OBSTETRICS

Pregnancy Research on Osteopathic Manipulation Optimizing Treatment Effects: the PROMOTE study

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OBJECTIVE: The purpose of this study was to evaluate the efficacy of osteopathic manipulative treatment (OMT) to reduce low back pain and improve functioning during the third trimester in pregnancy and to improve selected outcomes of labor and delivery.

STUDY DESIGN: Pregnancy research on osteopathic manipulation optimizing treatment effects was a randomized, placebo-controlled trial of 400 women in their third trimester. Women were assigned randomly to usual care only (UCO), usual care plus OMT (OMT), or usual care plus placebo ultrasound treatment (PUT). The study included 7 treatments over 9 weeks. The OMT protocol included specific techniques that were administered by board-certified OMT specialists. Outcomes were assessed with the use of self-report measures for pain and back-related functioning and medical records for delivery outcomes.

RESULTS: There were 136 women in the OMT group: 131 women in the PUT group and 133 women in the UCO group. Characteristics at baseline were similar across groups. Findings indicate significant treatment effects for pain and back-related functioning ($P < .001$ for both groups), with outcomes for the OMT group similar to that of the PUT group; however, both groups were significantly improved compared with the UCO group. For secondary outcome of meconium-stained amniotic fluid, there were no differences among the groups.

CONCLUSION: OMT was effective for mitigating pain and functional deterioration compared with UCO; however, OMT did not differ significantly from PUT. This may be attributed to PUT being a more active treatment than intended. There was no higher likelihood of conversion to high-risk status based on treatment group. Therefore, OMT is a safe, effective adjunctive modality to improve pain and functioning during the third trimester.

Key words: low back pain, osteopathic manipulation, pregnancy

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Low back pain (LBP) is encountered in an estimated 70% of pregnant patients,[1,2] but challenges persist in the identification of safe, effective treatment options. For example, most pain medications are not recommended during pregnancy, which leaves few options for pain control. Osteopathic manipulative treatment (OMT) is a body-based treatment that offers a conservative, noninvasive option for relieving pregnancy-related LBP while increasing back-related function.

OMT is defined as "the therapeutic application of manually guided forces by an osteopathic physician to improve physiologic function and/or support homeostasis that has been altered by somatic dysfunction."[3] Pregnancy brings dramatic musculoskeletal changes that alter normal biomechanics that are accompanied by ligamentous strain, increased muscle tension, and decreased range of motion and pain. OMT treats somatic dysfunctions with a variety of techniques, thereby increasing range of motion, improving tissue texture, and decreasing pain.[4-8]

Studies of OMT for LBP in nonpregnant populations have provided sufficient evidence of safety and efficacy for the establishment of practice guidelines for the recommendation of OMT for LBP.[9] Those studies reported greater pain relief, improved physical functioning, and reduced pain medication use with OMT compared with subjects who did not receive manipulation.[10-12] Because of the unique biomechanical changes during pregnancy, it was not

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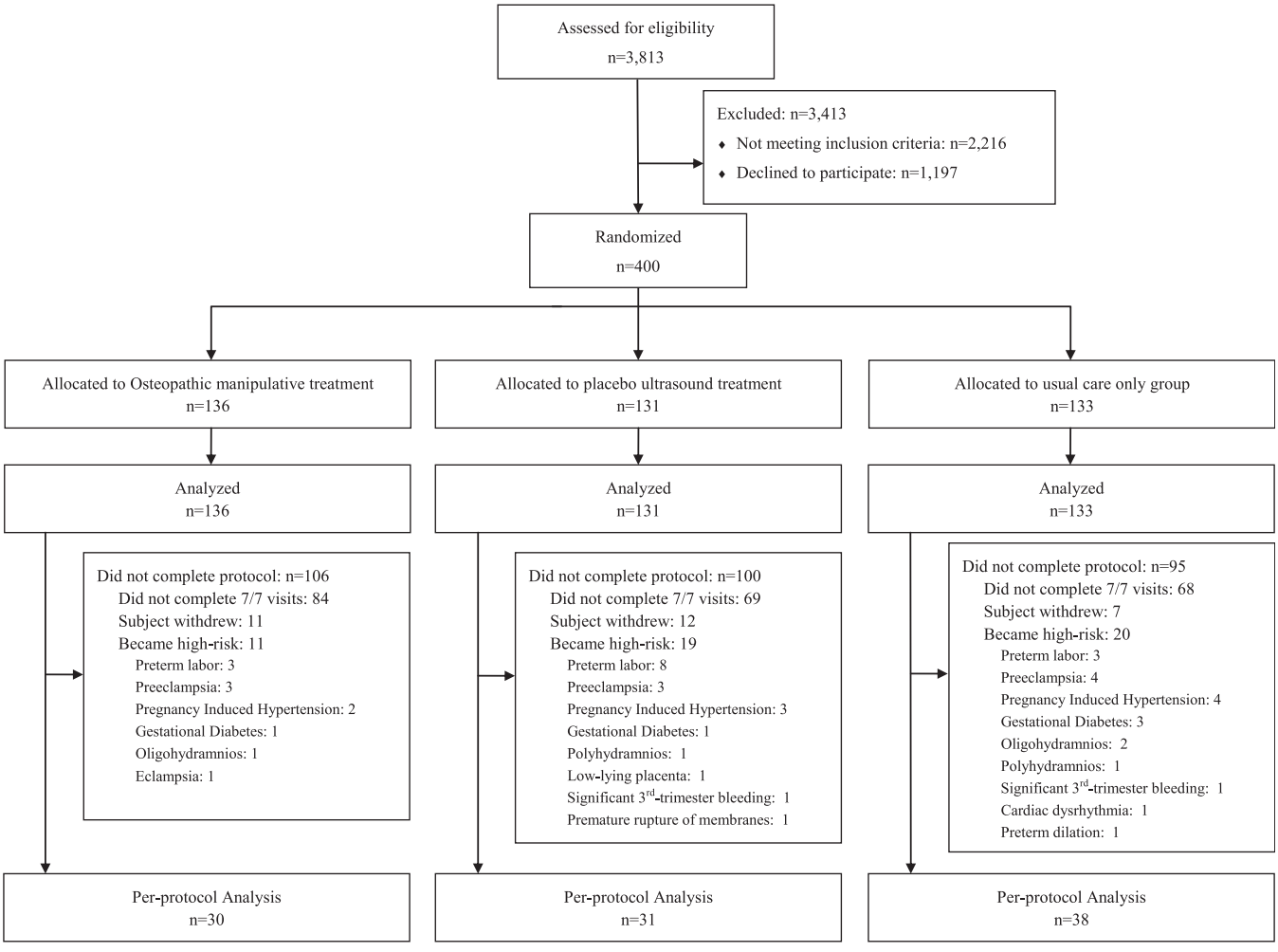
known if OMT would produce the same positive outcomes in pregnant women with LBP, although a pilot study found a slowing of decline in functional status.[13]

The Pregnancy Research in Osteopathic Manipulation Optimizing Treatment Effects (PROMOTE) study was designed to evaluate the efficacy of a 9-week regimen of OMT to reduce LBP during the third trimester. The primary objective was to evaluate the influence of OMT on self-reported pain and back-related functioning. A secondary objective was to corroborate an earlier study that found a relationship between receiving OMT during the third trimester and a decrease in meconium-stained amniotic fluid. We chose to examine this relationship based on a supposition that reducing maternal stress that is caused by pain may reduce meconium-staining, which is a potential objective measure of fetal stress.[14]

Materials and Methods

PROMOTE was a randomized, controlled clinical trial. Study visits were conducted from 2007-2011, at 3 Obstetrics and Gynecology clinics in Tarrant County, TX. The Institutional Review Boards at the University of North Texas Health Science Center and John Peter Smith Health Network approved the study. Clinic personnel referred interested women to the research coordinators for screening. Eligible women 18-35 years old who had reached gestational week 30 and were willing to participate were consented and enrolled (Figure 1). Women with high-risk conditions, as determined by their obstetrics provider, were excluded. High-risk conditions included, but were not limited to, preeclampsia/eclampsia, vaginal bleeding, oligohydramnios, gestational diabetes mellitus, and hypertension. Women were withdrawn from the study if their obstetrics provider identified a high-risk condition during their participation. Women were also unable to continue in PROMOTE if

FIGURE 1
Flow chart



Flow chart of women through the pregnancy research on osteopathic manipulation optimizing treatment effects trial.

Hensel. Osteopathic manipulation for LBP in pregnancy. Am J Obstet Gynecol 2015.

they reported using other body-based therapies including additional OMT, massage, physical therapy, or chiropractic therapy during the study. Obstetrics providers included physicians (medical doctors or doctors of osteopathy), certified nurse midwives, and women's health nurse practitioners; all providers were blinded to study group assignment. Providers knew that their patient was participating in the study, but both subject and provider were asked to not discuss the study or treatments. Study subjects were compensated for their time and travel.

After consent was obtained, subjects were assigned randomly to 1 of 3 groups: OMT, placebo ultrasound treatment (PUT), or usual obstetric care only (UCO). A computer-generated randomization program was used to allocate women in blocks of 15, by clinic location, to each of the 3 treatment groups. At the first study visit, the research coordinator collected baseline data. Then the OMT specialist opened the randomization envelope to reveal the subject's group assignment and provided the assigned treatment.

PROMOTE included 7 study visits that were scheduled to correspond with ongoing routine prenatal care at weeks 30, 32, 34, 36, 37, 38, and 39. Study visits occurred within 24 hours after routine prenatal appointments. The research coordinator scheduled each study appointment, confirmed medical clearance from the obstetrics provider, and collected data before treatment.

Both the OMT and PUT protocols addressed the same specific body regions that had been chosen for their relationship to common musculoskeletal changes in pregnancy that included bilateral cervical, thoracic, and lumbar paraspinal musculature; thoracolumbar junction; sacroiliac joint; hip, and anterior pelvis. Both OMT and PUT treatments were applied over clothing. OMT consisted of approximately 20 minutes of treatment provided by a physician board-eligible or certified by the American Osteopathic Board of Neuromusculoskeletal Medicine and trained in the PROMOTE protocol (Table 1). Each

TABLE 1
Summary of osteopathic manipulative treatment techniques applied in PROMOTE

Technique	Description
Seated thoracic articulation	• Patient's arms rest on physician's chest; physician reaches around patient to contact the articular pillars, then the rib heads.
	• Thorax is extended and side bent/rotated as necessary for articulation.
Cervical soft tissue	• Apply kneading, traction, inhibition, and/or stretching to cervical muscles.
Occipito-atlantal decompression	• Contact is near the occipital condyles with sustained anterior, lateral, and cephalad tension.
Thoracic inlet myofascial release	• Contacting the clavicles, upper thoracic spine, and ribs, the fascia is assessed in rotation, side-bending, and forward/backward bending motions.
	• Tissues are positioned either directly or indirectly and held until released.
Lateral recumbent scapulothoracic soft tissue	• With positioning to isolate the scapula, kneading, traction, and/or stretching are applied rhythmically to the musculature medial to the scapula.
	• Positioning is altered to contact the posterior axillary fold, with kneading, inhibition, and stretching are applied rhythmically.
Lateral recumbent lumbar soft tissue	• Kneading, lateral, rotational, and longitudinal stretching are applied in a rhythmic motion to the lumbar paraspinal musculature.
Abdominal diaphragm myofascial release	• With a lateral contact over the lower ribs, the motion of the diaphragm is assessed in rotation, side-bending, and forward/backward bending motions.
	• Tissues are taken either directly or indirectly and held until released.
Pelvic diaphragm myofascial release	• With anterior contact just superior to the pubic symphysis and posterior contact at the level of the coccyx and ischial tuberosities, the motion of the pelvic diaphragm is assessed in rotation, side-bending, and forward/backward bending motions.
	• Tissues are taken in either a direct or indirect position until released.
Sacroiliac articulation	• Hip and knee are flexed, with the leg supported.
	• Compression is applied through the knee to engage the femur into the acetabulum.
	• The leg is rotated internally and circumducted then externally rotated and circumducted several times, while maintaining compression
Pubic symphysis decompression	• Patient is in a supine position with the physician at the side of the patient.
	• Hips and knees are flexed, with feet together on the table.
	• Muscle energy is applied, first with the knees pulled apart against resistance then being pulled together against resistance.

Hensel. Osteopathic manipulation for LBP in pregnancy. Am J Obstet Gynecol 2015. *(continued)*

TABLE 1
Summary of osteopathic manipulative treatment techniques applied in PROMOTE *(continued)*

Technique	Description
Frog-leg sacral release	• Hips and knees are flexed, with feet together on table.
	• Physician's contact is cupping the sacrum with fingers at the base.
	• Sacrum is held at a balance point as the legs are externally rotated.
	• Inferior traction is applied while maintaining balance, and legs are straightened with the heels sliding down the table.
Compression of the fourth ventricle (CV4)	• Contact medial to the occipital-mastoid suture with thenar eminences
	• Encourage the occipital motion in extension phase, while resisting flexion until a still point is reached.
	• Allow the cranial rhythmic impulse to return to normal before disengaging.

PROMOTE, Pregnancy Research in Osteopathic Manipulation Optimizing Treatment Effects study.

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OMT technique was performed on every subject for 1-2 minutes until an adequate tissue response was felt.

The PUT provided tactile and manual stimulation over the same regions as OMT. The ultrasound wand was applied with a circular, steady contact for approximately 2 minutes to each of the specified areas, which resulted in treatment duration similar to OMT. Although the ultrasound machine provided credible cues, such as a ticking timer or digital display, the machines were set to not emit any ultrasound waves.

The UCO group completed study questionnaires but received no study interventions nor additional time or interaction with the treating physician.

There were 2 primary outcomes for PROMOTE: pain and back-related functioning. LBP was measured with the Quadruple Visual Analog Scale, a self-reported reliable measure of 4 aspects of pain (now, average, worst, and best), that was used to calculate characteristic pain intensity (CPI).[15] The CPI is a composite score reported on a scale of 0 to 100; higher values indicate higher pain. Back-related functioning was measured with the Roland-Morris Low Back Pain and Disability Questionnaire, a validated 24-item self-reported questionnaire for which higher scores indicate greater functional disability and sensitivity to change over time.[16-18] Labor and delivery records provided information for secondary outcomes. After delivery, the research coordinator collected data from the subject's medical records. All data were collected in paper form and transferred to an electronic dataset with the use of double data entry. Subjects completed the Short Form 12 version 2 Health Survey at the beginning of the study to estimate general health at baseline. Collected demographic information included race, ethnicity, age, weight, height, and parity.

Sample size calculations for primary outcomes indicated a sample size of 71 per treatment group would be needed to detect a 30% change in pain outcomes; however, this was less restrictive than the sample size required for the planned secondary outcome of meconium staining. Thus, calculations based on the secondary outcome were used for final sample size estimates. A sample size of 110 subjects per treatment group was estimated for 80% power at a 5% significance level ($P < .05$) to detect a 62% reduction in the incidence of meconium staining. The incidence and percent reduction estimate was based on a retrospective case-control study finding of a lower incidence of meconium staining in women who received OMT compared with a control group.[14] To allow for study attrition, the target recruitment goal was 400 subjects.

Data management and analyses were performed with the statistical software package IBM SPSS (version 19.0; IBM Corp, Armonk, NY). Demographic characteristics were described by frequencies and percentages for categoric data and by means and standard deviations for continuous data. Between-group comparisons were computed with the chi-square test for categoric data and analysis of variance for continuous data. Primary outcomes were analyzed with the use of a linear mixed model that was suitable for repeated measures with fixed effects for treatment group and treatment visit, which included an interaction term for treatment group and visit. For each of these variables, change from baseline was calculated and used as the data point for that visit. To address differences in baseline pain and disability, which might influence rates of change, models were adjusted for baseline values. Post-hoc analyses with Bonferroni adjustment were used to elucidate pairwise differences between treatment groups when main effects were detected. The linear mixed model analysis allowed for the use of all available data without censoring or imputation. Analysis was first performed with an intention-to-treat approach. An additional per-protocol analysis was performed on subjects who completed all 7 treatment visits. Finally, logistic regression was used for analysis of the secondary outcome of meconium staining.

RESULTS

In PROMOTE, a total of 400 subjects were enrolled and assigned randomly to groups. As shown in Figure 1, there were 136 women (34%) assigned to OMT, 131 women (33%) assigned to PUT, and 133 women (33%) assigned to UCO. Of these 400 women, 99 women (25%)

completed all 7 treatment visits and were considered to have completed the protocol.

Baseline characteristics were similar across groups with the exception of body mass index (BMI; Table 2). The OMT group had a lower mean prepregnancy BMI than the other 2 groups. Table 3 shows that baseline pain and functioning were similar among the 3 groups; except on pain subscales at baseline, the OMT group reported higher levels of "pain now" than the PUT group and higher levels of "pain at best" than the UCO group.

Analysis of primary outcomes used an intention-to-treat model to examine changes in pain and back-related functioning for each group across the study (n = 400). The intention-to-treat analysis included all randomly assigned subjects, regardless of the number of visits completed. These findings indicated significant treatment effects for both pain as assessed by CPI and back-related functioning as assessed by Roland-Morris Low Back Pain and Disability Questionnaire ($P < .001$ for both). Specifically, OMT was effective for mitigating the progression of pain and deterioration of back-related functioning compared with the UCO group.

For each of the outcomes, the OMT group either demonstrated improvement or remained stable across time (Figure 2). In contrast, the UCO group experienced worsening pain and functioning. Although there was an effect of treatment and OMT was different from UCO, it is important to note that OMT outcomes did not differ significantly from those of the PUT group (Table 4). The addition of baseline BMI, maternal age, and parity adjustments into the model yielded findings that were consistent with the nonadjusted analysis.

Although the study was designed to include 7 visits, it was expected that some participants would not be able to make all visits; 44% of them delivered by 39 weeks of gestation. Therefore, we investigated whether adherence to the protocol influenced findings by performing per-protocol analysis for subjects who received all 7 treatments and an analysis for those who received at least 4 of 7 treatments, which had previously been shown to be a therapeutic dose.[14] Results for the 99 women who completed all 7 visits as planned and the 357 women who completed at least 4 visits were consistent with the intention-to-treat findings for significant treatment effect.

Analyses of secondary outcomes focused on objective delivery measures. For the 329 women with available delivery information, only 61 women (18.5%) had meconium staining documented. Logistic regression indicated meconium staining was not influenced by treatment group; the overall model was not significant ($P = .611$). Analysis of gestational age at delivery indicated no difference based on group, with mean gestational age of 39 weeks 2 days. Conversion to high-risk status occurred for 12.5% of the women (OMT, 11; PUT, 19; UCO, 20). In a logistic regression model that used conversion to high-risk status as an indirect measure of safety, there was no higher likelihood of conversion to high risk based on treatment group ($P = .141$).

Comment

The primary objective of PROMOTE was to investigate whether adding OMT to UCO mitigated the progression of LBP and improved back-specific functioning during the third trimester. Our results show that OMT has benefits compared with UCO and demonstrate clinically and statistically significant

TABLE 2
Characteristics of subjects by study group

Variable	Osteopathic manipulative treatment (n = 136)	Placebo ultrasound treatment (n = 131)	Usual care only (n = 133)	*P* value
Age, y[a]	23.99 ± 4.13	24.11 ± 4.10	24.70 ± 4.54	.351
Marital status, n (%)				
Single	62 (45.6)	64 (48.9)	58 (43.6)	.712
Married	65 (47.8)	61 (46.6)	70 (52.6)	
Divorced or separated	9 (6.6)	6 (4.6)	5 (3.8)	
Race/ethnicity, n (%)				
White	32 (23.5)	36 (27.5)	31 (23.5)	.972
Black	25 (18.4)	23 (17.6)	22 (16.7)	
Hispanic	76 (55.9)	69 (52.7)	77 (58.3)	
Other	3 (2.2)	3 (2.3)	2 (1.5)	
Education level, n (%)				
Grade school	11 (8.2)	11 (8.4)	8 (6.1)	.761
High school	75 (56.0)	69 (52.7)	67 (50.8)	
Some college and above	48 (35.8)	51 (38.9)	57 (43.2)	
SF-12v2 Health Survey score[a]	37.43 ± 7.22	38.96 ± 7.30	38.74 ± 7.08	.185
Baseline body mass index, kg/m^2[a,b]	25.51 ± 4.56	27.50 ± 6.44	27.54 ± 6.61	.028
Weight gain, kg[a,b]	14.57 ± 6.48	15.14 ± 6.63	13.40 ± 7.27	.211
Nulliparous, n (%)	41 (34.2)	37 (35.6)	32 (29.9)	.658

[a] Data are given as mean ± standard deviation; [b] Data were missing for 30% of cases.

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TABLE 3
Baseline measurements of back pain and functioning

Variable	Osteopathic manipulative treatment (n = 136)	Placebo ultrasound treatment (n = 131)	Usual care only (n = 133)	*P* value
Roland Morris Disability Questionnaire[a]	6.70 ± 4.97	5.90 ± 4.68	6.55 ± 5.09	.375
Characteristic Pain Intensity[b]	53.38 ± 20.33	48.53 ± 20.13	49.21 ± 19.82	.103
Pain now	3.49 ± 2.54	2.75 ± 2.42[c]	2.93 ± 2.21	.030
Pain average	5.07 ± 2.39	4.71 ± 2.34	4.78 ± 2.41	.430
Pain best	2.49 ± 2.04	2.02 ± 1.80	1.65 ± 1.92[c]	.002
Pain worst	7.46 ± 2.36	7.12 ± 2.32	7.08 ± 2.17	.334

Data are given as mean ± standard deviation.

[a] The summary score (range between 0—24) is the unit of measure of the Roland Morris instrument (http://www.rmdq.org); [b] Score based on the visual analog scales, and does not have a unit of measure; [c] Different from osteopathic manipulative treatment.

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improvements in pain and back-related functioning scores.

Overall, the UCO group experienced increasing pain and decreasing function during the course of the study; the OMT and PUT groups' pain and functioning did not deteriorate. These findings were consistent, even when potential confounders such as BMI, maternal age, and parity were considered. In addition, incidences of conversion to high-risk status and meconium staining were not higher in the OMT group, which suggests that there is no additional risk associated with OMT for pregnant women in the third trimester. Additionally, there were fewer conversions to high-risk status in the OMT group, which may be clinically important, even though it was not statistically significant. A more nuanced examination of the plausible protective nature of OMT is warranted.

A secondary objective was to attempt to elucidate the mechanism by which OMT may cause benefit; therefore, the study was designed with a placebo group that would be controlled for some of the potentially therapeutic components of the OMT group. Our results failed to show differences between the OMT and PUT groups, which may indicate that the common treatment components of time, touch, intention, and interaction may be at least partially responsible for the observed beneficial effects.

Strengths of PROMOTE are that it is 1 of the largest randomized controlled trials ever conducted on the effectiveness of OMT and that it addressed pregnant women as a unique population. Other strengths include the use of reliable and valid questionnaires for pain and function, objective delivery outcomes, and close supervision by the obstetrics provider to ensure safety. Analysis included both intention-to-treat and per-protocol analyses and utilized a linear mixed model, which is less sensitive to censoring and missing data, to detect treatment effects. An important limitation was a higher than expected attrition rate in all groups. Of the 400 enrolled subjects, 99 women (24.75%) completed the 7-visit protocol. Although 80 women (20%) became ineligible or declined to continue, additional attrition was related to missed visits and delivery at <39 weeks of gestation, which results in a less than robust sample for the detection of effects in low-frequency outcomes such as conversion to high-risk status and meconium staining.

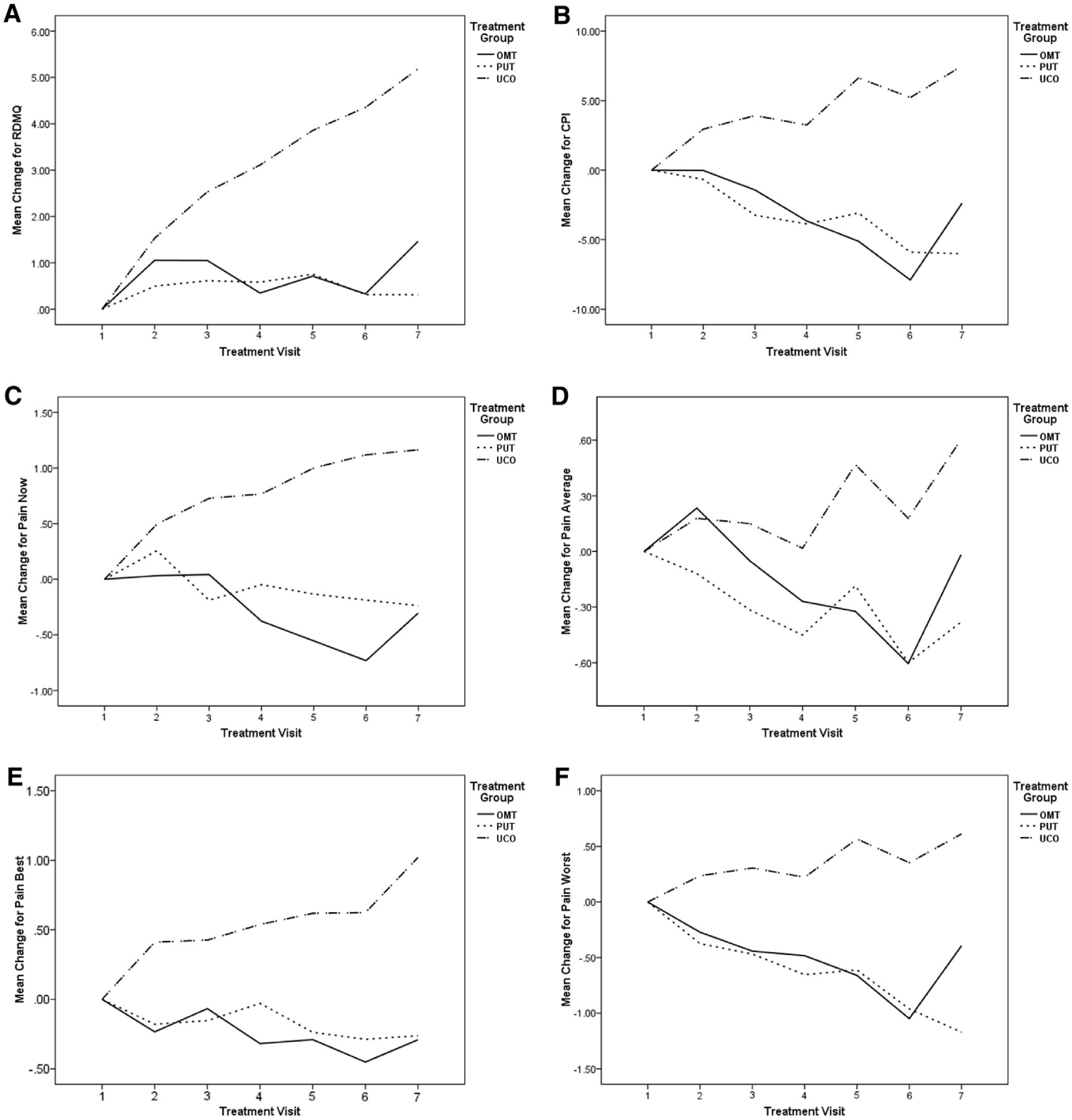
The specific OMT protocol designed for this study includes both strengths and limitations. It includes a standardized set of techniques that could be applied in a clinical or research setting, and each technique is described in contemporary osteopathic literature.[19-23] However, this protocol is a departure from the OMT provided by a physician in a clinical setting that would be customized to fit the specific musculoskeletal diagnoses of each patient. This may have resulted in suboptimal treatment for subjects who may have had better response with individualized treatment.

Including and selecting a placebo in manual therapy research is challenging, especially where outcome may be affected by many factors such as touch, time, intention, interaction, and expectation of benefit.[24] In designing PROMOTE, we reviewed placebo research and chose subtherapeutic ultrasound scanning because it has been shown to be credible.[25] We expected that PUT would be inert because the machines were not actually emitting any waves. However, since the study began in 2007, much research has been done on placebo potency, and we now suspect that components of PUT likely caused a therapeutic response, even though other studies have not shown the same degree of placebo effect.[13] In this trial, all treatments were provided by the same OMT specialists and contained study visit elements of assessment and observation, therapeutic ritual, and a supportive patient-practitioner relationship that have been found to contribute additively to a significant effect.[24] In addition, the repetitive pressure from the ultrasound wand, in combination with the friction that resulted from the contact on skin or clothing (without gel) may have affected the selected areas similar to light-to-moderate pressure massage, which has also been shown to decrease LBP in pregnancy.[26]

There have been few studies of the safety and efficacy of OMT during pregnancy for LBP, and previous research failed to detect reduction in pain or in the incidences of various high-risk outcomes.[13] PROMOTE has confirmed earlier findings of safety and the slowing of progression of back-related disability and demonstrated

FIGURE 2

Mean changes in self-reported pain and back functioning for each group by study visit



A, For Roland Morris Disability Questionnaire (*RDMQ*), there was an effect for treatment group, time, and interaction (all $P < .001$). **B,** For characteristic pain intensity (*CPI*), there was an effect for treatment group, time, and interaction ($P < .001$, $= .048$, and $< .001$, respectively). **C,** For "Pain Now," the treatment group was significant ($P < .001$), but not time ($P = .139$); however, there was an interaction for group and time ($P < .002$). **D,** For "Pain Average," both treatment group and time were significant ($P = .004$ and .012, respectively); however, the interaction was not ($P = .185$). **E,** For "Pain Best," treatment group was significant ($P < .001$), but not time ($P = .845$); however, there was an interaction for group and time ($P = .001$). **F,** For "Pain Worst," there were differences for treatment group, time, and interaction ($P < .001$, $= .004$, and $< .001$, respectively).

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TABLE 4
Primary outcomes estimated in a linear mixed effects model adjusted for baseline

Variable	Osteopathic manipulative treatment (n = 136)	Placebo ultrasound treatment (n = 131)	Usual care only (n = 133)	Difference between groups: Osteopathic manipulative treatment and placebo ultrasound treatment — Mean (95% confidence interval)	P value	Difference between groups: Osteopathic manipulative treatment and usual care only — Mean (95% confidence interval)	P value
Roland Morris Disability Questionnaire[a]	0.676	0.469	2.926	0.21 (−0.73 to 1.14)	> .999	−2.25 (−3.18 to −1.32)	< .001
Characteristic Pain Intensity[b]	−3.341	−3.488	3.769	0.15 (−3.07 to 3.36)	> .999	−7.11 (−10.30 to −3.93)	< .001
Pain now	−0.299	−0.034	0.707	−0.27 (−0.70 to 0.17)	.439	−1.01 (−1.44 to −0.57)	< .001
Pain average	−0.205	−0.364	0.175	0.16 (−0.24 to 0.56)	> .999	−0.38 (−0.78 to 0.02)	.065
Pain best	−0.202	−0.154	0.478	−0.05 (−0.38 to 0.28)	> .999	−0.68 (−1.00 to −0.36)	< .001
Pain worst	−0.482	−0.641	0.296	0.16 (−0.22 to 0.54)	.946	−0.78 (−1.15 to −0.4)	< .001

Values are estimates for mean change in pain, and probability values are pairwise comparisons with the use of Bonferroni adjustment.

[a] The summary score (range between 0—24) is the unit of measure of the Roland Morris instrument (http://www.rmdq.org); [b] Score based on the visual analog scales, and does not have a unit of measure.

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significance for pain outcomes. With few options for safely treating LBP during pregnancy, these findings are clinically meaningful. A common treatment for LBP is acetaminophen (paracetamol); however, considering the recent controversy that associated acetaminophen use during pregnancy with childhood asthma, adverse neurodevelopmental outcomes, and serious skin reactions,[27-30] it emphasizes the need to provide safe, effective, noninvasive treatments for women who seek nonpharmacologic options to reduce pain and increase back-related function. Based on these findings, obstetrics providers should consider adding body-based treatments for LBP into the care of pregnant women. Although OMT may be an important option, there are few board-certified OMT specialists readily available; doctors of osteopathy comprise only 7.2% of United States physicians, and <1000 doctors of osteopathy are board-certified in OMT.[31] Broad applicability may rely on training providers in the OMT protocol, which would create synergistic clinical partnerships between obstetrics providers and OMT-trained physicians and consider other body-based therapies when OMT is not available.

Future studies must carefully consider the placebo choice to select one that is truly inert, controls for the time and treatment interaction, and allows for isolation of the effect of different manual modalities. They will also need to choose between a standardized treatment protocol similar to PROMOTE and an individualized more clinical approach. Earlier enrollment of subjects may be considered to evaluate the effect of earlier intervention on musculoskeletal and physiologic changes that already have manifested by 30 weeks of gestation. In addition, although there were not statistically significant differences in the incidence of conversion to high-risk status, there may be some clinically meaningful protective effects of OMT that would warrant a more nuanced examination in future studies.

The treatment goals for LBP in pregnancy differ from other conditions in that it may not be reasonable to expect to eliminate pain and disability, but instead to slow the progression related to advancing pregnancy. In PROMOTE, both OMT and PUT demonstrated significant mitigating effects on pain and functional disability compared with UCO. Therefore, the inclusion of body-based therapies such as OMT that provide touch, time, and interaction may offer patients and providers a safe, effective adjunctive option to improve comfort and reduce the impact of pain that commonly is associated with third-trimester pregnancy. ■

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