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Aromatherapy for pain management in labour (Review)

Smith CA, Collins CT, Crowther CA

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[Intervention Review]

Aromatherapy for pain management in labour

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ABSTRACT

Background

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

Objectives

To examine the effects of aromatherapy for pain management in labour on maternal and perinatal morbidity.

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (31 October 2010), The Cochrane Complementary Medicine Field's Trials Register (October 2010), the Cochrane Central Register of Controlled Trials (*The Cochrane Library* 2010, Issue 4), MEDLINE (1966 to 31 October 2010), CINAHL (1980 to 31 October 2010), the Australian and New Zealand Trials Registry (31 October 2010), Chinese Clinical Trial Register (31 October 2010), Current Controlled Trials (31 October 2010), ClinicalTrials.gov (31 October 2010), ISRCTN Register (31 October 2010), National Center for Complementary and Alternative Medicine (NCCAM) (31 October 2010) and the WHO International Clinical Trials Registry Platform (31 October 2010).

Selection criteria

Randomised controlled trials comparing aromatherapy with placebo, no treatment or other non-pharmacological forms of pain management in labour.

Data collection and analysis

Two authors independently assessed trial quality and extracted data. We contacted study authors for additional information.

Main results

We included two trials (535 women) in the review. The trials found no difference between groups for the primary outcomes of pain intensity, assisted vaginal birth (risk ratio (RR) 1.04, 95% confidence interval (CI) 0.48 to 2.28, one trial, 513 women; RR 0.83, 95% CI 0.06 to 11.70, one trial, 22 women), and caesarean section (RR 0.98, 95% CI 0.49 to 1.94, one trial, 513 women; RR 2.54, 95% CI 0.11 to 56.25, one trial, 22 women); there were more babies admitted to neonatal intensive care in the control group of one trial (RR 0.08, 95% CI 0.00 to 1.42, one trial, 513 women) but this difference did not reach statistical significance. The trials found no differences between groups for the secondary outcomes of use of pharmacological pain relief (RR 0.35, 95% CI 0.04 to 3.32, one trial, 513 women; RR 2.50, 95% CI 0.31 to 20.45, one trial,

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22 women), spontaneous vaginal delivery (RR 1.00, 95% CI 0.94 to 1.06, one trial, 513 women; RR 0.93, 95% CI 0.67 to 1.28, one trial, 22 women) or length of labour and augmentation (RR 1.14, 95% CI 0.90 to 1.45, one trial, 513 women). The risk of bias was low in the trials.

Authors' conclusions

There is a lack of studies evaluating the role of aromatherapy for pain management in labour. Further research is needed before recommendations can be made for clinical practice.

PLAIN LANGUAGE SUMMARY

Aromatherapy for pain management in labour

Aromatherapy draws on the healing power of plants with the use of essential oils to enhance physical and mental wellbeing. The oils may be massaged into the skin, in a bath or inhaled using a steam infusion or burner. The pain of labour can be intense, with tension, fear and anxiety making it worse. Many women would like to labour without using drugs, or invasive methods such as an epidural, and turn to complementary therapies to help reduce their pain perception Many complementary therapies are tried and include acupuncture, mind-body techniques, massage, reflexology, herbal medicines or homoeopathy, hypnosis, music and aromatherapy. The review identified two randomised controlled trials of aromatherapy. One trial involving 513 women compared one of Roman chamomile, clary sage, frankincense, lavender or mandarin essentials oils with standard care. The aromatherapy was applied using acupressure points, taper, compress, footbath, massage or a birthing pool. The second trial involved 22 women randomised to bathe for at least an hour in water with either essential oil of ginger or lemongrass added. All women received routine care and had access to pain relief. The trials found no difference between groups for pain intensity, assisted vaginal birth, caesarean section or the use of pharmacological pain relief (epidural). Overall, there is insufficient evidence from randomised controlled trials about the benefits of aromatherapy on pain management in labour. More research is needed.



BACKGROUND

This review is one in a series of Cochrane reviews examining pain management in labour. These reviews contribute to an overview of systematic reviews of pain management for women in labour (Neilson 2011b), and share a generic protocol (Neilson 2011a).

Description of the condition

Labour presents a physiological and psychological challenge for women. As labour becomes more imminent this can be a time of conflicting emotions; fear and apprehension can be coupled with excitement and happiness. Pain associated with labour has been described as one of the most intense forms of pain that can be experienced (Melzack 1984). Pain experienced by women in labour is caused by uterine contractions, the dilatation of the cervix and, in the late first stage and second stage, the stretching of the vagina and pelvic floor to accommodate the baby. Tension, anxiety and fear are factors contributing towards women's perception of pain and may also affect their labour and birth experience.The neuromatrix theory of pain understands the influence of many factors including past experience and memory (Melzack 2001). In labour the theory of pain incorporates elements of the gate control theory, but also past experiences, cultural factors, emotional state, cognitive input, stress regulation and immune systems, as well as immediate sensory input (Trout 2004). Effective and satisfactory pain management needs to be individualised for each woman, and may be influenced by two paradigms: working with pain, or pain relief (Leap 1997). The working with pain paradigm includes the belief that there are long-term benefits to promoting normal birth, and that pain plays an important role in this process. The working with pain approach offers support and encouragement to women, advocates the use of immersion in water, comfortable positions and self-help techniques to cope with normal labour pain. The pain relief paradigm is characterised by the belief that no woman need suffer pain in labour and women are offered a variety of pharmacological pain relief.

Description of the intervention

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

The Complementary Medicine Field of the Cochrane Collaboration defines complementary medicine as 'practices and ideas which are outside the domain of conventional medicine in several countries', which are defined by its users as 'preventing or treating illness, or promoting health and wellbeing' (Manheimer 2008). This definition is deliberately broad, as therapies considered complementary practices in one country or culture may be conventional in another. Many therapies and practices are included within the scope of the Complementary Medicine Field. These include treatments people can administer themselves (e.g. botanicals, nutritional supplements, health food, meditation, magnetic therapy), treatments providers administer (e.g. acupuncture, massage, reflexology, chiropractic and osteopathic manipulations), and treatments people can administer under the periodic supervision of a provider (e.g. yoga, biofeedback, Tai Chi, homoeopathy, Alexander therapy, Ayurveda).

The most commonly cited complementary medicine and practices associated with providing pain management in labour can be categorised into mind-body interventions (e.g. yoga, hypnosis, relaxation therapies), whole medical systems (e.g. homoeopathy, traditional Chinese medicine), manual healing methods (e.g. massage, reflexology), pharmacologic and biological treatments, bioelectromagnetic applications (e.g. magnets) and herbal medicines.

Aromatherapy involves the use of the essential oils, which are volatile, fragrant organic compounds obtained by distillation for plant material derived from roots, leaves, bark, seeds and flowers. The essential oils are usually mixed with a carrier oil. These are virgin or cold-pressed and the clinical presentation is matched with the carrier oil. All-purpose carrier oils include grapeseed, sweet almond and sesame. Other carrier oils include herbal oils that contain active ingredients including calendula, arnica, shea butter or aloe vera. The mechanism of action for aromatherapy is unclear. Studies investigating psychological and physiological effects of essential oils showed no change on physiological parameters such as blood pressure or heart rate, but did produce psychological improvement in mood and anxiety levels (Stevensen 1995). Essential oils are thought to increase the output of the body's own sedative, stimulant and relaxing substances. The oils may be massaged into the skin, or inhaled by using a steam infusion or burner. Aromatherapy is increasing in popularity among midwives and nurses (Allaire 2000). The most common application of aromatherapy during labour is by massage, bath or inhalation, and two oils commonly used include lavender and frankincense (Simkin 2004). Other essential oils used during labour and delivery include eucalyptus, jasmine, roman chamomile (pain), clary sage (increase contractions), lemon (elevated mood), mandarin, nerdi, ylang ylang (relaxation) and rose (anxiety) (Burns 1999; Tiran 2000).

There have been no studies or published anecdotal evidence that demonstrate harm from essential oils to mother or fetus (Tillett 2010), although a review of the use of essential oils in 8058 women found 1% had a mild unpleasant response to oils including rose, jasmine, chamomile, eucalyptus, lemon, mandarin, clary sage, frankincense, lavender and peppermint; no responses were harmful to the woman or the fetus (Burns 2000). Essential oils are concentrated substances and in some cases can cause skin irritations; conducting a patch test on the skin can check for allergies (Tillett 2010).

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OBJECTIVES

To examine the effects of aromatherapy for pain management in labour on maternal and perinatal morbidity.

This review examines the hypotheses that the use of aromatherapy is:

- 1. an effective means of pain management in labour as measured by decreases in women's rating of labour pain: a reduced need for pharmacological intervention;
- 2. improved maternal satisfaction or maternal emotional experience; and
- 3. aromatherapy has no adverse effects on the mother (duration of labour, mode of deliver) or baby.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) only. (We do not plan to include results from quasi-RCTs in the analyses but we may be discuss them in the text if little other evidence is available.)

Types of participants

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

Types of interventions

This review is one in a series of Cochrane reviews examining pain management in labour. These reviews contribute to an overview of systematic reviews of interventions for pain management in labour (Neilson 2011b), and share a generic protocol (Neilson 2011a). To avoid duplication, the different methods of pain management have been listed in a specific order, from one to 15. Individual reviews focusing on particular interventions include comparisons with only the intervention above it on the list. Methods of pain management identified in the future will be added to the end of the list. The current list is as follows.

- 1. Placebo/no treatment
- 2. Hypnosis
- 3. Biofeedback (Barragán 2006)
- 4. Intracutaneous or subcutaneous sterile water injection (Derry 2011)
- 5. Immersion in water (Cluett 2009)
- 6. Aromatherapy (this review)
- 7. Relaxation techniques (yoga, music, audio)
- 8. Acupuncture or acupressure (Smith 2011)
- 9. Manual methods (massage, reflexology)
- 10.Transcutaneous electrical nerve stimulation (TENS) (Dowswell 2009)
- 11.Inhaled analgesia
- 12.Opioids (Ullman 2010)
- 13.Non-opioid drugs (Othman 2011)
- 14.Local anaesthetic nerve blocks

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15.Epidural (including combined spinal epidural) (Anim-Somuah 2005; Simmons 2007)

Accordingly, this review includes comparisons of one form of aromatherapy compared with any other form of aromatherapy, or aromatherapy compared with: 1. placebo/no treatment; 2. hypnosis; 3. biofeedback; 4. sterile water injection; or 5. immersion in water.

Types of outcome measures

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

Primary outcomes

Effects of interventions

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

Safety of interventions

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

Other outcomes

Cost (as defined by trialists)

Secondary outcomes

Maternal

Use of pharmacological pain relief in labour; spontaneous vaginal delivery; length of labour; need for augmentation with oxytocin; perineal trauma (defined as episiotomy and incidence of secondor third-degree tear); and maternal blood loss (postpartum haemorrhage defined as greater than 600 ml).

Neonatal

Need for mechanical ventilation; neonatal encephalopathy.

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 (31 October 2010).



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 and MEDLINE, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service can be found in the '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 Coordinator searches the register for each review using the topic list rather than keywords.

We searched the Cochrane Complementary Medicine Field's Trials Register using the terms (labor OR labour) (October 2010).

In addition, we searched the Cochrane Central Register of Controlled Trials (*The Cochrane Library* 2010, Issue 4) (Appendix 1), MEDLINE (1966 to 31 October 2010) (Appendix 2), CINAHL (1980 to 31 October 2010) (Appendix 3).

We also searched the following clinical trial registries and websites for ongoing trials on 31 October 2011:

Australian and New Zealand Trials Registry; Chinese Clinical Trial Register; Current Controlled Trials; ClinicalTrials.gov; ISRCTN Register; National Center for Complementary and Alternative Medicine (NCCAM); and the WHO International Clinical Trials Registry Platform (ICTRP) (Appendix 4).

We did not apply any language restrictions.

Data collection and analysis

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

Selection of studies

C Smith (CS) and CT Collins (CTC) screened the titles and abstracts of articles found in the search, and discarded trials that were clearly not eligible. Two out of the three review authors (CS, CTC, CA Crowther (CAC)) undertook trial selection.

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

Data extraction and management

Following an assessment for inclusion, CS and CTC independently extracted data using the form designed by the Review Group for this purpose. For eligible studies, two review authors extracted

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data using the agreed form. We resolved discrepancies through discussion or, if required, we consulted a third person. For each included trial, we collected information regarding the location of the trial, methods of the trial (as per assessment of risk of bias), the participants (age range, eligibility criteria), the nature of the interventions, and data relating to the outcomes specified above. We collected information on reported benefits and adverse effects. When information regarding any of the above was unclear, we attempted to contact authors of the original reports to provide further details. We entered data into Review Manager software (RevMan 2011) and checked for accuracy.

Assessment of risk of bias in included studies

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

The tool consists of six items. There are three potential responses: high risk, low risk or unclear risk. We also made a judgement of 'unclear' if what happened in the study was known but the risk of bias was unknown; or if an entry was not relevant to the study at hand (particularly for assessing blinding and incomplete outcome data, or when the outcome being assessed by the entry has not been measured in the study).

We assessed the following characteristics: sequence generation, allocation concealment, blinding (or masking), incomplete data assessment, selective outcome reporting, other sources of bias, described below. We generated a 'risk of bias assessment' table for each study.

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

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

We will assessed the method as:

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

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

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

We assessed the methods as:

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



(3) Blinding (checking for possible performance bias)

We judged that blinding of participants and caregiver would not be possible due to the type of intervention being assessed. For this reason we assessed whether the lack of blinding was likely to have introduced bias in the measure of outcomes of interest. Blinding was assessed for primary outcomes as:

• low, high or unclear risk of bias.

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

We described for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We stated whether attrition and exclusions were reported and the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information was reported, or could be 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 described for each included study how we investigated the possibility of selective outcome reporting bias and what we found.

We assessed the methods as:

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

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

We described for each included study any important concerns we had about other possible sources of bias.

We assessed whether each study was free of other problems that could put it at risk of bias:

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

(7) Overall risk of bias

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

Measures of treatment effect

Dichotomous data

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

Continuous data

We expressed continuous data as mean differences with 95% CIs, or as standardised mean differences if outcomes were conceptually the same in the different trials but measured in different ways. We expected there would be clinical and statistical heterogeneity in the trials included in the review, and analysed data using the randomeffects model.

Unit of analysis issues

Cluster-randomised trials

We aimed to include cluster-randomised trials in the analyses along with individually randomised trials. We would adjust their sample sizes or standard errors using the methods described in the *Handbook* using an estimate of the intracluster correlation coefficient (ICC) derived from the trial (if possible), from a similar trial or from a study of a similar population. If we use ICCs from other sources, we planned to report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. We considered 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. We would also acknowledge heterogeneity in the randomisation unit and perform a sensitivity or subgroup analysis to investigate the effects of the randomisation unit.

Dealing with missing data

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

For all outcomes, we carried out analyses, as far as possible, on an intention-to-treat basis, i.e. we attempted to include all participants randomised to each group in the analyses, and all participants were analysed in the group to which they were allocated, regardless of whether or not they received the allocated intervention. The denominator for each outcome in each trial was the number randomised minus any participants whose outcomes are known to be missing. We excluded trials with greater than 20% missing data from the analysis.

Assessment of heterogeneity

We assessed statistical heterogeneity in each meta-analysis using the $T^2,\ I^2$ and Chi^2 statistics. We regarded heterogeneity as

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substantial if T² was greater than zero and either I² was greater than 50% or there was a low P value (less than 0.10) in the Chi² test for heterogeneity.

Assessment of reporting biases

Cochrane

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

Data synthesis

We carried out statistical analysis using the Review Manager software (RevMan 2011). We used random--effects meta-analysis for combining data where it is 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 differed between trials, or if we detected substantial statistical heterogeneity, we used a randomeffects meta-analysis to produce an overall summary if an average treatment effect across trials was considered clinically meaningful. We treated the random-effects summary as the average range of possible treatment effects and we planned to discuss the clinical implications of treatment effects differing between trials. If the average treatment effect was not clinically meaningful we have not combined trials.

If we used the random-effects analyses, we have presented the results as the average treatment effect with its 95% CI, and the estimates of T^2 and $I^2.$

Subgroup analysis and investigation of heterogeneity

If we had identified substantial heterogeneity, we would have investigated it using subgroup analysis and sensitivity analyses. We would consider whether an overall summary was meaningful, and if it is, use random-effects analysis to produce it.

We planned to carry out the following subgroup analyses.

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

For random-effects inverse variance meta-analyses, we aimed to assess differences between subgroups by interaction tests. For random-effects meta-analyses using methods other than inverse variance, we would assess differences between subgroups by inspection of the subgroups' confidence intervals; non-overlapping confidence intervals indicate a statistically significant difference in treatment effect between the subgroups.

Sensitivity analysis

Where subgroup analysis failed to explain the heterogeneity, we would analyse data using the random-effects model. A priori, we

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planned to perform sensitivity analyses on results to look at the possible contribution of: (1) differences in methodological quality, with trials of high quality (low risk of bias) compared to all trials; and (2) publication bias by country. If publication bias was present, we planned to undertake a sensitivity analysis excluding trials from countries where there was a greater publication bias.

RESULTS

Description of studies

Results of the search

The original review included a range of complementary therapies (Smith 2006). This updated review includes aromatherapy trials only; we included two trials (Burns 2007, 513 women; Calvert 2000, 22 women), and excluded no trials. We identified two additional new trials (Hur 2003; Salem 2004) which are awaiting further assessment. See Characteristics of included studies, Characteristics of studies awaiting classification, and Characteristics of ongoing studies.

Included studies

Study design

Both studies used a parallel design with two study groups. Burns 2007 used standard care as a control group. Calvert 2000 used an active control of lemongrass.

Sample Size

Sample size ranged from 22 (Calvert 2000) to 513 (Burns 2007) participants.

Study location and sources of women

Burns 2007 recruited women from delivery suite in Italy. Calvert 2000 recruited women during the antenatal period, at a level II hospital in New Zealand.

Participants

Nulliparous and multiparous women with a singleton pregnancy.

Intervention

In the Burns 2007 trial the decision as to which essential oil to use, together with mode(s) of application was reached through discussion between the midwife and woman. They could use one of five essential oils (EOs): Roman chamomile (Chamaemelum nobile), clary sage (Salvia sclarea), frankincense (Boswellia carteri), lavender (Lavandula augustifolium) and mandarin (Citrus reticulata). Aromatherapy was administered for one of the following reasons: to reduce fear, reduce anxiety, alleviate pain or to augment contractions. Modes of application included acupressure points, taper, compress, footbath, massage or birthing pool. Each woman assigned aromatherapy received one EO (no blending).

In the Calvert 2000 study women were randomised to receive essential oil of ginger or essential oil of lemongrass in the bath. Women were required to bathe for at least one hour. All women received routine care and had access to pain relief.

Outcomes

The trials reported on pain intensity, assisted vaginal birth, caesarean section, side effects from essential oils, admission to

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neonatal intensive care unit, Apgar scores, use of pharmacological pain relief, spontaneous vaginal delivery, augmentation, perineal trauma, length of first and second stage of labour, frequency of contractions, cervical dilatation and direct rooming-in.

Baseline comparability

Baseline characteristics were similar in the Burns 2007 trial. Data on baseline comparability were not reported in the Calvert 2000 study.

Intention to treat

An intention-to-treat analysis was reported.

Source of funding

A university grant funded the Burns 2007 trial. No funding was reported in the Calvert 2000.

Excluded studies

We did not exclude any trials.

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 authors. Overall the risk of bias of bias was low on four out of six domains.

Figure 1. Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all included studies.





Figure 2. Methodological quality summary: review authors' judgements about each methodological quality item for each included study.



Allocation

Both studies had adequate sequence generation and allocation concealment.

Blinding

There was no blinding in the Burns 2007 trial. There was a low risk of bias from lack of blinding in the Calvert 2000 trial with the women, care providers, outcome assessor and analyst all blind to the woman's group allocation.

Incomplete outcome data

There were no losses to follow-up in the trials.

Selective reporting

The protocol was not available from the Burns 2007 and Calvert 2000 trials.

Other potential sources of bias

There appeared to be no other sources of bias in the Burns 2007 trial. However, in the Calvert 2000 trial a power calculation was performed indicating that 116 women were required and only 22 women were actually recruited into the study.

Effects of interventions

One trial of 513 participants compared aromatherapy essential oils with standard care (Burns 2007). One trial of 22 women evaluated the role of aromatherapy using ginger compared with lemongrass (Calvert 2000). We identified no studies comparing aromatherapy with immersion in water, sterile water injection, biofeedback, hypnosis or placebo/no treatment.

1. Aromatherapy versus standard care

Primary outcomes (513 women)

Outcomes were not reported on satisfaction with pain relief, sense of control in labour, satisfaction with childbirth experience, effect of mother baby interaction, breastfeeding, Apgar score less than seven at five minutes and poor infant outcomes.

1.1 Pain intensity

Women in the aromatherapy group only were asked to rate their level of pain after receiving aromatherapy. Comparable data were not available from the control group. Nulliparous women reported a reduction in pain following aromatherapy, there was no difference in pain for multiparous women. This data could therefore not be included in an analysis.

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1.2 Assisted vaginal delivery

Analysis 1.2

There was no difference with assisted vaginal birth between groups (risk ratio (RR) 1.04, 95% confidence interval (CI) 0.48 to 2.28, one trial, 513 women).

1.3 Caesarean delivery

Analysis 1.3

There was no difference in caesarean section between groups (RR 0.98, 95% Cl 0.49 to 1.94, one trial, 513 women).

1.4 Admission to NICU

Analysis 1.4

Six babies in the control group were admitted to neonatal intensive care, compared with no babies in the aromatherapy group (RR 0.08, 95% CI 0.00 to 1.42, one trial, 513 women). However, there was no statistically significant difference between groups.

Secondary outcomes (513 women)

1.5 Use of pharmacological analgesia

Analysis 1.5

There was no difference seen between groups in their use of epidural (RR 0.35, 95% CI 0.04 to 3.32, one trial, 513 women).

1.6 Spontaneous vaginal delivery

Analysis 1.6

There was no difference in vaginal delivery between groups (RR 1.00, 95% Cl 0.94 to 1.06, one trial, 513 women).

1.7 Augmentation

Analysis 1.7

There was no difference in augmentation between groups (RR 1.14, 95% CI 0.90 to 1.45, one trial, 513 women).

2. Specific aromatherapy oil versus another aromatherapy oil

Primary outcomes (22 women)

No data was reported on the outcomes of satisfaction with pain relief, sense of control in labour, satisfaction with childbirth experience, effect on mother baby interaction, breastfeeding and poor infant outcomes.

2.1 Pain intensity

There were no differences between groups on the visual analogue scale either before (P = 0.255), during (P = 0.964) or after the bath (P = 0.518) or on the McGill Pain Questionnaire 24 hours postpartum (P = 0.7663). We could not include these data in an analysis because only median and P values were reported.

2.2 Assisted vaginal delivery

Analysis 2.2

There was no difference in assisted vaginal birth between groups (RR 0.83, 95% CI 0.06 to 11.70, one trial, 22 women).

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2.3 Caesarean delivery

There was no difference in caesarean section between groups (RR 2.54, 95% Cl 0.11 to 56.25, one trial, 22 women).

Analysis 2.3

2.4 Side effects for mother and baby

No women in either group had a postpartum haemorrhage (one trial, 22 women).

2.5 Admission to neonatal intensive care

Analysis 2.5

No babies were admitted to neonatal intensive care (one trial, 22 women).

2.6 Apgar score less than seven at five minutes

Analysis 2.6

No infants had an Apgar score less than seven at five minutes (one trial, 22 women).

Secondary outcomes (22 women)

2.7 Use of pharmacological pain relief in labour

Analysis 2.7

There was no difference seen between women receiving ginger or lemongrass in their use of pharmacological pain relief (RR 2.50, 95% CI 0.31 to 20.45, one trial, 22 women).

2.8 Spontaenous vaginal delivery

Analysis 2.8

There was no benefit from the treatment intervention in relation to the occurrence of spontaneous vaginal delivery compared with the control group (RR 0.93, 95% CI 0.67 to 1.28, one trial, 22 women).

2.9 Length of labour

There was no difference in the length of the first stage of labour between groups; however, overall the length of labour was shorter for women in the experimental group (median 12 minutes, range four to 40 minutes versus 42 minutes range six minutes to one hour 17 minutes) P = 0.01).

We planned a sensitivity analysis of trials by risk of bias, but we were unable to undertake it due to the small number of trials.

We also planned a subgroup analysis by parity; however, we were unable to undertake this due to the inclusion of only a small number of trials whose data were not presented by parity.

DISCUSSION

Summary of main results

There is insufficient evidence about the effectiveness of aromatherapy on pain management in labour or any primary or secondary outcome from two randomised controlled trials comparing essential oils with an active control or standard care.

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Overall completeness and applicability of evidence

The two studies were undertaken in New Zealand and Italy, with differing sample sizes. Inclusion and exclusion criteria were specified and included multiparous and nulliparous women not planning a caesarean section, and were at low obstetric risk. The applicability of the trial findings is relevant to the application of women using oils in the bath, taper and massage which reflects clinical practice. The study did not provide information on the number of women approached compared to those actually recruited and randomised. Without this additional information it is difficult to judge the generalisability of the findings. Evidence from the Burns 2007 trial may also be applicable to maternity settings where a fixed active labour model of care is practised, and the external validity of the model of aromatherapy used in this trial may not represent common clinical practice as the midwives were not qualified aromatherapists.

Quality of the evidence

The risk of bias in the studies was low overall. Aromatherapy is a modality in which it is difficult to maintain a blind status to the therapist, women and care providers. However, it is possible that the collection of objective clinical outcomes and the data analyst can remain blind to group allocation. Although women were reported to be blind to their group allocation in the Calvert 2000 trial, this was not measured to confirm whether women recognised the aroma of lemongrass or ginger.

Potential biases in the review process

We attempted to minimise bias during the review process. Two authors assessed the eligibility of studies, carried out data extraction and assessed the risk of bias. We are aware that some literature on complementary therapies may not be published in mainstream journals and therefore maybe excluded from the main databases. We attempted to be as inclusive as possible.

Agreements and disagreements with other studies or reviews

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

AUTHORS' CONCLUSIONS

Implications for practice

The efficacy and effectiveness of aromatherapy has not been established, and implication for clinical practice cannot be made.

Implications for research

Further randomised controlled trials of aromatherapy for pain management in labour are needed. Further randomised trials should be adequately powered and include clinically relevant outcomes such as those described in this review. A methodological issue for trials of aromatherapy is the choice of an appropriate control group. Trials of aromatherapy may be difficult to blind in relation to participants and midwives, and pragmatic designs should be considered. There is a need for improving the quality and reporting of future trials. In particular, consideration should be given in the analysis and reporting on the person providing the intervention, for example, their training, length of experience and relationship to the woman. Future research should also consider evaluation of aromatherapy in a range of maternity care settings including obstetric units, alongside and freestanding midwifery units and home. In addition, further research is required which should include data measuring neonatal outcomes and the effects on analgesia requirements in institutions with and without an 'on demand' epidural service. A cost-benefit analysis should be incorporated into the design of future studies.

ACKNOWLEDGEMENTS

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

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), a member of the Pregnancy and Childbirth Group's international panel of consumers and the Group's Statistical Adviser.



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CHARACTERISTICS OF STUDIES

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Simmons 2007

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* Indicates the major publication for the study

	also included a preference arm.
Participants	513 women were recruited to the study on presentation at the delivery suite at San Gerardo Hospi- tal, Italy. Women were excluded if they were less than 36 weeks' gestation, had a multiple pregnancy, breech presentation or were booked for a caesarean section.

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Burns 2007 (Continued)	
Interventions	The experimental group received aromatherapy. The decision as to which EO to use, together with mode(s) of application was reached through discussion between the midwife and woman. They could use 1 of 5 EOs: Roman chamomile (Chamaemelum nobile), clary sage (Salvia sclarea), frankincense (Boswellia carteri), lavender (Lavandula augustifolium) and mandarin (Citrus reticulata). Aromatherapy was administered for one of the following reasons: to reduce fear, reduce anxiety, alleviate pain or to augment contractions. Modes of application included acupressure points, taper, compress, footbath, massage or birthing pool. each woman assigned aromatherapy received 1 EO (no blending). The control group received standard care only.
Outcomes	Pain intensity (only aromatherapy group), assisted vaginal birth, caesarean section, admission to NICU, Apgar score, use of pharmacological pain relief, spontaneous vaginal delivery, length of labour, aug- mentation, perineal trauma.
Notes	The study was conducted from May 1 to 31 December 2003. An intention-to-treat analysis was men- tioned and undertaken.
Risk of bias	

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	Computer-generated sequence (1:1 ratio) prepared by independent statisti- cian. Consecutively numbered.
Allocation concealment (selection bias)	Low risk	Sealed opaque envelopes.
Blinding (performance bias and detection bias) All outcomes	High risk	Neither participants, care providers, data collection or analyst was blind.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing data.
Selective reporting (re- porting bias)	Unclear risk	Study protocol was not available.
Other bias	Low risk	The study appears free of other bias.

Calvert 2000

Methods	Double-blind, randomised controlled trial of aromatherapy.
Participants	22 multiparous women with a singleton pregnancy were randomised to the trial. Women were exclud- ed with previous caesarean section, major medical complications, skin allergies, hypotension, previ- ous vaginal surgery (excluding dilatation and curettage) or not receiving continuity of midwifery care. Women were recruited during the antenatal period, at a level II hospital in New Zealand.
Interventions	Randomisation occurred on the delivery suite prior to the woman entering the bath. Once the woman was in the bath, the seal on the bottle was broken and the oil poured into the bath. The woman was re- quired to remain in the bath for at least 1 hour. The experimental group received essential oil of ginger and the control group received essential oil of lemon grass.
Outcomes	Pain intensity (only aromatherapy group), assisted vaginal birth, caesarean section, side effects from essential oils, admission to NICU, Apgar score, use of pharmacological pain relief, spontaneous vaginal

Aromatherapy for pain management in labour (Review)

Calvert 2000 (Continued)

delivery, length of first and second stage of labour, frequency of contractions, cervical dilatation and rooming-in.

Notes

A power calculation was performed, 116 women were required. 22 women were recruited. An intention-to-treat analysis was performed.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	Computer-generated randomisation sequence.
Allocation concealment (selection bias)	Low risk	Concealed by a coded number on the bottle.
Blinding (performance bias and detection bias) All outcomes	Low risk	The women, care providers, outcome assessor and analyst were all blind to the woman's group allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	There were no losses to follow-up. An intention-to-treat analysis was per- formed.
Selective reporting (re- porting bias)	Unclear risk	The study protocol was unavailable.
Other bias	High risk	A power calculation was performed, 116 women were required. However, only 22 women were recruited.

EO: essential oil NICU: neonatal intensive care unit RAT: respiratory autogenic training VAS: visual analogue scale

Characteristics of studies awaiting assessment [ordered by study ID]

Hur 2003	
Methods	
Participants	
Interventions	
Outcomes	
Notes	Awaiting translation.

Salem 2004	
Methods	
Participants	

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Salem 2004 (Continued)

Interventions	
Outcomes	
Notes	Awaiting access to thesis.

Characteristics of ongoing studies [ordered by study ID]

Vakilian 2009

Trial name or title	The effect of breath technique and aromatherapy essence of lavender on labor pain.
Methods	Randomised single blind trial.
Participants	Primiparous women planning a vaginal delivery.
Interventions	Essential oil of lavender with breath technique via nebuliser during contractions in the active phase of labour, versus breath only, versus lavender only.
Outcomes	Pain, duration of the first phase of labour.
Starting date	30/1/2009.
Contact information	Katayon Vakilian, Shahrood University of Medical Sciences and Health Sciences. Phone 009802122853567, email k_vakili@arakmur.ac.ir
Notes	Recruitment of 240 participants complete.

Walker 2010

Trial name or title	Effects of aromatherapy on childbirth.
Methods	Placebo controlled randomised trial.
Participants	Women in labour and expecting a normal delivery, aged greater than 16 years, singleton pregnan- cy, spontaneous or induced labour onset.
Interventions	Aromatherapy oil versus no essential oil.
Outcomes	Pain and anxiety.
Starting date	February 2010.
Contact information	Dr M Walker, University of Nottingham, United Kingdon. Phone +44 (0) 115 82 30511. Email dawn- marie.walker@nottingham.ac.uk
Notes	Sample size 90.

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DATA AND ANALYSES

Comparison 1. Aromatherapy versus standard care

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Pain intensity	0	0	Odds Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2 Assisted vaginal birth	1	513	Risk Ratio (M-H, Fixed, 95% CI)	1.04 [0.48, 2.28]
3 Caesarean delivery	1	513	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.49, 1.94]
4 Admission to NICU	1	513	Risk Ratio (M-H, Fixed, 95% CI)	0.08 [0.00, 1.42]
5 Use of pharmacological analgesia	1	513	Risk Ratio (M-H, Fixed, 95% CI)	0.35 [0.04, 3.32]
6 Spontaneous vaginal delivery	1	513	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.94, 1.06]
7 Augmentation	1	513	Risk Ratio (M-H, Fixed, 95% CI)	1.14 [0.90, 1.45]

Analysis 1.2. Comparison 1 Aromatherapy versus standard care, Outcome 2 Assisted vaginal birth.

Study or subgroup	Experimental	Control		Risk Ratio				Weight	Risk Ratio		
	n/N	n/N			M-H, Fi	xed, 9	95% CI				M-H, Fixed, 95% CI
Burns 2007	12/251	12/262				-				100%	1.04[0.48,2.28]
Total (95% CI)	251	262				\blacklozenge				100%	1.04[0.48,2.28]
Total events: 12 (Experimental), 12 (Control)										
Heterogeneity: Not applicable											
Test for overall effect: Z=0.11(P=0.91)										
	Favour	s aromatherapy	0.1	0.2	0.5	1	2	5	10	Favours standard care	

Analysis 1.3. Comparison 1 Aromatherapy versus standard care, Outcome 3 Caesarean delivery.

Study or subgroup	Aromtherapy	Control	Risk Ratio					Weight	Risk Ratio		
	n/N	n/N			M-H, Fi	ixed, 9	95% CI				M-H, Fixed, 95% CI
Burns 2007	15/251	16/262				-				100%	0.98[0.49,1.94]
Total (95% CI)	251	262				\blacklozenge				100%	0.98[0.49,1.94]
Total events: 15 (Aromtherapy), 16 (C	ontrol)										
Heterogeneity: Not applicable											
Test for overall effect: Z=0.06(P=0.95)											
	Favour	s aromatherapy	0.1	0.2	0.5	1	2	5	10	Favours standard care	

Aromatherapy for pain management in labour (Review)

Study or subgroup	Experimental	Control	Risk Ratio			Weight	Risk Ratio	
	n/N	n/N		M-H, Fix	(ed, 95% Cl			M-H, Fixed, 95% CI
Burns 2007	0/251	6/262	•	1	+		100%	0.08[0,1.42]
Total (95% CI)	251	262			-		100%	0.08[0,1.42]
Total events: 0 (Experimental), 6 (Cor	ntrol)							
Heterogeneity: Not applicable								
Test for overall effect: Z=1.72(P=0.09)							_	
	Favour	s aromatherapy	0.01	0.1	1	10 10	⁰ Favours standard care	1

Analysis 1.4. Comparison 1 Aromatherapy versus standard care, Outcome 4 Admission to NICU.

Analysis 1.5. Comparison 1 Aromatherapy versus standard care, Outcome 5 Use of pharmacological analgesia.

Study or subgroup	Experimental	Control	Risk Ratio			Weight	Risk Ratio		
	n/N	n/N		М-Н, F	ixed, 95%	CI			M-H, Fixed, 95% Cl
Burns 2007	1/251	3/262	-					100%	0.35[0.04,3.32]
Total (95% CI)	251	262	-					100%	0.35[0.04,3.32]
Total events: 1 (Experimental), 3 (Co	ntrol)								
Heterogeneity: Tau ² =0; Chi ² =0, df=0(P<0.0001); I ² =100%								
Test for overall effect: Z=0.92(P=0.36)			1		1			
	Favours	s aromatherapy	0.01	0.1	1	10	100	Favours standard care	

Analysis 1.6. Comparison 1 Aromatherapy versus standard care, Outcome 6 Spontaneous vaginal delivery.

Study or subgroup	Experimental	Control		Risk Ratio			Weight	Risk Ratio	
	n/N	n/N		M-H	I, Fixed, 95%	СІ			M-H, Fixed, 95% Cl
Burns 2007	224/251	234/262			+			100%	1[0.94,1.06]
					\top				
Total (95% CI)	251	262						100%	1[0.94,1.06]
Total events: 224 (Experimental), 234	4 (Control)								
Heterogeneity: Not applicable									
Test for overall effect: Z=0.03(P=0.98)								
	Favou	rs aromatherapy	0.01	0.1	1	10	100	Favours standard care	

Analysis 1.7. Comparison 1 Aromatherapy versus standard care, Outcome 7 Augmentation.

Study or subgroup	Experimental	Control	Risk Ratio				Weight	Risk Ratio	
	n/N	n/N		м-н,	Fixed, 95%	CI			M-H, Fixed, 95% CI
Burns 2007	92/251	84/262			+			100%	1.14[0.9,1.45]
Total (95% CI)	251	262			•			100%	1.14[0.9,1.45]
Total events: 92 (Experimental), 84 (Control)								
Heterogeneity: Not applicable									
Test for overall effect: Z=1.09(P=0.27)			1			1		
	Favour	s aromatherapy	0.01	0.1	1	10	100	Favours standard care	

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Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Pain intensity	0	0	Odds Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2 Assisted vaginal delivery	1	22	Risk Ratio (M-H, Fixed, 95% CI)	0.83 [0.06, 11.70]
3 Caesarean delivery	1	22	Risk Ratio (M-H, Fixed, 95% CI)	2.54 [0.11, 56.25]
4 Side effects	0	0	Odds Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
5 Admission to NICU	1	22	Odds Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
6 Apgar score < 7 at 5 minutes	1	22	Odds Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
7 Use of pharmacological analgesia	1	22	Risk Ratio (M-H, Fixed, 95% CI)	2.5 [0.31, 20.45]
8 Spontaneous vaginal delivery	1	22	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.67, 1.28]

Comparison 2. Specific aromatherapy oil versus another aromatherapy oil

Analysis 2.2. Comparison 2 Specific aromatherapy oil versus another aromatherapy oil, Outcome 2 Assisted vaginal delivery.

Study or subgroup	Ginger	Lemongrass	Risk Ratio			Weight	Risk Ratio				
	n/N	n/N			M-H, Fi	xed,	95% CI				M-H, Fixed, 95% CI
Calvert 2000	1/12	1/10	←			-			-	100%	0.83[0.06,11.7]
Total (95% CI)	12	10								100%	0.83[0.06,11.7]
Total events: 1 (Ginger), 1 (Lemongrass)											
Heterogeneity: Not applicable											
Test for overall effect: Z=0.14(P=0.89)											
		Favours ginger	0.1	0.2	0.5	1	2	5	10	Favours lemongrass	

Analysis 2.3. Comparison 2 Specific aromatherapy oil versus another aromatherapy oil, Outcome 3 Caesarean delivery.

Study or subgroup	Ginger	Lemongrass		Risk Ratio			Weight	Risk Ratio	
	n/N	n/N		M-H	Fixed, 95%	CI			M-H, Fixed, 95% CI
Calvert 2000	1/12	0/10						100%	2.54[0.11,56.25]
Total (95% CI)	12	10						100%	2.54[0.11,56.25]
Total events: 1 (Ginger), 0 (Lemongrass)									
Heterogeneity: Not applicable									
Test for overall effect: Z=0.59(P=0.56)									
		Favours ginger	0.01	0.1	1	10	100	Favours lemongrass	

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Analysis 2.5. Comparison 2 Specific aromatherapy oil versus another aromatherapy oil, Outcome 5 Admission to NICU.

Study or subgroup	Ginger	Lemongrass		Odds Ratio			Weight	Odds Ratio	
	n/N	n/N		м-н,	Fixed, 95	% CI			M-H, Fixed, 95% CI
Calvert 2000	0/12	0/10							Not estimable
					İ				
Total (95% CI)	12	10							Not estimable
Total events: 0 (Ginger), 0 (Lemongrass)									
Heterogeneity: Not applicable									
Test for overall effect: Not applicable									
	Favo	ours experimental	0.01	0.1	1	10	100	Favours control	

Analysis 2.6. Comparison 2 Specific aromatherapy oil versus another aromatherapy oil, Outcome 6 Apgar score < 7 at 5 minutes.

Study or subgroup	Ginger	Lemongrass		Odds Ratio			Weight	Odds Ratio	
	n/N	n/N		M-H	, Fixed, 95	% CI			M-H, Fixed, 95% CI
Calvert 2000	0/12	0/10							Not estimable
Total (95% CI)	12	10							Not estimable
Total events: 0 (Ginger), 0 (Lemongrass)									
Heterogeneity: Not applicable									
Test for overall effect: Not applicable									
	Favo	ours experimental	0.01	0.1	1	10	100	Favours control	

Favours experimental 0.01

Analysis 2.7. Comparison 2 Specific aromatherapy oil versus another aromatherapy oil, Outcome 7 Use of pharmacological analgesia.

Study or subgroup	Ginger	Lemongrass	Risk	Risk Ratio		Risk Ratio
	n/N	n/N	M-H, Fixe	d, 95% CI		M-H, Fixed, 95% CI
Calvert 2000	3/12	1/10			100%	2.5[0.31,20.45]
Total (95% CI)	12	10			100%	2.5[0.31,20.45]
Total events: 3 (Ginger), 1 (Lemongrass)						
Heterogeneity: Not applicable						
Test for overall effect: Z=0.85(P=0.39)						
	Га	vours ovporiment	0.01 0.1	1 10	100 Favours control	

Favours experiment 0.01 0.1 10 100 Favours control

Analysis 2.8. Comparison 2 Specific aromatherapy oil versus another aromatherapy oil, Outcome 8 Spontaneous vaginal delivery.

Study or subgroup	Ginger	Lemongrass			Risk Ratio			Weight	Risk Ratio
	n/N	n/N		M-H	l, Fixed, 95	% CI			M-H, Fixed, 95% CI
Calvert 2000	10/12	9/10			-+-			100%	0.93[0.67,1.28]
	Favo	ours experimental	0.01	0.1	1	10	100	Favours control	

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Study or subgroup	Ginger	Lemongrass			Risk Ratio			Weight	Risk Ratio
	n/N	n/N		M-H	I, Fixed, 95% C	:1			M-H, Fixed, 95% Cl
Total (95% CI)	12	10			•			100%	0.93[0.67,1.28]
Total events: 10 (Ginger), 9 (Lemong	rass)								
Heterogeneity: Tau ² =0; Chi ² =0, df=0(P<0.0001); I ² =100%									
Test for overall effect: Z=0.46(P=0.64))								
	Favo	ours experimental	0.01	0.1	1	10	100	Favours control	

APPENDICES

Appendix 1. CENTRAL search strategy

Authors wrote and ran the following search:

#1 (labor or labour):ti,ab,kw

#2 labo*r

- #3 (childbirth or child-birth or child birth) in Clinical Trials
- #4 midwife* in Clinical Trials
- #5 obstetric*in Clinical Trials
- #6 labo*r pain in Clinical Trials
- #7 pain* labo*r in Clinical Trials
- #8 contraction* in Clinical Trials
- #9 pain management in Clinical Trials
- #10 pain* manage* in Clinical Trials
- #11 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10)
- #12 MeSH descriptor Aromatherapy explode all trees
- #13 aromatherapy analgesia in Clinical Trials
- #14 aromatic oils in Clinical Trials
- #15 aroma in Clinical Trials
- #16 aroma* in Clinical trials
- #17 aromatherapy in Clinical trials
- #18 (#12 OR #13 OR #14 OR #15 OR #16 OR #17)

#19 (#11 AND #12)

Appendix 2. MEDLINE search strategy

Authors wrote and ran the following search:

- 1. exp Aromatherapy/
- 2. aromatherapy.mp. or *Aromatherapy/
- 3. aromatic oil\$.mp.

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4. Randomized Controlled Trials as Topic/ or Complementary Therapies/ or Societies, Medical/ or Aromatherapy/ or Oils, Volatile/ or aromatherapist.mp.

- 5. scent.mp. or Nose/ or Smell/ or Petunia/ or Flowers/ or Odo*rs/ or Rosa/
- 6. aromatherapy.tw.
- 7. (aroma therapy or aroma-therapy).tw.
- 8. or/1-7

9. (labor or labour).mp. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]

- 10. (childbirth or child birth or child-birth).tw.
- 11. (labour or labor).ab.
- 12. pain\$.mp.
- 13. pain manag\$.mp. or exp Pain/
- 14. exp Labor, Obstetric/ or labo*r.mp.
- 15. or/9-14
- 16. 8 and 15
- 17. randomi*ed controlled trial.pt.
- 18. controlled clinical trial.pt.
- 19. (randomized or randomised).ab.
- 20. placebo.ab.
- 21. drug therapy.fs.
- 22. randomly.ab.
- 23. trial.ab.
- 24. groups.ab.
- 25. or/17-24
- 26. (animals not (humans and animals)).sh.
- 27. 25 not 26
- 28. 16 and 27

Appendix 3. CINAHL search strategy

Authors wrote and ran the following search:

- S28. S25 and S26 and S27
- S27. S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17
- S26. S1 or S2 or S3 or S4 or S5 or S6 $\,$
- S25. S18 or S19 or S20 or S21 or S22 or S23 or S24
- S24. clinical trials
- S23. Randomi*ed control# trial#
- S22. random assignment

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- S21. random# allocation
- S20. placebo#
- S19. placebos/
- S18. quantitative studies/
- S17. AB(labo*r pain)
- S16. AB(pain or labo*r pain)
- S15. AB pain# manage#
- S14. AB pain#
- S13. AB midwife#
- S12. AB midwi#
- S11. AB obstetric#
- S10. AB (childbirth or child birth or child-birth)
- S9. AB labor or labour
- S8. MW labor or labour
- S7. labor or labour
- S6. oil#
- S5. odo#r
- S4. MW scent
- S3. MW aromatic
- S2. MW aromatherapy#
- S1. MW (aromatherapy or aroma therapy or aroma-therapy)

Appendix 4. Clinical Trial Registries

Search terms used: aromatherapy and pain management

WHAT'S NEW

Date	Event	Description
1 July 2011	Amended	'Pain relief' amended to 'pain management' within Types of out- come measures, as per generic protocol.

CONTRIBUTIONS OF AUTHORS

Caroline Smith and Carmel Collins conceptualised and wrote the protocol, reviewed trials, performed data extraction and jointly wrote the review and its update. Caroline Smith is the guarantor of the review. Caroline Crowther commented on each draft of the protocol and review and its update.

DECLARATIONS OF INTEREST

None known.

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External sources

• National Institute for Health Research, UK.

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

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

This updated review differs from the previously published Cochrane systematic review 'Complementary and alternative therapies for pain management in labour' (Smith 2006). This review has now been revised to three separate reviews.

NOTES

This new review is one of three which, collectively, update the previous review on a range of complementary therapies (Smith 2006). This review includes only trials of aromatherapy.

INDEX TERMS

Medical Subject Headings (MeSH)

Analgesia, Obstetrical [*methods]; Aromatherapy [*methods]; Labor Pain [*therapy]; Oils, Volatile [therapeutic use]; Randomized Controlled Trials as Topic

MeSH check words

Female; Humans; Pregnancy