions

Figure 2. *Activity/Goals of Care Questionnaire.*



address the participants ability to currently perform that activity, the pain they have while performing the activity, and fearful the participant is to engage in the activity.

Outcomes

All participants will be asked to complete the primary outcome measures for disability and pain. These measures include the Roland Morris Disability Questionnaire, the Oswestry Disability Index (ODI), The University of Alabama at Birmingham (UAB) Study of Life-space and Aging Assessment, and the Brief Pain Inventory (BPI) which is taken verbally on a 0-10 Likert scale. These measures will be administered 3 times: (1) immediately prior (within a week) to the first chiropractic visit/ treatment (pre), (2) immediately (same day) following the 6th visit (post) and at (3) 6-week post-treatment follow-up (scheduled call at 6-8 weeks after the previous treatment). Participants will answer the Global Rating of Change (GROC) questionnaire at post-treatment and six-weeks. Participants allocated to the experimental group will also answer an outcome tool identifying a specific goal (AGoC). All participants demographic and clinical characteristic information including age, sex, height, weight, BMI, race, duration of cLBP, lumbar surgical status, pain medication use, the Charlson Comorbidity Index (CCI) and the Keele STarT Back risk assessment tool will be collected/administered. The Global Rating of Change Scale (GROC) will be administered after the

6-treatment sessions and at 6-week follow up to measure participants self-reported improvement.

Participant Timeline

Participants can expect the trial to run at least 12 weeks (with 4-6 weeks of variability depending on patient availability.) The participants will undergo 6 weeks of care (with 1 treatment session per week) and the final follow up will concluded at 6-8 weeks following the final treatment.

Sample size

To account for attrition at 20%, 50 Veterans (25 per group) who receive care at the BVAHCS will be recruited to participate in the study, so that we will arrive at a sample of at least 40 veterans total for post treatment and study analysis. We believe that because this is a novel pilot study, this would be an appropriate sample size.

Recruitment

Participating veterans will be recruited by the chiropractic department (e.g. the chiropractors practicing at BVAHCS) in this clinic setting.

Allocation

Sequence generation

We will use randomizer.org, an online randomization tool, to randomize participants into experimental or control groups. The online tool will generate a list for assignment (1:1). This order will be followed when we encounter a potential participant.

Concealment

Participants will be assigned a number for which group they are assigned, and the PI, and co-investigators will have access.

Implementation

Participants will be enrolled by the chiropractors actively as new patient consults are requested.

Blinding

This study will be a single-blinded trial. Participants will not be informed as to which group they are allocated (control or experimental.) The provider will be informed as to the subjects allocated group (control or experimental) and provide patient-centered education to the experimental group on achieving their set "activity or goals."

Data Collection and Management Methods

Data will be collected on paper by recruiting provider. Hard copies of the patient forms will be kept in a locked filing cabinet in the office of PI. Data will be inputted to a REDcap dataset that will be available only on a specific password protected file specifically created for the study. Patients will be assigned a specific identification number to ensure confidentiality from co-investigators, statisticians, or any reviewers.

Statistical methods

Descriptive statistics will be generated, and group and time of measurement differences evaluated utilizing repeated measures ANOVA test with 2 factors: group 1 (SoC) and Group 2 (SoC+AgoC) and time (pre, post, and 6-week) to determine effects of intervention with regard to time. We will conduct cross tabulations and correlation analysis to examine the relationship of demographic and clinical characteristics with our primary outcome measures. Data will be analyzed via REDcap SPSS software.

Data monitoring

The PI and co-investigators, will be the only researchers with direct access to protected heath information prior to transferring to de-identified data

Harms

Because chiropractic treatments provided in this study are considered standard of care, the overall risks associated with study participation are minimal. No additional risks are anticipated as a result of the AGoC intervention. Minor risks include soreness following treatment, while major risks may rarely include falls and/or fractures. Special considerations for SMT in this population of older adults will be considered, such as low-velocity mobilization and flexion/distraction as an alternative forms of SMT. In the event of an adverse response (mild or serious), this will be reported to the IRB by the PI within 24 hours. Any deviations from the protocol will be reported to the IRB by the PI within 24 hours. Unanticipated problems will be reviewed by the PI and reported to the IRB on a case-by-case basis within 24-48 hours of the presenting issue.

Auditing

No anticipated auditing will take place during this trial.

Ethics and dissemination

Research ethics approval

This study was approved by the Birmingham VA Medical Center IRB on December 29, 2021. There was approval by the Birmingham VA Medical Center Combined Associate Chief of Staff for Research and Development (ACOS/R&D) and R&D Committee on January 07, 2022.

Protocol amendments

The PI will inform the IRB though email of any changes in protocol, informed consent, HIPAA authorization, subject withdrawal, and/or adverse or serious events that occur during the trial.

Consent

In a private setting, the PI will explain to potential participants the purpose, procedures, duration, potential benefits and risks associated with, and alternatives for care provided as part of this study. Interested participants will be provided informed consent in compliance with IRB and BVAHCS Research regulatory requirements. Informed consent will be collected and reviewed with the subjects by the PI of the study. If subjects have impaired decision-making ability, the use of a legally authorized representative will be required to complete the informed consent. If subject have a visual impairment, the consent will be reviewed with the subject by the obtaining investigator The PI obtaining informed consent was trained via the VA training modules for obtaining and documenting informed consent.

Confidentiality

Subject protected health information (PHI) will not be disclosed to any entity outside of the study PI. On initial intake, some PHI will be utilized to generate a score on the CCI. The PI has undergone patient confidentiality, privacy, HIPAA, and protection training. Hard copies of the patient forms will be kept in a locked filing cabinet in the office of PI. Data will be inputted to an excel spreadsheet that will be available only on a specific password protected file. Patients will be assigned a specific identification number to ensure confidentiality from co-investigators, statisticians, or any reviewers.

Declaration of interests

There are no financial incentives or other competing interests

Access to data

Final data will be accessible to the PI and co-investigators. An assigned statistician will also be given privileges to access de-identified data. This data will be accessed on an encrypted

Ancillary and post-trial care

There are no provisions for ancillary or post-trial care for this study. There is no compensation for this study.

Dissemination policy

After the trial is complete and data analysis is complete, a full manuscript will be prepared and submitted for publication to share results with healthcare professionals and the public. Subjects may inquire about results and a final manuscript may be shared with them upon request.

CONCLUSION

After conclusion and analysis of this study, we hope to understand more about what impact individualized goal setting has on outcomes for older Veterans with cLBP receiving chiropractic care. A prior review has noted that "current standard clinical outcome measures may not particularly align with categorically important individual patient goals." (15) This study will evaluate a number of standard chiropractic clinical outcome measures along with individualized goal-setting outcomes. We also hope to increase understanding of what's important or what matters to older Veterans regarding their management of cLBP, similar to that of AFHS "what matters most." The aims of this study may help to further understand older Veteran preferences for care for cLBP by examining and categorizing the individualized goals set. Further, the study may aid in understanding if chiropractic interventions play a role in achieving those goals and how they relate to current standard clinical outcome measures. We also hope to gain better understanding, through secondary analysis, how clinical conditions, such as co-morbidities, and demographic information plays a role in the older Veterans population response to chiropractic for cLBP. We hope the results of this pilot study set a basis for a large scale and multi-site study to further explore this topic.

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