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Hypnosis for induction of labour (Review)

Nishi D, Shirakawa MN, Ota E, Hanada N, Mori R

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[Intervention Review]

Hypnosis for induction of labour

Daisuke Nishi¹, Miyako N Shirakawa², Erika Ota³, Nobutsugu Hanada³, Rintaro Mori³

¹Department of Mental Health Policy and Evaluation, National Institute of Mental Health, National Center of Neurology and Psychiatry, Kodaira, Japan. ²Institute of Women's Health, Tokyo Women's Medical University, Tokyo, Japan. ³Department of Health Policy, National Center for Child Health and Development, Tokyo, Japan

Contact address: Rintaro Mori, Department of Health Policy, National Center for Child Health and Development, 2-10-1 Okura, Setagaya-ku, Tokyo, 157-8535, Japan. rintaromori@gmail.com.

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ABSTRACT

Background

Induction of labour using pharmacological and mechanical methods can increase complications. Complementary and alternative medicine methods including hypnosis may have the potential to provide a safe alternative option for the induction of labour. However, the effectiveness of hypnosis for inducing labour has not yet been fully evaluated.

Objectives

To assess the effect of hypnosis for induction of labour compared with no intervention or any other interventions.

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (31 January 2014), handsearched relevant conference proceedings, contacted key personnel and organisations in the field for published and unpublished references.

Selection criteria

All published and unpublished randomised controlled trials (RCTs) and cluster-RCTs of acceptable quality comparing hypnosis with no intervention or any other interventions, in which the primary outcome is to assess whether labour was induced.

Data collection and analysis

Two review authors assessed the one trial report that was identified (but was subsequently excluded).

Main results

No RCTs or cluster-RCTs were identified from the search strategy.

Authors' conclusions

There was no evidence available from RCTs to assess the effect of hypnosis for induction of labour. Evidence from RCTs is required to evaluate the effectiveness and safety of this intervention for labour induction. As hypnosis may delay standard care (in case standard care is withheld during hypnosis), its use in induction of labour should be considered on a case-by-case basis.

Future RCTs are required to examine the effectiveness and safety of hypnotic relaxation for induction of labour among pregnant women who have anxiety above a certain level. The length and timing of the intervention, as well as the staff training required, should be taken into consideration. Moreover, the views and experiences of women and staff should also be included in future RCTs.

PLAIN LANGUAGE SUMMARY

Hypnosis for induction of labour

Labour induction is the artificial stimulation of uterine contractions in order to bring about birth. It is commonly used in late pregnancy to address maternal and fetal problems. Induction of labour using pharmacological and mechanical methods can cause complications or side-effects such as bleeding, caesarean section uterine hyperstimulation and maternal and newborn infections. A complementary and alternative medicine method, such as hypnosis, may provide a safe alternative method for inducing labour.

Hypnosis is a relaxation technique in which the person closes down their awareness of external distractions to concentrate on a specific image, thoughts or feelings. Hypnosis has long been used to reduce pain perception during labour and hypnotic relaxation may be beneficial for women who are extremely anxious about giving birth. Hypnosis may increase self-confidence and well-being and be associated with decreased costs to the healthcare system if effective. The effectiveness of hypnosis for induction of labour has not however been evaluated. We searched for randomised controlled trials that examined the effect of hypnosis for induction of labour. We did not find any studies for inclusion in this review. Trials using hypnosis are required so that the effectiveness and safety of hypnotic relaxation to induce labour in pregnant women with high levels of anxiety can be fully evaluated. The length and timing of the intervention, as well as the staff training required, and the views and experiences of women and staff, should be taken into consideration. As hypnosis may delay standard care (in case standard care is withheld during hypnosis), its use in induction of labour should be considered on a case-by-case basis.

BACKGROUND

Description of the condition

Induction of labour is a technique to artificially stimulate commencement of labour. This is a common obstetric intervention carried out to address a variety of complications, such as prolonged pregnancy, maternal illness or fetal death. In recent years the rate of labour induction has been rapidly increasing (Grobman 2007). According to the World Health Organization (WHO) Global Survey on Maternal and Perinatal Health, which included 373 healthcare facilities in 24 countries and nearly 300,000 deliveries, approximately 10% of the deliveries were induced, ranging from 1.4% in Niger to 35.5% in Sri Lanka (WHO 2011). Possible complications that lead to induction of labour include post-term pregnancy, prelabour rupture of membranes, hypertensive disorders (e.g. gestational hypertension, pre-eclampsia, or eclampsia), maternal medical complications (e.g. diabetes mellitus, abruptio placentae), fetal death, fetal growth restriction, suspected fetal macrosomia (large baby), chorioamnionitis (inflammation of the fetal membranes), multiple pregnancy, vaginal bleeding and other complications (ACOG 2009; WHO 2011). A related Cochrane review shows that a policy of labour induction compared with expectant management in post-term women is associated with fewer perinatal deaths and fewer caesarean sections (Gulmezoglu 2012). However, induced labour can also give rise to increased complications, such as bleeding, caesarean section, uterine hyperstimula-

tion and rupture (WHO 2011). Although not advocated in current guidelines, induction of labour is sometimes elected by pregnant women, or for the convenience of clinicians (WHO 2011). There are a variety of methods available for induction, including the following: pharmacological methods (e.g. administration of oxytocin, prostaglandins, hyaluronidase, corticosteroids, or oestrogen); mechanical methods (e.g. manually rupturing the amniotic membranes, membrane sweeping, laminaria tents or balloon catheters); and alternative medicine methods (e.g. acupuncture, hypnosis or non-invasive interventions). It can be complicated to balance the benefits and risks of each method. For instance, a recent systematic review suggested that prostaglandin E2 (PGE2) reduced the possibility of failure to deliver vaginally within 24 hours and vaginal misoprostol reduced the need for caesarean deliveries, but both interventions heightened the risk of uterine hyperstimulation (Mozurkewich 2011). Mechanical methods such as laminaria tents and balloon catheters reduced uterine hyperstimulation, but increased maternal and neonatal infectious complications (Mozurkewich 2011). Given these possible problems, complementary and alternative medicine (CAM) methods may provide a safer strategy. Hypnosis comes under this category. Up to now, hypnosis has been used mostly during active labour while its effectiveness in the induction of labour is largely unknown. The purpose of this review is to search out evidence of its use and benefits, if any, in induction.

Description of the intervention

Hypnosis is a technique that enhances concentration and increases suggestibility, while simultaneously decreasing sensory awareness (Burrows 2001).

According to the Society for Psychological Hypnosis, Division 30 of the American Psychological Association, a definition of hypnosis is as follows: "Hypnosis typically involves an introduction to the procedure during which the subject is told that suggestions for imaginative experiences will be presented. The hypnotic induction is an extended initial suggestion for using one's imagination, and may contain further elaborations of the introduction. A hypnotic procedure is used to encourage and evaluate responses to suggestions. When using hypnosis, one person (the subject) is guided by another (the hypnotist) to respond to suggestions for changes in subjective experience, alterations in perception, sensation, emotion, thought or behavior. Persons can also learn selfhypnosis, which is the act of administering hypnotic procedures on one's own. If the subject responds to hypnotic suggestions, it is generally inferred that hypnosis has been induced" (Green 2005). Hypnosis is practiced as hypnotherapy in psychotherapy and has applications in many other fields, including pain management (Montgomery 2000). The effect of hypnosis is thought to be mediated by the brain's anterior cingulate cortex (ACC) (Faymonville 2000), which is understood to be involved in processing negative emotional responses (Etkin 2011). A growing body of literature suggests that the ACC in the brain is critically involved in the processing of anxiety (Allman 2001; Shin 2010), meaning that hypnosis could play a role in minimising an anxious emotional response from this part of the brain. The method can be administered either by a hypnotherapist or through self-hypnosis, which women can learn to master during their pregnancy.

How the intervention might work

It is currently unknown how hypnosis works for induction of labour. However, a case report suggests that hypnosis might effect better relaxation of the cervix (Fist 1960). Also, hypnosis may enhance self-esteem (Torem 1992; Valente 1990), self-confidence, mastery and well-being (Simkin 2004), which can help to reduce anxiety in pregnant women. Maternal conditions of anxiety were significantly associated with the onset of labour in a comparative analysis of induced and spontaneous labours in the UK (Humphrey 2009). Recently, oxytocin has been considered to have anxiolytic or anxiety-relieving effects (Marazziti 2008; Netherton 2011), and a previous study showed a significant negative correlation between oxytocin and anxiety (Scantamburlo 2007). Thus, it might be plausible to hypothesise that women who are extremely anxious about their impending labour are unable to produce the oxytocin necessary to stimulate contractions, and therefore, may find the relaxant properties of hypnosis beneficial. These findings hold promise for the application of hypnosis as a potentially effective technique to induce labour by decreasing stress in pregnant women.

Why it is important to do this review

Although there have been various reviews of CAM methods to manage pain during labour and childbirth (Cyna 2004; Jones 2012; Madden 2012), randomised controlled trials (RCTs) on hypnosis related to labour induction have not been fully evaluated. There have been some case reports or series on the effects of hypnosis on labour induction (Cyna 2003; Fist 1960; Rice 1961), but a lack of formal evidence. As induced labour is a standard obstetric intervention experienced by pregnant women when complications arise during pregnancy, it is important to find methods of labour induction that have minimal significant side effects. Hypnotic techniques have been used in obstetrics for over a 100 years (Werner 1982). A meta-analysis conducted by Cyna 2004 showed significantly less use of labour augmentation by oxytocin and an increased incidence of women delivering spontaneously in the hypnosis usage group. Reducing pharmaceutical interventions will prevent associated side effects. Few previous studies reported the costs of providing hypnosis in labour (Jones 2012). However, Cyna suggested that it was expected to be low in relation to the total costs of an episode of care, therefore, hypnosis may be associated with substantial decreased costs to the healthcare system if effective (Cyna 2006). This review will set out a clear summary of the effectiveness of hypnosis for induction of labour and its potential significance to healthcare professionals and consumers who are seeking safe, alternative methods of labour induction.

OBJECTIVES

The primary objective of the study is to investigate whether hypnosis is an effective means of inducing labour.

METHODS

Criteria for considering studies for this review

Types of studies

All published and unpublished RCTs of acceptable quality comparing hypnosis with no intervention or any other interventions, where the primary outcome was to assess whether labour was induced. We planned to include RCTs in which the units of randomisation are individuals and clusters. We planned to exclude quasi-RCTs and cross-over trials.

Types of participants

Pregnant women.

Types of interventions

Studies comparing pregnant women receiving hypnosis as a method of labour induction with those receiving no intervention or any other interventions for labour induction.

Types of outcome measures

Primary outcomes

- 1. Vaginal delivery within 96 hours or within the duration defined by the trialist
 - 2. Caesarean section

Secondary outcomes

Maternal outcomes

- 1. Serious maternal morbidity or death (e.g. uterine rupture, admission to intensive care unit, septicaemia)
 - 2. Uterine hyperstimulation
 - 3. Epidural analgesia
 - 4. Instrumental vaginal delivery
 - 5. Postpartum haemorrhage defined by the trial authors
 - 6. Maternal satisfaction
 - 7. Caregiver satisfaction
 - 8. Chorioamnionitis

Neonatal outcomes

- 1. Serious neonatal morbidity or perinatal death (e.g. seizures, birth asphyxia defined by the trial authors, neonatal encephalopathy, disability in childhood)
- 2. Neonatal admission to special care and/or intensive care unit
 - 3. Apgar score at five minutes less than seven

Search methods for identification of studies

Electronic searches

We contacted the Trials Search Co-ordinator to search the Cochrane Pregnancy and Childbirth Group's Trials Register (31 January 2014).

This register is maintained by the Trials Search Co-ordinator and contains trials identified from:

- 1. monthly 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 was 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. The Trials Search Co-ordinator searches the register for each review using the topic list rather than keywords.

Searching other resources

- 1. We searched conference proceedings from the American Society of Clinical Hypnosis from 2009 to 2013 (searched 20 January 2014).
- Personal communication: we contacted key personnel and organisations in the field for published and unpublished references.

We did not apply any language restrictions.

Data collection and analysis

Selection of studies

Two review authors (D Nishi, MN Shirakawa) independently assessed for inclusion potential studies identified as a result of the search strategy. There were no included studies.

The methods of data collection and analysis to be used in future updates of this review (if more data become available) are listed in Appendix 1.

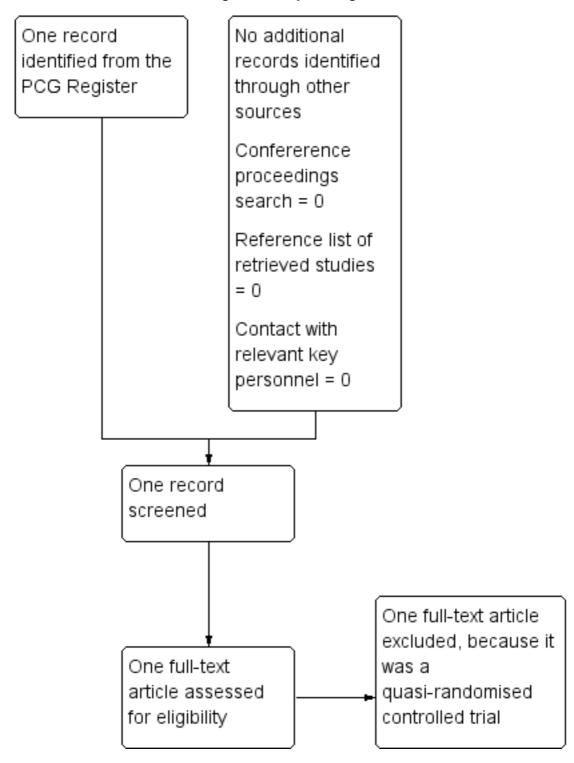
RESULTS

Description of studies

Results of the search

The search of the Cochrane Pregnancy and Childbirth Group's Trials Register identified one report (see Figure 1). We subsequently excluded this report because the study was a quasi-RCT (Omer 1987). We also handsearched proceedings of the American Society of Clinical Hypnosis from 2009 to 2013 and contacted key personnel in this field for published and unpublished references There were no RCTs or cluster-RCTs available to assess the effectiveness and safety of hypnosis for induction of labour.

Figure I. Study flow diagram.



Included studies

There are no included studies in this review.

Excluded studies

One quasi-RCT was excluded (Omer 1987).

Risk of bias in included studies

There are no included studies in this review.

Effects of interventions

There are no included studies in this review.

DISCUSSION

We found no RCTs or cluster-RCTs of acceptable quality that compared hypnosis with no intervention or any other interventions and in which the primary outcome was to assess whether labour had been induced.

To date, two meta-analyses have suggested that hypnosis might be beneficial for pain management during labour (Cyna 2004; Madden 2012). Although a recent large RCT failed to show the efficacy of hypnosis for the use of epidural analgesia during child-birth or self-reported pain, further studies are thought to be warranted that focus on specific subgroups, reconsider the length and timing of the intervention, and provide staff training in structured supportive behaviour before conclusions as to whether hypnosis is effective or not can be reasonably made (Werner 2013). The need for further studies focusing on these points also applies to hypnosis for induction of labour. Hypnotic relaxation may be beneficial for women who are extremely anxious and unable to produce the oxytocin necessary to stimulate contractions. Therefore, RCTs should ideally include pregnant women who have a high level of anxiety. It might also be helpful to assess the difference of the hypnotic

effect between those who have high anxiety and those who do not, in addition to the subgroup analysis which we planned to carry out. Moreover, as part of future economic analysis, the length and timing of the intervention, and the need for hypnosis training in hypnosis for staff who will be delivering the intervention, needs to be taken into consideration.

AUTHORS' CONCLUSIONS

Implications for practice

We did not find any randomised controlled trials (RCTs) to assess the effectiveness and safety of hypnosis for induction of labour. Generally, hypnosis is perceived to be a safe, low-cost relaxation technique. However, attention needs to be paid to the potential for a delay in standard care (i.e. where standard care may be withheld during hypnosis). Although hypnosis might be an option for induction of labour, its use should be determined on a case-by-case basis.

Implications for research

Future RCTs are required to examine the effectiveness and safety of hypnotic relaxation for induction of labour among pregnant women who have anxiety above a certain level. The length and timing of the intervention, as well as the staff training required, should be taken into consideration. Moreover, the views and experiences of women and staff should also be included in future RCTs.

ACKNOWLEDGEMENTS

We thank Ms Emma Barber for her editorial support.

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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Valente 1990

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Werner 2013

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WHO 2011

World Health Organization. WHO recommendations for induction of labour. Geneva: World Health Organization 2011

^{*} Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Omer 1987	This study was a quasi-RCT.

RCT: randomised controlled trial

APPENDICES

Appendix I. Methods of Data collection and analysis to be used in future updates of this review

Data collection and analysis

In future updates, if potential studies are identified, we will conduct the following methods of data collection and analysis, based on the Cochrane Pregnancy and Childbirth Group's standard methods text.

Selection of studies

Two review authors (D Nishi, MN Shirakawa) will independently assess for inclusion all potential studies identified as a result of the search strategy. We will resolve any disagreements through discussion or, if required, we will consult a third author (E Ota).

Data extraction and management

We will design a form to extract data. For eligible studies, two review authors will extract the data using the agreed form. We will resolve discrepancies through discussion or, if required, we will consult a third review author. We will enter data into Review Manager software (RevMan 2014) and check it for accuracy.

When information regarding any of the above is unclear e.g. abstracts only, 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 (DN, MNS) 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 through discussion or by involving a third assessor (EO).

(I) Random 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);
- unclear risk of bias.

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

We will describe for each included study the method used to conceal allocation to interventions prior to assignment and will assess 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);
- 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 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.

We will assess methods used to blind outcome assessment as:

low, high or unclear risk of bias.

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

We 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 and the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information is reported, or 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. 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 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 of 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 will describe for each included study any important concerns we have about other possible sources of bias. We will assess 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 will make explicit judgements about whether studies are at high risk of bias, according to the criteria given in the *Cochrane 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 a 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.

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 *Cochrane Handbook* 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 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.

Multi-armed trials

We will include multi-armed trials in the analyses. We will combine all relevant methods of hypnosis into a single group and incorporate all relevant control groups into a single group. Any other different intervention will be addressed in different meta-analyses. If one of the arms is irrelevant, we will exclude it from the analysis.

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 all participants will be 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 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 Tau², I² and Chi² statistics. We will regard heterogeneity as substantial if an I² is greater than 30% and either a Tau² is greater than zero, or there is a low P value (less than 0.10) in the Chi² 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. If asymmetry is suggested by a visual assessment, we will perform exploratory analyses to investigate it.

Data synthesis

We will carry out statistical analysis using the Review Manager software (RevMan 2014). 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. The random-effects summary will be treated 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, the results will be presented as the average treatment effect with 95% confidence intervals, and the estimates of Tau² and I².

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. previous caesarean section versus no previous caesarean section;
- 2. nulliparity versus multiparity;
- 3. membranes intact versus ruptured;
- 4. cervix favourable versus unfavourable or undefined;
- 5. history of previous induction of labour versus no history of induction;
- 6. preterm (36 weeks or less) delivery versus term delivery (37 weeks to 41 weeks) versus postterm delivery (42 weeks or more).

Only the primary outcomes will be included in the subgroup analyses. We will assess subgroup differences using interaction tests available within RevMan (RevMan 2014). We will report the results of subgroup analyses quoting the Chi² statistic and P value, and the interaction test I² value.

Sensitivity analysis

We will perform a sensitivity analysis to determine the effect on the results due to the high risk of bias of any of the included trials. For the purpose of this sensitivity analysis, we will define 'high quality' as a trial having low risk of random sequence generation, adequate allocation concealment and the percentage of missing data less than 20%, given the stated importance of attrition as a quality measure

(Tierney 2005). Only the primary outcomes will be included in the sensitivity analyses. If statistical heterogeneity exists in outcomes, we will carry out the sensitivity analysis to explore the effects of fixed-effect or random-effects analyses. Furthermore, if there are any assumptions for ICC value used in cluster-randomised trials, we will perform a sensitivity analysis.

CONTRIBUTIONS OF AUTHORS

Daisuke Nishi drafted the review with support from Erika Ota, Nobutsugu Hanada and Rintaro Mori.

Miyako N Shirakawa provided comments. All authors read and approved the final review.

DECLARATIONS OF INTEREST

None known.

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External sources

• Ministry of Health, Labour and Welfare, Japan.

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

In the protocol, we stated that we planned to handsearch relevant journals and conference proceedings of national and international conferences related to hypnosis interventions, but we did not specify the journals and conferences.

For the review, we only searched conference proceedings from the American Society of Clinical Hypnosis.

INDEX TERMS

Medical Subject Headings (MeSH)

*Hypnosis; Labor, Induced [*methods]

MeSH check words

Female; Humans; Pregnancy