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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

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Objective To investigate whether acupuncture has a greater treatment effect than non-penetrating sham acupuncture in women with pelvic girdle pain (PGP) during pregnancy.

Design Randomised double-blinded controlled trial.

Setting East Hospital, Gothenburg, and 25 antenatal primary care units in the region of Västra Götaland, Sweden.

Population A total of 115 pregnant women with a clinical diagnosis of PGP who scored ≥50 on a 100-mm visual analogue scale (VAS).

Method Women were randomly allocated to standard treatment plus acupuncture or to standard treatment plus non-penetrating sham acupuncture for 8 weeks.

Main outcome measures Main outcome measure was pain. Secondary outcomes were frequency of sick leave, functional status, discomfort of PGP, health-related quality of life and recovery of severity of PGP as assessed by the independent examiner.

Results After treatment, median pain decreased from 66 to 36 in the acupuncture group and from 69 to 41 in the non-penetrating sham group ($P = 0.493$) as assessed on a VAS. Women in the acupuncture group were in regular work to a higher extent than women in the sham group ($n = 28/57$ versus 16/57, $P = 0.041$). The acupuncture group had superior ability to perform daily activities measured with the disability rating index (DRI) (44 versus 55, $P = 0.001$). There were no significant differences in quality of life, discomfort of PGP and recovery from severity of PGP between the groups.

Conclusions Acupuncture had no significant effect on pain or on the degree of sick leave compared with non-penetrating sham acupuncture. There was some improvement in performing daily activities according to DRI. The data imply that needle penetration contributes to a limited extent to the previously reported beneficial effects of acupuncture.

Keywords Acupuncture, non-penetrating sham acupuncture, pelvic girdle pain, pregnancy.

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Introduction

Pelvic girdle pain (PGP) during pregnancy has great social impact because of the high cost for society since it is one of the most common causes of disability and sick leave during pregnancy.[1] It has been reported that 20% of all pregnant women suffer from the condition to such an extent that they require medical help. Six years after pregnancy, problems remain in about 7% of women with PGP, causing severe disability and reducing ability to work.[2] Known risk factors are previous low back pain (LBP) and/or previous PGP and previous trauma to the pelvis.[3] PGP is experienced between the posterior iliac crest and the gluteal fold, particularly in the vicinity of the sacroiliac joints. The pain may radiate in the posterior thigh

and can occur in conjunction with/or separately in the symphysis. The endurance capacity for standing, walking and sitting is diminished.[3] Diagnosis can only be reached after exclusion of lumbar causes, and it should be based on both reports from the women and a physical standardised examination together with specific clinical tests that reproduce pain in the pelvic girdle.[3]

As many pregnant women wish non-pharmacological pain relief options, PGP is managed mostly with advice, home training exercises and a pelvic belt. The European guidelines for diagnosis and treatment of PGP[3] state that available evidence is insufficient to recommend any particular treatment modality for PGP. However, the same guidelines as well as two newly published systematic reviews[4,5] conclude that there are data supporting that acupuncture may be helpful, although it is still unclear whether published favourable results are due to specific treatment effects that go beyond the effects of nonspecific effects and individual attention. We have previously shown that acupuncture as an adjunct to standard treatment is efficient for pain relief in pregnant women with PGP,[6] but until now, no randomised controlled study has been performed using patient blinding and non-penetrating sham acupuncture controls. Thus, the aim of this study was to assess whether acupuncture is superior to non-penetrating sham acupuncture as an adjunct to standard treatment for PGP in pregnant women.

Methods

A randomised double-blind trial was carried out to assess whether acupuncture has greater effects on pain, discomfort of PGP, function, sick leave and quality of life than validated non-penetrating sham acupuncture. The Regional Ethics Committee in Gothenburg, Sweden, approved the trial on the 20 February 2006 (reference: 059-06).

Eligible participants were healthy acupuncture-naive pregnant women with singleton fetuses at 12–29 completed gestational weeks that experienced evening pain (according to the patient-kept diary) of more than 50-mm on a 100-mm visual analogue scale (VAS)[7] during the baseline week. Participants had to speak Swedish fluently and were all diagnosed with PGP according to Ostgaards criteria[8] (Table 1). Women with other pain conditions, history of orthopaedic disease or surgery in the spine or pelvic girdle, systemic disorders, coagulation disturbances or increased risk of infection were excluded.

Participants were enrolled between June 2006 and May 2007 from 25 antenatal care units within the Västra Götaland region. Midwives and doctors consequently informed potential women about the study at their regular antenatal care units. If interested, they were invited to phone the study coordinator to make an appointment for screening. At screening, the study was further explained, a written leaflet was given, eligibility was confirmed and written consent to participate was obtained. The leaflet explained that participants would receive standard treatment and 'one of two different types of acupuncture needles that have shown pain-relieving effects' together with information about the needles mode of action (penetrating compared with non-penetrating). The women filled in a questionnaire that comprised demographic data (i.e. age, gestational week, number of pregnancies and body mass index), data on LBP and/or PGP before the index pregnancy and current frequency of exercise and sick leave. They filled in the European Quality of Life 5 Dimensions Questionnaire (EQ-5D) and the European Quality of Life health instrument thermometer (EQ-5D VAS).[9]

Table 1. PGP according to the criteria of Ostgaard[8]

Time and weight-bearing related pain in the posterior pelvis, deep in one or both gluteal areas
A pain drawing with markings in the gluteal area distal and lateral to L5-S1 with or without radiating pain on the posterior thigh but not down to the foot
Pain-free intervals with sudden pain attacks
Pain when turning in bed
Free range of motion in the hips and spine
No nerve root syndrome

All criteria have to be fulfilled for the diagnosis.

Measurement of back-specific functioning, that is daily activities that might be affected by PGP, was measured with the Oswestry Disability Index (ODI).[10] If the women were found eligible at screening, they were provided with a diary for baseline information for 1 week before the inclusion visit.

At inclusion visit, a specially trained physiotherapist performed a detailed standardised physical examination. Severity of PGP was measured with the active straight leg raise test,[11] and pain provocation tests shown to have sensitivity in provoking pelvic structures were used to discriminate PGP from LBP.[12,13] The women also marked their present pain on a pain drawing and answered a question concerning pain when turning in bed.

A statistician, from an independent institution not involved in the study, administered precoded numbered identical opaque envelopes to assign participants to the intervention groups. A computer-generated random table was used. H.E. randomised women who fulfilled all inclusion criteria individually to standard treatment plus acupuncture or to standard treatment plus non-penetrating sham acupuncture. The randomisation procedure took place directly before the first treatment session. Participants continued with the diaries during the treatment period. Antenatal care and decision about sick leave were handled by the women's regular antenatal units.

Interventions

Standard treatment was identical as in our previous study.[6] It included general information about the condition and anatomy of the back and pelvis and a pelvic belt (GULA REHAB

AB, Habo, Sweden). The women received adequate advice and home programme exercises designed to increase strength in the abdominal and gluteal muscles, and information was supplemented by a leaflet. The women were also instructed to avoid other treatments during the intervention period.

The acupuncture protocol was similar to the protocol in the previous trial,[6] and there was no variation in the techniques between the two treatment groups. The selection of acupuncture points was based on clinical experience and expert knowledge of acupuncture in pregnant women with PGP (Figure 1). Eight or nine tender acupuncture points and one or two trigger points were selected individually in the same segments as the location of PGP after diagnostic palpation to identify sensitive spots. Two acupuncture points on the medial side of the leg and foot were selected in the same segment as the PGP. The aim with the stimulation was to activate both segmental and central control systems. In addition, two points on the hands and head were chosen, extrasegmentally to the PGP, to strengthen and lengthen the effect on the central control systems.

All participants received 12 acupuncture treatments, each of 30-minute duration, twice a week for 4 weeks and once a week for 4 weeks. To ensure equal participant blinding in the groups and consistency of treatment, both treatments were performed by the same registered midwife trained in acupuncture and with long clinical experience. The women were treated in a prone position (i.e. unable to see the needles with one exception, needles located on the hands (LI 4). The therapist recorded adverse events and the needle sensations that the women reported. Fetal heart rate, maternal heart rate and blood pressure were monitored before and after all treatments.

In the acupuncture group, sterilised disposable needles (Asia-med Special No. 16 acupuncture needles and Hegu; Hegu AB, Landsbro, Sweden) (Ø 0.30) were used and inserted intramuscularly to a depth of 15–50 mm. The needles were left *in situ* for 30 minutes and manually stimulated every 10 minutes to induce de qi, described as tension, numbness and often a radiating sensation from the point of insertion, reflecting activation of muscle–nerve afferents.

Participants in the non-penetrating sham acupuncture group received a sham acupuncture device (Streitberger placebo/sham needles [0.30 × 30 mm]; Asia-med GmbH & Co., Pullach, Germany) that has been validated in several studies.[14–17] The device looks exactly like a real acupuncture needle, but the tip of the needle is blunted. The needles were left *in situ* for 30 minutes and manually stimulated every 10 minutes, although no attempt was made to evoke sensation of de qi. Both the genuine and the sham needles are delivered through a handle, but the shaft of the sham needle does not penetrate the skin; instead, it collapses into the handle and creates an illusion of insertion.

The same protocol was used in the acupuncture and in the non-penetrating sham acupuncture group; thus, all criteria for harnessing nonspecific effects were included (same contact time and interaction between therapist and patient, manual contact during search for acupuncture points and stimulation of the needles).

Blinding

The women were blinded to whether they were receiving sham or active treatment. The therapist maintained 'neutral' communications with the women and avoided providing cues

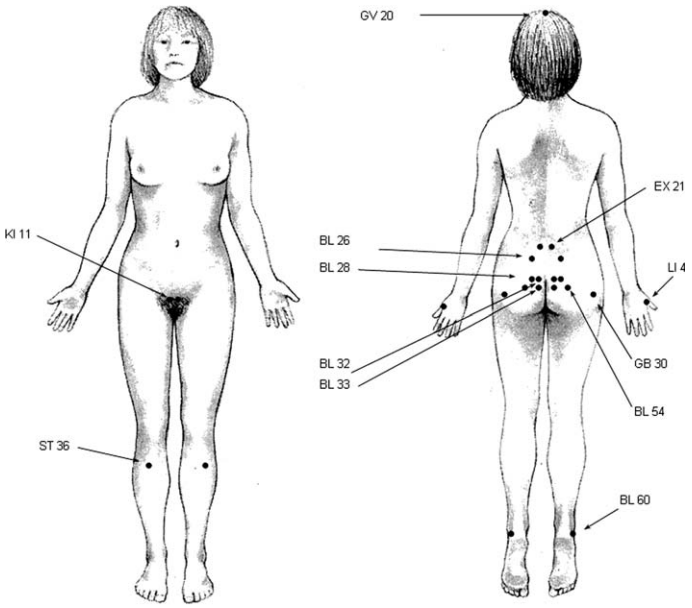

Figure 1. The location of the acupuncture points used in the study. In addition, one or two trigger points in the gluteal area could be used instead of one or two local acupuncture points. BL, bladder; EX, extra; GV, governor vessel; KI, kidney; LI, large intestinal; ST, stomach.

that might reveal whether she was performing real or non-penetrating sham acupuncture. The assessor who re-examined the women after end of treatment was blinded of treatment allocation. In addition, the doctors who handled the decisions about sick listing were blinded of treatment allocation.

Outcomes

Credibility of the intervention was evaluated after three treatments using an item adapted from previous literature.[18] Treatment diaries were collected at completion of the study period. On a return visit to the independent examiner within 1 week after end of treatment, the women completed a follow-up questionnaire containing the same outcome measures that were registered at screening, and the women's opinions of the treatment were obtained. The independent examiner performed the same standardised physical examination that was used before inclusion.

Primary outcome measure

Current intensity of PGP related to motion on a 100-point VAS in the morning and in the evening during the last treatment week[19] (0 represented no pain and 100 represented worst conceivable pain).

Secondary outcome measures

Back-specific functioning, that is daily activities that might be affected by PGP measured with the disability rating index (DRI)[20] and the ODI.[10] The DRI consists of a VAS 0–100 in which 0 represents 'able to perform activity without difficulty' and 100 represents 'unable to perform the activity'. The scored daily activities include dressing (without help), outdoor walks, climbing stairs, sitting for a longer time, standing bent over a sink carrying a bag, making a bed, running, light work, heavy work, lifting heavy objects and participating in exercises and sports. An index is achieved by measuring the distance in millimetre from 0 to the women's markings on the VAS. The mean of these measurements provides the DRI expressed in percent of the highest possible rating. Ten different items on perceived disability were rated on the ODI: pain intensity, personal care and lifting, walking, sitting, standing, sleeping, sexual life, social life and travelling. The items are scored from 0 to 5. The scores of all items are added, giving a possible maximum score of 50. The total score is then doubled and expressed as percentages where 0% represents no disability, 0–20% no or minimal disability, 20–40% moderate disability, 40–60% severe disability, 60–80% crippled and 80–100% bed bound.

Health-related quality of life was measured by the EQ-5D score[9] (–0.43 to 1.0 in which –0.43 is the lowest health and 1 highest health) and the EQ-5D VAS (0–100 in which 0 is the lowest thinkable health). The EQ-5D consists of five items that measure health state in terms of mobility, self-care, usual activities, pain and/or discomfort and anxiety. The women can select one of the following response alternatives: 1 = no problems, 2 = moderate problems and 3 = severe problems. The instrument has the possibility of defining 243 health states. Each health state has a linked value, and possible health states range from –0.43 to 1 in which –0.43 is the lowest health state and 1 the optimal health state. The EQ-5D VAS is a vertical VAS (0–100 in which 0 is the lowest thinkable health state and 100 the optimal health state).

Discomfort of PGP was measured on a VAS, where 0 represented 'no discomfort of PGP' and 100 represented 'worst imaginable discomfort of PGP'.

Frequency about sick leave and regular work.

Recovery from symptoms of PGP as assessed by the independent examiner.

Both VAS and DRI have been shown to have high reliability and validity[20,21] and have been used in previous studies of interventions for pregnant women with PGP and/or LBP included in the last published Cochrane review.[4] It has been reported that >30% or 13-mm reduction on a VAS represents, on average, the minimum change in acute pain that is clinically relevant.[22,23] The minimal importance change in disability on the ODI has been proposed to be 4–10%, and the minimal important difference for the EQ-5D VAS has been reported to range between 0.09 and 0.22 for improvement on the EQ-5D VAS and from 3.82 to 8.43 on the EQ-5D VAS.[24] The minimum clinically significant change on the DRI is not known.

Statistical analysis

The sample size calculation was carried out before the study was started. We assumed improvement in pain measured by VAS during the last treatment week. The sample size calculation was based on the ability to detect an improvement of 15 mm on the VAS. A minimum of 100 participants with data covering the last treatment week would be sufficient to detect this effect with 80% power at a 5% significance level (two tailed). To compensate for drop-outs, we included 115 participants.

In treatment studies, where baseline values of the efficiency variables are determined and no differences between the treatment groups at baseline are present, we have two possibilities to perform the comparisons. To assess efficiency, the groups can be compared with respect to the difference between the value at the end of follow up and the baseline value or with respect to the value at the end of follow up. Derivations yield that the last type of comparison is more powerful if the correlation coefficient between the baseline and the end of follow-up values is less than 0.5. Thus, a pre-test analysis could be performed without affecting the significance level but increasing the power to determine the best kind of comparison. The pre-test analysis showed that the correlation coefficient between the baseline and the end of follow-up values was less than

0.5 for all outcome variables except the 0–1 variable 'being on sick leave'. For the last mentioned variable, there was a substantial coincidence between the baseline and the post-treatment state. Thus, with the mentioned exception, the efficacy comparisons were performed with respect to the values at the end of the follow up.

For missing data and for participants who withdrew, intention-to-treat analysis was applied to outcome data using the last recorded data.[25] In the analysis of the pain diaries, we defined the median VAS baseline levels in the mornings and in the evenings for each woman by calculating the median of the days prior to treatment (5–7 days). The same calculation of median pain for the last week of treatment was carried out. For analysing DRI, every single item was assessed by measuring the distance in millimetre between 0 and the participants' markings on the VAS; the median of the measurements provides the DRI index. The median, CI, quartiles, means and SD were calculated when appropriate. Median and CI were calculated on the basis of the Mann–Whitney *U* test. The Mann–Whitney *U* test was used to compare differences between the groups concerning continuous variables and chi-square test, Fisher's exact test or test for trend in contingency table for categorical variables.[26] We used two-sided *P* values and considered $P < 0.05$ to be significant. The results were analysed with the SPSS, version 13.0 (SPSS Inc., Chicago, IL, USA).

Results

Of 165 women referred for the first assessment, 50 did not meet the inclusion criteria or did not want to participate (Figure 2). In total, 115 women were randomised: 58 to standard treatment plus acupuncture and 57 to standard

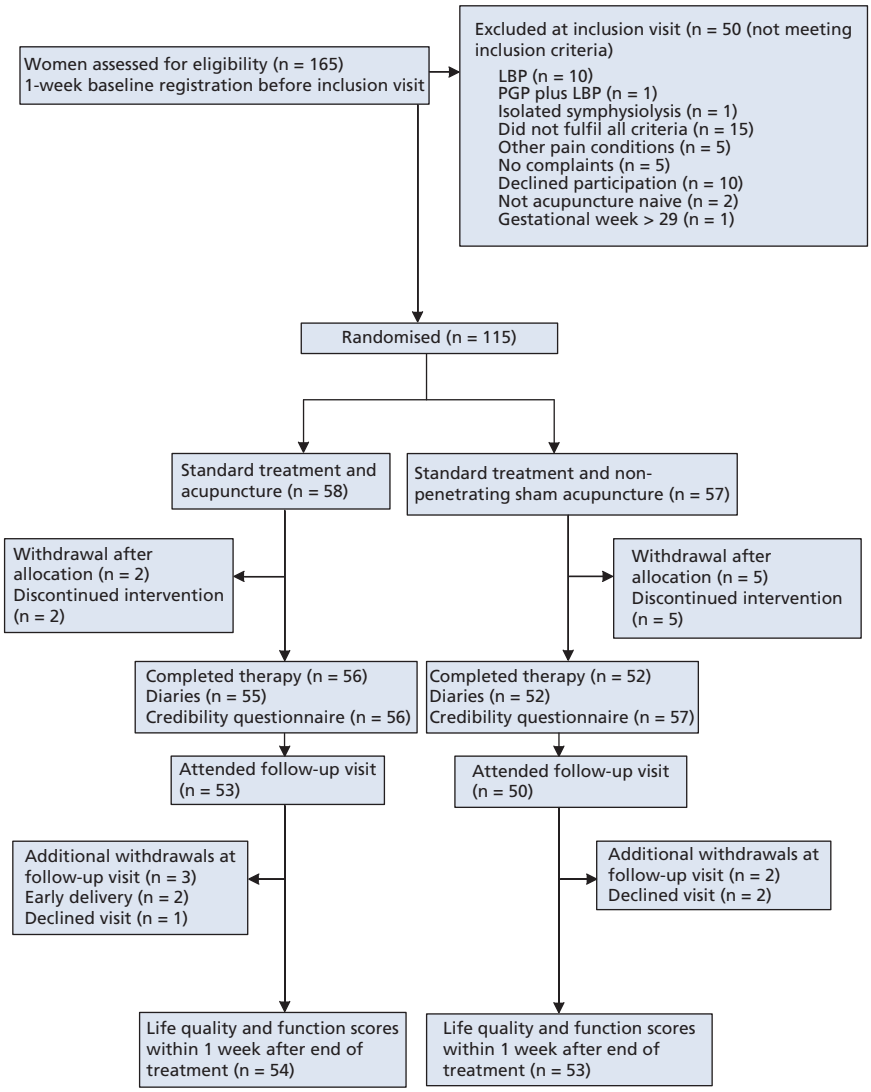

Figure 2. Flow chart of the participants' progress through trial and withdrawals.

treatment plus non-penetrating sham acupuncture. Baseline characteristics were similar in the treatment groups (Table 2). Thus, the randomisation process was capable in producing groups with equivalent variable outcomes at baseline.

Most treatment was administered according to the study protocol. A few participants violated the protocol: two in the acupuncture group and five in the non-penetrating sham acupuncture group. At follow up after end of treatment, there were three additional withdrawals in the acupuncture group, two delivered before follow up and one declined the visit. Two participants in the non-penetrating sham acupuncture group declined the visit (Figure 2).

Table 2. Characteristics of 115 women with PGP included in the trial

	Standard treatment and acupuncture ($n = 58$)	Standard treatment and non-penetrating sham acupuncture ($n = 57$)	Group comparisons, *P* value
Maternal age (years)	31 (4)	30 (4)	0.077*
Nulliparous women	21 [36]	28 [49]	0.185**
Body mass index before pregnancy	24 (5)	25 (4)	0.254*
Gestational weeks + days (SD)	22 + 3 (4 + 2)	23 + 4 (4 + 2)	0.804*
Previous PGP	29 [50]	22 [39]	0.260***
Missing data	0	2	
Subjects experience of back condition			
Very weak	2 [3]	2 [4]	
Weak	17 [29]	13 [23]	
Normal	23 [40]	28 [49]	
Strong	14 [24]	13 [23]	0.824****
Very strong	1 [2]	1 [2]	
Missing data	1	0	
Previous LBP	39 [67]	33 [58]	0.680**
Physical activity >30 minutes during leisure before pregnancy			
Not at all	13 [23]	19 [33]	
Once a week	19 [33]	17 [30]	
More than twice a week	24 [43]	21 [35]	0.422****
Missing data	1		
Gestational weeks at start of PGP	15 (6)	15 (6)	0.939***
Nature of participants' work			
Physically demanding work	36	35	1.000**
White collar workers	22	22	1.000**
Severity of PGP			
Mild complaints, PGP does not affect ability to work	1 [2]	0	
Moderate complaints, PGP only affect ability to work sporadically	8 [14]	10 [17]	
Not insignificant, cannot do some parts of my work	24 [41]	17 [30]	
Severe, can almost not work	23 [40]	24 [42]	0.374****
Severe, cannot work at all	2 [3]	6 [10]	

Values are given as *n* [%] or mean (SD) when appropriate.
**P* values from *t*-test.
***P* values from chi-square test.
****P* values from Mann–Whitney *U* test.
*****P* values from test for trend in contingency table.

Intervention credibility

Intervention credibility evaluated after three treatments showed that overall credibility of both treatments was good (Table 3). However, participants receiving acupuncture were more confident that treatment could help their PGP than participants receiving non-penetrating sham acupuncture ($P = 0.034$). Blinding seems to have been maintained as most participants, irrespective of group belonging, believed that they had received acupuncture with penetrating needles or did not know which form they had received (Table 4). Participants in both groups were also equally satisfied with treatment, and all women who completed treatment were willing to use the same treatment again.

Last treatment week, PGP decreased in both the non-penetrating sham acupuncture and the acupuncture group, but there was no difference between the groups (Table 5). Table 6 shows that women in acupuncture group showed better ability to take part in daily activities compared with those in non-penetrating sham acupuncture group according to DRI (44 versus 55, $P = 0.001$) (Table 6), although no difference in function as measured by the ODI was detected between treatment groups (Table 7).

Table 7 shows that fewer participants were on sick leave in the acupuncture group in the last treatment week (14/58 versus 32/57), but testing for frequency of women on sick leave at screening versus last treatment week, that is test for trend in contingency table, showed no significant differences between the groups ($P = 0.135$). However, more participants in the acupuncture group were kept in regular work ($n = 28/58$ versus 16/57, $P = 0.041$). Health-related quality of life improved similarly in both treatment groups. Decreasing discomfort of PGP and recovery from severity of PGP as assessed by the independent examiner were similar in the two treatment groups (Tables 7 and 8).

Table 3. Outcome and credibility of treatment after three acupuncture treatments

Women's response	Standard treatment and acupuncture ($n = 58$)	Standard treatment and non-penetrating sham acupuncture ($n = 57$)	Group comparisons *P* value*
Confident that treatment can help problem?			
Very	44 (77)	32 (57)	
Quite	12 (21)	21 (38)	0.034
Neither	1 (2)	3 (5)	
Not very	0	0	
Not at all	0	0	
Missing data	1	1	
Recommend treatment to friend with similar PGP?			
Very confident	50 (86)	47 (82)	
Quite confident	6 (10)	9 (16)	0.658
Neither	1 (2)	1 (2)	
Not very confident	0	0	
Not at all confident	0	0	
Missing data	1	0	
Does treatment make sense to you?			
Very logical	49 (86)	42 (74)	
Quite logical	6 (10)	14 (24)	0.331
No opinion	2 (4)	1 (2)	
Not very logical	0	0	
Not at all logical	0	0	
Missing data	1	0	
Do you think treatment would be successful in treating other problems?			
Very	39 (68)	40 (70)	
Quite	13 (23)	8 (14)	1.000
No opinion	3 (5)	9 (16)	
Not very	0	0	
Not at all	2 (4)	0	
Missing data	1	0	

Values are given as *n* (%).
**P* values from test in contingency table.

Table 4. Women's opinions of treatment

Women's response	Standard treatment and acupuncture ($n = 58$)	Standard treatment and non-penetrating sham acupuncture ($n = 57$)	Group comparison after treatment, *P* value
What kind of acupuncture do you think that you have received?			
Acupuncture with penetrating needles	35 (65)	35 (66)	
Acupuncture with non-penetrating needles	1 (2)	2 (4)	0.802*
Don't know	18 (33)	15 (30)	
Missing data	4	5	
Treatment helpful?			
No help	1 (2)	1 (2)	
Some help	13 (24)	14 (27)	
Good help	18 (33)	10 (19)	0.714**
Very good help	22 (41)	27 (52)	
Missing data	4	5	
Treatment again if similar problems?			
Yes	54 (100)	53 (100)	
No	0	0	0.547*
Missing data	4	4	
Disadvantages with treatment?			
No	45 (83)	43 (83)	
Yes	9 (17)	9 (17)	0.965*
Missing data	4	5	

Values are given as *n* (%).
**P* values from chi-square test.
***P* values from test for trend in contingency table.

Side effects

No serious adverse events were reported in either group. Table 9 shows that frequency of minor adverse events were similar in both groups and that de qi sensation was reported by significantly more women in the acupuncture group than in the non-penetrating sham acupuncture group (54 [93%] versus 16 [28%], $P = 0.001$).

Discussion

The main finding in this study was that acupuncture had no significant effect on PGP or on the degree of sick leave compared with non-penetrating sham acupuncture. There was some improvement in performing daily activities according to DRI. The data imply that needle penetration contributes to a limited extent to the previously reported beneficial effects of acupuncture.

A factor that could have influenced the result was that a higher proportion of participants in the sham group were on sick leave. Being on sick leave allowed them to rest, which in itself could have helped relieve the pain. Another factor could have been differences in occupation between the groups. However, the proportion of women with physically demanding work was similar in the two groups. It is well known that rest can relieve symptoms and that PGP typically increases in intensity in weight-bearing activities such as standing and walking.[27–31] PGP is often worse in the evenings and at night, and the degree of evening pain is often related to the amount of activity during the day. Hence, in our previous study,[6] it was found that acupuncture reduced pain compared with controls under conditions of equal frequency of sick leave. Speculatively, pain may have decreased more in the acupuncture group if an equal number of participants in that group would have had the opportunity to be on sick leave. However, the improved ability to perform daily activities in the acupuncture group may actually represent an equally important outcome for these women as pain relief. Also, a much larger number of women were on sick leave at the end of the study compared with the number at screening in both groups: 14 (24%) women compared with 7 (12%) women in the acupuncture group and 32 (56%) versus 14 (24%) women in the non-penetrating sham acupuncture group (data not shown). However, compared with Haugland *et al.*[32] who reported that two-thirds of pregnant women with PGP were on sick leave at gestational week 24, frequency of sick leave was low in both groups at screening as well as 9 weeks later. The problem with the unequal numbers on sick leave at baseline could have been solved if we had stratified for this factor at randomisation, but unfortunately, we did not consider that this could be a problem. However, in the

Table 5. Primary outcome measure: pain on VAS related to motion during last treatment week compared with baseline measurements

Pain	Standard treatment and acupuncture (n = 58)	Standard treatment and non-penetrating sham acupuncture (n = 57)	Group comparisons after treatment, P value*
Morning			
Baseline	46 (53)	45 (54)	0.727
Missing data	1	0	
Last treatment week	25 (18–31)	24 (13–33)	0.288
Missing data	0	0	
Evening			
Baseline	66 (62–73)	69 (66–73)	0.662
Missing data	1	0	
Last treatment week	36 (30–46)	41 (31–52)	0.483
Missing data	0	0	

Values are given as n and medians.
*P values from Mann–Whitney U test.

statistical analysis of sick leave, the unequal distribution has been taken into consideration, and we compared the change in frequency of women on sick leave between groups rather than the absolute levels.

We decided not to include a group receiving solely standard treatment as this would be difficult to justify. Our previous trial showed that PGP became aggravated in that group, and two systematic reviews[3,33] have concluded that the efficacy of this intervention remains questionable. In addition, the primary aim of this study was to investigate if specific treatment effects of acupuncture go beyond effects of non-specific effects and individual attention. However, baseline characteristics such as age, previous LBP, previous physical activity, evening pain scores and severity of PGP as assessed by the independent examiner were similar in the present and the previous study (data have been published elsewhere).[6] One difference between the study protocols was that the treatment period was 6 weeks in the previous study versus 8 weeks in the present study. As a consequence, the mean gestational week at inclusion was lower in the present study than in the previous study (22 + 3 and 23 + 4 versus 24 + 3). Our previous publication[6] showed that PGP was unchanged or worse after standard treatment alone. We therefore believe that the fact that the same criteria (Ostgaards) and the same treatments were used in both studies makes the studies comparable. The previous study demonstrated that acupuncture reduced pain, and it would be unethical and repetitious to include such a control group receiving standard care only.

Baseline measurements showed that health-related quality of life (EQ-5D score and EQ-5D VAS) and disability according to DRI and ODI were severely affected in all participants. After treatment, improvement of health-related quality of life was clinically significant in both groups on the EQ-5D VAS; however, no statistical significance was found between the groups. Function according to DRI improved and remained constant according to ODI. However, it has been reported that the ability to perform different activities usually decreases as the pregnancy advances.[34] The different results in function between the DRI and the ODI scales could have several reasons. Verbal rating scales have been found to be less sensitive than VAS, 0–100,[35] and the two scales most likely indicate different meaning of the rated functions. Moreover, the woman is forced to translate her ability in functions into predefined statements that possibly do not fit exactly to the women's experience and also that the same statement does not necessarily mean the same thing to each woman.[36] The rational behind the use of both the DRI and the ODI scales in the study was that DRI measures only physical functions contrary to the ODI, which also includes questions on sexual life and social functions. The use of ODI and DRI scales to measure function and disability is supported by two previous studies where the combination was applied successfully to evaluate treatment for subacute and chronic LBP as well as PGP postpartum.[37,38]

Comparison with other studies

Our result that acupuncture increases the capacity to perform general activities is supported by earlier research of acupuncture for PGP and/or LBP in pregnant women.[39–41] However, our findings are important as they provide evidence of higher methodological quality of effectiveness of acupuncture for the treatment of PGP in pregnant women. Previous studies of acupuncture for PGP have compared acupuncture with physiotherapy,[6,39,42] analgesic drug and spasmodic drug,[40] minimal acupuncture[41] or conventional treatment.[6,40] Our procedures differed in several important ways from those in previous trials. We included participants with a clinical diagnosis of PGP and used a credible validated non-penetrating

Table 6. Secondary outcome: ability to perform daily activities according to DRI the last treatment week compared with baseline measurements

	Standard treatment and acupuncture (n = 58)	Standard treatment and non-penetrating sham acupuncture (n = 57)	Group comparison after treatment, P value*
The 12 different items at baseline			
Dressing (without help)	20 (3–30)	22 (13–44)	
Outdoor walks	61 (43–72)	65 (53–70)	
Climbing stairs	63 (46–75)	66 (52–74)	
Sitting for a longer time	66 (57–72)	62 (53–68)	
Standing bent over a sink	51 (46–62)	59 (49–68)	
Carrying a bag	46 (34–56)	48 (43–55)	
Making a bed	55 (42–67)	57 (49–66)	
Running	86 (80–93)	97 (90–99)	
Light work	50 (44–56)	55 (50–60)	
Heavy work	87 (79–92)	92 (81–97)	
Lifting heavy objects	88 (81–94)	93 (85–100)	
Participating in exercise/sports	82 (72–91)	86 (80–98)	
Missing data	1	1	
The DRI	60 (52–70)	66 (55–75)	0.184
The 12 different items last treatment week			
Dressing (without help)	0 (0–0)	31 (24–33)	
Outdoor walks	15 (12–21)	46 (42–60)	
Climbing stairs	39 (31–57)	50 (38–60)	
Sitting for a longer time	38 (27–50)	46 (36–58)	
Standing bent over a sink	33 (27–46)	51 (37–62)	
Carrying a bag	33 (25–28)	44 (28–53)	
Making a bed	33 (25–42)	48 (31–57)	
Running	34 (20–47)	95 (81–99)	
Light work	80 (65–88)	45 (40–56)	
Heavy work	34 (28–49)	88 (75–97)	
Lifting heavy objects	77 (69–86)	90 (77–99)	
Participating in exercise/sports	77 (72–85)	74 (64–95)	
Missing data	0	0	
The DRI	44 (30–56)	55 (44–73)	0.001

Results are given as n and medians (25th–75th centiles).
The anchor points of the VAS are as follows: 0 mm represents 'able to perform activity without difficulty' and 100 mm represents 'unable to perform the activity'. The DRI = the mean of the 12 measurements provides the DRI expressed in percent of the highest possible rating.
*P values from Mann–Whitney U test.

sham acupuncture device and higher number of treatment sessions combined with more acupuncture needles. We used 12 treatment sessions and 17 needles compared with 10 sessions with almost exclusively auricular acupuncture,[39] 10 sessions with 4–8 needles with only initial recruitment of de qi,[42] 8–12 sessions with 12 needles[40] and 10 treatment sessions with 10 needles.[41] Also, the number of participants who completed therapy was higher in our study compared with previous trials by other researchers; 108 women in our trial completed therapy compared with 48 women,[39] 72 women,[42] 47 women[41] and 61 women,[40] respectively, in the previous reports.

Strengths and weaknesses of the study

A strength of our study includes the use of a validated non-penetrating sham acupuncture device. The device achieved good credibility and blinding of participants receiving the sham intervention, clinically relevant outcomes, a low drop-out rate and successful blinding of the independent examiner. The use of a comparison group that received sham provides reassurance that the nonspecific effects were equal between groups. Possible explanations of acupuncture effects suggested by previous trials such as the intensity of provider contact or the physiological effects of needling were thus excluded.

Standard treatment and the choice of acupuncture points and the method of stimulation in this study were identical with the procedure used in our earlier study[6] that showed favourable results. Also, baseline characteristics of previous controls were comparable to baseline characteristics of participants in the present study, and treatment response in the

Table 7. Secondary outcome measures: number of participants on sick leave (either reported sick or with doctor's certificate); pain unpleasantness; ODI, EQ-5D and EQ-5D VAS within 1 week after end of treatment compared with baseline

	Standard treatment and true acupuncture (n = 58)	Standard treatment and non-penetrating sham acupuncture (n = 57)	Group comparison after treatment, P value
Number of women on sick leave at screening	7	14	0.135*
Change in women on sick leave last treatment week			
Improved	1	2	0.284**
Unchanged	40	33	
Deterioration	11	19	
Number of women in regular work* **			
Last treatment week***	28	16	0.041*
Discomfort of PGP			
At baseline	55	63 (58 to 68)	0.110****
Missing data	3	2	
Last treatment week	36 (21–42)	41 (26–53)	0.146****
% ODI score			
At baseline	40 (34–42)	40 (34–44)	0.656****
Missing data	1	1	
At follow up	35 (30–42)	37 (30–42)	0.473****
EQ-5D score			
At baseline	0.62 (0.36–0.69)	0.55 (0.16–0.62)	0.216****
Missing data	1		
At follow up	0.62 (0.62–0.69)	0.67 (0.59–0.73)	0.511****
EQ-5D VAS			
At baseline	50 (40–59)	45 (40–50)	0.989****
Missing data	1		
At follow up	70 (60–70)	68 (60–70)	0.993****

Values are n and (95% CI).
*P values from Fisher's exact test.
**P values from test for trend in contingency table.
***Screening information not available.
****P values from Mann–Whitney U test.
*****Six women in the acupuncture group and three women in the non-penetrating sham acupuncture group were on maternity leave, that is were not on sick leave. ODI = 0–100 in which 100 is the highest disability. EQ-5D score= −0.43 to 1.0 in which −0.43 is the lowest health and 1 highest health. EQ-5D VAS = health instrument thermometer 0–100 in which 0 is the lowest thinkable health.

current study for genuine acupuncture was clinically relevant[22,23] and similar to the previous study. Thus, it is clear that the course of 12 sessions of acupuncture, adjusted according to individual womens' needs delivered together with advice, a semi-plastic belt and home-training exercises must be considered to be an effective treatment modality.

Participants were told that they might receive one of two forms of acupuncture (penetrating or non-penetrating). In spite of this, no difference in credibility and satisfaction of the interventions was found between the treatments. Actually, most participants believed that they had received penetrating acupuncture, which indicates a successful blinding of the participants.

Potential limitations of the study were sample size, inability to blind acupuncturists to the form of acupuncture and probably a positive attitude towards acupuncture among participants. An increased number of women could have improved the power of the study. However, we included women according to a reasonable power analysis, and the study included more participants than any of the previous trials. We succeeded in finding a difference in a clinically relevant outcome. In addition, we do not think that nonblinding of acupuncturists leads to a major bias because patient blinding to type of acupuncture was maintained.

The reported de qi sensations, needle pain, slight bleeding, fainting and sleepiness in the sham group suggest that the treatment was not totally inert. Thus, it is possible that a needle touching the skin can be considered a form of sensory stimulation that activates afferent nerve fibres. It has been demonstrated that light touching the skin stimulates mechanoreceptors coupled to slow-conducting unmyelinated (C) afferents and consequently elicits physiological responses.[43] Thus, it is also possible that the pressure of the blunted tip

Table 8. Secondary outcome measure: assessment of severity of PGP by an independent examiner before intervention and at follow up within 1 week after last treatment

	Standard treatment and acupuncture (n = 58)		Standard treatment and non-penetrating sham acupuncture (n = 57)		Group comparison after treatment, P value*
	Inclusion (n = 58)	Follow up (n = 57)	Inclusion (n = 57)	Follow up (n = 57)	
Positive pain drawing	58 (100)	43 (74)	57 (100)	41 (72)	0.790
Pain when turning in bed	58 (100)	43 (74)	57 (100)	44 (77)	0.703
Pain provocation tests					
PPPP test	58 (100)	43 (74)	57 (100)	49 (86)	0.113
Patrick's fabere test	32 (55)	19 (33)	35 (61)	27 (47)	0.110
Modified Trendelenburg test	26 (45)	17 (29)	27 (47)	18 (32)	0.792
Palpation of the pubic symphysis	26 (45)	21 (36)	29 (51)	17 (30)	0.467
Functional test					
ASLR test (sum of scores for left and right leg)	4 (0–9)	2 (0–8)	3 (0–8)	2.5 (0–9)	0.705
Women fulfilling all Ostgaards criteria for PGP	58 (100)	29 (50)	57 (100)	35 (61)	0.112

ASLR test, active straight leg test; Fulfilling all Ostgaards criteria for PGP: women with a positive pain drawing, a positive PPPP test, pain when turning in bed and daily pain (VAS $\geq$10 mm); PPPP test**,** posterior pelvic pain provocation test.Values are given as n (%).
*P values from chi-square test.

may inadvertently replicate forms of true Japanese and Korean acupuncture.[44] This could partly explain why non-penetrating acupuncture and minimal acupuncture have been shown as effective as acupuncture in reducing pain.[45–49] However, one could argue that the marked difference in the intensity of afferent stimulation between the groups would be expected to result in more pronounced difference in outcome than was actually seen. It seems possible that acupuncture can work in a variety of ways by reducing stress and by altering autonomic tone and psychoneuroimmunological state.[50] These findings are also consistent with the results of mechanistic studies demonstrating that acupuncture analgesia occurs centrally through the release of endorphins and monoamines,[51,52] which is also true for the placebo effect. It is probably true that acupuncture has powerful nonspecific effects. It has an aura of Eastern mystique, and it is performed in a ritualistic manner. In addition, it is associated with long consultations that are in themselves prone to be therapeutic.

Conclusions

Acupuncture had no superior effect compared with non-penetrating sham acupuncture on PGP as assessed by VAS and sick leave but improved the functional ability to perform daily activities. This data suggest that needle penetration, at least to some degree, is one important component in acupuncture therapy and provides additional support for the use of acupuncture as one of several means of treatment of PGP.

Table 9. Frequency of side effects of treatments

Adverse event	Standard treatment and acupuncture (n = 58)	Standard treatment and non-penetrating sham acupuncture (n = 57)	Group comparisons, P value*
Fainting	5 (8.6)	4 (7)	1.000
Slight bleeding	35 (6)	34 (6)	1.000
Haematoma	17 (3)	17 (3)	1.000
Needle pain	12 (21)	13 (23)	0.824
Experience of de qi sensation	54 (93)	16 (28)	0.001
Sleepiness	3 (5)	2 (4)	1.000

Values are given as n (%).
*P values from Fisher's exact test.

Disclosure of interest

None declared.

Contributions to authorship

All authors participated in the design, funding application, the interpretation of the results and drafting the article. H.E. contributed in the acupuncture interventions, the recruitment procedures, data collection and management of the trial. M.F-O. contributed to the recruitment procedures, data collection and management of the trial and analysis of the data. H.H. and H-C.O. are guarantors.

Details of ethics approval

The Regional Ethics Committee in Gothenburg, Sweden, approved the trial on the 20 February 2006 (reference: 059-06).

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