A systematic review investigating the effectiveness of Complementary and Alternative Medicine (CAM) for the management of low back and/or pelvic pain (LBPP) in pregnancy

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Abstract

Aim. To evaluate and summarize the current evidence on the effectiveness of complementary and alternative medicine for the management of low back pain and/or pelvic pain in pregnancy.

Background. International research demonstrates that 25–30% of women use complementary and alternative medicine to manage low back and pelvic pain in pregnancy without robust evidence demonstrating its effectiveness.

Design. A systematic review of randomized controlled trials to determine the effectiveness of complementary and alternative medicine for low back and/or pelvic pain in pregnancy.


Review methods. Selected studies were written in English, randomized controlled trials, a group 1 or 2 therapy and reported pain reduction as an outcome measure. Study quality was reviewed using Risk of Bias and evidence strength the Cochrane Grading of Recommendations and Development Evaluation Tool.

Results. Eight studies were selected for full review. Two acupuncture studies with low risk of bias showed both clinically important changes and statistically significant results. There was evidence of effectiveness for osteopathy and chiropractic. However, osteopathy and chiropractic studies scored high for risk of bias. Strength of the evidence across studies was very low.

Conclusion. There is limited evidence supporting the use of general CAM for managing pregnancy-related low back and/or pelvic pain. However, the restricted availability of high-quality studies, combined with the very low evidence strength, makes it impossible to make evidence-based recommendations for practice.

Keywords: complementary and alternative medicine, healthcare professionals, low back pain, nursing, pelvic pain, midwifery pregnancy, systematic literature review
Introduction

Pregnancy-related low back and/or pelvic pain is a common pregnancy problem, experienced by women globally (Charpentier et al. 2012). The international literature on low back and/or pelvic pain (LBPP) in pregnancy reports that more than two thirds of women experience low back pain and almost one fifth experience pelvic pain (Pennick & Liddle 2013). There is lack of clarity about whether LBPP in pregnancy should be considered together or separately, most likely because there is no accepted method of differentiating between the two (Ostgaard et al. 1996) and women themselves find it difficult to distinguish between them. The onset of LBPP usually occurs between the 5th and 7th month of pregnancy (Fast et al. 1987, National Institute of Clinical Excellence 2008a,b, 2010, Ansari et al. 2010) and increases as pregnancy advances, interfering with daily activities, preventing women from going to work and disturbing sleep (Berg et al. 1988, Mens et al. 1996, National Institute of Clinical Excellence 2008a,b, 2010, Pennick & Liddle 2013). The exact aetiology of LBPP in pregnancy remains unclear, although altered posture and increased levels of relaxin hormone are commonly cited in the literature as possible causes (Sabino & Graeur 2008, Richens et al. 2010).

Treatment options vary, frequently including physiotherapy, transcutaneous electrical nerve stimulation, pharmacological treatment, acupuncture, chiropractic treatment and stabilization belts (Sabino & Graeur 2008). Exercise in later pregnancy has been found to be beneficial for reducing pregnancy-related LBPP, as has exercise in water (Kihlstrand et al. 1999, Garshasbi & Faghih Zadeh 2005). There is conflicting evidence about the benefits of interventional back classes (Berg et al. 1988, Dumas et al. 1995). Pregnant women with LBPP may also use simple home remedies like heat pads (Sabino & Graeur 2008).

The use of Complementary and Alternative Medicine (CAM) is a popular strategy for this seemingly common pregnancy-related problem according to several surveys (Wang et al. 2005, Sinclair et al. 2013). These surveys report that about 25–30% of women use at least one form of CAM to manage their LBPP during pregnancy. The reasons for pregnant women using CAM are varied and include the belief that these therapies are safer than pharmaceuticals, they allow greater choice and control over the childbearing experience and they are congruent with their holistic health beliefs (Hall et al. 2011). Furthermore, Wang et al. 2005 reports that almost 62% of pregnant women would be willing to accept a form of CAM for treating low back pain in pregnancy and 61% of maternity health professionals would consider using CAM with pregnant women suffering from low back pain. CAM potentially offers women safe, natural alternatives for managing the problem of LBPP in pregnancy and could reduce the need for some pain medications in pregnancy, the effects of which are unclear. Research suggests that about one third of women use medications to manage LBPP during pregnancy, such as paracetamol, codeine, morphine, co-dyramol, fentanyl, ibuprofen and dihydrocodeine (Sinclair et al. 2013). In light of the apparent frequent high use of medications in pregnancy for managing LBPP, many of which are not recommended during pregnancy, there is an urgent need to investigate the effectiveness of non-pharmacological methods like, CAM for managing this problem.

The use of CAM for LBPP in the general population has been systematically reviewed (Van Tulder et al. 2005), yet no such review focusing on pregnant women appears to exist despite the seemingly good safety profile of CAM with pregnant women and its popularity with this population. However, several systematic reviews that have investigated the use of individual CAM therapies for low back and pelvic pain in pregnancy exist. Manheimer et al. (2008) investigated acupuncture for pelvic and back pain in pregnancy and concluded that there was some evidence for the effectiveness of acupuncture for back and pelvic pain, but the quality of the evidence was low and that there was a need to conduct additional high-quality trials. Stuber and Smith
(2008) investigated chiropractic treatment for pregnancy-related low back pain and concluded that there was some evidence to suggest improved outcomes from using chiropractic treatment for pregnancy-related low back pain, but again evidence quality was low. Pennick and Liddle (2013) investigated interventions for treating and preventing back and pelvic pain in pregnancy; this included CAM therapies and reported benefits of acupuncture, osteopathic Manipulative Therapy (OMT) and manual therapy for treating back pain, pelvic pain or mixed back and pelvic pain. In summary, all three systematic reviews concluded that there is a need for more and better designed studies on interventions investigating these conditions.

The review

Aim

The aim of this review was to evaluate and summarize the current evidence on the effectiveness of CAM for the management of LBPP in pregnancy.

Objective

The objective of this review was to examine if CAM was a beneficial management strategy for LBPP in pregnancy.

Design

A systematic review was carried out to meet the review aim and objective. An inclusion and exclusion protocol was devised to decide which studies were included. The Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) guidelines (Moher et al. 2009) were used as a template for carrying out this review. The methodological quality of trials included in this review was assessed by carrying out a risk of bias (ROB) assessment on each trial. The ROB assessments followed guidelines in the Cochrane Handbook for Systematic Reviews (Higgins & Green 2011). The strength of the evidence for trials in this review was assessed according to the constructs of the GRADE (Grading of Recommendations, Assessment, Development, Evaluation) tool (Schünemann et al. 2009), which were adapted for this review (Table 1).

Search methods

Eight computerized databases were searched for published research. The Cochrane Central Register of Controlled Trials (1898–2013) was initially searched for articles. However, as this register does not contain full text articles, additional database searching was required. PUBMED (1996–2013), AMED (1985–2013), EMBASE (1974–2013), MEDLINE (1946–2013), CINAHL (1937–2013) were then searched. These databases were searched as they cover a wide selection of journals in CAM, nursing, midwifery and other professions related to medicine, which is important as CAM crosses many disciplines. Finally, PhD databases Index to Thesis (1716–2013) and Ethos (1914–2013) were searched to source any PHD studies in the area.

Three groups of key words were used to search databases:

- Back and pelvic pain key works (low back pain, back pain, pelvic pain, back ache, back discomfort)
- pregnancy key words (pregnancy, pregnant women)
- CAM key words: CAM therapies as listed in the House of Lords Select Committee on Science and Technology Sixth Report (2000) for Group 1 professionally organized alternative therapies: Homeopathy, herbal medicine, acupuncture, chiropractic, osteopathy and Group 2 complementary therapy: Bach flower remedies, Maha-
Inclusion/exclusion criteria

- Population: Pregnant women with low back and/or pelvic pain
- Interventions: Group 1 and 2 CAM interventions as listed in the House of Lords report were included. This includes acupuncture, homeopathy, chiropractic, osteopathy, Alexander technique, body work therapies, massage, counselling stress therapy, hypnotherapy, meditation, reflexology, shiatsu, healing, yoga, Bach flower remedies, herbal medicine, aromatherapy, nutritional medicine and Maharishi Ayurvedic Medicine.
- Controls/comparators: Physiotherapy, sham treatment, stabilizing exercises, exercise, usual care.
- Outcome measures: Following recommendations from Bombardier (2000) suggesting five key areas for outcome measures to assess patient improvement and satisfaction in low back pain, studies assessing one or more of the following key areas for outcome measures for review were considered for inclusion, this included:
  1. Back specific function;
  2. Generic health status;
  3. Pain;
  4. Work disability;
  5. Satisfaction with care/treatment outcome.
- Language: Only articles on CAM for the management of LBPP in pregnancy that were published in the English language were selected.
- Study Design: Randomized controlled trial’s (RCTs) only

Studies with only the abstract were excluded, as this does not provide sufficient detail to assess ROB and evidence strength. Studies were also excluded if the primary outcome was not to reduce LBPP in pregnancy.

Search outcome

The literature searches resulted in the retrieval of 768 publications, of which the majority did not meet our inclusion criteria. The lead author reviewed all abstracts and identified 10 papers that met the inclusion criteria. The other authors then independently screened these 10 papers to ensure that they met the inclusion criteria, and all authors met together to compare findings. Differences between reviewers were resolved through discussions until consensus was reached. Following discussion, two papers were excluded; one because it had a quasi-experimental design, the other because the CAM intervention being investigated was multi-modal combining chiropractic treatment and exercise.

Papers meeting the inclusion and exclusion criteria, which were already included in previous systematic reviews investigating interventions for pregnancy LBPP, were also included in this review. The reason for including these papers was because the previous reviews used different methods for assessing risk of bias (ROB) and strength of the evidence, their inclusion criteria differed or the focus of the review differed to this review.

Quality appraisal

ROB was carried out with all eight extracted studies; this includes assessing selection bias, performance bias, detection bias, attrition bias and other sources of bias. This tool rates the ROB for each of the domains assessed, as high, unclear or low; these terms are defined under Table 5.

For determining the strength of the evidence, an adapted version of the GRADE tool (Schünemann et al. 2009) was used (Table 1). This tool assesses the strength of the evidence-based on six domains including study design, study limitations, consistency of results and directness of the evidence, precision of the evidence and publication bias. The GRADE tool rates the overall strength of the evidence as high, moderate, low, very low. These terms are defined in Table 2 (Balshem et al. 2011).

Table 2 Definitions for strength of the evidence: GRADE (Balshem et al. 2011).

<table>
<thead>
<tr>
<th>Strength level</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>We are very confident that the true effect lies close to that of the estimate of the effect</td>
</tr>
<tr>
<td>Moderate</td>
<td>We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different</td>
</tr>
<tr>
<td>Low</td>
<td>Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect</td>
</tr>
<tr>
<td>Very low</td>
<td>We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect</td>
</tr>
</tbody>
</table>
Data abstraction and synthesis

We transferred data onto a pre-designed form based on the form used by the Cochrane and Pregnancy and Childbirth group for carrying out systematic reviews. Data were then entered into a table (Table 3). Due to certain differences between the studies in this review such as study design, varying gestational ages and the use of different comparators, it was impossible to pool outcomes together for a meta-analysis.

The effects of the CAM intervention

To determine the level of effectiveness of a CAM intervention over a control, we initially looked at statistical significances, e.g. $P \leq 0.05$. $P$ values less than 0.05 in the context of RCTs are generally interpreted as being small enough to reject the null hypothesis that the intervention had no effect (Higgins & Green 2011). We also deemed it appropriate to look at clinically important change. When considering the overall effect of a CAM intervention for reducing pain severity and bothersomeness, the Minimal Clinically Important Difference (MCID) was set at 2 points (0–10 scale) and 20 points (0–100 scale) (Beurskens et al. 1996, Assendelft et al. 2003, Salaffi et al. 2004, Ostelo & De Vet 2005), and for other back pain outcome measures such as back specific function, we set the MCID at 30% from baseline (Stratford et al. 1998, Jordan et al. 2006).

Results

Papers ($n = 768$) were identified by database, citation and hand searches. One hundred and forty-nine duplicated studies were excluded (Figure 1). Eight studies were selected for inclusion; although only six were powered to determine statistical significances, one was a pilot RCT and another feasibility RCT. These studies were included due to the limited availability of RCTs on the topic.

Six studies focused on acupuncture, one on osteopathy and one on chiropractic treatment.

The characteristics of included studies are presented in Table 3. Overall, included studies in this review represent 1042 healthy pregnant women suffering from LBPP, with a mean maternal age of 29 years and a mean gestational age of 27 weeks.

Effectiveness of CAM interventions

Overall, three acupuncture studies and the osteopathy study showed both statistically significant results and clinically important change (Table 4), but as mentioned, it was not possible to establish if clinically important change occurred in some of the studies due to lack of detail provided.

Acupuncture

Six studies examined the effects of acupuncture, three focused on pelvic pain and the remaining three on a mixed population suffering from either back or pelvic pain. Control measures varied between studies and included sham treatment, usual care, stabilizing exercises and physiotherapy. Gestational age varied in each study from 12–38 weeks. Most of these acupuncture studies offered treatments over a period of weeks or months, although one offered an intense one week programme. Visual analogue scale (VAS) to measure pain reduction was a primary outcome measure in all the acupuncture studies. In terms of pain, three studies (Wedenberg et al. 2000, Kvorning et al. 2004, Elden et al. 2005) reported statistically significant improvements for pain levels for acupuncture in comparison with a control. One study (Lund et al. 2006) found that both true acupuncture and sham acupuncture reduced pain significantly, and another found no statistical significant reductions when acupuncture was compared with sham, although this study did report statistically significant results for level of disability (Elden et al. 2008). The remaining acupuncture study (Wang et al. 2009) was a pilot study, and while it found positive effects of acupuncture compared with control measures, these results were not statistically significant. Of the acupuncture studies where information was available on clinically important change, four showed clinically important reductions in pain. It remained unclear in the other two acupuncture studies (Kvorning et al. 2004, Lund et al. 2006) whether changes in pain or other outcome measures were clinically important.

Osteopathy

Only one osteopathy study (Licciardone et al. 2010) was retrieved in the literature searches. This focused on back pain and used both sham ultrasound and usual care only as comparators. Gestational age of participants was 28–38 weeks. Seven treatments were offered over 9 weeks. Primary outcome measures were the Numerical Rating Scale (NRS) and the Roland Morris Disability Questionnaire (RMDQ). This study found no statistically significant reductions in pain when the osteopathy group was compared with control measures, as well as no clinically important changes in pain. However, the study reported statistically significant results for osteopathy for back specific function when compared with control measures, and
Table 3 Characteristics of included studies.

<table>
<thead>
<tr>
<th>Study</th>
<th>Participants</th>
<th>Study design</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Intervention length</th>
<th>Adverse effects and drop outs</th>
<th>Main Outcome measure</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elden et al. (2005)</td>
<td>Pregnant women at 12–31 weeks of gestation with pelvic girdle pain</td>
<td>RCT N = 386</td>
<td>Acupuncture</td>
<td>Stabilizing exercises usual care</td>
<td>12 treatments in 6 weeks</td>
<td>Drop outs = 65/386 Adverse effects = none reported</td>
<td>VAS-Pain</td>
<td>The acupuncture group had less pain than the usual care group in the morning ($P &lt; 0.001$) and evening ($P &lt; 0.001$) and less pain in the evening than the stabilizing group ($P = 0.013$). Changes in pain were clinically important.</td>
</tr>
<tr>
<td>Elden et al. (2008)</td>
<td>Pregnant women at 12–29 weeks of gestation with pelvic girdle pain</td>
<td>RCT N = 115</td>
<td>Acupuncture</td>
<td>Sham acupuncture with Streitberger placebo/sham needles</td>
<td>12 treatments in 8 weeks</td>
<td>Drop outs = 8/115 Adverse effects = none reported</td>
<td>VAS-Pain</td>
<td>Pain scores in the acupuncture Group were not significantly different to the sham group ($P = 0.493$). Statistically significant disability rating scores were observed between groups ($P = 0.001$). Though results for pain reduction were not statistically important they were clinically important.</td>
</tr>
<tr>
<td>Kvorning et al. (2004)</td>
<td>Pregnant women at 24–37 weeks of gestation with low back or pelvic pain</td>
<td>RCT N = 72</td>
<td>Acupuncture</td>
<td>Usual care</td>
<td>Initial 2-week period twice a week and later once a week</td>
<td>Drop outs = 28/100 Adverse effects = none reported</td>
<td>VAS-Pain</td>
<td>43% of acupuncture patients were less bothered by their pain compared with 9% of the usual care participants ($P &lt; 0.01$). It is unclear if reductions in pain were clinically important.</td>
</tr>
<tr>
<td>Lund et al. (2006)</td>
<td>Pregnant women at a mean gestational age of 26 weeks with pelvic pain</td>
<td>RCT N = 47</td>
<td>Acupuncture</td>
<td>Sham acupuncture (15 mm length/0.20 mm diameter, Seirin)</td>
<td>10 treatments in 5 weeks</td>
<td>Drop outs = 23/70 Adverse effects = none reported</td>
<td>VAS-Pain</td>
<td>Both true and sham acupuncture reduced pelvic pain. For example, rated morning pain levels reduced significantly for both sham and true acupuncture ($P &lt; 0.0003$). It remains unclear if any changes in pain were clinically important.</td>
</tr>
<tr>
<td>Study</td>
<td>Participants</td>
<td>Method</td>
<td>Intervention</td>
<td>Comparison</td>
<td>Intervention length</td>
<td>Adverse effects and drop outs</td>
<td>Main Outcome measure</td>
<td>Results</td>
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</tbody>
</table>
| Peterson et al. (2012)        | Pregnant women with low back pain at varying gestational ages                 | Feasibility RCT      | Chiropractic-SMT and NET      | Exercise            | Once monthly until 28 weeks of gestation, twice monthly until 36 weeks of gestation and weekly thereafter | Drop outs = 7/57  
Adverse effects = soreness in 6% of exercise and SMT group and 18% NET group | RMDQ                 | 80% of SMT participants had clinically important change in pain and 67% had clinically important change in function. |
| Wedenberg et al. (2000)       | Pregnant women ≤32 weeks of gestation suffering from low back or pelvic pain | RCT                  | Acupuncture                   | Physiotherapy       | 10 treatments in 1 month             | Drop outs = 12 of physiotherapy group  
Adverse effects = minor; 2× subcutaneous haematomas | VAS-Pain             | The mean pain levels were lower after acupuncture than physiotherapy in the morning (P = 0.02) and in the evening (P < 0.01). Clinically important changes in pain were observed. 80% of the acupuncture group experienced a clinically important reduction in pain. |
| Wang et al. (2009)            | Pregnant women at 25–38 weeks of gestation suffering from low back/posterior pelvic pain | Pilot RCT            | Acupuncture                   | Sham acupuncture (auricular press needles at 3 non-specific points) and Control | 7 treatments in 1 week                                          | Drop outs = 7/159  
Adverse effects = few minor adverse effects, e.g. ear tenderness | VAS-Pain             | 80% of the acupuncture group experienced a clinically important reduction in pain. |
| Licciardone et al. (2010)     | Pregnant women at 28–38 weeks of gestation with back pain                    | RCT                  | Osteopathy                    | Usual care and Sham ultrasound | 7 treatments in 9 weeks                                   | Drop outs = 4/146  
Adverse effects = none reported | VAS-Pain             | No significant reductions in back pain were observed, although RMDQ scores deteriorated significantly less in the osteopathy group compared with the usual care only group (P = 0.001). Clinically important benefits for back specific function were reported. |

SMT, Spinal manipulation Therapy; NET, Neuro Emotional Technique; NRS, Numerical Rating Scale; VAS, Visual Analogue Scale; RMDQ, Roland Morris Disability Question.
there were clinically important benefits for back specific function.

**Chiropractic treatment**
One study was retrieved that focused on two types of chiropractic treatment, Spinal Manipulation Therapy (SMT) and Neuromuscular Technique (Peterson et al. 2012). This focused on low back pain and used exercise as a control. Gestational age was not restrictive and was inclusive of all stages of pregnancy. Treatments were carried out over a period of months. NRS to measure pain reduction was the primary outcome measure. This study was a feasibility study and thus not powered to determine statistical significances, although it did report a clinically important improvement in function for 80% of the SMT participants and 67% of the SMT participants for pain.

**Other forms of CAM**
No RCT's investigating other forms of CAM and meeting inclusion and exclusion criteria were retrieved in our searches.

**Adverse effects**
When reported, adverse effects for the studies were minor (Wedenberg et al. 2000, Wang et al. 2009, Peterson et al. 2012) and included ear tenderness, small subcutaneous haematomas and some mild soreness.

**Research Ethics Committee approval**
All studies reported receiving some level of Research Ethics Committee approval prior to commencing the study. The majority of which had Research Ethics Committee approval granted from a University. The fact that all the studies received Research Ethics Committee approval is reassuring considering the vulnerability of this population. Research Ethics Committee approval is necessary for many reasons including safeguarding participants’ health and safety while partaking in research studies.

**Risk of bias (ROB) and strength of the evidence**
ROB was carried out on all eight studies and is summarized in Table 5.

**High risk of bias**
Lack of participant blinding in six of the studies and lack of clinician blinding in all eight studies led to high risk of performance bias. In four of the studies, the author failed to address incomplete data appropriately leading to a high risk of attrition bias.
In three studies, sequence generation had been carried out robustly and allocation concealed properly, which means selection bias was low. Reporting bias was low in six of the eight studies. Three studies scored low for other sources of bias, which included differences in baseline characteristics.

Table 4 Summary of effectiveness of CAM interventions for LBPP in pregnancy.

<table>
<thead>
<tr>
<th>Study</th>
<th>Intervention</th>
<th>Is there Clinically important change?</th>
<th>Are there statistically significant improvements over a control in pain, back specific function, etc.?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lund et al. (2006)</td>
<td>Acupuncture</td>
<td>UNSURE Raw data not presented and no information on clinically important change provided in this study.</td>
<td>NO</td>
</tr>
<tr>
<td>Kvorning et al. (2004)</td>
<td>Acupuncture</td>
<td>UNSURE Raw data not presented and no information on clinically important change provided in this study.</td>
<td>YES 43% of acupuncture patients were less bothered by their pain compared with 9% of the usual care participants ($P &lt; 0.01$). $P$ value taken from paper.</td>
</tr>
<tr>
<td>Wedenberg et al. (2000)</td>
<td>Acupuncture</td>
<td>YES-PAIN The authors of this study did not report clinically important change. So, this was calculated based on a change of 20 on the VAS* from baseline. The mean morning pain on the VAS reduced by 25 in the acupuncture group and the mean evening pain reduced by 57.</td>
<td>YES Mean pain levels were lower after acupuncture than physiotherapy in the morning ($P = 0.02$) and in the evening ($P &lt; 0.01$). $P$ values taken from paper.</td>
</tr>
<tr>
<td>Wang et al. (2009)</td>
<td>Acupuncture</td>
<td>YES-PAIN Clinically important change in this study was defined by the authors as 30% reduction or more from baseline. The authors reported that clinically important change was seen in 81% of the acupuncture group. Raw data were not presented.</td>
<td>NO</td>
</tr>
<tr>
<td>Elden et al. (2005)</td>
<td>Acupuncture</td>
<td>YES-PAIN The authors of this study did not report any data on clinical important change. So, this was calculated based on a change of 20 on the VAS from baseline. There was a median reduction of 35 in evening pain in the acupuncture group.</td>
<td>YES The acupuncture group had less pain than the usual care group in the morning ($P &lt; 0.001$) and less evening ($P &lt; 0.001$) and less pain in the evening than the stabilizing group ($P = 0.0130$). $P$ values taken from paper.</td>
</tr>
<tr>
<td>Elden et al. (2008)</td>
<td>Acupuncture</td>
<td>YES-PAIN The authors of this study did not report any data on clinically important. So, this was calculated based on a change of 20 on the VAS from baseline. There was a median pain reduction of 30 in the acupuncture group.</td>
<td>YES The acupuncture group had superior ability to perform daily activities ($P = 0.001$). $P$ value taken from paper.</td>
</tr>
<tr>
<td>Licciardone et al. (2010)</td>
<td>Osteopathic manipulative treatment</td>
<td>YES-BACK SPECIFIC FUNCTION The authors reported that there were clinically important benefits of osteopathy for back specific function, although this was presented in a figure from which the raw data were unable to be retrieved.</td>
<td>YES RMDQ** scores deteriorated significantly less in the osteopathy group compared with the usual care only group ($P = 0.001$). $P$ value taken from paper</td>
</tr>
<tr>
<td>Peterson et al. (2012)</td>
<td>Chiropractic treatment</td>
<td>YES-PAIN. The authors of this study did not report any data on clinically important change. So, this was calculated based on a change of 20 on the VAS from baseline. Median pain on the VAS decreased by 30 in the acupuncture group.</td>
<td>NO</td>
</tr>
</tbody>
</table>

*VAS, Visual Analogue Scale; **RMDQ, Roland Morris Disability Questionnaire.
In one study, ROB remained unclear for both elements of selection bias (sequence generation and concealment). Furthermore, sequence generation remained unclear for four of the studies.

### Strength of the evidence

Results from our application of the adapted version of the GRADE tool are summarized in Table 6. All eight studies in this review were RCTs that, according to the GRADE tool, would initially rate studies as high quality for study design. There were very serious limitations in the majority of included studies, in terms of blinding, sequence generation, high loss to follow-up and lack of intention to treat analysis.

Overall, there were inconsistencies between studies. For example, both positive and negative results were found for acupuncture for reducing the level of pain in pregnancy. Six of the studies investigated acupuncture and only three reported statistically significant results for acupuncture for reducing LBPP. In addition, Elden et al. (2008) found no reduction in LBPP in pregnancy with an acupuncture intervention and this was one of the best designed studies of all the studies scoring low for risk of bias in six of the seven domains.

Although the studies were specific in terms of the population (pregnant women with LBPP) and used similar primary outcomes (pain reduction or back specific function), there was a level of indirectness across the studies. For example, a wide range of comparators were used including physiotherapy, usual care, sham treatment, stabilizing exercises or usual exercise (Table 3), and gestational age at the start of the intervention differed between studies.

It was impossible to extract data from individual studies to calculate a summary relative risk and corresponding confidence interval, but overall, the total number of participants was fairly large. Publication bias cannot be completely ruled out; however, studies reporting negative findings and positive studies were identified by the various searches.

Due to serious limitations and problems with directness and precision, the overall strength of the evidence for CAM

### Table 5 Risk of bias assessments for included studies.

<table>
<thead>
<tr>
<th>Study</th>
<th>Intervention</th>
<th>Adequate sequence generation</th>
<th>Allocation concealment</th>
<th>Blinding of participants</th>
<th>Blinding of clinicians</th>
<th>Incomplete data</th>
<th>Reporting bias</th>
<th>Other bias</th>
<th>Summary overall risk of bias</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lund et al. (2006)</td>
<td>Acupuncture</td>
<td>Unclear</td>
<td>Low</td>
<td>Low</td>
<td>High</td>
<td>High</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Wedenberg et al. (2000)</td>
<td>Acupuncture</td>
<td>Unclear</td>
<td>Low</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Elden et al. (2005)</td>
<td>Acupuncture</td>
<td>Low</td>
<td>Low</td>
<td>High</td>
<td>High</td>
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</tr>
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<td>Wang et al. (2009)</td>
<td>Acupuncture</td>
<td>Low</td>
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<td>Low</td>
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<td>High</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Kvorning et al. (2004)</td>
<td>Acupuncture</td>
<td>Low</td>
<td>Low</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Licciardone et al. (2010)</td>
<td>Osteopathic manipulative treatment</td>
<td>Unclear</td>
<td>Unclear</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>Low</td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td>Peterson et al. (2012)</td>
<td>Chiropractic</td>
<td>Unclear</td>
<td>Low</td>
<td>High</td>
<td>High</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
</tr>
</tbody>
</table>

Interpretation of above ROB assessments in accordance with the Cochrane handbook (Higgins & Green, 2011): High = plausible bias that seriously weakens confidence in results; unclear = plausible bias that raises doubts about the results; low risk of bias = plausible bias unlikely to alter results. Summary overall risk of bias was determined by the ROB in the majority of the seven domains. For summary overall ROB, unclear ROB was considered as high.

### Table 6 Assessment of strength of CAM evidence for the management of LBPP in pregnancy using the GRADE system.

<table>
<thead>
<tr>
<th>No. of studies and participants</th>
<th>Study limitations</th>
<th>Consistency of results</th>
<th>Directness of the evidence</th>
<th>Precision</th>
<th>Reporting bias</th>
<th>Overall strength of the evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>8 RCT’s (1042)</td>
<td>-2 (serious limitations)</td>
<td>-1 (some inconsistency in results)</td>
<td>-1 (some indirectness)</td>
<td>No serious imprecision (represents a fairly large number of women)</td>
<td>Unlikely as positive and negative effects found</td>
<td>Very low</td>
</tr>
</tbody>
</table>

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for managing LBPP in pregnancy was rated as very low, according to our application of an adapted version of the GRADE tool; this is summarized in Table 6. The specific criteria we used for downgrading the level of evidence strength are outlined in Table 1.

Discussion

Summary and interpretation of findings

This review suggests that CAM may be beneficial for managing LBPP in pregnancy as there was evidence of effectiveness for acupuncture, osteopathy and chiropractic treatment. In particular, acupuncture is a treatment of interest as we found two acupuncture studies with both statistically significant and clinically important results that also scored low for ROB. For the other CAM interventions, the evidence remains unclear, for example while the osteopathy study found both statistically significant and clinically important results, this study had many methodological flaws and thus scored high for ROB. Furthermore, although the chiropractic study showed clinically important results following chiropractic treatment, there were no statistically significant results as this was a small pilot study and it had considerable methodological flaws and scored high for ROB.

While there is a small body of evidence to support the use of CAM for managing LBPP in pregnancy, the evidence is sometimes conflicting, i.e. one study supporting the use of CAM, then another study supporting a control intervention. There was also conflicting evidence about the number and frequency of CAM treatments required to produce beneficial effects. Wang et al. (2009) reported that 1 week of daily acupuncture was found to be beneficial for reducing LBPP, whereas Elden et al. (2005) reported that 12 acupuncture treatments over 6 weeks was beneficial for reducing LBPP in pregnancy. Although Wang et al. (2009) reported positive results using an intensive intervention; this study scored high for risk of bias in more domains assessed compared with Elden et al. (2005). These conflicting findings could create confusion for health professionals and women alike on the use and effectiveness of CAM for LBPP in pregnancy.

Evidence Strength and Risk of Bias

Strength of the evidence across studies was very low, due to problems with study reporting and design, mainly blinding. Blinding is difficult in CAM studies unless a valid and believable sham treatment is available, and for the majority of CAM therapies, a good sham treatment is difficult to find. However, acupuncture is one such CAM therapy where blinding has been successful with the use of sham needles (Park et al. 2002, White et al. 2003, Tsukayama et al. 2006).

Three studies had high dropout rates. High dropout rates in trials can lead to attrition bias, which can result in misinterpretation of results (Biester et al. 2006). High drop-out rates often occur in studies due to participants experiencing adverse effects or dissatisfaction with treatment allocation (Chambers et al. 2006). In this review, adverse effects reported were minor, which would imply that participants that dropped out were unhappy with the treatment they were receiving, or they may have perceived no improvements. However, possible under-reporting of adverse effects cannot be ruled out, considering the few studies that reported adverse effects and the limited detail provided. In fact, under-reporting of adverse effects has been highlighted as an issue in CAM trials (Ernst & Posadski 2012).

Implications for practice

CAM and particularly acupuncture seems to be a useful intervention for managing LBPP; it appears safe with few adverse effects reported and therefore could possibly be considered in some cases by maternity healthcare professionals as a management strategy when other methods have proven ineffective or unsuitable (Pennick & Liddle 2013).

CAM as an option for managing LBPP extends the options available to women, at a time when management strategies like pain relief medications are limited. However, it is important that if maternity healthcare professionals do recommend CAM for LBPP in pregnancy, they must be realistic about the outcomes that can be expected in light of the limited available evidence supporting its use for managing LBPP in pregnancy.

Another important implication for practice is the availability of CAM in the maternity setting. While a survey has highlighted that midwives are the group of health professionals with the highest use of CAM in their practice, provision remains inconsistent and ad hoc and many midwives have no formal training on CAM (Williams & Mitchell 2007, Hall et al. 2012). One possible explanation of the lack of robust integration of CAM into midwifery practice is the limited evidence of its effectiveness and thus limited funding is likely to be available for its use in maternity settings. In the absence of the availability of CAM in maternity settings, midwives may consider referring pregnant women to CAM practitioners. This is concerning considering the poor
regulation of many CAM therapies. CAM practitioners are generally not subjected to the same level of regulation as other health professions, meaning that CAM users are not protected from incompetent or unqualified practitioners, which highlights a particular concern for pregnant women.

Strengths and limitations

To our knowledge, this is the first systematic review investigating the effectiveness of CAM therapies in general for managing LBPP in pregnancy although, as discussed, two systematic reviews exist that have investigated the effectiveness of individual CAM therapies for LBPP in pregnancy and another review has included CAM therapies as part of the interventions to manage LBPP (Manheimer et al. 2008, Stuber & Smith 2008, Pennick & Liddle 2013). While robust methods were used to complete this systematic literature review, there are several limitations to this review of note.

The main limitation of this review was the restriction to including only English language studies. This is a major problem as much of the CAM research takes place in the Far East where English is not the first language.

At present, few randomized controlled trials exist on this topic and the majority focus on acupuncture. Few or no RCT’s were retrieved by the literature searches investigating other CAM therapies for managing LBPP in pregnancy including massage and reflexology, although these have been shown to be beneficial for managing low back pain in the general population (Preyde 2000, Quinn et al. 2008).

Another limitation was the lack of distinction between back and pelvic pain. Three studies included in this review investigated mixed populations with back and pelvic pain. It remains unclear whether back and pelvic pain in pregnancy should be treated as separated entities. Some experts believe that the two can and should be distinguished clinically, respond differently to various treatments and have different risk factors, while others are of the contrary opinion (Ostgaard et al. 1994, 1996).

Missing information for the studies in this review is another serious limitation, for example information on randomization procedures was often missing. If randomization lists are not drawn up appropriately, by individuals independent of the study, this can introduce significant bias. Furthermore, the results sections in some of the papers lacked information on clinically important changes. This affects our ability in this review to determine overall if changes in pain levels, function, etc. were clinically important. There was also limited information on adverse effects. This is a cause for concern as the under-reporting of adverse effects could make treatments appear safer than they actually are, as well as possibly breaching publication ethics. The CONSORT Guidelines on the design and the reporting of RCTs emphasizes the strict importance of providing adequate information on adverse effects in trials and highlights the potential effects of under-reporting adverse effects (CONSORT 2010).

Interestingly, one of the acupuncture studies in this review showed significant reductions in pain following the delivery of sham acupuncture that could suggest the involvement of the placebo effect, which is well documented in CAM research. There is significant debate around whether the positive effects of acupuncture that are often observed are true effects or simply just placebo. The placebo effect explains how our expectations and beliefs can cause real change in our physical bodies (National Health Service (NHS) 2013). The placebo effect has been shown to have a powerful effect in clinical trials (Enck & Klorasterhalfen 2005, Sysko & Walsh 2007, Macedo et al. 2008). In some of these studies, the placebo group have had up to a 40% improvement in symptoms from baseline. A recent meta-analysis by Vickers et al. (2012) reported that while acupuncture was better for reducing pain than sham acupuncture, the difference was small and could be related to other factors on top of the needle effects, such as the placebo effect which is closely associated with the patient’s positive belief that the treatment will work. Sham interventions are often recommended in trials to determine the true effect of an intervention above and beyond the placebo effect. However, having a sham treatment as the only control measure may not be very appropriate for CAM trials, sham CAM treatments often offer relaxation and a positive therapist interaction and these can affect the outcomes of the sham treatment (Kaptchuk et al. 2008, Hughes et al. 2009). In particular, it has been well documented that the relationship between the CAM therapist and the patient is largely responsible for the benefits reported by CAM users (Vincent & Furnham 1996). Reasons for this may be that CAM therapists generally have more time with patients than conventional practitioners and the fact that they focus on the person as a whole entity and not just a series of symptoms to be treated (Vincent & Furnham 1996). Interestingly in most of the studies, treatment effects appear to be greatest when CAM interventions are compared with usual care only. A possible explanation of this is that the relaxation aspect of the sham treatment combined with building a patient therapist relationship helps reduce symptoms of LBPP in pregnancy to some extent. This could suggest that CAM interventions may work due to the environment and settings and not as a
result of the intervention itself; although until more well-designed CAM RCT’s for LBPP in pregnancy with three arms (intervention, sham and usual care only) are available, this remains unclear.

Overall, while the findings of this review have been to some extent positive, it is impossible to generalize them to the whole pregnant population as women in the included studies began interventions at varying stages in pregnancy and the range of countries of included studies were limited to Sweden and the USA.

Conclusion
As reported previously in the literature, this review indicates that there is limited evidence to support the use of CAM for managing LBPP in pregnancy, but this evidence is generally of low quality and strength. However, high-quality evidence was found supporting acupuncture for managing this problem. As this body of evidence is small, caution around this finding is advised.

At present, we simply do not have enough high-quality trials on CAM for managing LBPP in pregnancy. The restricted availability of high quality studies, combined with the very low evidence strength, makes it impossible to make evidence-based recommendations for practice.

However, there may be circumstances where maternity health professionals may consider using CAM for LBPP in pregnancy, for example if pain is becoming difficult to manage and other management strategies have proven ineffective. In these circumstances, our findings, combined with an apparent good safety profile, would suggest that acupuncture is the CAM therapy most likely to be effective.

Currently, there is a great need for more high-quality, well-designed RCT’s investigating a wider range of CAM therapies for managing this common pregnancy-related problem. As CAM appears to be an acceptable and popular management strategy for LBPP with pregnant women and maternity health professionals alike and may reduce the high use of medications used for managing this problem.

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- substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;
- drafting the article or revising it critically for important intellectual content.

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