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[Intervention Review]

Cephalic version by moxibustion for breech presentation

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ABSTRACT

Background

Moxibustion (a type of Chinese medicine which involves burning a herb close to the skin) to the acupuncture point Bladder 67 (BL67) (Chinese name *Zhiyin*), located at the tip of the fifth toe, has been proposed as a way of correcting breech presentation.

Objectives

To examine the effectiveness and safety of moxibustion on changing the presentation of an unborn baby in the breech position, the need for external cephalic version (ECV), mode of birth, and perinatal morbidity and mortality for breech presentation.

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (26 March 2012), MEDLINE (1966 to 1 August 2011), EMBASE (1980 to August 2011), CINAHL (1982 to 1 August 2011), MIDIRS (1982 to 1 August 2011) and AMED (1985 to 1 August 2011) and searched bibliographies of relevant papers.

Selection criteria

The inclusion criteria were published and unpublished randomised controlled trials comparing moxibustion (either alone or in combination with acupuncture or postural techniques) with a control group (no moxibustion), or other methods (e.g. external cephalic version, acupuncture, postural techniques) in women with a singleton breech presentation.

Data collection and analysis

Two review authors independently assessed eligibility and trial quality and extracted data. The outcome measures were baby's presentation at birth, need for external cephalic version, mode of birth, perinatal morbidity and mortality, maternal complications and maternal satisfaction, and adverse events.

Main results

Six new trials have been added to this updated review. One trial has been moved to studies awaiting classification while further data are being requested. This updated review now includes a total of eight trials (involving 1346 women). Meta-analyses were undertaken (where possible) for the main and secondary outcomes. Moxibustion was not found to reduce the number of non-cephalic presentations at birth compared with no treatment (P = 0.45). Moxibustion resulted in decreased use of oxytocin before or during labour for women who had vaginal deliveries compared with no treatment (risk ratio (RR) 0.28, 95% confidence interval (CI) 0.13 to 0.60). Moxibustion was found to result in fewer non-cephalic presentations at birth compared with acupuncture (RR 0.25, 95% CI 0.09 to 0.72). When combined with acupuncture, moxibustion resulted in fewer non-cephalic presentations at birth (RR 0.73, 95% CI 0.57 to 0.94), and fewer births by

caesarean section (RR 0.79, 95% CI 0.64 to 0.98) compared with no treatment. When combined with a postural technique, moxibustion was found to result in fewer non-cephalic presentations at birth compared with the postural technique alone (RR 0.26, 95% CI 0.12 to 0.56).

Authors' conclusions

This review found limited evidence to support the use of moxibustion for correcting breech presentation. There is some evidence to suggest that the use of moxibustion may reduce the need for oxytocin. When combined with acupuncture, moxibustion may result in fewer births by caesarean section; and when combined with postural management techniques may reduce the number of non-cephalic presentations at birth, however, there is a need for well-designed randomised controlled trials to evaluate moxibustion for breech presentation which report on clinically relevant outcomes as well as the safety of the intervention.

PLAIN LANGUAGE SUMMARY

Cephalic version by moxibustion for breech presentation

There is some evidence to suggest that moxibustion may be useful for turning babies from breech presentation (bottom first) to cephalic presentation (head first) for labour when used with either acupuncture or postural techniques of knee to chest or lifting buttocks while lying on the side.

Breech presentation of babies is common in the second trimester of pregnancy but most babies turn themselves before the onset of labour; some do not. A baby coming bottom first can have more difficulty being born, which causes trauma to the mother. A vaginal birth has to be planned or a caesarean section may be suggested. Moxibustion is a type of Chinese medicine that may be helpful in turning a breech baby. It involves burning a herb close to the skin at an acupuncture point on the little toe to produce a warming sensation. This review found eight randomised controlled trials involving 1346 women. Women randomly assigned to moxibustion had daily to twice weekly treatment at between 28 and 37 weeks. In one trial adverse events relating to treatment included an unpleasant odour (with or without throat irritation), nausea and abdominal pain from contractions. The included trials were of moderate methodological quality, sample sizes in some of the studies were small, how the treatment was applied differed and reporting was limited. While the results were combined they should be interpreted with caution due to the differences in the included studies. More evidence is needed concerning the benefits and safety of moxibustion.

BACKGROUND

Description of the condition

Breech presentation is common in the mid trimester of pregnancy, with the incidence of breech decreasing as the pregnancy approaches term. The incidence of breech presentation at term is reported to be 4% (Cruikshank 1986). Breech presentation may arise from placenta praevia, multiple gestation, uterine abnormalities, poor uterine tone, prematurity or unknown causes, and is associated with primigravidae, older mothers, small-for-gestational-age babies and female babies (Roberts 1999).

External cephalic version (ECV), where the position of the baby is manipulated through the mother's abdominal wall to be head down, is a safe and effective method of reducing the number of non-cephalic presentations at birth and the need for caesarean section when performed after 36 weeks' gestation (Hofmeyr 2002a). The benefits from ECV at term have been demonstrated in a Cochrane review reporting a 62% reduction in the chance of non-cephalic birth and a 45% reduction in caesarean section (Hofmeyr 2002a). Complications of ECV are reported to be rare, however, there is insufficient evidence to assess the complications.

The birth of a baby with breech presentation is usually by planned vaginal delivery or planned caesarean section, with trends toward caesarean section compared with planned caesarean section for women with a breech presentation. A large randomised trial reported poor perinatal outcome and neonatal morbidity from a planned vaginal birth after breech presentation (Hannah 2000), however, there was no difference in the risk of death or neurodevelopmental delay for babies who were assessed at two years of age (Whyte 2004).

Description of the intervention

There is increasing interest in exploring complementary medicine during pregnancy and towards labour. Moxibustion (a treatment method of traditional Chinese medicine) involves the burning of a herb (*Artemisia vulgaris*) close to the skin to induce a warming sensation (Turner 1991). Anecdotal evidence suggests that moxibustion to the acupuncture point Bladder 67 (BL67) (Chinese name *Zhiyin*), located at the tip of the fifth toe, may correct breech presentation (Cardini 1991). Women with a breech presentation may seek treatment with moxibustion from 32 to 38 weeks (West 2003). Moxa sticks have been shown to emit primarily long-wavelength infrared radiation (IR-C) indicating that moxa mainly affects the superficial skin, where heat receptors are located (Pach 2009). Due to the limited skin penetration of IR-C moxa sticks, thermal effects on internal organs are more likely to arise from reflex mechanisms (Kim 2009). It has been suggested that this technique stimulates the production of maternal hormones (placental oestrogens and prostaglandin), and encourages the lining of the uterus to contract which in turn stimulates fetal activity (Cooperative 1984), although the mechanism of action has not yet been determined. This technique involves holding moxa sticks (1.5 cm in diameter and 20 cm in length) or burning moxa cones on or over BL67 on both toes. The heat felt should be warm but not uncomfortable. Treatment regimens vary and there is no consensus on the best regimen, but moxibustion may be administered for 15 to 20 minutes, from one to 10 times daily, for up to 10 days (Budd 2000; Ewies 2002). The literature suggests this technique is best conducted preterm (between 28 and 37 weeks). There have been no side-effects reported. It has been suggested that the smoke generated while burning moxa may irritate the respiratory tract, although there is no evidence to support this. The effect of in utero exposure to moxa smoke is unknown (Ewies 2002). There is also a risk of blistering the skin with moxibustion; however, due attention reduces this risk significantly, especially when it is applied by an appropriately trained professional.

How the intervention might work

The effect of moxibustion is proposed to be associated with the chemical and thermal stimulation from the burning of moxa. The procedure is thought to stimulate the production of placental oestrogens and prostaglandin, encouraging fetal activity through contraction of the lining of the uterus (West 2003).

Why it is important to do this review

To reduce the incidence of breech presentation at term, several techniques have been used to correct the presentation prior to term. Current management options include external cephalic version (ECV; external rotation of the baby to cephalic presentation) and postural management (maternal movements involving knee to chest exercises or pelvic elevation). External cephalic version is usually performed at or after 37 weeks and appears to reduce the chance of breech births and caesarean delivery (Hofmeyr 2002a).

Postural techniques are often suggested by doctors and midwives to promote version of the baby. A Cochrane review found no benefit of postural management on presentation and method of delivery and perinatal outcome, although it acknowledged that the numbers of women included in studies to date were small (Hofmeyr 2002b). Increasingly, women are looking at other forms of health care to complement their pregnancy care. Moxibustion is one such modality.

In 2005 we published the first version of this systematic review. Since that time, new trials have been published. This review examined the evidence supporting the use of moxibustion for breech presentation both preterm and at term.

OBJECTIVES

To examine the effectiveness and safety of moxibustion on changing the presentation of an unborn baby in the breech position, the need for external cephalic version, mode of birth, and perinatal morbidity and mortality for breech presentation.

METHODS

Criteria for considering studies for this review

Types of studies

All published and unpublished randomised or quasi randomised controlled trials comparing moxibustion with a control group (no moxibustion) or other methods, e.g. ECV, acupuncture.

Types of participants

All women with a singleton breech presentation.

Types of interventions

Moxibustion (entailing application of heat to the acupuncture point Zhiyin (BL67)) alone or in combination with acupuncture or postural techniques.

Types of outcome measures

Primary outcomes

1. Baby's presentation at birth
2. Need for ECV

Secondary outcomes

3. Mode of birth
4. Perinatal morbidity and mortality
5. Maternal complications
6. Maternal satisfaction
7. Adverse events

Search methods for identification of studies

Electronic searches

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting the Trials Search Co-ordinator (26 March 2012).

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 MEDLINE (1966 to August 2011), EMBASE (1980 to August 2011), CINAHL (1982 to August 2011), MIDIRS (1982 to August 2011) and AMED (1985 to August 2011). (*See* Appendix 1) Due to the small number of results identified through the search, it was possible to review all results for inclusion in the review.

Searching other resources

We consulted University Departments of Complementary Medicine, Nursing and Midwifery to locate other published works, conference headings and text works. We also searched bibliographies of relevant papers.

We did not apply any language restrictions.

Data collection and analysis

For the methods used when assessing the trials identified in the previous versions of this review, *see* Appendix 2. For this update, we used the following methods for assessing the trials identified by the updated search.

Selection of studies

Meaghan Coyle and Caroline Smith independently assessed for inclusion all the potential studies identified as a result of the search strategy. Where there was uncertainty about inclusion of the study, the full text was retrieved. We contacted the original author for further information if necessary. Any disagreement was resolved through discussion, or if required, the third review author was consulted. Reasons for excluding trials have been stated.

Data extraction and management

A form to extract data was designed. Following an assessment for inclusion, we assessed the methodology of the trial. For eligible studies, Meaghan Coyle and Caroline Smith extracted the data using the agreed form, on participants, methods, interventions, outcome and results. Discrepancies were resolved through discussion or, if required, through consultation with the third review author. Data were entered into Review Manager software (RevMan 2011) and were checked for accuracy. Where information regarding any of the above was unclear, we attempted to contact authors of the original reports to provide further details.

Assessment of risk of bias in included studies

Meaghan Coyle and Caroline Smith independently assessed risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). Any disagreement was resolved by discussion or by involving the third review author.

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

We describe 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);
- unclear risk of bias.

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

We describe for each included study the method used to conceal allocation to interventions prior to assignment and assess whether the 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) Blinding of participants, personnel and outcome assessment (checking for possible performance bias)

We describe 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 studies to be at low risk of bias if they were blinded, or if we judged 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 for participants;
- low, high or unclear risk of bias for personnel;
- low, high or unclear risk of bias for outcome assessors.

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

We describe for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We state 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 where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information is reported, or was supplied by the trial authors, we re-included missing data in the analyses which we undertook.

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 describe 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 describe for each included study any important concerns we have 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 a high risk of bias, according to the criteria given in the *Cochrane Handbook for Systematic Reviews of Interventions* (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

Statistical analysis was performed using Review Manager (RevMan 2011) software.

Dichotomous data

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

Continuous data

For continuous data, we used the mean difference with 95% CI if outcomes were measured in the same way between trials. We planned to use the standardised mean difference (SMD) to combine trials that measured the same outcome, but used different methods.

Unit of analysis issues

Due to the nature of the intervention and types of participants, it is unlikely that a cross-over or cluster-randomised trial has been performed. However, in the event that this occurred, cross-over trials would be subject to within-subject analysis. If cluster-randomised trials were identified, we planned in the analyses to adjust their sample sizes using the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* using an estimate of the intra-cluster correlation co-efficient (ICC) derived from the trial (if possible), or from a similar trial or from a study of a similar population. If we used ICCs from other sources, we would report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. If both cluster-randomised trials and individually-randomised trials were identified, we planned to synthesise the relevant information. We consider it reasonable to combine the results from both if there was little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomisation unit was considered to be unlikely.

Dealing with missing data

Three trialists reported undertaking an intention-to-treat analysis, while the remaining five trials did not report undertaking an intention-to-treat analysis. We did not impute data for missing data but we did report the proportion lost to follow up and analysed per protocol.

For included studies, we noted the levels of attrition. We explored the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity

analysis. 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 identified and measured heterogeneity by visually inspecting the overlaps of the CIs for the results of individual studies. If there was poor overlap, this was suggestive of statistical heterogeneity and we included a more formal Chi^2 test. We assessed statistical heterogeneity in each meta-analysis using the T^2, I^2 and Chi^2 statistics. Heterogeneity was regarded as substantial if the T^2 was greater than zero and either the 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 measured inconsistency across trials in the meta-analysis using I^2. This described the percentage of total variation across studies that was due to heterogeneity rather than chance (Higgins 2011).

Assessment of reporting biases

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

Data synthesis

We carried out statistical analysis using the Review Manager software (RevMan 2011). Where moxibustion was used in combination with another intervention, a separate comparison was made due to incompatibility of the interventions. 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 were examining the same intervention, and the trials' populations and methods were judged sufficiently similar. If there was clinical heterogeneity sufficient to expect that the underlying treatment effects would differ between trials, or if substantial statistical heterogeneity was detected, we used random-effects meta-analysis to produce an overall summary if an average treatment effect across trials was considered clinically meaningful. The random-effects summary was treated as the average range of possible treatment effects and we discussed the clinical implications of treatment effects differing between trials. If the average treatment effect was not clinically meaningful, we did not combine trials. Where we use random-effects analyses, the results are presented as the average treatment effect with 95% CIs, and the estimates of T^2 and I^2.

Subgroup analysis and investigation of heterogeneity

We planned to carry out the following subgroup analyses.

1. Multiparous versus nulliparous.
2. Moxibustion (less than 34 weeks) versus moxibustion (greater than 34 weeks).

We investigated substantial heterogeneity using subgroup analyses and sensitivity analyses. We considered whether an overall summary was meaningful, and if it was, a random-effects analysis was undertaken.For fixed-effect inverse variance meta-analyses, we assessed differences between subgroups by interaction tests. For random-effects and fixed-effect meta-analyses using methods other than inverse variance, we assessed differences between subgroups by inspection of the subgroups' CIs; non-overlapping CIs indicated a statistically significant difference in treatment effect between the subgroups.

Sensitivity analysis

If heterogeneity could not be explained through subgroup analysis, we planned to analyse the data using a random-effects meta-analysis. Where studies were at high risk of bias, we assessed the likely magnitude and direction of the bias, and whether it was likely to impact on the findings of the review. We planned to perform sensitivity analysis to explore the impact of the level of bias.

RESULTS

Description of studies

Results of the search

In updating the review, eleven new trials were identified. Six new trials were included in the review (Cardini 2005; Chen 2004; Guittier 2009; Lin 2002; Neri 2007; Yang 2006), two were excluded (Huang 1990; Manyande 2009), two trials are ongoing (Smith 2009; Vas 2008) and one is awaiting classification (Millereau 2009) pending translation. One paper previously awaiting classification (Wu 1994) was also excluded. One paper previously included in the review has been reclassified as awaiting classification, pending further data from the trialists (Li 1996). In this updated review, eight trials (involving 1346 women) met the inclusion criteria (Cardini 1998; Cardini 2005; Chen 2004; Guittier 2009; Lin 2002; Neri 2004; Neri 2007; Yang 2006), while 10 trials were excluded (Beer 1995; Cardini 1991; Huang 1990; Kanakura 2001; Manyande 2009; Neri 2002; Qin 1989; Raben 1999; Wagner-Pankl 1990; Wu 1994).

Included studies

Design

A parallel design was used in all trials. Seven trials had two groups and one trial had three groups (Neri 2007). For the trial with three groups, comparisons were made of groups who received moxibustion (either alone or in combination with another intervention) with the control group (either no treatment, or alternative treatment). Four studies used a no treatment (observation) control (Cardini 1998; Cardini 2005; Guittier 2009; Neri 2004), three studies used a postural technique as a control (Chen 2004; Lin 2002; Yang 2006), one used a comparison with acupuncture (Neri 2007), and one used a comparison with moxibustion plus acupuncture (Neri 2007).

Sample size

The sample sizes of included studies ranged from 41 (Neri 2007) to 260 (Cardini 1998).

Setting

Three studies were undertaken in Italy, four in China, and one in Switzerland. The majority of trials recruited women from hospital clinics.

Participants

Breech was confirmed by ultrasound in four studies (Cardini 1998; Cardini 2005; Guittier 2009; Neri 2004), and the method of confir-

mation was not reported in the other four studies. Three trials recruited primiparous women only (Cardini 1998; Cardini 2005; Neri 2007). The gestational age at which women were recruited varied across the trials, from 28 weeks (Yang 2006) to 37 weeks (Lin 2002).

Interventions

Four studies used moxibustion alone to the acupuncture point BL67 (Cardini 1998; Cardini 2005; Guittier 2009; Neri 2007), one used moxibustion in combination with acupuncture (Neri 2004), and three used moxibustion in combination with postural techniques (Chen 2004; Lin 2002; Yang 2006). Treatment duration ranged from 10 minutes (Chen 2004) to 60 minutes (Cardini 1998), with the majority of studies applying moxibustion for 20 minutes. Treatment frequency included daily (Cardini 1998; Cardini 2005; Chen 2004), twice daily (Yang 2006), bi-weekly (Neri 2004; Neri 2007), and was unclear in two papers (Guittier 2009; Lin 2002). The intervention period ranged four days (Chen 2004) to two weeks (Cardini 2005; Guittier 2009; Yang 2006), and in one paper until version or delivery (Lin 2002).

Outcomes

Seven studies included the primary outcome of cephalic presentation, for the remaining study the primary outcome was fetal behaviour (Neri 2007). Other outcomes relevant to this review included caesarean section (Cardini 1998; Guittier 2009; Neri 2004), need for ECV (Cardini 1998; Guittier 2009), premature rupture of membranes (Cardini 1998; Cardini 2005), use of oxytocin (Cardini 1998), Apgar score less than seven at five minutes (Cardini 1998; Guittier 2009), intrauterine fetal death (Cardini 1998), placental abruption (Cardini 2005), adverse events (Cardini 2005), duration of hospital stay (Guittier 2009), and cord blood pH (Guittier 2009). Two trials did not report when the primary outcome of cephalic presentation was measured (Chen 2004; Lin 2002), however, as both papers reported confirmation of version by ultrasound or during delivery, the assumption was made that data reported presentation at birth.

For details of included studies, please *see* Characteristics of included studies.

Excluded studies

For details of excluded studies, please *see* Characteristics of excluded studies.

Risk of bias in included studies

See Figure 1 and Figure 2 for a graphical summary of the 'Risk of bias' assessment made by the review authors for the included trials, based on six domains. All trials were described as randomised. The risk of bias was low for allocation and allocation concealment in 50% of trials, was low for blinding in 88% of trials, was low for incomplete outcome data in 75% of trials, was low for free of selective reporting in 63% of trials, and was low for other forms of bias in 38% of trials.

Figure 1. Methodological quality summary: review authors' judgements about each methodological quality item for each included study.

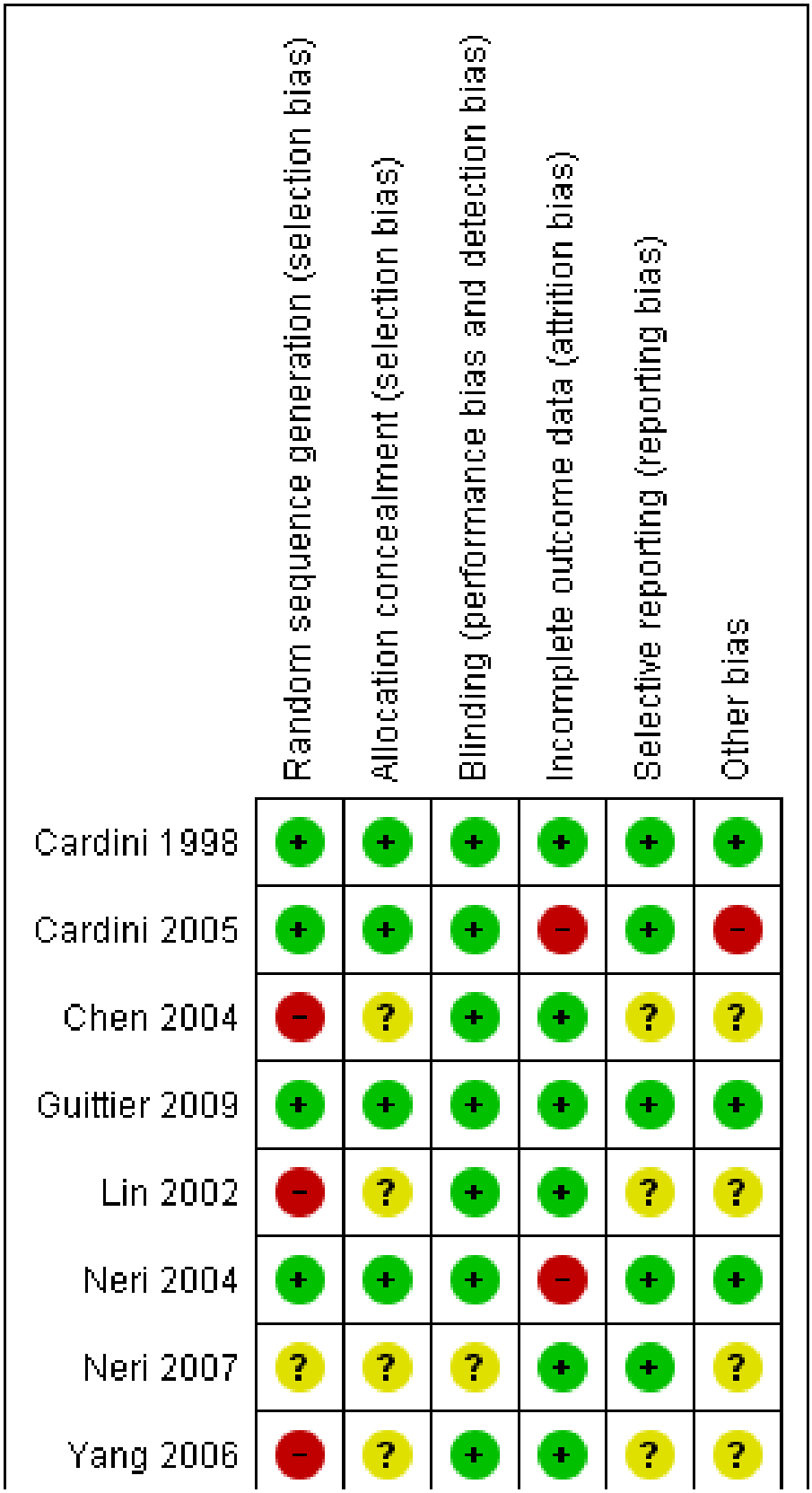


Figure 1. (Continued)

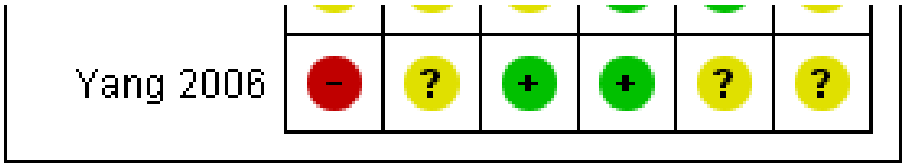
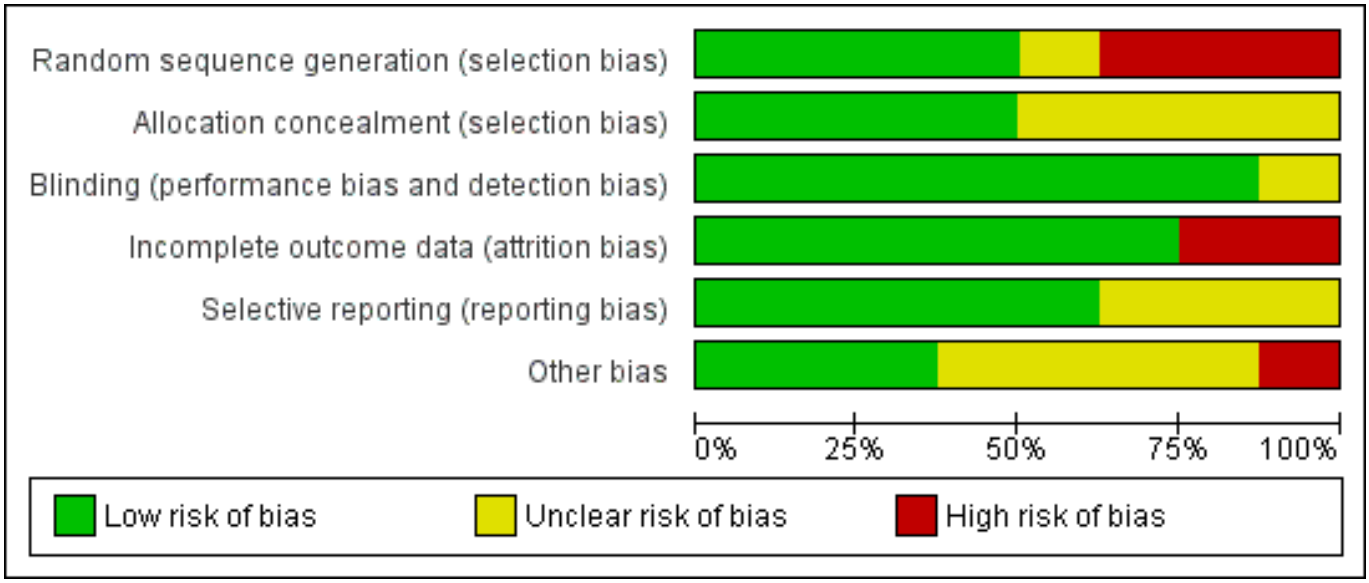


Figure 2. Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all included studies.



Allocation

Group allocation was determined by a computer-generated sequence in the Cardini 1998, Cardini 2005, Guittier 2009, and Neri 2004 trials, by date of admission in the Chen 2004, Lin 2002, and Yang 2006 trials, and was unclear in the Neri 2007 trial. Concealment of allocation was by central randomisation in the Neri 2004 trial, by sealed envelopes in the Cardini 1998, Cardini 2005 and Guittier 2009 trials, and was unclear in the remaining trials.

Blinding

It was not feasible to blind the patient or therapist in the included studies, however, the review authors judge that the outcome and the outcome measurement are not likely to be influenced by lack of blinding. The outcome assessor was blinded in the Cardini 2005 trial, and it was not clear whether the analyst was blinded to group allocation in any of the included studies.

Incomplete outcome data

In the Cardini 1998 trial, nine women in the treatment group withdrew from the treatment but were not exclusions. Data were available for all women randomised. In the Cardini 2005 trial, 14 women in the treatment group discontinued treatment but were not exclusions. One woman in the observation group was lost to follow up. Additional data were sought from the authors concerning the use of ECV by group. Twelve women in the treatment group underwent ECV, eight of which were successful. Nine women in the control group underwent ECV, four of which were successful. The trial was interrupted when interim analysis revealed poor compliance and a high number of treatment interruptions. In the Neri 2004 trial, eight women in the treatment group and six in the control group withdrew from the trial, and were not included in the analyses. In the Neri 2007 trial, two women were excluded after randomisation due to not meeting the baseline cardiotocographic criteria (one each from the moxibustion and moxibustion plus acupuncture groups). No loss to follow up was reported in the Guittier 2009, Lin 2002, and Yang 2006 trials.

Intention-to-treat analysis was performed in the Cardini 1998, Cardini 2005, and Guittier 2009 trials.

Selective reporting

The trial protocol was not available for any of the included studies, however, the published reports for the Cardini 1998, Cardini 2005, Guittier 2009, Neri 2004, and Neri 2007 include all expected outcomes. For the Chen 2004, Lin 2002 and Yang 2006 trials the study protocol was unavailable, and as the original papers were in Chinese, the review authors were unable to determine whether all outcomes were pre-specified.

Other potential sources of bias

Sample size calculations were performed in the Cardini 1998, Cardini 2005, Guittier 2009, and Neri 2004 trials. The Cardini 2005 trial was interrupted when interim analysis showed poor compliance and high numbers of treatment interruptions. Insufficient information was reported to determine whether other potential sources of bias exist for the Chen 2004, Lin 2002 and Yang 2006 trials. Unequal participant numbers in each group were seen in the Neri 2007 trial, but it is unclear whether this resulted from a failure of randomisation.

Effects of interventions

Eight trials involving a total of 1346 women were included in the review. Five meta-analyses were performed for comparison of moxibustion with no treatment, and one meta-analysis performed for comparison of moxibustion plus postural technique with postural technique. It was not possible to perform the planned subgroup analyses as data for the included trials were not reported by either gestational age or parity.

1. Moxibustion versus no treatment

Primary outcomes

1.1 Non-cephalic presentation at birth

Three trials, involving 594 women, comparing moxibustion with no treatment reported on the baby's presentation at birth (Cardini 1998, Cardini 2005; Guittier 2009). A meta-analysis using a random-effects model showed no difference between treatment and control groups in the number of non-cephalic presentations at birth (risk ratio (RR) 0.90, 95% confidence interval (CI) 0.67 to 1.19; random effects analysis, T^2= 0.04, I^2 = 60%). These results should be interpreted with caution due to clinical and statistical heterogeneity. *See* Analysis 1.1.

1.2 Need for ECV

Two trials (Cardini 1998; Guittier 2009) reported on the need for ECV (defined as breech presentation at the end of the trial intervention). Women were offered ECV at the end of the trial intervention period. A meta-analysis using a random-effects model showed no difference between groups in the need for ECV (RR 0.67, 95% CI 0.34 to 1.32; two trials, 472 women; T^2 = 0.22, I^2 = 91%) (Analysis 1.2). The results of this meta-analysis should be interpreted with caution due to clinical and statistical heterogeneity.

Secondary outcomes

1.3 Caesarean section

Two trials reported on the number of births by caesarean section (Cardini 1998; Guittier 2009), and a meta-analysis showed no difference in the rate of caesarean section between the treatment and control group (RR 1.05, 95% CI 0.87 to 1.26; two trials, 472 women) (Analysis 1.3). The results of this meta-analysis should be considered with caution, due to clinical heterogeneity.

1.4 Premature rupture of membranes

Two trials (Cardini 1998; Cardini 2005) reported on the outcome premature rupture of membranes. A meta-analysis using a random-effects model revealed no differences between groups in the risk of premature rupture of membranes (RR 0.82, 95% CI 0.07 to 9.31; two trials, 382 women; T^2 = 2.04, I^2 = 60%) (Analysis 1.4). The results of this meta-analysis should be interpreted with caution due to clinical and statistical heterogeneity.

1.5 Use of oxytocin

One trial (260 women) reported on the use of oxytocin for women who had a vaginal birth (Cardini 1998). Moxibustion resulted in decreased use of oxytocin before or during labour for women who had vaginal births (RR 0.28, 95% CI 0.13 to 0.60) (Analysis 1.5).

1.6 Apgar score less than seven at five minutes

Two trials (Cardini 1998; Guittier 2009) reported on Apgar score less than seven at five minutes. A meta-analysis using a random-effects model showed no difference between groups in Apgar scores less than seven at five minutes (RR 0.26, 95% CI 0.02 to 4.27; two trials, 472 women; T^2 = 1.98, I^2 = 49%) (Analysis 1.6). The results of this meta-analysis should be considered with caution due to clinical and statistical heterogeneity. It should be noted that the results of the Cardini 1998 trial are extreme. As the number of outcomes is small, this is more likely due either to chance or bias in outcome assessment than true treatment effect.

1.7 Intrauterine fetal death

One trial (260 women) reported on intrauterine fetal death (Cardini 1998). One instance of intrauterine fetal death was reported in the control group (RR 0.33, 95% CI 0.01 to 8.11) (Analysis 1.7).

1.8 Placental abruption

One trial (122 women) reported on placental abruption (Cardini 2005). One case of placental abruption was seen in the control group (RR 0.29, 95% CI 0.01 to 7.05) (Analysis 1.8).

1.9 Adverse events

One trial (122 women) reported adverse events data by study group (Cardini 2005). Women in the treatment group reported adverse events relating to treatment, including unpleasant odour (with or without throat problems) and nausea, and abdominal pain from contractions (RR 48.33, 95% CI 3.01 to 774.86) (Analysis 1.9).

Two additional trials reported adverse effects (Cardini 1998; Neri 2004), however, actual data were not reported. The main discomfort reported by women in both groups in the Cardini trial was pressure and tenderness in the epigastric region or in one of the hypochondria (epigastric crushing) attributed to the head of the breech baby pressing against maternal organs.

1.10 Duration of hospital stay (days)

One trial (212 women; Guittier 2009) found no difference between groups in duration of hospital stay (days) (mean difference (MD) -0.10, 95% CI -0.55 to 0.35) (Analysis 1.10).

1.11 Cord blood pH less than 7.1

One trial (212 women; Guittier 2009) found no difference between groups in the number of women with cord blood pH less than 7.1 using a random-effects model (RR 3.00, 95% CI 0.32 to 28.38) (Analysis 1.11).

2. Moxibustion versus acupuncture

Primary outcomes

2.1 Non-cephalic presentation at birth

One trial (25 women; Neri 2007) of moxibustion versus acupuncture found fewer women in the moxibustion group had a non-cephalic presentation at birth compared with the acupuncture group (RR 0.25, 95% CI 0.09 to 0.72) (Analysis 2.1).

3. Moxibustion plus acupuncture versus no treatment

Primary outcomes

3.1 Non-cephalic presentation at birth

One trial (226 women; Neri 2004) of moxibustion plus acupuncture versus no treatment found fewer women in the treatment group had a non-cephalic presentation at birth compared with the control group (RR 0.73, 95% CI 0.57 to 0.94) (Analysis 3.1).

Secondary outcomes

3.2 Caesarean section

One trial (226 women; Neri 2004) found a significantly lower rate of caesarean section for women who received moxibustion plus acupuncture group compared with no treatment (RR 0.79, 95% CI 0.64 to 0.98) (Analysis 3.2).

The Neri 2004 trial explored maternal heart rate and blood pressure, and fetal heart rate immediately after the intervention was applied. No fetal or maternal cardiovascular changes were detected, nor were any preterm uterine contractions detected.

4. Moxibustion plus acupuncture versus acupuncture

Primary outcomes

4.1 Non-cephalic presentation at birth

One trial (24 women; Neri 2007) found no differences in the number of non-cephalic presentations when comparing moxibustion plus acupuncture versus acupuncture (RR 0.54, 95% CI 0.27 to 1.06) (Analysis 4.1).

5. Moxibustion plus acupuncture versus moxibustion

Primary outcomes

5.1 Non-cephalic presentation at birth

One trial (29 women; Neri 2007) found no differences in the number of non-cephalic presentations when comparing moxibustion plus acupuncture versus moxibustion (RR 2.14, 95% CI 0.66 to 6.97) (Analysis 5.1).

6. Moxibustion plus postural technique versus postural technique

Primary outcomes

6.1 Non-cephalic presentation at birth

Three trials (470 women; Chen 2004; Lin 2002; Yang 2006) found fewer women in the moxibustion plus postural technique had a non-cephalic presentation at birth compared with postural technique alone (RR 0.26, 95% CI 0.12 to 0.56; random-effects analysis, $T^2 = 0.32$, $I^2 = 68\%$) (Analysis 6.1).

DISCUSSION

Summary of main results

While six new trials have been included in this updated review, overall, there are few high-quality trials evaluating the role of moxibustion to promote cephalic presentation. Moxibustion resulted in a decreased use of oxytocin compared with no treatment, and a reduction in the number of non-cephalic presentations at birth compared with acupuncture. When combined with acupuncture, moxibustion resulted in a reduction in the number of non-cephalic presentations at birth and the number of births by caesarean section compared with no treatment. When combined with postural techniques, moxibustion was found to reduce the number of non-cephalic presentations compared with the postural technique alone. However, the results must be interpreted with caution due to clinical heterogeneity (including differences in interventions, sample size, and study populations), and varying levels of statistical heterogeneity.

Overall completeness and applicability of evidence

All of the included studies reported on the primary outcome, while few studies reported on the secondary outcomes. The included studies have investigated the use of moxibustion in correcting a breech presentation in a variety of settings and from a variety of locations. Differences in the intervention (frequency, duration, and used alone, or in combination with acupuncture or postural techniques), as well as compliance, highlight the variation in current clinical practice internationally, as well as cultural differences in the acceptability of the intervention.

Quality of the evidence

This review included eight trials, involving 1346 women. The included trials were of moderate methodological quality, however, sample sizes in some studies were small, differences existed in interventions, and reporting was limited. For higher quality trials, differences in study design were noted, and results of meta-analyses should be interpreted with caution.

Potential biases in the review process

A potential source of bias of this review may originate from the search strategy. The search strategy utilised is more likely to detect English language publications. Efforts have been made to identify publications in languages other than English (e.g. Chinese), however, it is possible that relevant publications have not been identified.

Agreements and disagreements with other studies or reviews

The findings from this review differ from other evidence. A systematic review by Vas 2009 found moxibustion to be beneficial in correcting non-vertex presentation, although the authors acknowledged considerable heterogeneity was detected. A systematic review of moxibustion and other acupuncture point stimulation methods to correct breech presentation by Li 2009 found moxibustion to be effective in correcting breech presentations. The review included both randomised controlled trials and controlled clinical trials.

AUTHORS' CONCLUSIONS

Implications for practice

There is some evidence to suggest that moxibustion may reduce the number of non-cephalic presentations at birth, either alone or in combination with acupuncture or postural techniques. When used in combination with acupuncture, moxibustion may result in fewer births by caesarean section. Moxibustion may also be useful in decreasing women's use of oxytocin (compared with no treatment). There is some evidence that moxibustion combined with postural techniques (knee-chest therapy, and LBSL) may reduce the number of non-cephalic presentations at birth. Further evidence is needed to confirm (or refute) benefit for correcting breech presentation. Practitioners should ensure appropriate ventilation is available when performing moxibustion, to reduce the respiratory adverse events reported with the procedure.

Implications for research

There is a need for robust, methodologically sound, randomised controlled trials of adequate statistical power to evaluate this intervention. Clinically relevant outcome measures such as mode of birth, perinatal morbidity and mortality, maternal complications and maternal satisfaction must be reported, as well as any adverse events related to moxibustion. Parity, gestational age at time of intervention and ethnicity should also be included in analyses. Consideration should also be given to the timing of the intervention, and strategies to ensure compliance with treatment. As it is not currently feasible to blind participants to group allocation with moxibustion, a trial comparing moxibustion with external cephalic ver-

sion or postural management may be appropriate. Future trials should report on safety and women's views of the intervention, and explore the number, frequency and length of treatments.

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As part of the pre-publication editorial process, this review has been commented on by three peers (an editor and two referees who are external to the editorial team) and the Group's Statistical Adviser.

REFERENCES

References to studies included in this review

Cardini 1998 *{published data only}*

Cardini F, Weixin H. Moxibustion for correction of breech presentation. *JAMA* 1998;**280**(18):1580-4.

Cardini 2005 *{published data only}*

Cardini F, Lombardo P, Regalia AL, Regaldo G, Zanini A, Negri MG, et al. A randomised controlled trial of moxibustion for breech presentation. *BJOG: an international journal of obstetrics and gynaecology* 2005;**112**:743-7.

Chen 2004 *{published data only}*

Chen Y, Yang Lw. Moxibustion on Zhiyin plus raising buttocks in a lateral position for correction fetal presentation in 73 cases. *Clinical Journal of Traditional Chinese Medicine* 2004;**16**:333.

Guittier 2009 *{published data only}*

Guittier MJ, Klein TJ, Dong HG, Andreoli N, Irion O, Boulvain M. Side-effects of moxibustion for cephalic version of breech presentation. *Journal of Alternative and Complementary Medicine* 2008;**14**(10):1231-3.

* Guittier MJ, Pichon M, Dong H, Irion O, Boulvain M. Moxibustion for breech version: a randomised controlled trial. *Obstetrics & Gynecology* 2009;**114**(5):1034-40.

Lin 2002 *{published data only}*

Lin YP, Zhang DQ, Hao YQ, Duan XW. Combination of moxibustion at point Zhiyin and knee-chest position for correction of breech pregnancy in 63 cases. *Chinese Acupuncture and Moxibustion* 2002;**22**:811-2.

Neri 2004 *{published data only}*

Neri I, Airola G, Contu G, Allais G, Facchinetti F, Benedetto C. Acupuncture plus moxibustion to resolve breech presentation: a randomized controlled study. *Journal of Maternal-Fetal and Neonatal Medicine* 2004;**15**:247-52.

Neri 2007 *{published data only}*

Neri I, De Pace V, Venturini P, Facchinetti F. Effects of three different stimulations (acupuncture, moxibustion, acupuncture plus moxibustion) of BL67 acupoint at small toe on fetal behaviour of breech presentation. *American Journal of Chinese Medicine* 2007;**35**(1):27-33.

Yang 2006 *{published data only}*

Yang FQ. Comparison of knee-chest position plus moxibustion on Zhiyin with knee-chest position for breech presentation. *Journal of Sichuan of Traditional Chinese Medicine* 2006;**24**:106-7.

References to studies excluded from this review

Beer 1995 *{published data only}*

Beer AM, Danaei M, Keck V. Correction of breech presentation by moxibustion. *Akupunktur* 1995;**23**(2):100-2.

Cardini 1991 *{published data only}*

Cardini F, Basevi V, Valentini A, Martellato A. Moxibustion and breech presentation: preliminary results. *American Journal of Chinese Medicine* 1991;**19**(2):105-14.

Huang 1990 *{published data only}*

Huang WX. Comparison study on moxibustion and knee-chest position for conversion of fetal presentation. *Chinese Journal of Integrated Traditional and Western Medicine* 1990;**10**:105-6.

Kanakura 2001 *{published data only}*

Kanakura Y, Kometani K, Nagata T, Niwa K, Kamatsuki H, Shinzato Y, et al. Moxibustion treatment of breech presentation. *American Journal of Chinese Medicine* 2001;**29**(1):37-45.

Manyande 2009 *{published data only}*

Manyande A, Grabowska C. Factors affecting the success of moxibustion in the management of a breech presentation as a preliminary treatment to external cephalic version. *Midwifery* 2009;**25**:774-80.

Neri 2002 *{published data only}*

Neri I, Fazzio M, Menghini S, Volpe A, Facchinetti F. Non-stress test changes during acupuncture plus moxibustion on BL67 point in breech presentation. *Journal of the Society for Gynecologic Investigation* 2002;**9**:158-62.

Qin 1989 *{published data only}*

Qin GF, Tang HJ. 413 cases of abnormal fetal position corrected by auricular plaster therapy. *Journal of Traditional Chinese Medicine* 1989;**9**(4):235-7.

Raben 1999 *{published data only}*

Raben R. Treatment of breech presentation with acupuncture and moxibustion in primigravidae [Die Behandlung der Beckenendlage mit Akupunktur und Moxibustion bei Erstgebarenden]. *Deutsche Zeitschrift fur Akupunktur* 1999;**42**(3):156-60.

Wagner-Pankl 1990 *{unpublished data only}*

Wagner-Pankl TMU. Lageveranderung des feten durch akupunktur (Change of presentation of the fetus through acupuncture) [thesis]. Vienna: University of Vienna, 1990.

Wu 1994 *{published data only}*

Wu YC. Clinical and experimental observations of warm acupuncture for abnormal fetal position. *Shanghai Journal of Acupuncture and Moxibustion* 1994;**13**:149-50.

References to studies awaiting assessment

Li 1996 *{published data only}*

Li Q, Wang L. Clinical observation on correcting malposition of fetus by electro-acupuncture. *Journal of Traditional Chinese Medicine* 1996;**16**(4):260-2.

Millereau 2009 *{published data only}*

Millereau M, Branger B, Darcel F. Fetal version by acupuncture (moxibustion) versus control group [Etude comparative de la version foetale par acupuncture (moxibustion) versus groupe temoin]. *Journal de Gynecologie, Obstetrique et Biologie de la Reproduction* 2009;**38**(6):481-7.

References to ongoing studies

Smith 2009 {*unpublished data only***}**

Dahlen H, Smith C, Do C, Schmied V, Bisits A. Moxibustion for cephalic version: A feasibility study. Women and Birth 2011; Vol. 24 Suppl 1:S2.

Do C, Smith C, Dahlen H, Bissets A, Schmeid V. Moxibustion for cephalic version: A feasibility study. *Journal of Paediatrics and Child Health* 2011;**47**(Suppl 1):37.

Do CK, Smith CA, Dahlen H, Bisits A, Schmied V. Moxibustion for cephalic version: A feasibility randomised controlled trial. *BMC Complementary and Alternative Medicine* 2011;**11**:81.

Smith C. Moxibustion for cephalic version: a feasibility study. Australian New Zealand Clinical Trials Registry (www.anzctr.org.au) (accessed 8 February 2010).

Vas 2008 {*unpublished data only***}**

Vas J, Aranda JM, Baron M, Perea-Milla E, Mendez C, Ramirez C, et al. Correcting non cephalic presentation with moxibustion: study protocol for a multi-centre randomised controlled trial in general practice. *BMC Complementary and Alternative Medicine* 2008;**8**:22.

Additional references

Budd 2000

Budd S. Moxibustion for breech presentation. *Complementary Therapies in Nursing & Midwifery* 2000;**6**:176-9.

Clarke 2003

Clarke M, Oxman AD, editors. Cochrane Reviewers' Handbook 4.2 [updated March 2003]. In: Review Manager (RevMan) [Computer program]. Version 4.2. The Cochrane Collaboration. Oxford: Update Software.

Cooperative 1984

Cooperative Research Group of Moxibustion Version of Jangxi Province. Further studies on the clinical effects and mechanism of version by moxibustion. Abstracts of the Second National Symposium on Acupuncture, Moxibustion, and Acupuncture Anesthesia; 1984 Aug 7-10; Beijing, China. 1984:150-1.

Cruikshank 1986

Cruickshank DP. Breech presentation. *Clinical Obstetrics and Gynecology* 1986;**29**:255-63.

Egger 1997

Egger M, Smith GD, Schneider M, Minder C. Bias in meta-analysis detected by a simple, graphical test. *BMJ* 1997;**315**:629-34.

Ewies 2002

Ewies A, Olah K. Moxibustion in breech version - a descriptive review. *Acupuncture in Medicine* 2002;**20**(1):26-9.

Hannah 2000

Hannah ME, Hannah WJ, Hewson SA, Hodnett ED, Saigal S, Willan AR. Planned caesarean section versus planned vaginal birth for breech presentation at term: a randomised multicentre trial. *Lancet* 2000;**356**:1375-83.

Harbord 2006

Harbord RM, Egger M, Sterne JA. A modified test for small-study effects in meta-analyses of randomised controlled trials with binary endpoints. *Statistics in Medicine* 2006;**25**:3443-57.

Higgins 2011

Higgins JPT, Green S, editors. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

Hofmeyr 2002a

Hofmeyr GJ, Kulier R. External cephalic version for breech presentation at term. *Cochrane Database of Systematic Reviews* 1996, Issue 2. [DOI: 10.1002/14651858.CD000083]

Hofmeyr 2002b

Hofmeyr GJ, Kulier R. Cephalic version by postural management for breech presentation. *Cochrane Database of Systematic Reviews* 2000, Issue 3. [DOI: 10.1002/14651858.CD000051]

Kim 2009

Kim SY, Chae Y, Lee SM, Lee H, Park HJ. The effectiveness of moxibustion: an overview during 10 years. Evidence-Based Complementary and Alternative Medicine 2009 Oct 13 [Epub ahead of print]. [PUBMED: 19825873]

Li 2009

Li X, Hu J, Wang X, Zhang H, Liu J. Moxibustion and other acupuncture point stimulation methods to treat breech presentation: a systematic review of clinical trials. *BMC: Chinese Medicine* 2009;**4**(4):1-8.

Pach 2009

Pach D, Brinkhaus B, Willich SN. Moxa sticks: thermal properties and possible implications for clinical trials. *Complementary Therapies in Medicine* 2009;**17**:243-6.

RevMan 2002 [Computer program]

The Cochrane Collaboration. Review Manager (RevMan). Version Version 4.2 for Windows. Oxford, England: The Cochrane Collaboration, 2002.

RevMan 2011 [Computer program]

The Nordic Cochrane Centre, The Cochrane Collaboration. Review Manager (RevMan). Version 5.1. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2011.

Roberts 1999

Roberts CL, Algert CS, Peat B, Henderson-Smart D. Small fetal size: a risk factor for breech birth at term. *International Journal of Gynecology & Obstetrics* 1999;**67**(1):1-18.

Turner 1991

Turner RN, Low R. Moxibustion: its principles and practice. Wellingborough, Northamptonshire: Thorsons Publishing Group, 1987.

Vas 2009

Vas J, Aranda JM, Nishishinya B, Mendez C, Martin A, Pons J, et al. Correction of nonvertex presentation with moxibustion: a systematic review and metaanalysis. *American Journal of Obstetrics and Gynecology* 2009;**201**(3):241-59.

West 2003

West Z. Acupuncture in Pregnancy and Childbirth. Edinburgh, UK: Churchill Livingstone, 2003.

Whyte 2004

Whyte H, Hannah ME, Saigal S, Hannah WJ, Hewson S, Amankwah K, et al. Outcomes of children at 2 years after planned cesarean birth versus planned vaginal birth for breech presentation at term: The International Randomized Term Breech Trial. *American Journal of Obstetrics and Gynecology* 2004;**191**:864-71.

References to other published versions of this review

Coyle 2005

Coyle ME, Smith CA, Peat B. Cephalic version by moxibustion for breech presentation. *Cochrane Database of Systematic Reviews* 2005, Issue 2. [DOI: 10.1002/14651858.CD003928.pub2]

* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

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

Cardini 1998

Methods	Randomised controlled trial of moxibustion or no moxibustion (untreated) group.
Participants	260 women were randomised to the trial in Jiangxi province, China. Inclusion criteria were primigravidae, at 33 weeks' gestation, breech presentation diagnosed by ultrasound, normal fetal biometry. Exclusion criteria were pelvic defects, previous uterine surgery, uterine malformation, fibromyoma greater than 4 cm diameter, fetal malformation, twin gestation, tocolytic therapy during pregnancy, risk of premature birth, pathological pregnancy that contraindicated inclusion in the trial e.g. intrauterine growth retardation, gestosis, serious infections, placenta praevia, polyhydramnios, oligohydramnios.
Interventions	All women had breech presentation confirmed by ultrasound in the 33rd week of gestation, within 24 hours of randomisation. All women were asked to record fetal movements once daily for 7 days, during a 1-hour period. The first 87 women randomised to the treatment group were instructed to administer moxibustion to BL67 bilaterally once daily for 30 minutes (15 minutes each side) for 7 days, while the subsequent 43 women were instructed to administer moxibustion twice daily for 30 minutes (15 minutes per side). Participants were given an instruction session on how to administer the moxibustion. After 7 days fetal position was checked via fetal heartbeats and abdominal palpation, with ultrasound being used only when the other techniques were uncertain. If version had not occurred, women were advised to continue another week of treatment providing the woman agreed, and there were no adverse effects. Women with breech presentation at 35 weeks could undergo ECV.
Outcomes	The primary outcomes were the number of cephalic presentations at the 35th week and at birth, and fetal motor activity. Secondary outcomes included compliance with treatment, observation of possible adverse effects in the intervention group and adverse events in both groups, number of cephalic versions with 2 different dosages of moxibustion, number and causes of caesarean deliveries, spontaneous and induced deliveries, and Apgar score at 5 minutes.
Notes	Sample size calculation was performed.
Risk of bias	
Bias	**Authors' judgement** **Support for judgement**

Cardini 1998 *(Continued)*

Random sequence generation (selection bias)	Low risk	Computer-generated.
Allocation concealment (selection bias)	Low risk	Sealed envelopes.
Blinding (performance bias and detection bias) All outcomes	Low risk	There was no blinding of participant and therapist, but the review authors judge that the outcome and the outcome measurement are not likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) All outcomes	Low risk	There was complete follow-up of all women randomised.
Selective reporting (reporting bias)	Low risk	Study protocol unavailable but published report includes all expected outcomes.
Other bias	Low risk	No imbalances at randomisation. The study appears free of other sources of bias.

Cardini 2005

Methods	Single-blind randomised controlled trial. Women randomised to treatment (moxibustion) or control (observation) .
Participants	123 women were randomised to the trial through 6 hospital obstetric departments in northern and central Italy. Inclusion criteria were non-Chinese, nulliparous women with a singleton pregnancy at 32-33 weeks + 3 days, in good health with normal fetal biometry, and breech presentation confirmed by ultrasound within the previous 24 hours. Exclusion criteria were refusal of randomisation or treatment, defective pelvis, previous uterine surgery, recognised fetal/uterine malformation or fibroid greater than 4 cm in diameter, twin pregnancy, current or previous tocolytic therapy and any other pregnancy complications.
Interventions	All women were instructed to record active fetal movements for 2 x 1-hour periods per day for 2 weeks. Presentation was assessed by ultrasound 2 weeks after randomisation. Women with persistent breech were offered ECV after the 37th week if they were at a participating centre where ECV was routinely performed. Women allocated to the treatment group were trained in moxibustion treatment. Moxibustion was administered to BL67 bilaterally for 30 minutes (15 minutes per side), daily for 7 days. Presentation was assessed by ultrasound after 7 days. Women with persistent breech presentation were instructed to continue moxibustion for an additional 7 days.
Outcomes	The primary outcome was the proportion of cephalic presentations in the 35th week. Secondary outcomes included: number of cephalic presentations at birth, fetal motor count, compliance with treatment, and adverse events by allocated group.
Notes	Sample size calculation was performed.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Randomisation by computer-generated random numbers.

Cardini 2005 *(Continued)*

Allocation concealment (selection bias)	Low risk	Sealed opaque envelopes containing group allocation.
Blinding (performance bias and detection bias) All outcomes	Low risk	The outcome assessor was blinded to group allocation. It was not feasible to blind the patient and therapist, however, it was unlikely this would influence the outcome. It was unclear whether the analyst was blinded.
Incomplete outcome data (attrition bias) All outcomes	High risk	1 woman in the control group was lost to follow up, and was considered a positive result (cephalic version) in the intention-to-treat analysis. 14 women in the intervention group discontinued treatment, due to the treatment being unpleasant or associated with physical disturbances (e.g. unpleasant odour, with or without nausea and throat problems, abdominal pain with contractions).
Selective reporting (reporting bias)	Low risk	Trial protocol not available, however, published report includes all expected outcomes.
Other bias	High risk	The trial was interrupted when interim analysis revealed poor compliance and a high number of treatment interruptions.

Chen 2004

Methods	Randomised trial of moxibustion plus lifting-buttocks-side-lying position compared with lifting-buttocks-side-lying position.
Participants	142 women with breech presentation were randomised to the trial through a hospital in Zhejiang Province, China. Inclusion criteria was 30-34 weeks' gestation; no other inclusion or exclusion criteria were reported.
Interventions	73 women were allocated to the moxibustion plus lifting-buttocks-side-lying position. The details of lifting-buttock-side-lying position were not explained. Moxibustion was applied to BL67 for 10-15 minutes once daily, with 3 days constituting one course. 69 women were allocated to the lifting-buttocks-side-lying position only group. The duration of the intervention was unclear, but the average length of treatment was 4 days.
Outcomes	The primary outcome was cephalic presentation either confirmed by ultrasound or during labour. Details of measurement of outcome unclear.
Notes	No sample size calculation performed.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk	Group allocation by date of admission.
Allocation concealment (selection bias)	Unclear risk	The method of concealment was not reported.
Blinding (performance bias and detection bias) All outcomes	Low risk	It was not feasible to blind the participant or the therapist, and it was unclear whether the outcome assessor and analyst were blinded.
Incomplete outcome data (attrition bias)	Low risk	There was complete follow-up of all women.

Chen 2004 *(Continued)*

All outcomes		
Selective reporting (reporting bias)	Unclear risk	Study protocol unavailable; unable to determine whether all outcomes were pre-specified.
Other bias	Unclear risk	There is insufficient information to determine whether other bias is present.

Guittier 2009

Methods	Randomised trial of moxibustion or standard care.
Participants	212 women between 34-36 weeks' gestation with a single fetus in breech presentation verified by ultrasonography. Exclusion criteria were women with uterine malformation, placenta praevia, and transverse lie. The trial was conducted in a hospital maternity unit in Switzerland.
Interventions	Breech presentation was confirmed prior to randomisation. Fetal position was assessed by ultrasound prior to administration of moxibustion. Moxibustion was administered at the hospital by trained staff 3 times per week for the first 12 women allocated to the moxibustion group, while the remaining 94 women received moxibustion 3 times per week at the hospital and self-administered on the days they did not attend the hospital. Moxibustion was administered to the point BL67 for 10 minutes each side. A maximum of 14 sessions was scheduled over 2 weeks. ECV was offered if breech presentation persisted at 37 weeks' gestation.
Outcomes	The primary outcome was cephalic presentation at delivery or before ECV if attempted. Secondary outcomes included cephalic presentation at delivery including after successful ECV; mode of delivery; perineal injury or complications of delivery; proportion of neonates with Apgar scores less than 7 at 5 minutes; arterial cord blood pH less than 7.10; neonatal complications; total duration of hospital stay for woman and neonate.
Notes	Sample size calculation and intention-to-treat analysis performed.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation sequence in blocks of 4, 6 and 8. Stratified according to women's intention to attempt ECV if required at 37 weeks.
Allocation concealment (selection bias)	Low risk	Sealed and consecutively numbered opaque envelopes.
Blinding (performance bias and detection bias) All outcomes	Low risk	It was not feasible to blind the participant or the therapist, and it was unclear whether the outcome assessor and analyst were blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	There was complete follow-up of all women randomised.
Selective reporting (reporting bias)	Low risk	Study protocol unavailable, but published report includes all expected outcomes.
Other bias	Low risk	No imbalances at randomisation. The study appears free from other sources of bias.

Lin 2002

Methods	Randomised trial of moxibustion plus knee-chest position compared with knee-chest therapy.
Participants	122 women between 30 and 37 weeks' gestation with breech presentation were randomised to the trial. No inclusion or exclusion criteria were reported. While it was not reported whether all women had a singleton pregnancy, this was assumed. Women were recruited from a hospital in Hubei Province, China.
Interventions	Women were randomly allocated to receive either moxibustion plus knee-chest therapy, or knee-chest therapy alone (control group). 63 women received moxibustion to BL67 for 15 minutes, with 2 days constituting one course. The duration of intervention is unclear. 59 women were allocated to receive knee-chest therapy alone. The details of knee-chest therapy were not reported.
Outcomes	The primary outcome was cephalic presentation either confirmed by ultrasound or during labour. Details of measurement of outcome unclear.
Notes	No sample size calculation was performed.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Group allocation by date of admission.
Allocation concealment (selection bias)	Unclear risk	The method of concealment was not reported.
Blinding (performance bias and detection bias) All outcomes	Low risk	It was not feasible to blind the participant or the therapist, and it was unclear whether the outcome assessor and analyst were blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	There was complete follow-up of all women.
Selective reporting (reporting bias)	Unclear risk	Study protocol unavailable; unable to determine whether all outcomes were pre-specified.
Other bias	Unclear risk	There is insufficient information to determine whether other bias is present.

Neri 2004

Methods	Randomised controlled trial. Women were randomised to receive moxibustion plus acupuncture to BL67, or to receive routine care (observation).
Participants	240 women were randomised to the trial in Italy. Inclusion criteria were Caucasian, singleton pregnancy, between 33 and 35 weeks' gestation, breech presentation confirmed by ultrasound within 24 hours of randomisation. Exclusion criteria were greater than 35 weeks' gestation, previous uterine surgery (including caesarean section), uterine malformations, risk of premature birth, twin pregnancy, fetal malformations or chromosomal abnormalities, abnormal fetal biometry, renal/cardiac maternal disease, transverse or oblique lie.
Interventions	All women had breech presentation confirmed by ultrasound and were randomised within 24 hours. Women allocated to the acupuncture plus moxibustion group received twice weekly treatments for 2

Neri 2004 *(Continued)*

	weeks if necessary. To determine whether to continue with treatment, an ultrasound was performed before each session to determine presentation. Acupuncture needles were inserted bilaterally into BL67, and De Qi sensation was sought. Once obtained, needle stimulation ceased and needles were left in situ for 20 minutes. Moxibustion was applied for 20 minutes, with the side of moxibustion stimulation alternated every 2 minutes. After the first session a non-stress test was performed for 30 minutes and maternal blood pressure and heart rate were monitored. ECV was not offered to those participating in the study.
Outcomes	The primary outcome was presentation at birth, the secondary outcomes were incidence of caesarean section and adverse events relating to treatment.
Notes	Sample size calculation was performed.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The trial used a computer-generated sequence for allocation.
Allocation concealment (selection bias)	Low risk	Central randomisation.
Blinding (performance bias and detection bias) All outcomes	Low risk	It was not feasible to blind the patient or therapist, and it was unclear whether the outcome assessor and analyst were blinded to group allocation. However, it was unlikely this would influence the outcome.
Incomplete outcome data (attrition bias) All outcomes	High risk	8 women from the treatment group and 6 women from the control group withdrew from the trial. In the treatment group, 5 women withdrew due to uterine contractility observed by their obstetrician, 2 due to the onset of mild hypertension and 1 failed to comply. In the control group, 2 women withdrew due to threatened preterm labour and 4 refused to be assigned to the observation group after disclosure of their group allocation.
Selective reporting (reporting bias)	Low risk	Study protocol unavailable but published report includes all expected outcomes.
Other bias	Low risk	No imbalances at randomisation. The study appears free from other sources of bias.

Neri 2007

Methods	Randomised trial of moxibustion alone, acupuncture alone, or moxibustion plus acupuncture.
Participants	41 primiparous women were randomised to the trial through the acupuncture clinic of an obstetric department in Italy. Inclusion criteria were women with a singleton pregnancy of 33-36 weeks' gestation, with fetus in frank position. Exclusion criteria included previous uterine surgery, twin pregnancy, low level of amniotic fluid, maternal renal or cardiac disease and fetal malformation or chromosome abnormality.
Interventions	Treatment was administered bilaterally for 20 minutes, twice per week. Women were subject to a computerised cardiotocograph to measure fetal activity for 20 minutes before, during and for 20 minutes after treatment. Acupoint stimulation was elicited during an active period (defined as a period with presence of fetal movements and accelerations of fetal heart rate, and variability of fetal heart rate greater then 10 beats per minute). It was unclear when fetal presentation was assessed.

Neri 2007 *(Continued)*

Outcomes	The primary outcomes were fetal heart rate, fetal movements, and cephalic version.
Notes	The paper did not report a sample size calculation. Intention-to-treat analysis was not undertaken.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of group allocation was not reported.
Allocation concealment (selection bias)	Unclear risk	Method of group concealment was not reported.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	It was unclear whether the outcome assessor and analyst were blinded to group allocation. It was not feasible to blind the participant or therapist. However, it was unlikely this would influence the outcome.
Incomplete outcome data (attrition bias) All outcomes	Low risk	2 women (1 from the moxibustion group and 1 from the moxibustion plus acupuncture group) were excluded post-randomisation due to not meeting the baseline cardiotocographic criteria. The review authors deem this low risk.
Selective reporting (reporting bias)	Low risk	Study protocol unavailable but published report includes all expected outcomes.
Other bias	Unclear risk	While there were unequal numbers of participants per group, it is difficult to determine whether this was due to a failure of randomisation.

Yang 2006

Methods	Randomised trial of moxibustion plus knee-chest therapy compared with knee-chest therapy.
Participants	206 women with breech presentation were randomised to the trial. Women were between 28 and 34 weeks' gestation. No exclusion criteria were reported. While it was not reported whether all women had a singleton pregnancy, this was assumed. Women were recruited from a hospital in Shandong Province, China.
Interventions	Women were randomly allocated to receive either moxibustion plus knee-chest therapy, or knee-chest therapy alone (control group). 103 women received moxibustion to BL67 for 15-20 minutes twice daily, with 7 days constituting 1 course. The duration of intervention was 1 week. 103 women were allocated to receive knee-chest therapy alone. The details of knee-chest therapy were not reported.
Outcomes	The primary outcome was cephalic version.
Notes	No sample size calculation was performed.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Group allocation by date of admission.
Allocation concealment (selection bias)	Unclear risk	The method of concealment was not reported.

Yang 2006 *(Continued)*

Blinding (performance bias and detection bias) All outcomes	Low risk	It was not feasible to blind the participant or the therapist, and it was unclear whether the outcome assessor and analyst were blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	There was complete follow-up for all women.
Selective reporting (reporting bias)	Unclear risk	Study protocol unavailable; unable to determine whether all outcomes were pre-specified.
Other bias	Unclear risk	There is insufficient information to determine whether other bias is present.

BL67: Bladder 67
ECV: external cephalic version

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

Study	Reason for exclusion
Beer 1995	The study by Beer 1995 compared 55 women who received moxibustion to a observation group of 615 women, and to a laser-acupuncture group. The study was not a randomised controlled trial. The study found a lower version rate in the moxibustion group.
Cardini 1991	The study by Cardini 1991, which involved 33 women between 30 and 38 weeks' gestation, was not included in the review as it was not a randomised controlled trial. Moxibustion was applied to BL67 for 30 minutes daily, for 15 days. The study suggested that moxibustion may assist version of a breech presentation.
Huang 1990	The study by Huang 1990 compared moxibustion to knee-chest-side-lying position and to a no treatment control. 587 women were included in the trial, however, as the method of group allocation was not reported, the decision was made to exclude the trial from the review.
Kanakura 2001	The non-randomised trial by Kanakura 2001 compared moxibustion with low frequency percutaneous stimulation and a retrospective no intervention control. 548 women in the 28th week of pregnancy or beyond were included in the trial, with the primary outcome measure of correction rate of breech presentation. The trial was not randomised and therefore was not included in the review.
Manyande 2009	The trial by Manyande 2009 recruited 76 women between 32 and 38 weeks' gestation with a breech presentation. Women were taught to apply moxibustion at home. Moxibustion was applied twice per day for 7 days. The trial was not randomised, and therefore was not included in this review.
Neri 2002	The trial by Neri 2002 recruited 15 women between 33 and 34 weeks' gestation with a singleton pregnancy with breech presentation. Women received a single session of placebo acupuncture, followed 1 to 2 days later by additional sessions of acupuncture plus moxibustion to BL67. The primary outcome was fetal heart activity, and was not relevant to this review.
Qin 1989	The trial by Qin 1989 evaluated auricular plaster therapy for breech presentation in 536 women of 30 weeks' gestation or more. *Vacarria segetalis* seeds were fixed to 7 points on the ear, and participants were instructed to stimulate the points for five minutes, 3 times per day before meals. The trial did not evaluate moxibustion and was therefore not included in this review.
Raben 1999	The trial by Raben 1999 compared moxibustion plus acupuncture in 54 primigravidae with breech presentation between 34 and 37 weeks' gestation. Data were compared with expected rate of spontaneous version as reported in the literature. The trial was not randomised.

Study	Reason for exclusion
Wagner-Pankl 1990	The non-randomised trial by Wagner-Pankl 1990 compared moxibustion with no treatment from 30 weeks' gestation. The trial found the version rate was higher in the control group than in the intervention group.
Wu 1994	The study by Wu 1994 compared acupuncture plus moxibustion at 2 different acupuncture points at varying times during pregnancy. It was unclear whether women met inclusion/exclusion criteria, and the method of group allocation is unclear.

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

Li 1996

Methods	Randomised trial of acupuncture compared with electro-acupuncture and control (no treatment).
Participants	111 women were randomised to the trial, 76 were primiparous and 35 were multiparous. Inclusion criteria were women greater than 28 weeks' gestation, with a breech (40 women), transverse (34) or occipitoposterior presentation (28). The presentation of the remaining 9 women was not reported. While it was not reported whether all women had a singleton pregnancy, this was assumed. Exclusion criteria were not described. The setting for the trial was not reported, but was undertaken in China.
Interventions	Women were randomly allocated to either the moxibustion group, to an electroacupuncture group, or to a control group. 32 women were allocated to the moxibustion group, and received moxibustion to BL67 for 20 minutes. 48 women were randomised to the electroacupuncture group, and received electroacupuncture to BL67 for 30 minutes; the frequency and intensity of stimulation was determined by the maximum tolerance of the patient. In both groups, up to 6 sessions were administered, the timing of which was not mentioned. 31 women were allocated to the control group.
Outcomes	The primary outcomes were presentation at time of birth and number of treatments needed for correction.
Notes	No sample size calculation was performed. While occipitoposterior presentation is not classified as breech, the trial was still included as the majority of presentations (74/111) were in breech position. Further data being requested from trialists.

Millereau 2009

Methods	
Participants	
Interventions	
Outcomes	
Notes	Awaiting translation.

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

Smith 2009

Trial name or title	Moxibustion for cephalic version: a feasibility study.
Methods	Randomised controlled trial of moxibustion compared with usual care.
Participants	Pregnant women aged at least 18 years, with a singleton breech presentation confirmed by ultrasound at 34 weeks. Exclusion criteria: twin pregnancy, risk of premature birth, heart or kidney disease affecting the mother, placenta previa, a history of antepartum haemorrhage, intrauterine growth restriction, hypertensive disease, isoimmunization, previous uterine operations, uterine anomaly, prelabour rupture of the membranes, multiple pregnancy, fetal congenital abnormality, contraindication to vaginal delivery, or fetal death in utero.
Interventions	Moxibustion to acupuncture point BL67, located on the lateral side of the 5th toe. Training will demonstrate the safe use of moxa. Moxa will be applied twice a day, for a total time of 20 minutes. The procedure is performed for 10 days. The usual care group will receive standard care according to John Hunter Hospital protocol.
Outcomes	Need for external cephalic version, mode of birth; perinatal morbidity and mortality, maternal complications and maternal satisfaction, adverse events.
Starting date	December 2009.
Contact information	Associate Professor Caroline Smith +61 24620 3777
Notes	Australian New Zealand Clinical Trials Registry (accessed 8 February 2010).

Vas 2008

Trial name or title	Correcting non cephalic presentation with moxibustion: study protocol for a multi-centre randomised controlled trial in general practice.
Methods	Multi-centre randomised controlled trial.
Participants	Pregnant women with non-cephalic presentation. Inclusion criteria are over 18 years, gestational age of 33-35 weeks, non-cephalic presentation, normal fetal biometry, and no previous use of moxibustion to correct fetal position. Exclusion criteria are twin pregnancy, pelvic defect, previous uterine surgery, fetal malformation or chromosome disorder, uterine malformation, risk of premature birth, uterine fibromas > 4 cm, treatment with tocolytic drugs, heart of kidney disease affecting the mother, other non-pregnancy complications, or incapacity to complete the questionnaire or respond to assessor's questions.
Interventions	Random allocation to 1 of 3 groups: true moxibustion (moxibustion to BL67); sham moxibustion (moxibustion to SP1); or control group (standard care). All participants will be given postural recommendations.
Outcomes	Primary outcome is the rate of cephalic presentation at term. Secondary outcomes include the rate of cephalic presentation at 38 weeks' gestation, and the number of days of treatment until version occurs.
Starting date	April 2008.
Contact information	Corresponding author: Jorge Vas. Email jorgef.vas.sspa@juntadeandalucia.es
Notes	Due for completion Dec 2010.

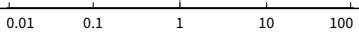
DATA AND ANALYSES

Comparison 1. Moxibustion versus no treatment

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Non-cephalic presentation at birth	3	594	Risk Ratio (M-H, Random, 95% CI)	0.90 [0.67, 1.19]
2 Need for ECV	2	472	Risk Ratio (M-H, Random, 95% CI)	0.67 [0.34, 1.32]
3 Caesarean section	2	472	Risk Ratio (M-H, Fixed, 95% CI)	1.05 [0.87, 1.26]
4 Premature rupture of membranes	2	382	Risk Ratio (M-H, Random, 95% CI)	0.82 [0.07, 9.31]
5 Use of oxytocin	1	161	Risk Ratio (M-H, Fixed, 95% CI)	0.28 [0.13, 0.60]
6 Apgar score < 7 at 5 minutes	2	472	Risk Ratio (M-H, Random, 95% CI)	0.26 [0.02, 4.27]
7 Intrauterine fetal death	1	260	Risk Ratio (M-H, Fixed, 95% CI)	0.33 [0.01, 8.11]
8 Placental abruption	1	122	Risk Ratio (M-H, Fixed, 95% CI)	0.29 [0.01, 7.05]
9 Adverse events	1	122	Risk Ratio (M-H, Fixed, 95% CI)	48.33 [3.01, 774.86]
10 Duration of hospital stay (days)	1	212	Mean Difference (IV, Fixed, 95% CI)	-0.10 [-0.55, 0.35]
11 Cord blood pH less than 7.1	1	212	Risk Ratio (M-H, Random, 95% CI)	3.0 [0.32, 28.38]

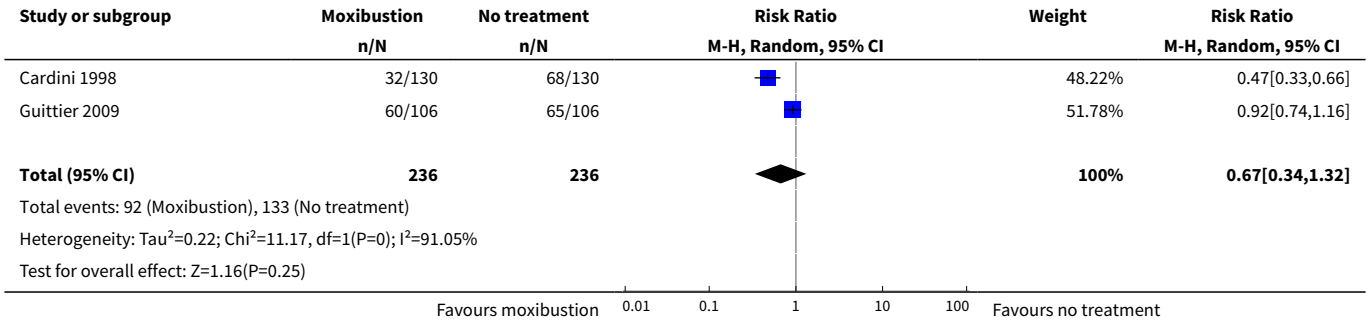
Analysis 1.1. Comparison 1 Moxibustion versus no treatment, Outcome 1 Non-cephalic presentation at birth.

Study or subgroup	Moxibustion n/N	No treatment n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Cardini 1998	32/130	49/130		28.59%	0.65[0.45,0.95]
Cardini 2005	31/65	28/57		29.07%	0.97[0.67,1.4]
Guittier 2009	66/106	63/106		42.34%	1.05[0.84,1.3]
Total (95% CI)	**301**	**293**		**100%**	**0.9[0.67,1.19]**
Total events: 129 (Moxibustion), 140 (No treatment)					
Heterogeneity: Tau^2=0.04; Chi^2=4.96, df=2(P=0.08); I^2=59.71%					
Test for overall effect: Z=0.76(P=0.45)					

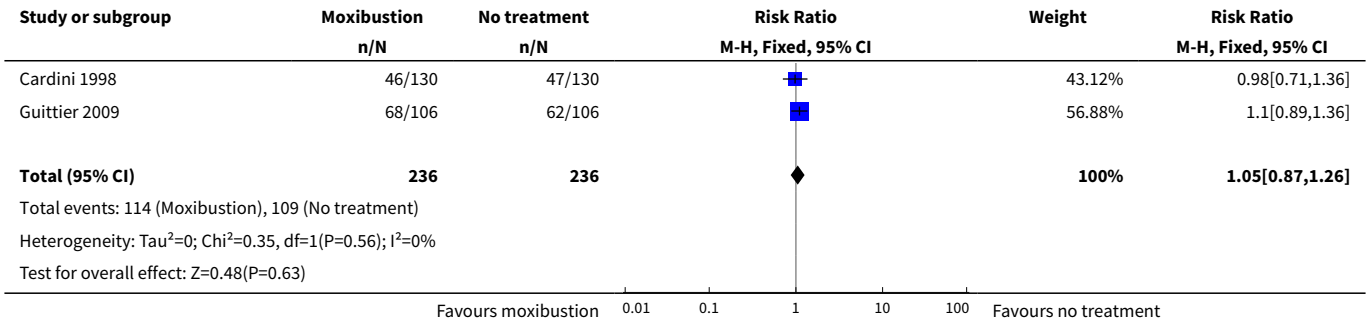


Favours moxibustion — Favours no treatment

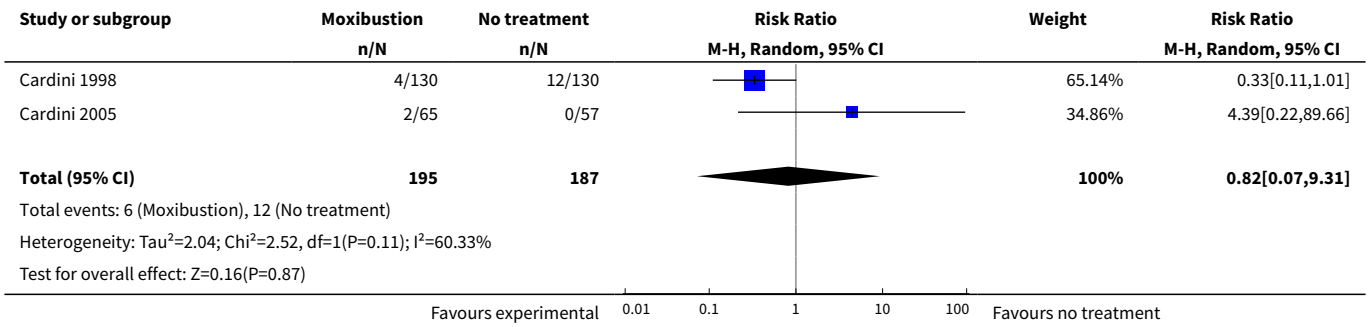
Analysis 1.2. Comparison 1 Moxibustion versus no treatment, Outcome 2 Need for ECV.



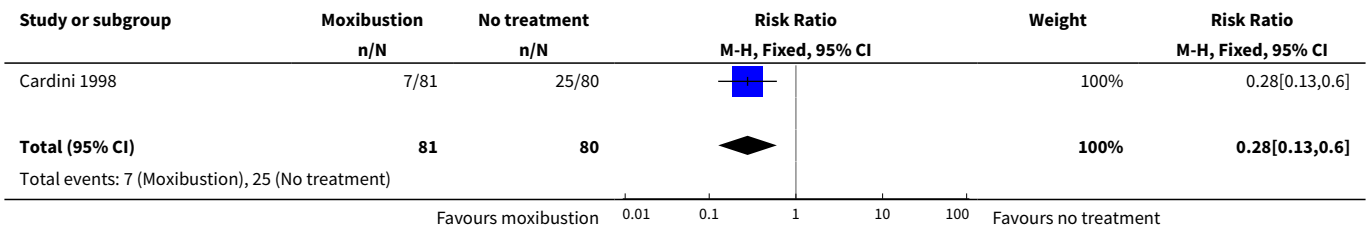
Analysis 1.3. Comparison 1 Moxibustion versus no treatment, Outcome 3 Caesarean section.

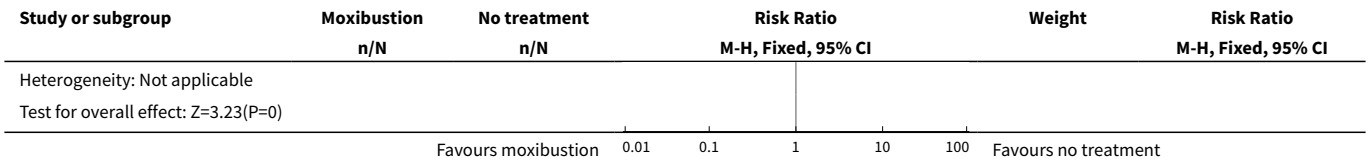


Analysis 1.4. Comparison 1 Moxibustion versus no treatment, Outcome 4 Premature rupture of membranes.

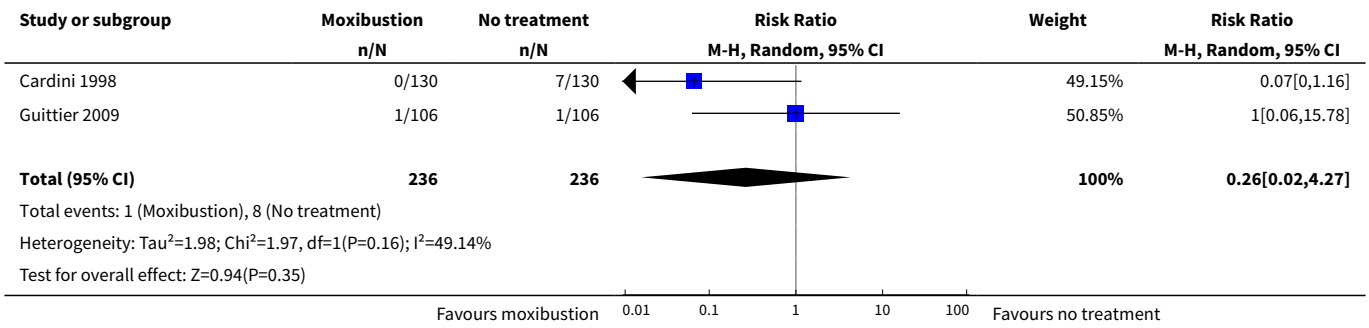


Analysis 1.5. Comparison 1 Moxibustion versus no treatment, Outcome 5 Use of oxytocin.

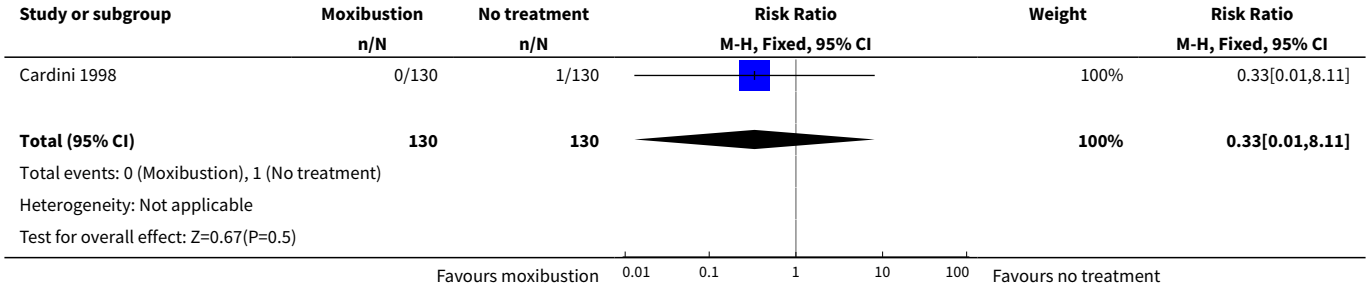




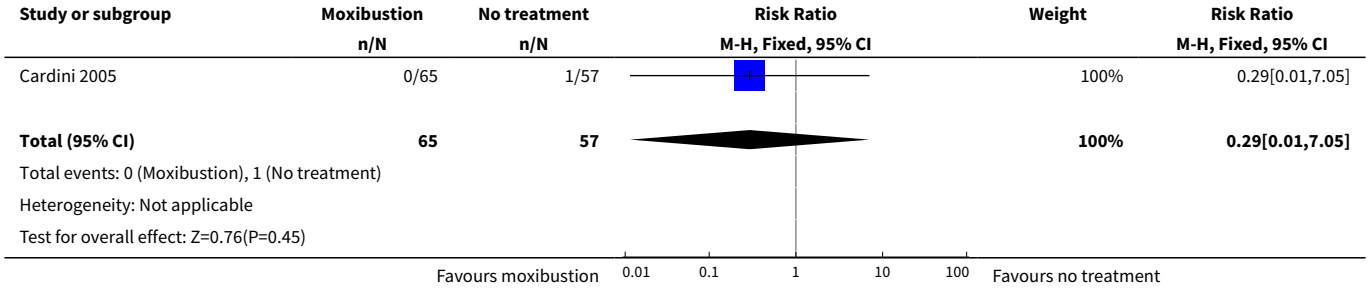
Analysis 1.6. Comparison 1 Moxibustion versus no treatment, Outcome 6 Apgar score < 7 at 5 minutes.



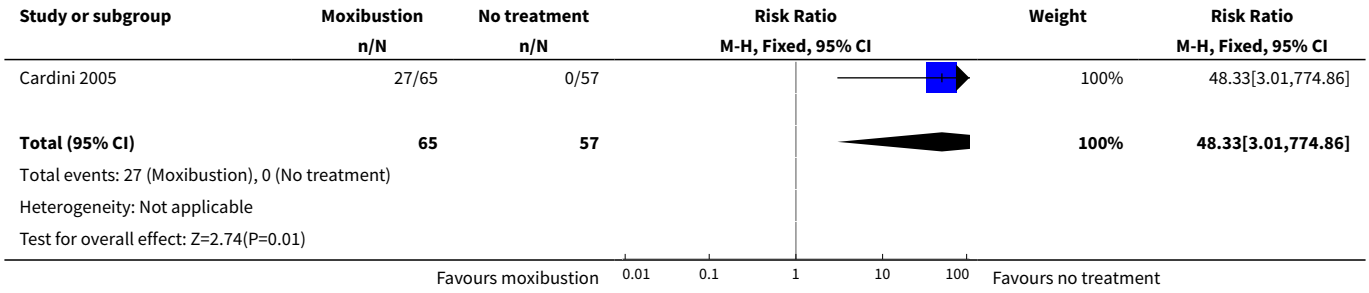
Analysis 1.7. Comparison 1 Moxibustion versus no treatment, Outcome 7 Intrauterine fetal death.



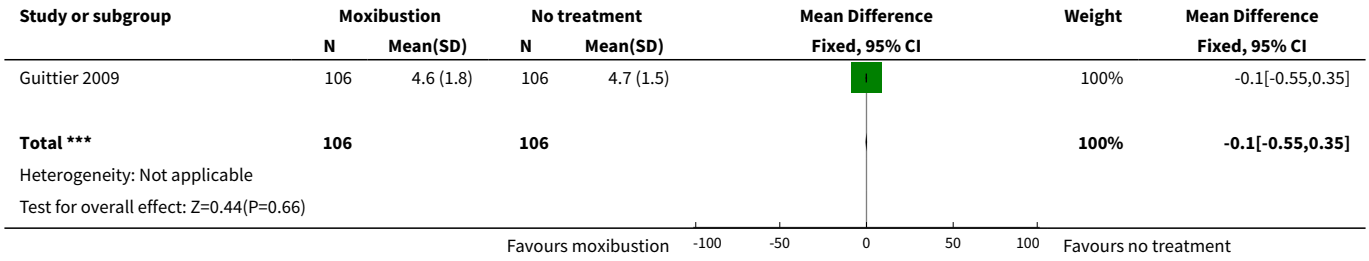
Analysis 1.8. Comparison 1 Moxibustion versus no treatment, Outcome 8 Placental abruption.



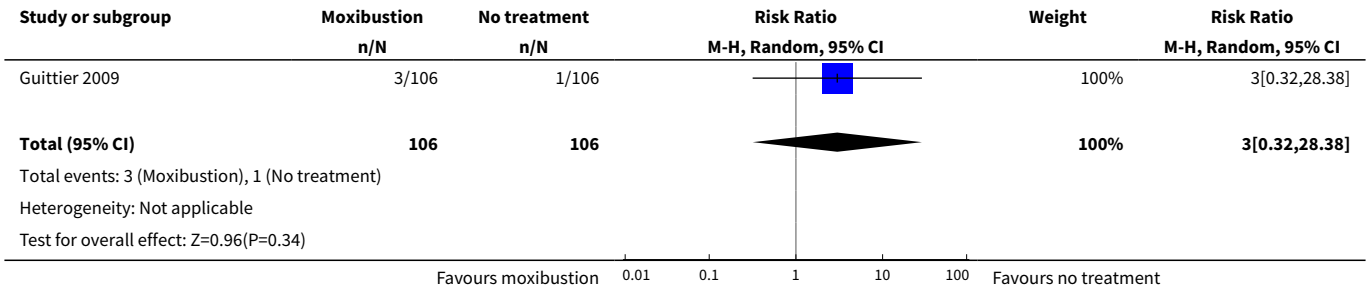
Analysis 1.9. Comparison 1 Moxibustion versus no treatment, Outcome 9 Adverse events.



Analysis 1.10. Comparison 1 Moxibustion versus no treatment, Outcome 10 Duration of hospital stay (days).



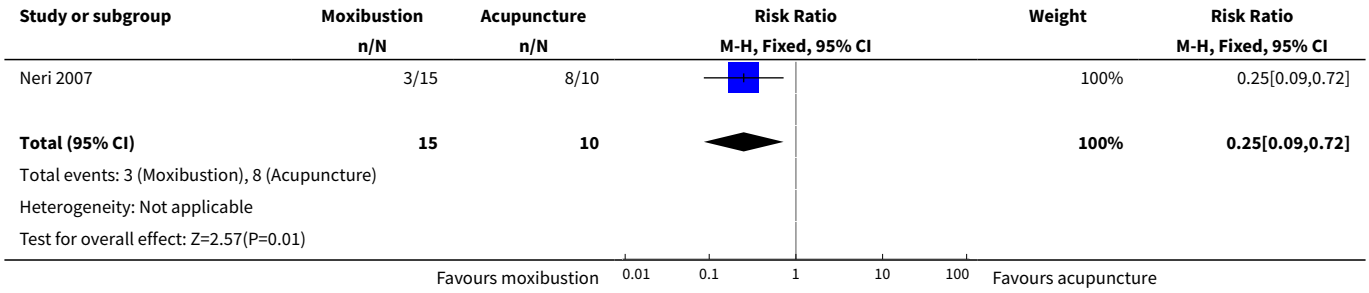
Analysis 1.11. Comparison 1 Moxibustion versus no treatment, Outcome 11 Cord blood pH less than 7.1.



Comparison 2. Moxibustion versus acupuncture

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Non-cephalic presentation at birth	1	25	Risk Ratio (M-H, Fixed, 95% CI)	0.25 [0.09, 0.72]

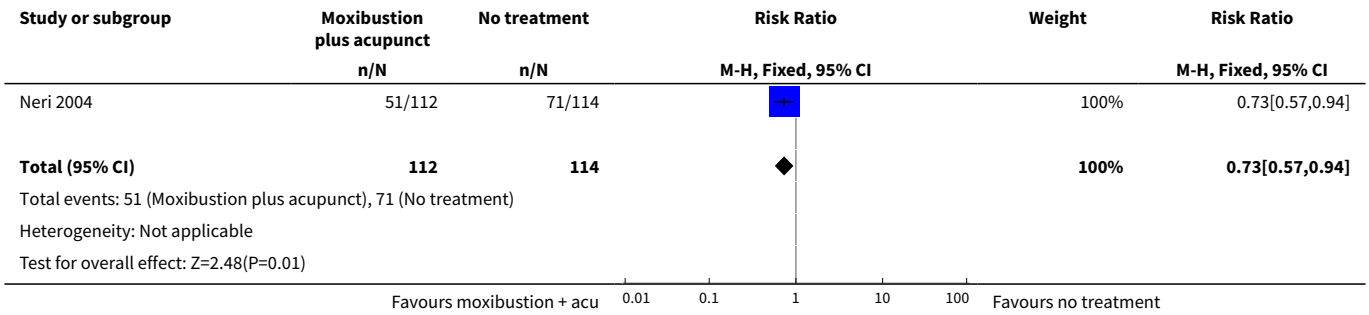
Analysis 2.1. Comparison 2 Moxibustion versus acupuncture, Outcome 1 Non-cephalic presentation at birth.



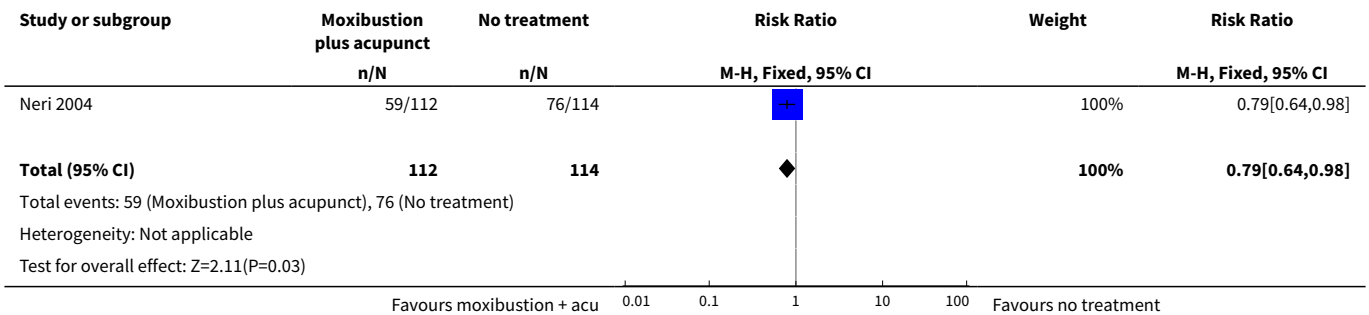
Comparison 3. Moxibustion plus acupuncture versus no treatment

Outcome or subgroup title	No. of studies	No. of partici-pants	Statistical method	Effect size
1 Non-cephalic presentation at birth	1	226	Risk Ratio (M-H, Fixed, 95% CI)	0.73 [0.57, 0.94]
2 Caesarean section	1	226	Risk Ratio (M-H, Fixed, 95% CI)	0.79 [0.64, 0.98]

Analysis 3.1. Comparison 3 Moxibustion plus acupuncture versus no treatment, Outcome 1 Non-cephalic presentation at birth.



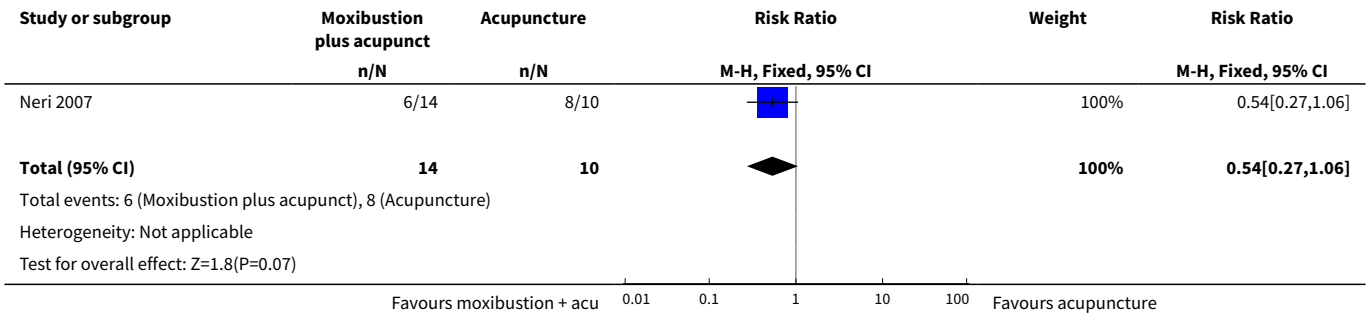
Analysis 3.2. Comparison 3 Moxibustion plus acupuncture versus no treatment, Outcome 2 Caesarean section.



Comparison 4. Moxibustion plus acupuncture versus acupuncture

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Non-cephalic presentation at birth	1	24	Risk Ratio (M-H, Fixed, 95% CI)	0.54 [0.27, 1.06]

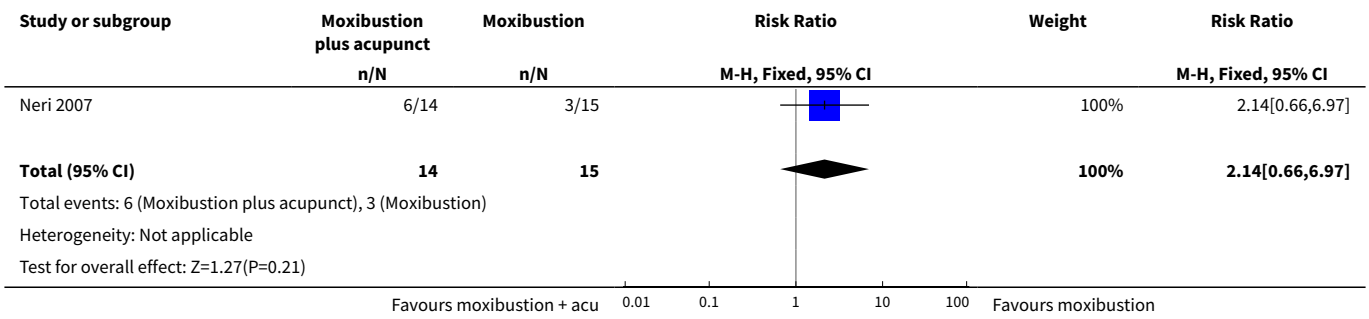
Analysis 4.1. Comparison 4 Moxibustion plus acupuncture versus acupuncture, Outcome 1 Non-cephalic presentation at birth.



Comparison 5. Moxibustion plus acupuncture versus moxibustion

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Non-cephalic presentation at birth	1	29	Risk Ratio (M-H, Fixed, 95% CI)	2.14 [0.66, 6.97]

Analysis 5.1. Comparison 5 Moxibustion plus acupuncture versus moxibustion, Outcome 1 Non-cephalic presentation at birth.

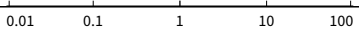


Comparison 6. Moxibustion plus postural technique versus postural technique

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Non-cephalic presentation at birth	3	470	Risk Ratio (M-H, Random, 95% CI)	0.26 [0.12, 0.56]

Analysis 6.1. Comparison 6 Moxibustion plus postural technique versus postural technique, Outcome 1 Non-cephalic presentation at birth.

Study or subgroup	Moxibustion plus postural n/N	Postural technique n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Chen 2004	6/73	33/69		32.17%	0.17[0.08,0.38]
Lin 2002	5/63	28/59		30.09%	0.17[0.07,0.4]
Yang 2006	13/103	26/103		37.74%	0.5[0.27,0.92]
Total (95% CI)	**239**	**231**		**100%**	**0.26[0.12,0.56]**
Total events: 24 (Moxibustion plus postural), 87 (Postural technique)					
Heterogeneity: Tau^2=0.32; Chi^2=6.34, df=2(P=0.04); I^2=68.44%					
Test for overall effect: Z=3.43(P=0)					



Favours experimental — Favours control

APPENDICES

Appendix 1. Additional search strategy

In addition to searching the Cochrane Pregnancy and Childbirth Group's Trials Register, we searched MEDLINE (1966 to 1 August 2011), EMBASE (1980 to 1 August 2011), CINAHL (1982 to 1 August 2011), AMED (1985 to 1 August 2011) and MIDIRS (1982 to 1 August 2011). Due to the small numbers of studies identified through the electronic searches it was possible to review the results of each line, for example, we reviewed all the results of lines 7 to 16 in the MEDLINE and AMED search and lines 9 to 12 in the EMBASE search.

MEDLINE and AMED search strategy:

1. Breech Presentation/ or breech.mp. or Labor Presentation/

2. acupuncture.mp.

3. moxbustion.mp. or *Moxibustion/

4. *Moxibustion/ or moxa.mp.

5. artemisia vulgaris.mp. or Artemisia/

6. version.mp. or Version, Fetal/

7. 1 and 3

8. 1 and 4

9. 1 and 5

10. 1 and 2

11. 2 and 6

12. 3 and 6

13. 4 and 6

14. 5 and 6

15. 3 and 10

16. 3 and 11

EMBASE search strategy

1. breech

2. 'breech position'/exp OR 'breech position'

3. version

4. 'moxibustion'/exp OR moxibustion

5. 'acupuncture'/exp OR acupuncture

6. moxa

7. 'artemisia'/exp OR Artemisia AND vulgaris

8. #1 AND #2 AND #3

9. #4 AND #8

10. #5 AND #8

11. #6 AND #8

12. #7 AND #8

CINAHL Plus search strategy

S1. acupuncture OR moxibustion

S2. acupuncture OR moxibustion OR moxa OR Artemisia vulgaris

S3. breech OR version

S4. (breech OR version) and (S2 and S3)

MIDIRS search- keyword search

Search query

1. moxibustion

2. moxa

3. acupuncture

4. artemisia vulgaris

5. breech

6. version

Appendix 2. Data collection and analysis methods used in previous versions of this review.

We evaluated the appropriateness of trials for inclusion. Where there was uncertainty about inclusion of the study, the full text was retrieved. We contacted the original author for further information if necessary. If there was disagreement between authors about the studies to be included that could not be resolved by discussion, we sought assistance from the third reviewer. Reasons for excluding trials were stated.

Following an assessment for inclusion, we assessed the methodology of the trial. We extracted the data onto hard copy data sheets. Meaghan Coyle and Caroline Smith extracted the data and assessed quality.

We assessed included trials according to the following five main criteria:

1. adequate concealment of treatment allocation (e.g. opaque/sealed numbered envelopes, sequentially numbered envelopes, central randomisation);
2. adequate method of allocation to treatment (e.g. by computer randomisation, random number tables, lot drawing, coin tossing, shuffling cards, throwing dice);
3. adequate documentation of how exclusions were handled after treatment allocation - to facilitate intention-to-treat analysis;
4. adequate blinding of outcome assessment (e.g. outcome assessor and data analyst blinded); and
5. losses to follow up (trials with losses greater than 25% will be excluded from the analysis).

We assigned quality scores to each trial, using the criteria described in section six of the Cochrane Reviewers' Handbook (Clarke 2003).
(A) was used to indicate a trial which has a high level of quality in which all the criteria are met;
(B) was used to indicate that one or more criteria were partially met or if it is unclear if all the criteria were met; and
(C) was used if one or more criteria were not met.

In addition, we assigned quality scores to each trial for completeness of follow up and blinding of outcome assessment as follows:
For completeness of follow up:
(A) less than 3% of participants excluded;
(B) 3% to 9.9% of participants excluded;
(C) 10% to 19.9% of participants excluded;
(D) 20% or more of participants excluded; and
(E) unclear.

For blinding of assessment outcome:
(A) double blind, neither investigator nor participant knew or were likely to guess the allocated group;
(B) single blind, either the investigator or the participant knew the allocation, or the trial is described as double blind but side-effects of one or other treatment meant that it is likely that for a significant proportion (7% to 20%) of participants could correctly identify their treatment allocation;
(C) no blinding, both investigator and participant knew (or were likely to guess) the allocated treatment; and
(D) unclear.

We entered data directly from the published reports into the Review Manager 4.2 software (RevMan 2002) with double data entry performed by the co-author (Caroline Smith). 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 telephone call.

Due to the nature of the interventions, double blinding of assessments was not possible; therefore, we considered for inclusion studies where there was no double blinding of assessments. An intention-to-treat analysis would have enhanced the quality of the trial but was not present in all retrieved trials. We included only studies in which data were reported by allocated group. Where moxibustion was used in combination with another intervention, a separate comparison was made due to incompatibility of the interventions. We performed statistical analysis using the Review Manager software (RevMan 2002). For dichotomous data, we calculated relative risks and 95% confidence intervals calculated. The I^2 statistic was used to detect statistical heterogeneity, with a score of greater than 50% indicating significant heterogeneity.

WHAT'S NEW

Date	Event	Description
21 February 2012	New citation required and conclusions have changed	There is now some evidence to support the use of moxibustion (in combination with other methods) to correct a breech presentation (as well as improve other outcomes relevant to this re-

Date	Event	Description
		view). However, the results should be interpreted with caution because of statistical and clinical heterogeneity.
31 August 2011	New search has been performed	Search updated. Eleven new trials were identified. Six new trials have been included (Cardini 2005; Chen 2004; Guittier 2009; Lin 2002; Neri 2007; Yang 2006) and two excluded (Huang 1990; Manyande 2009). Two trials are ongoing (Smith 2009; Vas 2008) and one is awaiting classification (Millereau 2009). One trial that was previously 'awaiting classification' has now been excluded (Wu 1994).

HISTORY

Protocol first published: Issue 4, 2002
Review first published: Issue 2, 2005

Date	Event	Description
14 April 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

Meaghan Coyle undertook additional searching to identify papers relevant to this review update. Meaghan Coyle and Caroline Smith selected trials for inclusion, performed data extraction and assessment of the quality of included trials. Meaghan Coyle performed statistical analysis and interpretation of the data in the review update. Caroline Smith was involved in interpreting data and commenting on drafts of the review update.

Meaghan Coyle conceptualised and took the lead in writing the original protocol and review, performed initial searches of databases for trials, was involved in selecting trials for inclusion, performed data extraction and assessment of the quality of included trials, was responsible for statistical analysis and interpretation of the data.

Caroline Smith was involved with selecting trials for inclusion in the original review, performed data extraction and assessment of quality of included trials, interpreting the data and commenting on drafts of the original protocol and the review.

Brian Peat commented on the protocol, the original review and this update.

DECLARATIONS OF INTEREST

Caroline Smith is an investigator of a pilot study (Smith 2009 ongoing study) to examine the effect of moxibustion on breech presentation. In future updates of this review, assessment of this trial for inclusion in this review (as well as assessment of trial quality and data extraction) will be carried out by other member of the review team who are not directly involved in the study.

SOURCES OF SUPPORT

Internal sources

- The University of Adelaide, Australia.
- The University of South Australia, Australia.
- Monash University, Australia.
- University of Western Sydney, Australia.

External sources

- Australian Department of Health and Ageing, Australia.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The methods have been updated to reflect the latest Cochrane Handbook (Higgins 2011).

INDEX TERMS

Medical Subject Headings (MeSH)

Acupuncture Points; Acupuncture Therapy [methods]; Breech Presentation [*therapy]; Moxibustion [adverse effects] [*methods]; Randomized Controlled Trials as Topic; Version, Fetal [*methods]

MeSH check words

Female; Humans; Pregnancy