

ORIGINAL ARTICLE

Effects of craniosacral therapy as experienced by pregnant women with severe pelvic girdle pain: An interview study

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Abstract

Background: Pelvic girdle pain (PGP) affects 50% of pregnant women worldwide. PGP increases with advancing pregnancy with considerable impact on quality of life, interfering with sleep, daily activities, work, motherhood and close interpersonal relationships. The use of Complementary and Alternative Medicine (CAM) is increasingly prevalent among pregnant women, particularly for pregnancy-induced back pain. Craniosacral treatment (CST) is a CAM that has shown symptom relieving effects in pregnancy-related back pain. The purpose of this study was to describe women's experiences of the treatment.

Methods: Twenty-seven women receiving CST plus standard treatment (ST) were interviewed following 3 of 5 treatments with CST by two qualified and experienced CST practitioners. Data were analysed using qualitative content analysis.

Results: The experience of CST by pregnant women diagnosed with severe PGP can be described in three categories: An unfamiliar and different treatment method; description of treatment effects, and regaining a personal and social life.

Women described how CST provided them with new awareness of their widespread muscle tension. They told of how they experienced increased body awareness, distraction from pain, relaxation and calm, and feelings of security and optimism. These factors may have helped them actively improve posture and lower muscle tension thereby relieving the symptoms of PGP.

Conclusions: The present study reports a contextual interpretation of previously published quantitative data, as it provides a deeper understanding of total symptom relief from PGP during pregnancy.

Trial registration: The trial is registered at Current Controlled Trials ISRCTN30566933.

Key words

Complementary and alternative medicine, Craniosacral therapy, Pregnancy, Pelvic girdle pain, Qualitative interview study

1 Introduction

Pelvic girdle pain (PGP) is a major health issue, affecting about 50% of pregnant women ^[1, 2] at all socio-economic levels ^[3], resulting in sick leave ^[4] and possible long-term pain ^[5-7]. Although the vast majority of studies have been carried

out in Scandinavia^[8-12], the condition has also been reported in Africa^[3], the Americas^[13], Asia^[14, 15], Australia^[13] and Europe^[16-18]. PGP is a musculoskeletal pain concentrated to an area between the posterior iliac crests and gluteal folds, particularly in the sacroiliac joint area. This can occur with or without pain in the symphysis^[19]. Prevalence estimates for PGP range widely from 20% in general^[19], to 35%-50% in early pregnancy, and 60%-70% in late pregnancy^[21, 22]. For 25% to 30% of pregnant women the problem becomes severe^[1-2]. The majority of women recover from PGP the first months after delivery regardless of treatment or not^[16, 22]. However, PGP from the postpartum stage to 3 years after childbirth has a reported prevalence of 9% to 20%; and 6% of women have persistent pain after 6 years^[5-7]. Women affected with PGP typically adapt abnormal antalgic patterns of muscle activity. The longer these patterns persist, the more pain arises from unphysiological loading of muscles and joints. The pain will in turn increase muscle dysfunction leading to a vicious cycle. PGP usually gets worse as pregnancy advances causing dysfunction and reduced health-related quality of life^[19]. We have previously described how PGP caused women to question and doubt their roles as mothers, spouses and professionals. PGP affected trust in their bodies as well as their capabilities to guide and control them. The fear of triggering pain and unpleasant sensations led them to avoid movement. In addition, they felt worse when their complaints were trivialized and not taken seriously by health care personnel^[23, 24]. Other studies have described how women with PGP saw their pain as predominant and beyond control, leading to feelings of uncertainty^[25], and sometimes even of fearing for their mental health^[26].

To date, no treatment can cure PGP during pregnancy. A recently published Cochrane review^[20] of 26 randomised trials including pregnant women (n= 4093) until 2012 reported moderate evidence for pain-relieving effects of acupuncture. Only low quality evidence was found for pain relief from a rigid belt as an adjunct to exercise, that exercise can generally relieve pain, and that a multi-modal intervention including manual therapy, exercise and education (MOM) can reduce disability and pain while improving physical function. Thus, research is needed to find effective treatment strategies for this widespread disabling condition.

The use of Complementary and Alternative Medicine (CAM) is increasing in pregnant women, particularly for pregnancy-induced back pain^[27, 28]. CAM is described as “the array of health care approaches with a history of use or origins outside of mainstream medicine”^[29]. It encompasses a wide range of therapies either parallel to conventional medicine (Complementary Medicine) or completely separate from it (Alternative Medicine). It has been stated that its use during pregnancy is not regarded as a criticism of conventional medicine but often an expression of women’s desires to actively participate in their health care. Its popularity for pregnancy-induced back pain may be that conventional treatment (exercises, pelvic belts and information) does not relieve symptoms of PGP, and that pregnant women regard CAM as more natural and safer than medication. In addition, they receive considerable support for its use by their midwives^[27, 28]. It has been reported that even obstetrical care providers consider the use of CAM more often than before but are unaware of about 50% of their patients’ use of it^[30].

Craniosacral therapy (CST) is one type of CAM. It is carried out by applying gentle sensory stimulation through “hands on” techniques to treat somatic dysfunctions of the head and body. It is applied mainly to the head and cervical area, and is thought to release tension in the fascia, ligaments and muscles of the sacral region. Its mechanisms are as yet unclear^[31], but it has been suggested that restrictions to the craniosacral system (bones, membranes and cerebrospinal fluid surrounding the brain and spinal cord) can be manually identified, and that palpation and manipulation of the system can affect sensory, motor, cognitive and emotional processes within the nervous system^[32]. This gentle “hands on” stimulation may also inhibit pain, activate gate control mechanisms on a segmental level, inhibit pain transmission on a spinal level^[33], and stimulate central pain inhibitory centres leading to activation of descending pain inhibitory pathways^[34]. It has been discovered that unmyelinated sensory neurons are activated by lightly touching the skin^[35]. Moreover, newly published research concludes that CT (C tactile) afferents, a distinct type of unmyelinated, low-threshold mechanoreceptive units, existing in the hairy but not glabrous skin of humans and other mammals, are attuned to respond to tactile stimuli with the specific characteristics of a gentle caress delivered at typical skin temperature, which is the case in CST. This stimulation provides a peripheral mechanism for signalling pleasant skin-to-skin contact in humans, which

promotes interpersonal contact and associated behaviour^[36]. It is also possible that the effects could be due to expectations of pain relief and the therapeutic relationship between patient and therapist.

CST is used in a variety of countries, such as Iceland, Spain, Sweden, the United Kingdom and the United States. This form of treatment is used by a wide variety of health care practitioners, such as chiropractors, physical therapists, physicians, and massage therapists^[31]. It is applicable in different clinical settings for both adults and children^[37], and has shown pain relieving effects and improvement of health-related quality of life in patients with fibromyalgia^[38], migraine^[39], asthma^[40] and pregnancy-related low back pain^[41]. It has recently been shown that according to a blinded examiner, a statistically significant number of pregnant women 11/51 (20%) receiving CST as an adjunct to standard treatment (ST) for PGP became symptom-free (no positive pain provocation tests, no markings on pain drawings, no history of diminished endurance capacity for standing, walking or sitting) and no pain (visual analogue scale ≤ 10 mm) compared to 2/56 (4%) of women who received ST alone^[10]. To our knowledge, no study has described experiences of CST.

Aim of the study

This study aims to describe pregnant women's experiences of the effects of CST on severe PGP.

2 Patients and methods

This qualitative descriptive^[41] study was conducted in western Sweden between May 2009 and June 2010. It was part of a project encompassing an RCT comparing CST plus ST with ST alone for well-defined PGP^[10]. ST (education, a pelvic belt and home exercise) was the same as in two previous treatment studies for PGP^[8,9]. CST was performed in a spacious room with windows and natural light. The women were treated in a supine position. Some women chose to have a small pillow under their back that allowed them to lie partly on their side. CST took 45 minutes once weekly for 2 weeks, and once every second week for 6 weeks, or a total of 5 treatments by one of two qualified, experienced (range 14 to 16 years) CST practitioners. As there were no previously published studies of CST for PGP, the protocol was based on clinical experience. The women were treated with a manual release technique of the pelvis in the supine position. The therapist attempted release of tension in the fascia, ligaments and muscles using L5-S1 release, sacroiliac release, superior and inferior pubis symphysis release^[41], i.e. a standardized functional therapy assumed effective for PGP during pregnancy.

2.1 Informants

Informants were the same as in two previously published qualitative studies of pregnant women's experiences of PGP related to daily life^[23], bodily experiences and the health care system^[24]. Twenty-seven women were asked to participate and all accepted and were included. None had received CST previously. They were selected^[42] to ensure a broad range of views and experiences of CST, e.g. both responders and non-responders. Mean age was 21-38 (mean = 27 years). All women were married/cohabiting, and 96% had completed at least some college or university studies. All but two women, one student and one unemployed, were working.

2.2 Qualitative method

Qualitative research takes consideration to subjectivity and complexity. It seeks not to quantify or reduce, but represent rich, subjective experiences to reflect on subtle and complex processes involved in the practice of CAMS, while retaining the nuances of the data^[43]. Qualitative studies are of particular importance for phenomena not previously investigated^[44], and this study may lead to greater understanding of favourable effects of CST^[45]. This research used qualitative content analysis^[46-48] with a long tradition within communication, journalism, sociology, business, and document analysis^[47].

2.3 Data collection

At a time and location convenient to participants, interviews were conducted by a registered nurse/midwife with extensive experience in supporting women with PGP. Data were collected after a minimum of 3 of 5 CST sessions using in-depth^[44], face-to face interviews. Participants described their experiences of living with PGP. An open-ended question was used “Please tell me of your experience of living with PGP?” If the woman did not relate their experiences of CST they were asked about them. This allowed issues of importance to the interview subject to emerge. Follow-up questions such as ‘How did that feel’ and ‘Can you please tell me more,’ were also asked to deepen understanding. The interview lasted 30 to 70 minutes (mean 60 minutes), and were audiotaped, transcribed and de-identified by HE. Interviews were conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee, University of Gothenburg, Sweden (703-09). All informants signed informed consent before interviews were conducted (WHO 2008).

2.4 Data analysis

Qualitative content analysis involves identification, coding and categorisation of primary patterns emerging from the collected data^[49]. In this study a qualitative content analysis was used inductively^[47]. The data were independently analysed by two of the authors (HE and ER). At first, transcripts were read repeatedly to obtain a composite perspective. Sentences or phrases containing information relevant to the questions were then selected. Finally, a systematic analysis of interview responses was performed. Each interview was read through several times and codes relevant to the study’s purpose were identified. Claims were cut out and sorted according to the selected categories. The multiple codes were sorted into subcategories by moving back and forth between the whole text and meaning units. These were then merged into main categories after a thorough, comparative analysis^[55]. NVivo8 was used to code and review categories (www.qsrinternational.com/).

3 Results

Three categories emerged from the analysis describing the women’s experiences of receiving CST: 1) an unfamiliar and different treatment method, 2) descriptions of treatment effects and 3) regaining a personal and social life. Selected quotations from the interviews are included to provide the reader with an opportunity to evaluate both the interpretations and credibility of the analysis^[50].

Table 1. Category system describing pregnant women’s experiences of CST for PGP

Sub-categories	Categories
No expectations, more likely a sceptical view	An unfamiliar and different treatment method
A pleasant and non-demanding treatment	
Professional care	
Effects on Muscle tension and pain	Description of treatment effects
Varying treatment effects	
CST has few disadvantages	
Awareness of how treatment influenced pain	
Spouse and workmate reactions to treatment effects	Regaining a personal and social life
Renewed spark	
Dare to get pregnant again	

3.1 An unfamiliar and different treatment method

3.1.1 No expectations, more likely a sceptical view

The women had no previous knowledge of CST. All they knew of the treatment was what they had read in the study’s participant information and on the Internet, which created no particular expectations of the method. The women stated fear

of using analgesics during pregnancy and that they were more open to alternative treatment forms such as CST. Many were also sceptical towards the treatment since it is not accepted in Swedish health care. One patient told of her scepticism at her first visit to the health care clinic.

So I sat just like this with my arms folded and looked him right in the eye and said: You should know I'm very sceptical and have no time for this (laughs). I'm in severe pain and I have to get to work. (IP 1)

3.1.2 A pleasant and non-demanding treatment

CST felt comfortable as a gentle touch or pressure. The women explained how they felt relaxed and calm; some women described it as intense and restful.

Well, there was quiet and calm, and I lay there with my eyes closed. (IP 12)

One woman said how the treatment helped her to be "here and now", which she felt was good. Several women also told of how much they valued treatment, not just being left to train on their own. They felt they could share responsibility for their health with someone else.

You are supposed to do the exercises yourself but sometimes it's nice to get help from the outside. (IP 2)

However, another woman told of how she was confused and believed in active treatment methods involving her own initiative (as a patient). Many women described a pleasant physical feeling after treatment.

And you leave there, how can I say, calm, calm and relaxed and..... (IP 12)

Many women expressed how they felt a sense of excitement when considering that treatment could have such a strong effect from so outwardly little taking place during treatment.

It felt very strange to receive this treatment since I was expecting massage (laughs). (IP 5)

The women reflected on the fact that the treatment relieved their pain when rating it in their diaries.

I really thought there were many crosses high up on the scale in the beginning. Now I think they're very low. It's been really good, very, very good. (IP 14)

3.1.3 Professional care

The women experienced the therapists as good listeners, careful, competent and professional.

Just to hear someone say I'm good at this, was very pleasing. It was pleasant going there, and being touched. (IP 11)

One woman pointed out how she appreciated that the therapist explained the holistic way of thinking in CST. That they were reminded to listen to their bodies, and rest when it signalled the need for rest, motivating them to take better care of themselves.

They always speak of being pregnant as such and such... take heed to your body...don't go jogging but take it easy...giving you something to think about. (IP 13)

3.2 Description of treatment effects

3.2.1 Effects on Muscle tension and pain

Women stated that prior to treatment their bodies were tense and stiff. Something happened during treatment, something that eased tension causing muscles to relax. This soothed the pain.

It feels as if much is going on inside my body. I feel secure and my entire body is in a state of total relaxation. At that point all the pain disappeared. It was gone. (IP 10)

A woman told of how when the therapist pressed on a specific area on the back of her head, she received an instant feeling of warmth all over her face and head. The women expressed how their bodies felt more relaxed, as if they had reached equilibrium. They said it felt like their bodies exhaled with relief.

Wow, amazing...I'm like a ragdoll, that's obvious...I think we are on to something here. (IP 2)

The women related how they became aware of muscle tension in the pelvic area. One woman who experienced no treatment effects on her PGP said that the treatments, however, made her aware of how physically tense she was; that it felt as if her body fought against the efforts of the therapist, making things worse. She speculated that it may have depended on her initial condition; that she had always been very tense physically.

3.2.2 Varying treatment effects

Even if most of the women expressed that treatment provided relief from their PGP they described the treatment effects in different ways, and that each session was different.

The first treatment was awesome. The following sessions didn't alter much but it still felt as if I had turned a page. (IP 1)

Some women said that several treatments were necessary before experiencing an effect.

After the second session I felt fantastic. I almost forgot that I had PGP when climbing stairs. (IP 8)

Some women reported some residual PGP, but that all other pain was almost completely gone, which of itself was of great value. For example, one woman pointed out that her tension headaches and neck pain had decreased. Another woman said her shoulder pain had disappeared and her mobility increased. Other women reported no effect whatsoever of CST, and some said the effect lessened after a while.

The effects lasted about 10 days, but were magical, and the pain doesn't disappear suddenly but gradually. (IP 1)

3.2.3 CST has few disadvantages

The women reported one disadvantage of the treatment, extreme fatigue, describing grogginess following treatment. It felt as if they could sleep around the clock. Some mentioned feeling uncomfortable lying on their backs or sides and someone reported soreness after treatment. One described feeling like she was going to faint until turning on her side. A few preferred having the same therapist for all treatments since they held their hands on the pubic bones and coccyx. The women reported feeling completely secure but some commented that the pelvis is an intimate, private area:

I've thought about the fact that the worst pain I've had comes from an area very near my sex, here. And I thought "they can't treat me here!". (IP10)

3.2.4 Spouses and workmates confirmed positive treatment effects

Several women pointed out that their partners had taken notice of how their movement patterns became more normal. Women complained less and appeared to have less pain. They even told of some husbands saying their wives had become symptom-free.

My husband said that ‘now you run around almost as if you were completely well’. (IP 5)

The women told how their husbands were very curious as to what the treatment implied and what took place at the treatment sessions. But the most important thing was that she herself believed in the treatment and benefited from it. One woman told of her husband’s comment that perhaps with proper knowledge and support the body can heal itself. Another said her husband felt that this pregnancy had been completely different due to CST.

The women told how workmates had noticed that treatments had helped. They received spontaneous comments on how they could see that the women moved more easily, that it took less time for them to get out of a chair, and that they could see they had less pain and problems.

Yes, someone actually said at work; Is that you? I thought your steps were a bit too quick (laughs). (IP 4)

My workmates told me I stopped limping as soon as I had been treated. (IP 3)

3.3 Regaining a personal and social life

3.3.1 Renewed spark

One woman told of how simply receiving CST made her see things brighter. She recommended it highly. Many discovered that they could “read” their bodies better and felt more at home, more at one with their bodies, while some thought that CST helped them better maintain control of their bodies. Other women commented that even if they had some pain they became more active and alert.

To walk normally again, not marathon walks but longer one... not nearly as much pain in the evenings. (IP 6)

3.3.2 Dare to get pregnant again

The women said that were they to suffer from PGP in future pregnancies it would be worth their while to pay for treatment themselves. Several women also said that the treatment made them re-evaluate their decision of no future pregnancies.

I experienced a completely fantastic effect of this treatment. I said to them today that I could actually consider going through this again because it was such a fantastic experience, so I’m overjoyed. (IP 3)

4 Discussion

To our knowledge, this is the first qualitative study to describe women’s experience of CST in pregnancy. The women described that CST provided them with a new awareness of their widespread muscle tension. This awareness helped them see their bodies more as a whole, not as something just to be disciplined, restrained or controlled. They could now better influence their feelings and accept their condition. As a result they felt more comfortable in daily life, enabling them to experience a greater sense of “control” over their situation.

This study uniquely reports a contextual interpretation of previously published quantitative data of favourable treatment effects of CST plus ST compared to ST alone for PGP in pregnancy ^[10]. That study showed statistical and clinically significant differences in the number of women free of PGP according to a blinded examiner. However, the clinical effects

on morning pain and deterioration in function in women receiving CST plus ST compared to controls receiving ST alone were questionable^[10].

4.1 Study method

CST was administered by two therapists who treated all the women, which led to two vital interactions with the participants. However, this study did not investigate participant-therapist interaction. Also, participants expressed scepticism, and some related no effect from the treatment whatsoever.

The researchers formulated the qualitative research questions when planning the study from the project's start to complement the RCT. However, the primary aim was to describe women's experiences of living with PGP during pregnancy, thus questions concerning the treatment received were also included. The researchers' (HE and ER) preconceptions (besides that which as midwives having taken care of women with PGP during pregnancy) of CST consisted of information that CST could relieve PGP in pregnant women. In addition, participants were, prior to the interviews, unknown to the interviewer who was uninvolved in the treatments. This aided the researcher's openness toward the women^[43]. Interviews were conducted during the treatment period, which prevented recall bias. In-depth interviews were used as they provided a way of entering the women's world, and helped gain an understanding of how they talked about their experiences of CST. That qualitative research methods complementing RCTs can greatly enhance understanding of CAM interventions has been confirmed by several researchers^[45, 51, 52]. They state that CAM treatments, which are complex, are divided into standardized treatment methods in RCTs^[51] and that the efficacy of CAMs in RCTs only address whether an intervention has a statistical effect or not^[45]. They state that the RCT design does not take into account that the main effect variable may not function on a conventional 'dose' level, or is dependent on the skill of the practitioners or tailored to individual needs^[52]. One strength of the study is the triangulation of methods to increase the understanding of how CST as an adjunct to ST can eliminate symptoms of PGP as assessed by an independent examiner^[10]. Increased pain and disability is expected in women with PGP as pregnancy advances, which was the case for women receiving ST alone. Moreover, results confirmed descriptions of awareness of diminishing pain (pain VAS), and that they were significantly more satisfied with treatment than those only receiving ST^[10]. Results also support previously reported treatment effects of CST in pregnancy-related back pain^[41], and research showing that lightly touching the skin^[36] can elicit physiological responses^[53].

Another strength of the study was that the manuscript conforms to the RATS guidelines for the reporting of qualitative studies^[54]. Informants involved were specifically selected. Selecting participants with diverse perspectives and backgrounds enriches and challenges emerging conceptualizations. To assess validity criteria we had to assure the credibility of the women's various experiences of CST, and highlight subtle differences in their voices to assure authenticity. Explicitness and integrity is assured through a careful analysis process involving thorough review of the data^[48]. Moving back and forth between the text and output of content analysis was performed to enhance trustworthiness. It provided progressive refining and validation of the category scheme. Moreover, researcher IL acted as an independent analyst reviewing data and confirming subcategories and main categories.

This study had, however, several limitations. One limitation was that results must be interpreted in relation to its context^[48]. The fact that qualitative findings are contextual does not imply lack of meaning in other contexts but must be related to the new context when findings are transferred^[48]. Further, this group consisted of women who chose to participate in an RCT involving a CAM treatment, thus they probably had a positive attitude towards CST. In addition, all had received additional information and treatment for PGP, which may have affected their perception of CST. Other limitations are that results only reflect experiences during one treatment period with CST and not long-term experiences. Also, results might apply only to pregnant women with PGP and not for patients with other sources of pain.

4.2 Discussion of the results

The results show that CST increased the women's awareness of their muscle tension. This implied that they saw their bodies more as a whole and not as just something to restrain or control. With this they could better influence their moods and accept their situation. As a consequence they felt more at home in their daily lives thus experiencing greater control. The women experienced the therapists as good listeners, careful, competent and professional. The study confirmed that patient satisfaction depends on empowerment and control of one's life, and achieving an empathetic therapeutic relationship ^[55].

The inclusion criterion for the study was a diagnosis of PGP. The aim was therefore to highlight this defined group of women's experiences of receiving CST. Expectations, are known to play an important role in patient satisfaction within healthcare environments ^[56], including an osteopathic training clinic ^[55]. However, the results show that before treatment, the women had no expectations of CTS, which is confirmed by their rating of credibility of the treatment ^[57] in the RCT ^[10]. But because there was no other available treatment, they decided to participate. Results are supported by previous studies showing that women with pregnancy-induced back pain are particularly prone to the use of CAM ^[58]. But, as the women became more confident in treatment benefits, such as decreased pain, halted deterioration of function, and positive effects on other conditions than PGP, they became less sceptical. Positive results may be related to increased awareness of body postures and tensions, providing a feeling of being able to relieve and prevent their pain. Another mechanism was activation of the reward system in the brain induced by light touch ^[59]. Some participants perceived this feeling of being a "complete person", providing them with a more relaxed approach and greater acceptance of the pregnancy's influence on their daily form. However, others expressed it as a way to control general well-being in daily life. An internal locus of health control has been shown to promote an individual's use of internal, active, coping strategies such as active strategies for lifestyle change ^[60]. Moreover, pain acceptance, striving to maintain psychosocial function regardless of pain, is linked to reduced pain, disability, inactivity, and depression ^[61].

The women described how therapists increased motivation to take care of themselves. Satisfaction with treatment was confirmed by expressed willingness to use it again for PGP or other complaints ^[10]. The informants description of the treatment is also in accordance with a large international Delphi survey ^[62], which described three important principles of CAM: treating the whole person; seeing the individual as a facilitator of health; and seeing the body as having an inherent ability to heal itself. The women told of how anxiety and worry were replaced by reward processing in the context of placebo analgesia ^[63]. Some women experienced an increased physical capacity allowing them greater activity. They described this as regaining their lives. This is important as it has been reported that social withdrawal increases mood disturbances such as depression and distress, recognized as back pain risk factors ^[64].

Although the experienced statistically significant reduced pain and improved function after CST in conjunction with ST compared with ST treatment alone had questionable clinical importance, most women were pleased with the treatment and were willing to use it again in the future for PGP or other complaints ^[10]. They said that when they became aware of widespread muscle tension it made them link it to their behaviour and wellbeing. This gave them a renewed sense of control freeing them from feeling steered by their pain.

5 Conclusion

The present study reports a contextual interpretation of earlier published quantitative data as it provides a deeper understanding of how/why CST may relieve symptoms of PGP in pregnant women. Women told of distraction, relaxation and tranquillity; emotions such as feelings of security and optimism, and the gaining of awareness of tensions in their bodies and their bodies' signals that allowed them to feel 'whole'. These factors may help women influence their posture and muscle tension actively thereby reducing and preventing pain. However, further studies of the effectiveness of CST for PGP during pregnancy are warranted.

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Contributors

All authors participated in the design and interpretation of the results and drafting of the article. HE contributed to recruitment procedures, data collection, data analysis and management of the trial. IL and ERO contributed to analysis of the data.

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