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Effects of craniosacral therapy as adjunct to standard treatment for pelvic girdle pain in pregnant women: a multicenter, single blind, randomized controlled trial

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Key words
Complementary medicine, alternative medicine, craniosacral therapy, pregnancy, pelvic girdle pain, randomized controlled trial

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All authors declare they had no support from any organization for the submitted work; no financial relation with any organizations that might have an interest in the submitted work in the previous 3 years; and no other relations or activities that could appear to have influenced the submitted work.

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Abstract

Objective. Pelvic girdle pain (PGP) is a disabling condition affecting 30% of pregnant women. The aim of this study was to investigate the efficacy of craniosacral therapy as an adjunct to standard treatment compared with standard treatment alone for PGP during pregnancy. *Design.* Randomized, multicenter, single blind, controlled trial. *Setting.* University hospital, a private clinic and 26 maternity care centers in Gothenburg, Sweden. *Population.* A total of 123 pregnant women with PGP. *Methods.* Participants were randomly assigned to standard treatment (control group, $n = 60$) or standard treatment plus craniosacral therapy (intervention group, $n = 63$). *Main outcome measures.* Primary outcome measures: pain intensity (visual analog scale 0–100 mm) and sick leave. Secondary outcomes: function (Oswestry Disability Index), health-related quality of life (European Quality of Life measure), unpleasantness of pain (visual analog scale), and assessment of the severity of PGP by an independent examiner. *Results.* Between-group differences for morning pain, symptom-free women and function in the last treatment week were in favor of the intervention group. Visual analog scale median was 27 mm (95% confidence interval 24.6–35.9) vs. 35 mm (95% confidence interval 33.5–45.7) ($p = 0.017$) and the function disability index was 40 (range 34–46) vs. 48 (range 40–56) ($p = 0.016$). *Conclusions.* Lower morning pain intensity and less deteriorated function was seen after craniosacral therapy in conjunction with standard treatment compared with standard treatment alone, but no effects regarding evening pain and sick-leave. Treatment effects were small and clinically questionable and conclusions should be drawn carefully. Further studies are warranted before recommending craniosacral therapy for PGP.

Abbreviations: ODI, Oswestry Disability Index; PGP, pelvic girdle pain; VAS, Visual Analog Scale.

Key Message

Significantly lower morning pain intensity and less functional deterioration was noted after craniosacral therapy provided in conjunction with standard treatment compared with standard treatment alone. There were no effects regarding evening pain and sick-leave. Treatment effects are small and clinically questionable and craniosacral therapy cannot be recommended for pelvic girdle pain in pregnancy.

Introduction

Pelvic girdle pain (PGP) is a condition affecting up to 30% of pregnant women (1,2). It causes pain, dysfunction, reduced health-related quality of life (2) and is one of the most common causes of sick leave during pregnancy (3). The risk for PGP in pregnancy is increased

in women with strenuous work (4) and women with previous PGP or back pain before pregnancy. No treatment cures PGP during pregnancy. The use of complementary and alternative medicine is increasingly prevalent among pregnant women, particularly for pregnancy-induced back-pain (5). The reasons for its popularity could be that pregnant women regard complementary and alternative medicine as more natural and safe compared with pharmaceutical drugs, and because they receive considerable support for its use from midwives (5).

Craniosacral therapy is one type of complementary/alternative medicine; a form of gentle "hands on" body work mainly applied to the head and neck area with claimed effects of released tension in the fascia, ligaments and muscles of the sacral region. Craniosacral therapy is recommended for all musculoskeletal problems, especially back pain. However, high-quality randomized controlled trials are lacking (6). The effect of craniosacral therapy is unclear. It is possible that the gentle "hands on" body work, i.e. sensory stimulation, activates central pain inhibitory centers leading to activation of descending pain inhibitory pathways or mechanoreceptors innervating sensory nerve fibers, leading to inhibition of pain transmission at the spinal level (7). It is also possible that effects could be due to expectation of pain relief, thus initiating placebo-elicited pain inhibition (8). Pregnancy is an important phase of life, therefore it is important to find effective care for PGP. The aim of this study was to compare the efficacy of craniosacral therapy as an adjunct to standard treatment with standard treatment alone for PGP during pregnancy.

Material and methods

A randomized multicenter single blind study was performed at Sahlgrenska Hospital, Sahlgrenska Academy, Tranbergs Private Health Clinic and 26 municipal antenatal clinics in Gothenburg between September 2009 and February 2011. Inclusion criteria were healthy pregnant women with singleton fetuses at 12–29 completed gestational weeks experiencing moderate evening pain, i.e. equal to or exceeding 40 mm on a 100-mm pain visual analog scale (VAS) during the baseline week. Participating women had to understand and read Swedish and be diagnosed with PGP according to European guidelines (2). This involved a history of pain between the posterior iliac crests and the gluteal folds, particularly in the vicinity of the sacroiliac joints along with or only in the symphysis pubis, a positive pain drawing with markings in the symphysis and/or in the gluteal areas distal and lateral to L5–S1, with or without radiating pain on to the posterior thigh but not to the foot, diminished endurance capacity for standing, walking and sitting, free range of motion in the hips and spine, and no nerve root syndrome, i.e. exclusion of lumbar causes such as a positive posterior pain provocation test (9) and/or the symphysis pubic pressure test (10). All criteria had to be be fulfilled for the diagnosis. Women with other pain conditions, a history of orthopedic disease or surgery of the spine or pelvic girdle or with systemic disorders, were excluded.

Midwives and physicians informed potential participants of the study at regular antenatal care clinic visits. Before screening, each woman completed self-administered questionnaires containing additional questions about demographics, body mass index**,** parity, previous back pain, medication, lifestyle issues, and filled out instruments for health-related quality of life and function. The latter were identical at baseline and follow up. Patients also made entries in a diary for baseline information during 5–7 days, and a pain drawing. At inclusion, a specially trained physiotherapist performed a detailed standardized physical examination for the diagnosis of PGP. The examination included Patrick's Faber test, a modified Trendelenburg test, the Symphysis pressure test and the Posterior Pelvic Pain Provocation test (9,10). These pain provocation tests were used to discriminate PGP from low back pain, as they have shown sensitivity for provoking pelvic structures (10). In addition a functional test, the Active Straight Leg Raising test, was used (11). All tests have been recommended by the guidelines (2). The study was approved by the Regional Ethical Committee in Gothenburg, Sweden (0915152009/099-09) and registered in Current Controlled Trials ISRCTN No. 30566933. Participants gave written consent before entering the study.

A research assistant not involved in the study administered pre-coded numbered identical opaque envelopes to assign participants to the intervention groups. A computer-generated random table was used. Stratified balanced randomization was performed to guarantee balance between groups for the frequency of sick leave. Sequences were derived from a table of correlatively ordered permutations of the letters A and B in groups of 10, with each letter appearing five times. The sequences assigned to women were placed in envelopes containing the allocation to each study group. One of the authors (H.E.) randomized women who fulfilled all inclusion criteria to standard treatment (control group) or to standard treatment plus craniosacral therapy (intervention group). Randomization occurred directly after screening.

Interventions

Women in the control group received the same standard treatment as in our previous studies (12,13). Standard treatment consisted of general information about the con-

dition and anatomy of the back and pelvis. The physiotherapist informed the woman of the relation between impairment, load demand, actual loading capacity and importance of necessary rest. Advice was given with respect to activities of daily living. The women received an elastic pelvic belt (Puff Igång AB, Gothenburg, Sweden) and a home training program including exercises to strengthen and stretch the trunk, hip and shoulder muscles (see Supplementary material, Figure S1). If exercises aggravated the pain, the women were advised to contact the physiotherapist for further instructions. In addition, they could always call the physiotherapist if they had questions or needed additional advice or crutches. Information was supplemented by a leaflet. All women met the physiotherapist twice, first at inclusion and then at the follow up. Women needing treatment at the follow-up visit were referred to a physiotherapist with special knowledge of PGP.

Women in the intervention group received the same treatment as the control group but received craniosacral therapy as well. They were treated with a manual release technique of the pelvis while supine. The therapist attempted release of tension in the fascia, ligaments and muscles using L5–S1 release, sacroiliac release, superior and inferior pubis symphysis release (14), i.e. a standardized functional therapy postulated as effective for PGP during pregnancy. The hands-on treatment took 45 minutes once weekly for 2 weeks, and every second week for 6 weeks. Two qualified, experienced (range 14–16 years of experience) craniosacral therapists provided the treatment. They met frequently throughout the trial to ensure that treatment and consultation types were as comparable and equivalent as possible.

Outcome measures

Primary outcome measures were frequency of sick leave and morning and evening pain on a 100-mm VAS (where 0 = no pain) assessed in the last treatment week. Secondary outcomes were the Oswestry Disability Index scale (ODI) (15), Disability Rating Index (16), European Quality of Life measure (17), intensity of discomfort of PGP (on a 100-mm VAS where 0 = no discomfort), and recovery of severity of PGP according to the blinded examiner. Women were requested to conceal any information concerning their treatment during assessment. Severity of PGP was assessed by positive pain provocation tests, markings on the pain drawing and pain levels (VAS). Symptoms were also divided into subgroups of PGP (18): symphysis pubis pain; one-sided or double-sided sacroiliac pain and pelvic girdle syndrome (=pain in sacroiliac joints plus symphysis pubis pain). Criteria for being free of symptoms from PGP according to the re-evaluation of the blinded examination were: no history of diminished endurance capacity for standing, walking or sitting; no positive pain provocation tests, no markings on the pain drawing and no pain = VAS $\leq$ 10 mm (19,20). The ODI contains 10 questions about limitations to activities of daily living. We used the revised version (2.0) as we considered it important to measure items concerning sexuality and pain intensity rather than pain medication. Each variable was rated on a 0 to 5 point scale, summed and converted into a percentage functional score ranging from 0 to 100 (where 0 = no disability). The Disability Rating Index contains ability for 12 activities indicated on a 100-mm VAS (where 0 = ability to perform the activity without difficulty). The European Quality of Life measure—five dimensions was used for measuring health-related quality of life. It assesses five dimensions: mobility, self-care, activities of daily life, pain and anxiety or depression. For each dimension, the woman describes three levels of problems (none, mild to moderate and severe). This descriptive system contains 243 index values for state of health. Range is from −0.43 to 1.0, in which −0.43 is the poorest health and 1 is the best health. The European Quality of Life measure—VAS is a vertical scale (0–100 in which 0 is the poorest imaginable health state and 100 is the optimal). Participants also scored their views of help from the treatment.

Statistical analysis

The sample size calculation was made before the study start. We assumed improvement in the primary outcome measure of pain, measured by VAS during the last treatment week. To detect a change of 15 mm between groups with 80% power and a 5% significance level, 50 women were needed in each group. To compensate for dropouts we included 123 women. An independent observer measured and entered the VAS on a separate spreadsheet without knowledge of the randomized assignment. The statistician performing the analysis was blinded to group and treatment. For missing data and dropouts, intention-to-treat analysis was applied to outcome data using the last value carried forward. In the analysis of the pain diaries, we defined the median VAS baseline levels morning and evening for each woman by calculating the median values before treatment (5–7 days). The same calculation was made for median pain for the last week of treatment. Medians, confidence intervals, quartiles, means and SDs were calculated when possible. The Mann–Whitney *U*-test was used to compare differences between groups concerning continuous variables, a chi-squared test or Fisher's exact test for categorical variables (21) and Test for Trend in a Contingency Table for categorically ordered variables (22). Median and confidence intervals were calculated

using the Mann–Witney *U*-test. All tests were two-sided using a significance level of 5%. Results were analyzed using SPSS, version 13.0 (SPSS Inc., Chicago, IL, USA) or SAS version 9 (SAS Institute, Cary, NC, USA).

Results

In all, 160 women were assessed for inclusion; 37 failed to meet the inclusion criteria, and 123 were included in the trial. The analysis was by originally assigned groups. Figure 1 shows participant progress during the study as well as dropouts. Five women in each group discontinued treatment, but were included in the intention-to-treat analysis. None gave birth before study completion. Baseline characteristics (Table 1) were similar in the treatment groups except for higher discomfort in the intervention group ($p = 0.046$).

Between-group analysis of data during the last treatment week is shown in Table 2. Lower pain intensity (VAS) in the morning ($p = 0.017$) and less detoriated functional ability (ODI) ($p = 0.016$) in the intervention group compared with the control group was seen. No significant between-group differences were found in the primary outcomes of evening pain intensity ($p = 0.275$) or sick-leave ($p = 0.084$). Neither was this seen as regards secondary outcomes of health-related quality of life scores (Table 2) or changes in sub-group affiliation of PGP according to re-examination by the blinded examiner (Table 3). However, 11 women (20%) in the intervention group compared with two (4%) in the control group were symptom-free ($p = 0.02$, Table 2).

No difference regarding credibility of treatment was found between the intervention group and controls 2 weeks after randomization (data not shown). Results from the women's scoring of their views on help derived from the treatment showed that more women in the intervention group found treatment helpful ($p = 0.001$). The number of women wishing to choose the treatment again if they had similar problems was not significantly different ($p = 0.38$, 38/48 or 79% of controls vs. 37/54 or 69% in the intervention group).

No serious adverse events were recorded. Ten women in each group reported disadvantages with treatment ($p = 0.93$, data not shown). Five minor adverse events were reported/listed in the intervention group: temporarily increased PGP ($n = 1$); elastic pelvic belt discomfort

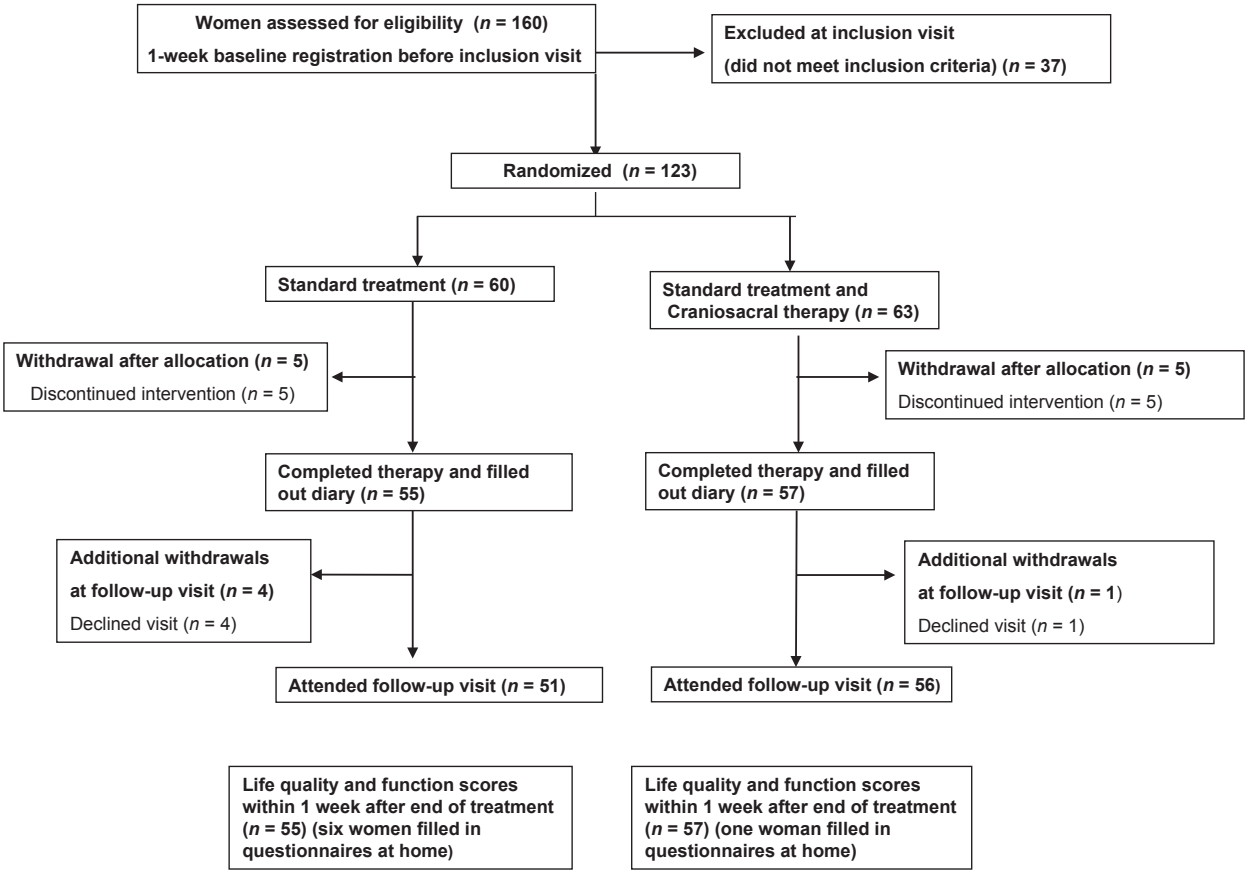

Figure 1. Flow-chart of the study showing participants' progress through the trial and withdrawals.

Table 1. Characteristics of the women before the treatment.

	Control group (n = 60)	Intervention group (n = 63)	Group comparisons, p-value
Maternal age, years	31.3 (4.3)	30.6 (3.9)	0.480a
Nulliparous women	18/58 (31.0)	19/63 (30.2)	0.917[b]
Body mass index before pregnancy	23.7 (3.6)	23.4 (3.4)	0.601a
Gestational week	22.3 (5.6)	21.0 (5.2)	0.208a
Women on sick-leave	12/57 (21.0)	17/62 (27.4)	0.435[c]
Previous low back pain	37/58 (63.8)	38/63 (60.3)	0.694[c]
Previous PGP	32/58 (55.2)	39/63 (61.9)	0.452[c]
Gestational week at start of PGP	15.2 (5.8)	14.3 (5.3)	0.365a
Pain related to motion, VAS			
Morning	28 (27 to 37)	27.5 (26 to 36)	0.084[c]
Evening	59 (53 to 62)	64.5 (60 to 66)	0.069[c]
Missing data	2 (3.0)	0	
Discomfort of PGP, VAS	45 (38 to 54)	55 (51 to 59)	0.046[c]
% ODI score	36 (30 to 40)	36 (32 to 40)	0.580[c]
DRI	53.5 (48 to 60)	58.5 (50 to 63)	0.540[c]
EQ-5D score	0.62 (0.59 to 0.70)	0.62 (0.36 to 0.62)	0.366[c]
EQ-VAS	50 (45 to 60)	50 (40 to 60)	0.405[c]
Severity of PGP			
Moderate complaints, PGP only affect ability to work sporadically	13 (23.6)	16 (25.4)	
Not insignificant, cannot do some parts of my work	23 (41.8)	19 (30.1)	
Severe, can almost not work	13 (23.6)	19 (30.1)	
Severe, cannot work at all	6 (10.9)	9 (14.3)	0.258[d]
Missing data	5/60 (8.3)	0	

Values are given as n (%), mean (SD) or median (95% confidence intervals) when appropriate. Control group = Standard treatment; Intervention group = Standard treatment plus craniosacral therapy.

PGP, pelvic girdle pain; VAS, visual analog scale; ODI, Oswestry Disability Index; DRI, Disability Rating Index; EQ-5D, European Quality of Life measure – five dimensions; EQ-VAS, European Quality of Life measure – visual analog scale.

[a]p-values from t-test for trend in a contingency table.

[b]p-values from chi-squared test.

[c]p-values from Mann–Whitney U-test.

[d]p-values from test for trend in a contingency table.

(n = 1) and drowsiness (n = 3). In the control group, four women found the elastic pelvic belt uncomfortable and two had temporarily increased PGP.

Discussion

The main finding was of lower morning pain intensity and less functional deterioration among the women receiving craniosacral therapy in conjunction with standard treatment compared with standard treatment alone, but no effects regarding evening pain and need for sick-leave were seen. Hence the treatment effects were small, clinically questionable and any conclusions should be drawn with care. Nevertheless, our findings support the conclusion of three previous studies suggesting that craniosacral therapy has pain-relieving effects and may halt deterioration of function (14,23,24). Still, the treatment effects did not reach the minimum clinically important differences between groups (25). It has been reported that a >30% or 13-mm reduction on a VAS represents, on average, the minimum change in acute pain considered clinically relevant (26,27). For low back pain the figures are 15 mm for VAS and $\geq$10points for the ODI (28). Minimum clinically important differences for PGP are not established and other values may be appropriate for different women and contexts according to the literature (28). The guidelines for the diagnosis of PGP state that PGP differs from ordinary back pain. For instance, low back pain improves after physical activity, whereas PGP worsens. Also, it it is well known that pain and disability increase in women with PGP as pregnancy advances (2). Consequently, even if women in the intervention group did not fully recover, their symptoms of PGP decreased compared with the standard group. Diminished function deterioration in combination with lesser morning pain may represent an important outcome for these women. This argument is strengthened by the result showing that significantly more women in the

Table 2. Between-group analysis of outcome measures after treatment. Analysis is by Intention-to treat analysis if not stated otherwise.

	Control group (n = 60)	Intervention group (n = 63)	p-value
Pain related to motion, VAS			
In the morning	35 (34 to 46)	27 (25 to 36)	0.0170[b]
In the evening	66 (55 to 67)	58 (48 to 60)	0.084[b]
Women on sick leave[a]	10 (16.6)	15 (23.8)	0.275[c]
Discomfort of pain (VAS)	51 (42 to 70)	51.5 (45 to 59)	0.432[b]
% ODI score	48 (40 to 56)	40 (34 to 46)	0.016[b]
DRI	61.5 (54 to 72)	58.0 (50 to 66)	0.303[b]
EQ-5D score	0.52 (0.18 to 0.69)	0.62 (0.59 to 0.69)	0.068[b]
EQ-VAS	47 (40 to 60)	57.5 (40 to 65)	0.319[b]

Values are given as n (%) and medians (95% confidence intervals). Control group = Standard treatment; Intervention group = Standard treatment plus craniosacral therapy.

VAS, visual analog scale; ODI, Oswestry Disability Index; DRI, Disability Rating Index; EQ-5D, European Quality of Life measure – five dimensions; EQ-VAS, European Quality of Life measure – visual analogue scale.

[a]Drop outs or missing diaries = per protocol analysis.

[b]p-values from Mann–Whitney U-test

[c]Fisher's exact test.

intervention group had fewer symptoms and found treatment helpful. One can argue that although symptom-free from PGP, participants did not return to their ordinary work, but sick leave is inexact for assessing pain. It is important to investigate the effects of complementary and alternative medicine with the same standards and scrutiny as for conventional medical procedures. We used the VAS for measurements of intensity and unpleasantness of pain, the Disability Rating Index for measurements of ability to perform daily activities and the ODI for measurement of back-specific function. These measurements have been shown to be highly reliable and valid and have been used in intervention studies for PGP in pregnant women (12,13).

The rationale for the large variation in gestational week was to enable women with early as well as late debut of PGP to participate. The study period included one baseline week and 8 weeks of treatment. Hence, all women had the possibility of reaching gestational week 37^{+0}, i.e. a time when pregnancy is considered "full term". If included later, the risk for delivery before study completion would have been greater.

Table 3. Between-group analysis of secondary outcome measure: assessment by an independent examiner before intervention and at follow-up within 1 week after end of treatment. There were no significant differences between the groups at inclusion.

	Control group		Intervention group		Group comparison after treatment p-value
	Inclusion (n = 60)	Follow-up (n = 51)	Inclusion (n = 63)	Follow-up (n = 56)	
Positive pain drawing	60 (100.0)	48 (98.0)	63 (100.0)	45 (78.9)	0.239[a]
Pain provocation tests					
P4-test	54 (90.0)	44 (89.8)	59 (93.7)	40 (70.2)	0.148[a]
Patrick's Faber test	37 (61.7)	35 (71.4)	39 (61.9)	28 (49.1)	0.063[a]
Modified Trendelenburg test	27 (45.0)	21 (43.8)	29 (46.0)	7 (12.3)	0.027[a]
Palpation of the pubic symphysis	27 (45.0)	21 (43.8)	35 (55.6)	26 (45.6)	0.606[a]
Functional test					
ASLR test (sum of scores)	3 (0–10)	4 (0–10)	2 (0–10)	3 (0-9)	0.880[a]
Subgroups of pelvic girdle pain					
Pelvic girdle syndrome	17 (28.3)	19 (38.8)	24 (38.1)	12/57 (21.1)	0.053[a]
Double-sided sacroiliac pain	29 (48.3)	15 (32.6)	19 (30.2)	15 (26.3)	
One-sided sacroiliac pain + symphysis pubis pain	4 (6.7)	3 (6.1)	10 (15.9)	13 (22.8)	
One-sided sacroiliac pain	4 (6.7)	8 (16.3)	6 (9.5)	2 (3.5)	
Symphyseal pain	6 (10.0)	5 (10.2)	3 (4.8)	2 (3.5)	
Symptom-free		2 (4.1)		11 (19.3)	0.020[b]

Control group = Standard treatment; Intervention group = Standard treatment plus craniosacral therapy.

Results are n (%) if not stated otherwise.

P4-test, posterior pelvic pain provocation test; ASLR-test, active straight leg raising test; Double-sided sacroiliac pain, pain in both sacroiliac joints; One-sided sacroiliac pain, pain in one sacroiliac joint; Pelvic girdle syndrome, pain in both sacroiliac joints plus symphyseal pain; Symptom-free, no positive tests, no markings on the pain drawing, no history of diminished endurance capacity for standing, walking and sitting and no pain (visual analog scale $\leq$ 10 mm).

Standard treatment versus Standard treatment plus craniosacral treatment with respect to distribution over subgroups of pelvic girdle pain at inclusion: p = 0.307, chi-squared test with four degrees of freedom.

[a]p-values from Chi-squared test

[b]Fisher's exact test.

Potential limitations of the study were sample size, but we calculated that 100 women would be sufficient and included 123, which permitted us to use the applied methods. Less attention to the control group, inability to blind participants to craniosacral therapy, intensity of provider contact in the craniosacral group, and a positive attitude towards complementary and alternative medicine among participants possibly affected results. The women in the control group received the best "usual care" provided individually by an experienced physiotherapist. It is likely that the women had more attention in general than usual because of their participation. We do not think the decision to not include a group receiving sham treatment biased the effects, because research of prefrontal non-opioid mechanisms in placebo analgesia have suggested that a placebo response may not be interpreted as passive control, because it is a highly active state in itself (8).

The strength of this study was that the women included had a verified clinical diagnosis of PGP, and that experienced therapists were consulted before carrying out the trial to ensure that craniosacral therapy would be directly comparable to what was normally provided for these women. Other strengths of the study included a low dropout rate (9%), clinically relevant outcomes, intention-to-treat analysis (29) and successful blinding of the examiner.

To minimize the influence of pre-existing beliefs and expectations with respect to craniosacral therapy, such as on its possible placebo effect, we informed participants that the study was designed to compare standard treatment with standard treatment in conjunction with craniosacral therapy and that the latter had not been evaluated for PGP. This decision reduced participants' expectations and was likely to minimize bias, as no differences were found in credibility of the treatments 2 weeks after randomization (data not reported), indicating that our neutral presentation of the interventions was successful.

Conclusion

Our study shows less pain intensity in the morning and less deteriorated function, both reaching a degree of significance, when craniosacral therapy was combined with standard treatment for PGP in pregnancy. Treatment effects were, however, small and clinically questionable. The interpretation must therefore be guarded and further studies of the effectiveness of craniosacral therapy for PGP during pregnancy are warranted.

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References

1. Björklund K, Bergström S. Is pelvic pain in pregnancy a welfare complaint? Acta Obstet Gynecol Scand. 2000;79:24–30.
2. Vleeming A, Albert HB, Östgaard HC, Sturesson B, Stuge B. European guidelines for the diagnosis and treatment of pelvic girdle pain. Eur Spine J. 2008;17:794–819.
3. Sydsjö A, Alexanderson K, Dastserri M, Sydsjö G. Gender differences in sick leave related to back pain diagnoses: influence of pregnancy. Spine. 2003;28:385–9.
4. Juhl M, Andersen PK, Olsen J, Andersen AM. Psychosocial and physical work environment, and risk of pelvic pain in pregnancy. A study within the Danish national birth cohort. J Epidemiol Community Health. 2005;59:580–5.
5. Ernst E, Watson LK, Midwives' use of complementary/alternative treatments. Midwifery 2012;28:772–7.
6. Green C, Martin C, Bassett K, Kazanjian A. A systematic review of craniosacral therapy: biological plausibility, assessment reliability and clinical effectiveness. Complement Ther Med. 1999;7:201–7.
7. Melzac R, Wall P. Pain mechanism: a new theory. Science. 1965;150:971–9.
8. Petrovic P, Kalso E, Petersson KM, Andersson J, Fransson P, Ingvar M. A prefrontal non-opioid mechanism in placebo analgesia. Pain. 2010;150:59–65.
9. Östgaard HC, Zetherstrom G, Roos-Hansson E. The posterior pelvic pain provocation test in pregnant women. Eur Spine J. 1994;3:258–60.
10. Albert H, Godskesen M, Westergaard J. Evaluation of clinical tests used in classification procedures in pregnancy-related pelvic joint pain. Eur Spine J. 2000;9:161–6.
11. Mens JM, Vleeming A, Snijders C, Koes BW, Stam HJ. Reliability and validity of the active straight leg raise test in posterior pelvic pain since pregnancy. Spine. 2001;26:1167–71.
12. Elden H, Ladfors L, Olsen MF, Östgaard HC, Hagberg H. Effects of acupuncture and stabilising exercises as adjunct to standard treatment in pregnant women with pelvic girdle pain: randomised single blind controlled trial. BMJ. 2005;330:761–64.
13. Elden H, Fagevik-Olsen M, Östgaard HC, Stener-Victorin E, Hagberg H. Acupuncture as an adjunct to standard treatment for pelvic girdle pain in pregnant women: randomised double-blinded controlled trial comparing

acupuncture with non-penetrating sham acupuncture. BJOG. 2008;115:1655–68.
14. Licciardone J, Buchanan S, Hensel K, King H, Fulda K, Stoll S. Osteopathic manipulative treatment of back pain and related symptoms during pregnancy: a randomized controlled trial. Am J Obstet Gynecol. 2010;202:e1–8.
15. Fairbank J, Couper J, Davies J, O'Brien J. The Oswestry low back pain disability questionnaire. Physiotherapy. 1994;66:271–3.
16. Salen BA, Spangfort E, Nygren AL, Nordemar R. The Disability Rating Index: an instrument for the assessment of disability in clinical settings. J Clin Epidemiol. 1994;47:1423–35.
17. Rabin R, De Charro F. EQ-5D: a measure of health status from the EuroQol Group. Ann Med. 2001;33:337–43.
18. Albert H, Godskesen M, Westergaard J. Prognosis in four syndromes of pregnancy-related pelvic pain. Acta Obstet Gynecol Scand. 2001;80:505–10.
19. Enthoven P, Skargren E, Kjellman G, Oberg B. Course of back pain in primary care: a prospective study of physical measures. J Rehabil Med. 2003;35:168–73.
20. Elden H, Hagberg H, Olsen M, Ladfors L, Östgaard H. Regression of pelvic girdle pain after delivery: follow-up of a randomised single blind controlled trial with different treatment modalities. Acta Obstet Gynecol Scand. 2008;87:201–8.
21. Maxwell AE. Analyzing qualitative data. London: Methuen, 1961.
22. Cochran W. Some methods for strengthening the common chi-squared tests. Biometrics (International Biometric Society). 1954;10:417–51.
23. Castro-Sánchez AM, Matarán-Peñarrocha GA, Sánchez-Labraca N, Quesada-Rubio JM, Granero-Molina J, Moreno-Lorenzo C. A randomized controlled trial investigating the effects of craniosacral therapy on pain and heart rate variability in fibromyalgia patients. Clin Rehabil. 2011;25:25–35.
24. Harrison RE, Page JS. Multipractitioner upledger craniosacral therapy: descriptive outcome study 2007–2008. J Altern Complement Med. 2011;17:13–17.
25. Copay AG, Subach BR, Glassman SD, Polly DW Jr, Schuler TC. Understanding the minimum clinical important difference: a review of concepts and methods. Spine J. 2007;7:541–6.
26. Vas J, Perea-Milla E, Méndez C, Sánchez Navarro C, León Rubio JM, Brioso M, et al. Efficacy and safety of acupuncture for chronic uncomplicated neck pain: a randomised controlled study. Pain. 2006;126:245–55.
27. Gallagher EJ, Liebman M, Bijur PE. Prospective validation of clinically important changes in pain severity measured on a visual analog scale. Ann Emerg Med. 2001;38:633–8.
28. Ostelo RW, de Vet HC. Clinically important outcomes in low back pain. Best Pract Res Clin Rheumatol. 2005;19:593–607.
29. Hollis S, Campbell F. What is meant by intention to treat analysis? Survey of published randomised controlled trials BMJ. 1999;319:670–4.

Supporting information

Additional Supporting Information may be found in the online version of this article:

Figure S1. Home training program.

