OBSTETRICS

A randomized controlled trial comparing a multimodal intervention and standard obstetrics care for low back and pelvic pain in pregnancy

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OBJECTIVE: Women commonly experience low back pain during pregnancy. We examined whether a multimodal approach of musculoskeletal and obstetric management (MOM) was superior to standard obstetric care to reduce pain, impairment, and disability in the antepartum period.

STUDY DESIGN: A prospective, randomized trial of 169 women was conducted. Baseline evaluation occurred at 24-28 weeks' gestation, with follow-up at 33 weeks' gestation. Primary outcomes were the Numerical Rating Scale (NRS) for pain and the Quebec Disability Questionnaire (QDQ). Both groups received routine obstetric care. Chiropractic specialists provided manual therapy, stabilization exercises, and patient education to MOM participants.

RESULTS: The MOM group demonstrated significant mean reductions in Numerical Rating Scale scores (5.8 ± 2.2 vs 2.9 ± 2.5; $P < .001$) and Quebec Disability Questionnaire scores (4.9 ± 2.2 vs 3.9 ± 2.4; $P < .001$) from baseline to follow-up evaluation. The group that received standard obstetric care demonstrated no significant improvements.

CONCLUSION: A multimodal approach to low back and pelvic pain in mid pregnancy benefits patients more than standard obstetric care.

Key words: back pain, exercise, manipulation, pregnancy

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Musculoskeletal pain in pregnant women commonly is viewed as transient, physiologic, and self-limited. However, most women report either low back pain (LBP) or pelvic pain (PP) during pregnancy[1-6] and the morbidity that is associated with such complaints.[7,8] Moreover, up to 40% of patients report musculoskeletal pain during the 18 months after delivery,[2,7,9,10] and one-fifth of these women have severe LBP that leads to major personal, social, or economic problems.[7,9,11] Pregnancy-related LBP contributes substantially to health care costs. For example, one-fifth of pregnant women in Scandinavian countries experience back pain as an indication for up to 7 weeks of sick leave in the perinatal period.[7,9] Ninety-four percent of women who experienced LBP in an index pregnancy have recurrent symptoms with subsequent pregnancy, and two-thirds of these patients experience disability and require sick leave during pregnancy. Notably, 19% of women with pain in an initial pregnancy report avoidance of a future pregnancy out of fear of recurrence of the musculoskeletal symptoms.[11]

Most past investigations that have evaluated interventions to reduce morbidity in women with LBP/PP during pregnancy have used modalities that have included prescription exercise,[12] manual manipulation,[13] education,[14] acupuncture,[15] or pelvic belts.[16] Recently, a multimodal randomized trial compared osteopathic manipulation to usual obstetric care and sham ultrasonic therapy on 144 participants.[13] Importantly, this trial did not include behavioral and exercise therapies. We conducted a prospective, randomized, masked clinical trial to test the hypothesis that a multimodal approach of manual therapy, exercise, and education for LBP/PP in pregnant women is superior to standard obstetric care

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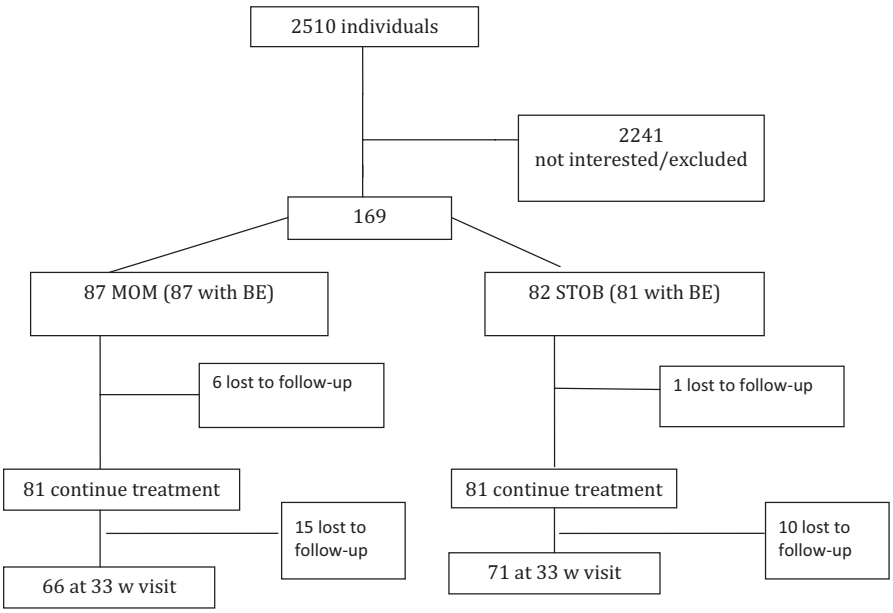
FIGURE
Consolidated Standards of Reporting Trials diagram illustrates the flow of patients through the trial



BE, baseline; *MOM*, multimodal musculoskeletal and obstetric management; *STOB*, standard obstetric care; *W*, week.
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(STOB) for the reduction of pain, impairment, and disability in the antepartum period.

Materials and Methods

The institutional review boards of Logan University, College of Chiropractic, St. Louis, MO, and Washington University School of Medicine, St. Louis, MO, approved this study. Subjects were recruited from 3 clinical settings. The Women's Health Center included a state-approved collaborative practice of Washington University attending physicians and nurse practitioners who worked with residents in obstetrics and gynecology and maternal fetal medicine fellows to serve both high- and low-risk patients, regardless of payer status. The 2 additional sites were university-affiliated private practices that were staffed by nurse practitioners, board-certified or board-eligible obstetrician-gynecologists, perinatologists, or a combination of these.

The study design is outlined in the Figure. Patients 15-45 years old with a single fetus from 24-28 weeks' gestation were evaluated by their obstetric provider for LBP, PP or both. Gestational age was calculated with a last menstrual period that corroborated with a first- or second-trimester ultrasound evaluation. Candidate patients with symptoms were screened by a dedicated study coordinator to identify exclusion criteria that included acute inflammatory disease, acute infectious disease, chronic back pain for >8 weeks before pregnancy, a mental health disorder, back pain from visceral disease, ongoing treatment for previous back pain, peripheral vascular disease, substance abuse, or litigation pending from back pain. Patients were not excluded if they had lower extremity neurologic symptoms or radiculopathy. A single, masked chiropractic specialist conducted the baseline evaluation (BE) with eligible volunteers before randomization. A blocked-randomization scheme was used across the 3 locations. With the use of an online Web Data Entry System that uses a computer-generated list of randomized numbers, subjects were allocated to the STOB group or the STOB plus multimodal musculoskeletal and obstetric treatment (MOM) group.[17,18]

Three subjective questionnaires and 4 physical tests were used to quantify pain, disability, and physical function at the 24- to 28-week BE. Current pain levels were assessed by the numeric rating scale (NRS), which is a subjective pain assessment tool that uses a rating of zero for no pain to a rating of 10 for a maximum level of pain.[19] The Quebec task force disability questionnaire (QDQ) assessed the impact of pain. The personal pain history (PPH) detailed the previous course and features of pain complaints.[20] The physical assessments to identify the origin of pain included the straight leg raise (SLR), posterior PP provocation test, active SLR, and long dorsal ligament test.[21-24] These assessment tests commonly are used for lumbar and pelvic examinations.

Patients in the STOB group received total care from a self-chosen obstetric provider who had the discretion to recommend ≥1 of the following remedies: rest, aerobic exercise, heating pad application for a maximum length of 10 minutes, use of acetaminophen for mild pain, or narcotics for discomfort unrelieved by other measures. Referral to orthopedic or neurologic services was used for cases in which pain was debilitating or unresponsive to standard modalities.

Like the STOB group, the frequency of obstetrics visits for patients in the MOM group was also dictated by their self-chosen obstetrics providers. The MOM group additionally had weekly visits with a chiropractic specialist who provided education, manual therapy, and stabilization exercises, based on the biopsychosocial model.[14] The biopsychosocial model explains that a patient's pain syndrome is not comprised solely of the injured body structure but also includes psychologic and social components, such as fear of movement and high pain expectancy. Patients were reassured the pain experienced was unlikely pathologic and that reactivation of joint and muscle mobility by exercise would likely improve symptoms and signs without posing risk to the patient or her fetus. The goal of manual therapy was to restore joint motion and reduce muscle