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A feasibility study assessing manual therapies to different regions of the spine for patients with subacute or chronic neck pain☆

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Abstract

Objective: The purpose of this project was to develop and test protocols for a randomized clinical trial of a combined therapeutic approach (thoracic spine and sacroiliac joint high-velocity, low-amplitude spinal manipulation [HVLA SM] + cervical spine postisometric relaxation) and cervical spine HVLA SM for patients with subacute or chronic neck pain.

Methods: Patients were recruited in the Quad Cities in Iowa and Illinois. After a baseline assessment visit, eligible patients were randomly assigned to cervical spine HVLA SM or to the combined therapeutic approach for 4 treatment visits over 2 weeks. Outcome assessments included the Neck Disability Index, visual analog scale, and posttreatment response questionnaire. Patient outcomes were not aggregated or compared by treatment group.

Results: It took approximately 8 months of planning, which included the development of forms and protocols, pretesting the forms, and training staff and clinicians in the standardized protocols. Twelve participants were screened, and 6 patients were enrolled and randomly allocated to care over a 6-week period. All patients completed 5 visits. Five of 6 patients had an improvement on the Neck Disability Index. On the visual analog scale, 2 patients improved at 2 weeks, whereas the other 4 got worse. Five patients completed the posttreatment response questionnaire; 2 of the 5 indicated they experienced discomfort or an unpleasant reaction from the study treatments.

Conclusions: Designing a successful feasibility randomized clinical trial requires considerable planning, development and pretesting of the forms and protocols, and training clinicians and staff for standardized protocols. Patients were willing to be randomized, follow treatment protocols, complete baseline and outcome assessments, and return 83% of the follow-up questionnaires.

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Introduction

Neck pain is a common musculoskeletal problem affecting up to 30% of adults in a given year.[1,2] Similar to low back pain, neck pain can be a chronic and disabling problem. Up to 5% to 10% of adults will be disabled with chronic neck pain.[1,2] Presently, there is no conclusive evidence for the effectiveness of high-velocity, low-amplitude spinal manipulation (HVLA SM) or other conservative manual therapy techniques for patients with acute, subacute, or chronic neck pain. A systematic review of the effectiveness of HVLA SM and mobilization for mechanical neck disorders revealed that HVLA SM and/or mobilization when done alone was not beneficial and that, when compared with one another, neither was superior.[3]

High-velocity, low-amplitude spinal manipulation is commonly used by manual therapists and doctors of chiropractic to treat spinal pain; but it is also commonly associated with minor transient adverse reactions such as local pain and stiffness, fatigue, or headaches. Observational studies have investigated the frequency and percentage of patients who experience these minor transient adverse reactions. A prospective, clinic-based survey of 102 Norwegian chiropractors reported that at least one minor adverse reaction was reported by 55% of the patients some time during the course of a maximum of 6 treatment visits.[4] Studies from Sweden and Great Britain reported similar percentages of patients with minor adverse reactions.[5,6] Recent randomized clinical trials (RCTs) of patients with neck pain have also reported minor adverse reactions in which HVLA SM and other manual therapies were used as the primary interventions.[7,8] The frequencies reported in these RCTs ranged from 9% to 28% for the most common reaction, increased neck pain.

There is preliminary evidence that HVLA SM to the thoracic spine and muscle energy technique(s) to the cervical musculature may be helpful for neck pain. Cassidy et al[9,10] found that there was no statistically significant difference in patients with neck pain between HVLA SM and a muscle energy technique in terms of pain intensity. Both treatment groups demonstrated decreased pain immediately after treatment. However, only one treatment was performed; and there was no follow-up assessment beyond immediate effects. In another study, it was found that thoracic spine HVLA SM reduced neck pain more than a sham thoracic HVLA SM when measured immediately after treatment.[11] The results were statistically significant; but because the sample size was small and only immediate effects were measured, the results need to be interpreted with caution. We believe that there is potential for muscle energy techniques and thoracic spine HVLA SM for relieving neck pain.

Although there are no published clinical studies that suggest sacroiliac HVLA SM is helpful for neck pain, there is anecdotal evidence to suggest that a biomechanical relationship exists between the spinal regions caudal to the cervical spine and the cervical spine.[12,13] Because of the scarcity of studies investigating the muscle energy technique—postisometric relaxation (PIR), and thoracic and sacroiliac HVLA SM for neck pain—this study looked at a combined therapeutic approach using thoracic spine and sacroiliac HVLA SM and PIR in patients with subacute or chronic neck pain. A long-term goal is to identify specific types of combined therapeutic approaches that are most effective in reducing neck pain and disability and that result in a low percentage of minor, transient adverse reactions.

Because RCTs are expensive and involve human participants, feasibility studies are recommended to test a study's protocols. Feasibility studies are especially important for new investigators and for investigators who are recruiting participants in a particular geographic area for the first time. The purpose of this study was to develop and test protocols for an RCT of a combined therapeutic approach and cervical spine HVLA SM for patients with subacute or chronic neck pain. Protocols tested included patient recruitment, telephone and face-to-face screening interviews, informed consent, physical examination, enrollment, and treatment procedures for HVLA SM as well as for the PIR technique to the cervical spine musculature.

Methods

It took approximately 7 months to design and pretest the study protocols and forms. An additional 3 weeks was needed to train 4 research staff and 2 clinicians for eligibility screening protocols, patient flow and administration of self-report questionnaires, and examination and treatment protocols. All members of the study team were trained with standardized protocols before patient recruitment.

Our target enrollment for this project was 6 patients with subacute or chronic neck pain. Patients were recruited using study fliers, a classified newspaper ad, and by word of mouth in Davenport, IA, and the surrounding Quad Cities in Iowa and Illinois. Patients were also recruited from a list of ineligible patients for a low back pain study at the Palmer Center for Chiropractic Research (PCCR). Initial screening was