

Integrative Acupuncture and Spinal Manipulative Therapy Versus Either Alone for Low Back Pain: A Randomized Controlled Trial Feasibility Study

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ABSTRACT

Objectives: The objective of this study was to assess the feasibility of conducting a large-scale randomized controlled trial (RCT) examining whether an integrative care model combining spinal manipulative therapy (SMT) and acupuncture can lead to better outcomes for low back pain (LBP) than either therapy alone.

Methods: This study was conducted at a complementary and alternative medicine university health center. Participants with acute or chronic LBP were randomized to (1) acupuncture, (2) SMT, or (3) integrative acupuncture and SMT groups. Treatments were provided over 60 days by licensed doctors of chiropractic and acupuncturists. Acupuncture treatments consisted of needling of acupoints combined with electrotherapy, moxibustion, cupping, and Tui Na. SMT used specific contact points on vertebral processes, along with soft tissue therapy and physiotherapy. Primary outcome measures were the Roland-Morris LBP Disability Questionnaire and 0 to 10 Numeric Rating Scale for LBP.

Results: Participants in all 3 groups experienced clinically meaningful improvements in the primary outcome measures; however, no between-group differences in outcomes were apparent.

Conclusions: This study indicated that it is feasible to conduct an RCT to compare the effectiveness of integrative acupuncture and SMT for LBP to either therapy alone. Future studies should include a larger sample to increase the power for detecting clinically meaningful differences between groups. (J Manipulative Physiol Ther 2017;xx:1-13)

Key Indexing Terms: *Low Back Pain; Acupuncture; Spinal Manipulative Therapy; Integrative Therapy*

INTRODUCTION

Low back pain (LBP) is often considered one of the most substantial health care challenges affecting modern society.^{1,2} In the United States, among adults younger than age 65, LBP is the most common cause for chronic or permanent impairment.³ Worldwide, LBP is considered the leading cause of disability.¹ Low back pain also imposes a tremendous financial burden on society. In the US alone, biennial costs for ambulatory services have been estimated to be as high as \$35.7 billion⁴ and indirect costs have been reported to range from \$84.1 to \$624.8 billion.^{2,5}

Integrative health care, which Shankar defines as “integrating and mainstreaming seven other legally sanctioned health systems with allopathy,” has been described as the future model of health care for the 21st century.⁶ Despite more than 1000 randomized controlled trials published on the management of LBP,⁷ the most effective approach still remains unclear. Limitations of conventional medical care in managing this enigmatic condition^{8,9} have led many patients to seek out complementary and alternative medicine (CAM) approaches to care.¹⁰ Acupuncture and spinal manipulative therapy (SMT) are among the most popular CAM therapies sought for LBP management¹¹ and have both been reported to be effective care options in the management of LBP.¹²⁻¹⁴

Although various studies have evaluated the effectiveness of integrative care for LBP, in a recent systemic review of integrative therapies for LBP no studies were found that explored whether a combination of acupuncture and SMT would lead to better outcomes than either intervention alone.¹⁵

Therefore, the primary objective of this study was to assess the feasibility of conducting a large-scale randomized controlled trial (RCT) examining whether an

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integrative care model combining SMT and acupuncture might lead to better outcomes for LBP than either therapy alone. The secondary objective was to collect preliminary data on the effectiveness of an integrative care model combining SMT and acupuncture compared with either therapy alone.

METHODS

Trial Design

This study was a single-site, prospective RCT approved by the Southern California University of Health Sciences Institutional Review Board. This trial was registered with ClinicalTrials.gov as number NCT01357343.

Participants

A total of 101 study participants were recruited from the communities surrounding the study site. Multimethod recruitment strategies were used, including mass mailings, advertisements in local magazines, and flyer distribution. The study was conducted at the Southern California University of Health Sciences.

Inclusion criteria included participants who were 18 years of age or older and had a current episode of LBP. Exclusion criteria included candidates who had received chiropractic or acupuncture treatment within the previous 6 months, or those with the following: visceral, systemic, or joint inflammatory disease; referred pain to the back or pelvis; nonmechanical LBP; history of low back surgery, osteoporosis, spondylolisthesis, coagulation disorder, or use of anticoagulant medication; prolonged use of systemic corticosteroid medication; progressive unilateral lower limb muscle weakness; symptoms or signs of cauda equina syndrome (eg, bowel or bladder dysfunction); severe concurrent illness (eg, cancer, heart diseases, psychiatric disorders); and known pregnancy.

Eligibility Determination and Informed Consent

Potential participants responded to recruitment materials by contacting the research office and were screened for initial eligibility criteria by trained research assistants using a computer-assisted telephone interview module. Participants meeting the eligibility criteria were scheduled for an in-person screening interview and physical examination.

Participants who passed the initial screening received a physical examination by a licensed chiropractic clinical faculty member. Informed consent was obtained from those who passed the screening and consented to participate.

Interventions

In this pragmatic study each provider determined the appropriate course of therapy for assigned participants

within the boundaries of the research framework. All treatments were provided by licensed doctors of chiropractic and acupuncturists with more than 5 years of experience. All treatments were provided at a CAM university health center.

All activities related to study treatments were documented using the health center's standardized treatment records. Participants were directed not to seek additional care for their LBP during the intervention phase. An attempt was made to capture any outside health care visits by asking participants to record them and to notify their assigned clinicians. Clinicians also asked the participants at each visit if there had been visits to any outside health care providers. Furthermore, clinicians asked participants at each visit if there had been any adverse effects from the therapy.

The duration of the intervention phase was 60 days. The frequency of visits was at the discretion of the doctors of chiropractic or acupuncturist assigned to the participant. This varied according to each participant's history and specific clinical condition (eg, history of injury, length of time with LBP, presence of radiation of pain). The number of visits for each participant was recorded and considered in the analysis. Participants were informed that they must attend all of their scheduled treatment sessions.

SMT Group. Doctors of chiropractic provided SMT using specific contact points on vertebral processes in order to improve the biomechanics of their associated joints. The segments to be treated were determined based on static and motion palpation and reports of tenderness to palpation. Adjunctive therapies applied included passive articular mobilization of the lumbosacral spinal joints, paraspinal soft tissue stretching, digital pressure on tender points, and postisometric muscular relaxation procedures. If necessary, physical therapeutic modalities such as heat, cold, ultrasound, and electrical muscle stimulation as well as active care exercises were also used. The typical visit lasted 15 to 30 minutes.

Acupuncture Group. Acupuncture care was based on a traditional Chinese medicine (TCM) approach. Treatment involved acupuncture needling, moxibustion, electrical acupuncture, Tui Na, and cupping. Chinese herbs were excluded because of the added cost and difficulty in guaranteeing quality.

Each clinician selected acupoints based on the TCM diagnosis. The depth of needle insertion ranged between 10 and 30 mm depending on the location of acupoints and body build. Needles were inserted and manually stimulated at the body points until the *de qi* sensation of heaviness and numbness was elicited, usually 5 to 20 seconds. Needles were left in situ for 30 minutes. The needles used were stainless steel, sterilized Seirin J type (Seirin America, Weymouth, MA) with guide tubes. Needles were 0.25 mm

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