Research

Methodology of a Randomized Controlled Trial of Manipulation and Physical Therapy for Chronic Low Back Pain and Balance Problems in the Geriatric Population.

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Topics in Integrative Health Care 2011, Vol. 2(4) ID: 2.4003

Published on December 31, 2011 | Link to Document on the Web

ABSTRACT

Introduction: Postural control problems are one of the most common conditions affecting the geriatric population. This paper discusses the design of a prospective randomized controlled trial that examines a mixed modal treatment protocol for geriatric patients with non-vestibular related balance problems with or without chronic low back pain.

Methods: This three-year study will randomly assign a total of 300 consecutive community dwelling subjects between the ages of 65 and 80 years old into treatment groups receiving 6 weeks of either physical therapy or chiropractic care. Primary outcomes for balance include the NeuroCom balance tests, Berg Balance Scale, and POMA. The primary outcomes for low back pain are the VAS and 21-point box scale. Secondary outcomes are the Timed Up and Go Test for mobility and the Falls Efficacy Scale for confidence in performing everyday activities. Participants will be tested prior to randomization, and after 6 weeks of treatment, and again 6 weeks later. The data analysis for this intent-to-treat design will be mixed-model analysis of variance (ANOVA) with an alpha level of 0.05 for statistical significance for each outcome measure.
**Conclusion:** The methodology and design of a multimodal treatment protocol for balance disorders and low back pain in the geriatric population is described in this paper. By examining geriatric patients in separate cohorts with or without cLBP, we hope to identify effective treatment protocols and further define the relative contribution of cLBP to balance problems.

**Introduction**

Postural control problems are one of the most common conditions affecting the geriatric population.\(^1\) Over 25% of individuals over the age of 65 will experience a fall related injury each year. Often the result of an underlying pathology, falls are a known predictor of morbidity among the elderly.\(^2\) Low back pain (LBP) is the most frequently reported musculoskeletal condition, Affecting between 20% and 40% of adults over 65 and a leading comorbidity directly linked to the incidence of falls in the elderly.\(^3,4,5,6,7\) LBP is sharply on the rise, having increased in the last fourteen years from 3.9% to 10.2%.\(^5,6,8,9\) Repeated bouts of back pain can impact the daily functioning of the elderly patient.\(^10\) This is especially true for the frail elderly, who may already be subsisting with marginal independence.\(^10,8\)

The pathology of LBP-related balance problems in the elderly is multifactorial, including inhibition of core stabilizing muscles, multifidus muscle atrophy, altered muscle activation patterns, loss of proprioception, and an inability to control normal postural sway.\(^11,12,13,14\) Both acute and chronic LBP affects the ability to recover from perturbations and decreases postural control.\(^12,13,14\) Balance problems and non-specific LBP share some similarities in etiology. The ability to maintain normal balance is not only a function of the visual, vestibular, and somatosensory systems but also requires proper sensory-motor integration. Nonspecific multilevel degenerative disc disease with related myofascial injury remains the most common etiology behind chronic back pain in the elderly.

There is evidence that the most effective treatment strategies for LBP and balance problems in the general population consist of a multimodal approach of manual therapy, exercise, and behavioral modification programs.\(^15,16\) A review of 40 randomized controlled trials combining different interventions showed a significant reduction in the risk and rate of falls when multiple therapies were utilized.\(^16\) Manipulation as a method of restoring normal motion of the low back and pelvis has been demonstrated in many studies.\(^17,18,19\) Practitioners have long held that biomechanical dysfunction of the spine and pelvis as a source of low back pain can be appropriately treated with manipulation.\(^18,19\)

While it is performed by other health care providers, spinal manipulation as a treatment for LBP is delivered primarily by the chiropractic profession.\(^20\) A survey in Ontario by Li & Bombardier revealed that while 29.9% of physical therapists agreed or strongly agreed that spinal manipulation was an effective treatment for acute LBP, only 5% utilized the procedure.\(^20\) A national survey by Liddle et al. of physiotherapists reported that only 1.1% of respondents ranked manipulation as a first treatment option for LBP.\(^21\)
When compared to other populations, older adults utilize chiropractic care far less than the general adult population. In a study of 4,310 self respondents 70 years old or older, the average annual rate of chiropractic use was 4.6%. Among older adults who had seen a chiropractor, the number of visits was less for those who lived alone, had lower incomes, and poorer cognitive abilities, while it was greater for overweight individuals and those with lower body limitations. Older adults tended to view chiropractic care as a specialty and not a substitute for visits to their primary care physician.

While older adults represent the fastest growing population segment, research into age-related conditions such as balance and LBP has failed to keep pace with the growth in this demographic. Geriatric studies are under-represented in the back pain literature, and there is a need to improve epidemiologic reporting of LBP in the elderly. Many novel therapies and rehabilitation techniques involving older adults with postural control problems are of unknown effectiveness and warrant further investigation. The growing geriatric population and rise in age-related low back pain and balance problems indicate the need for additional systematic reviews. This randomized controlled clinical trial is designed to test the efficacy of a multimodal treatment program using manual therapy or physical therapy among older adults with balance problems and with or without chronic low back pain.

Methods

This prospective clinical trial includes 300 consecutive participants between the ages of 65 to 80 years randomly assigned into two treatment groups. This multisite study is currently being conducted at the Saint Louis University (SLU) Division of Geriatric Medicine and the St. Louis Veterans Affairs (VA) Geriatric Research Education and Clinical Center (GRECC). This study was approved by the Institutional Review Boards (IRB) at Logan College of Chiropractic, Saint Louis University School of Medicine, and St. Louis Department of Veterans Affairs Medical Center. The primary study aims are to assess the efficacy of manual therapy and physical therapy to treat balance problems in older adults with or without chronic low back pain (cLBP). By examining these separate cohorts of patients with or without cLBP, we also hope to further define the relative contribution of cLBP to balance problems.

Study population

This three year study randomly assigns 300 consecutive community dwelling subjects with balance problems into two groups that will receive 6 weeks of either physical therapy or manual therapy treatment. Each treatment group includes two subgroups; one (n=75) with cLBP and one (n=75) without cLBP (Fig 1). Participants will be recruited from the St. Louis metropolitan region through referrals from physician outpatients clinics, community outreach, presentations to retirement homes, flyers and newspaper advertising.
Figure 1. Geriatric Low Back Pain and Balance Study Flowchart

- Baseline Balance Evaluation
  - Balance Problem
    - Yes: Baseline Musculoskeletal Assessment (BMA)
    - No: Excluded – failed to meet inclusion criteria

- cLBP
  - Yes: Randomization
    - Manipulation Management Protocol a n = 75
    - PT Management Protocol b n = 75
  - No: Randomization
    - Manipulation Management Protocol a n = 75
    - PT Management Protocol b n = 75

- Post treatment testing at week 6
  - Post treatment testing at week 12
    - Optional 6 Wks of Therapy in the opposite treatment
    - Data Analysis
Inclusion criteria

Study participants must be ages 60-85 (inclusive) and have balance problems. Balance problems are defined as the inability to keep one’s center of gravity over the base of support during both static and dynamic situations (Fig 2). Half of the study participants will have self-reported chronic low back pain and half will not.

Exclusion criteria

Study participants are not eligible for randomization to receive manual or physical therapy treatment if they present with any of the following criteria:

- History of recent fracture or surgery of lumbar spine, pelvis, hip or femur
- History of recent neoplasm (minor skin cancers are not excluded)
- Acute infectious disease
- Low back pain of less than 8 weeks’ duration
- Severe disabling health problems so that patient is not ambulatory
- Non-mechanical low back pain
- Recent unstable peripheral vascular disease and or cardiac disease requiring recent hospitalization < 6 months ago
- Patients with balance problems related to the following: Meniere’s disease, vertigo, or vestibular disorders
- Recent history of self reported substance abuse
- Ongoing treatment for balance problems or low back pain by chiropractor, physical therapist, or orthopedic physician or other physician.
- Current use of medication from the following categories: antipsychotics, anxiolytics, and sedative/hypnotics

Screening, baseline, 6-week, and 12-week measures

The nurse coordinator initially screens interested parties by phone for eligibility criteria. Subjects who pass the initial screening meet with the clinical trial nurse coordinator who reviews the study details with them and obtains written informed consent. The nurse coordinator then collects participants’ relevant medical and surgical history, falls history and fear of falling and demographic information (age, sex, ethnicity, years of education, smoking history, alcohol consumption); and use of prescription medication, over the counter medications, and supplements. Medical records are ordered and reviewed by the geriatric physician, chiropractic physician and research nurse coordinator prior to patient acceptance into the study. Participants then complete functional performance tests and self-report questionnaires regarding, health, low back pain, and balance. Patients are randomized into their treatment groups after testing in order to mask testers.
The functional performance tests include the following:

- Balance tests - Berg Balance Scale\textsuperscript{23,24}, Performance-Orientated Mobility Assessment (POMA)\textsuperscript{25}, and NeuroCom Balance Tests, the Limits of Stability (LOS) & Modified Clinical Test for the Sensory Integration of Balance (Mod. CTSIB)\textsuperscript{26}
- Mobility - Timed Get Up and Go Test\textsuperscript{27,278}

**Fig. 2 Balance testing with the NeuroCom Balance Master.**

The NeuroCom Balance Master provides data on reaction time, postural sway, and directional control; and determines how effectively the visual, vestibular and somatosensory systems are utilized in maintaining balance.
The self-report questionnaires include the following:

- Pain - Visual Analogue Scale\(^{29}\), 21-point Box Pain Scale\(^{30,31}\), Oswestry Pain Questionnaire\(^{32,33}\)
- Fear of Movement and Confidence in Performing Daily Activities – Tampa Scale for Kinesiophobia\(^{34}\) and Falls Efficacy Scale\(^{35}\)
- Health Related Quality of Life: SF-36\(^{36,37}\)

Participants also will complete the functional performance tests and self-report questionnaires after 6 weeks of physical or manual therapy treatment and 6 weeks after receiving physical or manual therapy treatment (i.e., 12 weeks after baseline).

**Treatment allocation**

All participants have balance problems (N=300) are randomly assigned to a treatment group after categorization of their status as presence or absence of cLBP, with equal distribution of cLBP status between groups. One hundred fifty participants with chronic low back pain will be randomly assigned to one of two treatment groups: a) manual therapy group (n=75) or b) physical therapy group (n=75), and 150 participants without chronic low back pain will be randomly assigned to one of two treatment groups: a) manual therapy group (n=75) or b) physical therapy group (n=75). Participants are considered noncompliant and removed from the study if they miss more that 4 consecutive treatments.

**Treatments**

Both physical therapy and chiropractic treatments will be provided at the VA hospital at Jefferson Barracks Geriatrics Research, Education and Clinical center (GRECC) and the Saint Louis University School of Medicine’s Center for Biomedical and Healthcare research.

**Manual Therapy.** Standard of care to treat older adults with balance problems (with or without low back pain) in chiropractic medicine is manual therapy. Patients (50%; 150/300) randomized to receive manual therapy will receive 6 weeks of treatment. Manual therapy will be performed by a licensed chiropractic physician.

Chiropractic treatments will be based on patient history and the chiropractor’s initial patient evaluation and examination findings. Hypomobile or dysfunctional joints will be diagnosed using standard functional and provocation tests. Indications for treatment procedures will be based on provocative and functional tests, confirmed by manual palpation of the structure identified. Diagnosis of the segmental joint dysfunction will be supported throughout using the Medicare P.A.R.T.s system to document tissue/tone changes, asymmetry/misalignment, range of motion abnormality, pain/tenderness. These tests will include standard orthopedic tests, the P.A.R.T.s assessment and palpation methods. All treating chiropractors in the study have the same education and clinical training, having received their Doctor of Chiropractic degree from Logan College of Chiropractic. They will use identical examination techniques and
treatment protocols.

There will be 3 treatment sessions per week and each session will take approximately 30-45 minutes. Manual Therapy may include any combination of the following: manipulation, mobilization, flexion-distraction therapy and PNF stretching and gentle soft tissue therapy. Mobilization of the soft tissues will include manual procedures to muscles, ligaments, tendons and connective tissue. The soft tissue procedures will consist of post-isometric relaxation (PIR) and stretching techniques commonly used by chiropractic physicians and other providers. PIR is a method of soft tissue mobilization used to lengthen hypertonic or spastic muscles. The standardized treatment protocols will emphasize the conservative application of manipulative therapy, mobilization and stretching techniques to assist in maintaining joint mobility and stability, decrease pain and increase ranges of motion. The goal with these procedures is to increase joint mobility, restore normal function, increase flexibility and remove fixations that may serve as a source of irritation to pain generating structures; thereby decreasing the patients' pain and assisting in functional restoration of normal motion. There will be no manipulation of the cervical spine as part treatments provided in this study.

**Physical Therapy.** Patients (50%; 150/300) randomized into the physical therapy group will receive 6 weeks of treatment. The standard of care used in this study for Physical Therapists to treat older adults with balance problems (with or without low back pain) is consistent with the Federation of State Boards of Physical Therapy Standards of Competence 2000.

Physical Therapy will be based on patient history and the physical therapist’s initial patient evaluation and examination findings. After randomization into the PT group, the Physical Therapist will perform a thorough physical therapy evaluation to identify and assesses the problems that are related to deficits in balance and / or cause low back pain. The therapist will determine treatments that are the most effective in addressing any deficits present. Treatments are patient specific and may include any or all of the exercises described or modalities such as electrical stimulation and ultrasound if determined necessary. All patients receiving physical therapy will be treated by the same licensed physical therapist who received her Doctor of Physical Therapy degree from Saint Louis University. There will be 3 treatment sessions per week and each session will take approximately 30-45 minutes. Physical therapy techniques to address low back pain may include any combination of the following: heat packs, TENS units, interferential electrical stimulation, and ultrasound. Physical therapy will also utilize a patient-specific combination of exercises, flexibility stretches, muscle endurance and strength training exercises, as well as instruction on proper posture and lifting techniques, safety training, and education on a home exercise program to prevent further recurrences. Strengthening of postural and core muscles as well as neuromuscular re-education will be a primary focus to facilitate balance improvements. Specific muscle weakness and asymmetry as well as postural defects will be assessed using the standard Kendall manual muscle and length tests upon evaluation. A set of specific balance exercises will be prescribed through individual instruction. The exercises will be selected from a standardized set of exercises commonly utilized for balance rehabilitation training. These will include exercises specific for low back and pelvis coordination, flexibility, neuromuscular re education, endurance, and strength training.
Delayed onset muscle soreness may occur post treatment session in the muscles where resistance training occurs.

**Outcome measures**

The primary outcomes for balance are the NeuroCom balance tests (LOS, Mod. CTSIB), Berg Balance Scale, and POMA. The primary outcomes for low back pain are the VAS and horizontal 21-point (0-100) box scale. Secondary outcomes are the Timed Up and Go Test for mobility and the Falls Efficacy Scale for confidence in performing everyday activities. All participants completed the low back pain questionnaires regardless of their pain status. The functional outcome tests will be administered by an investigator blinded to participant treatment condition, and participants will be instructed not to discuss or reveal their treatment condition to the investigator at the time of the functional outcome assessments at 6 weeks and 12 weeks.

**Data analysis and sample size**

This study is a randomized, mixed-model design. The mixed-model design includes a repeated measures variable (baseline, week 6, & week 12) and a between subjects variable (manual therapy vs. physical therapy). The data analysis approach for this intention-to-treat design will be mixed-model analysis of variance (ANOVA) for each outcome measure. The power to detect a main effect of study group (manual therapy vs. physical therapy) is a function of sample size (n= 75 per group) and an alpha level of 0.05 for statistical significance. At a power level of 1- ß = 0.80, the study is adequately powered to detect a main effect of treatment group at effect sizes of f > 0.19 to evaluate the study outcome measures. Values of the f effect size are interpreted as follows: 0.10-0.24 are considered small effects, 0.25-0.39 are considered medium effects, and values ≥ 0.40 are considered large signs.

**Conclusion**

The methodology and design of a multimodal treatment protocol for balance disorders and low back pain in the geriatric population is described in this paper. By examining geriatric patients in separate cohorts with or without cLBP, we hope to identify effective treatment protocols and further define the relative contribution of cLBP to balance problems.

**Acknowledgements**

This study was funded by a grant from the U.S. Department of Health and Human Services, Health Resources and Services Administration, (HRSA award number R18HP15125-01-00).

**References**


