# Interventions for preventing and treating pelvic and back pain in pregnancy (Review)

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## TABLE OF CONTENTS

[Intervention Review]

# Interventions for preventing and treating pelvic and back pain in pregnancy

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**Editorial group:** Cochrane Pregnancy and Childbirth Group.
**Publication status and date:** Edited (no change to conclusions), published in Issue 4, 2008.
**Review content assessed as up-to-date:** 7 February 2006.

**Citation:** Pennick V, Young G. Interventions for preventing and treating pelvic and back pain in pregnancy. *Cochrane Database of Systematic Reviews* 2007, Issue 2. Art. No.: CD001139. DOI: 10.1002/14651858.CD001139.pub2.



## ABSTRACT

### Background

More than two-thirds of pregnant women experience back pain and almost one-fifth experience pelvic pain. The pain increases with advancing pregnancy and interferes with work, daily activities and sleep.

### Objectives

To assess the effects of interventions for preventing and treating back and pelvic pain in pregnancy.

### Search strategy

We searched the Cochrane Pregnancy and Childbirth Review Group's Trials Register (February 2006).

### Selection criteria

Randomised controlled trials of any treatment to prevent or reduce the incidence or severity of back or pelvic pain in pregnancy.

### Data collection and analysis

Two authors independently assessed trial quality and extracted data.

### Main results

We found no studies dealing specifically with prevention of back or pelvic pain. We included eight studies (1305 participants) that examined the effects of adding various pregnancy-specific exercises, physiotherapy, acupuncture and pillows to usual prenatal care.

For women with low-back pain, participating in strengthening exercises, sitting pelvic tilt exercises (standardised mean difference (SMD) -5.34; 95% confidence interval (CI) -6.40 to -4.27), and water gymnastics reduced pain intensity and back pain-related sick leave (relative risk (RR) 0.40; 95% CI 0.17 to 0.92) better than usual prenatal care alone.

The specially-designed Ozzlo pillow was more effective than a regular one in relieving back pain (RR 1.84; 95% CI 1.32 to 2.55), but is no longer commercially available. Both acupuncture and stabilising exercises relieved pelvic pain more than usual prenatal care. Acupuncture gave more relief from evening pain than exercises. For women with both pelvic and back pain, in one study, acupuncture was more effective than physiotherapy in reducing the intensity of their pain; stretching exercises resulted in more total pain relief (60%) than usual care (11%); and 60% of those who received acupuncture reported less intense pain, compared to 14% of those receiving usual prenatal care. Women who received usual prenatal care reported more use of analgesics, physical modalities and sacroiliac belts.

**Authors' conclusions**

All but one study had moderate to high potential for bias, so results must be viewed cautiously. Adding pregnancy-specific exercises, physiotherapy or acupuncture to usual prenatal care appears to relieve back or pelvic pain more than usual prenatal care alone, although the effects are small. We do not know if they actually prevent pain from starting in the first place. Water gymnastics appear to help women stay at work. Acupuncture shows better results compared to physiotherapy.

## PLAIN LANGUAGE SUMMARY

**Interventions for preventing and treating pelvic and back pain in pregnancy**

Many women experience back or pelvic pain during pregnancy. This pain generally increases as pregnancy advances and it interferes with daily activities (like carrying, cleaning, sitting and walking), can prevent women going to work and sometimes disturbs sleep. Suggestions to help manage the pain are varied and include special pregnancy exercises, frequent rest, hot and cold compresses, a supportive belt, massage, acupuncture, chiropractic, aromatherapy, relaxation, herbs, yoga and Reiki. Sometimes drugs like acetaminophen have also been suggested. No studies were found dealing with the prevention of back and pelvic pain. For treatment, the review of trials found eight studies, involving 1305 participants, that examined the effects of various pregnancy-specific exercises, physiotherapy programs, acupuncture and using special pillows added to usual prenatal care. They were compared to usual pregnancy care or other treatments. The quality of the studies was not the best, and so the findings should be treated with caution. The review found that specifically tailored strengthening exercise, sitting pelvic tilt exercise programs and water gymnastics all reported beneficial effects. The Ozzlo pillow seemed to be effective but is no longer available. In addition, acupuncture seemed more effective than physiotherapy. Adverse effects, when reported, appeared minor and transient. More research is needed on this widespread problem of pregnancy.

## BACKGROUND

Back and pelvic pain are common in pregnancy and tend to increase as pregnancy advances. It interferes with ordinary daily activities such as carrying, cleaning, sitting and walking, prevents women from going to work and disturbs sleep. In a prospective study of 200 Swedish women, Kristiansson 1996 found that 76% reported back pain at some point in their pregnancy. In a review article, MacEvilly 1996 states that more than one third of pregnant women find back pain a severe problem. In a recent survey of pregnant women in the USA, 68.5% (95% confidence interval 65% to 71%) of the respondents reported having low-back pain during their current pregnancy, but only 32% of them had reported their back pain to their prenatal care providers. The increased incidence of back pain in pregnancy is believed to arise from several causes: altered posture with the increased lumbar lordosis (exaggerated curvature of the lower spine) necessary to balance the increasing anterior weight of the womb, ligamentous laxity (loosening of the ligaments in the pelvic area) caused by relaxin, a polypeptide hormone produced by the corpus luteum, and fluid retention within connective tissue (MacEvilly 1996). The problem is usually worse at night and causes insomnia, especially in the last trimester. A recent study (Ostgaard 1997) provides useful information on long-term follow up (six years). Ostgaard 1997 found that by two years after giving birth the prevalence of back pain had fallen to the same level found before the pregnancy (18%).

Although estimates of prevalence of pregnancy-related pelvic pain vary (depending on the type of study, diagnostic criteria and precision of identifying the pain), the best evidence suggests a range of 16% to 20% (European 2004). In a detailed cohort study of 405 women with pelvic pain (posterior pain arising from the region of the sacro-iliac joints, anterior pain from the pubic symphysis, or both), Albert 2001 found that six months after giving birth all the women with symphysial pain were better. However, two years after giving birth, 4.2% and 6.5% of women who had unilateral and bilateral sacro-iliac pain, respectively, were continuing to have pain and 18% of women who had anterior and posterior pelvic pain (pelvic girdle pain) were still having pain. Both Albert 2001 and Ostgaard 1994 provide details of the tests used to distinguish pelvic pain from lumbar back pain.

Prenatal practitioners in the United Kingdom and Nordic coun-

tries give women information on how to manage low-back pain during their pregnancy and may refer them to physiotherapy. In the United States, women are taught that low-back pain is a normal part of pregnancy. Suggestions to help manage the pain include exercises, frequent rest, hot and cold compresses, a supportive belt, massage, acupuncture, chiropractic, aromatherapy, relaxation, herbs, yoga, Reiki and acetaminophen (Wang 2004). With the prevalence of back and pelvic pain in pregnant women and this broad range of management suggestions, it seemed prudent to update this review.

# OBJECTIVES

To assess prevention of, and treatments for, pelvic and back pain in pregnancy.

# METHODS

## Criteria for considering studies for this review

### Types of studies

All randomised controlled trials evaluating methods for preventing or treating pelvic and back pain in pregnancy. We excluded quasi-randomised studies (those which use techniques for allocation to groups that may be prone to bias).

### Types of participants

Any pregnant woman suffering from, or at risk of, pelvic or back pain.

### Types of interventions

Any intervention intended to reduce the incidence or severity of pelvic and back pain in pregnancy. We grouped the studies to allow us to examine interventions that specifically addressed back pain, pelvic pain or both.

### Types of outcome measures

Women's own rating of the usefulness of a treatment in reducing pelvic and back pain, both during daytime activities and at night. These outcomes were measured using tools such as Visual Analogue Scales, days off work because of pain and measures of difficulty when undertaking everyday activities. We recorded adverse effects for the mother, neonate or both, which were noted in the studies.

## Search methods for identification of studies

### Electronic searches

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting the Trials Search Co-ordinator (February 2006).

The Cochrane Pregnancy and Childbirth Group's Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from:

1. quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
2. monthly searches of MEDLINE;
3. handsearches of 30 journals and the proceedings of major conferences;
4. weekly current awareness search of a further 37 journals.

Details of the search strategies for CENTRAL and MEDLINE, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service can be found in the 'Search strategies for identification of studies' section within the editorial information about the Cochrane Pregnancy and Childbirth Group.

Trials identified through the searching activities described above are given a code (or codes) depending on the topic. The codes are linked to review topics. The Trials Search Co-ordinator searches the register for each review using these codes rather than keywords.

We also identified ongoing studies while trying to trace full text articles of published abstracts. We did not apply any language restrictions.

## Data collection and analysis

### Selection of studies

Two authors (VE Pennick, G Young) independently reviewed the full text of potential studies identified by the Cochrane Pregnancy and Childbirth Group's search strategy and selected studies that met our inclusion criteria. We resolved any disagreements through discussion.

### Assessment of methodological quality of included studies

We then independently evaluated the studies that met our inclusion criteria for methodological quality, without consideration of their results, and again resolved disagreements through discussion. For a description of the criteria used, *see* Appendix 1. We excluded studies at this point that used methods of allocation that are prone to bias (quasi-randomised trials), such as the use of date of birth, date of admission, hospital numbers or alternation.

### Data extraction

For studies that met our inclusion criteria and methodological assessment, we independently extracted the data onto a form that had been predesigned by the Cochrane Pregnancy and Childbirth Group, then transferred them into Review Manager software ( RevMan 2006) for analyses. We resolved disagreements through discussion.

### Measures of treatment effect

Our primary analyses for each category of low-back pain or pelvic pain, or both, examined these comparisons:
(i) intervention added to usual prenatal care versus no treatment (usual prenatal care); and
(ii) intervention added to usual prenatal care versus another treatment added to usual prenatal care.
Where there was clinical homogeneity, suggesting it made sense to synthesise the data, and when there were sufficient data, we had planned to complete statistical analysis of the results using a fixed-effect meta-analysis in RevMan 2006 software. However, in the absence of clinical homogeneity or sufficient data, or both, we briefly described the studies and their results, rather than performing meta-analyses.

For dichotomous data, we had planned to present the results as a summary relative risk with 95% confidence intervals. For continuous data, we had intended to use the weighted mean difference for outcomes that were measured in the same way between trials and the standardised mean difference to combine trials that measured the same outcome, but used different methods. In the absence of sufficient data to complete our own analyses for outcomes across studies, we used the summary statistics reported by the authors in the study reports.

### Dealing with missing data

We planned to use data for all participants with available data in the group to which they were allocated, regardless of whether or not they received the allocated intervention. In most cases, data in the study reports were only given for participants who had completed the intervention and provided follow-up outcome measures. Participants' data were generally analysed in the groups to which they had been allocated.

## RESULTS

### Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of ongoing studies.

The review completed in 2002 contained three studies that looked at interventions for women with low-back pain (Kihlstrand 1999; Thomas 1989) or for a mixed population with pelvic and low-back pain (Wedenberg 2000).
This updated review includes an additional two studies examining women with low-back pain (Garshasbi 2005; Suputtitada 2002), one examining women with pelvic pain (Elden 2005), and two more examining a mixed population with pelvic and back pain ( Kvorning 2004; Martins 2005). In total, we included nine reports (1305 participants), describing eight studies. One report was the abstract of one of the published articles and only gave preliminary results. Seven of the studies were randomised controlled trials; the eighth used a cross-over design (Thomas 1989).
The trials looked at the effects of exercise (Elden 2005; Garshasbi 2005; Martins 2005; Suputtitada 2002; Wedenberg 2000), water exercises (Kihlstrand 1999), use of a special pillow (Thomas 1989), and acupuncture (Elden 2005; Kvorning 2004; Wedenberg 2000). The controls used were described as no treatment, which was, in reality, usual prenatal care. There were also three trials comparing two or more interventions: two styles of pillow (Thomas 1989), and physiotherapy exercises versus acupuncture (Elden 2005; Wedenberg 2000).
*See* table of 'Characteristics of included studies' for further details. For details of excluded studies and ongoing studies, see the tables of 'Characteristics of excluded studies' and 'Characteristics of ongoing studies'.

### Risk of bias in included studies

Overall, the methodological quality of the studies was poor, raising concerns about the potential for bias in the results. Of the eight reports, only half of them reported adequate methods of allocation concealment; three reported that the outcome assessor was blinded; and all but one of them analysed individuals' outcomes in the group to which they had originally been randomised. The last one was a cross-over study in which all participants were analysed when they received one treatment then the other, without allowing for either a wash-out period, or advanced stage of pregnancy and increased risk of back pain. Attrition rates ranged from zero to more than 20%. In several of the reports, it was difficult to determine the exact numbers randomised and withdrawn, reasons for the withdrawal and the group membership of those who withdrew. None of the studies blinded the participants or caregivers to the intervention due to the nature of the interventions. It was also difficult to follow the analyses and results in some of these studies since the progression from invitation to participation to final analysis was not always clear, and data were not always presented in a format that was easy to extract. *See* table of 'Characteristics of included studies' for study-specific details.

## Effects of interventions

### Study selection

In the earlier review, the authors included three studies and excluded one study because it was a quasi-randomised trial. For this update, there were 11 potentially relevant reports identified by the Cochrane Pregnancy and Childbirth Group's search strategy at the last communication with the Trials Search Co-ordinator on February 6th, 2006. Of these, six were included, three were excluded because they were quasi-randomised trials and two were identified as ongoing studies, one of which had originally been an abstract of preliminary results of a pilot study that went on to be funded as a full-scale study. We therefore ended up with nine included reports (eight studies), four excluded studies and two ongoing studies. *See* tables of 'Characteristics of included studies', 'Characteristics of excluded studies' and 'Characteristics of ongoing studies' for further details.

### Measures of treatment effect

#### Low-back pain

Four studies (690 participants) examined the effects of exercise (Garshasbi 2005; Suputtitada 2002) and water gymnastics ( Kihlstrand 1999) added to usual prenatal care versus usual prenatal care alone, and the effects of two different pillows (Thomas 1989) on back pain. None of the interventions, gestational ages or outcomes was sufficiently similar, nor were sufficient data provided to allow us to perform a meta-analysis to determine size of effect. Having said that, compared to women who did not participate in the exercise programs, women who participated in any of the three specially-designed exercise programs reported better relief of their back pain. In Garshasbi 2005, women participating in a strengthening exercise program for pregnant women reported the intensity of their back pain decreased significantly (measured on the KEBEK questionnaire, range 0 to 100, 0 = no pain: P = 0.006, but correct supporting data were not provided). In Suputtitada 2002, women who participated in a program to teach them sitting pelvic tilt exercises reported better pain relief measured on a Visual Analogue Scale (VAS) (0 to 10, 0 = no pain) after eight weeks of exercises (standardised mean difference (SMD) -5.34; 95% confidence interval (CI) -6.40 to -4.27). In Kihlstrand 1999, women in a water gymnastics program reported significantly less pain intensity at one week postpartum, measured on a VAS (0 to 10, 0 = no pain) (P = 0.034).

In Kihlstrand 1999, 12.9% of the women in the water gymnastics program (total of 982 days) and 21.7% of the women in the usual prenatal care group (total of 1484 days) were on sick leave due to low-back pain at some point during their pregnancy (P = 0.09).

The earliest trial (Thomas 1989) compared the efficacy of a specially-designed pillow for supporting the pregnant abdomen (Ozzlo pillow) with a standard hospital (Tontine) pillow, using a cross-over study design. When using the Ozzlo pillow, women reported significantly lower intensity of backache at night measured on a VAS (0 to 100, 0 = no pain) (median 10, range 0 to 80 versus median 16, range 0 to 85; P = 0.005) and during the day (median 17, range 0 to 86 versus median 16, range 0 to 88; P = 0.04), but no significant difference in their ability to sleep through the night. The women's impressions were that the Ozzlo pillow was at least moderately more effective for preventing or relieving their back pain (relative risk (RR) 1.84; 95% CI 1.32 to 2.55) and at least moderately more valuable for supporting them while sleeping (RR 1.62; 95% CI 1.23 to 2.13). There were no specific data given to support the notion that the Ozzlo pillow prevented back pain. There is further discussion about these data in the 'Discussion' section.

There were no serious adverse effects noted for either the mother or the neonate in any of the studies. Women who participated in water gymnastics did not develop any more urinary tract or uterine infections than those who received usual prenatal care.

#### Pelvic pain

One study (386 participants) examined the effects of adding acupuncture or stabilising exercises to usual prenatal care versus usual prenatal care alone on pelvic girdle pain (Elden 2005). After one week of treatment, those who received usual care reported significantly more intense morning pain than those who had received either acupuncture (difference of medians: 12; 95% CI 5.9 to 17.3; P < 0.001) or stabilising exercises (difference of medians: 9; 95% CI 1.7 to 12.8; P = 0.0312). There was no significant difference in intensity of morning pain between those who received acupuncture and those who received exercises. After one week of treatment, those who received usual care also reported significantly more intense evening pain than those who had received either acupuncture (difference of medians: 27; 95% CI 13.3 to 29.5; P < 0.001) or stabilising exercises (difference of medians: 13; 95% CI 2.7 to 17.5; P = 0.0245). Those who received acupuncture reported significantly less intense evening pain than those who received physiotherapy (difference of medians: -14; 95% CI -18 to -3.3; P = 0.0130). There was no significant difference observed by the outcome assessors in positive pain drawings between any of the three groups: 93% of those receiving usual care, 85% of those receiving acupuncture and 87% of those receiving physiotherapy reported pain.

There were no adverse effects noted.

#### Mixed population with pelvic and low-back pain

Three studies (229 participants) examined the effects of adding acupuncture (Kvorning 2004; Wedenberg 2000) and exercise or

physiotherapy (Martins 2005; Wedenberg 2000) to usual prenatal care compared to either usual care or each other. Once again, there were insufficient data and clinical heterogeneity, so we could not perform a meta-analysis. In Wedenberg 2000, 12 of 30 women dropped out of the physiotherapy group, while none withdrew from the acupuncture group, leading to potential attrition bias. Based on baseline data, there were no obvious reasons for the difference in withdrawals between the two groups.

Women who received either acupuncture or physiotherapy ( Wedenberg 2000) all reported a reduction in pain intensity in morning and evening measures after completing their program, with the acupuncture group reporting significantly less intense pain than the physiotherapy group (P = 0.02 in the morning; P < 0.01 in the evening). In Martins 2005, 61% of the women who participated in the stretching exercise group reported that their pain was totally gone, compared to only 11% of women who continued to receive usual care. Forty-eight per cent of the exercise group reported baseline pain greater than five (on a 10-point VAS), while 61% of the group who received usual prenatal care reported the same level of pain. In Kvorning 2004, 60% of the women who completed the acupuncture treatment reported their pain intensity had decreased, compared to only 14% of the control group, who received usual prenatal care. The women who received usual prenatal care also used analgesics (5/35), TENS (6/35), physiotherapy (6/35) and a sacroiliac belt (15/35) to help them relieve the pain. Four out of the 37 women in the acupuncture group also used a sacroiliac belt for support.

Wedenberg 2000 also reported significantly lower disability scores in those who received acupuncture as opposed to those who received physiotherapy, but supporting summary data or analyses were not provided.

There were only minor, transient adverse effects reported by those who received acupuncture (small subcutaneous hematomas at insertion site) in Wedenberg 2000 and although the adverse effects reported by those who received physiotherapy (preterm uterine contractions, pre-eclampsia) were unlikely to have been caused by the physiotherapy, they withdrew from the study. Thirty-eight per cent of the women who received acupuncture in Kvorning 2004 also reported some minor, transient adverse effects (local pain, heat or sweating, local hematoma, tiredness, nausea, weakness). There were no reported problems with any of the deliveries or neonates. A recent systematic review on the safety profile of acupuncture for back pain concluded, from reports on over 100,000 patients from the US, UK, and Sweden that reported incidents from acupuncture, that they were, on the whole, minor and transient. They listed fainting (10 patients), unexpected exacerbation of symptoms (12 patients), pain at site of needle (6 patients), needle left in place (5 patients), seizure after needle insertion (1 patient with known epilepsy), slurred speech (1 patient), pneumothorax (2 patients), broken needle (2 patients) and minor bleeding at site (15% of treatments) as the most notable problems (Cherkin 2003).

## DISCUSSION

Although many of the studies spoke of the hope of preventing back or pelvic pain, for the most part, there were insufficient data presented that dealt with this aspect of the research question and no studies looked specifically at it. Thomas 1989 measured women's impressions that the special pillow prevented their backache, but there were no data to support this impression.

We included eight studies (1305 participants) in this review. Overall, the reports of the studies were poorly written and it was difficult to follow some of the analyses. We only included randomised controlled trials (one of which was a cross-over study) in this review, but in two of the studies, the methods of randomisation were unclear and in four, the methods of allocation concealment were unclear. On the other hand, we excluded three studies because the techniques they described for randomisation did not produce true randomisation. Current wisdom suggests that randomisation and concealment of allocation are key study characteristics that reduce the potential for bias. Taken together with other factors that lead to potential bias, such as high or uneven attrition rates and assessor blinding, all but one of the included studies (Elden 2005) could be said to have moderate to high potential for bias. This means that we cannot have full confidence in the results of the studies and they should be viewed with caution.

We also questioned the analysis in Thomas 1989, the cross-over study looking at the effects of different pillows. Rather than comparing the results from week one versus the results from week two, they calculated the outcomes from all of the women when they were using the Ozzlo pillow against their outcomes when they were using the standard pillow, making it look as if there were 184 people in the study rather than just 92. There was no allowance made to allow the effects of one pillow subside before starting to use the second. There was also no allowance made for the fact that the women in group two were one week further into their pregnancy. While this is not a long time, most women do report that back pain increases as pregnancy progresses; therefore, technically putting the two groups at a different risk for back pain. The authors did report that there were no differences in the main outcomes between the two weeks. It would be important to divide the results from the two weeks if future trials merited a meta-analysis.

Regardless of the treatment received, women reported increased pain intensity as their pregnancy advanced. Because there was such a variety of treatments provided even within the umbrella term physiotherapy, or exercise therapy, and the timing and data provided for the outcomes measured were so different, it was not possible to get an overall estimate of effect. It appeared that those who participated in an exercise program in addition to their usual prenatal care, regardless of the duration or composition of the program, reported less intense pain than those who received usual prenatal care alone. However, one cannot rule out a possible placebo

effect in studies that looked at usual prenatal care (no treatment) versus active participation in exercise programs. Women who participated in water gymnastics, either alone or as a part of their physiotherapy or exercise program, reported they enjoyed the weightlessness and relaxation of being in the water. Women who received acupuncture along with their usual prenatal care reported greater pain relief than those who received physiotherapy with their usual prenatal care. However, it was unclear whether the effect was due to the specific treatment, or the fact that acupuncture was delivered individually, while the physiotherapy was delivered in a group setting. There was little attempt to explore the reason behind the fact that no women dropped out of the acupuncture group, whereas 12 women dropped the physiotherapy. Analyses were only done on those who completed treatment. Adverse effects, when reported, were minor and transient. There were no significant differences noted in deliveries or health of neonates between the groups of women. It is plausible that the addition of these different treatments to usual prenatal care reduced the pain intensity to a tolerable level, recognising that it continued to increase as the pregnancies advanced.

Only one study (Kihlstrand 1999) reported on the positive impact of the interventions on the women's absenteeism due to their back pain. Considering the number of women who now participate in the paid workforce, this is a limitation that should be rectified in future studies.

The special, hollowed out, nest-shaped Ozzlo pillow provided better pain relief at night than a standard pillow. Contact with the original author in 1999 revealed that the Ozzlo pillow was no longer made or available and nobody since seems to have taken it upon themselves to consider it a possible business venture. However, entrepreneurial women could design their own, based on the picture in the original article (Thomas 1989).

Many women, who participated in additional exercise programs, received acupuncture or used a pillow to support their pregnant stomachs while sleeping, expressed satisfaction with the interventions and felt they would consider them in subsequent pregnancies. Despite methodological limitations, women in the studies who received more than usual prenatal care appeared to experience some pain relief. However, these results must be considered with caution.

# AUTHORS' CONCLUSIONS

## Implications for practice

Pregnant-specific exercise programs, physiotherapy and acupuncture added to usual prenatal care appear to reduce back or pelvic pain more than usual prenatal care. When compared to each other, acupuncture seems to be more effective than physiotherapy, but it is unclear whether the effect is due to the treatment or the fact that acupuncture was delivered individually, while the physiotherapy was delivered in a group setting. Participating in a water gymnastics program seemed to reduce the number of back pain-related work absences. Women found some pain relief from using pillows to support their pregnant stomachs while lying down, with the specially-designed Ozzlo pillow providing more support than an ordinary pillow. Unfortunately, the Ozzlo pillow is no longer commercially available. Entrepreneurial women could, if they wished, design their own supportive pillow, since a picture is available in the original article (Thomas 1989). Due to methodological limitations, these results should be treated with caution.

## Implications for research

Given the high incidence of back and pelvic pain in pregnancy and the distress this causes many women in late pregnancy, more research would be helpful to inform advice given by prenatal practitioners. Possible areas might include: education in early pregnancy on specially-adapted exercises, the use of support belts particularly for pain arising from the sacro-iliac joints and pubic symphysis, and the efficacy and safety of analgesics in late pregnancy. More and better designed studies of the effects of physiotherapy, acupuncture and other conservative and complementary treatments already being used by women (Wang 2004) are also needed. Preventive studies beginning early in pregnancy would be welcome to see if any of these interventions will really prevent the development of back and pelvic pain. Studies should measure adverse effects and work-related outcomes as well as pain and general disability.

# ACKNOWLEDGEMENTS

The authors would like to thank the Scientific Foundation Board of the Royal College of General Practitioners for the grant which made the 2002 updating of this review possible. Gavin Young would like to thank Paul Shekelle of the Cochrane Back Group for helping with the 2002 analyses and Victoria Pennick would like to thank Andrea Furlan for her helpful comments and help with translation. We would both like to acknowledge the contributions made by David Jewell to the first two versions of this review.

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**Quinlivan 2005** *{unpublished data only}*

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**Cherkin 2003**

Cherkin DC, Sherman KJ, Deyo RA, Shekelle PG. A review of the evidence for the effectiveness, safety and costs of acupuncture, massage therapy and spinal manipulation for back pain. *Annals of Internal Medicine* 2003;**138**:898–906.

**European 2004**

Anonymous. European guidelines on the diagnosis and treatment of pelvic girdle pain. http://www.backpaineurope.org/(accessed March 31 2006).

**Kristiansson 1996**

Kristiansson P, Svardsudd K, von Schoultz B. Back pain during pregnancy: a prospective study. *Spine* 1996;**21**(6):702–9.

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**CDSR 1998**

Young G, Jewell D. Interventions for preventing and treating pelvic and back pain in pregnancy (Cochrane Review). *Cochrane Database of Systematic Reviews* 1998, Issue 3.[Art. No.: CD001139. DOI: 10.1002/14651858.CD001139.pub2]

**CDSR 2002**

Young G, Jewell D. Interventions for preventing and treating pelvic and back pain in pregnancy. *Cochrane Database of Systematic Reviews* 2002, Issue 1. [Art. No.: CD001139. DOI: 10.1002/14651858.CD001139]

**Young 1995**

Young GL. Special vs standard pillow for backache in late pregnancy [revised 13 May 1993]. In: Enkin MW, Keirse MJNC, Renfrew MJ, Neilson JP, Crowther C (eds.) Pregnancy and Childbirth Module. In: The Cochrane Pregnancy and Childbirth Database [database on disk and CDROM]. The Cochrane Collaboration; Issue 2, Oxford: Update Software; 1995.

* *Indicates the major publication for the study*

## CHARACTERISTICS OF STUDIES

### Characteristics of included studies *[ordered by study ID]*

**Elden 2005**

| | |
|---|---|
| Methods | 386 women consecutively selected by doctors and midwives and randomised to three groups by distribution of presealed opaque envelopes, with group assignment by computer-generated random table to determine the allocation sequence before the study.<br>Participants and caregiver not blinded; assessor blinded.<br>Acupuncture group: randomised = 125; analysed = 110 (88%) (10 declined treatment, 1 declined visit, 5 had early delivery).<br>Stabilising exercises group: randomised = 131; analysed = 112 (85.5%) (9 declined treatment, 1 moved from area, 4 had early delivery, 5 declined visit).<br>Standard treatment group (control); randomised = 130; analysed = 108 (83.0%) (15 declined treatment, 3 had early delivery, 3 declined visit, 1 moved from area).<br>Intention to treat: those who finished the trial were analysed in the group to which they had been assigned.<br>Funding: The Vardal Foundation, the Dagmar Foundation, the Trygg-Hansa Insurance Company, the Sahlgrenska University Foundation. |
| Participants | Location: East Hospital, Sahlgrenska Academy and 27 maternity care centres in the hospital's reference area in Gothenburg, Sweden; 2000-2002 .<br>Inclusion criteria: healthy women at 12 to 31 weeks' gestation, fluent in Swedish, singleton fetuses, had defined pregnancy-related pelvic girdle pain.<br>Exclusion criteria: those with other pain conditions, systemic disorders, contraindications to treatment. |
| Interventions | Experiment group 1 - acupuncture.<br>General information about the condition, anatomy of the back and pelvis, advice about activities of daily living, given a pelvic belt and a home exercise program by physiotherapist + acupuncture treatment given twice a week over 6 weeks using 10 local acupuncture points in sensitive spots + 7 extra-segmental points - needles inserted to evoke De Qi - left in situ for 30 minutes, stimulated every 10 minutes - given by 2 experienced medical acupuncturists.<br>Experiment group 2 - stabilising exercises.<br>General information about the condition, anatomy of the back and pelvis, advice about activities of daily living, given a pelvic belt and a home exercise program by physiotherapist + individual stabilising exercises (modified for pregnancy)for a total of 6 hours over 6 weeks - given by 2 experienced physiotherapists.<br>Control group: standard treatment.<br>General information about the condition, anatomy of the back and pelvis, advice about activities of daily living, given a pelvic belt and a home exercise program by physiotherapist - given by 3 experienced physiotherapists. |
| Outcomes | Measured at one week post-treatment:<br>self-report pain each a.m. - 100 mm VAS; examiner assessment of recovery from symptoms - positive pain drawing; examiner assessment of recovery from symptoms - posterior pelvic pain provocation test; examiner assessment of recovery from symptoms - pain when turning in bed.<br>Adverse events: none reported for any of the 3 groups. |
| Notes | |
| ***Risk of bias*** | |

**Elden 2005** (*Continued*)

| Item | Authors' judgement | Description |
|---|---|---|
| Allocation concealment? | Yes | A - Adequate |

**Garshasbi 2005**

| | |
|---|---|
| Methods | 266 randomised: those who couldn't exercise were excluded from the exercise group, but it's unclear why 54 people dropped out of exercise group and none out of control.<br>Excluded before randomisation = 14 with UTI, threatened abortion, lack of time, leaving 266 to be randomised.<br>Randomised to exercise group = 161- 54 who couldn't participate in exercises = 107.<br>Randomised to control group = 105.<br>Participants and caregiver not blinded; assessor blinded.<br>Analysis of pain and flexibility measures were conducted on those who completed the intervention in the group to which they had been randomised.<br>Funding: not stated. |
| Participants | 280 women invited to participate from those registered at Hazrat Zaynab Hospital prenatal clinic in Tehran, Iran (no details about how they were selected from the 2358 who had registered at the clinic during the study period).<br>Inclusion criteria: primigravida, 20 to 28 years old, 17 to 22 weeks' gestation, housewives, high school graduates.<br>Exclusion criteria: women with contraindications to aerobic exercise during pregnancy according to ACOG guidelines, history of exercise before pregnancy, history of orthopaedic disease or surgery, those who missed 3 exercise sessions.<br>Baseline characteristics.<br>2 groups similar in age, weight, height, BMI.<br>Exercise group = 73 women (68%) had LBP during pregnancy.<br>Control group = 78 women (70.5%) had LBP during pregnancy. |
| Interventions | Experiment group.<br>Exercises recommended by Tarbiat Modares Faculty of Sport and tested for pregnant women by physiotherapists, to strengthen abdominal muscles, hamstring muscles and increase traction of iliopsoas and para vertebral muscles.<br>15 movements in 60 minutes: 5 minutes of slow walking, 5 minutes of extension movements, 10 minutes of general warming up, 15 minutes anaerobic exercise, 20 minutes of specific exercise, 5 minutes return to the 1st position - offered to exercise 3 times a week - supervised by midwife - intensity of exercises controlled by maternal pulse rate - stopped if > 140/minute.<br>Control group: no treatment. |
| Outcomes | Adverse events: none reported.<br>No scales/units given for outcomes measured, but one may assume they are reporting the group mean, measured on the KEBEK questionnaire (range 0 to 100, higher = worse pain); change scores don't appear to be included, the degree of lordosis and degree of flexibility of the spine. |
| Notes | All numbers do not add up; there are contradictions in text; we tried unsuccessfully to clarify data with lead author. |

**Garshasbi 2005** (*Continued*)

| *Risk of bias* | | |
|---|---|---|
| **Item** | **Authors' judgement** | **Description** |
| Allocation concealment? | Unclear | B - Unclear |

**Kihlstrand 1999**

| | |
|---|---|
| Methods | Preventive randomised controlled trial.<br>329 women invited to participate, 258 were randomised 'using sealed envelopes'. Enrolment was done in segments of time, since only 60 women could participate in the pool program at the same time.<br>Participants and caregiver not blinded; assessor blinding unclear; those who completed the intervention were analysed in the group to which they had been randomised.<br>Funding: Dalarna Research Institute; Local Insurance Office. |
| Participants | Women registering at 1 of 6 maternity clinics run by Falun County Health Care Board in Sweden and had their ultrasound between gestational age 15 to 18 weeks.<br>329 women invited to study, from 967 who registered. 60 invitees declined because they couldn't participate in water gymnastics.<br>258 randomised to 2 groups of 129 each.<br>Inclusion criteria<br>Gestational age less than 19 weeks; fluent in Swedish; expectations of a normal pregnancy.<br>Exclusion criteria<br>Women with epilepsy, a previous preterm birth before week 32, younger than 18 years, women already participating in a water gymnastics program.<br>Drop-outs due to inability to participate in water gymnastics, recurrent UTIs, shift work, baby-sitting problems, miscarriage, intrauterine death, lack of time, invited to participate after date of closure. |
| Interventions | Intervention.<br>20 1-hour weekly water gymnastics classes involving exercise (tested for pregnant women) and relaxation in water (32 to 34 degrees).<br>First 10 sessions with exercises suitable for early pregnancy; last 10 sessions with exercises suitable for later pregnancy.<br>Hour session divided into 30 minutes exercise + 30 minutes relaxation.<br>Control: no treatment. |
| Outcomes | Back pain - VAS; number of days taken as sick leave because of back pain in pregnancy.<br>Adverse effects: no excess risk for pregnancy associated with water gymnastics observed: no differences with gyn/UTI infections, maternal weight gain, gestational age at delivery, weight/height of neonate, delivery characteristics. |
| Notes | Not enough data were given to allow use of the VAS.<br>Difficult to follow the path of recruitment, drop-outs since numbers given in text don't add up. |

| *Risk of bias* | | |
|---|---|---|
| **Item** | **Authors' judgement** | **Description** |

**Kihlstrand 1999** (*Continued*)

| | | |
|---|---|---|
| Allocation concealment? | Yes | A - Adequate |

**Kvorning 2004**

| | |
|---|---|
| Methods | 100 women, enrolled and randomised to one of two groups. The code for group allocation was obtained in advance by throwing dice in pairs of 10, and enclosed in advance in an envelope, marked with the order number of inclusion and opened consecutively by midwife on inclusion to the study.<br>Participants and caregiver not blinded; assessor blinded.<br>Those who finished the trial were analysed in the assigned groups.<br>Lost to follow-up: 1 ward closed to recruitment after 12 months because women no longer wished to be included in the study.<br>Acupuncture group = randomised 50, analysed 37; (lost 6 due to clinic closure, 3 delivered, 2 didn't like acupuncture, 1 didn't complete assessment correctly, 1 lost due to vacation of midwife).<br>Control group = randomised 50, analysed 35 (lost 6 due to clinic closure, 5 didn't complete forms correctly, 3 insisted on acupuncture, 1 was admitted to hospital for pain management and rest).<br>Study in Sweden.<br>No mention of funding.<br>Length of study or follow-up not given. |
| Participants | Inclusion criteria: 3rd trimester of pregnancy, presented at the maternity ward centres in southern Sweden, complaining of pelvic girdle or low-back pain.<br>Exclusion criteria: those participating in study for less than 3 weeks.<br>Baseline.<br>Two groups didn't differ significantly in age (30 ± 5.0 years); gestational week at first visit (30 ± 4.2 weeks); employed (75%); had acupuncture before (20%); negative attitude to acupuncture (20%).<br>Pain in sacroiliac region or over symphysis with no motor or sensory disturbances: A = 78%; C = 80%.<br>Duration of pain: A = 8.8 ± 5.6 weeks; C = 6.0 ± 3.8 weeks (P < 0.001).<br>Duration of pain in past 24 h: A = 9.8 ± 7.1 hours; C = 9.2 ± 7.4 hours.<br>Number of participants on analgesics: A = 1; C = 0. |
| Interventions | Experiment group.<br>Acupuncture given according to written instructions and periostal stimulation.<br>Started with LR3 and GV20 points + local tender points, added BL60, SI3 and 1 of lumbar and sacral bladder points (BL22-26) if needed; stimulated to De Qi, needles left in place for increasing length of time.<br>Time: patient received acupuncture twice a week during first 2 weeks; after this, they only received it once a week (note - no total duration of treatment time given).<br>Control group: no treatment. |
| Outcomes | Pain increased, pain unchanged, pain decreased, no pain during last 3 weeks of pregnancy, pain on activity decreased, Visits to maternity centres, number of participants who used analgesics, number of participants who used TENS, number of participants who used sacroiliac belt, number of participants who used physiotherapy, baby's birthweight, baby's Apgar at 1/5/10 minutes.<br>Adverse effects: reported by 38% of acupuncture group - local pain (6); heat or sweating (5); local hematoma (2); tiredness (2); nausea (2); weakness (1). |
| Notes | |

**Kvorning 2004** (*Continued*)

| *Risk of bias* | | |
|---|---|---|
| **Item** | **Authors' judgement** | **Description** |
| Allocation concealment? | Yes | A - Adequate |

**Martins 2005**

| | |
|---|---|
| Methods | The physiotherapist conducting the research randomised the women into two groups by means of a 'raffle' or 'lottery'.<br>Exercise group = 33; control group = 36.<br>Participants, caregiver or assessor not blinded.<br>There appeared to be no drop-outs and although analysis is unclear, there appears to be no contamination of groups in analysis; outcomes for control group not reported.<br>Funding: not reported. |
| Participants | Inclusion criteria: women with lumbar or pelvic pain, gestational age greater than 12 weeks, live in city of Paulinia, Brazil.<br>Exclusion criteria: twin pregnancy, neurological symptoms in the lower limbs, restrictions for exercise, those already engaged in a physiotherapy program to ease symptoms.<br>Baseline pain levels.<br>Exercise group = 48% greater than 5 on VAS 0-10.<br>Usual care group = 61% greater than 5 on VAS 0-10. |
| Interventions | Experiment group: exercises in groups for 'global activity and stretching'.<br>Control group: routine medical recommendations. |
| Outcomes | Proportion of women with improvement, VAS after 8 weeks.<br>Adverse events: not reported. |
| Notes | |

| *Risk of bias* | | |
|---|---|---|
| **Item** | **Authors' judgement** | **Description** |
| Allocation concealment? | No | C - Inadequate |

**Suputtitada 2002**

| | |
|---|---|
| Methods | 74 women were allocated to experimental or control groups by using a 'random sampling technique' (no description).<br>Exercise group: randomised = 42; analysed = 32 (76.2%).<br>Control group: randomised = 42; analysed = 35 (83.3%).<br>Lost to follow up: toxemia (3), wouldn't deliver at hospital (3), preterm labour due to oligohydramnios (1), group membership not noted, nor the reasons for the other losses.<br>Only analysed participants who completed follow up at 8 weeks (56 days).<br>Participants and caregiver not blinded; assessor blinding unclear.<br>Funding: not mentioned. |
| Participants | Inclusion criteria: primigravida, healthy - no underlying disease, 20 to 35 years old, 26 to 30 weeks' gestation, at least 140 cm tall, BMI before becoming pregnant less than 25 kg/m2, non-smoker, no previous severe back and pelvic pain, no contraindication for exercise during pregnancy, did not exercise regularly (< 1/week), attending prenatal clinic and intend to deliver at King Chulalongkorn Memorial Hospital, Bangkok, fluent in Thai, willing to participate in study regimen.<br>Exclusion criteria<br>Underlying disease that would effect exercise, pregnancy and labour, e.g. heart disease, diabetes mellitus, thyrotoxicosis, hypertension, infection, unable to follow exercise program 5 days/week for 8 weeks, weight gain more than 25 kg or less than 10 kg, do not intend to deliver at King Chulalongkorn Memorial Hospital.<br>Women were similar at baseline for all factors except job activities: exercise group sat more often at work (NS); control group stood more often at work and income: exercise group were in higher paid jobs than the control (P = 0.008). |
| Interventions | Experiment group.<br>Sitting pelvic tilt exercise: week 1 = do 4 cycles (hold position for 5 seconds then relax for 5 seconds) of exercises each morning and evening; increase by 2 cycles/session in weeks 2 to 4, until you are doing 10 cycles/session, then continue at this level for the next 4 weeks.<br>Exercises should be done twice a day, 5 days/week (twice under supervision of exercise instructor at the hospital; 3 times unsupervised at home) for a total of 8 weeks.<br>Record kept of exercises done; instructor checked agility and overall fitness when at clinic.<br>Control group: no treatment (nothing noted in article). |
| Outcomes | Pain improved, pain worsened, pain measured with VAS, gestational age at birth, baby's Apgar score at 1 minute, baby's Apgar score at 5 minutes.<br>Adverse events: 'no negative effects on mother or fetus; no preterm labour; no premature rupture of membranes'. |
| Notes | Numbers are not consistently reported throughout the article. |

***Risk of bias***

| Item | Authors' judgement | Description |
|---|---|---|
| Allocation concealment? | Unclear | B - Unclear |

**Thomas 1989**

| | |
|---|---|
| Methods | Crossover trial: order of use of pillows being 'randomly assigned' -- further details on randomisation not given.<br>109 women recruited; 92 women finished the 2-week observational period.<br>Participants and caregiver not blinded; assessor blinding unclear.<br>Analysis unclear (cross-over study) - analysed results of everyone who had one intervention against the results of those who received the 2nd intervention.<br>Funding source not noted. |
| Participants | Inclusion criteria.<br>36 weeks' gestation, attending an antenatal clinic in Brisbane, Australia.<br>Low-risk pregnancy.<br>Drop-outs related to delivery, failure to present to clinic for assignment of 2nd pillow, failure to return completed questionnaires. |
| Interventions | Provision of 2 different types of pillow to support the pregnant abdomen when lying in a lateral position. The pillows were taken home and used for 1 week each, consecutively. The Ozzlo pillow was a locally designed, curved, sloping, soft cushion conforming to the shape of the abdomen; the control pillow was a standard hospital pillow. |
| Outcomes | Numbers of women reporting moderate improvement in backache or better. Numbers of women reporting relief of insomnia.<br>No adverse effected noted. |
| Notes | There was no comparison with no treatment. We contacted the authors in 1999 and the Ozzlo pillow seems no longer to be made. |

***Risk of bias***

| Item | Authors' judgement | Description |
|---|---|---|
| Allocation concealment? | Unclear | B - Unclear |

**Wedenberg 2000**

| | |
|---|---|
| Methods | Randomised controlled trial - 60 women who accepted invitation to join study 'drew a closed envelope from a box to randomise to either the acupuncture or physiotherapy group'.<br>Participants and caregiver not blinded; assessor blinding unclear; analysed those who completed the intervention in the group to which they had been randomised.<br>2 of 30 women were not analysed in the acupuncture group since they had both inadvertently received both acupuncture and physiotherapy.<br>12 of 30 women in the physiotherapy group dropped out: preterm contractions (3), delivered during study (1), pre-eclampsia (1), no pain-diary notes (1), failed to attend (3), inconvenient treatment hours (3).<br>Study funded by the Council of Research and Development of Vrinnevi Hospital, Norrkoping, Sweden. |
| Participants | Swedish women with pelvic or back pain arising before 32 weeks' gestation. |

**Wedenberg 2000** (*Continued*)

| | |
|---|---|
| Interventions | Acupuncture.<br>3 times/week for 2 weeks, then 2 times/week for 2 weeks = total 10; each session = 30 minutes.<br>2 to 10 needles used, started with fossa triangularis points in ear adding body points, local points as needed; needles were gently tapped or rotated 15 minutes after insertion until De Qi reached.<br>Physiotherapy.<br>1 to 2 times/week within 6 to 8 weeks = total 10 physiotherapy group sessions; 50 minutes each.<br>Individualised treatment based on assessment + trochanter-belt for pelvic support, warmth, massage, soft-tissue mobilization if needed.<br>All were offered water gymnastics according to a defined program. |
| Outcomes | VAS (pain), disability rating indices and rating of overall effect all assessed by the women in the trial.<br>Adverse effects: no serious adverse effects reported, but 2 women reported small subcutaneous hematomas in the ear from acupuncture. |
| Notes | There was no comparison with no treatment.<br>The pain and disability scales were not used in this review because of insufficient data. |

***Risk of bias***

| **Item** | **Authors' judgement** | **Description** |
|---|---|---|
| Allocation concealment? | Yes | A - Adequate |

ADL: activities of daily living
BMI: body mass index
gyn: gynaecological
h: hour
kg/m2: kilogram/meters squared
LBP: low blood pressure
N/S: not significant
UTI: urinary tract infection
VAS: visual analogue scale

## Characteristics of excluded studies *[ordered by study ID]*

| | |
|---|---|
| Ciardi 2002 | QRCT - pilot study of 8 women assigned to groups based on ability to attend classes. |
| da Silva 2004 | QRCT - women assigned to groups based on the day they attended the prenatal clinic - Tuesday and Thursday were assigned to study group; Monday and Wednesday were assigned to control group. |
| Nilsson-Wikmar 2005 | QRCT - women stratified by previous pregnancies, then assigned to 1 of 3 treatment groups in sequence (1st primigravida to group 1, 2nd primigravida to group 2, 3rd primigravida to group 3, etc). |

(*Continued*)

| | |
|---|---|
| Ostgaard 1994 | QRCT - 3 groups divided by whether date of birth was 1-10 day in the month, 11-20 or 21-31. |

QRCT: Quasi-randomised controlled trial

## Characteristics of ongoing studies *[ordered by study ID]*

**Quinlivan 2005**

| | |
|---|---|
| Trial name or title | Evaluating the impact of a belly bra on back pain in pregnancy. |
| Methods | |
| Participants | Pregnant women in 2nd half of pregnancy. |
| Interventions | Belly bra versus tubigrip. |
| Outcomes | Pain, function. |
| Starting date | August 2005. |
| Contact information | A/Professor Julie Quinlivan: julieq@unimelb.edu.au |
| Notes | |

**Wang 2005**

| | |
|---|---|
| Trial name or title | Acupuncture and low back pain during pregnancy. |
| Methods | |
| Participants | Pregnant women with low-back pain. |
| Interventions | Auricular acupuncture for 1-week. |
| Outcomes | Pain, function, quality of life. |
| Starting date | February 2005. |
| Contact information | Dr Shu-Ming Wang: shu-ming.wang@yale.edu |
| Notes | |

## DATA AND ANALYSES

### Comparison 1. Low-back pain: sitting pelvic tilt exercises + usual prenatal care versus usual prenatal care

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Pain intensity (Visual Analogue Scale, range 0 to 10) | 1 | 65 | Std. Mean Difference (IV, Fixed, 95% CI) | -5.34 [-6.40, -4.27] |
| 2 Pain improved | 1 | 67 | Risk Ratio (M-H, Fixed, 95% CI) | 64.36 [4.09, 1011.86] |

### Comparison 2. Low-back pain: water gymnastics + usual prenatal care versus usual prenatal care

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Number of women taking sick leave because of back pain after 32 weeks' gestation | 1 | 241 | Risk Ratio (M-H, Fixed, 95% CI) | 0.40 [0.17, 0.92] |

### Comparison 3. Low-back pain: women's impression of the Ozzlo pillow's ability to prevent or relieve their backache

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Effect of Ozzlo pillow on backache (improvement rated moderate or better) | 1 | 184 | Risk Ratio (M-H, Fixed, 95% CI) | 1.84 [1.32, 2.55] |
| 2 Effect of Ozzlo pillow on sleep (benefit rated moderate or better) | 1 | 184 | Risk Ratio (M-H, Fixed, 95% CI) | 1.62 [1.23, 2.13] |

**Comparison 4. Pelvic pain: acupuncture + usual prenatal care versus usual prenatal care**

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Reduction of pain - assessed by independent examinor | 1 | 255 | Risk Ratio (M-H, Fixed, 95% CI) | 0.98 [0.85, 1.12] |
| 2 Pain when turning in bed - assessed by independent examinor | 1 | 255 | Risk Ratio (M-H, Fixed, 95% CI) | 0.80 [0.67, 0.96] |

**Comparison 5. Pelvic pain: stabilising exercises + usual prenatal care versus usual prenatal care**

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Reduction of pain - assessed by independent examinor | 1 | 261 | Risk Ratio (M-H, Fixed, 95% CI) | 0.96 [0.84, 1.11] |
| 2 Pain when turning in bed - assessed by independent examinor | 1 | 261 | Risk Ratio (M-H, Fixed, 95% CI) | 0.84 [0.70, 0.99] |

**Comparison 6. Pelvic + low-back pain: acupuncture + usual prenatal care versus individualised physio + usual prenatal care**

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Numbers of women rating treatment as good or excellent | 1 | 46 | Risk Ratio (M-H, Fixed, 95% CI) | 1.24 [0.96, 1.60] |

**Comparison 7. Pelvic + low-back pain: stretching exercises + usual prenatal care versus usual prenatal care**

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Women who reported no pain on Visual Analogue Scale | 1 | 69 | Risk Ratio (M-H, Fixed, 95% CI) | 5.45 [2.08, 14.30] |

**Comparison 8. Pelvic + low-back pain: acupuncture + usual prenatal care versus usual prenatal care**

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Number of women who reported decreased pain | 1 | 72 | Risk Ratio (M-H, Fixed, 95% CI) | 4.16 [1.77, 9.78] |

**Analysis 1.1. Comparison 1 Low-back pain: sitting pelvic tilt exercises + usual prenatal care versus usual prenatal care, Outcome 1 Pain intensity (Visual Analogue Scale, range 0 to 10).**

Review: Interventions for preventing and treating pelvic and back pain in pregnancy

Comparison: 1 Low-back pain: sitting pelvic tilt exercises + usual prenatal care versus usual prenatal care

Outcome: 1 Pain intensity (Visual Analogue Scale, range 0 to 10)

| Study or subgroup | Pelvic tilt exercise N | Mean(SD) | Usual care N | Mean(SD) | Std. Mean Difference IV,Fixed,95% CI | Weight | Std. Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|---|
| Suputtitada 2002 | 31 | 2.03 (1) | 34 | 7.49 (1.02) | | 100.0 % | -5.34 [ -6.40, -4.27 ] |
| **Total (95% CI)** | **31** | | **34** | | | **100.0 %** | **-5.34 [ -6.40, -4.27 ]** |

Heterogeneity: not applicable

Test for overall effect: Z = 9.83 (P < 0.00001)

### Analysis 1.2. Comparison 1 Low-back pain: sitting pelvic tilt exercises + usual prenatal care versus usual prenatal care, Outcome 2 Pain improved.

Review: Interventions for preventing and treating pelvic and back pain in pregnancy

Comparison: 1 Low-back pain: sitting pelvic tilt exercises + usual prenatal care versus usual prenatal care

Outcome: 2 Pain improved

| Study or subgroup | Pelvic tilt exercis n/N | Usual care n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Suputtitada 2002 | 29/32 | 0/35 | | 100.0 % | 64.36 [ 4.09, 1011.86 ] |
| **Total (95% CI)** | **32** | **35** | | **100.0 %** | **64.36 [ 4.09, 1011.86 ]** |
| Total events: 29 (Pelvic tilt exercis), 0 (Usual care) | | | | | |
| Heterogeneity: not applicable | | | | | |
| Test for overall effect: Z = 2.96 (P = 0.0030) | | | | | |

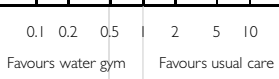

### Analysis 2.1. Comparison 2 Low-back pain: water gymnastics + usual prenatal care versus usual prenatal care, Outcome 1 Number of women taking sick leave because of back pain after 32 weeks' gestation.

Review: Interventions for preventing and treating pelvic and back pain in pregnancy

Comparison: 2 Low-back pain: water gymnastics + usual prenatal care versus usual prenatal care

Outcome: 1 Number of women taking sick leave because of back pain after 32 weeks' gestation

| Study or subgroup | Water gymnastics n/N | Usual care n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Kihlstrand 1999 | 7/123 | 17/118 | | 100.0 % | 0.40 [ 0.17, 0.92 ] |
| **Total (95% CI)** | **123** | **118** | | **100.0 %** | **0.40 [ 0.17, 0.92 ]** |
| Total events: 7 (Water gymnastics), 17 (Usual care) | | | | | |
| Heterogeneity: not applicable | | | | | |
| Test for overall effect: Z = 2.16 (P = 0.031) | | | | | |



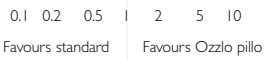
**Analysis 3.1. Comparison 3 Low-back pain: women's impression of the Ozzlo pillow's ability to prevent or relieve their backache, Outcome 1 Effect of Ozzlo pillow on backache (improvement rated moderate or better).**

Review: Interventions for preventing and treating pelvic and back pain in pregnancy

Comparison: 3 Low-back pain: women's impression of the Ozzlo pillow's ability to prevent or relieve their backache

Outcome: 1 Effect of Ozzlo pillow on backache (improvement rated moderate or better)

| Study or subgroup | Ozzlo pillow n/N | Standard pillow n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Thomas 1989 | 57/92 | 31/92 | | 100.0 % | 1.84 [ 1.32, 2.55 ] |
| **Total (95% CI)** | **92** | **92** | | **100.0 %** | **1.84 [ 1.32, 2.55 ]** |
| Total events: 57 (Ozzlo pillow), 31 (Standard pillow) | | | | | |
| Heterogeneity: not applicable | | | | | |
| Test for overall effect: Z = 3.64 (P = 0.00028) | | | | | |




**Analysis 3.2. Comparison 3 Low-back pain: women's impression of the Ozzlo pillow's ability to prevent or relieve their backache, Outcome 2 Effect of Ozzlo pillow on sleep (benefit rated moderate or better).**

Review: Interventions for preventing and treating pelvic and back pain in pregnancy

Comparison: 3 Low-back pain: women's impression of the Ozzlo pillow's ability to prevent or relieve their backache

Outcome: 2 Effect of Ozzlo pillow on sleep (benefit rated moderate or better)

| Study or subgroup | Ozzlo pillow n/N | Standard pillow n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Thomas 1989 | 63/92 | 39/92 | | 100.0 % | 1.62 [ 1.23, 2.13 ] |
| **Total (95% CI)** | **92** | **92** | | **100.0 %** | **1.62 [ 1.23, 2.13 ]** |
| Total events: 63 (Ozzlo pillow), 39 (Standard pillow) | | | | | |
| Heterogeneity: not applicable | | | | | |
| Test for overall effect: Z = 3.41 (P = 0.00065) | | | | | |

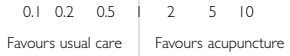
### Analysis 4.1. Comparison 4 Pelvic pain: acupuncture + usual prenatal care versus usual prenatal care, Outcome 1 Reduction of pain - assessed by independent examinor.

Review: Interventions for preventing and treating pelvic and back pain in pregnancy

Comparison: 4 Pelvic pain: acupuncture + usual prenatal care versus usual prenatal care

Outcome: 1 Reduction of pain - assessed by independent examinor

| Study or subgroup | Acupuncture n/N | Usual care n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Elden 2005 | 94/125 | 100/130 | | 100.0 % | 0.98 [ 0.85, 1.12 ] |
| **Total (95% CI)** | **125** | **130** | | **100.0 %** | **0.98 [ 0.85, 1.12 ]** |
| Total events: 94 (Acupuncture), 100 (Usual care) | | | | | |
| Heterogeneity: not applicable | | | | | |
| Test for overall effect: Z = 0.32 (P = 0.75) | | | | | |



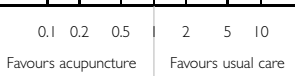

### Analysis 4.2. Comparison 4 Pelvic pain: acupuncture + usual prenatal care versus usual prenatal care, Outcome 2 Pain when turning in bed - assessed by independent examinor.

Review: Interventions for preventing and treating pelvic and back pain in pregnancy

Comparison: 4 Pelvic pain: acupuncture + usual prenatal care versus usual prenatal care

Outcome: 2 Pain when turning in bed - assessed by independent examinor

| Study or subgroup | Acupuncture n/N | Usual care n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Elden 2005 | 73/125 | 95/130 | | 100.0 % | 0.80 [ 0.67, 0.96 ] |
| **Total (95% CI)** | **125** | **130** | | **100.0 %** | **0.80 [ 0.67, 0.96 ]** |
| Total events: 73 (Acupuncture), 95 (Usual care) | | | | | |
| Heterogeneity: not applicable | | | | | |
| Test for overall effect: Z = 2.43 (P = 0.015) | | | | | |

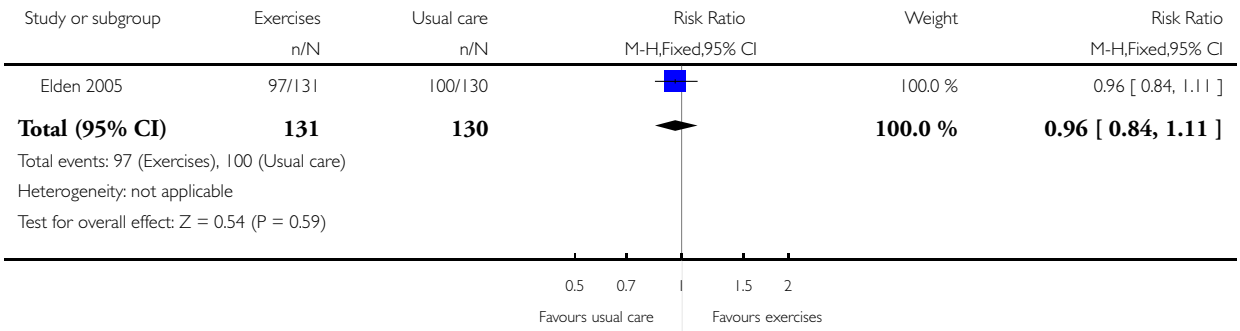


### Analysis 5.1. Comparison 5 Pelvic pain: stabilising exercises + usual prenatal care versus usual prenatal care, Outcome 1 Reduction of pain - assessed by independent examinor.

Review: Interventions for preventing and treating pelvic and back pain in pregnancy

Comparison: 5 Pelvic pain: stabilising exercises + usual prenatal care versus usual prenatal care

Outcome: 1 Reduction of pain - assessed by independent examinor

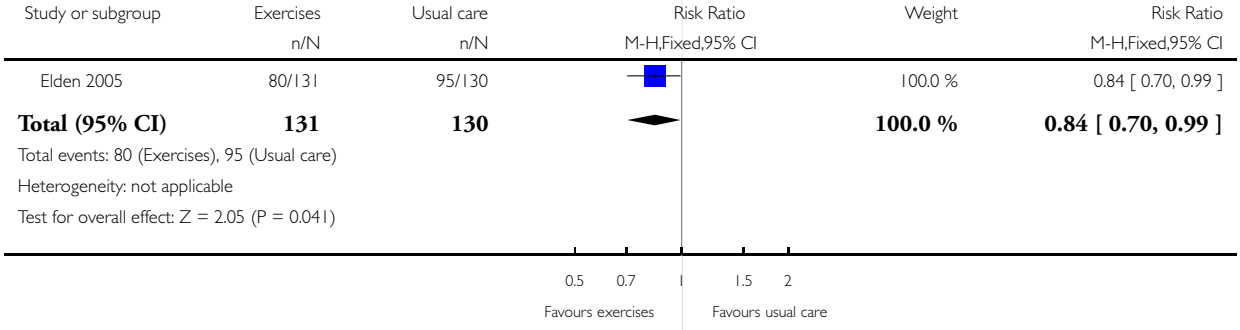



### Analysis 5.2. Comparison 5 Pelvic pain: stabilising exercises + usual prenatal care versus usual prenatal care, Outcome 2 Pain when turning in bed - assessed by independent examinor.

Review: Interventions for preventing and treating pelvic and back pain in pregnancy

Comparison: 5 Pelvic pain: stabilising exercises + usual prenatal care versus usual prenatal care

Outcome: 2 Pain when turning in bed - assessed by independent examinor



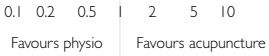
### Analysis 6.1. Comparison 6 Pelvic + low-back pain: acupuncture + usual prenatal care versus individualised physio + usual prenatal care, Outcome 1 Numbers of women rating treatment as good or excellent.

Review: Interventions for preventing and treating pelvic and back pain in pregnancy

Comparison: 6 Pelvic + low-back pain: acupuncture + usual prenatal care versus individualised physio + usual prenatal care

Outcome: 1 Numbers of women rating treatment as good or excellent

| Study or subgroup | Acupuncture n/N | Physiotherapy n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Wedenberg 2000 | 27/28 | 14/18 | | 100.0 % | 1.24 [ 0.96, 1.60 ] |
| **Total (95% CI)** | **28** | **18** | | **100.0 %** | **1.24 [ 0.96, 1.60 ]** |
| Total events: 27 (Acupuncture), 14 (Physiotherapy) | | | | | |
| Heterogeneity: not applicable | | | | | |
| Test for overall effect: Z = 1.64 (P = 0.10) | | | | | |



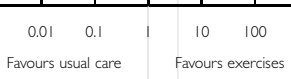

### Analysis 7.1. Comparison 7 Pelvic + low-back pain: stretching exercises + usual prenatal care versus usual prenatal care, Outcome 1 Women who reported no pain on Visual Analogue Scale.

Review: Interventions for preventing and treating pelvic and back pain in pregnancy

Comparison: 7 Pelvic + low-back pain: stretching exercises + usual prenatal care versus usual prenatal care

Outcome: 1 Women who reported no pain on Visual Analogue Scale

| Study or subgroup | Exercises n/N | Usual care n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Martins 2005 | 20/33 | 4/36 | | 100.0 % | 5.45 [ 2.08, 14.30 ] |
| **Total (95% CI)** | **33** | **36** | | **100.0 %** | **5.45 [ 2.08, 14.30 ]** |
| Total events: 20 (Exercises), 4 (Usual care) | | | | | |
| Heterogeneity: not applicable | | | | | |
| Test for overall effect: Z = 3.45 (P = 0.00056) | | | | | |



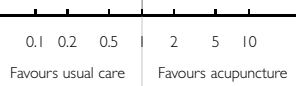
**Analysis 8.1. Comparison 8 Pelvic + low-back pain: acupuncture + usual prenatal care versus usual prenatal care, Outcome 1 Number of women who reported decreased pain.**

Review: Interventions for preventing and treating pelvic and back pain in pregnancy

Comparison: 8 Pelvic + low-back pain: acupuncture + usual prenatal care versus usual prenatal care

Outcome: 1 Number of women who reported decreased pain

| Study or subgroup | Acupuncture n/N | Usual care n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Kvorning 2004 | 22/37 | 5/35 | | 100.0 % | 4.16 [ 1.77, 9.78 ] |
| **Total (95% CI)** | **37** | **35** | | **100.0 %** | **4.16 [ 1.77, 9.78 ]** |
| Total events: 22 (Acupuncture), 5 (Usual care) | | | | | |
| Heterogeneity: not applicable | | | | | |
| Test for overall effect: Z = 3.27 (P = 0.0011) | | | | | |




# APPENDICES

## Appendix 1. Assessment of methodological quality of included studies

**Criteria assessed**

(1) Selection bias (randomisation and allocation concealment):
Method of allocation generation: was it adequate, unclear or inadequate?
(A) adequate randomisation: such as computer-generated random number table;
(B) unclear: study reports a randomisation technique was used, but does not give details of the method;
(C) inadequate: such as allocated using date of birth, date of admission, hospital numbers, alternation.

(2) Allocation concealment:
(A) adequate concealment of allocation: such as telephone randomisation, consecutively-numbered, sealed opaque envelopes;
(B) unclear whether adequate concealment of allocation: such as list or table used, sealed envelopes, or study does not report any concealment approach;
(C) inadequate concealment of allocation: such as open list of random-number tables, use of case record numbers, dates of birth or days of the week.

(3) Attrition bias (loss of participants, eg, withdrawals, dropouts, protocol deviations):
(A) less than 5% loss of participants;
(B) 5% to 9.9% loss of participants;
(C) 10% to 19.9% loss of participants;
(D) more than 20% loss of participants.

(4) Performance bias (blinding of participants, researchers and outcome assessment):

(*Continued*)

(A) blinding of participants (yes/no/unclear);
(B) blinding of caregiver (yes/no/unclear);
(C) blinding of outcome assessment (yes/no/unclear).

(5) Intention-to-treat analysis: used/unclear/not used:
(A) used: analysis of randomised participants in randomised groups, regardless of noncompliance or cointerventions;
(B) unclear: not clearly reported in study, but analysis appears to be in line with randomisation;
(C) not used: analysis of participants in group to which they self-selected after randomisation.

## FEEDBACK

### Herxheimer, September 1998

#### Summary

Characteristics of included studies:
Thomas 1989 was a crossover trial, was it reported as such? The outcome for the first crossover should be reported separately from the second crossover. Data for women who did not complete the second period could then be included for the first period. More information about when and for how long women used the pillows would be useful, and at what gestation.
Information about how to get the OZZLO pillow should be presented, and whether it is a patented design. A drawing of the pillow would also be helpful.
Results:
If the reviewers have contact with the trialists it would be useful to know whether they still use the OZZLO pillow, and if not why not.

#### Reply

These comments have now been incorporated into the updated review. It is not possible to provide a drawing of the OZZLO pillow within the Cochrane review but we have mentioned in the update that a drawing can be found in the original study, which is referenced. [reply from Gavin Young, October 2001]

#### Contributors

Comments received from Andrew Herxheimer, September 1998.

## WHAT'S NEW

Last assessed as up-to-date: 7 February 2006.

| | | |
|---|---|---|
| 9 June 2008 | Amended | Converted to new review format. |

## HISTORY

Protocol first published: Issue 3, 1998

Review first published: Issue 3, 1998

| | | |
|---|---|---|
| 15 April 2006 | New citation required but conclusions have not changed | A new author, Victoria Pennick, joined the review team and is now the guarantor of the review. |
| 8 February 2006 | New search has been performed | This updated review (February 2006) includes an updated search, which identified five new trials that met the inclusion criteria: two studies examined women with low-back pain (Garshasbi 2005; Suputtitada 2002); one study examined women with pelvic pain ( Elden 2005); and two studies examined a mixed population with pelvic and back pain (Kvorning 2004;Martins 2005). In total, we included nine reports (1305 participants), describing eight studies. One report was the abstract of one of the published articles and only gave preliminary results.<br><br>Despite the addition of these studies, the conclusions remain essentially the same. The specially-designed Ozzlo pillow was more effective than a regular one in relieving back pain, but is no longer commercially available. Pregnant-specific exercise programs, physiotherapy and acupuncture added to usual prenatal care all appeared to reduce back or pelvic pain more than usual prenatal care. However, all but one study had moderate to high potential for bias, prohibiting full confidence in these results.<br><br>The updated search also identified three new reports, which we excluded because they are quasi-randomized controlled trials (Ciardi 2002C; da Silva 2004; Nilsson-Wikmar 2005) and two ongoing trials (Quinlivan 2005; Wang 2005). |
| 31 October 2001 | New citation required but conclusions have not changed | The background section has been enlarged, giving more information about prevalence and prognosis. A distinction is made between pain arising from the lumbo-sacral region (back pain) and pain in the region of the sacroiliac joints and pubic symphysis (pelvic pain). Two new studies are included which assess the role of acupuncture versus physiotherapy, and water gymnastics versus no treatment. |

(*Continued*)

| | | |
|---|---|---|
| 31 October 2001 | New search has been performed | Search updated. Two new studies are included which assess the role of acupuncture versus physiotherapy, and water gymnastics versus no treatment. |
| 1 October 2001 | Feedback has been incorporated | Authors replied to feedback. |
| 9 January 1998 | Feedback has been incorporated | Feedback received from Andrew Herzheimer. |

## CONTRIBUTIONS OF AUTHORS

For the 2006 update: Victoria Pennick (VEP) and Gavin Young (GY) selected and assessed the methodological quality of the articles and extracted and analysed the data. VEP wrote the first draft of the review; GY reviewed and offered his comments.

For the original review and 2002 update: Both review authors, GY and David Jewell, assessed all articles and contributed to the analyses. GY entered the data and wrote the text.

## DECLARATIONS OF INTEREST

None known.

## SOURCES OF SUPPORT


### Internal sources

- Institute for Work and Health, Canada.

### External sources

- Royal College of General Practitioners, UK.


## INDEX TERMS

## Medical Subject Headings (MeSH)

Back Pain [*prevention & control]; Pelvic Pain [prevention & control]; Physical Therapy Modalities; Pregnancy Complications [*prevention & control]; Randomized Controlled Trials as Topic

## MeSH check words

Female; Humans; Pregnancy