A Systematic Review of Randomised Controlled Trials of Non-Pharmacological pain relief strategies for pregnant women in labour

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Declaration:

By submitting this thesis electronically, I declare that the entirety of the work contained therein is my own, original work, that I am the authorship owner thereof (unless to the extent explicitly otherwise stated) and that I have not previously in its entirety or in part submitted it for obtaining any qualification.

March 2011

Abstract

Background

For several decades childbirth educators and midwives have focused on the alleviation or reduction of pain and suffering during the childbirth experience (Brown, Douglas & Flood 2001:1). Nursing professionals who care for labouring women require current, evidence-based knowledge regarding pain management options, including mode of action, benefits, risks and efficacy (Florence & Palmer 2003:238).

Objectives

This study examined the effects of non-pharmacological pain relief strategies for pain management during labour.

Search methods

The researcher conducted a search between February and May 2010 on PubMed, CINAHL and CENTRAL for randomised controlled trials published from inception to 2010. The Medical Search Headings (MeSH) included non-pharmacological, alternative, pain management, labour, pregnant, complementary, randomised, randomly, midwifery, natural birth, relaxation, breathing, positioning, hypnosis, water birth, acupuncture, aromatherapy.

Selection criteria

The studies included reported on pregnant women, primigravida or multigravida, term (37 weeks and more), spontaneous labour (first or second stage) without any complications in previous or current pregnancies. The researcher searched for randomised controlled trials with an intervention and a control group. Due to financial restrictions the researcher assessed studies that were published in English only. Interventions were childbirth education, continuous support, relaxation, breathing techniques, movement and positioning, music, manual healing, aromatherapy, hydrotherapy, hypnosis and acupuncture.

Data collection and analysis

Meta-analysis was performed using Relative Risks and 95% Confidence Interval for dichotomous outcomes and Weighted mean differences and 95% Confidence Interval for continuous outcomes. Review Manager (RevMan), a statistical software was used. Where meta-analyses were impossible results were presented in narrative form. The outcome measures were a decreased need for pharmacological pain relief, maternal satisfaction with the overall childbirth experience, length of labour (normal or shorter progress), incidence of postnatal depression, incidence of postpartum haemorrhage, an Apgar score of more than seven at five minutes, resuscitation of the neonate and admission to the neonatal intensive care unit.

Results

Thirteen (13) eligible RCT's were included in the systematic review. Four trials involved hydrotherapy (n=585), two trials involved acupuncture (n=480), two trials involved childbirth education (n=6398), one trial involved continuous support (n=2844), one trial involved aromatherapy (n=513), one trial involved maternal positioning (n=2547), one trial involved music, massage and relaxation (n=90) and one trial involved hypnosis (n=82). In the Freeman trial (1986) women in the hypnosis group required less pharmacological pain relief 15/29 compared to women in the control group 20/36. Women in the intervention group also experienced greater satisfaction with the childbirth experience 15/29 (52%) compared to women in the control group 8/36 (23%). The trials of acupuncture showed a decreased need for pharmacological pain management in Skilnand (2002) (n=208) for epidural 11/106 (10%) for the intervention and 27/102 (26.5%) for the control group as well as Pethidine 15/106 (14%) for the intervention and 36/102 (35%) for the control group. In the Borup trial (2009) it was reported that acupuncture during labour reduced the need for pharmacological pain management for the intervention group 185/314 (58.9%) compared to control 124/149 (83.2%) without affecting the birth outcome. The secondary outcome of length of labour (minutes) in the Skilnand trial is significantly in favour of the acupuncture group with a mean value of 212 (SD, 155), compared to the control group with a mean value of 283 (SD, 225) with a p-value of 0.01.

Conclusions

Acupuncture may relieve labour pain and also shorten the duration of labour, and women experience greater satisfaction with the childbirth experience. Hypnosis may decrease the need for pharmacological pain relief requirements, and may also increase an overall maternal satisfaction with the childbirth experience. There is insufficient evidence about the benefits of childbirth education, continuous support, aromatherapy, music, massage, movement and positioning, breathing and relaxation.

Opsomming

Agtergrond

Vir talle dekades het die verloskundiges en vroedvroue gefokus op die verligting of vermindering van pyn en lyding gedurende die ervaring van kindergeboorte (Brown, Douglas & Flood 2001:1). Professionele verpleegkundiges wat omsien na vrouens wat kraam het die huidige, bewyslewerende kennis aangaande pynbestuuropsies nodig, insluitende die wyse van optrede, voordele, risiko en effektiwiteit (Florence & Palmer 2003:238).

Doelstellings

Hierdie studie het die effekte van nie-farmakologiese pynverligtingstrategieë vir die beheer van pyn gedurende die kraamproses nagevors.

Ondersoekmetodes

Die navorser het gedurende Februarie en Mei 2010 ’n ondersoek gedoen na PubMed, CINAHL en CENTRAL vir ewekansigbeheerde proewe gepubliseer vanaf die aanvang tot 2010. Die Mediese Ondersoekhoofde het farmakologiese, alternatiewe, pynbeheer, kraam, swangerskap, komplementêre, ewekansigheid, toevalligheid, verloskunde, natuurlike geboorte, ontspanning, asemhaling, posisionering, hipnose, watergeboorte, akupunktuur en aromaterapie ingesluit.

Seleksie kriteria

Die studies het navorsing oor swanger vroue, primigravida of multigravida, tydperk (37 weke en meer), spontane kraam (eerste of tweede stadium) sonder enige komplikasies in vorige of huidige swangerskappe ingesluit. Die navorser het ewekansigbeheerde toetsing met ’n intervensie en ’n kontrole groep ondersoek. As gevolg van finansiële beperkings het die navorser studies wat alleenlik in Engels gepubliseer is, geassesseer. Intervensies soos die opvoeding oor kindergeboorte, deurlopende ondersteuning, ontspanning, asemhalingstegnieke, beweging en posisionering, musiek, handegenesing, aromaterapie, hidroterapie en akupunktuur is bestudeer.

Data-insameling en analise

Meta-analise is uitgevoer deur gebruik te maak van Relatiewe Risiko's en 95% Betroubaarheidsinterval vir tweeledige uitkomste en Gewigdraende gemiddelde afwykings en 95% Betroubaarheidsinterval vir deurlopende resultate. Review Manager (RevMan), 'n statistiese sagteware is gebruik. Waar dit ontmoontlik was om meta-analise uit te voer, was resultate gepresenteer in narratiewe vorm. Die uitkomste meting is 'n afname in die behoefte vir farmakologiese pynverligting, moederskapbevrediging met die algehele geboorteskenkervaring, die duur van die bevalling (normale of korter vordering), gevalle van postnatale depressie, voorkoms van postpartum bloeding , 'n Apgartelling van meer as sewe teen vyf minute, resussitasie van die neonaat en toelating tot die neonatale intensiewe sorgeenheid.

Resultate

Dertien (13) geskikte ewekansigbeheerde proewe is ingesluit in die sistematiese oorsig. Vier proewe het hidroterapie (n=585), twee proewe akupunktuur (n=480), twee proewe die opvoeding van kindergeboorte (n=6398), een proef deurlopende ondersteuning (n=2844), een proef aromaterapie (n=513), een proef moederlike posisionering (n=2547), een proef musiek, massering en ontspanning (n=90) en een proef het hipnose (n=82). Die proef vir hipnose het 'n afname in die behoefte vir farmakologiese pynbeheer met 15/29 vroue in die hipnose groep en 20/36 vroue in die kontrole groep getoon. Vroue in die hipnose groep het ook groter bevrediging gevind met die ervaring van die geboorteskenking met 15/29 (29%) in vergelyking met 8/36 (23%) in die kontrole groep. Die proewe vir akupunktuur het 'n afname in die behoefte vir farmakologiese pynbeheer Skilnand (2002) (n=208), met 'n gemiddelde waarde van 11/106 (10%) vir epiduraal en 15/106 (14%) vir Pethidien in die intervensie groep en 'n gemiddelde waarde van 27/106 (26.5%) vir epidural en 36/102 (35%) in die kontrole groep. Borup (2009) (n=384) toon ook 'n afname in die behoefte van farmakologiese pynbeheer met 'n waarde van 185/314 (58.9%) in vergelyking met die kontrole groep 124/149 (83.2%). Die sekondêre uitkomste van die duur van die kraamproses (minute) in Skilnand (2002), is noemenswaardig ten gunste van die akupunktuurgroep met 'n gemiddelde waarde van 212 (SA, 155) in die intervensie groep en 'n gemiddelde waarde van 283 (SA, 225) in die kontrole groep met 'n p-waarde van 0.01.

Gevolgtrekkings

Akupunktuur mag kraampyn verlig en ook die duur van die kraamproses verkort, vandaar dat vrouens groter bevrediging mag ervaar met die ervaring van geboorteskenk. Hipnose mag die begeerte na farmakologiese pynverligting verminder en sodoende vroue groter ervaring met geboorteskenk mag ervaar. Daar is onvoldoende bewys aangaande die voordele van die opvoeding van kindergeboorte, deurlopende ondersteuning, aromaterapie, musiek, massering, beweging en posisionering, asemhaling en ontspanning.

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Terminology

Systematic Review: A systematic review attempts to collate all empirical evidence that fits pre-specified eligibility criteria to answer a specific research question. It uses explicit, systematic methods that are selected with a view to minimising bias, thus providing reliable findings from which conclusions can be drawn and decision made.

Meta-analysis: Met-analysis is the use of statistical techniques to integrate and summarise the results of included studies. By combining information from all relevant studies, meta-analysis can provide more precise estimates of the effects of health care than those derived from the individual studies included within a review.

Bias (synonym: systematic error): the distortion of the outcome, as a result of a known or unknown variable other than intervention (i.e. the tendency to produce results that depart from the "true" result).

Cochrane Collaboration: The Cochrane Collaboration is an international organization that aims to help people make well-informed decisions about healthcare by preparing, maintaining & promoting the accessibility of systematic reviews of the effects of healthcare interventions.

Cochrane Controlled Trials Register (CCTR): CCTR is a database of references to controlled trials in health care.

Critical appraisal: systematically finding, appraising and interpreting evidence of effectiveness. It is aimed to examine research evidence to assess its validity, results and relevance before using it to inform a decision.

Cumulative meta-analysis: the repeated performance of meta-analysis whenever a new trial becomes available for inclusion. In cumulative meta-analysis studies are added one at a time in a specified order.

Effect size: refers to the size of a relationship between an expose and an outcome. The term is applied to measurement of the differences in the outcome between the

study groups. Relative risk, odds ratio, and risk differences can be defined as effect sizes for dichotomous scale. Effect size of continuous variable is the standardized mean differences.

Fixed-effect model: a mathematical model that combines the results of studies that assume the effect of the intervention is constant in all subject population studied. Only within study variation is included when assessing the uncertainty of results.

Forest plot: a forest plot presents the means and variance for the difference for each pooled primary study. The line represents the standard error of the difference; the box represents the mean difference and its size proportional to the number of subjects in the study. The bottom entry in a forest plot is the summary estimate of the treatment difference and confidence interval for the summary difference

Funnel plot: a graphical method of assessing bias; the effect size of each study is plotted against some measure of study information. If the shape of the plot resembles an inverted funnel, it can be stated that there is no evidence of publication bias within the systematic review.

Heterogeneity: the variability between studies in terms of key characteristics (i.e. ecological variables) quality (i.e. methodology) or effect (i.e. results). Statistical tests of heterogeneity may be used to assess whether the observed variability in effect size (i.e. study results) is greater than that expected to occur purely by chance.

Meta-regression: a multivariable model investigating effect size from individual studies, generally weighted by sample size, as a function of various study characteristics (i.e. to investigate whether study characteristics are influencing effect size).

Outlier*:* an outlier study in meta-analysis is study that results very different from the rest of the studies. Outlier could alter the conclusions of a meta-analysis.

Overall estimate: is the pooled estimate from a meta-analysis. The overall estimate from a meta-analysis is always displayed with its confidence interval.

Primary studies: Individual studies contributing to a systematic review are called primary studies whereas a systematic review is a form of a secondary study.

Publication bias: publication bias refers to the problem that positive results are more likely to be published than negative results and this may therefore give a misleading assessment of the impact of an intervention. Publication bias can be examined via a funnel plot.

Random-effects model: a mathematical model for combining the results of studies that allow for variation in the effect of the intervention amongst the subject populations studied. Both within-study variation and between-study variation is included when assessing the uncertainty of results.

Review: article that summarizes a number of primary studies and discusses the effectiveness of a particular intervention. It may not be a systematic review.

Search strategy: description of the methodology used to locate and identify research articles pertinent to a systematic review, as specified within the relevant protocol. It includes a list of search terms, based on the subject, intervention and outcome of the review, to be used when searching electronic databases, websites, reference lists and when engaging with personal contacts. If required, the strategy may be modified once the search has commenced.

Sensitivity analysis: repetition of the analysis using different sets of assumptions in order to determine the impact of variation arising from these assumptions, or uncertain decisions, on the results of a systematic review.

Subgroup analysis: used to determine if the effects of an intervention vary between subgroups in the systematic review.

Weighted mean difference: a method used to combined measures on continuous scales (where the mean, standard deviation and sample size in each group are known) and the weight given to each study is determined by the precision of its estimate of effect.

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List of Abbreviations

RCT	-	Randomised Controlled Trials
CENTRAL	-	Cochrane Central Register of Controlled Trials
CINAHL	-	Cumulative Index of Nursing and Allied Health
PEDro	-	Physiotherapy Evidence Database
RR	-	Relative Risk
CI	-	Confidence Interval
WMD	-	Weighted Mean Difference
EC	-	Ethical Committee
CTG	-	Cardio-tocograph
ICU	-	Intensive Care Unit
CAM	-	Complementary Alternative Medicine
SD	-	Standard Deviation

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1. Chapter 1: Introduction

Title: A Systematic review of Randomized Controlled Trials of non-pharmacological pain relief strategies for pregnant women in labour.

1.1. Abstract

For several decades, childbirth educators have focused on the alleviation or reduction of pain and suffering during the childbearing experience (Brown, Douglas & Flood 2001:1). Birth can be a joyful and empowering experience, but can end with negative and tragic results, leaving women filled with fear and anxiety for future births. The absence of knowledge can influence the choices that pregnant women make regarding their labour. (Florence & Palmer 2003:338). Ultimately, the nurse's role is to support the labouring woman to make informed choices in order to achieve overall satisfaction of the birth experience, while ensuring the safety of both mother and infant (Florence & Palmer 2003:238).

A wide variety of pharmacological and non-pharmacological pain relief measures are available to women in labour. Many women would like to avoid pharmacological or invasive methods of pain management in labour and this may contribute towards the popularity of non-pharmacological methods of pain relief (Smith, Collins, Cyna & Crowther 2009:1).

This systematic review examines the effectiveness of the different types of non-pharmacological pain relief strategies that labouring women use most. These interventions are:

- childbirth education,
- continuous support,
- relaxation,
- breathing techniques,
- movement and positioning,
- music,
- massage,
- hot and cold therapy,
- hydrotherapy,
- hypnotherapy,

- aromatherapy,
- acupuncture,
- sterile water injections

This information can provide direction for childbirth educators and midwives in designing and implementing an effective childbirth preparation plan. It will also equip labouring women with adequate information to make informed decisions so that they can have empowered birth experiences.

1.2. Introduction

There are a number of ways to relieve labour pain among women delivering babies. Pain is part of the childbirth process. Exceptionally, a very few women may not feel pain; others can control their response so as to reduce pain. Most women think that pain is going to be a major part of giving birth (Findley & Chamberlain 2000:927). Natural birth is best for the baby and the mother, because there are no inherent risks of drugs that will affect either the mother or the baby.

Even though delivery is a natural phenomenon, it has been demonstrated that the accompanying pain is considered severe or extreme on more than half of cases (Tournaire & Yonneau 2007:409). Women are encouraged to make use of a collection of simple, non-pharmacological pain relief strategies to decrease or modify labour pain that has no potential to cause harm to the mother or infant (Brown et al. 2001:1). These strategies are attractive to pregnant women who want to be more involved in their own care and feel that such interventions are more in harmony with their personal philosophies.

1. 3. Background

A scientific definition of pain is “an unpleasant sensory and emotional experience associated with actual or potential tissue damage” (Yournaire & Yonneau 2007:410). Acute pain such as labour pain has two dimensions: a sensory or physical dimension, with the transmission of information, the pain stimuli to the brain, and an affective dimension due to the interpretation of these stimuli through the interaction of a wide variety of emotional, social, cultural and cognitive variables unique to the individual (Tournaire & Younneau 2007:410).

A wide variety of non-pharmacological pain relief strategies are presently available to pregnant women in labour to cope with the pain or to decrease the effect of labour pain (Brown et al 2001:1). Childbirth education, continuous support, relaxation, breathing

techniques, positioning and movement, hot and cold therapy, hydrotherapy, music, manual healing, aromatherapy, hypnotherapy and acupuncture are all means of coping strategies for labouring women to ensure a positive birth experience (Brown et al. 2001:1). These interventions have been shown to promote a higher satisfaction with the labour experience because of perceived control and empowerment. Included among the benefits of using non-pharmacological pain relief strategies are their attributes of being non-intrusive, non-invasive, low-cost, simple and effective, and without adverse effects (Brown et al.2001:1). Nursing professionals who care for labouring women require current, evidence-based knowledge regarding pain management options, including mode of action, benefits, risks and efficacy (Florence & Palmer 2003:238).

According to Melzack and Wall (1995:338), anyone who has suffered severe pain and has tried to explain it to a friend or doctor, often finds herself at a loss for words. Labour has been described as the worst pain ever. In an intervention review conducted by Smith, Collins, Cyna and Crowther (2009:2) examining the effects of complementary and alternate therapies for pain management in labour, it was found that labour presents a physiological and psychological challenge for women. The authors examined currently available evidence regarding the efficacy of non-pharmacological pain relief strategies such as acupressure, acupuncture, aromatherapy, audio-analgesia, hypnosis and relaxation on the same primary outcomes and secondary outcomes of this review but also included mode of delivery, instrumental vaginal delivery, need for augmentation with oxytocin, perineal trauma (defined as episiotomy and incidence of second and third degree tear), perception of pain experienced, assessment of mother-baby interaction and breastfeeding at hospital discharge. Neonatal outcomes included admission to neonatal intensive care unit, need for mechanical ventilation and neonatal encephalopathy.

Psychologically, a woman needs to know when she is in labour, how far along she is and when the baby will be coming. She also needs knowledge about the different levels of pain she will feel during the different stages of labour. The pain experienced by women during labour is caused by uterine contractions, the dilatation of the cervix in the late first stage and second stage and the stretching of the vagina and pelvic floor to accommodate the baby (Smith et al. 2009:2). As labour becomes imminent, this can be a time of conflicting emotions. Tension, anxiety and fear influence women's perceptions of pain and it may affect the labour and birth (Smith et al. 2009:2). Birth can be a joyful experience, but it can also end with tragic results. Childbirth initiates strong feelings both positive and negative. When the experience is extremely negative it might have an unfavourable effect

on the woman's adaptation to her role as a mother and increases the risk for an early disturbance in the relation between the mother and the child (Olin & Faxelid 2003:153).

According to Brown et al. (2001:2) controlling pain without harm to the mother, the foetus or the labour progress remains a primary focus during the labour experience. Pharmacological measures for labour are generally found to be more successful than non-pharmacological measures in lowering pain levels. However, it is more costly with potential adverse effects. While the traditional focus in Lamaze education (childbirth education) has been on achieving childbirth that is both painless and natural, many clients today are selecting epidural anaesthesia to ensure a "painless" childbirth, Brown et al. (2001:3). Jimeneze (1996) suggests in Brown et al. (2001:3) that the focus must change from pain management to comfort management, as educators equip clients with skills that can result in increased comfort. According to Leeman, Fontaine, King, Klein & Ratcliff (2003:1115), it was established that although epidural analgesia is the most effective form of pain relief, its use is associated with a prolonged labour, a growing incidence of maternal fever and increased rates of operative vaginal deliveries.

However, the complete removal of labour pain by epidural analgesia does not necessarily mean a more satisfying birth experience (Brown et al 2001:3). All analgesic and anaesthetic medication have risks. Analgesia means pain relief without total loss of sensation, while anaesthesia is defined as pain relief with total loss of sensation (Tveit, Halvorsen & Rosland 2009:794). Although Pethidine has been the most frequently used opioid for decades; there has been a continuous debate as to whether the main effect of Pethidine is sedative or analgesic. Morphine has been recommended and used as an alternative; however, both Pethidine and Morphine have active metabolites that may induce side effects in the newborn. The ideal opioid for labour analgesia should have a rapid onset, a short half-life and no cumulative effect in either the mother or foetus (Tveit et al 2009:794). Faucher and Brucker (2000:170) have found that Catecholamine, a pharmacological pain relief drug, can lead to dysfunctional uterine contractions and prolonged labour. Barbiturates have minimal analgesic effect and can actually increase the reaction to pain stimuli. The sedative effect of analgesia causes women to sleep between contractions, and then wake up with the contraction only as a memory. A study conducted by Kaindl et al. (2008) on the brains of newborn mice shows that analgesic and sedative drugs often used in pregnancy and during labour can have long-term negative effects, even after minimal exposure (Sensitive Midwifery February 2009:52). In a

previous study, the same authors confirmed the negative effects of drug treatment on learning and memory in the infant (Sensitive Midwifery February 2009:52).

Although more research is needed, this may mean that drug overuse on even one occasion, for example during birth, can have long-term negative effects. It highlights the caution that should be used when administering medication to pregnant or labouring women (Sensitive Midwifery February 2009:52). There is no doubt that maternal medication for pain relief has some effect on the baby (Faucher & Brucker 2000:178).

1.4. Problem Statement

The researcher has found in her midwifery practice that there is a lack of information amongst pregnant women regarding pharmacological and non-pharmacological pain relief strategies for labour pain. The researcher investigated randomized controlled trials to determine the effects of non-pharmacological pain relief strategies for pregnant women in labour.

1.5. Goal of the Study

The goal of this study is to investigate the effects of the different non-pharmacological pain relief strategies for pregnant women in labour. Interventions are childbirth education, continuous support, relaxation and breathing, positioning and movement, hydrotherapy, music, massage, aromatherapy, hypnotherapy, acupuncture and sterile water injections. The efficacy of the said methods is compared to a control group that receive the routine intrapartum care. These methods can be utilised to improve current practices in the maternity ward. This information will be used as a tool for childbirth educators and midwives to provide direction in designing and implementing an effective childbirth preparation plan. It will also assist labouring women with adequate information to make informed decisions so that they can have empowered birth experiences.

1.6. Research Question

How effective is the use of non- pharmacological pain relief strategies for pregnant women in labour with a gestational age of 37 weeks and more?

1.7. Objectives

1. To determine the effects of non-pharmacological pain relief strategies for women in labour compared to a control group.

2. To provide relevant data for theory generation or to develop a selected theory through the research process.
3. To provide evidence about non-pharmacological pain relief strategies where the answer is uncertain.
4. To confirm the appropriateness of current practices that are in use.
5. To help pregnant women make informed decisions about pain relief methods during labour.

1.8. Research Methodology

1.8.1. Research Design

Systematic review

A systematic review of research is a narrowly focused synthesis of the findings from quantitative studies that focus on a particular practice intervention or problem (Burns & Grove 2007:557). A systematic review that focuses on studies of similar methodologies to determine the best evidence of non-pharmacological interventions that will improve pain relief for women in labour will be applied. This systematic review will be used to gather evidence to assess whether the expected effects of the interventions do indeed confirm or improve the appropriateness of current practices.

1.8.2. Research Outcomes

1.8.2.1. Primary outcomes

1. The use of pharmacological pain relief in labour.
2. The incidence of postnatal depression.

1.8.2.2 Secondary outcomes

1. Length of labour (whether it is normal progress or increased progress).
2. The incidence of post–partum haemorrhage.
3. An overall satisfaction with the general childbirth experience.
4. An Apgar score of more than seven at five minutes in the neonate.
5. The need for resuscitation of the neonate.
6. Admission to the neonatal intensive care unit.

1.8.3. Criteria for considering studies for this review

1.8.3.1. Inclusion criteria

Types of studies

Inclusion criteria were published randomised controlled trials (RCT's) that included at least one treatment group and one control group with non-pharmacological interventions relevant to this review. The reason for using RCT's is that it is more likely to provide reliable information than other sources of evidence (Cochrane Handbook 2006:65).

Types of participants

Studies included reported on pregnant women, primigravidas or multigravidas, term (37 weeks and more), spontaneous labour (first or second stage of labour) without any complications in their previous and current pregnancies.

Types of interventions

Types of interventions included childbirth education, continuous support throughout the labour process, relaxation and breathing techniques, positioning and movement, hot and cold therapy, hydrotherapy, music, manual healing, aromatherapy and hypnotherapy and acupuncture, compared to control or no treatment groups.

1.8.3.2. Exclusion criteria

Studies without a comparison group and studies with a participant withdrawal of more than 15% were excluded. According to Burns and Grove (2009) if the attrition rate is high this will inevitably have an effect on the power of the final quantitative analyses, because a lower retention rate (participants retained in the study) may not be sufficient to test the hypothesis, resulting in making a type II error (no significant difference), when in fact a difference exists. Studies with relevant outcomes but not relevant interventions were also excluded for this review.

1.8.4. Search strategy for the identification of studies

1.8.4.1. Electronic searches

The researcher conducted a search between February and May 2010 on the following electronic database: PubMed, CINAHL and CENTRAL (Cochrane Central Register for Clinical Trials) for randomised controlled trials published from inception to 2010.

1.8.4.2. Other sources

The researcher had discussions with experts' gynaecologists A. Brink and W.Viljoen. A textbook of pain from Melzack and Wall (1995) was also used. Reference lists of articles found was considered to identify more studies.

1.8.4.3. Search keywords used

Non –pharmacological, alternative, pain management, labour, pregnant, complementary, randomized, randomly, midwifery, natural birth, relaxation, breathing, positioning, hypnosis, water birth, acupuncture.

1.8.5. Data Extraction

1.8.5.1. Studies identified

Randomized controlled trials published from inception to 2010.

1.8.5.2. Types of data

Data types identified for the outcome measurements were the dichotomous data and continuous data. Dichotomous data is where each individual's outcome is one of only two possible categorical responses: clinical improvement or no clinical improvement. Continuous data refers to data that can take any value in a specified range (Cochrane Handbook 2007:106). For dichotomous data relative risk and 95% Confidence Interval were calculated. For continuous data weighted mean difference and 95% Confidence Interval were calculated. Relevant data for meta-analysis were entered into the Review Manager, a statistical software.

1.8.5.3. Data extraction form

Reviewers M.Abelgas extracted the data and M.Taha assessed the data. A standardized data extraction tool from the Cochrane website was used to extract data. The PeDro scale (Physiotherapy Evidence Database) and Cochrane tool were used as instruments for

rating the quality of the studies. The PeDro scale consists of eleven criteria with a user guide that explains all the criteria (Maher, Sherrington, Herbert & Moseley 2003:713). The Cochrane tool consists of five criteria: randomisation, allocation concealment, blinding, incomplete outcome data addressed and free of selective reporting (see list of Appendices).

1.8. 5.4. Missing data

Authors of published studies would be contacted for missing data, but it was not deemed necessary.

1.8.6 .Data Management and Analysis

1.8.6.1. Selection of studies

Data were collected from randomized controlled trials that were published from inception to 2010.

1.8. 6.2. Heterogeneity

"Heterogeneity is any kind of variability among studies in a systematic review. Inevitably, studies brought together in a systematic review will differ."(Cochrane Handbook 2006:137). Variability in treatment effects were evaluated in different randomized controlled trials, known as statistical heterogeneity. The heterogeneity was measured by using a statistical test named the chi-squared test. "The chi-squared test of independence determines whether two variables are independent or related." (Burns and Grove 2007:420). "It assesses whether observed differences in results are compatible with chance alone."(Cochrane Handbook 2006:137). "A low p-value (or a large chi-squared statistic relative to its degree of freedom) provides evidence of heterogeneity of treatments effects" (Cochrane Handbook 2006:137). A p-value of 0.10 was used to determine statistical significance.

1.8.6.3. Data synthesis

An meta-analysis was conducted on the outcomes of similar studies. "Meta-analysis statistically pools the results from previous studies into a single quantitative analysis, that provides the highest level of evidence for an intervention's efficacy" (Conn & Rantz, 2003; Whittemore, 2005). Comparisons were done between outcomes of intervention and control groups and data was displayed in a forest plot. The statistician was contacted for

statistical measurement of data and interpretation of the findings that was included in the report. Where meta-analysis was impossible, the results were presented in narrative form.

1.8.6.4. Subgroup analysis

Subgroup analysis was done on the mean length of the first and second stage of labour to determine if the effects of the interventions vary between subgroups in this systematic review.

1.8.6.5. Biases

Bias is the distortion of the outcomes as a result of a known or unknown variable other than the intervention (Cochrane Handbook 2006:80). There are four sources of bias in trials of the effects of interventions that should be investigated, it is selection (systematic differences in the comparison groups), performance (systematic differences in the care provided apart from the intervention being evaluated), attrition (systematic difference in withdrawals from the trial) and detection (systematic differences in outcome assessment). The researcher assessed the risk of bias in the randomised controlled trials in terms of randomisation, allocation concealment, intention-to-treat analysis, blinding and losses to follow-up. In selection bias the researcher assessed the method of randomisation for preventing foreknowledge of treatment assignment in a trial. In performance bias an assessment was done to determine whether those who provided and received care were blinded so that they did not know the group to which the recipients of care have been allocated. In attrition bias the researcher assessed the trials to determine how losses were handled. In detection bias the researcher assessed whether the people who assessed the outcomes in the studies were blinded to the intervention allocation.

1.8.7. Results

All relevant data was entered into the Review Manager for meta-analysis and displayed into a forest plot. Methodological quality of included studies were summarized in tables in terms of design type, sample size, setting, participants, intervention and outcomes, author findings and reviewer comments. A description of included studies as well as exclusion reasons for excluded studies was given.

1.8.8. Discussion

The summary of main results i.e. balancing important benefits against important harms was be discussed. Results were assessed for overall completeness and applicability of

evidence. Studies identified were assessed to determine if they are sufficient to address all of the objectives of this review. The relevance of the evidence of the identified studies to the review question was described. Potential bias in the review process was identified and discussed. Agreements and disagreements with the results of other studies were discussed.

1.8.9. Conclusion

Implications for practice

Practical implications for practice were addressed. Best practice guidelines were developed from the recommendations of this review.

Implications for research

Clear and concise recommendations were made based on findings, gaps and weaknesses in literature.

1.9. Reliability and Validity

Reliability refers to the degree to which a study yields the same results under similar conditions when administered by different individuals. In the context of a systematic review, the validity of a study is the extent to which its design and conduct are likely to prevent systematic errors (Cochrane Handbook 2006:79). Two independent reviewers, M. Abelgas and Dr. M.Taha, performed the research tasks. If there was disagreement between the two reviewers about studies to be included, a third reviewer was consulted. A standardized PeDro scale and the Cochrane tool were used to assess data for methodological quality. A standardized data extraction form was used from the Cochrane website to extract data. Statistical analysis was performed using a statistical software Review Manager from Cochrane Collaboration.

1.10. Ethical Consideration

In a systematic review no actual participants will be recruited for the study but published peer reviewed articles will rather be used. Permission to conduct the proposed study was obtained from the Committee of Human Research at the Stellenbosch University.

1.11. Pilot Study

A pilot study was done on two to three selected randomized controlled trials, which were included in the actual study.

1.12. Timeline

June – December (2009)	Preparation of Proposal
February (2010)	Submit Proposal
February (2010)	Pilot test of studies
February (2010)	Ethical Approval
February – April (2010)	Data Extraction
April – May (2010)	Data Management and Analysis
June (2010)	Submit first draft of report
December (2010)	Submit final report

1.13. Budget

Budget	**Amount**
Long distance telephone calls	R800
Ink Cartridges and Paper	R2000
Library	R2000
Language expert	R6 000
Total	**R10 800**

1.14. Conclusion

Pharmacological pain management is introduced to nearly every labouring woman who walks through the door of the maternity ward, though it may not be her first choice of pain relief (Thomas 1998:1). Various non-pharmacological strategies of pain relief can be initiated during labour. Nurses and childbirth educators must be willing to provide thorough childbirth education that introduces women to a variety of non-pharmacological management techniques (Brown et al. 2001:6). Nurses and childbirth educators must also be willing to provide sensitive, continuous care that is a partnership effort with the woman to assist her in coping with pain and mastering the experience of childbirth (Brown et al. 2001:6).

Psychological preparation is also extremely important due to the close link between pain and anxiety (Brown et al. 2001:6). Studies show that confidence is greater after childbirth education and that confidence is powerfully related to decreased pain perception and decreased analgesia use during labour. Lowe (1996); McCaffery & Pasero (1999) quoted in Brown et al (2001:6) that although non-pharmacological methods can be effective in helping patients relax during labour; few well-controlled studies demonstrate that these methods actually decrease perceived pain. Continued investigation is needed to establish pharmacological and non-pharmacological pain relief strategies that are safe and effective and that will enhance patient satisfaction during the birth experience - one of life's most memorable and challenging experiences (Brown et al. 2001:6).

2. Chapter 2: Literature Review

2.1. Introduction

In the 21st century, pregnant women and their care providers have a variety of non-pharmacological options available for the relief of pain and discomfort during childbirth (Florence & Palmer 2003:238). A historical philosophy of birth is that it is an inherently natural process. Satisfaction with the birth experience depends on variables that include cultural influence, previous experiences, communication from family and providers and prenatal education (Florence & Palmer 2003:238). Research has shown that maternal satisfaction after the birth experience is influenced by the degree of pain endured, but is far more influenced by whether the actual birth event met personal expectations (Florence & Palmer 2003:238).

The three C's i.e. continuity, choice and control have been identified as important aspects of maternity care for the patient as well as the midwife. The woman's wellbeing can be negatively affected if she experiences lack of control and information, and not having an active say in decision (Olin & Faxelid 2003:153). It is important for the woman to be seen and respected and to have a trustful relationship with the midwife, to be listened to and to be supported and guided on her own terms (Olin & Faxely 2003:153).

Nurses caring for labouring women use a wide range of non-pharmacological and pharmacological pain relief strategies (Brown et al 2001:1). The nurse's role is to support the labouring woman to make informed choices regarding her birth experience so that she can achieve a personal vision of birth, while at the same time ensuring the safety of both mother and infant (Florence & Palmer 2003:238).

Pain has both a sensory and emotional component (Florence & Palmer 2003:239). Within the sensory component, pain is interpreted by the woman through her personal construct of cultural, emotional, social and cognitive variables. Each individual has a unique labour experience based on these variables and selects coping methods that are acceptable within her personal construct (Florence & Palmer 2003:239).

Florence and Palmer (2003:239) explained that Melzack and Wall's gate-control theory of pain offers a framework for understanding labour pain and the interventions used in pain management. The theory suggests that a neural mechanism exists within the dorsal horn of the spinal cord that allows painful, noriceptive impulses to proceed through a "gating mechanism" to the higher brain centres. Only a certain amount of stimuli can pass through

the gate. Additional pain impulses are blocked by the gating mechanism when maximum density of impulses is reached. Many of the non-pharmacological interventions for pain act to either create competing impulses in the central nervous system by preventing painful stimuli from proceeding through the gate, or by stimulating the release of endogenous endorphins (Florence & Palmer 2003:239)

2.2. Non-pharmacological pain relief methods

2.2.1. Childbirth education

Good pain management strategies begin with the woman's preparation for childbirth through information gathering. Childbirth education classes, as well as the internet, books and baby magazines can provide accurate up-to-date information that assists the mother to be well prepared for the birth experience and to have an empowered birth experience (Brown et al 2001:2).

Components of education include information about the onset and stages of labour, specific assistance with labour including non-pharmacological and pharmacological pain relief, adjusting to life with a new baby and infant feeding (Spiby, Slade, Escott, Henderson & Fraser 2003: 189). Prenatal classes come in various formats, and cannot be considered a single entity. Some of the childbirth classes are often based on the assumption that parents will receive epidural analgesia and other pharmacological and medical interventions. They may not cover non-pharmacological pain measures or self-help measures to improve the birth experience (Spiby et al 2003:189).

The quality of information and length of classes may vary with each programme and the organization's goal and objective may differ from the recipient's. The mother should investigate the various classes so she can make an informed decision about selecting the one that will meet her needs and expectations best.

2.2.2. Continuous support

Historically and cross-culturally, women have been attended to and supported by other women during labour and birth. However, since the middle of the 20th century, the majority of women gave birth in hospital rather than at home. In many countries (high, middle and low-income) continuous support during labour has become the exception rather than the rule. Concerns about the recurrent dehumanisation of women's birth experiences have led to calls for a return to continuous, one- on-one support to women by women during labour (Hodnett, Gates, Hofmeyr & Sakala 2009:2).

Continuous support during labour should be the rule, rather than the exception. Hofmeyr (1991) quoted in Hodnett et al (2009:2) two complementary theoretical explanations for the effects of labour support on childbirth outcomes. The first theoretical explanation considers possible mechanisms when companionship during labour is used in stressful, threatening and disempowering clinical birth environments (Hodnett et al 2009:2). During labour women may be uniquely vulnerable to environmental influences; modern obstetric care frequently subjects women to institutional routines, high rates of clinical intervention, unfamiliar personnel, lack of privacy and other conditions that may be experienced as harsh (Hodnett et al 2009:2). These conditions may have an adverse effect on the progress of labour and on the development of feelings of competence and confidence; this may in turn impair adjustment to parenthood and establishment of breastfeeding, and increase the risk of depression. This process may to some extent be minimized or prevented by the provision of support and companionship during labour. The second theoretical explanation does not focus on a specific type of birth environment but it rather describes two pathways – enhanced passage of the foetus through the pelvis and soft tissues, as well as decreased stress response – by which labour support may reduce the likelihood of operative birth and subsequent complications, thus enhance women's feelings of control and satisfaction with their childbirth experience (Hodnett et al. 2009:3).

Clarification of the effects of continuous support during labour, overall and within specific circumstances, is important in light of public and social policies and programmes that encourage this type of care. For example, the Congress in Uruguay passed a law in 2001 declaring that all women have the right to companionship during labour. In several low- and middle-income countries (including China, South Africa, Tanzania and Zimbabwe), the Better Birth Initiative promotes labour companionship as a core element of care for improving maternal and infant health (Hodnett et al. 2009:3). In North America, the services of women with special training in labour support have become available. Most commonly known as a doula (a Greek word for "handmaiden"), this new member of the caregiver team may also be called a labour companion, birth companion, labour support specialist, labour assistant or birth assistant. Countries such as Australia, Bermuda, Brazil, China, the Czech Republic, Israel and South Africa are also making an effort to make doula services available (Hodnett et al. 2009:3).

Most women delivering in South African State Maternity Hospitals do not have a childbirth companion (Brown, Hofmeyr, Nikodem, Smith & Garner 2007:1). Private obstetric units have organisational rules that allow a doula or support person to be with the patient from

the onset of birth until the baby is born with flexible visiting hours thereafter. Public obstetric units only allow the doula or support person from the active phase of labour until the baby is born, or even only when the patient gives birth. Doctors may feel that doulas or support people are in their way, whereas midwives may see them as some form of comfort to the patient.

2.2.3. Relaxation

Relaxation is the most common behavioural technique discussed in non-pharmacological pain management literature. It is most effective as a pain relief method when it is learnt and practiced during the antenatal period. Relaxation can increase pain tolerance through a number of mechanisms, including reduction of anxiety, increased uterine blood flow and decreased muscle tension (Brown et al 2001:2).

2.2.4. Breathing

Another technique uses a focus on specific relaxation and patterned breathing exercises as a distraction from the discomforts of labour. Simple breathing techniques can be very effective at reducing pain during contractions, especially in the earlier part of labour with the assistance of a doula or birth partner (NetDoctor.co.uk 2005). It is especially useful at helping the woman feel in control, but should be practiced in advance. In the second stage of labour, it can prevent the woman from pushing at the wrong time and can assist with ensuring a smooth delivery (NetDoctor.co.uk 2005). Breathing is not going to be effective for a very anxious or uncooperative woman, because these women are usually not prepared for the childbirth experience and they concentrate mostly just on the labour pain.

2.2.5. Maternal positioning and movement

When a woman in labour is positioned other than flat on her back, blood flow to the uterus is increased and the woman feels less pain. This means more oxygen to the baby, normal foetal heart patterns, more effective uterine contractions, a shortened second stage of labour and a lessened need for pharmacological pain management (Lamaze International Educational Council 2004:1).

These are all positive factors that encourage a normal vaginal birth (Lamaze International Educational Council 2004:1). In addition, women like giving birth in upright or lateral positions, which convey a sense of normalcy and allow women some degree of autonomy and control. Women in early labour that maintain a vertical position demonstrates less

pain, while some find that specific rhythmic movements increase their tolerance for contraction-related pain (Lamaze International Educational Council 2004:1). Movement and position changes may decrease pain and enhance uterine blood flow, uterine activity, foetal descent and personal control (Brown, Douglas & Flood 2001:2).

Continuous electronic foetal monitoring should only be done if indicated and not as a continuous screening procedure, because it may restrict the patient's mobility. Alternative birth positions (vertical or lateral) may increase discomfort for the inexperienced midwife as vertical positions are associated with difficult access. Subsequent studies' authors have recommended the use of the hands and knees posture during labour, or doing the hands and knees exercise for ten minutes twice a day (beginning in the 37th week of gestation and continuing until the time of labour), as the optimal method of facilitating anterior foetal rotation in especially occiput posterior positions. It will thereby contribute towards a shorter duration of birth. (Kariminia, Chamberlain, Keogh & Shea 2004:1).

Hands and knees exercise in late pregnancy can be quite uncomfortable though. Women who are advised to do these exercises to help to rotate the baby may feel a sense of failure or shame if they do not follow that advice. They may also find their confidence in their caregiver diminished if they follow the advice but the expected outcome does not occur. (Kariminia et al 2004:4).

2.2.6. Manual healing

Modern manual healing methods used during delivery include therapeutic touch and massage therapy. The purpose of therapeutic touch in labour is to communicate caring and reassurance (Tournaire & Yonneau 2007:414) Painful contractions of the uterus can be treated by applying pressure with the hands to the woman's back, abdomen, hips, thighs, sacrum or perineum. Whether touch is perceived as positive or not dependents on who is touching the patient. Some women may even not want to be touched at all during labour. In one study, touch was perceived as positive by 94% of patients when it was a relative or friend, 86% by their husbands, 73% by a nurse and 21% by a physician. There is less anxiety in patients who receive reassuring touch. (Tournaire & Yonneau, 2007:414).

Chang, Wang and Chen (2007:72) quoted in a study that was done in Hong Kong (2007) that Chinese people use distance to regulate their privacy and level of intimacy in encounters. Therefore, appropriate touch at appropriate times may help the woman to feel in control of her body and maintain a sense of body boundary integrity (Chang et al 2007:71).

Massage is a manual healing method that involves manipulation of the body's soft tissues. It is commonly used to help relax tense muscles and to soothe and calm the individual. A woman who is experiencing backache during labour may find massage over the lumbo-sacral area soothing. Some women find abdominal massage comforting. It has been found that massage can be an effective therapy to decrease pain, anxiety, agitation and a depressed mood during labour (Smith et al 2009:2). Hodnett et al (2003) quoted in Kimber et al (2008:966) that social support is essential for massage interventions in labour, since the presence of a trusted companion reduces the need for pharmacological analgesia and obstetric interventions for the mother.

2.2.7. Hot and cold therapy

The application of hot and cold therapy has been a sensory intervention used for many years. Hot compresses applied to the abdomen, groin or perineum, a warm blanket over the entire body and/or ice packs on the lower back, anus or perineum are effective pain relief interventions for labour pain (Brown et al 2001:2). This practice is not used in every day midwifery practice which could explain why there are no clinical trials researching the efficacy of this intervention.

2.2.8. Music

According to Tournaire and Younneau (2007:413) music addresses many of the physical and psychological needs of women that are in labour. In obstetrics, a slow and restful type of music may be used as a sedative to promote relaxation during the early stage of labour (Tournaire & Yonneau 2007: 413). Music with a steady beat may be used as a stimulant to promote movement during the later stage of labour. Some women in labour who want to concentrate on their breathing exercises for example may find such music irritating.

2.2.9. Hydrotherapy

Immersion in warm water is a common human experience used for relaxation and relief of discomfort. Increasingly, women in labour perceive the availability of hydrotherapy as a criterion for the selection of a hospital, and as a result more labour units now include tubs.

Immersion has a number of physiological effects that influence labour and pain perception. The warmth and buoyancy of water is often associated with a reduction in muscle tension, which may promote relaxation (Florence & Palmer 2003:240). Warm water provides soothing stimulation to nerves in the skin, promoting vasodilatation, reversing of sympathetic nervous system responses, and a reduction in Catecholamine production.

The potential combined effects of these changes are postulated to result in increased intravascular volume, improved perfusion, decreased pain, increased relaxation and shortened labour (Florence & Palmer, 2003:240).

Hydrotherapy can also be utilized at home for women who choose homebirths. Some women may not want to use hydrotherapy at all and choose the shower instead. In conclusion, hydrotherapy appears to reduce pain and anxiety for labouring women without adverse effects. In South Africa most of the private obstetric institutions have birth baths. Patients from public obstetric units can generally not benefit from this intervention.

2.2.10. Aromatherapy

Aromatherapy uses essential oils extracted from aromatic botanical sources to treat and balance the mind, body and spirit. Some essential oils may act to reduce the mother's level of anxiety and thus reduce her perception of pain. Such mothers would be less likely to need an epidural analgesia or an instrumental delivery (Burns, Blamey, Ersser, Barnetson & Lloyd 2000:146). The outcomes of births from women who used aromatherapy were very good. There was no post-partum bleeding, no meconium stained liquor, no infants with an Apgar score less than seven at five minutes, and no neonates that were admitted into a neonatal intensive care (Smith et al 2009:4).

Although aromatherapy may work well for some women, the smell of certain oils may irritate other labouring women and may even cause nausea and vomiting. Aromatherapy may not be an advisable option in South African state hospitals as these hospitals have staff shortages, and many don't allow a birth companion. Even if a birth companion is allowed, there may be a lack of privacy due to limited space and overcrowded obstetric units.

2.2.11. Hypnosis

Hypnosis is a technique that produces a focused state similar to daydreaming. Hypnotherapy is the clinical use of suggestions during hypnosis to achieve specific therapeutic goals such as the alleviation of pain or anxiety. Suggestions are verbal or non-verbal communications that result in apparent spontaneous changes in perception, mood or behaviour. The use of hypnotherapy in pregnancy and childbirth has been practiced for more than a century, and is said to be one of the most useful and rewarding applications of hypnosis (Cyna, McAuliff & Andrew 2004:505).

Self-hypnosis is a form of hypnosis in which a certified practitioner or therapist teaches an individual to induce his or her own state of altered consciousness. When used in childbirth, the main goal of self-hypnosis is to help the woman maintain control by managing anxiety and discomfort through a focused state of relaxation. Hypnosis always requires the woman's willing participation (Ketterhagen, VandeVusse & Berner 2002:336). However, not all women are appropriate candidates for hypnosis; for example, a woman who is unable to follow verbal directions (e.g. a woman with severe mental retardation) would probably not be successful. Some women may also feel that due to their "hypnotic state" they have lost out on the events of the childbirth experience by not remembering all the details.

2.2.12. Acupuncture

Acupuncture is defined as the insertion of fine needles into specific areas of the body. This form of Chinese medicine has been practiced for approximately 3000 years. Classical Chinese teachings suggest that there are channels of energy throughout the body that regulate body functions when in balance. Pain reflects an imbalance or obstruction of the flow of energy. The purpose of acupuncture is to restore the flow of energy, thereby decreasing the pain (Tournaire & Yonneau 2007:414).

Acupuncture was reported to be beneficial in the treatment of labour pain, although better designed studies need to be completed. Electing to use acupuncture may be problematic because the procedure is time consuming and both the patients and personnel should be specially trained (Tournaire & Yonneau 2007:414). Furthermore, the qualified acupuncturist may not be allowed in the maternity ward due to internal organizational rules.

2.2.13. Sterile water injections

According to Martensson, Stener-Victorin & Wallin (2008:171) sterile water injections have been shown to provide good pain relief, particularly for low back pain during labour. This method has been used in Scandinavian countries, and in many urban and rural childbirth units in the United States of America and Canada. Sterile water injections are easy and quick to administer. Injections of sterile water are administered over the painful area (sacrum). The pain relief sometimes manifests as early as during the next contraction, and the effect remains for approximately two hours (Martensson et al 2008:1740). However, a disadvantage of the method is the intense pain accompanying the administration of the injections. Because of this disadvantage, despite good pain relief

during labour, a considerable amount of women would reject this treatment if in need of pain relief (Martenson et al 2008:1740). It is unsure whether sterile water injections are considered a pharmacological or non-pharmacological pain relief strategy, and therefore it was not used for this review.

2.3. Summary

There is no argument that the labour and delivery process produces different feelings and sensations for each individual. Health care providers are valuable resources for pain relief management information for labouring women. It is critical though that health care providers' knowledge and expertise relating to all aspects of the relief of pain and discomfort during labour, is evidence-based (Florence & Palmer 2003:248).

Any medication administered to a labouring woman has both maternal and foetal effects (Florence & Palmer 2003:248). Women who received epidural anaesthesia were more likely to be dissatisfied, compared to women who received other forms of pharmacological pain relief. Epidural anaesthesia may be associated with serious complications of dural tap, spinal injection and epidural haematoma, as well as more frequent longer term side effects such as headaches and backache. Women in labour who used Pethidine have a higher incidence of vomiting. Neonatal respiratory depression associated with Pethidine is likely to be most severe if delivery takes place within 2.5 and 3.5 hours after intramuscular injection. Opiods definitely have an effect on the neonate (Fairlie, Marshall, Walker & Elbourne 1999:1186).

Effective pharmacological pain relief does not ensure a satisfactory birth experience. By knowing and understanding the indications, risks and benefits of the various pharmacological agents as well as the non-pharmacological strategies, health care providers can guide the patient's decisions for appropriate and safe pain management interventions (Florence & Palmer 2003:248).

Numerous non-pharmacological strategies of pain relief can be initiated during labour. Antenatal education aims to offer women information about labour and birth and ways of coping with pain and emotional distress. Research investigated the effect of attending of antenatal classes versus non-attendance. It showed that class attendance has been associated with increased knowledge and confidence about coping with labour, increased ability to tolerate pain, lower levels of the affective stages of pain and less use of pain relieving agents in labour (Spiby, Slade, Escott, Henderson & Fraser 2003:189).

Women who experienced one-to-one support during labour were more likely to give birth without using analgesia or anaesthesia, more likely to have a vaginal birth and less likely to report dissatisfaction with their childbirth experience. Continuous support during labour should be the rule, rather than the exception (Hodnett, Gates, Hofmeyr & Sakala 2009:10).

Caregivers' physical touch influenced the woman's reaction to pain, made her feel safer and calmer, and improved well-being during labour. Touch and massage can convey concern, security, closeness and encouragement, and at the same time serve as a psychosocial intervention (Chang et al 2002:72).

Aromatherapy was found to be an effective therapy during labour for mothers experiencing anxiety, pain, nausea or poor contractions. The mothers that used it rated aromatherapy as helpful for the relief of anxiety, pain, nausea and dysfunctional labour. Midwives were also keen to adopt this knowledge into their practice (Burns et al 2000:146).

While more research is needed to fully understand the effects of hypnosis on labouring women and their infants, it is known from clinical observation that hypnosis can be a powerful intervention for women to use during childbirth. It appears to be safe, has no known side effects, has positive physical and psychological maternal outcomes and seems to produce calm and alert infants (Ketterhagen et al 2002:339).

Research has shown that acupuncture reduces the experience of pain in labour. Acupuncture for labour pain has received little attention in the literature; thus more research is needed to determine whether there is a direct influence on labour progress as well (Skilnand, Fossen & Heiberg 2002:948).

Sterile water injections provide a high degree of pain relief during childbirth despite the transient intense pain accompanying administration and the uncertainty of whether this method is maybe pharmacological or non-pharmacological (Martensson et al 2008:174).

3. Chapter 3: Methodology

Criteria for considering studies for this review

3.1. Types of studies

The researcher searched for randomised controlled trials, determining the effects of non-pharmacological pain relief interventions, which include at least one treatment group and one control or placebo group. Randomized controlled trials were used because they are more likely to provide reliable information than other sources of evidence (Cochrane Handbook 2006:65).

3.2. Types of participants

Trials that involved pregnant women with a gestation of more than 37 weeks, singleton pregnancy with cephalic presentation, primigravidas or multigravidas in spontaneous labour, first or second stage of labour without any complications in their previous and current pregnancies.

3.3. Types of interventions

Trials that included interventions such as childbirth education, continuous support, breathing and relaxation techniques, positioning and movement, hot and cold therapy, hydrotherapy, music, manual healing, aromatherapy, hypnotherapy, acupuncture and sterile water injections compared to a control or placebo group.

3.4. Research outcomes

3.4.1. Primary outcomes

1. The need for pharmacological pain relief in labour.
2. An incidence of postnatal depression.

3.4.2. Secondary outcomes

1. Length on labour, whether it is normal or increased progress.
2. An incidence of post-partum haemorrhage.
3. To achieve an overall satisfaction with the general birth experience.
4. An Apgar score of more than seven at five minutes in the neonate.
5. Resuscitation of the neonate.
6. Admission to the neonatal intensive care unit.

3.5. Search methods for identification of studies

A thorough search for all relevant randomized controlled trials with non-pharmacological interventions consisting of an intervention group compared to a control or placebo group was done. Studies were limited to humans and pregnant women only. The researcher conducted a search between February and May 2010 on electronic databases such as PubMed, CINAHL and CENTRAL (Cochrane Central Register of Controlled Trials) for randomised controlled trials published from inception to 2010. Another search was done on the Website of Stellenbosch University Archive for theses and dissertations relevant to this review, but no relevant studies were found. The researcher assessed the citations for possible inclusion; abstracts were discarded when it appeared that these papers did not meet the criteria for this review. The remaining citations were examined in more detail for possible inclusion for this review, and if found relevant full text were retrieved. The following Medical Subject Headings (MeSH) were used for all databases; non-pharmacological, labour, pregnancy, childbirth, delivery, alternative, pain relief, randomized, randomly, childbirth education, hypnosis, water births, music, manual healing, aromatherapy, acupuncture. References from retrieved papers and bibliographies of relevant interventions were also examined for potential studies.

3.6. Selection of Studies

All randomized controlled trials with the relevant interventions that consisted of a treatment and control or placebo group, and that had at least one outcome for the purpose of this review, were selected. Due to financial restrictions and time limitation only studies published in English were selected.

Possible eligibility was assessed independently by the researcher M.A and the assessor M.T. The citations identified were initially evaluated on the basis of their titles and/or abstracts and full texts were retrieved if it were found to be eligible. All citations considered to be clearly irrelevant were excluded. If the information provided by titles or abstracts was considered insufficient to decide on inclusion or exclusion, the full text article was retrieved and evaluated.

Studies with a participant withdrawal of more than 15% were excluded as well as studies which had no control or placebo group. Studies with relevant outcomes but not relevant interventions were also excluded for this review.

3.7. Data analysis and abstraction

3.7.1. Data abstraction

Independent data abstraction was performed by the researcher M.A and cross-checked by the assessor M T. Data abstraction was performed on the standardized data abstraction form from the Cochrane website. Data suitable for meta-analysis was entered into the Review Manager Computer Software that was downloaded from the Cochrane Collaboration website.

3.7.2.Type of data

Dichotomous outcome data were calculated as relative risk and 95% confidence intervals (CI). Dichotomous data represents each individual's outcome as one of only two possible categorical responses i.e. clinical improvement or no clinical improvement. Continuous data refers to data that can take any value in a specified range (Cochrane Handbook 2007:106). For continuous outcome data weighted mean difference and 95%CI were calculated.

3.7.3. Data synthesis

An meta-analysis was conducted on the outcomes of similar studies. "A meta-analysis statistically pools the results from previous studies into a single quantitative analysis that provides the highest level of evidence for intervention efficacy" (Conn & Rantz 2003; Whittemore 2005). Statistical analysis was assessed by the Review Manager Computer programme that was downloaded from the Cochrane website.

A fixed effects model was used for meta-analysis in the individual studies, because all studies were measuring the same treatment effect. Variability in effect treatment (known as statistical heterogeneity) was measured by a statistical test named the chi-squared test. The chi-squared test of independence determines whether two variables are independent or related (Burns & Grove 2007:420).). "A low p-value (or a large chi-squared statistic relative to its degree of freedom) provides evidence of heterogeneity of treatments effects" (Cochrane Handbook 2006:137). A p-value of 0.05 was used to determine statistical significance. A random effects model was used to test for heterogeneity between trials, because both within-study variation and between-study variation is included when assessing the uncertainty of results.

Initially it was mentioned in the protocol that comparisons will be done between interventions, but after consultation with the statistician it was not possible to do this

comparison therefore outcomes of the intervention groups were compared with outcomes of control or placebo groups.

3.7.4. Reliability and validity assessment

A standardized data abstraction form from the Cochrane website was used to extract data from the original studies. The researcher M.A selected the trials to be included in the review. If there was disagreement between review authors about the studies to be included that could not be resolved by discussion, assistance from a third review author was sought.

The quality of randomized controlled trials was assessed by using the PeDro scale (Physiotherapy Evidence Database) and the Cochrane assessment tool. The PeDro tool consists of eleven criteria with a user guide that explains all the criteria (Maher, Sherrington, Herbert & Moseley 2003:713). Each satisfied item or criteria (except the first item) contributes one point towards the total PeDro score (range = 0 – 10 points). The method of randomization, concealment, blinding, completeness of follow–up and intention to treat analysis were documented to determine internal validity. The Cochrane tool consists of five criteria, randomisation, concealment, blinding, incomplete outcome data addressed and free of selective reporting.

3.7.5. Ethical consideration

The researcher submitted the proposal to the Committee of Ethics at the University of Stellenbosch, but was exempted from ethical review because in this review no actual participants were recruited for this study as published peer reviewed articles were used.

3.7.6. Pilot study

A pilot study was done on two randomized controlled trials that were included in this review. The standardized data extraction form from the Cochrane website was pilot tested to identify irrelevant or missing data.

4. Chapter 4: Results

The search of PubMed, CINAHL and CENTRAL provided a total of 106 citations. Of these, 66 were discarded because after reviewing the abstracts it appeared that these papers did not meet the criteria for this review. The full text of the remaining 40 citations was examined in more detail whereby a total of 19 randomised controlled trials studying 18534 women met inclusion criteria for this review. Only 13 RCT'S that included 14873 women examined the primary and secondary outcomes of interest and 6664 were included in the meta-analysis (see flow diagram in table 1). No unpublished relevant studies were obtained. Most of the studies excluded from the review were high loss to follow up (four); two others had relevant outcomes but not relevant interventions for this review.

Three randomised controlled trials of sterile water injections that involved 321 women were identified but not used for this review due to uncertainty whether this method is indeed pharmacological or non-pharmacological.

The main characteristics of studies included in the review are presented in Table 2. All studies were published in English and were carried out in various countries such as Norway, Belgium, Australia, Brazil, Taiwan, USA as well as the UK. Randomization methods were fully described in four studies. The allocation concealment was considered adequate in eight studies and unclear in the other five studies. Blinding was reported in seven studies and unclear in the other six studies. Six trials reported on an intention-to-treat analysis and it was not clear whether the other seven trials used an intention-to-treat analysis.

The earliest studies were published in 1993, 1994 and 1999 and the other nine were published up to 2009. Comparisons were done between the outcomes of the intervention and control groups. Where meta-analysis were impossible, results were presented in narrative form.

Assessment of heterogeneity

Results of trials that had clinical homogeneity were combined for example the hydrotherapy trials. A random-effects model was used to test for heterogeneity between trials using the I^2 statistic. A p-value of less than 0.10 was used to determine statistical significance. A random effects model assesses both within-study variation and between study variation. Heterogeneity will always exist whether or not it is able to detect it by using a statistical test (Cochrane Handbook 2006:138). Further heterogeneity were

explored by doing subgroup analyses on the mean length of labour, first and second stage.

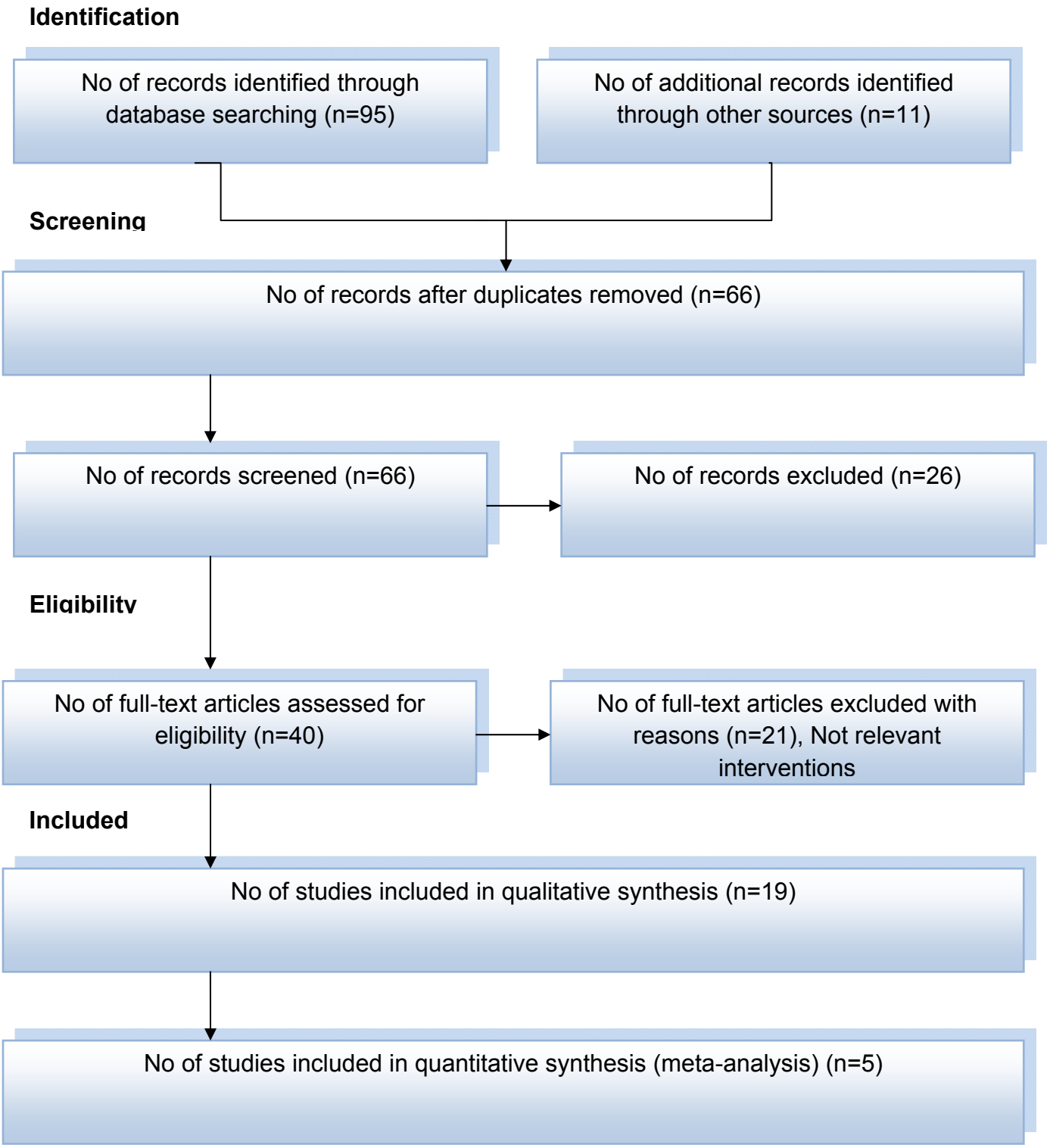

Figure 1. Flow diagram of electronic search results

4.1. Risk of bias in included studies

Randomisation

The method of randomisation was described in eight studies. Schorn's (1993) randomisation was computer generated, Eckert (2001) used random number tables, Skilnand (2002) used lot drawings, Kariminia (2004) used assignment by generating permutated blocks of size four for each participant, Burns (2007) randomisation was computer generated, Kimber (2008) used a computer randomisation program, Da Silva (2009) used a computer generated list, Borup's (2009) randomisation was stratified according to parity. Cammu (1994), Bergstrom (2009), O Caithan (2002), Hundley (1997) and Freeman (1986), state that allocation was random but failed to report the method of allocation.

Allocation concealment

Cammu (1994), Hundley (1997), Eckert (2001), Skilnand (2002), Kariminia (2004), Burns (2007), Da Silva (2009), Borup (2009), all used consecutively sealed opaque envelopes. None of the other trials stated allocation concealment.

Intention-to-treat analysis

Six trials reported data on an intention-to-treat analysis i.e. Hundley (1997), Eckert (2001), O'Caithan (2002), Kariminia (2007) Bergstrom (2009) and Borup (2009). The remaining trials did not report whether they performed an intention-to-treat analysis.

Adequate blinding of outcome assessment

It was not clear whether the participant, care provider, outcome assessor or analyst was blinded in the Freeman (1986).

In Schorn (1993) the patient was blinded, the care provider not blinded but it was not clear whether the outcome assessor or analyst was blinded.

It was unclear whether the participant, care provider, outcome assessor or analyst was blinded in Cammu (1994)

In Hundley (1997) it was not clear whether the participant, care provider, outcome assessor or analyst were blinded

The participant and the data analyst were blinded to the group allocation but the care provider was not blinded in Eckert (2001).

It was unclear whether the participant, care provider, outcome assessor or analyst was blinded in O'Caithan (2002).

The participant and care provider were not blinded to the group allocation, but the outcome assessor was blinded in Skilnand (2002).

In Kariminia (2004) participants were not blinded, the care provider and outcome assessor were blinded.

The participant was blinded to the group allocation, the care provider was not blinded, but the outcome assessor was blinded in Borup (2007).

In the Kimber trial (2008) blinding was not possible at all.

There was no blinding in Da Silva (2009).

It was not clear whether the participant, care provider, outcome assessor or analyst were blinded in Bergstroom (2009).

There was no blinding in the Borup (2009) trial.

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4.2. Characteristics of included studies

4.2.1. Freeman 1986

Methods	Single-blind, randomised controlled trial.
Participants	82 primigravidas women with a normal pregnancy. Women were recruited from an antenatal clinic in England. 13 women were excluded due to obstetric complications and four women failed to attend hypnosis.
Interventions	Women were seen individually on a weekly basis from 32 weeks. Women were encouraged to imagine warmth in one hand and shown how to transfer this to the abdomen. Patients were questioned about pain relief and satisfaction of labour using a linear analogue scale. The control group received standard antenatal care.
Outcomes	analgesic requirements, maternal satisfaction
Notes	No power calculations and no baseline characteristics were presented.

Risk of bias table

Item	Judgement	Description
Randomisation	yes	Method of randomisation was not stated
Allocation concealment	unclear	Allocation concealment was not stated
Intention-to-treat analysis	unclear	No report on whether intention-to-treat analysis was used
Blinding	unclear	No report on whether the participant, care provider or outcome assessor was blinded
Losses to follow-up	yes	13 women withdrew, leaving 29 women in the hypnosis group and 36 in the control group.

4.2.2. Schorn 1993

Methods	A prospective randomised controlled trial.
Participants	93 women were randomised; 45 in the intervention group and 48 in the routine care group. There were no looses to follow up.
Interventions	The intervention group used a hot tub with air jets and with a moulded seat for increased comfort. Women were encouraged to stay in the tub for as long as they wanted to and controlled the water temperatures themselves. The maternal vital signs, foetal heart rate, contraction frequency and cervical examination were recorded one hour before and after using the tub.
Outcomes	Pharmacological pain relief requirements, length of labour and Apgar score

Risk of bias table

Item	Judgement	Description
Randomisation	yes	Randomisation was computer generated
Allocation concealment	unclear	Allocation concealment not stated
Intention-to-treat analysis	unclear	No report on whether intention-to-treat analysis was used
Adequate blinding	yes	The participant was blinded, the care provider not blinded, it was not clear whether the outcome assessor or analyst was blinded.
Losses to follow-up	no	There were no losses to follow-up

4.2.3. Cammu 1994

Methods	This was a prospective randomised trial
Participants	110 women were randomised, 54 had a bath and 56 served as controls. Criteria for enrolment were true spontaneous labour with a cervical dilatation between three and five centimetres, ruptured membranes with clear liquor and no evidence of dystocia at inclusion. All women were primigravidas, at low risk and at term (more than 37 weeks), with a singleton foetus in cephalic presentation. Three women in the bath group refused to bath and were excluded leaving 51 women in the bath group.
Interventions	All patients had a private labour and delivery room and received personalised midwifery care. Telemetric heart beat recording allowed the author to monitor the foetus while the patient was bathing. The oval shaped bath tub is 160cm long and 50cm deep. It is filled with tap water at a temperature at the patient's convenience but not exceeding 37 degrees Celsius. No chemicals were added.
Outcomes	Pharmacological pain relief requirements and Apgar score at five minutes.

Risk of bias table

Item	Judgement	Description
Randomisation	yes	Failed to report method of randomisation
Allocation concealment	yes	Consecutively sealed opaque envelopes
Intention-to-treat analysis	unclear	No report on whether an intention-to-treat analysis was performed
Blinding	unclear	No report on whether the participant, care provider or outcome assessor was blinded
Losses to follow-up	yes	Three women in the bath group refused to bath and were excluded leaving 51 women in the bath group.

4.2.4. Hundley 1997

Methods	A pragmatic randomised controlled trial
Participants	A total of 2844 low risk women were randomised, 1900 in the intervention group and 944 in the control group 80 women were excluded in the intervention group because (n=35) miscarried, (n=11) had terminations of pregnancy and (n=34) moved from the Grampian area. 26 women were excluded from the control group because (n=13) miscarried, (n=4) had terminations of pregnancy and (n=9) moved to the Grampian area.
Interventions	To compare women's satisfaction with care and delivery in a midwife-managed delivery unit with that in a consultant-led labour ward. A questionnaire was given to the women participating in the study to grade their overall satisfaction with the birth experience on an ordinal scale from 0 to 10, with 0 being “thoroughly unsatisfactory” and 10 being “an absolutely wonderful experience”.
Outcomes	Maternal satisfaction with the overall birth experience

Risk of bias table

Item	Judgement	Description
Randomisation	yes	Method of randomisation was not stated
Allocation concealment	yes	The researcher used consecutively opaque envelopes.
Intention-to-treat analysis	yes	Data were analysed according to intention-to-treat principle.
Blinding	unclear	It was not clear whether the participant, care provider, outcome assessor or analyst were blinded.
Losses to follow-up	yes	80 women were excluded in the intervention group because (n=35) miscarried, (n=11) had terminations of pregnancy and (n=34) moved from the Grampian area. 26 women were excluded from the control group because (n=13) miscarried, (n=4) had terminations of pregnancy and (n=9) moved to the Grampian area.

4.2.5. Eckert 2001

Methods	A prospective double-blinded randomised controlled trial.
Participants	274 women were randomised; 137 women to the intervention group and 137 to the control group. 40 women in the intervention group withdrew for common reasons such as the need for pharmacological pain relief requirements (10), labour progressed too quickly (10), continuous monitoring was required (2), the presence of group B streptococcal colonization (1), women who did not wish to bath (4), the bath was not available and (12) women gave no reason. 36 women from the routine maternity care group withdrew of which all chose to use a bath.
Interventions	Bath tubs were permanently installed in the corners of the rooms with a step up to provide easier access. The bath tubs are triangular shaped and are bounded on two sides by a wall. If a woman was assigned to the bath group and in established labour, she was allocated to the appropriate delivery room, in which she could bath as short or long as she wished during labour, but had to stop when the second stage was apparent or imminent. Postnatal depression was measured using the Edinburgh Postnatal Depression Scale using a 9-item scale. A self-report questionnaire was collected at 24 to 48 hours after delivery to measure maternal satisfaction with the birth experience.
Outcomes	Pharmacological pain relief requirements, length of labour, maternal satisfaction with overall birth experience, postnatal depression and Apgar score of more than seven at five minutes.

Risk of bias table

Item	Judgement	Description
Randomisation	yes	Adequate, used random number tables
Allocation concealment	yes	Used consecutively sealed opaque envelopes
Intention-to-treat	yes	Data were analysed according to intention-to-treat principle.
Blinding	yes	The participant and data analyst were blinded to the group allocation, the care provider was not blinded.
Losses to follow-up	yes	40 women in the intervention group withdrew for common reasons such as the need for pharmacological pain relief requirements (10), labour progressed too quickly (10), continuous monitoring was required (2), the presence of group B streptococcal colonization (1), women who did not wish to bath (4), the bath was not available and (12) women gave no reason. 36 women from the routine maternity care group withdrew of which all chose to use a bath.

4.2.6. O'Caithan 2002

Methods	A cluster randomised controlled trial.
Participants	Four separate samples of women using maternity services. Antenatal samples: women reaching 28 weeks gestation before (n=1386) and after (n=1778) the intervention. Postnatal samples: women at eight weeks after delivery before (n=1741) and after (n=1547) the intervention. 170 women withdrew from the antenatal group and 624 withdrew from the postnatal group.
Interventions	Informed Choice leaflets (information leaflets) were provided to the women using maternity services in order to promote informed choice regarding their childbirth experience. Questionnaires were posted to participants to determine satisfaction with childbirth experience.
Outcomes	If participants had enough information to make informed decisions regarding their maternity care to ensure maternal satisfaction with the childbirth experience.

Risk of bias table

Item	Judgement	Description
Randomisation	yes	Failed to report method of randomisation
Allocation concealment	unclear	No report on allocation concealment
Intention-to-treat analysis	yes	Data were analysed according to intention-to-treat principle.
Blinding	unclear	It was not clear whether the participant, care provider, outcome assessor or analyst was blinded
Losses to follow-up	yes	170 women withdrew from the antenatal group and 624 withdrew from the postnatal group

4.2.7. Skilnand 2002

Methods	A single-blinded randomised controlled trial
Participants	210 healthy women with singleton cephalic gestation and anticipating normal delivery, presenting in spontaneous or active labour between 37 and 42 weeks were randomly assigned to receive either real acupuncture or false acupuncture. Two women were excluded from the control group because they delivered prior to this intervention being administered.
Interventions	Midwives providing the intervention had received formal training in acupuncture.
Outcomes	Pain relief requirements and Apgar score of more than five at seven minutes.
Notes	No power analysis was reported

Risk of bias table

Item	Judgement	Description
Randomisation	yes	Used lot drawings
Allocation concealment	yes	Used consecutively sealed opaque envelopes
Intention-to-treat analysis	unclear	No report on whether an intention-to-treat analysis was used.
Blinding	yes	The participant and care provider were not blinded, but the outcome assessor was blinded
Losses to follow-up	yes	Two women were excluded from the control group because they delivered prior to this intervention being administered.

4.2.8. Kariminia 2004

Methods	A multicentre randomised controlled trial.
Participants	2547 women were randomised at 37 weeks gestation; 1292 randomised to the intervention group and 1255 randomised to the control group. 246 women withdrew from the intervention group and 46 women withdrew from the control group.
Interventions	Hands and knees position and pelvic rocking exercises from 37 weeks gestation until the onset of labour.
Outcomes	Primary outcome of incidence of foetal occiput posterior position at birth. Secondary outcomes of pharmacological pain relief requirements, length of labour and Apgar score.

Risk of bias table

Item	Judgement	Description
Randomisation	yes	Adequate, used assignment by generating permutated blocks of size four for each participants
Allocation concealment	yes	Used consecutively sealed opaque envelopes.
Intention-to treat analysis	yes	Data were analysed according to intention-to-treat principle.
Blinding	yes	Participants were not blinded, the care provider and outcome assessor was blinded
Losses to follow-up	yes	246 women withdrew from the intervention group and 46 women withdrew from the control group.

4.2.9. Burns 2007

Methods	This was a prospective randomised controlled trial.
Participants	251 women randomised to aromatherapy and 262 women to the control group. Two women in the aromatherapy group declined as both were in advanced labour already.
Interventions	For women randomised to use aromatherapy, the decision about which oil to use and why as well of mode of application was reached through discussion between the midwife and participant. All aromatherapy oils used in the study had a certificate of analysis and gas chromatography prior to use to ensure that it was as free from contaminants as possible.
Outcomes	Main outcomes comprised of pharmacological pain relief requirements, length of labour and Apgar score.

Risk of bias table

Item	Judgement	Description
Randomisation	yes	Adequate, computer generated
Allocation concealment	yes	Used consecutively sealed opaque envelopes.
Intention-to-treat	unclear	No report on whether an intention-to-treat analysis was performed.
Blinding	yes	The participant was blinded, the care provider was not blinded, and the outcome assessor was blinded.
Losses to follow-up	yes	Two women in the aromatherapy group declined as both were in advanced labour already.

4.2.10. Kimber 2008

Methods	A randomised controlled trial.
Participants	The study consisted of an intervention and control group of 30 each totalling 60 women. Two women withdrew from the control group, one who did not attend the class and one withdrew in early labour.
Interventions	The intervention group had a massage programme with relaxation techniques, and the control group had the routine maternity care. Women allocated to the intervention group attended a two and a half hour class between 35 and 37 weeks of gestation with their chosen birth partner. Massage techniques were taught by the midwife/therapist. For the duration of the trial there were three two and a half hour classes, which included an antenatal and labour session incorporating information about labour, methods of pain relief and types of delivery.
Outcomes	Pharmacological pain relief requirements, length of labour and Apgar score

Risk of bias table

Item	Judgement	Description
Randomisation	yes	Used a computer randomisation program
Allocation concealment	unclear	Did not state allocation concealment
Intention-to-treat analysis	unclear	Did not state whether an intention-to-treat analysis was performed.
Blinding	no	Blinding was not possible at all
Losses to follow-up	yes	Two women withdrew from the control group, one who did not attend the class and one withdrew in early labour.

4.2.11. Bergstrom 2009

Methods	A single-blinded randomised controlled multicentre trial.
Participants	A total of 1087 primigravidas were randomly assigned to their study group. 64 women were excluded from the intervention group due to inconvenient timing of classes, preterm labour and medical complications. 54 women withdrew from the standard routine group for the same reasons as the intervention group leaving 484 women in each group.
Interventions	Consists of an intervention of 484 women in group who received antenatal education focusing on natural childbirth preparation with training in breathing and relaxation techniques, and a control group of 484 women who received antenatal education focussing on both childbirth and parenthood, without training in breathing and relaxation. Both groups had four 2-hour sessions during pregnancy and one follow up session within 10 weeks after delivery. The Wijma Delivery Experience Questionnaire was used to measure the experience of the childbirth with 33 items with six-point response scales covering various feelings and cognitive appraisal of childbirth.
Outcomes	Pharmacological pain relief requirements, maternal satisfaction with overall childbirth experience

Risk of bias table

Item	Judgement	Description
Randomisation	yes	Failed to report method of randomisation
Allocation concealment	unclear	Did not state allocation concealment
Intention-to-treat	yes	Data were analysed according to intention-to-treat principle.
Blinding	unclear	It was not clear whether the participant, care provider, outcome assessor or analyst was blinded.
Losses to follow-up	yes	64 women were excluded from the intervention group due to inconvenient timing, preterm labour and medical complication. 54 women withdrew from the standard routine group for the same reasons as the intervention group leaving 484 women in each group.

4.2.12. Borup 2009

Methods	A randomised controlled trial was conducted
Participants	314 women were allocated to the intervention group and 149 women were allocated to the control group. Healthy Danish-speaking women in labour with a normal singleton pregnancy who were giving birth giving birth at term (37-42 weeks) and with a foetus in cephalic presentation were eligible for the study. 42 women withdrew from the intervention group because there was no project midwife available (n=13), (n=6) did not want the allocated treatment, (n=1) had rapid progression of labour and (n=3) withdrew for other reasons. 37 women in the control group withdrew for because there was no project midwife available (n=13), (n=6) did not want the allocated treatment, (n=1) had rapid progression of labour and (n=4) withdrew for other reasons.
Interventions	Project midwives who were trained and certified cared for all participants, after completing a 5-day course in Western techniques of obstetric acupuncture and receiving at least 6 months clinical training using acupuncture during labour. Treatment was individualised according to the woman's mobility and localisation of pain. The duration of needling could vary from 30 minutes to 2 hours and could be repeated.
Outcomes	Primary outcomes comprised of pharmacological pain relief requirements and overall maternal satisfaction with the childbirth experience. Secondary outcomes were length of labour, postpartum haemorrhage and Apgar score.

Risk of bias table

Item	Judgement	Description
Randomisation	yes	Adequate, randomisation was stratified according to parity.
Allocation concealment	yes	Used consecutively sealed opaque envelopes
Intention-to-treat	yes	An intention-to-treat analysis was performed.
Blinding	no	There was no blinding in this trial.
Losses to follow-up	yes	23 women (5%) withdrew from the acupuncture (n=314), n=13 due to no project midwife, n=6 did not want the allocated treatment, n=1 for rapid progression of labour, n=3 had other reasons. 24 (4%) of the routine maternity care (n=149) withdrew, n=13 had no project midwife available, n=6 did not want the allocated treatment, n=1 had rapid progression of labour and n=4 had other causes for withdrawing.

4.2.13. Da Silva 2009

Methods	This was a randomised controlled trial.
Participants	108 women were randomised, 54 to the intervention group and 54 women to the control group. Data were collected in the following sequence: interview and randomisation. Four women in the intervention group were excluded due to tocographic symptoms. Two in the control group were excluded because the required continuous blood pressure monitoring. The first evaluation was carried out at 6-7cm dilatation, including pain evaluation according to the numeric and behavioural scales, and cervical dilatation verification. The second evaluation was performed at the end of the immersion bath period, 1h after the initial pre-bath assessment.
Interventions	When the intervention group presented at 6-7cm of cervical dilatation, they were placed in an immersion bath for 60 minutes.
Outcomes	Pharmacological pain relief requirements and Apgar score at one and five minutes

Risk of bias table

Item	Judgement	Description
Randomisation	yes	Adequate, used a computer generated list
Allocation concealment	unclear	Did not report on allocation concealment
Intention-to-treat	unclear	Did not report on whether an intention-to-treat analysis was performed.
Blinding	no	There was no blinding in this trial
Losses to follow-up	yes	Four women in the intervention group (n=54) were excluded due to cardio-tocographic symptoms, two women in the routine maternity care group were excluded because antihypertensive drugs were administered to them and therefore they required continuous blood pressure monitoring.

Risk of bias

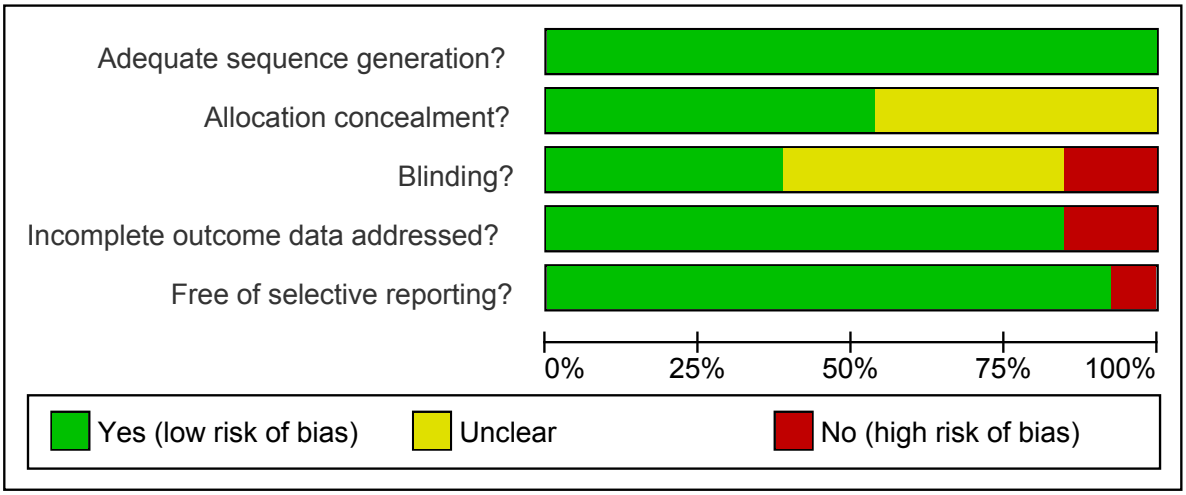


Figure 4.2 Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all studies

The risk of bias assessment was done on 13 trials, sequence generation was confirmed in 100% of all trials, allocation concealment was confirmed in approximately 50% of all trials, blinding was confirmed in about 40% of all trials, incomplete outcome data was confirmed in 80% and the 90% of studies were free of selective reporting.

Risk of bias	Interpretation	Relationship to individual criteria
A. Low risk of bias	Plausible bias unlikely to seriously alter the results.	All of the criteria met
B. Moderate risk of bias	Plausible bias that raises some doubt about the results.	One or more criteria partly met.
C. High risk of bias	Plausible bias that seriously weakens confidence in the results.	One or more criteria not met.

Figure 4.3 Taken from the Cochrane Handbook (2006:83)

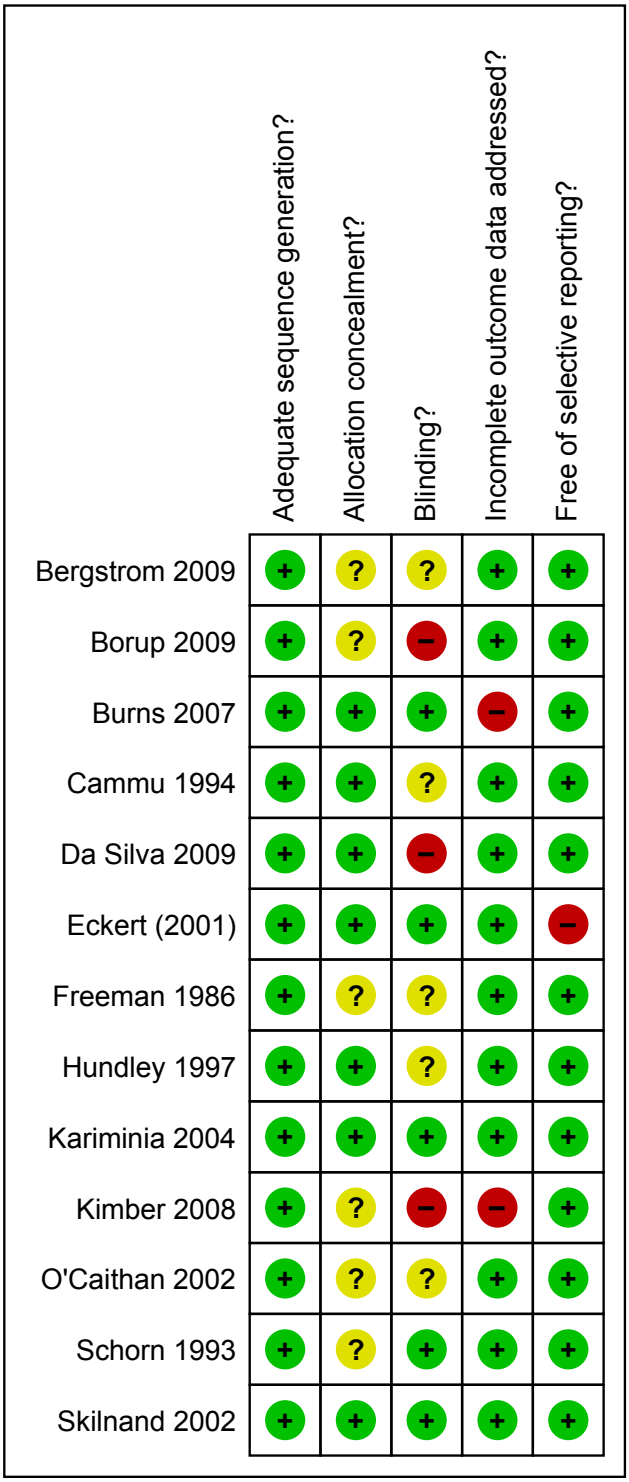


Figure 4.4 Methodological quality summary: review authors' judgements about each methodological quality item for each study.

The risk of bias graph indicates that allocation concealment and blinding in some studies were unclear or absent, which posed a potential high risk towards selection and performance bias in the studies being examined.

4.3. Losses to follow up

In the hypnosis trial of Freeman (1986), 82 women were randomised. 42 women were allocated to the hypnosis group and 40 women to the control group. 13 women (14%) withdrew because of pre-eclampsia (1), breech presentation (3), delivery by caesarean section (9) and failure to attend hypnosis classes (4), leaving 29 women in the hypnosis group and 36 in the control group.

In Schorn's (1993) trial of 110 women there were no losses to follow up.

In the Cammu (1994) study which involved 110 women, 54 were allocated to the bath and 56 were allocated to receive routine maternity care, and there were no losses to follow up.

In the continuous support trial of Hundley (1997), 2844 women were randomised. 1900 women were in the intervention group and 944 in the control group. 80 women in the intervention group withdrew; 35 had miscarriages, 11 had termination of pregnancies and 34 moved to the Grampian area. 26 women withdrew from the control group of which13 had miscarriages, 4 had terminations of pregnancies and 9 moved to the Grampian area.

Losses to follow up in the hydrotherapy trial were as follow: In Eckert's (2001) 274 women were randomised to the trial. 137 were allocated to the bath group and 137 were allocated to receive routine maternal care. Of the 137 women allocated to the bath group, 40 women withdrew. Common reasons given for not bathing included the need for pharmacological analgesia (10), labour progressed too quickly (10), continuous monitoring was required (2), the presence of group B streptococcal colonization (1), the women did not wish to use a bath (4) or the bath was not available (1). 12 women gave no reason. Of the 137 women allocated to receive routine maternity care, 36 women (13%) withdrew of which all chose to use a bath.

In O'Caithan (2002) there were four samples of women using maternity services; Antenatal samples women reaching 28 weeks gestation before (n=1386) and after (n=1778) the intervention. Post natal samples; women at eight weeks after delivery before (n=1741) and after (n-1547) the intervention, 170 women withdrew from the antenatal group and 624 withdrew from postnatal group. Informed Choice leaflets (information leaflets) were given to the women using maternity services to promote informed choice in order to participate in their childbirth experience

In Skilnand (2002), a total of 210 women were randomised; 106 were allocated to real acupuncture, whereas 104 were allocated to false acupuncture. Two women (1%) from the latter group were excluded from the study because they delivered before treatment could be initiated.

Kariminia's trial of hands and knees posturing (2004) had a total of 2547 women randomised - 1292 to the intervention group and 1255 to the control group,246 women (19%) withdrew from the intervention group and 46 women (4%) from the control group.

In the aromatherapy trial of Burns (2007), 513 women were randomised. 251 received aromatherapy and 261 were the control with routine maternity care group. 511 women completed the trial as randomised; 249 (99%) of the aromatherapy group and 262 (100%) of the control group. Two women in the aromatherapy group declined as both were in advance labour, so it may be assumed that time did not allow aromatherapy administration.

In Kimber's music and massage trial (2008), a total of 60 women were randomised. The study included 30 women in the intervention group (massage program with relaxation techniques), and 30 were in the control group (routine care). Two women (2%) withdrew from the control group - one did not attend the class and the other withdrew in early labour.

In the childbirth education trials of Bergstrom (2009), 484 women were allocated to the intervention group and 933 women to the standard routine group. 64 women did not receive the allocated intervention due to inconvenient timing of classes, preterm labour and medical complications. 54 women from the standard routine group withdrew for the same reasons as the intervention group.

In the Da Silva (2009) study, of the108 women participating, 54 were assigned to the bath group and 54 were assigned to receive routine maternity care. Two women in the bath group were excluded due to cardio-tocographic symptoms and two for thick meconium liquor. Two women in the routine maternity care group were administered antihypertensive drugs and therefore required continuous blood pressure monitoring (6%).

In the acupuncture trials, Borup's (2009) trial included a total of 463 women, of which 314 were allocated to the acupuncture group and 149 were allocated to routine maternity care. 23 women (5%) withdrew from the acupuncture group; (n=13) due to no project midwife being available, (n==6) did not want the allocated treatment, (n=1) for rapid progression of

labour and (n=3) had other reasons. 24 (4%) of the routine maternity care withdrew; (n=13) had no project midwife available, (n=6) did not want the allocated treatment, (n=1) had rapid progression of labour and (n=4) had other causes for withdrawal.

4.4. Characteristics of excluded studies

4.4.1. Mei-Yueh Chang 2002

Reason for exclusion	High loss to follow up (27%)

4.4.2. Dickinson 2003

Reason for exclusion	This study had the relevant clinical outcomes for this review, but compared epidural versus no epidural techniques on term labour outcomes.

4.4.3. Phumdoung 2003

Reason for exclusion	The data were not in a suitable form for analysis and there was a high loss to follow (23%)

4.4.4. Salvesen 2004

Reason for exclusion	High loss to follow up (26%)

4.4.5. Brown 2007

Reason for exclusion	This trial randomised hospital units and did not report on any clinical outcomes of this review.

4.4.6. Wan - Yim Ip 2009

Reason for exclusion	High loss to follow up (31%)

4.5. Comparisons of interventions

4.5.1. Childbirth education compared with control

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
Maternal satisfaction with the childbirth experience	1	2821	Risk Ratio (M-H, Fixed, 95% CI)	0.12 [0.07, 0.16]
Antenatal sample before intervention	1	1446	Risk Ratio (M-H, Fixed, 95% CI)	0.12(0.07, 0.16)
Antenatal sample after intervention	1	1365	Risk Ratio (M-H, Fixed, 95% CI)	0.12(0.07, 0.16)
Maternal satisfaction with the childbirth experience	1	3280	Risk Ratio (M-H, Fixed, 95% CI)	1.27 (0.82, 1.98)
Postnatal sample before the intervention	1	1808	Risk Ratio (M-H, Random, 95% CI)	1.27 (0.82, 1.98)
Postnatal sample after the intervention	1	1480	Risk Ratio (M-H, Random, 95% CI)	1.27 [0.82, 1.98)

4.5.3. Immersion in water in the first stage of labour compared with control

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
Pharmacological pain relief requirements	1	234	Risk Ratio (M-H, Fixed, 95% CI)	0.92 [0.80, 1.05]
A decrease in the incidence of postnatal depression	1	234	Risk Ratio (M-H, Fixed, 95% CI)	0.95 [0.46, 1.94]
Length of labour, first stage	1	234	Mean Difference (IV, Fixed, 95% CI)	-2.98 [-60.85, 54.89]
Length of labour, second stage	1	234	Mean Difference (IV, Fixed, 95% CI)	-3.86 [-21.53, 13.81]
A decrease in the incidence of postpartum haemorrhage	1	234	Risk Ratio (M-H, Fixed, 95% CI)	1.18 [0.53, 2.62]
An Apgar score of less than seven at five minutes	1	234	Risk Ratio (M-H, Fixed, 95% CI)	2.28(0.09, 55.48)

4.5.4. The effect of immersion bath on labour compared with control

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
An Apgar score of more than seven at five minutes	1	108	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.43, 2.32]

4.5.5. Water immersion and the effect on labour compared with control

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
10.1 Length of labour, first stage, mean and SD	1	93	Mean Difference (IV, Fixed, 95% CI)	0.00 [-2.67, 2.67]
10.2 Length of labour, second stage, mean and SD	1	93	Mean Difference (IV, Fixed, 95% CI)	1.20 [0.10, 2.30]
10.3 Pharmacological pain relief requirements	1	93	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.61, 1.42]

4.5.6. “To bathe or not to bathe” compared with control

21.5 Mean length of first stage (SD)	1	110	Mean Difference (IV, Fixed, 95% CI)	-20.00 [-77.94, 37.94]
21.6 New Outcome	1	110	Mean Difference (IV, Fixed, 95% CI)	-1.00 [-8.85, 6.85]
21.7 Pharmacological pain relief requirements	1	110	Risk Ratio (M-H, Fixed, 95% CI)	0.91 [0.35, 2.33]

4.5.7. The effect of immersion in water on labour

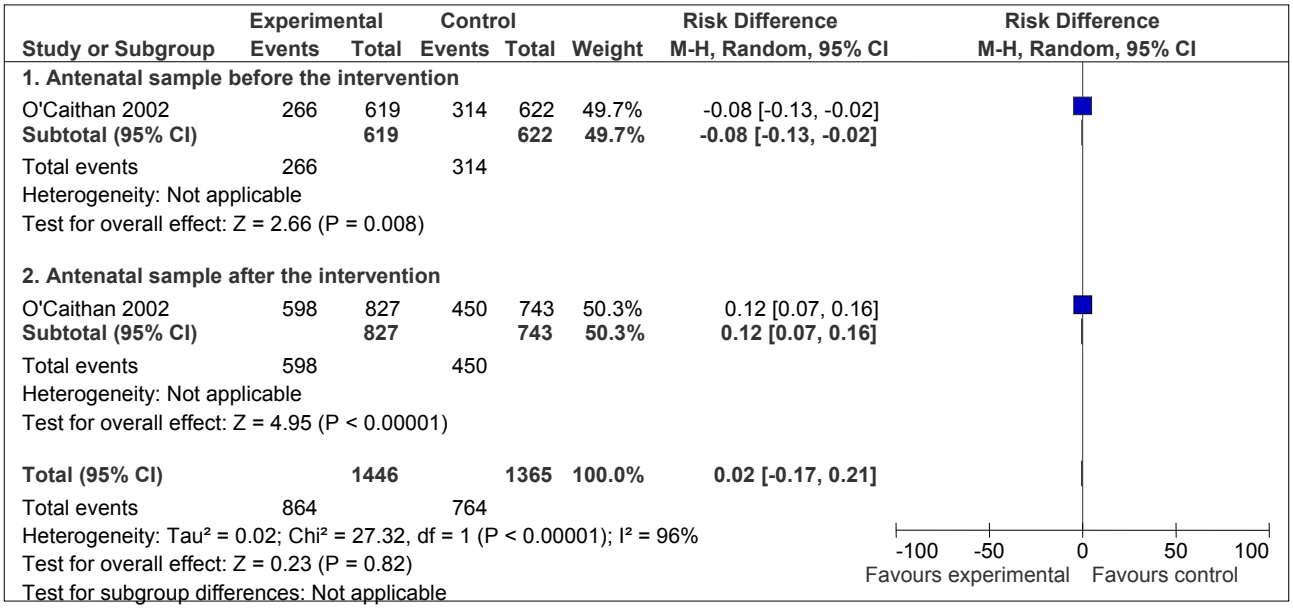
Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
Pharmacological pain relief requirements	3	437	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.81, 1.04]
Length of labour, first stage, mean and SD	3	437	Mean Difference (IV, Random, 95% CI)	-0.05 [-2.71, 2.61]
Length of labour, second stage	3	437	Mean Difference (IV, Random, 95% CI)	1.14 [0.05, 2.23]
Apgar score of more than seven at five minutes	2	342	Risk Ratio (M-H, Random, 95% CI)	0.88 [0.48, 1.62]

4.5.8. Subgroup analysis

Mean length of first stage	5	1010	Mean Difference (IV, Random, 95% CI)	-0.10 [-2.75, 2.56]
Mean length of second stage	5	1010	Mean Difference (IV, Random, 95% CI)	1.45 [-1.40, 4.30]

4.6. Data Analysis and comparisons

Analysis 1. Comparison 1: Childbirth education compared to control

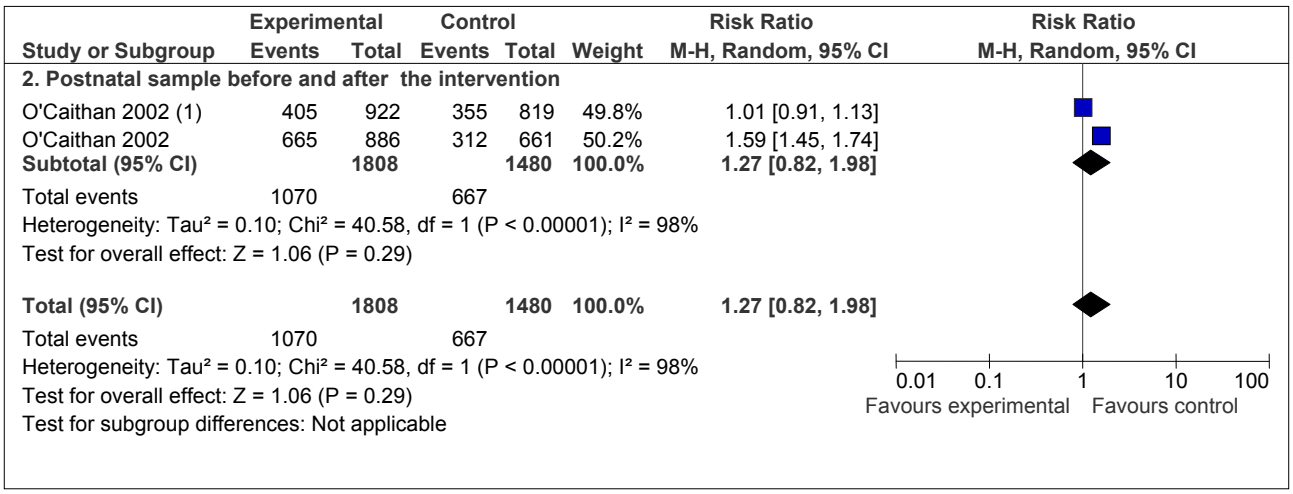


Outcome 1: Maternal satisfaction with the childbirth experience

O'Caithan, Walters, Nicholl, Thomas & Kirkham (2002)

This trial assessed the effect of leaflets on promoting informed choice in women using maternity services.

The figure above (figure 2.1) shows that there is no difference in the outcomes between childbirth education intervention group and control group who received no childbirth education (RR 1.04. 95% CI 1.00, 1.09). Strong evidence of heterogeneity was available (96%).

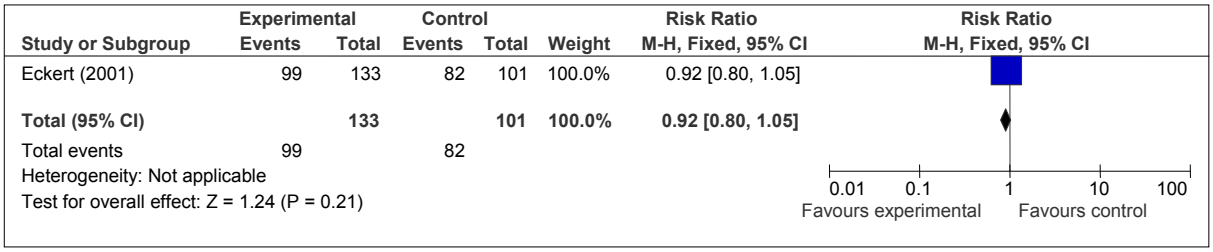


Outcome 2: Maternal satisfaction with childbirth experience

O'Caithan, Walters, Nicholl, Thomas & Kirkham (2002)

The figure above (figure 2.2) shows that there was no difference in outcomes between the childbirth education intervention group and control group which received no childbirth education RR (1.01), 95% CI (0.87, 1.17). Strong evidence of heterogeneity was available (98%). Possible causes of heterogeneity might be that the postnatal sample after the intervention were more empowered with childbirth education, ensuring that they are more in control of the childbirth leading to greater satisfaction of the childbirth experience.

Analysis 2. Comparison 2: Water immersion compared to control

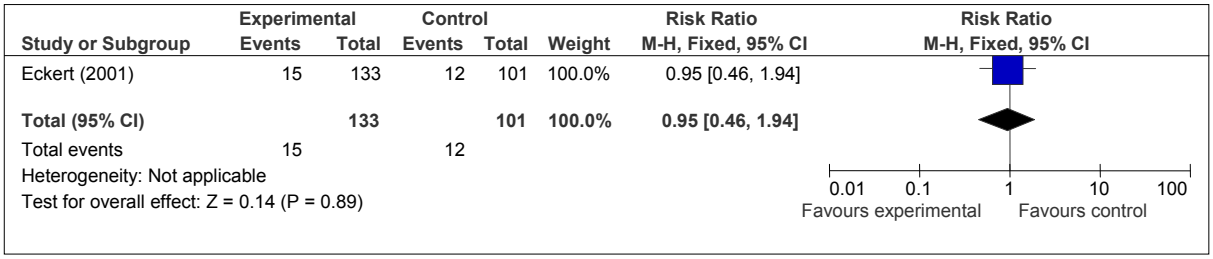


Outcome 1: Pharmacological pain relief requirements

Eckert, Turnbull & MacLennan (2001)

The objective of this trial was to compare immersion in warm water during labour with traditional pain management for a range of clinical and psychological outcomes.

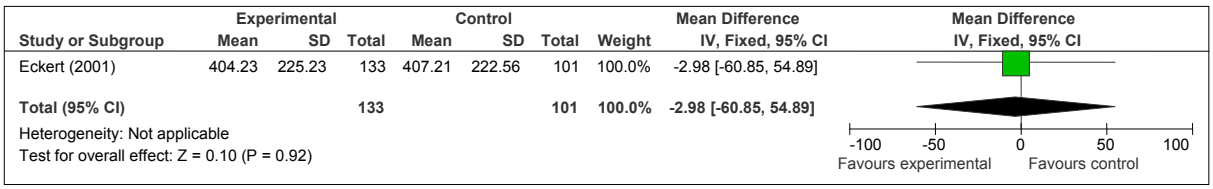
The figure above (figure 7.1) shows that there is no difference in the use of pharmacological pain relief requirements between the intervention and control group (RR 0.92, 95% CI 0.80, 1.06).



Outcome 2: A decrease in the incidence of postnatal depression

Eckert, Turnbull & MacLennan (2001)

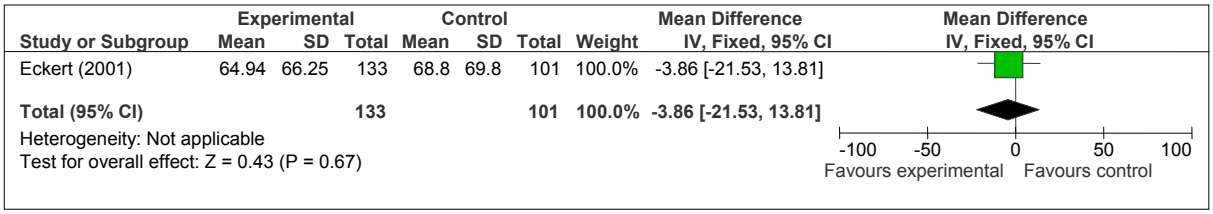
The figure above (figure 7.2) shows that there is no difference in the incidence of postnatal depression between the intervention and control group (RR 0.86, 95% CI 0.48, 1.94).



Outcome 3: Length of labour, first stage, mean (SD)

Eckert, Turnbull & MacLennan (2001)

The figure above (figure 7.3) shows that there is no difference in the length of labour (first stage) between the intervention and control group (WMD -2.98, 95% CI -60.85, 54.89).

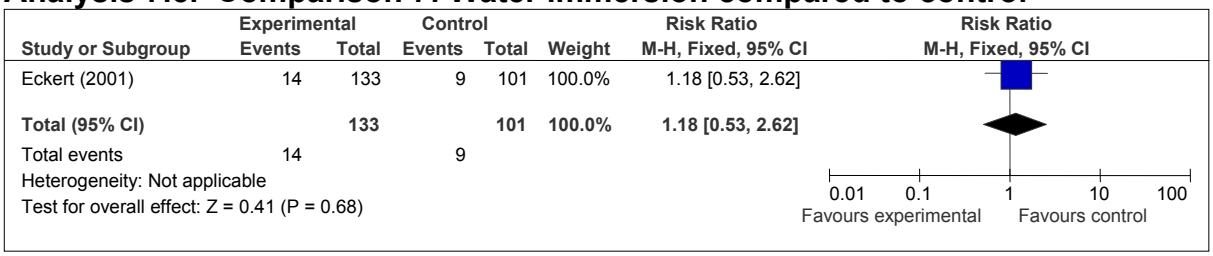


Outcome 4: Length of labour, second stage, mean (SD)

Eckert, Turnbull & MacLennan (2001)

The figure above (figure 7.4) shows that there is no difference in the length of labour, second stage, between the intervention and control group (WMD -3.86, 95% CI -21.63, 13.81).

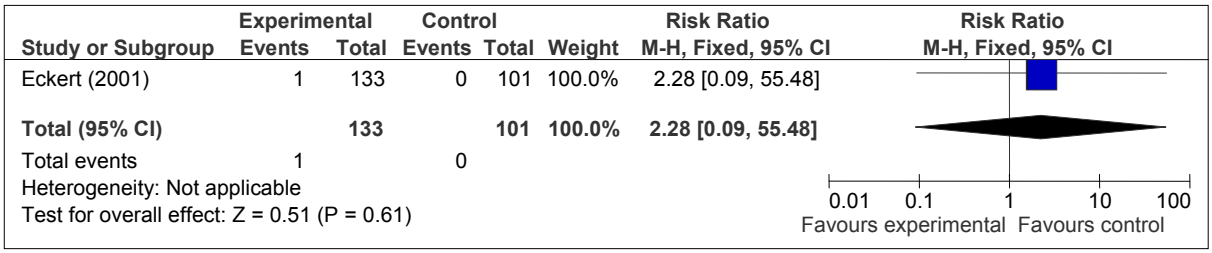
Analysis 7.5. Comparison 7: Water immersion compared to control



Outcome 5: A decrease in the incidence of postpartum haemorrhage

Eckert, Turnbull & MacLennan (2001)

The figure above (figure 7.5) shows that there is no difference in the incidence of postpartum haemorrhage between the intervention and control group (RR 1.18, 95% CI 0.53, 2.62).

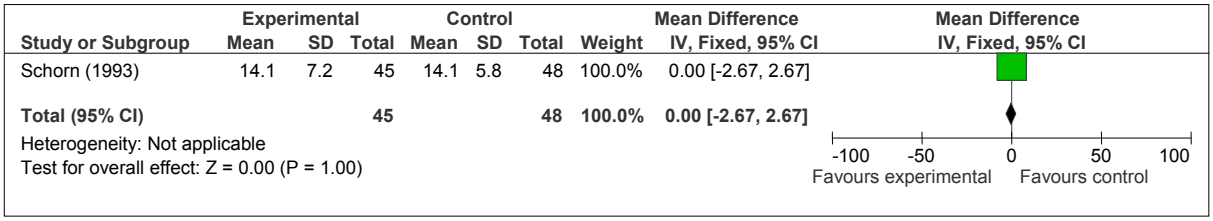


Outcome 6: An Apgar score of less than seven at five minutes

Eckert, Turnbull & MacLennan (2001)

The figure above (figure 7.6) shows that there is no difference in the Apgar score of less than seven at five minutes between the intervention and control group (RR 2.28, 95% CI 0.09, 55.48).

Analysis 3. Comparison 3: Water immersion and the effect on labour compared to control

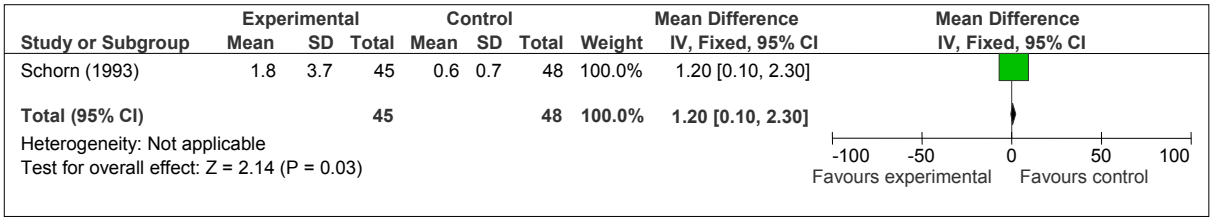


Outcome 1: Length of labour, first stage, mean (SD)

Schorn, McAllister & Blanco (1993)

This prospective, randomised controlled trial was conducted to determine the safety and effect of water immersion on the women in labour.

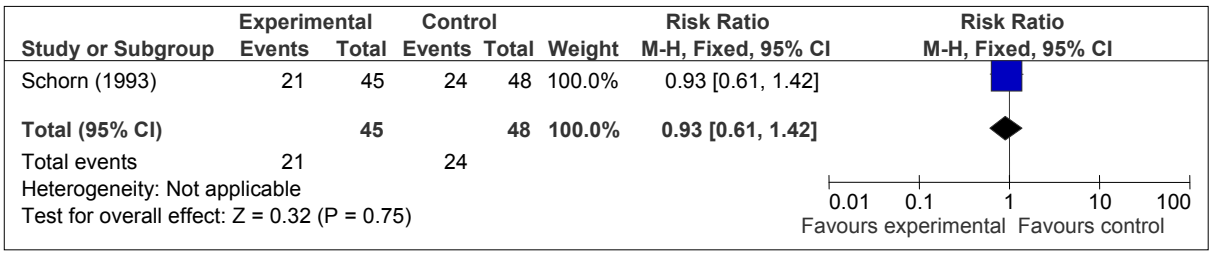
The figure above (figure 8.1) shows that there is no difference in the length of labour (first stage) between the intervention group and control group (WMD 0.00, 95% CI -2.87, 2.87).



Outcome 2: Length of labour, second stage, mean (SD)

Schorn, McAllister & Blanco (1993)

The figure above (figure 8.2) shows that there is no difference in the length of labour (second stage) between the intervention group and control group (WMD 1.20, 95% CI 0.10, 2.30).

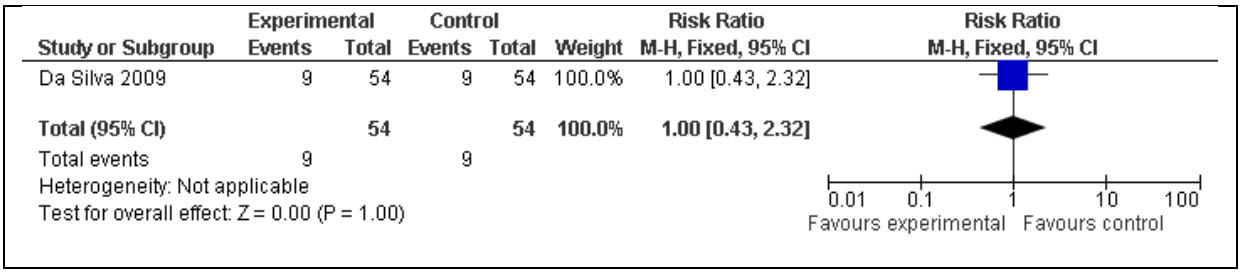


Outcome 3: Pharmacological pain relief requirements

Schorn, McAllister & Blanco (1993)

The figure above (figure 8.3) shows that there is no difference in the need of pharmacological pain relief between the intervention group and control group (RR 0.93, 0.61, 1.42).

Analysis 4. Comparison 4: The effect of immersion bath on labour compared to control



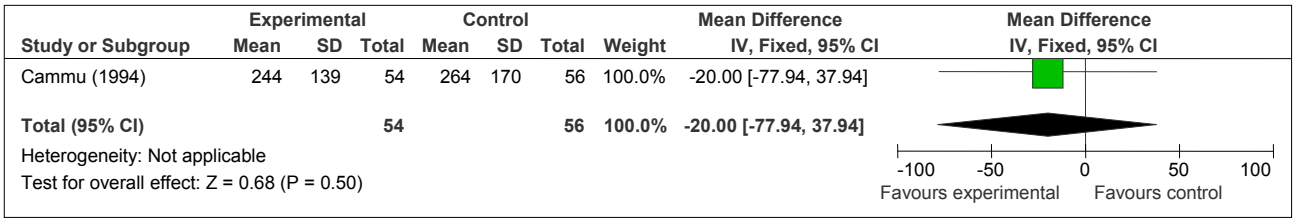
Outcome 1: Apgar score at five minutes

Da Silva, Junqueira & Nobre (2009)

The objective of this trial was to evaluate the effect of an immersion bath on pain magnitude during the first stage of labour.

The figure above (figure 9) shows that there is no difference in the Apgar score at five minutes between the intervention group and control group (RR 1.00, 95% CI 0.43, 2.32).

Analysis 5. Comparison 5: “To bathe or not to bathe” during first stage of labour.

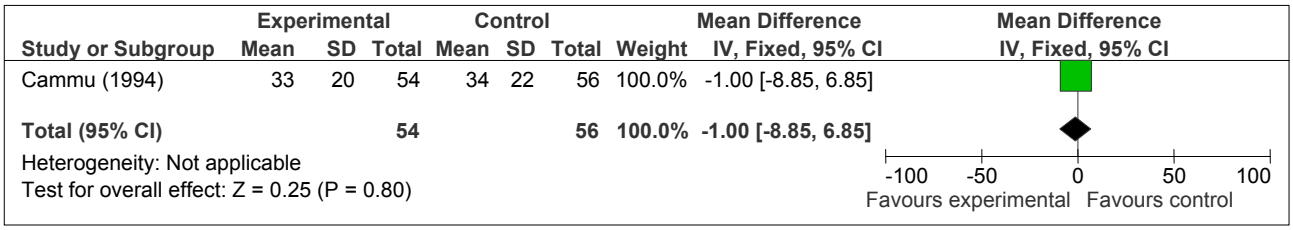


Outcome 1: Mean length of labour, first stage

Cammu, Clasen, Van Wettere & Derde (1994)

The objective of the study was to determine if a warm bath relieve labour pain.

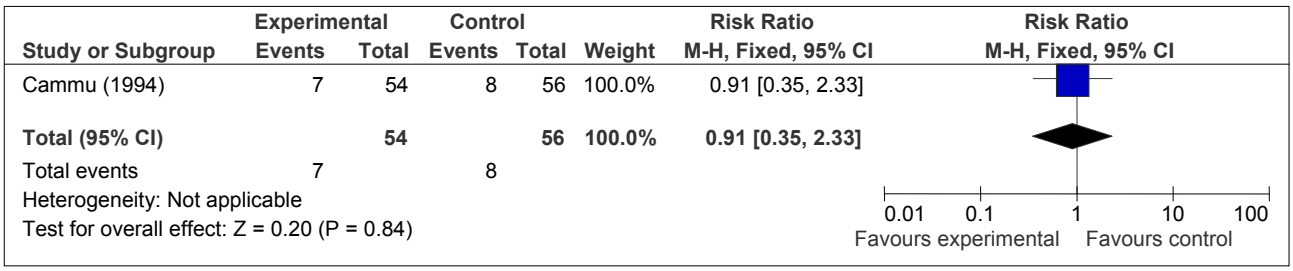
The figure above (figure 10.1) shows that there is no difference between women in the intervention group and women in the control group (WMD -20.00, 95% CI -77, 94, 37.94).



Outcome 2: Mean length of labour, second stage

Cammu, Clasen, Van Wettere & Derde (1994)

The figure above (figure 10.2) shows that there is no difference in the mean length of labour (second stage) between women in the intervention and control group (WMD -1.00, 95% CI -8.85, 6.85)

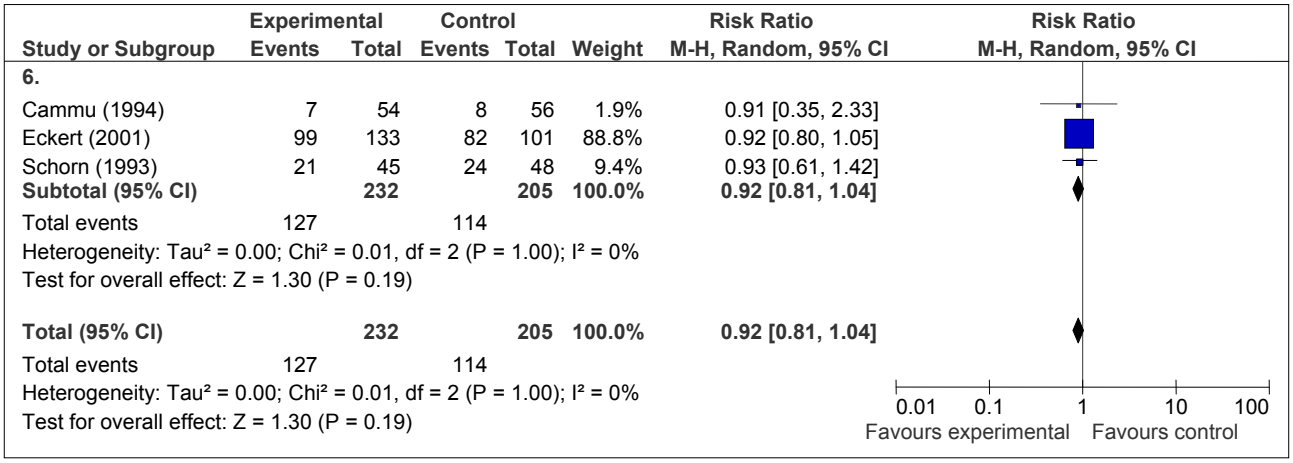


Outcome 3: Pharmacological pain relief requirements

Cammu, Clasen, Van Wettere & Derde (1994)

The figure above (figure 10.3) shows that there is no difference in the need for pharmacological pain relief between the intervention and control group (RR 0.91, 95% CI 0.35, 2.33).

Analysis 6. Comparison 6: The effect of water immersion on labour compared to control



Outcome 1: Pharmacological pain relief requirements

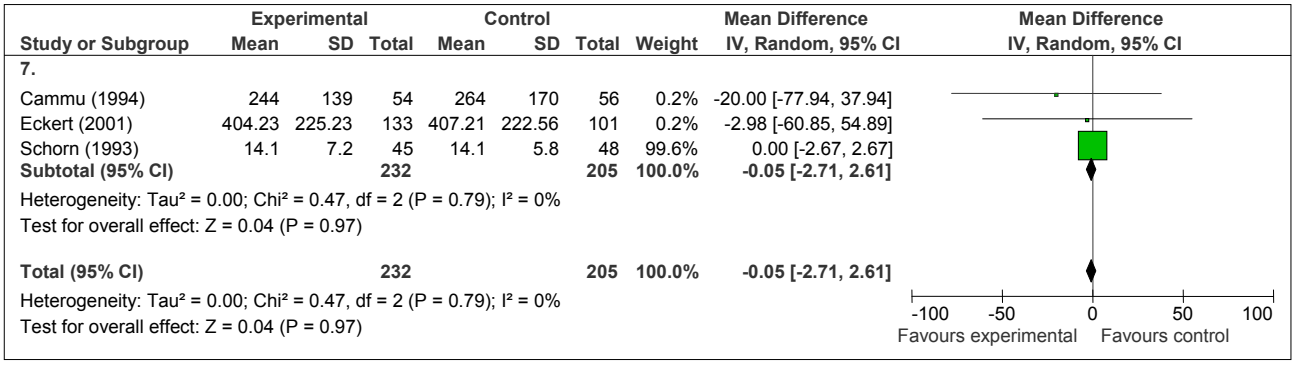
Schorn, McAllister & Blanco (1993)

Cammu, Clasen, Van Wettere & Derde (1994)

Eckert, Turnbull & MacLennan (2001)

The figure above (figure 14) shows that there is no difference between women in the intervention group and women in the control group in the need for pharmacological pain relief (RR 0.92, 95% CI 0.81, 1.04).

Analysis 7. Comparison 7: The effect of water immersion on labour compared to control



Outcome 1: Length of labour, first stage, mean (SD)

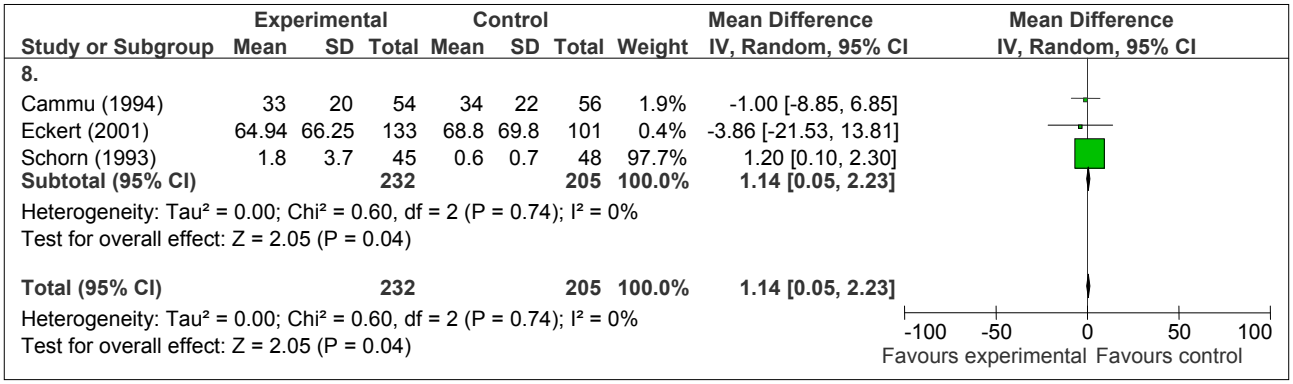
Schorn, McAllister, Blanco & (1993)

Cammu, Clasen, Van Wettere & Derde (1994)

Eckert, Turnbull & MacLennan (2001)

The figure above (figure 15) shows that there is no difference in length of labour (first stage) between the intervention and control groups (WMD -0.05, 95% CI -2.71, 2.61).

Analysis 8. Comparison 8: The effect of water immersion on labour compared to control



Outcome 1: Length of labour, second stage, mean (SD)

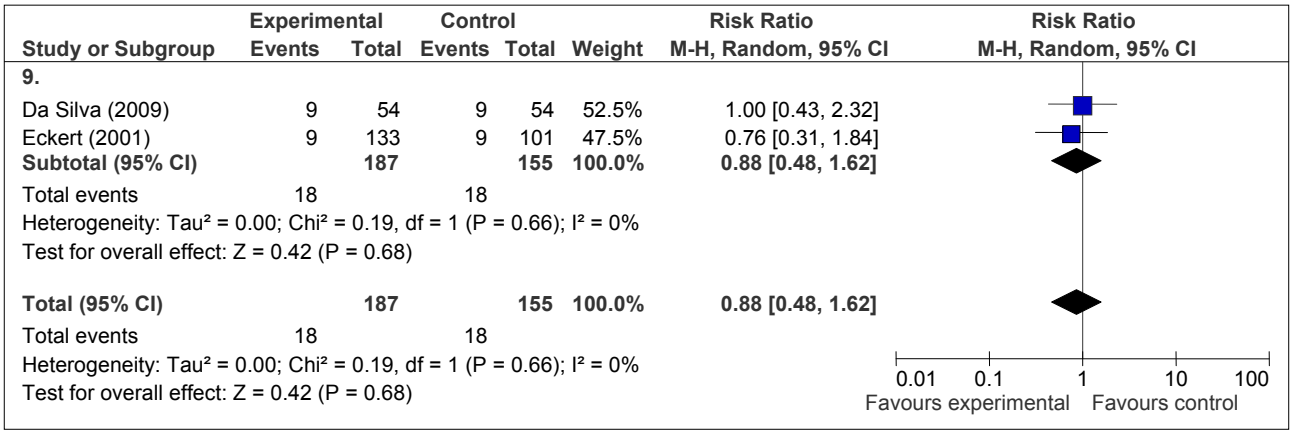
Schorn, McAllister, Blanco & (1993)

Cammu, Clasen, Van Wettere & Derde (1994)

Eckert, Turnbull, MacLennan & (2001)

The figure above (figure 16) shows that there is no difference in the length of labour (second stage) between the intervention and control groups (WMD 1.14, 95% CI 0.05, 2.23).

Analysis 9. Comparison9: The effect of water immersion on labour compared to control



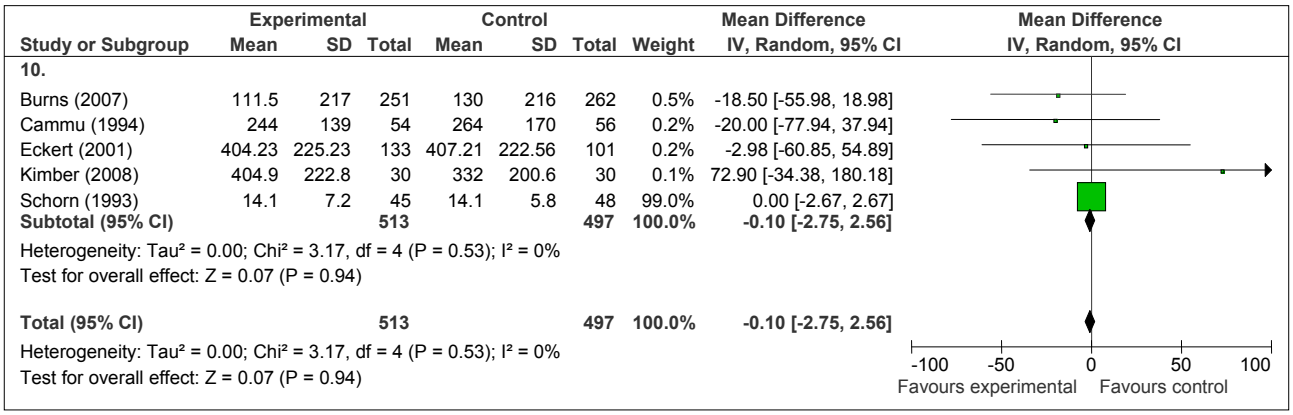
Outcome 1: Apgar score at five minutes

Da Silva, De Oliveira & Nobre & (2009)

Eckert, Turnbull & MacLennan (2001)

The figure above (figure 17) shows that there is no difference in the Apgar score at five minutes between the intervention and control groups in the two studies (RR 0.88, 95% CI 0.48, 1.62).

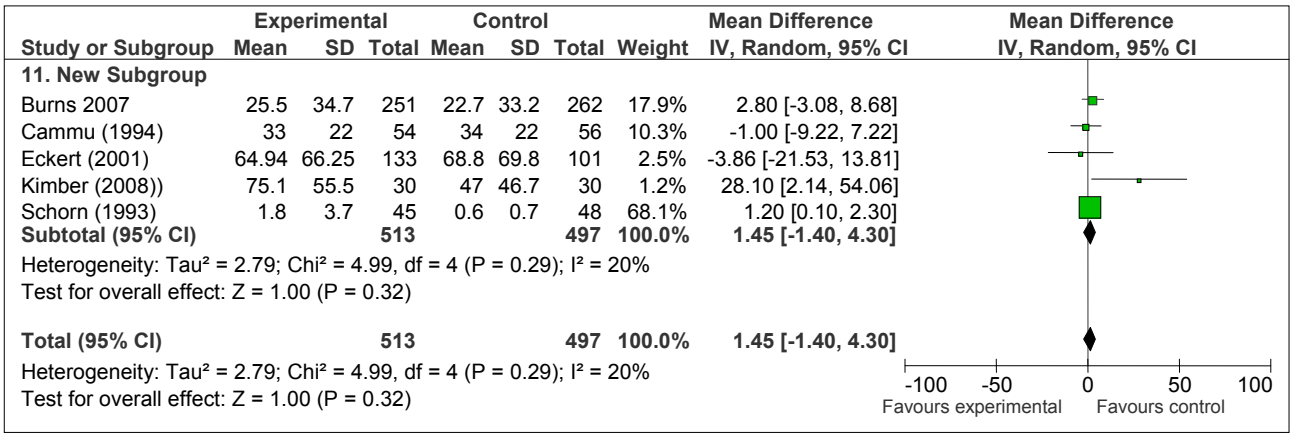
Analysis 10.Comparison 10: Mean length of first stage



Schorn et al. 1993; Cammu et al. 1994; Eckert et al. 2001; Burns et al 2007; Kimber et al. 2008

The figure above (figure 18) shows that there is no difference between studies in the mean length of labour (first stage) (WMD -0.10, 95% CI -2.75, 2.56).

Analysis 11. Comparison 11: Mean length of second stage



Schorn et al. 1993; Cammu et al. 1994; Eckert et al 2001; Burns et al 2007; Kimber et al 2008

The figure above (figure 19) shows that there is no difference in the mean length of labour (second stage) between the different studies (WMD 1.45, 95% CI -1.40, 4.30).

Causes of heterogeneity might be due to the fact that women in the control group from the Kimber trial (2008) were more in favour compared to women in the intervention group in the mean length of labour (second stage) (WMD 28.10, 95% CI 2.14, 54.06). The Kimber trial also used a different intervention (massage and music) compared to the hydrotherapy trials.

4.7. Discussion

The finding of this systematic review suggests that childbirth education or training does not reduce the need for pharmacological analgesia or improve the birth experience (Bergstrom, Kieler & Waldenstrom 2009:11174). There were no differences between the intervention and control groups in the use of pharmacological pain relief with women in the intervention group 247/484 (52%) and women in the control group with 252/493 (52%). For maternal satisfaction with the overall childbirth experience women in the intervention group had a mean of 49.6 (SD 26) for the intervention group and a mean of 50.1 (SD 25) for the control group. According to Bergstrom et al (2009:1169), antenatal education has been sensitive to opinions and trends and has undergone dramatic changes without the medical profession/obstetrics professionals knowing much about its effect on relevant outcomes. With the development of obstetric care, information about pharmacological methods of pain relief and medical interventions now constitute a large component of antenatal education**.**

Ip Tang & Goggins (2009:2125) does not agree and suggest that childbirth education does indeed improve the coping skills of particular primigravidas in labour. It also decreases their perceived pain and anxiety in the first two stages of labour. These authors believe that antenatal childbirth education is widely accepted as a positive approach to prepare pregnant women for the experience of childbirth. However, the relationships among childbirth education and labour outcomes are inconclusive. The most recent meta-analysis concludes that there is insufficient evidence to determine the effects of antenatal education on psychological, physical and social adjustment (Ip et al. 2009:2126).

In the trial of O'Caithan Informed Choice leaflets did not change the amount of women who reported exercising informed choice in maternity care. Satisfaction in childbirth is an important indicator of the quality of maternity care given to woman today. This includes satisfaction with pain relief. Positive childbirth outcomes such as satisfaction are, however, exposed to a range of individual/environmental factors which must be taken into account in any assessment (McCrea 2000:493). For most women childbirth is viewed as a positive experience especially if they are provided with information and are able to feel in control during the birth experience.

According to Hundley, Milne, Glazener & Mollison (1997:1273) the three C's (continuity, choice and control) have been identified as important aspects of maternity care, with an overall p-value of 0.1 for maternal satisfaction with the childbirth education. The authors believed that the issues surrounding the measurement of satisfaction with childbirth need

further investigation. Personal control is an integral part of woman centred care if the goal is to encourage women to be active in their care during childbirth (McCrea, Wright, & Stringer 2009:493).

According to Brown, Douglas & Flood (2001:2) relaxation can increase pain tolerance through a number of mechanisms including reduction of anxiety, increased uterine blood flow and decreased muscle tension. Relaxation and breathing is most effective as a pain relief method if learned during the antenatal period in advance of the birth experience. In the Kimber trial (2008), 18/30 (60%) women in the intervention group used pharmacological pain relief compared with 21/30 (70%) in the control group. There was a trend though towards more positive views of labour preparedness and sense of control in the intervention and control group. Women in the control group‘s labour with an average mean of 332.0, (SD) 200.06 was significantly shorter (minutes) as women in the intervention group with a mean of 404.09, (SD) 222.8 for first stage, and second stage for control with a mean of 47.0, (SD) 46.7 and intervention with a mean of 75.1, (SD) 55.5. Women in the intervention group experienced a higher satisfaction with the childbirth experience with 22/30 women compared to 18/30 women in the control group. However, one baby (3%) in the control group required resuscitation compared with two babies (7%) in the intervention group. Consequently, massage has the potential to improve the relationship between nurses/midwives and women in labour, as well as between the couple (Chang et al. 2002:72).

Hands and knees exercise has been reported and widely adopted in practice as an intervention to especially rotate a posterior baby to the anterior position. Persistent foetal occiput posterior position is associated with deflexion of the foetal head and an increased incidence of prolonged painful labour, operative delivery, postpartum haemorrhage, vaginal trauma, maternal infection and neonatal morbidity. Kariminia, Chamberlain, Keogh & Shea (2004:3) reported that this advice is based on mainly personal belief. In Kariminia et al (2004:3) during a multicentre randomized controlled trial , the hands and knees position with slow pelvic rocking during the last few weeks of pregnancy did not reduce the number of babies with persistent occiput posterior position at birth. No differences were found between the intervention and control groups for duration of labour with an average mean of 422, (SD) 282.3 for the intervention group and an average mean of 419, (SD) 267.9 for the control group. The Apgar score of the neonate at five minutes had a median of 9.0. Many women with cultural preferences also choose this position for giving birth.

Although hot and cold therapy has been a sensory intervention used for many years, are there no clinical trials available researching the effects of this practice.

There are reasons to believe that warm water has beneficial effects during labour. The water will transform heat to the body, it will decrease the pressure on the abdominal muscle and by eliciting pleasurable sensations it will have a central effect. All these stimuli are able to close the gate for pain at the level of the dorsal horn and therefore lessen the pain (Cammu, Clasen, Van Wettere & Derde, 1994: 470). In the Schorn (1993) in the need for pharmacological pain relief, there was no difference between the intervention and control groups (RR 0.93, 95% CI 0.61, 1.42), as well as in Cammu (1994) there was no difference in the use of pharmacological pain management (RR 0.91, 95% CI 0.35, 2.3). However, the decrease in pain at 25 minutes in bathing participants compared with the increase in pain at the same time in non-bathing participants was statistically significant ($p<0.01$). Postpartum 80% of the bathing participants in the Cammu (1994) confirmed that bathing had a soothing effect on pain, and 53/54 women stated that the hydrotherapy had relaxed their body, particular between contractions. There was no difference in minutes in the mean length of labour , first stage for both Schorn 1993 (WMD 0.00, 95% CI -2.67, 2.67) and Cammu 1994 (WMD -20.00, 95% CI -77.94, 37.94) There was no difference in the mean length of labour, second stage in both trials Schorn (WMD 1.20, 95% CI 0.10, 2.30), and Cammu (WMD -1.00, 95% CI -8.85, 6.85). There were no admissions in the neonatal intensive care unit for neonates in both groups in the Schorn trial. In the Cammu trial one baby in the bathing group had an Apgar score of six and was kept for 24hours in the neonatal intensive care unit for observation, in the control group one baby was intubated because of meconium aspiration. In the Da Silva (2007) trial the only outcome effect measured was the Apgar score at five minutes, there was no difference between the intervention and control groups (RR 1.00, 95% CI 0.43, 2.32). In the subgroup analysis of length of labour (first and second stage) no significant differences occur between intervention and control groups. Findings are also confounded by wide variations in intervention protocols: In two studies control participants showered and therefore received a different form of hydrotherapy (Eckert 2001, Schorn 1993). In one study, participants were allowed to set their own water temperature (Schorn 1993). Tubs used varied in shape and depth (Eckert 2001). Units of measurement for the duration of the intervention have varied, for example, minutes or the time from fixed centimetres of cervical dilatation to the beginning of the second stage of labour.

Bathing women experience relaxation much more than they experienced pain relief. The majority of women said they would like to bath again during a next labour. All authors agree that bathing produce favourable responses on patient satisfaction. In the Eckert trial (2001) the use of pharmacological pain relief was similar in both groups (RR 0.92, 95% CI 0.80 to 1.05). No differences were observed in the length of labour first stage (WMD -2.98, 95% CI -60.85, 54.89), and length of labour second stage with a (WMD -3.86, 95% CI of -21.53 to 13.81). There were no significant differences in Apgar score between infants whose mothers had hydrotherapy and infants of mothers who received routine care. This finding seems puzzling considering more infants of the bathing group required resuscitation (RR 1.41, 95% CI 1.06, 1.89, p=0.01). If resuscitation was needed more often in the bathing group, this need should have been reflected in lower Apgar scores and increased need for bag, mask and oxygen. Routine care women rated their overall experience of childbirth more positively as women in the bath group. Psychological outcomes such as postnatal depression were the same for both groups (RR 0.95, 95% CI 0.46, 1.94).

Anxiety is a key factor in a mother's labour (Burns & Blamey 1994:54). Aromatherapy was found to be an effective therapy during labour for mothers who are experiencing anxiety, pain, nausea or poor contractions. Aromatherapy was rated highly both by mothers and midwives; it was shown to be associated with very few side effects and it was an inexpensive care option (Burns, Blamey, Ersser, Barnetson & Lloyd, 2000:146). In the Burns trial (2007), the use of aromatherapy on a wide range of intrapartum outcomes were examined. One of the outcomes was the need for pharmacological pain relief but no data were presented on this outcome. There was no difference in the Apgar score after five minutes between the two groups with an average mean of 10, (SD) 0.17 for the intervention and a mean of 10, (SD) 0.46 for the control group, although the study showed a reduction in neonatal intensive care unit admission for infants of the aromatherapy group. 2% (6) of neonates in the control group (n=262) were admitted in the neonatal intensive care unit (icu) compared to no neonates for admission in the icu in the intervention group There were no differences found in the mean length of labour (first stage) 217, (SD) 111.5 for intervention and a mean of 216 (SD) 130 for control, and the mean length of labour (second stage) 34.7, (SD) 25.5 for the intervention and 33.2 (SD) 22.7 for the control group.

Hypnosis has been used to control pain during labour and delivery for more than a century, but the introduction of chemo-anaesthesia and inhalation anaesthesia during the

late 19th century led to the decline of its use. Recently there has been a return of this technique in obstetrics. According to Martin, Schauble, Rai & Currr (2001:1) hypnotherapy has been found to be effective in providing pain relief, reducing the need for pharmacological pain management and reducing anxiety, fear, and pain related to childbirth. In the Freeman trial (1986) women in the intervention group required less pharmacological pain relief 15/29 compared to women in the control group 20/36. Women in the intervention group also experienced greater satisfaction with the childbirth experience 15/29 (52%) compared to women in the control group 8/36 (23%).

Acupuncture is a form of Chinese medicine that has been practiced for more than 3000 years. In the Borup trial (2009) it was reported that acupuncture during labour reduced the need for pharmacological pain management for the intervention group 185/314 (58.9%) compared to control 124/149 (83.2%) without affecting the birth outcome. Maternal satisfaction with the childbirth experience in Borup (2009) was slightly in favour of the control group 100/149 (89%) compared to the intervention group 240/314 (88%). This study was the largest randomized controlled study so far to examine the effect of acupuncture on labour pain. Women in the acupuncture group tended to report a higher degree of relaxation and control 86/314 (32%) compared to the control group 26/149 (23%), and the feeling of control contributes to a good birth experience. According to Skilnand, Fossen & Heiberg (2002:946) who had an acupuncture group and a control group with minimal acupuncture, women who had real acupuncture experienced significantly less labour pain than women in the control group. Through its analgesic effect, acupuncture reduced the need for epidural 11/106 (10%) for the intervention and 27/102 (26.5%) for the control group as well as for Pethidine 15/106 (14%) for the intervention and 36/102 (35%) for the control group , both methods that can be accompanied by adverse side-effects (Skilnand et al 2002:946). The study also shows that there is a shorter duration of labour (minutes) for women who used acupuncture with a mean value of 212 (SD, 155) compared to the control group with a mean value of 283 (SD, 225) with a p-value of 0.01.

4.8. Limitations

This study has several limitations. The author experienced difficulty in finding randomised controlled trials of good methodological quality. The quality of the studies varied. Randomisation was adequate in all the studies. Seven of the studies did not report whether analysis of data was according to intention-to-treat principle, which could have lead to overestimation of treatment effect in these trials. Only single studies were used for most of the interventions which results were presented in narrative form. Some single studies had small numbers of participants which might contribute to a Type ii error (suggesting there is no significant difference, when in fact there is) . The potential for bias by missing eligible trials has been maximized by having language restrictions in the study. Due to financial and time constraints only trials that were published in English were considered. Data for this review is from published studies only which may be biased towards overestimating the effectiveness of the interventions. A comprehensive search of more than one database for RCT's was implemented to minimise selection bias.

The studies that were used for this review only focused on the antenatal, intrapartum and postnatal stages, so there is a lack of information concerning the puerperal stage after discharge of the mothers and babies. Limited neonatal outcomes were reported in most of the studies.

There is a need for further research of randomised controlled trials in institutions on non-pharmacological pain relief strategies which include data measuring maternal and neonatal outcomes to investigate the effectiveness of these interventions. The insufficient reporting of outcomes in some studies made data extraction difficult. Consideration should be given in the analysis and reporting to the person providing the intervention, for example their training and experience to the research field. .

5. Chapter 5: Conclusion

5.1. Implications for practice

A wide variety of non-pharmacological pain relief strategies are available to pregnant women in labour. Different non-pharmacological pain relief strategies will benefit different women. Factors such as social status, antenatal expectations, organisational rules and practices, cultural preferences and types of childbirth education should be considered before women choose a non-pharmacological pain relief strategy for their childbirth experience.

According to the results of this review the data available suggested that childbirth education does not reduce the need for pharmacological pain relief or improve the childbirth experience. The results also suggest that a positive birth experience does not exclude pain. Current evidence suggests that acupuncture reduces the need for pharmacological pain relief in labour and that more women in the acupuncture groups experienced greater satisfaction with the childbirth experience. The length of labour was also significantly shorter in the acupuncture group. Hypnosis may reduce the need for pharmacological pain relief, and provide a higher satisfaction with the childbirth experience. No significant benefit is evident for the other interventions in this review.

Continuous support should be the rule rather than the exception. However, most women delivering in South African State Maternity Hospitals do not have a birth companion (Brown, Hofmeyr, Nikodem, Smith & Garner 2007:1). Women should be encouraged to be active and equal partners in the care process so that they are involved in decisions regarding their maternity care. This rule should tie in with the attempts by the South African State Hospitals of integrating a Mother Friendly plan into The Baby Friendly Hospital Initiative Plan where each labouring woman is allowed to have a birth companion. Health facilities are already training their staff on policies and practices related to mother – friendly care.

Continuity of care (care by one individual) is recognised as the gold standard, and recommendations regarding improving this type of care have been made to government and professional bodies. Ideally a system of continuity in carer, where one midwife or a small group of midwives work with the women throughout their pregnancy and childbirth, would foster and encourage personal control in pain relief.

Every effort should be made to ensure that women's birth environments are empowering, non-stressful, private, communicate respect and are not characterised by routine

interventions that add risk without clear benefit. Finally, effective pain relief depends not only on innovative practice but it also requires the support of managers. Midwives' initiatives must be recognised and encouraged and the resources made available to put them into practice. In this way midwives and managers can work with women to increase satisfaction with pain relief and the overall childbirth experience.

5.2. Recommendations

Further research of randomised controlled trials of non-pharmacological pain relief strategies for pain management in labour are needed. Even though hot and cold therapy is used in everyday midwifery practice, no trial or research were found on this intervention. There is a need for improving the quality and reporting of data in future trials. Further randomised trials should be adequately powered and include clinically relevant outcomes such as described in this review. Further research is required to assess which factors are important to women if they are to have a positive childbirth experience and how these priorities change from time to time.

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Appendix 6.1: Study Selection, Quality Assessment & Data Extraction Form

First author	Journal/Conference Proceedings etc	Year

Study eligibility

RCT/Quasi/CCT (delete as appropriate)	Relevant participants	Relevant interventions	Relevant outcomes
Yes / No / Unclear	Yes / No / Unclear	Yes / No / Unclear	Yes / No* / Unclear

*** Iissue relates to selective reporting – when authors may have taken measurements for particular outcomes, but not reported these within the paper(s). Reviewers should contact trialists for information on possible non-reported outcomes & reasons for exclusion from publication. Study should be listed in 'Studies awaiting assessment' until clarified. If no clarification is received after three attempts, study should then be excluded.**

Do not proceed if any of the above answers are 'No'. If study to be included in 'Excluded studies' section of the review, record below the information to be inserted into 'Table of excluded studies'.

1

2

References to trial

Check other references identified in searches. If there are further references to this trial link the papers now & list below. All references to a trial should be linked under one *Study ID* in RevMan.

Code each paper	Author(s)	Journal/Conference Proceedings etc	Year
A	***The paper listed above***		
B	***Further papers***		

Participants and trial characteristics

Participant characteristics	
	Further details
Age (mean, median, range, etc)	
Sex of participants (numbers / %, etc)	
Disease status / type, etc (if applicable)	
Other	

Trial characteristics

see Appendix 1, usually just completed by one reviewer

Methodological quality

We recommend you refer to and use the method described by Jüni (**Jüni 2001**)

Allocation of intervention	
State here method used to generate allocation and reasons for grading →	*Grade (circle)*
	Adequate (Random)
	Inadequate (e.g. alternate)
	Unclear

Concealment of allocation **Process used to prevent foreknowledge of group assignment in a RCT, which should be seen as distinct from blinding**	
State here method used to conceal allocation and reasons for grading →	*Grade (circle)*
	Adequate
	Inadequate
	Unclear

Blinding	
Person responsible for participants care	Yes / No
Participant	Yes / No
Outcome assessor	Yes / No
Other (please specify)	Yes / No

3

Intention-to-treat An **intention-to-treat analysis is one in which all the participants in a trial are analysed according to the intervention to which they were allocated, whether they received it or not.**	
All participants entering trial	
15% or fewer excluded	
More than 15% excluded	
Not analysed as 'intention-to-treat'	
Unclear	

Were withdrawals described? Yes □ No □ Not clear □

Discuss if appropriate……
……

Data extraction

Outcomes relevant to your review Copy and paste from 'Types of outcome measures'	
	Reported in paper (circle)
Outcome 1	Yes / No
Outcome 2	Yes / No
Outcome 3	Yes / No
Outcome 4	Yes / No
Outcome 5	Yes / No
Outcome 6	Yes / No
Outcome 7	Yes / No
Outcome 8	Yes / No

For Continuous data							
Code of paper	Outcomes (rename)	Unit of measurement	Intervention group		Control group		Details if outcome only described in text
			n	Mean (SD)	n	Mean (SD)	
A etc	Outcome A						
	Outcome B						
	Outcome C						
	Outcome D						
	Outcome E						
	Outcome F						

5

[5] Cochrane CFGD November 2004[5]

For Dichotomous data			
Code of paper	Outcomes (rename)	Intervention group (n) n = number of participants, not number of events	Control group (n) n = number of participants, not number of events
A	Outcome G		
	Outcome H		
	Outcome I		
	Outcome J		
	Outcome K		
	Outcome L		

Other information which you feel is relevant to the results
Indicate if: any data were obtained from the primary author; if results were estimated from graphs etc; or calculated by you using a formula (this should be stated and the formula given). In general if results not reported in paper(s) are obtained this should be made clear here to be cited in review.

6

[6] Cochrane CFGD November 2004[6]

[7]

References to other trials

Did this report include any references to published reports **of potentially eligible trials not already identified for this review?**		
First author	**Journal / Conference**	**Year of publication**
Did this report include any references to unpublished data **from potentially eligible trials not already identified for this review? If yes, give list contact name and details**		

[77] Cochrane CFGD November 2004[7]

Appendix 1

Trial characteristics	
	Further details
Single centre / multicentre	
Country / Countries	
How was participant eligibility defined?	
How many people were randomised?	
Number of participants in each intervention group	
Number of participants who received intended treatment	
Number of participants who were analysed	
Drug treatment(s) used	
Dose / frequency of administration	
Duration of treatment ***(State weeks / months, etc, if cross-over trial give length of time in each arm)***	
Median (range) length of follow-up reported in this paper ***(state weeks, months or years or if not stated)***	
Time-points when measurements were taken during the study	
Time-points reported in the study	
Time-points you are using in Meta-View	[8]

[8] Cochrane CFGD November 2004[8]

Trial design ***(e.g. parallel / cross-over*)***	
Other	

* If cross-over design, please refer to the Cochrane Editorial Office for further advice on how to analyse these data[9]

References

Jüni P, Altman DG, Egger M.. Systematic reviews in health care: Assessing the quality of controlled clinical trials. BMJ. 2001 Jul 7;323(7303):42-6.

[9] Cochrane CFGD November 2004[9]

Appendix 6.2: The PeDro Scale for Rating the Quality of Randomised Controlled Trials

1. Eligibility criteria were specified
2. Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)
3. Allocation was concealed
4. The groups were similar at baseline regarding the most important prognostic indicators
5. There was blinding of all subjects
6. There was blinding of all therapists who administered the therapy
7. There was blinding of all assessors who measured at least one key outcome
8. Measurements of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups
9. All subjects for whom outcome measurements were available received the treatment or control condition as allocated, or where this was not the case, data for at least one key outcome were analyzed by "intention to treat"
10. The results of between-group statistical comparisons are reported for at least one key outcome
11. The study provides both point measurements and measurements of variability for at least one key outcome

Figure.
PEDro Scale items. Each satisfied item (except the first item) contributes1 point to the total PEDro score (range=0–10 points). Operational definitions of each item are given in the Appendix.

Appendix.
Operational Definitions for the 11 PEDro Criteria

Criterion	Operational Definition
All criteria	Points are awarded only when a criterion is clearly satisfied. If, on a literal reading of the trial report, it is possible that a criterion was not satisfied, a point should not be awarded for that criterion.
Criterion 1	This criterion is satisfied if the report describes the source of subjects and a list of criteria used to determine who was eligible to participate in the study.
Criterion 2	A study is considered to have used random allocation if the report states that allocation was random. The precise method of randomization need not be specified. Procedures such as coin tossing and dice rolling should be considered random. Quasi-randomization allocation procedures such as allocation by hospital record number or birth date, or alternation, do not satisfy this criterion.
Criterion 3	Concealed allocation means that the person who determined if a subject was eligible for inclusion in the trial was unaware, when this decision was made, of which group the subject would be allocated to. A point is awarded for this criterion, even if it is not stated that allocation was concealed, when the report states that allocation was by sealed opaque envelopes or that allocation involved contacting the holder of the allocation schedule who was "off-site."
Criterion 4	At a minimum, in studies of therapeutic interventions, the report must describe at least one measure of the severity of the condition being treated and at least one (different) key outcome measure at baseline. The rater must be satisfied that the groups' outcomes would not be expected to differ, on the basis of baseline differences in prognostic variables alone, by a clinically significant amount. This criterion is satisfied even if only baseline data of subjects completing the study are presented.
Criteria 4, 7–11	Key outcomes are those outcomes that provide the primary measure of the effectiveness (or lack of effectiveness) of the therapy. In most studies, more than one variable is used as an outcome measure.
Criteria 5–7	Blinding means the person in question (subject, therapist, or assessor) did not know which group the subject had been allocated to. In addition, subjects and therapists are only considered to be "blind" if it could be expected that they would have been unable to distinguish between the treatments applied to different groups. In trials in which key outcomes are self-reported (eg, visual analog scale, pain diary), the assessor is considered to be blind if the subject was blind.
Criterion 8	This criterion is satisfied only if the report explicitly states both the number of subjects initially allocated to groups and the number of subjects from whom key outcome measurements were obtained. In trials in which outcomes are measured at several points in time, a key outcome must have been measured in more than 85% of subjects at one of those points in time.
Criterion 9	An intention-to-treat analysis means that, where subjects did not receive treatment (or the control condition) as allocated and where measures of outcomes were available, the analysis was performed as if subjects received the treatment (or control condition) they were allocated to. This criterion is satisfied, even if there is no mention of analysis by intention to treat, if the report explicitly states that all subjects received treatment or control conditions as allocated.
Criterion 10	A between-group statistical comparison involves statistical comparison of one group with another. Depending on the design of the study, this may involve comparison of 2 or more treatments or comparison of treatment with a control condition. The analysis may be a simple comparison of outcomes measured after the treatment was administered or a comparison of the change in one group with the change in another (when a factorial analysis of variance has been used to analyze the data, the latter is often reported as a group × time interaction). The comparison may be in the form hypothesis testing (which provides a *P* value, describing the probability that the groups differed only by chance) or in the form of an estimate (eg, the mean or median difference, a difference in proportions, number needed to treat, a relative risk or hazard ratio) and its confidence interval.
Criterion 11	A point measure is a measure of the size of the treatment effect. The treatment effect may be described as a difference in group outcomes or as the outcome in (each of) all groups. Measures of variability include standard deviations, standard errors, confidence intervals, interquartile ranges (or other quartile ranges), and ranges. Point measures and/or measures of variability may be provided graphically (eg, standard deviations may be given as error bars in a figure) as long as it is clear what is being graphed (eg, as long as it is clear whether error bars represent standard deviations or standard errors). Where outcomes are categorical, this criterion is considered to have been met if the number of subjects in each category is given for each group.

Appendix 6.3. **The Cochrane Collaboration's tool for assessing risk of bias**

Domain	Description	Review authors' judgement
Sequence generation.	Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.	Was the allocation sequence adequately generated?
Allocation concealment.	Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment.	Was allocation adequately concealed?
Blinding of participants, personnel and outcome assessors *Assessments should be made for each main outcome (or class of outcomes).*	Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.	Was knowledge of the allocated intervention adequately prevented during the study?
Incomplete outcome data *Assessments should be made for each main outcome (or class of outcomes).*	Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors.	Were incomplete outcome data adequately addressed?
Selective outcome reporting.	State how the possibility of selective outcome reporting was examined by the review authors, and what was found.	Are reports of the study free of suggestion of selective outcome reporting?
Other sources of bias.	State any important concerns about bias not addressed in the other domains in the tool. If particular questions/entries were pre-	Was the study apparently free of other problems that could put it at a high risk of bias?

	specified in the review’s protocol, responses should be provided for each question/entry.	

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jou kennisvennoot · your knowledge partner

19 March 2010 **MAILED**

Mrs M Abelgas
Division of Nursing
2nd Floor Teaching Block
Tygerberg Campus

Dear Mrs Abelgas

A systematic review of Non-Pharmacological pain relief strategie for pregnant women in labour

ETHICS REFERENCE NO: N10/03/093

RE : ETHICAL REVIEW NOT REQUIRED

Thank you for your email dated 19 March 2010 confirming that all data to be collected for the systematic review will be from the public domain. In light of this confirmation the cluster head for Research Ethics has considered this proposal to be exempt from ethical review.

This letter confirms that this project is now registered and you can proceed with the work.

Yours faithfully

DR LYN HORN
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