Pregnancy Research on Osteopathic Manipulation Optimizing Treatment Effects: The PROMOTE Study Protocol

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The structural and physiologic changes in a woman’s body during pregnancy can predispose pregnant women to low back pain and its associated disability, as well as to complications of pregnancy, labor, and delivery. Anecdotal and empirical evidence has indicated that osteopathic manipulative treatment (OMT) may be efficacious in improving pain and functionality in women who are pregnant. Based on that premise, the Pregnancy Research on Osteopathic Manipulation Optimizing Treatment Effects (PROMOTE) study was designed as a prospective, randomized, placebo-controlled, and blinded clinical trial to evaluate the efficacy of an OMT protocol for pain during third-trimester pregnancy. The OMT protocol developed for the PROMOTE study was based on physiologic theory and the concept of the interrelationship of structure and function. The 12 well-defined, standardized OMT techniques used in the protocol are commonly taught at osteopathic medical schools in the United States. These techniques can be easily replicated as a 20-minute protocol applied in conjunction with usual prenatal care, thus making it feasible to implement into clinical practice. This article presents an overview of the study design and treatment protocols used in the PROMOTE study.

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Since osteopathic manipulative treatment (OMT) was developed by Andrew Taylor Still, MD, DO, in the late 19th century, osteopathic physicians have firmly believed that removing impediments to optimal function is key to promoting healing and normalization of the body’s processes.1 During pregnancy, physiologic and biomechanical changes can cause substantial pain, disability, and stress to the mother and may pose risks to the fetus.2 Although anecdotal reports support OMT to reduce complications of pregnancy, labor, and delivery, a paucity of well-designed research evaluating the safety and efficacy of OMT in pregnant patients exists. The Pregnancy Research on Osteopathic Manipulation Optimizing Treatment Effects (PROMOTE) study was a prospective, randomized, placebo-controlled, blinded clinical trial that investigated the effects of OMT on the selected pregnancy-related outcomes of low back pain, functional status, and labor and delivery complications. The purpose of this article is to describe the study design and treatment protocols used in this clinical trial.


Video of the treatment protocol is available online.
Background

Back pain is common during pregnancy, with reported incidence rates between 48% and 90%. Pain can either be mild or severe enough to interfere with daily activities. As a gravid uterus grows, its increasing size and weight puts pressure on the pubis and tilts the pelvis anteriorly, which increases lumbar lordosis. This structural change leads to a compensatory exaggeration of the thoracic kyphosis and anterior head position. These postural alterations strain ligaments, muscles, and joints of the surrounding areas, which can cause pain. Hormones, especially relaxin, contribute to pelvic structural instability by allowing sacroiliac joints and the pubic symphysis to widen. Because of bony instability and strain, muscles frequently become hypertonic to add structural support. Hypertonic muscles contribute to the feeling of pain and stiffness and may also affect tissue circulation and lymphatic flow, leading to tissue congestion and edema.

Other musculoskeletal factors shown to relate to the development of low back pain during pregnancy are depth of lumbar lordosis, sacroiliac subluxation, sacral shearing, and muscle fatigue. For many years, osteopathic physicians have been managing these conditions with OMT. Pregnant women have few options to manage pain, which may increase throughout pregnancy. Because of the potential risk to mother and fetus, many prescription medications commonly used for low back pain, such as muscle relaxants and pain medications, are not recommended for use during pregnancy. Even acetaminophen has become controversial because of the potential adverse effects, including prolonged wheezing and asthma and neurodevelopmental delays. Osteopathic manipulative treatment has been shown to affect some musculoskeletal dysfunctions common during pregnancy. Several small pilot studies have shown reduction or elimination of sacroiliac or low back pain. Chiropractic manipulation, which tends to primarily use high-velocity, low-amplitude—or thrust—techniques, has also been shown to decrease or relieve back pain during pregnancy.

Low back pain can be a source of significant disability during pregnancy. In 2004, Wang et al. reported that of 950 pregnant women with low back pain, 57% complained that their daily activities were adversely affected, 46.7% avoided certain activities, 30.5% avoided exercise, and 10.6% had missed work. This amount of disability can make it difficult for women to care for themselves or their other children, or to work outside the home.

A pilot study at the University of North Texas Health Science Center (UNTHSC) assessed the effect of OMT on low back pain and functional status in pregnant women. Results from that study indicated that OMT lessens or halts the deterioration in back-specific functioning that often characterizes the third trimester of pregnancy and thereby provides an important clinical benefit. With slight modification, the OMT protocol used in that pilot study was the prototype for the PROMOTE study.

The primary hypothesis of the PROMOTE study was that application of an OMT protocol would improve low back pain and functional status in the third trimester of pregnancy and would reduce the incidence of certain complications of pregnancy, labor, and delivery. This hypothesis was measured by selected outcomes of pregnancy: low back pain, functional status, and complications of labor and delivery.

PROMOTE Study Design Overview

Before initiation of the study (ClinicalTrials.gov number NCT00426244), institutional review board approval was obtained, and all participants gave informed consent. Additionally, a Data Safety and Monitoring Board was established and closely monitored the trial for participant safety.
Blinding
The obstetrical providers were aware of their patients’ enrollment in the study, but they were blinded to treatment group assignment. Unblinding to their patient’s group assignment did not occur without prior discussion with and agreement of the principal investigator. Participants were asked not to disclose their treatment details unless specifically asked by their obstetrical providers if blinding interfered with appropriate care. Participants were told of their group assignment but were not told that the ultrasonography protocol was a placebo, thereby allowing blinding of the participants between the treatment groups.

A team of physicians who were board-eligible or board-certified by the American Osteopathic Board of Neuromusculoskeletal Medicine performed both the OMT and PUT.

Treatment Protocols

Group 1: Usual Care Plus OMT
A physician used a combination of myofascial release, articular treatment, muscle energy treatment, balanced ligamentous tension, and soft tissue treatment for 12 standardized OMT techniques (Table) during the 20-minute sessions. A demonstration of this protocol is available in the eVideo.

The OMT techniques were relatively gentle. A major OMT modality that was excluded from this protocol was high-velocity, low-amplitude, a direct technique that mobilizes joints with a short impulse of force. By eliminating this modality, we might have eliminated a potentially useful technique. However, owing to the increasing ligamentous laxity that occurs in later pregnancy, the force used in a thrust technique was not generally considered necessary.

Although the OMT protocol encompassed the majority of tissues from the base of the head to the pelvis, specific rationales were used for treating certain areas. These rationales involved the application of osteopathic philosophy and the concept of interrelationship of structure and function. The goals and rationale for treatment according to body region were as follows:

Inclusion and Exclusion Criteria
To be eligible for inclusion, a potential participant had to be aged between 18 and 35 years, at 30 weeks of gestation at the start of the trial, and medically cleared by her obstetrical provider to participate at each study visit. Participants were ineligible for inclusion if they were deemed high risk by the obstetrical provider, including having abruptio placentae, placenta previa, severe pre-eclampsia or eclampsia, vaginal bleeding, gestational diabetes, or pregnancy-induced hypertension.

Recruitment
Participants were recruited from 3 UNTHealth sites: the Obstetrics and Gynecology (OB/GYN) clinic at the UNTHealth Patient Care Center, Harris Health OB/GYN clinic, and JPS Health Center for Women and Children. Patients at these clinics were approached about the study during a regularly scheduled obstetrical visit at or before 30 weeks of gestation. If they agreed to participate, a clinical research coordinator provided them with information about the study and obtained written informed consent before enrollment. Participants could withdraw at any time without penalty, and refusal to participate did not jeopardize their obstetrical care. All participants were compensated for their time, effort, and travel expenses at each study visit.

Study Visits
Treatments began during the participants’ 30th gestational week. After enrollment, participants were randomly assigned to 1 of 3 treatment groups: usual care plus OMT (OMT), usual care plus placebo ultrasonography treatment (PUT), or usual care only (UCO). The randomization process was blocked to ensure equivalent numbers in each treatment group.

Study visits were scheduled immediately after or within 24 hours of the participants’ regular obstetrical appointment. These visits occurred at 30, 32, 34, 36, 37, 38, and 39 weeks’ gestation, for a total of 7 visits if the participant reached normal-term gestation. At each visit, the participants completed outcome questionnaires and received their respective treatment.
■ **Occipitoatlantal joint:** The occiput is the attachment site for many of the cervical muscles, which can become hypertonic because of the alteration of posture during pregnancy. The vagus nerve, which exits the skull through the jugular foramen, courses through the cervical region to provide parasympathetic nerve supply to the upper gastrointestinal, pulmonary, and cardiac systems.\(^{21}\)

■ **Cervical vertebrae:** The phrenic nerve arises from the third, fourth, and fifth cervical nerves and innervates the thoracoabdominal diaphragm. Somatic dysfunction of these vertebrae may affect the functioning of the phrenic nerve and, therefore, the thoracoabdominal diaphragm.\(^{22}\)

■ **Clavicles and Sibson fascia:** Terminal vessels of the lymphatic system drain into the subclavian veins in the infraclavicular space and pass through the Sibson fascia (thoracic inlet fascia) on their way back to the heart. A strain pattern induced in the Sibson fascia may decrease the caliber of lymphatic vessels and their ability to efficiently return lymph through the thoracic duct or lymphatic duct.\(^{23}\) Obstruction of lymphatic return results in edema and stasis of interstitial fluids.\(^{24}\)

■ **Thoracoabdominal diaphragm and lower 6 ribs:** As the uterus expands superiorly, the thoracoabdominal (respiratory) diaphragm becomes more restricted in motion. This change can affect ventilation, rib and spine movement, venous and lymphatic fluid flow, and digestion as the esophagus passes through the diaphragm. The thoracoabdominal diaphragm attaches to the lower 6 ribs; therefore, their position and motion directly affect its function.\(^{25-27}\)

■ **Thoracolumbar junction:** This junction is the attachment site of the crura of the diaphragm; the position and motion of the thoracolumbar vertebrae directly affects the function of the thoracoabdominal diaphragm. Also, sympathetic nervous supply to the uterus and pelvic organs is from spinal segments T12 to L2. Thus, OMT in this region is directed to improve autonomic tone of the uterus and its arterial supply.\(^{21,25,26}\)

■ **Pelvic diaphragm:** Managing strain patterns in the myofascial planes of the pelvic diaphragm aims to improve the mobility and supportive ability of the pelvic diaphragm and to decrease neural impingement. Because of the increasing pressure of the uterus on the veins of the pelvis, these tissues are prone to lymphatic congestion, and treatment to improve lymphatic flow may potentially decrease the incidence of constipation, hemorrhoids, and perineal lacerations.\(^{23,24}\)

■ **Innominates:** Decreased somatic dysfunction in this area is thought to directly decrease low back pain and improve functional status. Addressing the somatic dysfunctions of the innominate may help restore the mobility of the bony pelvis that is necessary to optimize its physical dimensions for accommodation of the fetus as it moves through the delivery process.\(^{26,27}\)

■ **Sacrum:** Techniques for somatic dysfunction of the sacrum aim to improve its mobility and alignment so that the fetus has an uncompromised path of descent.\(^5\) Also, reducing sacral somatic dysfunction may affect the parasympathetic neural tone to the uterus through the pelvic splanchnic nerves, thus preventing poor cervical dilation due to decreased parasympathetic tone during labor and delivery. Sacroiliac dysfunction is thought to be the most common reason for severe low back pain during pregnancy.\(^9,10\)

■ **Hips:** Somatic dysfunction of the hip flexors, internal and external rotators of the lower extremity, and femur can affect the alignment of the innominate and sacrum and can therefore affect gait. Treatment was directed to improve the position and mobility of these structures and their associated myofascial components.\(^{24}\)

■ **Cranium:** Compression of the fourth ventricle is a cranial technique generally described as a method...
Table. OMT Techniques Applied in the PROMOTE Study

<table>
<thead>
<tr>
<th>OMT Technique</th>
<th>Steps of Technique</th>
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| Seated forward-leaning thoracic spine articulation | ■ Physician controls upper extremity and thorax (best position chosen based on body habitus and location of restriction).  
■ Physician's knee blocks against patient's knee to stabilize the participant on the table.  
■ Contact on transverse process or costotransverse junction.  
■ Patient is drawn forward to restrictive barrier.  
■ Low-velocity, medium-amplitude springing is applied until release is felt.  
■ Component of sidebending or rotation may be added.  
■ Focus may be on rib or segmental motion.  
■ Recheck. |
| Supine cervical soft tissue | ■ Contact medial aspect of cervical paraspinal muscles.  
■ Draw anteriorly in a kneading fashion.  
■ Continue until relaxation of tissues.  
■ Recheck. |
| Occipitoatlantal decompression | ■ Contact is on the occiput as close to the condyles as possible.  
■ Tension is applied toward the participant's orbits.  
■ Traction is created between the fingers by moving the elbows medially.  
■ Respiratory assistance may be used to enhance release.  
■ Position is held until release is felt and motion is improved, at least 20-30 s.  
■ Recheck. |
| Thoracic inlet MFR | ■ Anterior contact is across sternoclavicular junction and ribs 1 and 2.  
■ Posterior contact is T1-2 and costovertebral junction.  
■ Assess rotation with sidebending and flexion/extension.  
■ Use all 3 planes to approach barrier (direct) or position if ease (indirect) to point of balance.  
■ Hold 20-60 s until tissue creep indicates a release of tissue tension.  
■ Recheck. |
| Lateral recumbent scapulothoracic soft tissue | **Part 1:**  
■ Contact is on the superior and inferior medial angles of the scapula with the patient's arm over the physician's caudal arm.  
■ The cephalad hand initiates a circular motion into the shoulder, and the scapula is carried laterally in a rhythmic fashion to release muscular attachment.  
■ The caudal hand contacts the rhomboids and paraspinal muscles along the medial border of the scapula.  
■ Fascial restrictions are then assessed in superior/inferior, medial/lateral, and rotary motions.  
■ Scapula is taken either directly or indirectly to balance point and held for 20-60 s or until release is palpated.  
■ Recheck.  

**Part 2:**  
■ Patient’s arm is moved to drape over physician’s cephalad arm.  
■ Contact is broad over the superior aspect of the shoulder, with the caudal hand’s thenar eminence engaged in the posterior axillary fold.  
■ Tissue texture is assessed.  
■ Compressive force is applied into the axillary and subscapular tissues in a rhythmic fashion until a change in tissue texture is felt.  
■ Recheck. |
| Lateral recumbent lumbosacral soft tissue | ■ Physician's arms are braced on the patient’s axilla and iliac crest.  
■ Contact is medial aspect of lumbar (up to lower thoracic) paraspinal muscles.  
■ Three motions are then applied rhythmically:  
   1. Physician’s arms carry patient’s arms and ilia apart to stretch and sidebend the lumbar area.  
   2. Physician’s arms twist to push the patient’s shoulder posteriorly and her iliac crest anteriorly.  
   3. Lateral motion is applied with hands to “bowstring” the muscles.  
■ Repeat to softening of muscles throughout the lumbar region.  
■ Recheck. |
| Abdominal diaphragm MFR | ■ Contact either with fingers spread over lower ribs laterally or anteroposteriorly diaphragm MFR with hands at subxiphoid and thoracolumbar junction.  
■ Assess rotation with sidebending and flexion/extension.  
■ Use all 3 planes to approach barrier (direct) or position of ease (indirect).  
■ Add respiratory cooperation to assist in release.  
■ Hold 20-60 s or until release is felt.  
■ Recheck. |
## Table (continued).
### OMT Techniques Applied in the PROMOTE Study

<table>
<thead>
<tr>
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| Pelvic diaphragm MFR              | - Posterior contact is low on the sacrum and coccyx with fingers toward contralateral ischial tuberosity.  
- Anterior contact is across and slightly above the pubic symphysis.  
- Assess rotation with sidebending and flexion/extension.  
- Use all 3 planes to approach barrier (direct) or position of ease (indirect).  
- Hold until release is felt.  
- Recheck.                                                                                     |
| Sacroiliac articulation           | - Use pelvic compression test to assess sacroiliac motion.  
- Contact is on the patient’s flexed knee and hip with mild compression to engage the femur into the acetabulum.  
- The hip is externally rotated and circumducted into straightened position, maintaining compression.  
- Then, the hip is internally rotated and circumducted into straightened position, maintaining compression.  
- Repeat the technique 4-5 times until motion improves.  
- Repeat on opposite side.  
- Recheck.                                                                                     |
| Frog-leg sacral release           | - Contact is on sacrum with fingers at the base and palm at apex.  
- Patient’s hips and knees are flexed with feet together.  
- Sacrum is taken to point of ligamentous balance with respiratory assistance.  
- As patient holds breath in most useful phase, she lets her knees fall to the sides and straightens out legs to rotate innominates.  
- As patient straightens her legs, inferior traction is applied to the sacrum.  
- Repeat 3-5 times, until sacral motion is significantly more symmetrical.  
- Recheck.                                                                                     |
| Posterior innominate muscle energy | - Leg on side of dysfunction is extended off side of table.  
- Contact is on ipsilateral thigh and contralateral ASIS.  
- Thigh is extended to restrictive barrier of the innominates.  
- Patient’s effort is to pull knee toward ceiling for 3-5 s.  
- After relaxation, innominate is taken to new barrier and forces are repeated 3-5 times.  
- Return to neutral and recheck.                                                                 |
| Anterior innominate muscle energy  | - Leg on side of dysfunction is flexed at knee and hip.  
- Contact is on ipsilateral PSIS and ischial tuberosity with patient’s knee against chest.  
- Leg is flexed to restrictive barrier of the innominates.  
- Patient’s effort is to push knee against physician’s chest for 3-5 s.  
- After relaxation, the innominate is taken to new barrier and forces repeated 3-5 times.  
- Return to neutral and recheck.                                                                 |
| Pubic symphysis decompression     | - Hips and knees flexed with feet together.  
- Knees are hugged together and patient attempts to pull them apart for 3-5 s while the physician provides isometric counterforce.  
- Patient ceases force, and knees are rocked side to side 3 times.  
- These steps are repeated 2 more times.  
- Then, patient’s knees are spread apart to fist-width and patient attempts to pull them together for 3-5 s while physician provides counterforce or blocks with fist.  
- Patient ceases force, and knees are rocked side to side 3 times.  
- Knees are then spread to 2-fist width and steps repeated.  
- Knees are then spread to forearm width and steps repeated.  
- Recheck.                                                                                     |
| Compression of the fourth ventricle | - 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.                    |

a A video presentation of these osteopathic manipulative treatment (OMT) techniques, with exception of compression of the fourth ventricle, is provided in the eVideo.
b Only used when needed.

Abbreviations: ASIS, anterior superior iliac spine; MFR, myofascial release; PROMOTE, Pregnancy Research in Osteopathic Manipulation Optimizing Treatment Effects; PSIS, posterior superior iliac spine.
to normalize function through fluctuation of the cerebrospinal fluid. A small study\(^ {28} \left(n=6\right)\) showed that this technique may induce uterine contractions in postterm women. Although it has been described as a treatment for uterine inertia, compression of the fourth ventricle is not considered as a way to instigate uterine contractions like the administration of pitocin.\(^ {29} \)

A standardized OMT protocol is difficult to apply for every patient. In this study, the goal was to create a protocol that would address the dysfunctions seen in most pregnant patients. The protocol was designed to address the entire body to remove or improve any structural impediments to optimal neural, lymphatic, circulatory, and respiratory function and by doing so help the patients’ body to better cope with and adapt to the advancing biomechanical and physiologic stresses of pregnancy.

**Group 2: Usual Care Plus PUT**

The issue of placebo control interventions in OMT research is controversial. A placebo treatment is advocated in studies of osteopathic manipulation because there may be many reasons a patient exhibits benefit from treatment aside from the biomechanical, fluid, or neurologic consequences of the manipulation itself. In addition to the structural changes induced by OMT, OMT may generate a positive clinical response because of the ancillary effects of “laying on of hands,” greater attention from and interaction with the treating physician, and an expectation of therapeutic effect.\(^ {30} \)

For the PROMOTE study, the PUT was subtherapeutic ultrasonography systematically administered over the same body regions as those targeted by the OMT protocol by the same physician who treated the OMT group and for the same duration. The ultrasound wand was applied for 2 minutes bilaterally at each of the areas of primary focus for the OMT protocol, including the neck, scapular region, thoracolumbar junction, lumbosacral junction, lumbar paraspinous region, sacroiliac joint, and inguinal ligament. The ultrasonography machine, though turned on, was not set to emit any ultrasonic waves. Any effect of the treatments, therefore, was due to the contact of the wand on the tissues or other placebo effects. These treatments were applied through participants’ clothes in the same manner that the OMT protocol was provided. This protocol may have provided similar ancillary affects as OMT because of the tactile stimulation, time with the physician, and anticipation of therapeutic effect.

**Group 3: UCO**

The treatment group receiving UCO received it from their obstetrical provider. They had study appointments on the same schedule.

**Outcome Measures**

Low back pain was measured with the Quadruple Visual Analog Scale, a 4-question form that asks participants to rate their back pain now, at its average level, at its best, and at its worst since the last visit.\(^ {31} \) Functional status was measured with the Roland Morris Disability Questionnaire, a brief self-reported measure of low back pain and function.\(^ {32} \) This instrument is a well-established measure of functional status and has been translated into many languages for use around the world. It has been shown to be sensitive to change in low back pain over time.\(^ {33,34} \) Labor and delivery outcomes were collected by abstracting data from the participants’ delivery record, including high-risk status, weeks of gestation, labor time, and amniotic fluid color. Demographic data, including age, race, marital status, education level, occupation, and insurance type, were collected for all participants.

**PROMOTE Results**

Published in 2015, the PROMOTE study\(^ {20} \) confirmed previous findings\(^ {19} \) of a slower rate of deterioration of back-specific functioning in participants receiving an OMT protocol compared with participants receiving UCO. It also showed that OMT mitigated pain progression compared with UCO. No statistically significant difference was found between the OMT group and the PUT group, however, which may be attributable to several
placebo potency factors. The study also showed no higher conversion rate to high-risk status in the OMT group, indicating that this OMT protocol is a safe, effective adjunctive modality to improve pain and functioning during the third trimester of pregnancy. The OMT protocol did not increase risk of precipitous labor, conversion to cesarean delivery, or meconium-stained amniotic fluid. In all of the maternal outcomes examined, no difference was reported among the 3 study groups with the exception of incidence of prolonged labor. Participants in the OMT group had longer labor duration, with no increased incidence of complications, including perineal laceration, episiotomy, or need for forceps or vacuum device.

Discussion

Low back pain is a common complaint of pregnant women, and few safe treatment options are available. Many women may endure the pain throughout their pregnancies without relief. The significance of the PROMOTE study is that the application of an OMT protocol throughout the third trimester appears to be a safe and effective way to manage low back pain and its associated disability during pregnancy when compared with current UCO. The techniques in the protocol are relatively simple and easily taught, making the protocol an attainable skill for obstetrical providers and, therefore, a model that could be generally applicable to clinical practice. The protocol has been taught at osteopathic convention workshops and could easily be expanded into a module for allopathic obstetrical providers, thus increasing the availability of this approach.

To the authors’ knowledge, the PROMOTE study is the third-largest clinical trial of OMT to date. Data analysis indicated statistical significance on many outcomes when compared with UCO, but a lack of statistical significance when compared with the PUT, which leads us to question what aspect of OMT produces a clinical effect, or whether the PUT was not an inert placebo. Also, because the protocol involved multiple OMT techniques applied to different body regions, it was difficult to determine precisely which technique could decrease the incidence of a particular dysfunction. However, the scope of the PROMOTE study was to determine the efficacy of an OMT protocol to decrease pain and increase functional status in participants in their third trimester. Future studies will need to further delineate the relationship between specific OMT techniques and specific therapeutic benefits and carefully consider the choice of placebo and the OMT techniques used. Another option for future research may be to have a more clinical osteopathic approach, with more emphasis on specific diagnoses. Although this approach would be more individualized, and may therefore be more effective, it is also much more difficult to reproduce or generalize to other medical professionals.

Conclusion

The results of the PROMOTE study show that when compared with UCO, participants who received an OMT protocol in addition to usual care had a slower rate of deterioration of their pain and back-specific functioning during the third trimester. Additionally, the data indicate that participants who received the OMT protocol did not have a higher incidence of common labor- or delivery-related complications. Therefore, the PROMOTE OMT protocol, consisting of 12 standardized techniques, appears to be a safe and effective way to manage back pain and function during pregnancy. In light of the limited safe options for controlling pain during pregnancy, implementation of this protocol during prenatal care could have positive effects on both maternal and fetal well-being.

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