# Massage, reflexology and other manual methods for pain management in labour (Review)

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[Intervention Review]

# Massage, reflexology and other manual methods for pain management in labour

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## ABSTRACT

### Background

Many women would like to avoid pharmacological or invasive methods of pain management in labour, and this may contribute towards the popularity of complementary methods of pain management. This review examined currently available evidence supporting the use of manual healing methods including massage and reflexology for pain management in labour.

### Objectives

To examine the effects of manual healing methods including massage and reflexology for pain management in labour on maternal and perinatal morbidity.

### Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (30 June 2011), the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2011, Issue 2 of 4), MEDLINE (1966 to 30 June 2011), CINAHL (1980 to 30 June 2011), the Australian and New Zealand Clinical Trial Registry (30 June 2011), Chinese Clinical Trial Register (30 June 2011), Current Controlled Trials (30 June 2011), ClinicalTrials.gov, (30 June 2011) ISRCTN Register (30 June 2011), National Centre for Complementary and Alternative Medicine (NCCAM) (30 June 2011) and the WHO International Clinical Trials Registry Platform (30 June 2011).

### Selection criteria

Randomised controlled trials comparing manual healing methods with standard care, no treatment, other non-pharmacological forms of pain management in labour or placebo.

### Data collection and analysis

Two authors independently assessed trial quality and extracted data. We attempted to contact study authors for additional information.

**Main results**

We included six trials, with data reporting on five trials and 326 women in the meta-analysis. We found trials for massage only. Less pain during labour was reported from massage compared with usual care during the first stage of labour (standardised mean difference (SMD) -0.82, 95% confidence interval (CI) -1.17 to -0.47), four trials, 225 women), and labour pain was reduced in one trial of massage compared with music (risk ratio (RR) 0.40, 95% CI 0.18 to 0.89, 101 women). One trial of massage compared with usual care found reduced anxiety during the first stage of labour (MD -16.27, 95% CI -27.03 to -5.51, 60 women). No trial was assessed as being at a low risk of bias for all quality domains.

**Authors' conclusions**

Massage may have a role in reducing pain, and improving women's emotional experience of labour. However, there is a need for further research.

## PLAIN LANGUAGE SUMMARY

**Massage, reflexology and other manual methods for managing pain in labour**

The pain of labour can be intense, with tension, anxiety and fear making it worse. Many women would like to labour without using drugs such as narcotics or epidurals, and turn to complementary therapies to help them manage the pain of labour. Many complementary therapies are tried and in this review we have looked to see if massage, reflexology and other manual healing methods are effective. Other complementary therapies like acupuncture, mind-body techniques, hypnosis and aromatherapy have been studied in other reviews. Massage involves manipulating the body's soft tissues and it can be done by the midwife or partner. It helps women relax and so reduces the tension which increases pain in labour. Reflexology is gentle manipulation or pressing on certain parts of the foot to produce an effect elsewhere in the body. Other manual healing methods include osteopathy, shiatsu and zero balancing etc.

We found six studies, with data available from five trials on 326 women, looking at the use of massage in labour for managing pain. There were no studies on any of the other manual healing methods. The six studies were of reasonable quality but more participants are needed to provide robust information. We found that women who used massage felt less pain during labour when compared with women given usual care during first stage. However, more research is needed.

## BACKGROUND

This review is one in a series of Cochrane reviews examining pain management in labour. These reviews contribute to an overview of systematic reviews of pain relief for women in labour (Jones 2011b) and share a generic protocol (Jones 2011a). This generic protocol provides a template for all relevant reviews of pain management in labour. This will allow all reviews to use standard methods and collect data on the same set of outcomes so that the evidence from the different reviews can be more easily compared within a single overview. This generic protocol differs from others published in *The Cochrane Library* because it will be retained permanently as a protocol to describe the methods that shaped the production of all pain management in labour reviews, unlike other Cochrane protocols which usually develop into full reviews. In addition to the general background in this generic protocol, each of the individual pain management in labour reviews will include its own intervention-specific background information.

### Description of the condition

Labour presents a physiological and psychological challenge for women. As labour becomes more imminent, this can be a time of conflicting emotions; fear and apprehension can be coupled with excitement and happiness. Pain associated with labour has been described as one of the most intense forms of pain that can be experienced (Melzack 1984), although some women do not experience intense pain during labour. Pain experienced by women in labour is caused by uterine contractions, the dilatation of the cervix and, in the late first stage and second stage, by stretching of the vagina and pelvic floor to accommodate the baby. Tension, anxiety and fear are factors contributing towards women's perception of pain and may also affect their labour and birth experience. The neuromatrix theory of pain understands the influence of many factors including past experience and memory (Melzack 2001). In labour the theory of pain incorporates elements of the gate control

theory, but also past experiences, cultural factors, emotional state, cognitive input, stress regulation and immune systems, as well as immediate sensory input (Trout 2004).

Effective and satisfactory pain management needs to be individualised for each woman, and may be influenced by two paradigms: *working with pain*, or *pain relief* (Leap 1997). The working with pain paradigm includes the belief that there are long-term benefits to promoting normal birth, and that pain plays an important role in this process. The working with pain approach offers support and encouragement to women, advocates the use of techniques such as immersion in water, comfortable positions and self-help techniques to cope with normal labour pain. The pain relief paradigm is characterised by the belief that no woman need suffer pain in labour and women are offered a variety of pharmacological pain relief.

The relationship between childbirth satisfaction, labour pain and analgesia is complex (Hodnett 2002). A systematic review by Hodnett 2002, which included two large population surveys, found that women who were very anxious about labour pain prenatally were less satisfied after the birth; and, secondly, women who were most satisfied were those using no pharmacological pain relief during labour. Indeed, labour pain is only one factor related to satisfaction with childbirth, with further studies indicating that women who experienced less labour pain report higher levels of childbirth satisfaction compared with women who report higher pain levels in labour (Waldenstrom 1999; Windridge 1999). Personal control is also related to satisfaction with the childbirth experience (Goodman 2004), and studies highlighted by (Leap 2010) describe women's experience of childbirth as difficult yet empowering, leading to achievement and a feeling of pride in their ability to cope with intense pain (Lundgren 1998; McCrea 2000; Niven 2000).

## Description of the intervention

The use of complementary and alternative medicine (CAM) has become popular with consumers worldwide. Studies suggest that between 36% and 62% of adults in industrialised nations use some form of CAM to prevent or treat health-related problems (Barnes 2004). Complementary therapies are more commonly used by women of reproductive age, with almost half (49%) reporting use (Eisenberg 1998). It is possible that a significant proportion of women are using these therapies during pregnancy. A recent review of 14 studies with large sample sizes ($N \geq 200$) on the use of CAM in pregnancy identified a prevalence rate ranging from 1% to 87% (with nine falling between 20% and 60%) (Adams 2009). The review identified use of various complementary therapies including acupuncture and acupressure, aromatherapy, massage, yoga, homeopathy, and chiropractic care. The review also showed many pregnant women had used more than one complementary product or service (Adams 2009). Many women would like to avoid pharmacological or invasive methods of pain relief in labour, and this may contribute towards the popularity of complementary methods of pain management (Bennett 1999).

The Complementary Medicine Field of The Cochrane Collaboration defines CAM as 'practices and ideas which are outside the domain of conventional medicine in several countries', which are defined by its users as 'preventing or treating illness, or promoting health and well-being' (Cochrane 2006). This definition is deliberately broad as therapies considered complementary practices in one country or culture may be conventional in another. Many therapies and practices are included within the scope of the Complementary Medicine Field.

The most commonly cited CAM practices associated with providing pain management in labour can be categorised into mind-body interventions (e.g. yoga, hypnosis, relaxation therapies), alternative medical practice (e.g. homoeopathy, traditional Chinese medicine), manual healing methods (e.g. massage, reflexology), pharmacologic and biological treatments, bio-electromagnetic applications (e.g. magnets) and herbal medicines. Manual healing methods used to manage pain in labour include massage and reflexology.

Massage involves manipulation of the body's soft tissues. It is commonly used to help relax tense muscles and to soothe and calm the individual. Massage may help to relieve pain by assisting with relaxation, inhibiting sensory transmission in the pain pathways or by improving blood flow and oxygenation of tissues (Vickers 1999). Massage therapy can include specific physical techniques or manual therapy, such as deep tissue work, Swedish massage, neuromuscular massage or shiatsu (Rich 2002). Different massage techniques may suit different women. A woman who is experiencing backache during labour may find massage over the lumbosacral area soothing. Some women find light abdominal massage, known as effleurage, comforting. The pressure from massage may pre-empt the processing of painful stimuli because pressure fibres are longer and more myelinated, and relay signals to the brain more quickly than pain fibres (Melzack 1965). The potential positive effects from massage may decrease pain intensity, relieve muscle spasm, distract from pain, provide a sense of relaxation and reduce anxiety (McCaffery 1989). Massage therapists generally hold certification or licensure to practice massage in those countries or jurisdictions where such qualifications are recognised. Professional training programs for massage therapists also vary from country to country and may be undertaken as part of a broader health professional training or as a profession in its own right (Rich 2002).

Reflexologists propose that there are reflex points on the feet corresponding to organs and structures of the body, and that pain may be reduced by gentle manipulation or pressing certain parts of the foot. Pressure applied to the feet has been shown to result in an anaesthetising effect on other parts of the body (Ernst 1997). Reflexology involves the application of the thumb and forefinger to apply deep pressure to specific areas of the feet that are claimed to correspond to internal organs, gland and other parts of the body (Botting 1997). It has been claimed that by applying pressure to

'reflex zones', energy blocks or disturbances such as calcium, lactate or uric acid crystals are reabsorbed and later eliminated. This process is more commonly known as detoxification (Botting 1997). It has also been proposed that reflexology may reduce stress, tension and maintain balance or homeostasis. There is anecdotal evidence that reflexology maybe useful with reducing pre- and postnatal discomfort.

The intent is for these interventions to be included as separate reviews in the future.

### Why it is important to do this review

There is interest by women to use additional forms of care to assist with their pain management in labour. It is important to examine the efficacy, effectiveness and safety of under-evaluated forms of treatment to enable women, health providers and policy makers to make informed decisions about care.

## OBJECTIVES

To assess the effect, safety and acceptability of massage, reflexology and other manual healing methods to manage pain in labour.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

Randomised controlled trials (RCTs) and cluster RCTs. (We will not include results from quasi-RCTs in the analyses, but we may be discuss them in the text if little other evidence is available). We included studies only presented as abstracts if additional information was obtained from the author on the methods and results.

#### Types of participants

Women in labour. (This will include women in high-risk groups, e.g. preterm labour or following induction of labour. We planned to use subgroup analysis for any possible differences in the effect of interventions in these groups.)

#### Types of interventions

To avoid duplication, the different methods of pain management have been listed in a specific order, from one to 15. Individual reviews focusing on particular interventions include comparisons with only the intervention above it on the list. Methods of pain management identified in the future will be added to the end of the list. The current list is as follows.

1. Placebo/no treatment.
2. Hypnosis (Madden 2011).
3. Biofeedback (Barragán 2011).
4. Intracutaneous or subcutaneous sterile water injection (Derry 2011).
5. Immersion in water (Cluett 2009).
6. Aromatherapy (Smith 2011b).
7. Relaxation techniques (yoga, music, audio) (Smith 2011c).
8. Acupuncture or acupressure (Smith 2011a).
9. Manual methods (massage, reflexology) (this review)
10. Transcutaneous electrical nerve stimulation (Dowswell 2009).
11. Inhaled analgesia (Klomp 2011).
12. Opioids (Ullman 2010).
13. Non-opioid drugs (Othman 2011).
14. Local anaesthetic nerve blocks (Novikova 2011).
15. Epidural (including combined spinal epidural) (Anim-Somuah 2005; Simmons 2007).

Accordingly, this review includes comparisons of any type of manual healing method with any other type of manual healing method, as well as any type of manual healing method compared with: 1. placebo/no treatment; 2. hypnosis; 3. biofeedback; 4. intracutaneous or subcutaneous sterile water injection; 5. immersion in water; 6. aromatherapy; 7. relaxation techniques (yoga, music, audio); or 8. acupuncture or acupressure.

#### Types of outcome measures

This review is one in a series of Cochrane reviews examining pain management in labour. These reviews contribute to an overview of systematic reviews of interventions for pain management in labour (Jones 2011b), and share a generic protocol (Jones 2011a). The following list of primary outcomes are the ones which are common to all the reviews.

##### Primary outcomes

**Effects of interventions**

- Pain intensity (as defined by trialists).
- Satisfaction with pain relief (as defined by trialists).
- Sense of control in labour (as defined by trialists).
- Satisfaction with childbirth experience (as defined by trialists).

**Safety of interventions**

- Effect (negative) on mother/baby interaction.
- Breastfeeding (at specified time points).

- Assisted vaginal birth.
- Caesarean section.
- Side effects (for mother and baby; review specific).
- Admission to special care baby unit/neonatal intensive care unit (as defined by trialists).
- Apgar score less than seven at five minutes.
- Poor infant outcomes at long-term follow-up (as defined by trialists).

#### Other outcomes

- Cost (as defined by trialists).

#### Secondary outcomes

#### Maternal

Use of pharmacological pain relief in labour; length of labour; need for augmentation with oxytocin; perineal trauma (defined as episiotomy and incidence of second or third degree tear); and maternal blood loss (postpartum haemorrhage defined as greater than 500 ml), women's emotional experience of the intervention.

#### Neonatal

Need for mechanical ventilation; neonatal encephalopathy.

## Search methods for identification of studies

### Electronic searches

We contacted the Trials Search Co-ordinator to search the Cochrane Pregnancy and Childbirth Group's Trials Register (30 June 2011).

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. weekly searches of MEDLINE;
3. weekly searches of EMBASE;
4. handsearches of 30 journals and the proceedings of major conferences;
5. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

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

Trials identified through the searching activities described above are each assigned to a review topic (or topics). The Trials Search Co-ordinator searches the register for each review using the topic list rather than keywords.

In addition, we searched the Cochrane Central Register of Controlled Trials (T*he Cochrane Library* 2011, Issue 2 of 4), MEDLINE (1966 to 30 June 2011) and CINAHL (1980 to 30 June 2011). See Appendix 1, Appendix 2, and Appendix 3 for search strategies used.

We also searched the following clinical trial registries for ongoing trials: Australian and New Zealand Trials Registry (30 June 2011); Chinese Clinical Trial Register (30 June 2011); Current Controlled Trials (30 June 2011); ClinicalTrials.gov (30 June 2011); ISRCTN Register (30 June 2011); National Center for Complementary and Alternative Medicine (NCCAM) (30 June 2011); and the WHO International Clinical Trials Registry Platform (ICTRP) (30 June 2011). See Appendix 4 for search terms used.

We did not apply any language restrictions.

## Data collection and analysis

For the methods used when assessing the trials identified in previous versions of this review, *see* Appendix 5

We used the following methods when assessing any reports identified by the updated search.

### Selection of studies

Two of three review authors (C Smith (CS), K Levett (KL), C Collins (CTC)) independently screened the titles and abstracts of articles found in the search and discarded trials that were clearly not eligible.

CS, KL or CTC independently assessed whether the trials met the inclusion criteria, with disagreements resolved by discussion. When articles contained insufficient information to make a decision about eligibility, CS attempted to contact authors of the original reports to obtain further details.

### Data extraction and management

Following an assessment for inclusion CS, KL or CTC independently extracted data using the form designed by the Review Group for this purpose (Appendix 6). We resolved discrepancies through discussion with CTC. For each included trial, we gathered information on the location of the trial, methods of the trial (as per assessment of risk of bias), the participants (age range, eligibility criteria), the nature of the interventions, and data relating to the outcomes specified above. We collected information on reported benefits and adverse effects. When information regarding any of

the above was unclear, we attempted to contact authors of the original reports to provide further details. We entered data into Review Manager software (RevMan 2011) and checked for accuracy.

When information regarding any of the above was unclear, CS attempted to contact authors of the original reports to provide further details.

## Assessment of risk of bias in included studies

Two review authors (CS, KL) independently assessed risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We resolved any disagreement by discussion or by involving a third assessor (CTC).

### (1) Random sequence generation (checking for possible selection bias)

We described for each included study the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.

We assessed the method as:

- low risk of bias (any truly random process, e.g. random number table; computer random number generator);
- high risk of bias (any non-random process, e.g. odd or even date of birth; hospital or clinic record number); or
- unclear risk of bias.

### (2) Allocation concealment (checking for possible selection bias)

We described for each included study the method used to conceal allocation to interventions prior to assignment and assessed whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.

We assessed the methods as:

- low risk of bias (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
- high risk of bias (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear risk of bias.

### (3.1) Blinding of participants and personnel (checking for possible performance bias)

We described for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We considered that studies were at low risk of bias if they were blinded, or if we judge that the lack of blinding would be unlikely to affect results. We assessed blinding separately for different outcomes or classes of outcomes.

We assessed the methods as:

- low, high or unclear risk of bias participants;
- low, high or unclear risk of bias for personnel;

### (3.2) Blinding of outcome assessment (checking for possible detection bias)

We described for each included study the methods used, if any, to blind outcome assessors from knowledge of which intervention a participant received. We assessed blinding separately for different outcomes or classes of outcomes.

We assessed methods used to blind outcome assessment as:

- low, high or unclear risk of bias.

### (4) Incomplete outcome data (checking for possible attrition bias due to the amount, nature and handling of incomplete outcome data)

We described for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We stated whether attrition and exclusions were reported and the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion were reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information was reported, or it was supplied by the trial authors, we planned to re-include missing data in the analyses undertaken.

We assessed methods as:

- low risk of bias (e.g. no missing outcome data; missing outcome data balanced across groups);
- high risk of bias (e.g. numbers or reasons for missing data imbalanced across groups; 'as treated' analysis done with substantial departure of intervention received from that assigned at randomisation);
- unclear risk of bias.

### (5) Selective reporting (checking for reporting bias)

We described for each included study how we investigated the possibility of selective outcome reporting bias and what we found.

We assessed the methods as:

- low risk of bias (where it is clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review have been reported);
- high risk of bias (where not all the study's pre-specified outcomes have been reported; one or more reported primary outcomes were not pre-specified; outcomes of interest are reported incompletely and so cannot be used; study fails to include results of a key outcome that would have been expected to have been reported);
- unclear risk of bias.

#### (6) Other bias (checking for bias due to problems not covered by (1) to (5) above)

We described for each included study any important concerns we had about other possible sources of bias.
We assessed whether each study was free of other problems that could put it at risk of bias:

- low risk of other bias;
- high risk of other bias;
- unclear whether there is risk of other bias.

#### (7) Overall risk of bias

We made explicit judgements about whether studies were at high risk of bias, according to the criteria given in the *Handbook* ( Higgins 2011). With reference to (1) to (6) above, we assessed the likely magnitude and direction of the bias and whether we considered it was likely to impact on the findings. We explored the impact of the level of bias through undertaking sensitivity analyses - *see* Sensitivity analysis.

### Measures of treatment effect

#### Dichotomous data

For dichotomous data, we presented results as summary risk ratio (RR) with 95% confidence intervals (CI).

#### Continuous data

For continuous data, we used the mean difference if outcomes were measured in the same way between trials. We used the standardised mean difference to combine trials that measure the same outcome, but used different methods.

#### Ordinal data

For ordinal data measured on scales (e.g. pain measured on visual analogue scales), we analysed as continuous data and expressed the intervention as a difference in means or standardised difference in means. For ordinal data (e.g. satisfaction with pain relief) measured on shorter ordinal scales, e.g. (excellent, very good, good) we analysed as dichotomous data by combining categories (e.g. excellent and very good) and expressed the intervention using RR.

### Dealing with missing data

For included studies, we noted levels of attrition. We excluded trials with greater than 20% missing data from the analysis. We aimed to explore the impact of studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis.

For all outcomes, we carried out analyses, as far as possible, on an intention-to-treat basis, i.e. we attempted to include all participants randomised to each group in the analyses, and analysed all participants in the group to which they were allocated, regardless of whether or not they received the allocated intervention. The denominator for each outcome in each trial was the number randomised minus any participants whose outcomes were known to be missing.

### Assessment of heterogeneity

We assessed statistical heterogeneity in each meta-analysis using the $T^2$, $I^2$ and $Chi^2$ statistics. We regarded heterogeneity as substantial if $I^2$ was greater than 30% and either $T^2$ was greater than zero, or there was a low P value (less than 0.10) in the $Chi^2$ test for heterogeneity.

### Assessment of reporting biases

If there were 10 or more studies in the meta-analysis we planned to investigate reporting biases (such as publication bias) using funnel plots. We assessed funnel plot asymmetry visually, and used formal tests for funnel plot asymmetry. For continuous outcomes we used the test proposed by Egger 1997, and for dichotomous outcomes we used the test proposed by Harbord 2006. If we detected asymmetry in any of these tests or by a visual assessment, we proposed to perform exploratory analyses to investigate it.

### Data synthesis

We carried out statistical analysis using the Review Manager software (RevMan 2011). We planned to analyse trials for reflexology, massage or other modality separately. We used fixed-effect meta-analysis for combining data where it was reasonable to assume that studies were estimating the same underlying treatment effect: i.e. where trials are examining the same intervention, and we judged the trials' populations and methods sufficiently similar. If there was clinical heterogeneity sufficient to expect that the underlying treatment effects differed between trials, or if substantial statistical heterogeneity was detected, we used a random-effects meta-analysis to produce an overall summary if an average treatment effect across trials was considered clinically meaningful. We treated the random-effects summary as the average range of possible treatment effects and we planned to discuss the clinical implications of treatment effects differing between trials. If the average treatment effect was not clinically meaningful, we did not combine trials.
If we used the random-effects analyses, we have presented the results as the average treatment effect with its 95% confidence interval, and the estimates of $T^2$ and $I^2$.

### Subgroup analysis and investigation of heterogeneity

We investigated substantial heterogeneity using subgroup analyses and sensitivity analyses. We considered heterogeneity as substantial if $T^2$ was greater than zero and either $I^2$ was greater than 30% or there was a low P value (less than 0.10) in the $Chi^2$ test for heterogeneity. We considered whether an overall summary was meaningful, and if it was, used a random-effects analysis.

We planned to carry out the following subgroup analyses.

1. Spontaneous labour versus induced labour.
2. Primiparous versus multiparous.
3. Term versus preterm birth.
4. Continuous support in labour versus no continuous support.

We planned to restrict subgroup analyses to the review's primary outcomes.

We planned to visually examine the forest plots of subgroup analyses to look at whether there was overlap between 95% CIs for the effects of different groups; with non-overlapping CIs suggesting a difference between subgroups. We also planned to conduct more formal statistical subgroup analyses classifying whole trials by interaction test as described in the *Handbook* (Higgins 2011).

### Sensitivity analysis

Where subgroup analysis fails to explain the heterogeneity, we planned to analyse the data using the random-effects model. We planned to perform sensitivity analyses on the primary outcomes to look at the possible contribution of: (1) differences in methodological quality, with trials of high quality (low risk of bias) compared to all trials; and (2) publication bias by country. If publication bias was present, we planned to undertake a sensitivity analysis excluding trials from countries where there was a greater publication bias.

## RESULTS

## Description of studies

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

### Results of the search

The original reviews included a range of complementary therapies. This updated review includes massage trials only. We found no trials of reflexology eligible for inclusion were found. We included six studies (Abasi 2009; Chang 2002; Field 1997; Karami 2007; Kimber 2008; Taghinejad 2010) and excluded one study (Yildirim 2004) and three studies await further assessment. *See* Characteristics of included studies, Characteristics of excluded studies, Characteristics of studies awaiting classification and Characteristics of ongoing studies.

### Included studies

#### Study design

All studies were parallel design and five included two groups, and one study included three groups (Kimber 2008). All included active controls including standard care (Abasi 2009; Chang 2002; Karami 2007; Kimber 2008), breathing exercises (Field 1997) and music (Kimber 2008; Taghinejad 2010).

#### Sample size

Studies included in the review ranged from 28 (Field 1997) to 101 (Taghinejad 2010) participants.

#### Study location and sources of women

Three studies were undertaken in Iran (Abasi 2009; Karami 2007; Taghinejad 2010), and one study each in Taiwan (Chang 2002), United Kingdom (Kimber 2008) and the United States (Field 1997).

#### Participants

Four studies recruited primiparous women only, and at term (Abasi 2009; Chang 2002; Karami 2007; Taghinejad 2010). Kimber 2008 recruited women between 35 and 37 weeks' gestation, and the characteristics of women in the Field 1997 study were not reported.

#### Types of intervention

In three studies massage was taught to the partner who applied massage during labour (Chang 2002; Field 1997; Kimber 2008). Who applied massage in the Karami 2007 and Taghinejad 2010 studies was unclear. In the Abasi 2009 trial, massage was administered by a masseuse.There was variation in the frequency, duration and technique in how the massage was applied. Abasi 2009 and Chang 2002 delivered massage 30 minutes during each phase of labour using a variety of massage techniques. Massage was applied during contractions for a total of 30 minutes (no technique specified) (Taghinejad 2010). Kimber 2008 delivered slow rhythmic long stroke massage, with the hands moving up and down with slow rhythmic breathing. Effleurage was applied in Karami 2007 trial (no other details reported). The Field 1997 study trained the partner to deliver a massage from 3 cm to 5 cm dilation involving

a 20-minute sequence of stroking movements around four regions including head, neck, shoulder, back and foot.

#### Outcome measures

All studies reported on pain. Clinical outcomes were reported in four studies (Field 1997; Karami 2007; Kimber 2008; Taghinejad 2010). Maternal outcomes reporting on emotional experience, sense of control or satisfaction were reported in three studies ( Chang 2002; Field 1997; Kimber 2008).

### Excluded studies

We excluded one trial (*see* Yildirim 2004). Yildirim 2004 was excluded due to the intervention of the control group included in the relaxation for pain management review (Smith 2011c).

## Risk of bias in included studies

*See* Figure 1 and Figure 2 for a graphical summary of the risk of bias assessments by authors of the included studies based on the seven risk of bias domains. No study was at a low risk of bias on all domains.

**Figure 1. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.**

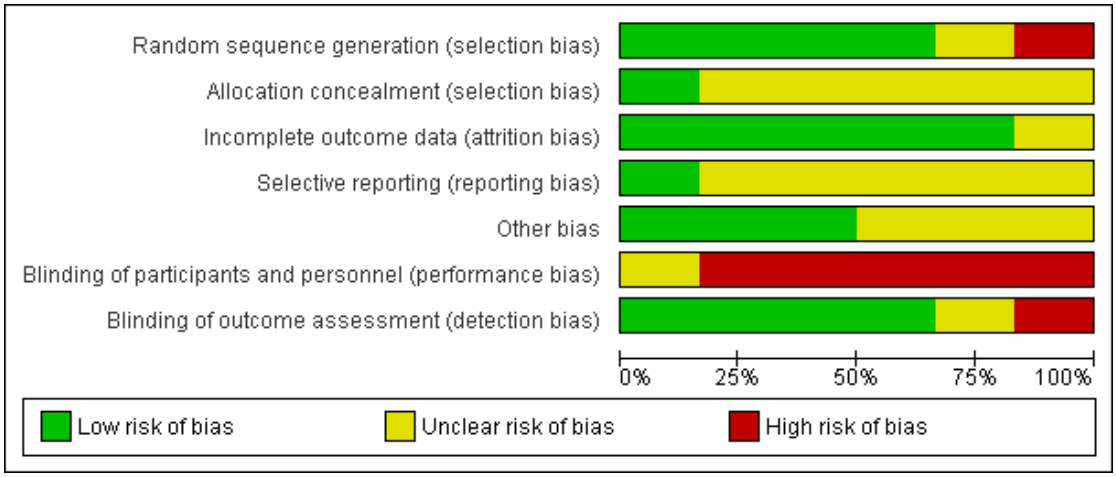
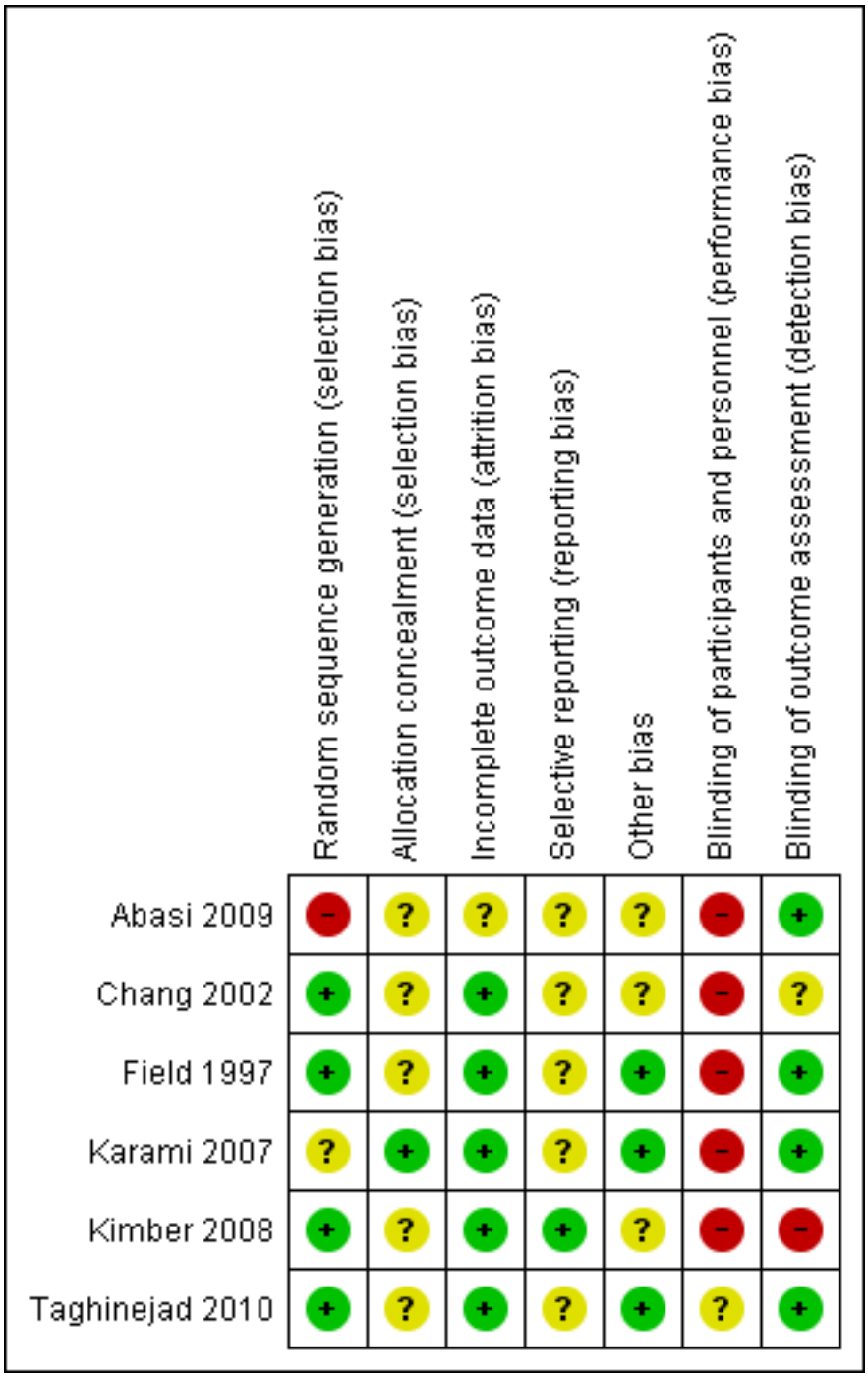


**Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.**



### Allocation

#### Method of allocation

Most trials (57%) were rated at a low risk of bias for adequate generation of the randomisation sequence. In two trials the randomisation was computer generated (Kimber 2008; Taghinejad 2010). The sequence was by ball tossing in one trial (Chang 2002) and by random number tables in one trial (Field 1997).

#### Allocation concealment

Allocation concealment was described as low risk in one trial. Sealed envelopes were used in one trial (Karami 2007).

### Blinding

It was not possible to blind the intervention from study participants. In one study (Taghinejad 2010) it was unclear if the care providers were blind to group allocation. Four studies were at a low risk of bias, with the outcome assessor blind to group allocation (Abasi 2009; Field 1997; Karami 2007; Taghinejad 2010).

### Incomplete outcome data

Outcome reporting was assessed at a low risk of bias in six trials.

### Selective reporting

The risk of bias from selective reporting was at a low risk of bias in two trials (Field 1997; Taghinejad 2010), and unclear in four trials (Abasi 2009; Chang 2002; Karami 2007; Kimber 2008).

### Other potential sources of bias

The risk of bias from other sources of bias was rated as low in four trials (Field 1997; Karami 2007; Kimber 2008; Taghinejad 2010).

## Effects of interventions

We compared trials comparing massage versus usual care and massage versus music.

We included five trials in the meta-analysis, with data reporting on 326 women. Data were not in a form that could be included in the meta-analysis from the Field 1997 study.

### 1. Massage versus usual care

### Primary outcomes

#### 1.1) Outcome: pain intensity

Data on pain intensity were reported in four trials with 225 women (Analysis 1.1).

The studies reported on the intensity of pain during the three stages of labour. The intensity of pain during the first stage of labour was reduced in the massage group compared with usual care (standardised mean difference (SMD) -0.82, 95% confidence interval (CI) -1.17, to -0.47) four trials, 225 women). There was no differences in reduced pain intensity between groups during the second stage of labour (SMD -0.98, 95% CI -2.23 to 0.26, two trials, 124 women) and third stage of labour (SMD -1.03 95% CI -2.17 to 0.11, two trials 124 women). Field 1997 reported less labour pain for the massage group compared with the control (mean 3.5 versus 5.0).

#### 1.2) Outcome: satisfaction with pain relief

There was significant heterogeneity indicated, as evidenced by the $I^2$ for this comparison, and we applied a random-effects model. Due to the heterogeneity of the results between studies, we have not combined data in the analysis. There was no difference in satisfaction with pain relief between groups (Chang 2002 MD 0.47, 95% CI -0.13 to 1.07, and Kimber 2008 MD -14.40, 95% CI -32.70 to 3.90).

#### 1.3) Outcome: sense of control in labour

One small trial found no difference in the sense of control in labour (MD -6.10, 95% CI -13.11 to 0.91, one trial, 40 women) (Analysis 1.3).

#### 1.4) Outcome: assisted vaginal birth

There were no differences between groups in assisted vaginal birth (RR 0.46, 95% CI 0.14 to 1.50), two trials 105 women) (Analysis 1.4).

#### 1.5) Outcome: caesarean section

There were no differences between groups in caesarean delivery (RR 0.73, 95% CI 0.24 to 2.22, two trials, 105 women) (Analysis 1.5).

#### 1.6) Outcome: admission to neonatal intensive care unit

One small trial found no difference in admission to neonatal intensive care (RR 1.93, 95% CI 0.13 to 28.79, one trial, 44 women) (Analysis 1.6).

### Secondary outcomes

#### 1.7) Outcome: use of pharmacological pain relief

There were no differences in use of pharmacological pain relief between groups (RR 1.19, 95% CI 0.28 to 5.08, two trials, 105 women). There was significant heterogeneity and we applied a random-effects model ($I^2$ = 34%) (Analysis 1.7).

#### 1.8) Outcome: augmentation

Two trials found no difference in the use of augmentation between groups (RR 1.09, 95% CI 0.40 to 2.97, two trials, 105 women). There was significant heterogeneity ($I^2$ = 31%) (Analysis 1.8).

#### 1.9) Outcome: length of labour

Two trials found no differences between groups with the length of labour (SMD 0.34, 95% -0.07 to 0.75). There was significant heterogeneity and we applied a random-effects model (Analysis 1.9).

In addition, two trials reported on the length of the first stage of labour only. These was significant heterogeneity ($I^2$ = 83%) and we did not combine trials. Karami 2007 found reduced length of labour in the first stage of labour for women receiving massage compared with usual care (MD -116.34, 95% -172.68 to -60.00). Kimber 2008 found no difference between groups (MD 77.90, 95% -67.16 to 222.96).

#### 1.10) Outcome: emotional experience in labour

Chang 2002 examined women's experience of anxiety during labour. This small trial found less anxiety during the first stage of labour for women receiving massage compared to usual care (MD -16.27, 95% CI -27.03 to -5.51, 60 women, one trial) (Analysis 1.10).

There were no differences between groups during the second stage of labour (MD -8.97, 95% CI -20.79 to 2.85, one trial, 60 women), and third stage of labour (MD -4.57, 95% CI -14.04 to 4.90).

Field 1997 reported improved outcomes for the massage group compared with the control with less depressed mood (mean 6.9 versus 14.9), and lower stress levels (mean 5.2 versus 3.5).

## 2. Massage versus music

#### Primary outcomes

#### 2.1) Outcome: pain intensity

The Taghinejad 2010 trial assessed this outcome as a categorical variable and we report on women reporting severe pain. One small trial found pain was reduced in the massage group versus music group (risk ratio (RR) 0.40, 95% CI 0.18 to 0.89, one trial, 101 women) (Analysis 2.1).

#### Secondary outcomes

#### 2.2) Outcome: use of pharmacological pain relief

There were no differences in the use of pharmacological pain relief in the massage group compared with music (RR 0.41, 95% CI 0.16 to 1.08, one trial, 101 women) (Analysis 2.2).

## 3. Massage versus hypnosis

No studies found.

## 4. Massage versus biofeedback

No studies found.

## 5. Massage versus intracutaneous or sterile water injection

No studies found.

## 6. Massage versus immersion in water

No studies found.

## 7. Massage versus aromatherapy

No studies found.

## 8. Massage versus relaxation techniques

No studies found.

## 9. Massage versus acupuncture or acupressure

No studies found.

### Sensitivity analysis

We proposed to undertake a sensitivity analysis on the results to look at the possible contribution of (1) differences in methodological quality, with trials of high quality (low risk of bias) compared to all trials; and (2) publication bias by country. This was not done as there were no trials of high quality; there were also few trials within comparisons to examine the influence of publication bias. Where there was heterogeneity, we applied a random-effects model.

### Subgroup analysis

We did not undertake subgroup analysis, based on insufficient reporting of trials with the variables of interest by outcome.

## DISCUSSION

### Summary of main results

Evidence from five trials and 326 women included in the meta-analysis suggest limited benefit from massage in relation to the primary outcome of pain intensity, and emotional experience during labour. There was a reduction in the intensity of labour pain during the first stage of labour in the massage group compared with usual care in four trials (SMD -0.82, 95% CI -1.17 to 0.47), and in one trial of massage compared with music (RR 0.40, 95% CI 0.18 to 0.89, one trial, 101 women). One trial found less anxiety during the first stage of labour for women receiving massage compared to usual care (MD -16.27, 95% CI -27.03 to -5.51). Currently there are a small number of trials included within each comparison, and this limits the power of the review to detect meaningful differences between groups and analyses, suggesting these limited benefits should be interpreted with caution.

### Overall completeness and applicability of evidence

There are few trials of any manual methods that assess the role of these therapies of pain management in labour. The completeness and applicability of the evidence is limited from these six trials, and there are no well designed trials at a low risk of bias. The inclusion of relevant outcomes was limited in the majority of trials with a lack of outcome relating to both safety and effectiveness. Trials recruited nulliparous and multiparous women at term with the interventions administered in the labour ward environment. Studies were conducted in different countries, and this may reflect the use of particular modalities or techniques as part of their culture. The systematic review illustrates variation in how these modalities were practiced, although it is unclear how generalisable the treatment protocols used in the research are to clinical practice or practice within the community.

### Quality of the evidence

The risk of bias table (Figure 1, Figure 2) demonstrates massage has not been subject to consistent rigorous evaluation. The quality of reporting was poor in all trials, consequently it is difficult to assess the overall risk of bias across studies and domains. For all studies blinding of participants and the practitioner was not possible, and reporting indicated that some outcomes may have been influenced by a lack of blinding by the outcome assessor in two trials. The small number of studies within comparisons and lack of high quality trials indicates there is currently insufficient evidence of a consistent treatment effect from massage trials included in the review. The chief investigators of some studies were contacted to provide additional methodological and statistical information: however; only a few responses were obtained (Abasi 2009; Field 1997; Karami 2007).

The quality of evidence was affected by unexplained heterogeneity in some comparisons arising from the heterogeneity of massage and study designs. The small numbers of studies within comparisons, and the lack of high quality trials prevented further investigation of the heterogeneity and the impact on treatments effects.

### Potential biases in the review process

We attempted to minimise bias during the review process. Two authors assessed the eligibility of studies, carried out data extraction and assessed the risk of bias. We are aware that some literature on relaxation therapies may not be published in mainstream journals and therefore maybe excluded from the main databases. Our search was comprehensive, but we cannot rule out the possibility that some studies may have been missed.

### Agreements and disagreements with other studies or reviews

Due to the lack of research examining the effect of massage on pain management in labour, we are limited to making comparisons with other trials and reviews.

## AUTHORS' CONCLUSIONS

### Implications for practice

The limited data available suggest massage may be a helpful modality for pain management in labour; however, there is insufficient

evidence to make clinical recommendations. Overall there are insufficient data to demonstrate whether massage provides an additive benefit when used in combination with usual care, or whether they are more effective than usual care. Due to the unknown risk of bias in the majority of trials, and the limited number of trials, recommendations for clinical practice cannot be made until further high quality research has been undertaken.

### Implications for research

Additional randomised controlled trials of massage for pain management in labour are needed. Trials should be adequately powered and include clinically relevant outcomes such as those described in this review. A methodological issue for trials of massage is the choice of an appropriate control group. Trials of massage maybe difficult to blind in relation to participants and midwives and pragmatic designs should be considered enabling meaningful comparisons to be made. There is a need to improve the quality and reporting in future trials. In particular, consideration should be given in the analysis and reporting on the person providing the intervention; for example, their training, length of experience and relationship to the woman. In addition, further research is required that include data measuring neonatal outcomes and other maternal and clinical outcomes.

## ACKNOWLEDGEMENTS

The assistance of the staff in the editorial office of the Cochrane Pregnancy and Childbirth Group for their help with preparing this review.

As part of the pre-publication editorial process, this review has been commented on by two peers (an editor and referee who is external to the editorial team), a member of the Pregnancy and Childbirth Group's international panel of consumers and the Group's Statistical Adviser.

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* *Indicates the major publication for the study*

## CHARACTERISTICS OF STUDIES

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

**Abasi 2009**

| | |
|---|---|
| Methods | Single blind RCT. |
| Participants | 62 primiparous women with a gestational age of 37-42 weeks, with a singleton pregnancy, vertex presentation, spontaneous onset of labour, cervical dilatation 2-3 cm and planning a vaginal delivery were recruited to the trial<br>Exclusion criteria: fever, infection, disc injury, skin condition, broken bones<br>The study was undertaken at the Bentolhoda maternity hospital, Bojnord, Iran, during 2005 |
| Interventions | Back massage was continuous, firm and steady for 30 minutes during each phase of labour. Massage applied from sacral spine upward to the lumbar spine, then back down to the sacrum. A masseuse applied the intervention. No other details reported<br>Control: standard care, no other details provided. |
| Outcomes | Pain intensity measured using the visual analogue scale. |
| Notes | |

***Risk of bias***

| **Bias** | **Authors' judgement** | **Support for judgement** |
|---|---|---|
| Random sequence generation (selection bias) | High risk | Date of admission. |
| Allocation concealment (selection bias) | Unclear risk | No details reported. |
| Incomplete outcome data (attrition bias)<br>All outcomes | Unclear risk | Unclear from paper. |
| Selective reporting (reporting bias) | Unclear risk | Protocol unavailable but appears free of selective reporting |
| Other bias | Unclear risk | No other biases apparent. |
| Blinding of participants and personnel (performance bias)<br>All outcomes | High risk | No participants or other study personnel were blind to group allocation |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Low risk | The assessor was blind. |

**Chang 2002**

| | |
|---|---|
| Methods | RCT - sequentially recruited and randomly allocated to two groups, massage and standard care |
| Participants | 60 women recruited from a regional hospital in southern Taiwan between September 1999 and January 2000<br>Inclusion criteria: primiparous; 37-42 weeks' pregnant; normal pregnancy and childbirth to date; partner present during labour; dilation no more than 4 cm<br><br>Exclusion criteria**:** not described. |
| Interventions | Massage: couples given detailed description of the massage protocol. Then the primary researcher gave massage during uterine contractions in each phase and taught the method to the partner. Received directional, reasonably firm and rhythmic massage for 30 minutes and comprising abdominal effleurage, sacral pressure and shoulder and back kneading. Subject chose most useful site at time. The same 30-minute massage repeated in phase 2 and 3. After the 30-minute massage at each stage, pain and anxiety states were evaluated to assess the immediate effects of the massage. The partners repeated the massage at each phase of labour after the 30-minute massage by the researcher was complete<br>Control: standard care and 30 minutes of the researcher's attendance and casual conversation during each phase |
| Outcomes | Pain intensity and anxiety measures in all three phases of labour; need for pain relief |
| Notes | |

***Risk of bias***

| **Bias** | **Authors' judgement** | **Support for judgement** |
|---|---|---|
| Random sequence generation (selection bias) | Low risk | 4 balls were used for sequence generation. 2 with E (experimental) and 2 with C (control) printed on them |
| Allocation concealment (selection bias) | Unclear risk | Reported as concealed but method not reported. |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | Clearly described. |
| Selective reporting (reporting bias) | Unclear risk | Protocol unavailable but appears free of selective reporting |
| Other bias | Unclear risk | No other biases apparent. |
| Blinding of participants and personnel (performance bias) All outcomes | High risk | Blinding not possible. |

**Chang 2002** (*Continued*)

| | | |
|---|---|---|
| Blinding of outcome assessment (detection bias)<br>All outcomes | Unclear risk | Not reported. |

**Field 1997**

| | |
|---|---|
| Methods | RCT of massage plus breathing exercises versus breathing alone |
| Participants | 28 subjects recruited from Lamaze classes during the last trimester of pregnancy. The study was undertaken in Florida, USA. No inclusion or exclusion criteria reported |
| Interventions | Massage therapy plus breathing exercises learned in prenatal classes. Massage taught to birth partner for a mean of 10 minutes by massage therapist. At approximately 3-5 cm dilation, subjects received 20 minutes of head, shoulder/back, hand and foot massage, respectively. Moderate pressure and smooth movements specifically to relax stressed areas of labouring body. Clockwise circular stroking movements 5 minutes consecutive periods in each of the 4 regions while woman lying on side. Repeated every hour for 5 hours<br>The attention control consisted of breathing exercises learned in prenatal classes |
| Outcomes | Mood sates depression scale, pain, stress level, labour and neonatal measures |
| Notes | |

***Risk of bias***

| **Bias** | **Authors' judgement** | **Support for judgement** |
|---|---|---|
| Random sequence generation (selection bias) | Low risk | Table of numbers. |
| Allocation concealment (selection bias) | Unclear risk | Not reported. |
| Incomplete outcome data (attrition bias)<br>All outcomes | Low risk | No losses were reported. |
| Selective reporting (reporting bias) | Unclear risk | Study protocol unavailable but comprehensive range of outcomes reported |
| Other bias | Low risk | Appears to be free of other bias. |
| Blinding of participants and personnel (performance bias)<br>All outcomes | High risk | Unable to blind. |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Low risk | Research assistant examined hospital records blind to group allocation |

**Karami 2007**

| | |
|---|---|
| Methods | Parallel RCT of massage compared with usual care. |
| Participants | 60 pregnant women recruited from Hedayat and Mahdiyeh Hospitals, Tehran, Iran during 2004. Primiparous women aged 20-35 years, with single alive fetus and gestational age of 38 to 42 weeks, with cervical dilation at 4 cm |
| Interventions | Massage group: massage therapy using effleurage technique during delivery. The massage is administered on sacrum, buttocks, shoulders, waist, foot and hand during different phases of labor<br>Control group: routine standard care. |
| Outcomes | Pain intensity using the VAS, some clinical outcomes. |
| Notes | |

***Risk of bias***

| Bias | Authors' judgement | Support for judgement |
|---|---|---|
| Random sequence generation (selection bias) | Unclear risk | No details obtained. |
| Allocation concealment (selection bias) | Low risk | Sealed envelopes. |
| Incomplete outcome data (attrition bias)<br>All outcomes | Low risk | None. |
| Selective reporting (reporting bias) | Unclear risk | No protocol available but report appears complete. |
| Other bias | Low risk | No differences in baseline characteristics. |
| Blinding of participants and personnel (performance bias)<br>All outcomes | High risk | No blinding. |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Low risk | Staff were blind to group allocation. |

**Kimber 2008**

| | |
|---|---|
| Methods | RCT of massage plus relaxation, music plus relaxation and usual care |
| Participants | 90 women booked from Horton Maternity Unit, Banbury, UK. Inclusion criteria: women booked for care and birth at the unit during the study period<br>Exclusion criteria: planned elective caesarean section, multiple pregnancy, existing medical problems that precluded the use of massage, previous use of the massage programme or a strong preference for a particular form of pain relief. Women who did not speak |

| | |
|---|---|
| | fluent English and those not intending to have a birth companion were also excluded |
| Interventions | Massage programme with relaxation techniques. Attended a 2.5-hour class between 35 and 37 weeks' gestation with chosen birth companion. Massage techniques were taught by the midwife/therapist. Birth partner learnt to perform slow rhythmic long stroke massage movements using the flats of the hands. These strokes were combined with slow rhythmic breathing and performed primarily on the lower back and also the upper and lower limbs. The massaging hands move upwards during inspiration and downwards during expiration. The woman and her birth partner were taught to synchronise massage strokes with controlled breathing. The visualisation/mind mapping component was taught by asking the woman to visualise/focus on the massaging hands. Participants were asked to practise the programme at least 3 evenings a week, for about 30-45 minutes, until 39 weeks and then a combination of techniques every evening, until hospital admission for labour/induction. Able to attend the usual antenatal classes<br>Active control: music with relaxation techniques. The placebo class taught breathing and visualisation techniques, and music instead of massage. The woman and her birth partner were encouraged to practise a slow breathing rhythm and visualisation techniques. The woman and her birth partner chose their favourite music. Able to attend the usual antenatal classes<br><br>Control**:** given the option and encouraged to attend the usual antenatal preparation classes currently available at the trial site |
| Outcomes | Self-reported labour pain; 2 separate VAS scales were used to record labour and birth pain(s), around 90 minutes following birth, before transfer from labour care<br><br>Secondary: use of pharmacological analgesia, obstetric interventions, birth outcomes and women's birth-related worries based on the Cambridge Birth Worry Scale, maternal satisfaction and sense of control (Labour Agentry Scale) |
| Notes | Recruitment between December 2004 and January 2006. Power analysis reported to detect a reduction in VAS scores from 8.5 to 7.5 (standard deviation 2), with 80% power and 5% significance |

***Risk of bias***

| **Bias** | **Authors' judgement** | **Support for judgement** |
|---|---|---|
| Random sequence generation (selection bias) | Low risk | Computer-based randomisation program using minimisation for parity |
| Allocation concealment (selection bias) | Unclear risk | Not reported. |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | Missing data were balanced between groups: Clinical details labour: 30/28/28, VAS 1: 29/28/28, VAS 2: 25/26/25<br><br>2 withdrew in placebo group, 1 after randomisation and 1 in labour |

**Kimber 2008** (*Continued*)

| | | |
|---|---|---|
| Selective reporting (reporting bias) | Low risk | Protocol not available, but all outcomes of interest to this type of study have been reported, so unlikely to have selective reporting bias |
| Other bias | Unclear risk | Unclear. |
| Blinding of participants and personnel (performance bias)<br>All outcomes | High risk | Not possible to blind participants or clinicians. |
| Blinding of outcome assessment (detection bias)<br>All outcomes | High risk | Would have been possible to blind outcome assessors. |

**Taghinejad 2010**

| | |
|---|---|
| Methods | Parallel design randomised controlled trial of massage versus active control of music |
| Participants | 101 women recruited from Mustafa Hospital in the Ilam Province of Western Iran<br><br>Inclusion criteria: primiparous, singletons, 20-30 years old, dilation < 4 cm, 37-42 weeks' gestation, cephalic presentation, normal birthweight<br><br>Exclusion criteria: women receiving analgesic or antipsychotic medications or were labour-induced, SROM greater than 20 hours, mothers with hearing and visual difficulties, infectious diseases, inflammation and dermal sensitivities in the massage fields |
| Interventions | Massage: at up to 3-4 cm dilation, women in the massage therapy group were requested to close their eyes and take rhythmic breaths deeply. During contractions, they were asked to take breaths more deeply and calmly by concentrating on the massage. Massage points were the lower area of the abdomen, shoulders, back and pressed pubic area. All received 30 minutes of massage<br>Active control music: women were requested to listen to soft traditional music (1 of 5 optional types) without lyrics using head-phones for 30 minutes, starting early in the active phase of labour |
| Outcomes | Pain intensity using VAS before and after intervention, duration of latent phase or labour, expression of need for some other pain relief |
| Notes | 101 pregnant women. |

***Risk of bias***

| **Bias** | **Authors' judgement** | **Support for judgement** |
|---|---|---|

**Taghinejad 2010** (*Continued*)

| | | |
|---|---|---|
| Random sequence generation (selection bias) | Low risk | Computerised minimisation program to assign participants to massage or music groups |
| Allocation concealment (selection bias) | Unclear risk | Not described. |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | None. |
| Selective reporting (reporting bias) | Unclear risk | There are no suggestions of selected reporting bias, protocol unavailable. |
| Other bias | Low risk | None. |
| Blinding of participants and personnel (performance bias) All outcomes | Unclear risk | Participants not blind, caregivers unclear. |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | VAS was administered by research colleagues who were not aware of the assignment of participants |

RCT: randomised controlled trial
SROM: spontaneous rupture of membranes
VAS: visual analogue scale

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

| Study | Reason for exclusion |
|---|---|
| Yildirim 2004 | This study is included in the relaxation for pain management systematic review, the intervention is of relaxation |

## Characteristics of studies awaiting assessment *[ordered by study ID]*

**Dolatian 2010**

| | |
|---|---|
| Methods | 3-arm RCT. |
| Participants | 120 women aged 18-35 years in labour. |
| Interventions | 40 minutes of reflexology at the beginning of the active phase of labour, group 2, emotional support, group 3 routine care only during labour |

**Dolatian 2010** (*Continued*)

| | |
|---|---|
| Outcomes | Intensity of pain. |
| Notes | |

**Faezah 2010**

| | |
|---|---|
| Methods | 2-arm parallel RCT. |
| Participants | 120 primiparous women at term. |
| Interventions | 30 minutes of massage involving firm and rhythmic strokes during the 3 phases of labour compared to control |
| Outcomes | Anxiety, satisfaction. |
| Notes | |

**Zhang 2000**

| | |
|---|---|
| Methods | No details available, awaiting translation. |
| Participants | |
| Interventions | |
| Outcomes | |
| Notes | |

RCT: randomised controlled trial

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

**Janssen 2008**

| | |
|---|---|
| Trial name or title | To measure the benefits of massage, administered by a registered massage therapist, to pain management for women in active labour |
| Methods | Setting: the study will take place at BC Women's Hospital in Vancouver, British Columbia, Canada. BC Women's is an academic teaching hospital. It provides primary care to women who are residents of the City of Vancouver, regional referral care to residents of the lower mainland or southwest corner of the province, and tertiary referral care for the entire province. Approximately 7500 take place at this hospital annually; about 7000 are to women who reside in Vancouver. All women for whom delivery is not imminent are triaged in a large assessment room adjacent to the delivery suite prior to being admitted for intrapartum care. Women in labour have 1-to-1 care in a private labour room. They may have whomever else they want in the room to support them |

**Janssen 2008** (*Continued*)

| | |
|---|---|
| Participants | Inclusion criteria<br>• Healthy primiparous women.<br>• Nulliparous.<br>• Singleton gestation.<br>• Cephalic presentation.<br>• Term gestation (37-41 completed weeks of pregnancy).<br>• Maternal age between 18 and 35 years of age.<br>• In spontaneous labour, defined for our purposes as painful contractions which have resulted in cervical change, i.e. cervix is 1 cm dilated or more with effacement at 25% (0.5 cm) or more on admission to the labour unit.<br>• Able to speak and read English or speak a language for which there is a nursing interpreter available.<br>Exclusion criteria<br>• Pre-existing medical conditions including but not limited to: insulin dependent diabetes, renal, cardiac, or thyroid conditions, hypertension, epilepsy, psychosis, use of illicit street drugs.<br>• Conditions arising during pregnancy which require non-routine surveillance and/or intervention including but not limited to gestational diabetes, gestational hypertension, 2nd or 3rd trimester haemorrhage, intrauterine growth restriction, presence of a fetal congenital anomaly, history of preterm pre-labour rupture of membranes.<br>• Statement by women on admission that she has been in labour for more than 24 hours.<br>• Cervical dilatation 10 cm (full dilatation) on admission to the labour ward. |
| Interventions | Massage therapy by a regulated massage therapist versus usual care |
| Outcomes | Primary outcome is timing of epidural analgesia with respect to cervical dilatation. Secondary outcomes include use of epidural and narcotic analgesia, and measures of intensity and characteristics of pain |
| Starting date | January 2008. |
| Contact information | BC Women's Hospital, Vancouver, British Columbia, Canada, V6H 3N1 |
| Notes | Recruitment complete. |

## DATA AND ANALYSES

### Comparison 1. Massage versus usual care

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Pain intensity | 4 | | Std. Mean Difference (IV, Random, 95% CI) | Subtotals only |
| 1.1 First stage of labour | 4 | 225 | Std. Mean Difference (IV, Random, 95% CI) | -0.82 [-1.17, -0.47] |
| 1.2 Second stage of labour | 2 | 124 | Std. Mean Difference (IV, Random, 95% CI) | -0.98 [-2.23, 0.26] |
| 1.3 Third stage of labour | 2 | 122 | Std. Mean Difference (IV, Random, 95% CI) | -1.03 [-2.17, 0.11] |
| 2 Satisfaction with pain relief | 2 | | Mean Difference (IV, Random, 95% CI) | Totals not selected |
| 3 Sense of control in labour | 1 | 40 | Mean Difference (IV, Fixed, 95% CI) | -6.10 [-13.11, 0.91] |
| 4 Assisted vaginal birth | 2 | 105 | Risk Ratio (M-H, Fixed, 95% CI) | 0.46 [0.14, 1.50] |
| 5 Caesarean delivery | 2 | 105 | Risk Ratio (M-H, Fixed, 95% CI) | 0.73 [0.24, 2.22] |
| 6 Admission to neonatal intensive care unit | 1 | 44 | Risk Ratio (M-H, Fixed, 95% CI) | 1.93 [0.13, 28.79] |
| 7 Use of pharmacological pain relief | 2 | 105 | Risk Ratio (M-H, Random, 95% CI) | 1.19 [0.28, 5.08] |
| 8 Augmentation | 2 | 105 | Risk Ratio (M-H, Random, 95% CI) | 1.09 [0.40, 2.97] |
| 9 Length of labour | 2 | 97 | Std. Mean Difference (IV, Random, 95% CI) | 0.34 [-0.07, 0.75] |
| 10 Emotional experience (reduced anxiety) in labour | 1 | | Mean Difference (IV, Fixed, 95% CI) | Subtotals only |
| 10.1 Anxiety first stage | 1 | 60 | Mean Difference (IV, Fixed, 95% CI) | -16.27 [-27.03, -5.51] |
| 10.2 Anxiety second stage | 1 | 60 | Mean Difference (IV, Fixed, 95% CI) | -8.97 [-20.79, 2.85] |
| 10.3 Anxiety third stage | 1 | 60 | Mean Difference (IV, Fixed, 95% CI) | -4.57 [-14.04, 4.90] |

### Comparison 2. Massage versus music

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Severe pain intensity | 1 | 101 | Risk Ratio (M-H, Fixed, 95% CI) | 0.40 [0.18, 0.89] |
| 2 Use of pharmacological pain relief | 1 | 101 | Risk Ratio (M-H, Fixed, 95% CI) | 0.41 [0.16, 1.08] |

## Analysis 1.1. Comparison 1 Massage versus usual care, Outcome 1 Pain intensity.

Review: Massage, reflexology and other manual methods for pain management in labour

Comparison: 1 Massage versus usual care

Outcome: 1 Pain intensity

| Study or subgroup | Massage N | Mean(SD) | Usual care N | Mean(SD) | Std. Mean Difference IV,Random,95% CI | Weight | Std. Mean Difference IV,Random,95% CI |
|---|---|---|---|---|---|---|---|
| 1 First stage of labour | | | | | | | |
| Abasi 2009 | 32 | 2.83 (1.64) | 30 | 4.94 (1.75) | | 25.7 % | -1.23 [ -1.78, -0.68 ] |
| Chang 2002 | 30 | 43.13 (15.96) | 30 | 57.03 (15.11) | | 26.5 % | -0.88 [ -1.41, -0.35 ] |
| Karami 2007 | 30 | 7.22 (0.83) | 30 | 7.94 (1.02) | | 26.9 % | -0.76 [ -1.29, -0.24 ] |
| Kimber 2008 | 14 | 69.9 (18.7) | 29 | 75.2 (16.6) | | 20.8 % | -0.30 [ -0.94, 0.34 ] |
| **Subtotal (95% CI)** | **106** | | **119** | | | **100.0 %** | **-0.82 [ -1.17, -0.47 ]** |
| Heterogeneity: $Tau^2 = 0.05$; $Chi^2 = 4.77$, df = 3 (P = 0.19); $I^2 = 37\%$ | | | | | | | |
| Test for overall effect: Z = 4.56 (P < 0.00001) | | | | | | | |
| 2 Second stage of labour | | | | | | | |
| Abasi 2009 | 32 | 3.64 (1.04) | 32 | 6.53 (2.26) | | 49.5 % | -1.62 [ -2.19, -1.05 ] |
| Chang 2002 | 30 | 76 (16.8) | 30 | 82.43 (19.05) | | 50.5 % | -0.35 [ -0.86, 0.16 ] |
| **Subtotal (95% CI)** | **62** | | **62** | | | **100.0 %** | **-0.98 [ -2.23, 0.26 ]** |
| Heterogeneity: $Tau^2 = 0.73$; $Chi^2 = 10.59$, df = 1 (P = 0.001); $I^2 = 91\%$ | | | | | | | |
| Test for overall effect: Z = 1.55 (P = 0.12) | | | | | | | |
| 3 Third stage of labour | | | | | | | |
| Abasi 2009 | 32 | 5.1 (2.22) | 30 | 8.4 (1.76) | | 49.3 % | -1.62 [ -2.20, -1.04 ] |
| Chang 2002 | 30 | 91.33 (12.73) | 30 | 96.2 (7.79) | | 50.7 % | -0.46 [ -0.97, 0.06 ] |
| **Subtotal (95% CI)** | **62** | | **60** | | | **100.0 %** | **-1.03 [ -2.17, 0.11 ]** |
| Heterogeneity: $Tau^2 = 0.60$; $Chi^2 = 8.72$, df = 1 (P = 0.003); $I^2 = 89\%$ | | | | | | | |
| Test for overall effect: Z = 1.77 (P = 0.077) | | | | | | | |
| Test for subgroup differences: $Chi^2 = 0.17$, df = 2 (P = 0.92), $I^2 = 0.0\%$ | | | | | | | |

### Analysis 1.2. Comparison 1 Massage versus usual care, Outcome 2 Satisfaction with pain relief.

Review: Massage, reflexology and other manual methods for pain management in labour

Comparison: 1 Massage versus usual care

Outcome: 2 Satisfaction with pain relief

| Study or subgroup | Massage N | Mean(SD) | Usual care N | Mean(SD) | Mean Difference IV,Random,95% CI | Mean Difference IV,Random,95% CI |
|---|---|---|---|---|---|---|
| Chang 2002 | 30 | 4.17 (1.05) | 30 | 3.7 (1.32) | | 0.47 [ -0.13, 1.07 ] |
| Kimber 2008 | 25 | 50.6 (32.3) | 25 | 65 (33.7) | | -14.40 [ -32.70, 3.90 ] |


### Analysis 1.3. Comparison 1 Massage versus usual care, Outcome 3 Sense of control in labour.

Review: Massage, reflexology and other manual methods for pain management in labour

Comparison: 1 Massage versus usual care

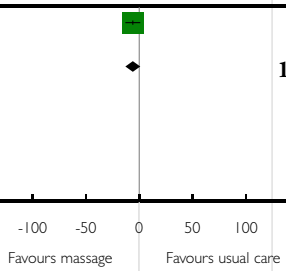
Outcome: 3 Sense of control in labour

| Study or subgroup | Massage N | Mean(SD) | Usual care N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Weight | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|---|
| Kimber 2008 | 14 | 27.5 (11.1) | 26 | 33.6 (10.2) | | 100.0 % | -6.10 [ -13.11, 0.91 ] |
| **Total (95% CI)** | **14** | | **26** | | | **100.0 %** | **-6.10 [ -13.11, 0.91 ]** |

Heterogeneity: not applicable

Test for overall effect: Z = 1.70 (P = 0.088)

Test for subgroup differences: Not applicable



### Analysis 1.4. Comparison 1 Massage versus usual care, Outcome 4 Assisted vaginal birth.

Review: Massage, reflexology and other manual methods for pain management in labour

Comparison: 1 Massage versus usual care

Outcome: 4 Assisted vaginal birth

| Study or subgroup | Massage n/N | Usual care n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Karami 2007 | 1/30 | 4/30 | | 50.0 % | 0.25 [ 0.03, 2.11 ] |
| Kimber 2008 | 2/15 | 6/30 | | 50.0 % | 0.67 [ 0.15, 2.92 ] |
| **Total (95% CI)** | **45** | **60** | | **100.0 %** | **0.46 [ 0.14, 1.50 ]** |

Total events: 3 (Massage), 10 (Usual care)

Heterogeneity: $Chi^2$ = 0.56, df = 1 (P = 0.45); $I^2$ =0.0%

Test for overall effect: Z = 1.29 (P = 0.20)

Test for subgroup differences: Not applicable


### Analysis 1.5. Comparison 1 Massage versus usual care, Outcome 5 Caesarean delivery.

Review: Massage, reflexology and other manual methods for pain management in labour

Comparison: 1 Massage versus usual care

Outcome: 5 Caesarean delivery

| Study or subgroup | Massage n/N | Usual care n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Karami 2007 | 0/30 | 1/30 | | 24.3 % | 0.33 [ 0.01, 7.87 ] |
| Kimber 2008 | 3/15 | 7/30 | | 75.7 % | 0.86 [ 0.26, 2.85 ] |
| **Total (95% CI)** | **45** | **60** | | **100.0 %** | **0.73 [ 0.24, 2.22 ]** |

Total events: 3 (Massage), 8 (Usual care)

Heterogeneity: $Chi^2$ = 0.30, df = 1 (P = 0.58); $I^2$ =0.0%

Test for overall effect: Z = 0.55 (P = 0.58)

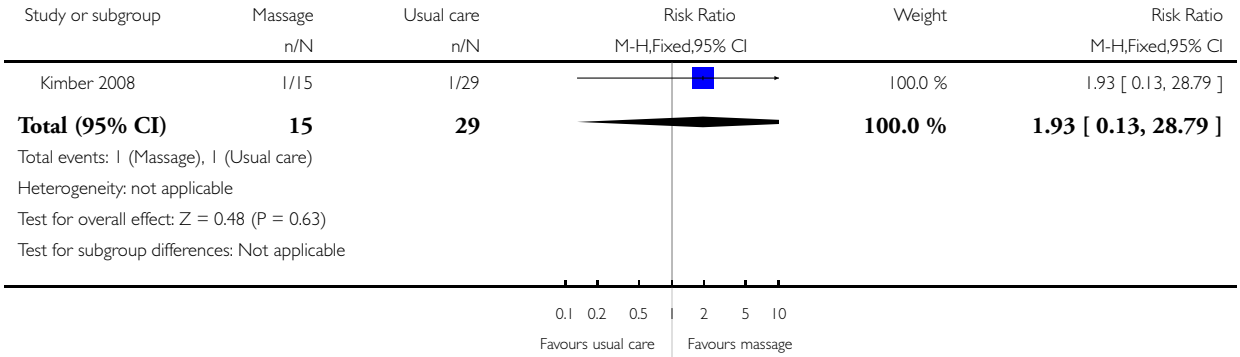
Test for subgroup differences: Not applicable

### Analysis 1.6. Comparison 1 Massage versus usual care, Outcome 6 Admission to neonatal intensive care unit.

Review: Massage, reflexology and other manual methods for pain management in labour

Comparison: 1 Massage versus usual care

Outcome: 6 Admission to neonatal intensive care unit

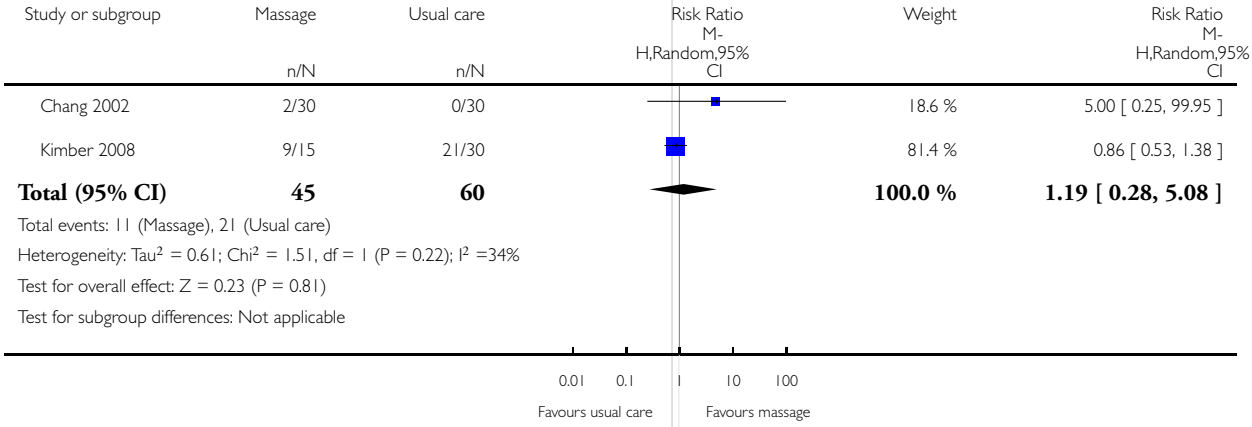



### Analysis 1.7. Comparison 1 Massage versus usual care, Outcome 7 Use of pharmacological pain relief.

Review: Massage, reflexology and other manual methods for pain management in labour

Comparison: 1 Massage versus usual care

Outcome: 7 Use of pharmacological pain relief



### Analysis 1.8. Comparison 1 Massage versus usual care, Outcome 8 Augmentation.

Review: Massage, reflexology and other manual methods for pain management in labour

Comparison: 1 Massage versus usual care

Outcome: 8 Augmentation

| Study or subgroup | Massage n/N | Usual care n/N | Risk Ratio M-H,Random,95% CI | Weight | Risk Ratio M-H,Random,95% CI |
|---|---|---|---|---|---|
| Chang 2002 | 18/30 | 13/30 | | 80.7 % | 1.38 [ 0.84, 2.29 ] |
| Kimber 2008 | 1/15 | 5/30 | | 19.3 % | 0.40 [ 0.05, 3.12 ] |
| **Total (95% CI)** | **45** | **60** | | **100.0 %** | **1.09 [ 0.40, 2.97 ]** |

Total events: 19 (Massage), 18 (Usual care)

Heterogeneity: $Tau^2 = 0.26$; $Chi^2 = 1.44$, df = 1 (P = 0.23); $I^2 = 31\%$

Test for overall effect: Z = 0.17 (P = 0.87)

Test for subgroup differences: Not applicable


### Analysis 1.9. Comparison 1 Massage versus usual care, Outcome 9 Length of labour.

Review: Massage, reflexology and other manual methods for pain management in labour

Comparison: 1 Massage versus usual care

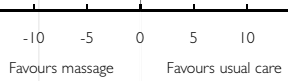
Outcome: 9 Length of labour

| Study or subgroup | Massage N | Mean(SD) | Usual care N | Mean(SD) | Std. Mean Difference IV,Random,95% CI | Weight | Std. Mean Difference IV,Random,95% CI |
|---|---|---|---|---|---|---|---|
| Chang 2002 | 30 | 10.96 (4.81) | 30 | 9.61 (4.24) | | 65.2 % | 0.29 [ -0.22, 0.80 ] |
| Kimber 2008 | 12 | 494.9 (255.3) | 25 | 388.7 (233.7) | | 34.8 % | 0.43 [ -0.26, 1.13 ] |
| **Total (95% CI)** | **42** | | **55** | | | **100.0 %** | **0.34 [ -0.07, 0.75 ]** |

Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 0.10$, df = 1 (P = 0.75); $I^2 = 0.0\%$

Test for overall effect: Z = 1.63 (P = 0.10)

Test for subgroup differences: Not applicable



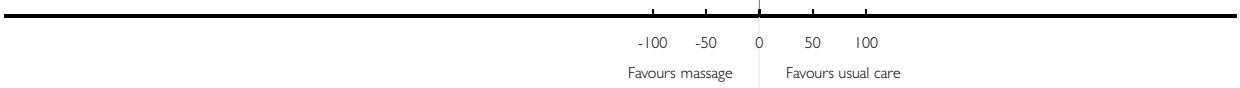
## Analysis 1.10. Comparison 1 Massage versus usual care, Outcome 10 Emotional experience (reduced anxiety) in labour.

Review: Massage, reflexology and other manual methods for pain management in labour

Comparison: 1 Massage versus usual care

Outcome: 10 Emotional experience (reduced anxiety) in labour

| Study or subgroup | Massage N | Mean(SD) | Usual care N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Weight | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|---|
| 1 Anxiety first stage | | | | | | | |
| Chang 2002 | 30 | 37.2 (20.3) | 30 | 53.47 (22.18) | | 100.0 % | -16.27 [ -27.03, -5.51 ] |
| **Subtotal (95% CI)** | **30** | | **30** | | | **100.0 %** | **-16.27 [ -27.03, -5.51 ]** |
| Heterogeneity: not applicable | | | | | | | |
| Test for overall effect: Z = 2.96 (P = 0.0030) | | | | | | | |
| 2 Anxiety second stage | | | | | | | |
| Chang 2002 | 30 | 64.9 (24.07) | 30 | 73.87 (22.64) | | 100.0 % | -8.97 [ -20.79, 2.85 ] |
| **Subtotal (95% CI)** | **30** | | **30** | | | **100.0 %** | **-8.97 [ -20.79, 2.85 ]** |
| Heterogeneity: not applicable | | | | | | | |
| Test for overall effect: Z = 1.49 (P = 0.14) | | | | | | | |
| 3 Anxiety third stage | | | | | | | |
| Chang 2002 | 30 | 80.6 (19.11) | 30 | 85.17 (18.29) | | 100.0 % | -4.57 [ -14.04, 4.90 ] |
| **Subtotal (95% CI)** | **30** | | **30** | | | **100.0 %** | **-4.57 [ -14.04, 4.90 ]** |
| Heterogeneity: not applicable | | | | | | | |
| Test for overall effect: Z = 0.95 (P = 0.34) | | | | | | | |
| Test for subgroup differences: $Chi^2$ = 2.57, df = 2 (P = 0.28), $I^2$ =22% | | | | | | | |



### Analysis 2.1. Comparison 2 Massage versus music, Outcome 1 Severe pain intensity.

Review: Massage, reflexology and other manual methods for pain management in labour

Comparison: 2 Massage versus music

Outcome: 1 Severe pain intensity

| Study or subgroup | Massage n/N | Music n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Taghinejad 2010 | 7/51 | 17/50 | | 100.0 % | 0.40 [ 0.18, 0.89 ] |
| **Total (95% CI)** | **51** | **50** | | **100.0 %** | **0.40 [ 0.18, 0.89 ]** |

Total events: 7 (Massage), 17 (Music)
Heterogeneity: not applicable
Test for overall effect: Z = 2.25 (P = 0.024)
Test for subgroup differences: Not applicable


### Analysis 2.2. Comparison 2 Massage versus music, Outcome 2 Use of pharmacological pain relief.

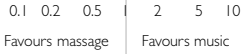
Review: Massage, reflexology and other manual methods for pain management in labour

Comparison: 2 Massage versus music

Outcome: 2 Use of pharmacological pain relief

| Study or subgroup | Massage n/N | Music n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Taghinejad 2010 | 5/51 | 12/50 | | 100.0 % | 0.41 [ 0.16, 1.08 ] |
| **Total (95% CI)** | **51** | **50** | | **100.0 %** | **0.41 [ 0.16, 1.08 ]** |

Total events: 5 (Massage), 12 (Music)
Heterogeneity: not applicable
Test for overall effect: Z = 1.81 (P = 0.070)
Test for subgroup differences: Not applicable



# APPENDICES

## Appendix 1. CENTRAL search strategy

The authors wrote and ran the following search:
#1 (labor or labour):ti,ab,kw
#2 (labor or labour):ti,ab,kw or (childbirth or child-birth or child birth):ti,ab,kw and (obstetric*):ti,ab,kw and (midwife*):ti,ab,kw and (pain manage*):ti,ab,kw in Clinical Trials
#3 contraction* in Clinical Trials
#4 labo*r pain in Clinical Trials
#5 (pain management or pain* manage*) in Clinical Trials
#6 (#1 OR #2 OR #3 OR #4 OR #5)
#7 reflexology in Clinical Trials
#8 massage in Clinical Trials
#9 chiropract* in Clinical Trials
#10 osteopath* in Clinical Trials
#11 (cranio-sacral or craniosacral or cranio sacral therapy) in Clinical Trials
#12 musculoskeletal manipulations in Clinical Trials
#13 deep tissue body work in Clinical Trials
#14 myofacial release in Clinical Trials
#15 neuromuscular therapy in Clinical Trials
#16 shiatsu or tui na in Clinical Trials
#17 therapeutic touch in Clinical Trials
#18 trigger point in Clinical Trials
#19 myotherapy in Clinical Trials
#20 zero balancing in Clinical Trials
#21 (#7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20)
#22 (#6 AND #21)
#23 placebo controlled in Clinical Trials
#24 randomised controlled trials in Clinical Trials
#25 randomly in Clinical Trials
#26 random assignment in Clinical Trials
#27 (#23 OR #24 OR #25 OR #26)
#28 (#22 AND #27)

## Appendix 2. MEDLINE search strategy

Authors wrote and ran the following search:
1 Labor, Obstetric/ or Labo*r.mp.
2 (childbirth or child birth or child-birth).
3 (labour or labor).ab.
4 pain$.mp.
5 pain manag$.mp. or exp pain/
6 1 or 2 or 3 or 4 or 5
7 exp reflexology/
8 exp massage/
9 chiropract$.mp. or osteopath$ manipulation/ [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]
10 (cranio-sacral or craniosacral or cranio sacral therapy).mp. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]
11 exp Musculoskeletal Manipulations/ or deep tissue bodywork.mp.
12 myofascial release.tw.
13 neuromuscular therapy.tw.

14 (shiatsu or tui na).tw.
15 therapeutic touch.tw.
16 trigger point.tw.
17 myotherapy.tw.
18 zero balancing.tw.
19 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18
20 6 and 19
21 randomi*ed controlled trial.pt.
22 controlled clinical trial.pt.
23 (randomised or randomized).ab.
24 placebo.ab.
25 drug therapy.fs.
26 randomly.ab.
27 trial.ab.
28 groups.ab.
29 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28
30 (animals not (humans and animals)).sh.
31 29 not 30
32 20 and 31

## Appendix 3. CINAHL search strategy

Authors wrote and ran the following search:
S37. S35 and S36
S36. (S19 and S26)
S35. (S27 or S28 or S29 or S30 or S31 or S32 or S33 or S34)
S.34. AB quantitative
S33. AB quantitative studies
S32. AB placebo$
S31. AB random allocation
S30. AB random assignment
S29. AB randomi*ed controlled trials
S28. AB randomi?ed control$ trial$
S27. AB clinical trial*
S26. (S20 or S21 or S22 or S23 or S24 or S25)
S25. AB midwife$
S24. AB (pain or labo*r pain)
S23. AB pain manage$
S22. AB obstetric
S21. AB (childbirth or child birth or child-birth)
S20. AB (labour or labor)
S19. S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18
S18. MW zero balancing
S17. MW trigger point
S16. MW therapeutic touch
S15. MW shiatsu
S14. MW reflexology
S13. MW osteopath
S12. MW osteopathic$
S11. MW neuromuscular massage
S10. MW neuromuscular facilitation
S9. MW myotherapy

S8. MW myofacial release
S7. MW (musculo-skeletal or musculoskeletal or musculo skeletal)
S6. MW manual therapy$
S5. MW massage
S4. MW Deep tissue massage
S3. MW (craniosacral or cranio sacral or cranio-sacral therapy)
S2. MW Chiropractic$
S1. MW (Bio energy or bioenergy or bio-energy therapy)

## Appendix 4. Search terms used Clinical Trials Registries

Authors searched

1. Australian and New Zealand Trials Registry (30 June 2011)
2. Chinese Clinical Trial Register (30 June 2011)
3. Current Controlled Trials (30 June 2011)
4. ClinicalTrials.gov (30 June 2011)
5. ISRCTN Register (30 June 2011)
6. National Center for Complementary and Alternative Medicine (NCCAM) (30 June 2011)
7. WHO International Clinical Trials Registry Platform (ICTRP) (30 June 2011).

We used the terms: obstetrics, labor, birth, pain and reflexology, massage, chiropractic/osteopathic manipulation, craniosacral therapy, deep tissue bodywork, healing touch, myofascial release, neuromuscular therapy, shiatsu, trigger point, myotherapy and zero balancing.

## Appendix 5. Methods used to assess trials included in previous versions of this review

We evaluated trials for their appropriateness for inclusion. Where there was uncertainty about inclusion of the study, the full text was retrieved. The original author was contacted for further information where possible. If there was disagreement between review authors about the studies to be included that could not be resolved by discussion, assistance from the third review author was sought. Reasons for excluding trials have been stated. Excluded studies are detailed in the 'Characteristics of excluded studies' table.

Following an assessment for inclusion, we assessed the methodology of the trial. The data were extracted onto hard copy data sheets. Caroline Smith, Carmel Collins and Allan Cyna extracted the data and assessed the quality. Two review authors assessed and extracted data for each trial.

Included trials were assessed according to the following five main criteria:

(1) adequate concealment of treatment allocation (for example, opaque, sealed, numbered envelopes);
(2) method of allocation to treatment (for example, by computer randomisation, random-number tables);
(3) adequate documentation of how exclusions were handled after treatment allocation - to facilitate intention-to-treat analysis; and
(4) adequate blinding of outcome assessment.

Letters were used to indicate the quality of the included trials (Higgins 2005), for example:

(1) A was used to indicate a trial that had a high level of quality in which all the criteria were met;
(2) B was used to indicate that one or more criteria were partially met or it was unclear if all the criteria were met; and
(3) C was used if one or more criteria were not met.

We entered data directly from the published reports into the Review Manager software (RevMan 2003) with double data entry performed by a co-author (Carmel Collins). Where data were not presented in a suitable format for data entry, or if data were missing, we sought additional information from the trialists by personal communication in the form of a letter or email.

Due to the nature of the interventions, double blinding of assessments may not be possible. Therefore, studies without double blinding of assessments were considered for inclusion. Data extracted from the trials were analysed on an intention-to-treat basis (when this was not done in the original report, re-analysis was performed if possible). Where data were missing, we sought clarification from the original authors. Statistical analysis was performed using the Review Manager (RevMan 2003) software. For dichotomous data, we calculated relative risks and 95% confidence intervals (CIs). We calculated weighted mean difference and 95% CIs for continuous data. In the protocol we stated that losses to follow up greater than 25% would be excluded from the analysis. Postpublication, we have changed this to include a sensitivity analysis. This was undertaken on trials excluding those with a loss to follow up of 25% or greater. We tested for heterogeneity between trials using the $I^2$ statistic. Where significant heterogeneity was present (greater than 50%), we used a random-effects model. No trials reported outcomes by parity and therefore no subgroup analyses by parity were undertaken.

## Appendix 6. Data extraction form

| Review ID: | Study ID: | Reference ID: |
|---|---|---|
| Person extracting data: | Date of date extraction: | Year of study publication: |
| Title: | | |
| Author: | | |
| Reference: | | |

Study design

| Type of study design (cluster RCT; block randomisation; stratified randomisation; multi-arm; factorial etc):<br>Unit of randomisation: |
|---|

### Participants and setting

| Describe setting<br>Inclusion criteria:<br>Exclusion criteria: |
|---|

### Intervention

| Experimental intervention: |
|---|

Comparison

| Control/comparison intervention: |
|---|

### Study methods

**Risk of bias**

| | |
|---|---|
| **Adequate sequence generation**<br>Was the allocation sequence adequately generated? | Yes /<br>Unclear / No<br>Describe: |
| **Allocation concealment**<br>Was allocation concealment adequate? | Yes /<br>Unclear / No<br>Describe: |
| **Blinding**<br>Was knowledge of the allocated intervention adequately prevented during the study? | Participant: Yes /<br>Unclear / No<br>Clinician: Yes /<br>Unclear / No<br>Outcome assessor : Yes /<br>Unclear / No<br><br>Describe: |
| **Incomplete outcome data addressed**<br>Were complete outcome data adequately addressed? | Yes /<br>Unclear / No<br><br>Describe any loss of participants to follow-up at each data collection point:<br><br>Describe any exclusion of participants after randomisation:<br><br>Was the analysis intention to treat? If not has the data been able to be re-included? |
| **Free of selective reporting bias**<br>Are reports of study free of suggestions of selective reporting bias? | Yes /<br>Unclear / No<br>Describe: |
| **Free of other bias**<br>Was the study apparently free of other problems that could put it at high risk of bias? | Yes /<br>Unclear / No<br>If the study was stopped early, explain the reasons:<br><br>Describe any baseline in balance:<br><br>Describe any differential diagnosis: |

**Outcomes for main analysis**

| | Outcome measures (dichotomous) | Total number of participants in study = | | | |
|---|---|---|---|---|---|
| | | **Intervention group** total no. in study = | | Control group Total no. in study = | |
| | | events | Total | events | total |
| | Primary: | | | | |
| 1 | **Reduced need for pain relief** | | | | |
| 2 | | | | | |
| | Secondary: | | | | |
| 3 | Mode of birth<br>Vaginal<br>C/S | | | | |
| 4 | Instrumental vaginal birth | | | | |
| 5 | Augmentation with oxytocin | | | | |
| 6 | Perineal trauma | | | | |
| 7 | Breastfeeding at discharge | | | | |
| 8 | Assessment of mother baby interaction | | | | |
| 9 | Apgar score <7 | | | | |
| 10 | Admission to NICU | | | | |
| 11 | Need for mechanical ventilation | | | | |
| 12 | Neonatal encephalopathy | | | | |

| | Outcome measures (continuous) | Total number of participants in study = | | | | |
|---|---|---|---|---|---|---|
| | | **Intervention group** Total no. in study = | | | Control group Total no. in study = | |
| | | total | mean | SD | total | mean SD |
| | Primary: | | | | | |
| 1 | **Maternal satisfaction or maternal emotional experience with pain management** | | | | | |
| 2 | | | | | | |
| | Secondary: | | | | | |
| 3 | **Satisfaction with general birth experience** | | | | | |
| 4 | Length of labour<br>First stage<br>**Second stage** | | I | | | I |
| 5 | **Post partum haemorrhage (>600mls)** | | I | | | I |
| | **Maternal perception of pain relief** | | | | | |

**Outcomes for sub-group analyses**

| | Outcome measures (dichotomous) | Total number of participants in study = | | | |
|---|---|---|---|---|---|
| | | **Intervention group** total no. in study = | | Control group Total no. in study = | |
| | | events | Total | events | total |
| | Primary: | | | | |

(*Continued*)

| | | | | | |
|---|---|---|---|---|---|
| 1 | | | | | |
| 2 | | | | | |
| | Secondary: | | | | |
| 3 | | | | | |
| 4 | | | | | |
| 5 | | | | | |

| | **Outcome measures (continuous)** | Total number of participants in study = | | | | | |
|---|---|---|---|---|---|---|---|
| | | **Intervention group** Total no. in study = | | | Control group Total no. in study = | | |
| | | total | mean | SD | total | mean | SD |
| | Primary: | | | | | | |
| 1 | | | | | | | |
| 2 | | | | | | | |
| | Secondary: | | | | | | |
| 3 | | | | | | | |
| 4 | | | I | | | I | |
| 5 | | | I | | | I | |

## General conclusions

**Very brief summary of study authors main findings/conclusions:**

**Exclusion after data extraction**

**Reasons for exclusion: (study design? participants? interventions/ outcomes? attrition? bias?)**

**Dates:**
**Date entered into RevMan and by whom?**

**Date checked and by whom?**

**Date copy sent to editorial base and by whom?**

## HISTORY

Protocol first published: Issue 9, 2011

Review first published: Issue 2, 2012

## CONTRIBUTIONS OF AUTHORS

Leanne Jones wrote the protocol with Caroline Smith and Carmel Collins contributing to the initial conceptualisation of the generic protocol. Kate Levett commented on the protocol. Caroline Smith, Kate Levett and Carmel Collins reviewed trials, performed data extraction. All authors contributed to writing and commenting on the review and its update. Caroline Smith is the guarantor of the review.

## DECLARATIONS OF INTEREST

None known.

## SOURCES OF SUPPORT


### Internal sources

- University of Western Sydney, Women's and Children's Health Research Institute, Child, Youth and Women's Health Services, Australia.

### External sources

- National Institute for Health Research, UK.

Cochrane-NHS Engagement Project No: 10/4000/02

## NOTES

In future updates this review may be split into separate reviews on massage and reflexology.