Hypnosis for pain management during labour and childbirth (Protocol)

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Hypnosis for pain management during labour and childbirth

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Editorial group: Cochrane Pregnancy and Childbirth Group.

Citation: Madden K, Middleton P, Cyna AM, Matthewson M. Hypnosis for pain management during labour and childbirth. Cochrane Database of Systematic Reviews 2011, Issue 10. Art. No.: CD009356. DOI: 10.1002/14651858.CD009356.

ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To assess the effects of hypnosis for pain management during labour and childbirth.

BACKGROUND

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

Description of the condition

Women's experiences of pain during labour are complex phenomena. Although almost all women report some pain during childbirth, their sensory and affective perceptions can vary widely (Lowe 2002). For example, some women describe the sensations of labour as more akin to extreme muscular exertion from physical activity, some as productive pain which signals that their baby's birth is closer, some compare it with intense period pain and others describe it as agony or like torture (Green 1998; Lundgren 1998; McCutcheon-Rosegg 1996). A range of physiological and psychosocial factors have been identified, which may explain labour pain and its variability (Lowe 2002).

Traditionally labour pain has been defined similarly to acute pain, “a complex constellation of unpleasant sensory, perceptual and emotional experiences and certain associated autonomic, physiologic, emotional and behavioural responses” (Bonica 1990a). However, unlike other acute pain, which can usually be attributed to pathologic processes, labour pain does not signal harm or pathology and is considered a normal part of birth (Lowe 2002). The physiological processes thought to cause pain during labour include uterine contractions dilating the cervix in the first stage of labour and the stretching of the vagina and pelvic floor as the baby descends during the second stage of labour (Bonica 1990b). Although pain intensity has been found to increase with frequency of contractions and greater cervical dilatation, these patterns are not consistent across women (Melzack 1984). Physical factors such as maternal positioning have also been found to affect pain, with women randomised to upright positions in the first stage of labour less likely to use epidural analgesia than women randomised to recumbent positions (Lawrence 2009).

Psychosocial factors including anxiety, fear, feelings of self-efficacy, coping skills and social support have also been shown to have a
relationship with women’s experiences of labour and labour pain (Hodnett 2007; Lowe 2002). For example, anxiety and fear of pain have been positively correlated with reported pain levels during labour (Lowe 2002). By contrast, women were less likely to use pain medications if they had a continuous support person for labour, and women’s confidence in their ability to cope has also been associated with reduced pain perception (Hodnett 2007; Lowe 1989).

The measurement of pain generally and the measurement of labour pain in particular is challenging given the subjective nature of the experience and the complex interpretations involved. Indeed, there is evidence that the way pain is measured can affect the way it is interpreted by individuals (Cho et al. 2011). Studies have also shown low levels of agreement between the subjective assessments of pain by patients and the estimates of medical staff (for example, Trentin 2001). Given these challenges, more objective measures such as use of pharmacological pain relief can be usefully supplemented with a range of subjective measures of pain experience.

**Description of the intervention**

A wide range of methods for pain management are currently used by women during childbirth (Caton 2002). Commonly, these include pharmacological methods such as epidural analgesia and/or physical methods such as water immersion (Caton 2002). The use of psychological methods for comfort in childbirth has a very long history and concentrated forms of suggestion were reportedly used in Egyptian and Chinese societies (Bonica 1990b). The term ‘hypnosis’ was proposed by James Braid in the 1840s and it has been reported that the technique was soon adopted as a method of pain relief for childbirth (Platonov 1960).

There is considerable academic debate about whether hypnosis represents a distinct state of consciousness or whether it is a normal state where social influence and cognitive-behavioural skills are used to enhance suggestibility (Gamsa 2003). However, the core components of hypnosis are generally described as involving reduced awareness of external stimuli, focused attention as well as increased absorption in and responsiveness to suggestions (Gamsa 2003). Several basic steps have been identified as common across hypnotic techniques “(a) the patient’s interest and cooperation are obtained, (b) the range of attention is narrowed, (c) attention is directed inwards, and usually, (d) a deeply relaxed state is induced” (Gamsa 2003). For hypnosis focused on pain management, the hypnotherapist follows up by offering verbal suggestions aimed at increasing the client’s comfort and developing imagery to reduce pain (Gamsa 2003). In the context of childbirth, a wide range of suggestions and images may be made at directed at increasing feelings of relaxation, well being and may also include developing sensations of analgesia such as numbing. For example, in one trial women were encouraged to imagine themselves in a special safe place in their mind where they could relax, refresh themselves and feel contented; suggestions were also offered inviting them to imagine the power of the contractions working for them as they drifted and floated in their own special anaesthetic spa bath (Cyna 2007).

There are two main methods for providing hypnosis interventions for childbirth: hypnotherapy delivered in-person by a practitioner; and self-hypnosis, where the woman is taught to enter hypnosis on her own or using an audio recording. For example, in one trial in Philadelphia a trained medical student provided hypnosis to women in active labour in hospital (Rock 1969). This method of delivering the intervention was chosen as it was considered to be less time consuming than antenatal training and more predictable results were expected (Rock 1969). Self-hypnosis can be taught to women individually or in groups, and can be supplemented with audio recordings for use at home. For example, in one US trial groups of 15 pregnant women had one-hour hospital-based training sessions each week for six weeks (Harmon 1990). The women were also given audio recordings of the hypnotic induction for daily practice leading up to the birth (Harmon 1990). The benefits of teaching women self-hypnosis before labour include the promotion of women’s active participation and sense of control for managing anxiety and discomfort (Martin 2001).

**How the intervention might work**

There is promising evidence that hypnosis may be effective in reducing acute pain across a range of settings including burns treatment and other invasive medical procedures (Montgomery 2000; Patterson 2003). A meta-analysis of 18 studies of experimentally induced and clinical pain found that hypnotic analgesia provided a moderate to large analgesic effect for both types of pain (Montgomery 2000). Although most of the participants were reported to be randomly assigned to treatment or control conditions, most of the trials included in the analysis were small (Montgomery 2000) and there was no explicit assessment of potential sources of selection, attrition and selective reporting bias in the trials. Patterson 2003 also reported that several well-designed controlled trials supported the efficacy of hypnosis for acute pain in a large review of hypnosis and clinical pain. This review provided more detailed information about each trial, but again did not explicitly assess all potential sources of bias. A Cochrane Review of clinical hypnosis for acute pain in adults is planned which will include explicit assessment of potential biases (Hallquist 2007).

Neuro-imaging studies have provided evidence about the nature of neuro-physiological changes during hypnosis generally and during hypnotically induced analgesia (Faymonville et al. 2000; Maquet 1999). A positron emission tomography and magnetic resonance imaging study found hypnosis reduced pain experienced from hot, noxious stimuli and that the process was mediated by the anterior cingulate cortex (Faymonville et al. 2000). Both the affective and sensory aspects of pain perception were reduced when participants used hypnosis (Faymonville 2000). Hypnosis has also been used to selectively alter the degree of unpleasantness of hot, noxious stimuli without...
changing the perceived intensity of the pain in a study designed to
differentiate the cortical areas involved in the affective and sensory
dimensions of pain (Rainville 1997).
In the context of pain management for childbirth, hypnosis is
often considered alongside other non-pharmacological methods
as focused on the affective aspects of the pain experience such as
reducing anxiety, fear, muscular tension as well as enhancing
mood and increasing the woman's sense of control (Simkin 2004).
However, there have been case reports of hypnosis used as the only
analgesia for surgical procedures, including caesarean section, for
highly hypnotisable individuals (for example, Kroger 1957).
Hypnotisability refers to the degree to which individuals follow
suggestions during hypnosis and a number of scales have been con-
structed to measure and predict hypnotic suggestibility (Gamsa
2003). Some studies have found that highly hypnotisable individ-
uals experienced greater pain relief than those who scored low on
hypnotisability scales although other studies did not replicate this
finding (Gamsa 2003). Hypnotisability may not be a stable trait
with evidence that the ability to control pain can improve with
training in hypnoanalgesia (Gamsa 2003) and that the physiolog-
ical and hormonal changes associated with pregnancy may affect
individuals’ responsiveness to hypnosis (Alexander 2009). For ex-
ample, a recent study found that women were significantly more
hypnotisable when pregnant (Alexander 2009). This study used a
repeated-measures design with 37 women and found a large, clinic-
ally meaningful effect ($d = 0.84$) for increased hypnotisability dur-
ing pregnancy. Measured on the Creative Imagination Scale (CIS)
(Barber 1979), which has a maximum score of 40, the women’s
mean CIS score when pregnant was 23.5 (standard deviation (SD)
6.9), compared with a mean CIS score of 18.7 (SD 6.6) when the
women were between 14 and 28 months postpartum (Alexander
2009).
The safety of hypnosis for pregnant women was considered in
an earlier systematic review (Cyna 2004). There were no reports
of adverse effects attributed to the hypnosis intervention in the
reviewed trials, but two previously published reports of maternal
mental disturbances were noted (Cyna 2004). The current review
will also note any reports of adverse events.

**Why it is important to do this review**

A range of pharmacological methods of pain management for
labour exist; however, not all methods are routinely available across
international maternity care settings. Some methods, such as par-
enteral opioids and epidural, have also been associated with in-
creased risks of adverse maternal effects and increased rates of
other medical intervention (Anim-Somuah 2005; Ullman 2010).
The Australian and New Zealand College of Anaesthetists rec-
ommends consideration of non-pharmacological options before
pharmacological options for pain during pregnancy as pain med-
ications generally cross the placenta (McIntyre 2010). Hypno-
sis has been recognised by organisations including the British
Medical Association, the American Medical Association and the
British Psychological Society as an effective clinical tool (AMA
Council on Mental Health 1958; BMA Working Party 1955; BPS
Working Party 2001). Like other non-pharmacological methods
of pain management for childbirth, hypnosis can be used au-
tonomously by women in labour and may enhance feelings of self-
confidence, mastery and well-being (Simkin 2004). There is also
interest among expectant parents about the use of hypnosis for
childbirth and at least two programs are available for community-
An earlier Cochrane Review of complementary and alternative
therapies for pain management in labour found that women taught
self-hypnosis used less pharmacological analgesia and were more
satisfied with pain management in labour than women randomised
to control conditions (Smith 2006). The authors concluded that
hypnosis may be beneficial as a method of pain management in
labour but noted that only a small number of women had been
studied (Smith 2006). This review provides the opportunity to
separate hypnosis into a standalone review and update it with re-
results from recently completed trials of hypnosis for pain manage-
ment in childbirth.

**OBJECTIVES**

To assess the effects of hypnosis for pain management during
labour and childbirth.

**METHODS**

*Criteria for considering studies for this review*

**Types of studies**

Randomised-controlled trials (RCTs) only. We will not include
results from quasi-RCTs in the analyses.

**Types of participants**

Pregnant women. (This will include women in high-risk groups,
e.g. preterm labour or following induction of labour. We will use
subgroup analysis for any possible differences in the effects of
hypnosis in these groups.)

**Types of interventions**

Preparation for labour using hypnosis and/or use of hypnosis dur-
ing labour, with or without concurrent use of pharmacological or
non-pharmacological pain relief methods versus placebo, no treatment or any analgesic drug or technique.

As noted, this review is one in a series of Cochrane reviews examining pain management in labour. The current list of reviews is as outlined below. Methods of pain relief 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 (this review)
3. Biofeedback (Barragán 2011)
4. Intracutaneous or subcutaneous sterile water injection (Derry 2011)
5. Immersion in water (Cluett 2009)
6. Aromatherapy (Smith 2011a)
7. Relaxation techniques (yoga, music, audio)*
8. Acupuncture or acupressure (Smith 2011b)
9. Manual methods (massage, reflexology)*
10. Transcutaneous electrical nerve stimulation (Dowswell 2009)
11. Inhaled analgesia
12. Opioids (Ullman 2010)
13. Non-opioids (Othman 2011)
14. Local anaesthetic nerve blocks (Novikova 2011)
15. Epidural (including combined spinal epidural) (Anim-Somuah 2005; Simmons 2007)

*In future updates these individual reviews may be split into separate reviews on yoga, music, audio and massage and reflexology, respectively.

Types of outcome measures

Primary outcomes
- Use of pharmacological pain relief or anaesthesia at any time during labour and childbirth (as defined by trialists)
- Satisfaction with pain relief (as defined by trialists)
- Sense of coping with labour (as defined by trialists)
- Spontaneous vaginal birth

Secondary outcomes
- Pain intensity (as defined by trialists)
- Maternal pain score as measured by visual analogue pain scores or verbal numerical rating scores
- Severe pain experienced during the birth (as defined by trialists), measured in labour or postnatally
- Sense of control in labour (as defined by trialists)
- Satisfaction with childbirth experience (as defined by trialists)
- Birth experience worse than expected
- Effect (negative) on mother/baby interaction
- Breastfeeding at discharge from hospital
- Assisted vaginal birth
- Caesarean section
- Admission to special care baby unit/neonatal intensive care unit (as defined by trialists)
- Apgar score less than seven at five minutes
- Poor infant outcomes at long-term follow-up (as defined by trialists)
- Cost (as defined by trialists)
- Use of epidural/neuroaxial block as additional analgesia
- Preterm birth
- Induction of labour
- Augmentation of labour with oxytocin
- Length of labour (as defined by trialists)
- Perineal trauma (defined as episiotomy and incidence of tear - greater than first degree)
- Primary postpartum haemorrhage (> 500 ml)
- Need for postpartum blood transfusion
- Postnatal depressive symptoms (as defined by trialists)
- Number of maternal days in hospital after the birth
- Number of neonatal days in hospital after the birth
- Any other incidences or adverse events, e.g. post-dural puncture headache; maternal/neonatal death; maternal mental disturbance

Search methods for identification of studies

Electronic searches

We will contact the Trials Search Co-ordinator to search the Cochrane Pregnancy and Childbirth Group's Trials Register. 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.
Searching other resources

We will search the reference lists of all available primary studies and review articles and contact the primary authors of known studies to seek other published or unpublished trials. We will not apply any language restrictions.

Data collection and analysis

Selection of studies

Two review authors (Kelly Madden (KM) and Philippa Middleton (PM)) will independently assess for inclusion all the potential studies we identify as a result of the search strategy. We will resolve any disagreement through discussion or, if required, we will consult a third author (Allan Cyna (AMC)).

Data extraction and management

We will design a form to extract data. For eligible studies, two review authors (KM and PM) will extract the data using the agreed form. We will resolve discrepancies through discussion or, if required, we will consult a third review author (AMC). We will enter data into Review Manager software (RevMan 2011) and check for accuracy. When information regarding any of the above is unclear, we will attempt to contact authors of the original reports to provide further details.

Assessment of risk of bias in included studies

Two review authors (KM and PM) will independently assess risk of bias for each study using the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011). We will resolve any disagreement by discussion or by involving a third assessor (AMC).

(1) Sequence generation (checking for possible selection bias)

We will 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 will assess 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 will describe for each included study the method used to conceal the allocation sequence in sufficient detail and determine whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment. We will assess 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); or
- unclear risk of bias.

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

We will 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 will consider that studies are at low risk of bias if they were blinded, or if we judge that the lack of blinding would be unlikely to affect the results. We will assess blinding separately for different outcomes or classes of outcomes. We will assess the methods as:

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

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

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

- 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 will 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 will state whether attrition and exclusions were reported, 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 can be supplied by the trial authors, we will re-include missing data in the analyses which we undertake. We will assess methods as:

- low risk of bias (e.g. where there are no missing data or where reasons for missing data are 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); or
• unclear risk of bias.

(5) Selective reporting bias (checking for reporting bias)
We will describe for each included study how we investigated the possibility of selective outcome reporting bias and what we found. We will assess 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; the study fails to include results of a key outcome that would have been expected to have been reported); or
• unclear risk of bias.

(6) Other sources of bias (checking for bias due to problems not covered in (1) to (5) above)
We will describe for each included study any important concerns we have about other possible sources of bias. For example, where there was a potential source of bias related to a specific study design or where a trial was stopped early due to some data-dependent process.
We will assess whether each study was free of other problems that could put it at risk of bias and categorise as:
• low risk of other bias;
• high risk of other bias; or
• unclear whether there is a risk of other bias.

(7) Overall risk of bias
We will make 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 will assess the likely magnitude and direction of the bias and whether we consider it is likely to impact on the findings. We will 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 will present results as summary risk ratio with 95% confidence intervals.

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

Ordinal data
For ordinal data measured on scales (e.g. pain measured on visual analogue scales), we will analyse as continuous data and express the intervention effect as a difference in means or standardised difference in means. For ordinal data (e.g. satisfaction with pain relief) measured on shorter ordinal scales (e.g. excellent, very good, good), we will analyse as dichotomous data by combining categories (e.g. excellent and very good) and express the intervention effect using risk ratios.

Unit of analysis issues

Cluster-randomised trials
We will include cluster-randomised trials in the analyses along with individually randomised trials. We will adjust their sample sizes using the methods described in the Handbook (Higgins 2011) using an estimate of the intracluster correlation co-efficient (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 will report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. If we identify both cluster-randomised trials and individually-randomised trials, we will plan to synthesise the relevant information. We will consider it reasonable to combine the results from both if there is little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomisation unit is considered to be unlikely.

We will also acknowledge heterogeneity in the randomisation unit and perform a sensitivity analysis to investigate the effects of the randomisation unit.

Dealing with missing data
For included studies, we will note levels of attrition. We will 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 will carry out analyses, as far as possible, on an intention-to-treat basis, i.e. we will attempt to include all participants randomised to each group in the analyses, and analyse all participants in the group to which they were allocated, regardless of whether or not they received the allocated intervention. The
denominator for each outcome in each trial will be the number randomised minus any participants whose outcomes are known to be missing.

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

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

Data synthesis
We will carry out our statistical analysis using the Review Manager software (RevMan 2011). We will use fixed-effect meta-analysis for combining data where it is reasonable to assume that studies are estimating the same underlying treatment effect; i.e. where trials are examining the same intervention, and the trials’ populations and methods are judged sufficiently similar. If there is clinical heterogeneity sufficient to expect that the underlying treatment effects differ between trials, or if substantial statistical heterogeneity is detected, we will use random-effects meta-analysis to produce an overall summary if an average treatment effect across trials is considered clinically meaningful. We will treat the random-effects summary as the average range of possible treatment effects and we will discuss the clinical implications of treatment effects differing between trials. If the average treatment effect is not clinically meaningful we will not combine trials.

If we use random-effects analyses, we will present the results as the average treatment effect with its 95% confidence interval, and the estimates of $T^2$ and $I^2$.

Subgroup analysis and investigation of heterogeneity
If we identify substantial heterogeneity, we will investigate it using subgroup analyses and sensitivity analyses. We will consider whether an overall summary is meaningful, and if it is, use random-effects analysis to produce it.

We plan 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.
5. Trimester (first versus second versus third trimester; first and second trimester versus third trimester) at commencement of hypnosis sessions.
6. Number of hypnosis sessions (less than four versus four or more).
7. Method of hypnosis intervention delivery (one-to-one versus group classes, audio CD versus no audio CD, hypnosis preparation prior to labour versus practitioner assisted hypnosis in labour).
8. Maternal anxiety levels (high versus low).

We will restrict subgroup analysis to the primary outcomes. For fixed-effect inverse variance meta-analyses we will assess differences between subgroups by interaction tests. For random-effects and fixed-effect meta-analyses using methods other than inverse variance, we will 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
We will carry out sensitivity analysis to explore the effect of trial quality for primary outcomes in the review. Where there is risk of bias associated with a particular aspect of study quality (e.g. inadequate allocation concealment), we will explore this by sensitivity analyses.

Acknowledgements
We would like to thank the staff in the Editorial Unit, Cochrane Pregnancy and Childbirth Group, Liverpool, UK.

As part of the pre-publication editorial process, this protocol 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.
Additional references

Alexander 2009

AMA Council on Mental Health 1958

Anim-Somuah 2005

Barber 1979

Barragán 2011

BMA Working Party 1955

Bonica 1990a

Bonica 1990b

BPS Working Party 2001

Caton 2002

Chooi 2011

Cluett 2009

Cyna 2004

Cyna 2007

Derry 2011

Dowswell 2009

Egger 1997

Faymonville 2000

Gamsa 2003

Green 1998

Hallquist 2007

Harbord 2006
Harbord RM, Egger M, Sterne JA. A modified test for small-study effects in meta-analyses of controlled trials.
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Harmon 1990

Higgins 2011

Hodnett 2007

Howell 2009

Jones 2011a

Jones 2011b

Kroger 1957

Lawrence 2009

Lowe 1989

Lowe 2002

Lundgren 1998

Maquet 1999

Martin 2001

McCutcheon-Rosegg 1996

McIntyre 2010

Melzack 1984

Mongan 2005

Montgomery 2000

Novikova 2011

Othman 2011

Patterson 2003

Platonov 1960

Rainville 1997

RevMan 2011
Rock 1969

Simkin 2004

Simmons 2007

Smith 2006

Smith 2011a

Smith 2011b

Trentin 2001

Ullman 2010

* Indicates the major publication for the study

**HISTORY**

**CONTRIBUTIONS OF AUTHORS**
K Madden: drafted the background and adapted part of the methods.

AM Cyna: conceived the review topic, contributed to writing the draft manuscript.

P Middleton: reviewed the entire protocol, adapted part of the methods and provided advice on statistical analysis and methodology.

M Matthewson: commented on drafts.

**DECLARATIONS OF INTEREST**
K Madden used hypnosis during the births of her two children and teaches private childbirth education classes, which include psychological strategies for comfort.

AM Cyna recently completed the Hypnosis Antenatal Training for Childbirth (HATCH) RCT which is expected to be included in the review. M Matthewson will substitute for AM Cyna if K Madden and P Middleton require consultation with a third author when assessing that study for inclusion, quality and completing data extraction. Neither K Madden or P Middleton were involved in the HATCH trial although AM Cyna was K Madden’s secondary supervisor for honours and is the secondary supervisor for a masters thesis which will be based on this Cochrane Review.
SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

- Nursing and Allied Health Scholarship and Support Scheme (NAHSSS), Australia.
  K Madden has been supported by a scholarship from the NAHSSS funded by the Department of Health and Ageing. The views expressed in this protocol do not necessarily represent those of the NAHSSS, its Administrator, Services for Australian Rural and Remote Allied Health (SARRAH) and/or the Australian Government Department of Health and Ageing.