

Osteopathic Manipulative Therapy in Women With Postpartum Low Back Pain and Disability: A Pragmatic Randomized Controlled Trial

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Context: Persistent low back pain (LBP) is a common complaint among women during and after pregnancy, and its effects on quality of life can be disabling.

Objective: To evaluate the effectiveness of osteopathic manipulative therapy (OMTh; manipulative care provided by foreign-trained osteopaths) in women with persistent LBP and functional disability after childbirth.

Methods: A pragmatic randomized controlled trial was conducted among a sample of women with a history of pregnancy-related LBP for at least 3 months after delivery. Participants were identified from the general population in Germany. By means of external randomization, women were allocated to an OMTh group and a waitlist control group. Osteopathic manipulative therapy was provided 4 times at intervals of 2 weeks, with a follow-up after 12 weeks. The OMTh was tailored to each participant and based on osteopathic principles. The participants allocated to the control group did not receive OMTh during the 8-week study; rather, they were put on a waiting list to receive OMTh on completion of the study. Further, they were not allowed to receive any additional treatment (ie, medication, physical therapy, or other sources of pain relief) during the study period. The main outcome measures were pain intensity as measured by a visual analog scale and the effect of LBP on daily activities as assessed by the Oswestry Disability Index (ODI).

Results: A total of 80 women aged between 23 and 42 years (mean [SD], 33.6 [4.5] years) were included in the study, with 40 in the OMTh group and 40 in the control group. Pain intensity decreased in the OMTh group from 7.3 to 2.0 (95% CI, 4.8-5.9; $P<.001$) and in the control group from 7.0 to 6.5 (95% CI, -0.2 to -0.9; $P=.005$). The between-group comparison of changes revealed a statistically significant improvement in pain intensity in the OMTh group (between-group difference of means, 4.8; 95% CI, 4.1-5.4; $P<.001$) and level of disability (between-group difference of means, 10.6; 95% CI, 9.9-13.2; $P<.005$). The follow-up assessment in the OMTh group ($n=38$) showed further improvement.

Conclusion: During 8 weeks, OMTh applied 4 times led to clinically relevant positive changes in pain intensity and functional disability in women with postpartum LBP. Further studies that include prolonged follow-up periods are warranted. (German Clinical Trials Register: DRKS00006280.)

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About 50% of pregnant women will have low back pain (LBP) at some point during or after their pregnancies,¹ and the impact of LBP on quality of life can be considerable.² The literature describes LBP during and after pregnancy using terminology such as *pregnancy-related LBP*, *pelvic girdle pain (PGP)*, *pregnancy-related pelvic girdle pain*, *lumbopelvic pain*, and *lumbar pain*.¹⁻³ The symptoms may appear during the first trimester of pregnancy or may not develop until labor or the postpartum period.³ Wu et al,⁴ in their systematic review of 28 studies, found that around 45% of all pregnant women and 25% of all postpartum women had LBP or PGP.

To our knowledge, no uniform procedures for the diagnosis of LBP and PGP after childbirth exist. The European guidelines² for the diagnosis and management of PGP recommend pain provocation tests of the sacroiliac joint and the symphysis pubis and functional test of the pelvic girdle.

Standard therapy includes physiotherapy, stabilization belts, nerve stimulation, medications, acupuncture, massage, relaxation, and yoga.^{5,6} The European guidelines² recommend an individualized program focusing specifically on exercises for control and stability as part of a multifactorial postpartum treatment plan and prescription of pain medication if necessary (first choice, paracetamol; second, nonsteroidal anti-inflammatory drugs). Because of the heterogeneity and the varying quality of the studies, it seems that no strong evidence exists concerning the effect of physical therapy on the prevention and management of pregnancy-related LBP and PGP.^{7,8} A Cochrane review⁹ found moderate-quality evidence for the commonly used interventions.

A few randomized controlled clinical trials on the effectiveness of osteopathic manipulative therapy (OMTh; manipulative care provided by foreign-trained osteopaths) for women with pregnancy-related LBP have been carried out. Most of them investigated the effects of OMTh on LBP during pregnancy,^{10,11} but 1 trial studied patients with postpartum LBP.¹² In this trial,¹² the intensity of pain improved significantly (70%) after OMTh was applied 4 times.

The aim of the present randomized controlled trial was to evaluate the effectiveness of OMTh in reducing postpartum LBP and PGP and functional disability.

Methods

The 8-week study was designed as a pragmatic randomized controlled trial. In Germany, approval by an official ethics committee installed by the medical faculties of German universities and medical associations only applies to studies carried out by physicians. Therefore, the approval for the study protocol was obtained from the private Institutional Review Board of the German Academy of Osteopathy. The study meets the standards of the Declaration of Helsinki and the Good Clinical Practice standard. Informed consent was obtained from all participants before enrollment.

Two osteopaths (K.R. and D.R.) carried out the study in their private practices. Each was an experienced Heilpraktiker (the medical profession in Germany approved to treat patients directly without supervision of a physician, with particular emphasis on complementary medicine), had successfully completed 5 years of osteopathic training (approximately 1300 hours), and had passed a final clinical examination (reflecting the highest possible standard of osteopathic training in Germany).

Recruitment and Randomization

Between 2010 and 2012, participants were identified from the general population in the Karlsruhe area of Germany. Recruitment was performed through word of mouth and flyers displayed in pediatric and gynecologic surgical centers, midwifery practices, kindergartens, childcare facilities, and daycare centers. Interested candidates were screened for inclusion criteria by telephone interview.

Women were included if they were aged between 18 and 42 years, delivered a child within the past 3 to 15 months, and had at least 3 months of nonspecific LBP or PGP diagnosed according to the European guidelines.² In addition, they had to rate LBP intensity as 5 or higher

on a 10-point visual analog scale (VAS). Results from the participants' most recent postpartum gynecologic examination were required. Study-specific exclusion criteria were LBP before pregnancy, the use of other therapies or analgesics during the study phase, and pregnancy. General exclusion criteria were any of the following diagnoses as determined by a physician before study enrollment: severe trauma, skeletal injury or fractures, osteoarthritis, neurologic diseases (eg, radiculopathy, myelopathy), chronic inflammatory disorders, primary neoplasm, metastases, and osteoporosis.

Participants were randomly allocated to 2 groups: an OMTh group and a control group. The assignment was performed externally by the German Institute for Health Research. The institute held a computer-generated randomization list with variable block length of 4 to 8 for each therapist (block lengths were not revealed to any party involved in the trial).¹³ Participants' allocation to the respective groups was revealed only after their date of birth and initials had been conveyed by telephone.

Study Groups

OMTh

Participants in the OMTh group received a series of 4 full osteopathic examinations (at baseline, 2 weeks, 4 weeks, and 6 weeks) and OMTh, lasting 40 to 60 minutes each. Two osteopaths performed all examinations and manipulations. Before each visit and 2 weeks after the last visit (ie, at 8 weeks), participants completed the VAS and Oswestry Disability Index (ODI). A follow-up evaluation was carried out 3 months after the end of the study, in which the OMTh group completed the VAS and ODI.

At each visit, participants underwent full-body osteopathic examination according to osteopathic principles. Somatic dysfunctions were evaluated in the parietal, visceral, and craniosacral systems, including observation, screening tests, palpation, and motion testing. For documentation purposes, both therapists used a standardized examination form. This form was also important to monitor changes over the course of OMTh. At each visit, OMTh

was applied only to those structures with relevant osteopathic findings. Standard OMTh techniques (Glossary of Osteopathic Terminology²²) were applied, including direct (high-velocity, low-amplitude; muscle energy; and myofascial release), indirect (functional techniques and balanced ligamentous tension), visceral, and cranial techniques. No predefined, standardized OMTh protocol was implemented; each osteopath was free to decide which techniques to use. Participants were not allowed to receive any additional treatment (ie, medication, physical therapy, or other sources of pain relief) during the study period.

Control

Participants in the control group did not receive OMTh, nor were they evaluated for somatic dysfunctions during the 8-week study period. At the first visit, control participants were required to fill out the VAS and ODI. The osteopath then told them that they would be placed on a waiting list for OMTh to be scheduled 2 months later. At 2 months, the control participants filled out the VAS and ODI for the second time. During the study period, participants were not allowed to receive any additional treatment for pain relief (eg, medication, physical therapy, or other sources of pain relief). After study completion, they were offered 2 free appointments for OMTh.

Outcome Measures

Pain intensity as assessed by a 10-point VAS and functional disability as measured by the ODI were the main outcome measures. The VAS is an established reliable and valid measure for pain intensity and has been shown to be highly responsive to clinical changes.¹⁴⁻¹⁶ The ODI, also known as the Oswestry Low Back Pain Disability Questionnaire, is a commonly used tool that researchers and disability evaluators use to measure functional disability in patients with LBP. The test is considered the criterion standard of low back functional outcome tools.^{17,18} A validated German version is available.^{19,20} The ODI has 10 sections covering the assessment of pain intensity, personal care, lifting, walking, sitting, standing,

sleeping, sex life, social life, and traveling. Scores are calculated as a percentage, with higher percentage scores indicating increasing disability, with a maximum score of 50 points.²¹ For both assessments, women were asked to rate the average pain intensity and functional disability during the previous 2 weeks. Additional questions asked about urinary or anal incontinence, dyspareunia, headache, and hemorrhoids to document other typical signs and symptoms associated with childbirth.

Statistical Analysis

Data used for analysis were restricted to the 8-week study period. The sample size was calculated using the response rates and variances of the main outcome measures from the trial of Recknagel et al¹² and from the literature (minimal clinically important difference) on patients with LBP.²³ According to common standards in clinical trials, the type I error was set at .05, and type II error, .2 (ie, set at a power of 80%). Pain intensity was used to determine the sample size. The trial was designed to be able to detect an overall clinically important difference in changes of 2.4 points with assumed SDs of 2.4. Therefore, the effect size was .65. The sample size calculation estimated that 76 participants would be required. We decided to aim at including 40 participants in each group to account for potential additional variation.

All statistical evaluations were performed with PASW Statistics (version 17; SPSS Ltd). In the confirmatory analysis, longitudinal changes in different aspects of the main outcome measures of pain intensity (quantified on the VAS) and functional disability (quantified on the ODI) in the course of OMTh were compared between both groups by unpaired, 2-sided *t* tests. For all comparisons, $P < .05$ was considered statistically significant, and 95% CIs were calculated for all point estimates. For the presentation of the baseline values, commonly used methods of descriptive statistics were used. An intention-to-treat analysis was performed with the last observation carried forward for dropouts.

Results

Of 137 women initially identified, 80 fulfilled the criteria and were included in the study: 40 in the OMTh group and 40 in the control group (Figure 1). Two participants in the OMTh group and 1 participant in the control group dropped out during the study owing to pregnancy (1), absence of pain (1), and intake of medication (1), respectively. Because an intention-to-treat analysis was performed, data for all 80 women were included into the analysis (last observation carried forward). Table 1 shows the demographic data at baseline, which indicates that randomization was successful. Clinical and demographic characteristics at baseline were similar in both groups. Structural equality was confirmed by an analysis of baseline data, which revealed a significant difference in the ODI score only ($P = .001$).

The most frequently mentioned conditions were urinary incontinence (14 [18%]), headache (13 [16%]), dyspareunia (11 [14%]), hemorrhoids (11 [14%]), and anal incontinence (5 [4%]).

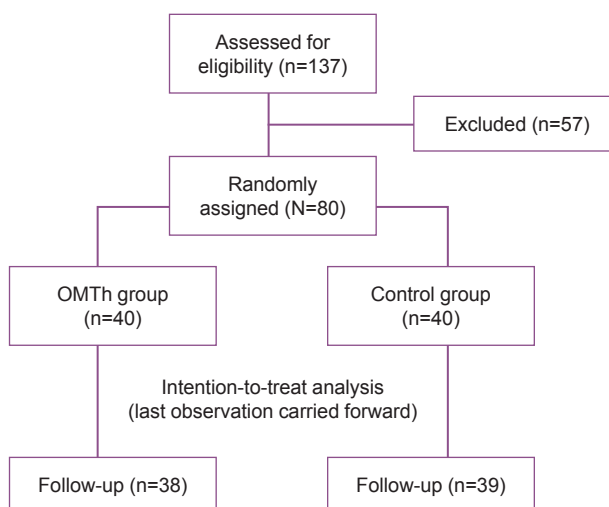


Figure 1.

Study flow chart of participants (N=80) with postpartum low back pain and disability who underwent either osteopathic manipulative therapy (OMTh; manipulative care provided by foreign-trained osteopaths) or received no therapy or pain control.

Table 1.
Baseline Characteristics of Study Participants
With Postpartum Low Back Pain and Disability^a

Characteristics	OMTh Group (n=40)	Control Group (n=40)	P Value
Age, y	33.9 (4.4)	33.3 (4.3)	.6
No. of Deliveries, mean	1.6	1.5	.6
1	22	24	.6
2-4	18	16	
Labor Duration of First Pregnancy, h	8.6 (5.7)	9.6 (8.2)	.5
Pain Duration, mo	9.8 (3.4)	9.7 (3.2)	.9
Pain Intensity at Baseline			
Visual analog scale ^b	7.3 (0.9)	7.0 (1.0)	.7
Oswestry Diabetes Index ^c	16.8 (6.7)	22.1 (7.2)	.001

^a Data are given as mean (SD) unless otherwise indicated.

^b The visual analog scale scores were 0 to 10 with 0 indicating no pain and 10 indicating the highest level of pain intensity.

^c Oswestry Disability Index scores (maximum score, 50 points) are calculated as a percentage (point total / 50 x 100 = % disability).

Abbreviation: OMTh, osteopathic manipulative therapy (manipulative care provided by foreign-trained osteopaths).

Table 2.
Comparison of Mean Pain Score Changes Among Participants With
Postpartum Low Back Pain and Disability, From Baseline to Study Conclusion

Pain Measure	Longitudinal Changes, Mean (SD)		Difference in Longitudinal Changes (95% CI)	P Value
	OMTh Group (n=40)	Control Group (n=40)		
Visual analog scale ^a	-5.3 (1.7)	-0.5 (1.2)	-4.8 (-4.1 to -5.4)	<.001
Oswestry Disability Index ^b	-12.6 (6.5)	-2.0 (5.2)	-10.6 (-8.0 to -13.2)	<.001

^a The visual analog scale scores were 0 to 10 with 0 indicating no pain and 10 indicating the highest level of pain intensity.

^b Oswestry Disability Index scores are calculated as a percentage, with higher percentage scores indicating increasing disability (maximum score, 50%).

Abbreviation: OMTh, osteopathic manipulative therapy (manipulative care provided by foreign-trained osteopaths).

Table 3.
Within-Group Longitudinal Changes Among Participants With Low Back Pain and Disability at Baseline and at Study Conclusion (N=80)^b

Pain Measure	Score, Mean (SD)		Difference in Longitudinal Changes (95% CI)	P Value
	Baseline	Conclusion		
Visual Analog Scale^a				
OMTh group	7.3 (0.9)	2.0 (1.6)	-5.3 (-4.8 to -5.9)	<.001
Control group	7.0 (1.0)	6.5 (1.2)	-0.5 (-0.2 to -0.9)	.005
Oswestry Disability Index^b				
OMTh group	16.8 (6.7)	4.2 (3.1)	-12.6 (-10.5 to -14.7)	<.005
Control group	22.1 (7.2)	20.0 (6.7)	-2.1 (-0.4 to -3.7)	.02

^a The visual analog scale scores were 0 to 10 with 0 indicating no pain and 10 indicating the highest level of pain intensity.

^b Oswestry Disability Index scores are calculated as a percentage, with higher percentage scores indicating increasing disability (maximum score, 50%).

Abbreviation: OMTh, osteopathic manipulative therapy (manipulative care provided by foreign-trained osteopaths).

The difference in longitudinal changes during the 8-week study period using the main outcome measure of mean pain intensity on a VAS was significantly more pronounced in the OMTh group than in the control group (difference of means [95% CI], -4.8 [-4.1 to -5.4]; $P<.001$), as was the ODI (difference of means [95% CI], -10.6 [-8.0 to -13.2]; $P<.001$) (Table 2). Between baseline and study conclusion, the decrease in pain intensity in the OMTh group was statistically significant, from 7.3 at baseline to 2.0 at 8 weeks, which corresponds to an improvement of 73%. In the control group, the mean values changed marginally during the waiting period (7% improvement; Table 3 and Figure 2). Longitudinal changes for the disability of daily life revealed an improvement of 75% in the OMTh group. At the follow-up appointment, 3 months after the end of OMTh, the pain intensity and disability on the 2 main outcome measures had further improved, with mean pain intensity decreasing from 2.0 to 1.6 on the VAS (Figure 3).

The secondary outcome measures were location of somatic dysfunctions and most frequently encountered dysfunctions. The most frequent and noticeable somatic

dysfunctions were in the area of the sacral bone (95%), at the base of the skull (92%), and in the area of the abdominal and pelvic diaphragms (82% and 80%, respectively). Other somatic dysfunctions were predominantly found in the thoracic and lumbar spine areas and in the cranial membranes. No serious adverse events were recorded during the study period. Occasionally, participants reported being tired after receiving OMTh.

Discussion

Pelvic girdle pain is considered to be a specific form of LBP that can occur separately or in conjunction with LBP.^{2,24} In pregnant and postpartum women, LBP and PGP of varying intensities may be regarded anywhere between a normal sequela and a severely disabling problem. In a longitudinal study, Saurel-Cubizolles et al²⁵ found that more than half of women surveyed had backache, anxiety, and extreme tiredness 1 year after giving birth. Brown and Lumley²⁶ described the prevalence of maternal physical and emotional health problems 6 months after delivery. The most common health problems were tiredness (69%),

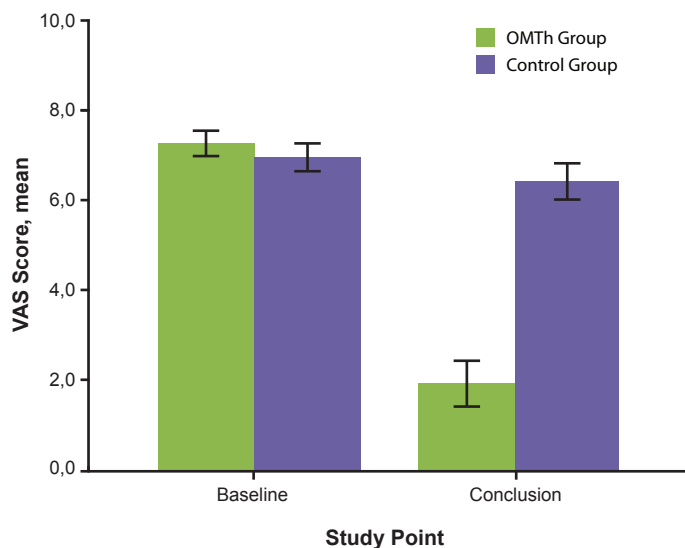


Figure 2.

Mean pain scores on a 10-point visual analog scale at baseline and at study conclusion (8 weeks) in women with postpartum low back pain and disability. The error bars represent 95% CIs. *Abbreviation:* OMTh, osteopathic manipulative therapy (manipulative care provided by foreign-trained osteopaths).

backache (43.5%), sexual problems (26.3%), hemorrhoids (24.6%), and perineal pain (21%).²⁶ Postpartum PGP has been associated with considerable perceived disability in movement-related activities.^{27,28} Pelvic girdle pain is the most common cause of sick leave after delivery.^{2,29} Bjelland et al³⁰ studied the association between mode of delivery and persistent PGP at 6 months postpartum. The results suggested an increased risk of severe PGP 6 months after childbirth in women who underwent cesarean delivery compared with that in women who had unassisted vaginal delivery.

The current study aimed to examine the effectiveness of OMTh compared with no intervention on pain intensity and functional disability in women with persistent LBP after childbirth. The study design was considered appropriate because the LBP symptoms in the control group were not expected to change appreciably without

intervention—indeed, they remained stable during the 8-week study period. We used a pragmatic approach to assess the perceived effects of OMTh delivered in a standard clinical setting. A pragmatic trial can broadly be defined as a randomized controlled trial, with the purpose of aiding informed decision making in clinical practice; the pragmatic approach aims to model the real-life situation of deliberately seeking treatment or not.^{31,32} Thus, the current study aimed to test the value of seeking help from an osteopath (ie, perceived effectiveness of OMTh in general rather than the efficacy of particular OMTh techniques). Results may therefore have important external validity.^{33,34}

For the participants in the control group, participation was not associated with any disadvantage, because they had not been receiving therapy for their complaints before entering the trial and had not planned to do so in the following weeks. Rather than feeling deprived of therapy, they anticipated having 2 free OMTh appointments once the waitlist time ended.

The inclusion criterion of the 3- to 15-month postpartum periods created a more concrete relationship between the time of pregnancy, childbirth, and pain. The literature describes that postpartum PGP either disappears after the puerperium (6-8 weeks) or, at the latest, after 6 months.²⁹ Low back pain before pregnancy was an exclusion criterion because existing postpartum literature indicates that previous LBP episodes are a risk factor for developing lumbopelvic pain after pregnancy (prevalence, 24% without vs 43% with previous LBP).⁴

The outcome measures VAS and ODI are quite different, both in content and in how they are constructed. The ODI assesses impairments, activity limitations, and social functioning, whereas the VAS simply quantifies pain intensity. The ODI assesses areas of life that cannot be applied to women after childbirth in their new life situation (eg, sleeping, sitting, lifting, leisure). It seems that pain intensity and functional disability are not readily interchangeable problems, as demonstrated in the current study by remarkably high pain intensity ratings (about

7 out of 10 on the VAS) and mild disability ratings (11%-39% in the ODI) early in the study period. Pierce et al³⁵ stated that “the ODI is not a scale for pregnancy, and this limits the interpretation of the scale and the results of the study.” In future studies, the Pelvic Girdle Questionnaire could be used.³⁶ Designed as the first specific questionnaire for pelvic pain during pregnancy and after delivery, the Pelvic Girdle Questionnaire measures the quality of life of affected participants in terms of pain and function.

Unlike in the United States, where osteopathic physicians have full, unlimited medical practice rights, the vast majority of osteopaths in Germany are health care providers with nationally defined practice rights and are not licensed to prescribe drugs, perform surgical procedures, or assist in childbirth. Most osteopaths in Germany work in private practices and are exclusively concerned with OMTh; appointments usually last 45 to 60 minutes and include an in-depth examination of somatic dysfunctions.

The osteopathic rationale is not to make a differential diagnosis as in mainstream medicine. Consequently, for LBP, patients are not treated with a set of manual techniques assigned to the condition; rather, manual techniques are assigned to the patient’s individual needs as determined by a thorough examination. The osteopathic examination in the current study allowed a detailed and precise documentation of all examined parts of the body and gave a good overview of all somatic dysfunctions found.

In the current study, participants in the OMTh group reported an average pain intensity score of about 7.0 at baseline. This level of pain can be considered clinically meaningful. After 4 OMTh appointments in which techniques were individualized to each participant, pain intensity improved by more than 70%. This finding corresponds to an effect size of about 3, which is remarkably high. The effect size may reflect that all effects—not just the specific effect of OMTh—were depicted. The ODI scores also revealed a statistically significant improvement in function. A relationship between preg-

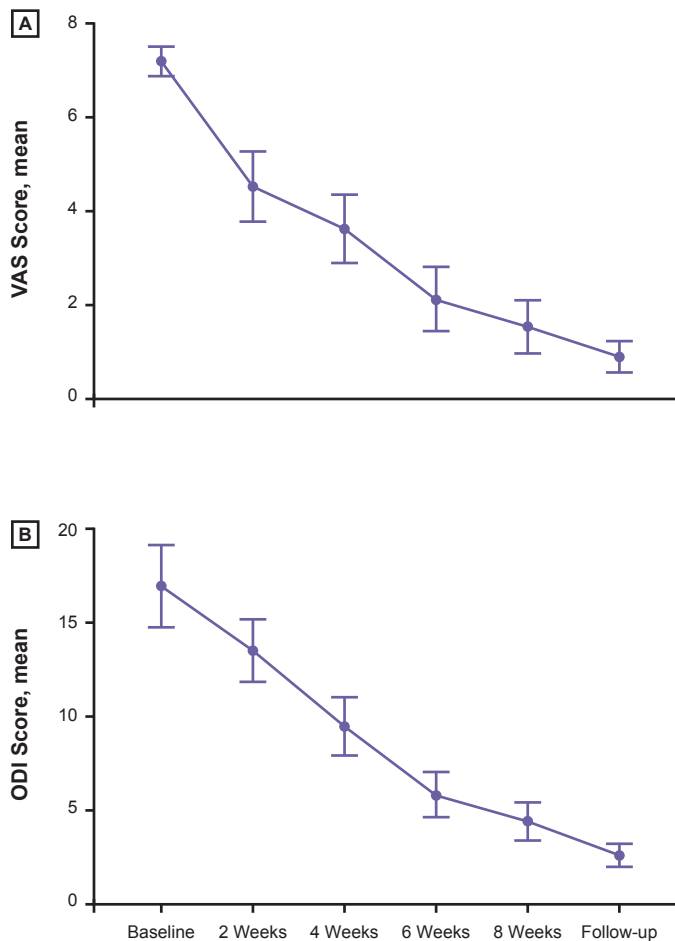


Figure 3.

Mean scores on (A) a 10-point visual analog scale (VAS) for pain and (B) Oswestry Disability Index (ODI) in the group who received osteopathic manipulative therapy (manipulative care provided by foreign-trained osteopaths) for low back pain and disability. Follow-up for the OMTh group occurred 3 months after the 8-week visit. The error bars represent 95% CIs.

nancy-related LBP and PGP and specific anamnestic data, such as patient age, number of births, duration of birth, mode of delivery, perinatal interventions, injuries to the perineum, and birth weight, could not be established in the current study.

Our results are in agreement with the study by Recknagel et al,¹² whose study design (untreated control group), outcome measures, and number of OMTh applications were similar. Furthermore, their study sample comprised 40 women with nonspecific postpartum LBP. In the OMTh group, pain intensity as measured by a VAS decreased from 68.3 to 20.6.

Clinical trials of manual therapy or other interventions directly delivered by a health care practitioner are prone to bias if just 1 person delivers the therapy. To test the approach and not the practitioner in the current study, 2 experienced osteopaths performed the OMTh. The trial included adequately concealed random allocation. Through intention-to-treat analysis, all participants could be analyzed.

Various limitations are inherent in a waiting list design. Participants know whether they get the intervention or not, which may trigger nonspecific effects, such as expectation. The lack of blinding allows for a relationship to be established between patient and therapist. The above reasoning implies that the waiting list design does not allow differentiation between specific and nonspecific components of an overall perceived therapy effect, but it can still give valid information with regard to the reliability and reproducibility of the extent of change associated with OMTh.

Because the VAS and ODI are self-assessment instruments, participants may have felt urged to positively overestimate their ratings. Hence, we cannot exclude that this factor may have influenced ratings in one way or another. A setting in which the evaluator administering the surveys is blinded might be preferable.

The OMTh techniques used were based on the treating osteopath's judgment of which techniques would be most appropriate under the circumstances and were not detailed. This variability may limit the reproducibility of the trial.

Another limitation of the waiting list design is that the follow-up can only be carried out for the intervention group because the control group receives OMTh at the end

of the study. Therefore, the data obtained at follow-up do not fulfill the criteria of a randomized controlled trial.

Conclusion

Persistent postpartum LBP and PGP are still poorly understood. The results of this study provide some evidence that patients with pregnancy- and childbirth-related LBP and PGP may be successfully treated with OMTh. Further studies to corroborate the current findings and that include prolonged follow-up periods are warranted.

Author Contributions

Mr Schwerla, Ms Rother, Mr Rother, and Ms Ruetz provided substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; Mr Schwerla drafted the article or revised it critically for important intellectual content; Dr Resch gave final approval of the version of the article to be published; and all authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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