



Original article

Adverse events among seniors receiving spinal manipulation and exercise in a randomized clinical trial

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ABSTRACT

Spinal manipulative therapy (SMT) and exercise have demonstrated effectiveness for neck pain (NP). Adverse events (AE) reporting in trials, particularly among elderly participants, is inconsistent and challenges informed clinical decision making.

This paper provides a detailed report of AE experienced by elderly participants in a randomized comparative effectiveness trial of SMT and exercise for chronic NP.

AE data, consistent with CONSORT recommendations, were collected on elderly participants who received 12 weeks of SMT with home exercise, supervised plus home exercise, or home exercise alone. Standardized questions were asked at each treatment; participants were additionally encouraged to report AE as they occurred. Qualitative interviews documented participants' experiences with AE. Descriptive statistics and content analysis were used to categorize and report these data.

Compliance was high among the 241 randomized participants. Non-serious AE were reported by 130/194 participants. AE were reported by three times as many participants in supervised plus home exercise, and nearly twice as many as in SMT with home exercise, as in home exercise alone. The majority of AE were musculoskeletal in nature; several participants associated AE with specific exercises. One incapacitating AE occurred when a participant fell during supervised exercise session and fractured their arm. One serious adverse event of unknown relationship occurred to an individual who died from an aneurysm while at home. Eight serious, non-related AE also occurred.

Musculoskeletal AE were common among elderly participants receiving SMT and exercise interventions for NP. As such, they should be expected and discussed when developing care plans.

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1. Background

Neck pain is common and a growing public health concern among seniors (Vaupel et al., 1998; Hartvigsen et al., 2003, 2004). Spinal manipulative therapy (SMT) and exercise are two non-pharmacological therapies with demonstrated effectiveness for neck pain in the general population (Hurwitz et al., 2008; Miller et al., 2010; Kay et al., 2012) including the elderly (Maiers et al., 2013). When considering the clinical utility of any intervention, it is essential to weigh the balance of benefit versus harm (Ioannidis et al., 2004). This may be of greater consequence for an elderly population, where risk of harm is heightened due to general decline in health, competing co-morbid conditions, poorer balance, and slower recovery times. Further, there has been a call for increased

research of non-pharmacological treatments in the elderly to minimize the risks associated with pain medication, including complications associated with drug interactions (Fitzcharles et al., 2010; Abdulla et al., 2013).

There are few clinical trials reporting AE associated with SMT and exercise (Gross et al., 2010; Kay et al., 2012) and fewer still that include the elderly (Dougherty et al., 2012). While generally underreported in the literature, studies report AE in 31–56% of adults receiving SMT. These are typically described as non-serious, transient, and musculoskeletal in nature (Cagnie et al., 2004; Hurwitz et al., 2004; Thiel et al., 2007; Rubinstein et al., 2008; Eriksen et al., 2011; Bronfort et al., 2012; Walker et al., 2013). A recent randomized clinical trial (RCT) investigated the occurrence of AE associated with usual chiropractic care (primarily manipulation, soft tissue therapy, range of motion exercises, and mobilization) compared to sham treatment. Among adults aged 20–85 with spine pain, the authors found no difference in relative risk. Further, the authors concluded that AE after chiropractic treatment

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may likely be the result of natural history variation and nonspecific effects (Walker et al., 2013). While the exercise literature has more studies of AE among older adults, it too suffers from under-reporting. One systematic review examined trials investigating progressive strength training in adults over 60 years of age (Liu and Latham, 2010). Among 121 studies identified, 68 assessed AE, 43 of which reported that AE occurred. The majority of AE were musculoskeletal in nature, including muscle strain and joint pain. Serious AE were more rare, and were most commonly falls and cardiovascular events.

AE were systematically collected on a sub-sample of individuals participating in an RCT performed by our group, comparing the effectiveness of spinal manipulative therapy and exercise interventions among seniors with chronic neck pain (Maiers et al., 2013). The purpose of this paper is to report on the AE that were recorded, including occurrence, categorization by seriousness, and type of adverse event by intervention group. Additionally, patients' qualitative experiences with AE are described.

2. Methods

An RCT was conducted to determine the relative short- and long-term effectiveness of spinal manipulative therapy with home exercise (SMT with home exercise), supervised rehabilitative exercise and home exercise (supervised plus home exercise), and home exercise alone for seniors with neck pain (Maiers et al., 2007). Participants needed to have a primary complaint of weekly, mechanical neck pain with an average rating of ≥ 3 (0–10) over the previous two weeks. Additional inclusion criteria consisted of age 65 years or older, independent ambulation and community dwelling, stable pain medication, and a score of ≥ 20 on the Folstein Mini-Mental State Examination (Folstein et al., 1975).

Approval for the trial was granted by the institutional review boards of all participating institutions. Informed consent was obtained from all participants. Risks described in the consent form included pain and muscle soreness with any of the treatments. In addition, it was noted that, while rare, cervical spinal manipulation had been associated with vertebralbasilar stroke (Cassidy et al., 2008).

2.1. Home exercise

Home exercise consisted of four, 45–60 min sessions provided by 9 practitioners (exercise therapists or chiropractors) certified by study investigators to give instruction on standardized exercises and patient education (Maiers et al., 2007). Sessions included basic pain management and postural information and practical demonstrations of body mechanics for common activities of daily living. Simple neck and back exercises to improve flexibility, balance, and coordination were demonstrated and prescribed to do daily at home (American Geriatrics Society Panel on Exercise and Osteoarthritis, 2001). These exercises were individualized based on patient ability and included graded progressions once 20 repetitions of an exercise could be done with proper form.

2.2. Spinal manipulative therapy

Spinal manipulative therapy (SMT) was delivered by 11 chiropractors with a minimum 5 years of clinical practice (Maiers et al., 2007). Areas of the cervical spine treated were identified by pain provocation (Seffinger et al., 2004) and static/motion palpation (Haldeman, 1983) findings. Treatment consisted primarily of manual SMT to induce joint motion, using a diversified, thrust technique. Mobilization, a low velocity type of joint oscillation, was less frequently employed (Peterson & Bergmann, 2011). The patient

position, provider contact, and level of force applied were modified to accommodate the age and physical condition of the study participants. Adjunct therapies included limited use of light soft tissue massage, assisted stretching, and hot and cold packs applied to the cervical and upper thoracic area. The number and frequency of treatments was determined by the individual chiropractor, with a maximum of 20 visits.

2.3. Supervised rehabilitative exercise

Supervised rehabilitative exercise consisted of 20, 1-h exercise sessions supervised by one of 9 exercise therapists certified to deliver the intervention by study investigators (Maiers et al., 2007). Exercises were individualized according to patients' abilities in terms of load and repetitions. Supervised exercise sessions expanded on the home exercise program with additional strengthening exercises for the neck and upper torso and progressions to participant tolerance. Exercise therapists supervised each session to monitor form, modify exercises, and provide encouragement to complete repetitions.

2.4. Adverse events data collection

Consistent with CONSORT recommendations (Ioannidis et al., 2004), AE are defined in this paper as "side effects that are harmful."

Several methods were used to collect AE data on study participants, including standardized solicitation by providers, unsolicited reporting by patients as AE occurred, and qualitative interviews. Standardized questions were employed with the entire sample of individuals in the SMT with home exercise group. Due to a delay in protocol implementation, AE questions were collected in a consecutive convenience sub-sample of those in the supervised plus home exercise ($n = 59$) and home exercise alone ($n = 57$) groups. Questions were asked by providers prior to each treatment visit. Inquiry began with, "Did you experience any side effects or problems after the last treatment?" A simple "yes" or "no" response from the patient was elicited. If "yes," the patient was asked to describe their experience, which was recorded in a narrative format in the treatment notes. Interventions were modified if necessary, as per the study provider with consultation from the investigative team. Study participants were also encouraged to report AE as they occurred outside their treatment appointments by contacting study staff. In these instances, study clinicians made contact with the participant to document clinical details.

An AE was classified as "severe" if it resulted in incapacitation for more than 24 h, resulting in loss of work, bed rest, or decreased social activities. An adverse event was defined as "serious" if it resulted in permanent or severe disability, hospitalization, or death (http://www.grants.nih.gov/ClinicalTrials_fdaaa/definitions.htm). Severe and serious AE triggered extensive evaluation to determine possible causal relationship, adjudicated by the principal investigator and co-investigative team, who were not blinded to treatment allocation. All serious AE were reported to the IRB.

Qualitative interviews, conducted with all participants at the end of the 12-week intervention phase, created an additional, incidental opportunity to collect information about AE (Maiers et al., 2007). Assured confidentiality, those who consented to be recorded were asked semi-structured questions about satisfaction with care, perceived change, whether study care was worthwhile, and what was liked most and least about study treatment.

2.5. Analysis

Descriptive statistics were used to analyze baseline and clinical characteristics of study participants, as well as AE data collected

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