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## Immersion in water in labour and birth

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#### **Abstract**

**Background**—Enthusiasts suggest that labouring in water and waterbirth increase maternal relaxation, reduce analgesia requirements and promote a midwifery model of care. Critics cite the risk of neonatal water inhalation and maternal/neonatal infection.

**Objectives**—To assess the evidence from randomised controlled trials about immersion in water during labour and waterbirth on maternal, fetal, neonatal and caregiver outcomes.

**Search methods**—We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (30 June 2011) and reference lists of retrieved studies.

**Selection criteria**—Randomised controlled trials comparing immersion in any bath tub/pool with no immersion, or other non-pharmacological forms of pain management during labour and/or birth, in women during labour who were considered to be at low risk of complications, as defined by the researchers.

**Data collection and analysis**—We assessed trial eligibility and quality and extracted data independently. One review author entered data and the other checked for accuracy.

**Main results**—This review includes 12 trials (3243 women): eight related to just the first stage of labour: one to early versus late immersion in the first stage of labour; two to the first and second stages; and another to the second stage only. We identified no trials evaluating different baths/pools, or the management of third stage of labour.

Results for the first stage of labour showed there was a significant reduction in the epidural/spinal/paracervical analgesia/anaesthesia rate amongst women allocated to water immersion compared to controls (478/1254 versus 529/1245; risk ratio (RR) 0.90; 95% confidence interval (CI) 0.82 to 0.99, six trials). There was also a reduction in duration of the first stage of labour (mean difference –32.4 minutes; 95% CI –58.7 to –6.13). There was no difference in assisted vaginal deliveries (RR 0.86; 95% CI 0.71 to 1.05, seven trials), caesarean sections (RR 1.21; 95% CI 0.87 to 1.68,

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CONTRIBUTIONS OF AUTHORS Two review authors (E Cluett (EC) and E Burns (EB)) read all newly identified reports and reached consensus about inclusion and exclusion for each study. Using an agreed form, we separately extracted data from each included study, then met to compare these and agree about data to be analysed. We jointly considered the analysis and wrote the review. EC entered the data onto Review Manager and EB evaluated them for accuracy. EC is the contact author.

**DECLARATIONS OF INTEREST** The first review author (E Cluett) is chief investigator of two trials related to the subject of this review (Cluett 2001; Cluett 2004); we have excluded both.

INDEX TERMS

Medical Subject Headings (MeSH)

\*Immersion; \*Labor Stage, First; \*Labor Stage, Second; \*Water; Analgesia, Obstetrical [utilization]; Natural Childbirth; Randomized Controlled Trials as Topic

MeSH check words

Female; Humans; Pregnancy

eight trials), use of oxytocin infusion (RR 0.64; 95% CI 0.32 to 1.28, five trials), perineal trauma or maternal infection. There were no differences for Apgar score less than seven at five minutes (RR 1.58; 95% CI 0.63 to 3.93, five trials), neonatal unit admissions (RR 1.06; 95% CI 0.71 to 1.57, three trials), or neonatal infection rates (RR 2.00; 95% CI 0.50 to 7.94, five trials).

Of the three trials that compared water immersion during the second stage with no immersion, one trial showed a significantly higher level of satisfaction with the birth experience (RR 0.24; 95% CI 0.07 to 0.80).

A lack of data for some comparisons prevented robust conclusions. Further research is needed.

**Authors' conclusions**—Evidence suggests that water immersion during the first stage of labour reduces the use of epidural/spinal analgesia and duration of the first stage of labour. There is limited information for other outcomes related to water use during the first and second stages of labour, due to intervention and outcome variability. There is no evidence of increased adverse effects to the fetus/neonate or woman from labouring in water or waterbirth. However, the studies are very variable and considerable heterogeneity was detected for some outcomes. Further research is needed.

#### **BACKGROUND**

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

Throughout this review, 'water immersion' refers to the immersion in water by a pregnant woman during any stage of labour (first, second, third) where the woman's abdomen is completely submerged. This implies the use of a receptacle that may be called a pool, tub or bath, and which is larger than a normal domestic bath. The period of immersion by the woman may be for one or more stages of labour, and for any duration. Labour is understood to be as defined by the woman or clinicians at the time, and includes regular painful uterine contractions, leading to full cervical dilation, expulsion of the fetus, and the placenta and membranes.

#### **History**

The use of water immersion as a therapeutic medium is not new. Its exact origins are unknown, but there is evidence of immersion in water being used as a treatment for physical and psychological ill health by the Chinese, Egyptians, Japanese and Assyrians, as well as Greeks and Romans (Reid Campion 1990; Reid-Campion 1997). Warm water immersion during labour, including birth, used for relaxation and pain relief, has a long history in lay and clinical care (Garland 2000). Igor Tjarkovsky, a Russian boat builder, stimulated the foundation of a movement to promote waterbirth in Soviet Russia in the 1970s. He became convinced of the benefits of water immersion as a means of maximising physiological potential. Michel Odent subsequently popularised water immersion in other European countries (Odent 1983). Although considered a fad by some, the use of water during labour and birth appeals to both women and their carers, particularly those striving for a womancentred, intervention free, 'normal' experience. In 1995, the first international waterbirth conference was held in London, followed by many subsequent study events and international conferences.

Official acceptance of the use of water immersion as a care option during labour came in the UK in 1993, with the publication of the Changing Childbirth report (Department of Health 1993), which recommended that a pool facility should be an option available to women in all UK maternity units. Professional recognition of the use of water during labour and birth

came in 1994 when both the Royal College of Midwives (RCM 1994) and the United Kingdom Central Council for Nursing, Midwifery and Health Visiting (UKCC 1994) published position statements, which incorporated water immersion during labour into the role of the midwife. The use of water during labour/birth is now integrated in the UK Midwifery Rules and standards (Nursing and Midwifery Council 2010), and UK policy for maternity services with section 8.4 of the National Service Framework for Children, Young People and Maternity Service (Department of Health 2004).

Most of the evidence on the use of water immersion is based on observational studies (Garland 1997; Garland 2002; Geissbuehler 2004; Ohlsson 2001; Thoeni 2005). A tension has arisen with regard to the perceived acceptability of randomised controlled trial (RCT) design, as some midwives and women perceive this as obviating maternal choice to what is now a widely available option, while women with strong preferences may decline to participate (Garland 1994). Factors such as depth of water, size of the pool and whether the water is still or aerated/whirlpool water have not been compared, as pool design and practice have tended to be based on local availability and customs.

#### Water immersion during first stage of labour - what it offers women

The positive physiological effects of hydrotherapy such as buoyancy, hydrostatic pressure, and associated thermal changes, are relevant to women labouring in water, where labour is defined as including the first, second (birth) and third stages. The buoyancy of water enables a woman to move more easily than on land (Edlich 1987). This can facilitate the neuro-hormonal interactions of labour, alleviating pain, and potentially optimising the progress of labour (Ginesi 1998a; Ginesi 1998b). Water immersion may be associated with improved uterine perfusion, less painful contractions, a shorter labour with fewer interventions (Aird 1997; Garland 2000; Moneta 2001; Otigbah 2000; Geissbuehler 2004; Thoeni 2005; Zanetti-Daellenbach 2007). In addition, the ease of mobility that water immersion offers women may optimise fetal position by encouraging flexion (Ohlsson 2001).

Hydrotherapy has marked physiological effects on the cardiovascular system (Cefalo 1978). Shoulder-deep warm water immersion reduces blood pressure due to vasodilatation of the peripheral vessels and redistribution of blood flow. It is suggested that water immersion during labour increases maternal satisfaction and sense of control (Hall 1998; Richmond 2003). A woman who feels in control during childbirth experiences greater emotional wellbeing postnatally (Green 1998).

The UK is promoting water immersion during labour and waterbirth as a means of empowering women and is consistent with the current agenda of normalising birth (Royal College of Midwives 2011), the consensus statement from the maternity Care Working Party (Maternity Care Working Party 2007); both of whom use a waterbirth image to illustrate normal birth, as does the Vision for Midwifery expressed by the Midwifery 2020 programme (Midwifery 2020 Program 2010).

Although the use of additives such as essential oils to the water appears to be gaining popularity (Calvert 2000), to date no trial has generated reliable evidence to support or refute the use of any additive.

#### Waterbirth (second stage of labour) - what it offers women

It has been suggested that waterbirth may reduce the uptake of pharmacological pain relief and likelihood of perineal trauma (Burke 1995; Burns 2001; Garland 2000; Geissbuehler 2000; Otigbah 2000). There may also be increased maternal satisfaction with the birth experience.

#### Water immersion and the fetus/neonate (first and/or second stage)

It could be argued that the fetus benefits from a relaxed mother, as this maximises placental oxygen perfusion. 'Nature's opiates', endogenous endorphins, predominate. When the mother is not fearful, oxytocin is released to stimulate effective contractions. Labouring in water, compared to land, has been found to reduce stress hormones, catecholamines, which inhibit oxytocin and labour progress. The fetus may be more likely to adopt a flexed position, because the mother can easily explore different positions to maximise her pelvic diameters if the pool is sufficiently large (Ohlsson 2001).

Concerns raised in a survey and case reports about birth in water for the baby include 1) thermoregulation during labour, 2) infection, 3) respiratory difficulties and 4) snapped cord (Gilbert 1999; Kassim 2005; Mammas 2009; Nguyen 2002; Pinette 2004).

**1. Thermo regulation**—As with any labouring woman, it is important to avoid her becoming pyrexial. Therefore, the water temperature of a pool should not exceed the maternal body temperature, as immersing a woman in water above her natural core temperature will result in fetal hyperthermia and associated cardiovascular and metabolic disturbances (Johnson 1996). High temperatures have been identified as a safety issue by several authors as being associated with fetal mortality and morbidity, based on individual case studies and/or theory (Deans 1995; Johnson 1996; Rosevear 1993). The theory underpinning this was originally based on a study on pregnant ewes (Cefalo 1978). The fetus responded to an increase in maternal temperature by becoming tachycardiac, reducing resistance in the placenta bed and thus heat dissipation. As the temperature increased, there was a tendency to exceed the heat that could be dissipated by the placenta, leading to an increased risk of fetal mortality (Cefalo 1978). A review of the literature on temperature control in mammalian fetuses, mainly sheep, primates and a limited number of human participants, identified that the fetal metabolic processes produce heat (Power 1989). This heat is transferred to the mother primarily via the circulatory system, the umbilical cord and placenta where the large surface area and constant blood flow facilitate heat transfer. A second pathway for heat transfer is via fetal skin, to amniotic fluid, the uterus and maternal system. To enable this heat transfer, the fetus is 0.5°C warmer than the mother. This difference is apparently constant across species, although the basal temperatures differ (Power 1989). When maternal temperature increases, heat transfer is inhibited and the fetal temperature rises, until transfer is again possible. However, there is a concomitant rise in metabolic activity and oxygen demands as temperature increase, the effect of which may be seen in fetal heart rate changes, and which may contribute to fetal compromise during labour. Temperature regulation, and its assessment, are therefore important during labour/ birth irrespective of the use of water immersion.

**2. Respiration**—The diving reflex prevents a healthy baby born in water from drowning. This is an apnoea on expiration (the opposite of an adult who dives having taken a breath), with a closed larynx. The fetal larynx has a myriad of airway chemoreceptors which prevent fluid aspiration. The diving reflex is stimulated via facial skin receptors conveying stimuli along the trigeminal nerve, triggered as these receptors make contact with the water (Johnson 1996).

Fetal breathing is inhibited at the hypo-pharynx. This mechanism is associated with hormonal factors such as prostaglandin and adenosine; sensors in the oral pharynx, including free nerve endings/taste buds, prevent aspiration, and indeed the normal mechanism is that any lung fluid rising into the oro-pharynx is swallowed. Mild hypoxia further inhibits breathing until chronic sub lethal override point, leading to the belief that an uncompromised human neonate will not breathe under water (Johnson 1996). A

compromised neonate born underwater has the potential to gasp before the nose and mouth are above the surface, thus inhaling bath water into the lungs. Inhalation of even a small quantity of fresh water can be absorbed quickly into the circulation causing appreciable haemodilution and fluid overload - as seen in fresh water drowning.

There have been two reports of neonatal death following waterbirth attended by a midwife (Burns 2001; Rosser 1994). These adverse outcomes are very rare, and causality cannot be inferred on the evidence to directly link the reported case studies of rare adverse outcomes with waterbirth.

**3. Infection**—It has been suggested that fetal/neonatal infection may occur due to cross-contamination from the water and pool, and from the woman (Hawkins 1995; Rawal 1994). However, several comparative studies, cohort studies, and audits report no increase risk of infection for the fetus/neonate (Alderdice 1995; Anderson 1996; Eriksson 1997; Otigbah 2000; Rush 1996; Robertson 1998; Zanetti-Daellenbach 2007). As with all maternity provision, it is incumbent upon practitioners to ensure they have appropriate cleaning protocols for labour and birthing pools, and employ universal precautions.

To date, there is no evidence of increased maternal, fetal or neonatal risk associated with water immersion, compared with labouring and giving birth on land. Two UK national surveys were undertaken during the 1990s: Alderdice 1995 included 2885 women and their neonates, while Gilbert 1999 evaluated the neonatal outcomes for 4032 infants. Both surveys indicated that there was no reliable evidence to justify denying the choice of water immersion for labour and/or birth to women at low risk of complications. In addition, multiple cohort studies/audits have suggested the safety of water immersion during labour and birth for women at low risk of complication (Garland 2006; Geissbuehler 2004; Otigbah 2000; Thoeni 2005). RCTs have been conducted which are the focus of this review.

Maternal adverse effects of water immersion during labour have been theorised. These include the possibility that it may promote unrealistic expectations about labour, restrict choice of analgesia, restrict mobility, reduce contraction effectiveness, and increase perineal trauma (McCandlish 1993). Increased risk to the mother of infection caused by water entering the uterus has been proposed (Rosevear 1993). If warmth has a relaxing effect on the uterine muscles, the uterus may contract less efficiently postpartum (Church 1989; Deans 1995). A theoretical risk of water embolism has been hypothesised (Odent 1983). The logic of this hypothesis has been challenged (Wickham 2005). To date no studies have reported an association between water immersion during labour/birth with this adverse event.

**4. Snapped umbilical cord**—Concerns have been raised about the dangers of umbilical cords at water births (Gilbert 1999). Cords also snap in land births; there are however, no data for this. Cord snaps associated with waterbirth may be related to undue traction exerted on the cord as the baby is lifted out of the water.

#### Third stage of labour

We are not aware of any studies which have compared third stage of labour management or whether the placenta was delivered in or out of the water.

#### Water immersion during labour and birth: what it offers caregivers

Labour and birth is a complex, multifaceted and major life event encompassing physiological, emotional, psychological and social elements. It is therefore highly individualised and its features and outcome cannot be predicted with certainty. Although

much of health care is based on understanding pathology and ill health, and while that may be appropriate for some, in maternity care, women are experiencing a normal physiological process. Midwives Downe and McCourt (Downe 2004) advocate that midwifery care should be set in the context of salutogenesis.

The salutogenic theory originated from interviews conducted with Israeli women who had survived the Holocaust about their time in concentration camps during the Second World War. It was noted that some stayed healthy despite horrendous experiences. This epidemiological study stimulated sociologist Antonovsky to develop the salutogenic paradigm as a way of focusing on health rather than disease (Antonovsky 1979; Antonovsky 1987). Central to salutogenesis is a person's sense of coherence, which Antonovsky defined as a global orientation that denotes the degree of self-esteem and confidence an individual possesses to enable them to deal with life's vicissitudes. In essence salutogenesis involves fostering a positive outlook and sense of self-worth to empower the individual to realize their potential. Empowerment is a key element of woman-centred care and the drive to normalise birth - an international initiative, led in the UK by the Royal College of Midwives (RCM 2008). The development of normal birth care pathways is consistent with these aims (NHS Wales 2004). Another stimulus to normalise birth is the international concern over the rise in caesarean sections in particular, but the medicalisation of labour and birth in general (RCOG 2001). The medicalisation of childbirth has many women believing that childbirth is inherently dangerous (Green 2007). It can be argued that water as an environment changes the context in which care is provided; it facilitates the paradigm shift, from professionalcentred to woman-centred, from pathology dominated to normality expected. The woman is in her own 'world' and access to her is mediated by the water.

Water implies relaxation and warmth, and many would suggest it also conveys femininity and sexuality (Odent 1999). Clarke 2007 report an increase in the use of water immersion during labour and birth as one result of increasing the focus of one maternity unit to normality through the use of a care pathway. A birthing pool therefore offers midwives an opportunity to develop the skills required to provide woman-centred care, form a therapeutic rapport with women, facilitate their freedom and participation in decision making, and support them in having choice and control over their care (Nursing and Midwifery Council 2010).

#### **OBJECTIVES**

To assess the effects of water immersion during labour and/or birth (labour stages one, two and three) on maternal, fetal, neonatal and caregiver wellbeing. For the purpose of this review wellbeing is defined as outcomes measuring physical and psychological health. This review addresses the benefits and risks of immersion in water versus no immersion during each stage of labour. In addition, the review compares early (cervical dilation less than 5 cm) with late (cervical dilation more than 5 cm) immersion, different pool designs, still versus moving water, and water with or without additives.

## **METHODS**

#### Criteria for considering studies for this review

**Types of studies**—Randomised controlled trials (RCTs) only. (We will not include results from quasi-RCTs in the analyses but we may be discuss them in the text if little other evidence is available.)

We have reported trials that included randomised and non-randomised subjects if the randomised data are presented separately. We have included published, unpublished and ongoing studies with reported data.

**Types of participants**—Nulliparous or multiparous women in labour with a singleton pregnancy, irrespective of gestation or labour characteristics.

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

- 1. Placebo/no treatment
- 2. Hypnosis
- 3. Biofeedback (Barragán 2011)
- **4.** Intracutaneous or subcutaneous sterile water injection (Derry 2011)
- **5.** Immersion in water (this review)
- **6.** Aromatherapy (Smith 2011a)
- 7. Relaxation techniques (yoga, music, audio)\*
- **8.** Acupuncture or acupressure (Smith 2011b)
- **9.** Manual methods (massage, reflexology)\*
- 10. Transcutaneous electrical nerve stimulation (TENS) (Dowswell 2009)
- **11.** Inhaled analgesia
- 12. Opioids (Ullman 2010)
- **13.** Non-opioid drugs (Othman 2011)
- **14.** Local anaesthetic nerve blocks (Novikova 2011)
- **15.** Epidural (including combined spinal epidural) (Anim-Somuah 2005; Simmons 2007)

Accordingly, this review includes comparisons of any kind of bath/tub/pool that enabled immersion during any stage of labour, regardless of care setting, compared with: 1. no treatment (no immersion); 2. hypnosis; 3. biofeedback; 4. intracutaneous or subcutaneous sterile water injection; and 5. immersion during a different stage of labour.

**Types of outcome measures**—We chose primary outcomes that we thought would be the most clinically valuable in assessing safety and effectiveness for the woman, fetus/neonate and caregivers. We identified all outcomes that were considered to be of interest from the perspective of the woman and her baby, primary caregivers and related service providers. These (list below) are analysed within the comparison groups:

- immersion in water versus no immersion during the first stage of labour;
- immersion in water versus no immersion during the second stage of labour;
- comparison of different types of bath/pool;

additives versus no additives to water used for immersion during labour and/or birth;

• early (cervical dilation less than 5 cm) with late (cervical dilation more than 5 cm) immersion.

## **Primary outcomes**

#### **Maternal outcomes**

•	Morbidity	-	side	effects
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•	<ul> <li>Blood loss during labour (first, second, third stage, and immediate postnatal period)</li> </ul>
	○ Infection during labour/postnatal period
	O Perineal trauma
	O Postpartum depression
	O Post-traumatic stress disorder
•	Labour
•	O Pain intensity (first and second stage, as defined by trialists)
	O Mode of delivery (spontaneous birth, assisted vaginal births and caesarean sections)
•	Wellbeing
	O Satisfaction with childbirth experience (as defined by trialists)
	○ Satisfaction with pain relief (as defined by trialists)
	○ Sense of control in labour (as defined by trialists)
	○ Effect (negative) on mother/haby interaction

#### **Fetal outcomes:**

- Abnormal heart rate pattern
- Meconium liquor

#### **Neonatal outcomes:**

•	Morbidity - sic	le effects
	<b>~</b> .	

○ Apgar score less than seven at five minutes
O Cord pH immediately after birth (arterial and or venous cord blood)
○ Admission to special care baby unit/neonatal intensive care unit
○ Respiratory support (oxygen/ventilation required)
○ Lung hypoplasia
○ Infection, including markers of infection such as pyrexia and raised white cell count

O Neurological pathology, e.g. seizures, cerebral palsy

O Snapped cord

○ Birth injury
O Poor infant outcomes at long term follow-up (as defined by trialists)
Wellbeing markers
O Breastfeeding (at specified time points)

Other outcomes: Cost (as defined by trialists)

#### **Secondary outcomes**

#### **Maternal outcomes:**

- Mortality
- Labour

<ul> <li>Augmentation of labour (artificial rupture of membranes and/ administration)</li> </ul>	or oxytoxic
○ Use of non-pharmacological analgesia	
○ Use of pharmacological analgesia (including regional and ger anaesthesia) during any stage of labour	neral
O Duration of labour (first, second and third stage)	

- Wellbeing
  - O Temperature (first and second stage)
  - O Pulse and blood pressure (first, second and third stage)
  - O Maternal self-esteem
  - O Preference for care in subsequent labour

#### **Fetal outcomes:**

- Birthweight
- Gestational age at birth

#### **Neonatal outcomes:**

Mortality

#### **Caregiver outcomes:**

- Satisfaction
- Injuries (any reported physical injury attributed to care of women in water)

#### Search methods for identification of studies

**Electronic searches**—We searched the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting the Trials Search Co-ordinator (30 June 2011).

The Cochrane Pregnancy and Childbirth Group's Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from:

**1.** quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);

- 2. weekly searches of MEDLINE;
- **3.** weekly searches of EMBASE:
- **4.** handsearches of 30 journals and the proceedings of major conferences;
- weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

Details of the search strategies for CENTRAL, MEDLINE and EMBASE, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service can be found in the 'Specialized Register' section within the editorial information about the Cochrane Pregnancy and Childbirth Group.

Trials identified through the searching activities described above are each assigned to a review topic (or topics). The Trials Search Co-ordinator searches the register for each review using the topic list rather than keywords.

**Searching other resources**—We used personal contacts to identify other potential trials (published and unpublished) and we retrieved and assessed relevant references referred to in the reviewed papers for appropriateness for inclusion in this review.

We did not apply any language restrictions.

## Data collection and analysis

**Selection of studies**—We re-evaluated trials included and excluded within the previous review and confirmed their inclusion or exclusion. As previously, two review authors independently examined abstracts of all potential studies identified by the search to ascertain which met the inclusion criteria. We resolved any disagreement through discussion among all review authors. We have added one new paper since the last update.

**Data extraction and management**—We used a data extract template provided by the Cochrane Pregnancy and Childbirth Group and modified for the topic for the evaluation and data identification/extraction process. Elizabeth Cluett (EC) entered data into Review Manager software (RevMan 2011), and Ethel Burns (EB) checked for accuracy.

**Assessment of risk of bias in included studies**—For this current review two review authors, EC and EB, independently assessed risk of bias for each study using the criteria outlined in *the Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We resolved any disagreement through discussion.

(1) Random sequence generation (checking for possible selection bias): We described for each included study the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.

We assessed the method as:

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

(2) Allocation concealment (checking for possible selection bias): We described for each included study the method used to conceal allocation to interventions prior to assignment and assessed whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment. We assessed the methods as:

- low risk of bias (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
- high risk of bias (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear risk of bias.
- (3) Blinding (checking for possible performance bias): Due to the nature of the intervention, blinding is not possible and therefore this could not be considered.
- (4) Incomplete outcome data (checking for possible attrition bias due to the amount, nature and handling of incomplete outcome data): We described for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We stated whether attrition and exclusions were reported and the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information is reported, or can be supplied by the trial authors, we will re-include missing data in the analyses which we undertake.

We assessed methods as:

- low risk of bias (e.g. no missing outcome data; missing outcome data balanced across groups, less than 20% loss);
- high risk of bias (e.g. numbers or reasons for missing data imbalanced across groups; 'as treated" analysis done with substantial departure of intervention received from that assigned at randomisation);
- unclear risk of bias.
- (5) Selective reporting (checking for reporting bias): We described for each included study how we investigated the possibility of selective outcome reporting bias and what we found. We assessed the methods as:
  - low risk of bias (where it is clear that all of the study's prespecified outcomes and all expected outcomes of interest to the review have been reported);
  - high risk of bias (where not all the study's pre-specified outcomes have been reported; one or more reported primary outcomes were not pre-specified; outcomes of interest are reported incompletely and so cannot be used; study fails to include results of a key outcome that would have been expected to have been reported);
  - unclear risk of bias.
- (6) Other bias (checking for bias due to problems not covered by (1) to (5) above): We described for each included study any important concerns we had about other possible sources of bias.

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

• low risk of other bias;

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

(7) Overall risk of bias: We will make explicit judgements about whether studies are at high risk of bias, according to the criteria given in the *Handbook* (Higgins 2011). With reference to (1) to (6) above, we will assess the likely magnitude and direction of the bias and whether we consider it is likely to impact on the findings. We will explore the impact of the level of bias through undertaking sensitivity analyses - *see* Sensitivity analysis.

#### Measures of treatment effect

<u>Dichotomous data:</u> For dichotomous data, we used odds ratio with 95% confidence intervals. We analysed data for this review as presented in original papers, therefore by allocation (intention to treat).

<u>Continuous data:</u> For continuous data, we use the mean difference if outcomes are measured in the same way between trials.

**Dealing with missing data**—We have analysed data on all participants with available data in the group to which they were allocated, regardless of whether or not they received the allocated intervention, and irrespective of whether they used additional interventions. If, in the original reports, participants were not analysed in the group to which they were randomised, and there was sufficient information in the trial report, we have attempted to restore them to the correct group. For included studies we have noted levels of attrition.

Where data were not reported for some outcomes or groups we attempted to contact the study authors.

**Assessment of heterogeneity—**As part of the meta-analyses we examined heterogeneity between trials using the I<sup>2</sup> statistic.

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

**Data synthesis**—We carried out statistical analysis using the Review Manager software (RevMan 2011).

**Subgroup analysis and investigation of heterogeneity—**For the primary outcomes, where data were available, we planned the following subgroup analyses.

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

**Sensitivity analysis**—We planned to carry out sensitivity analyses to explore the effect of trial quality assessed by concealment of allocation, high attrition rates, or both, with poor

quality studies being excluded from the analyses in order to assess whether this made any difference to the overall result.

#### **RESULTS**

#### **Description of studies**

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of studies awaiting classification.

One-to-one care in labour is known to affect labour outcomes (Hodnett 2007), and this was clearly documented in four trials (Cammu 1994; Da Silva 2006; Nikodem 1999; Taha 2000). Where it was stated that normal/routine/standard care was provided, this was understood to mean that the practitioners who normally provided intrapartum care to women in labour in the study centre provided care for the study participants (Da Silva 2006; Eckert 2001; Eriksson 1997; Nikodem 1999; Rush 1996; Schorn 1993; Woodward 2004). Cammu 1994 indicated that care was supervised by obstetric staff.

Water temperature is known to be important in the care of women using water immersion during labour. This varied across trials, with some using a temperature up to 37°C (Cammu 1994; Eckert 2001; Kuusela 1998); others up to 38°C (Da Silva 2006; Eriksson 1997; Taha 2000); and still others not stated (Chaichian 2009; Ohlsson 2001; Schorn 1993; Woodward 2004). Rush 1996 refers to a temperature of 38 to 39°C. The higher temperatures may affect outcomes, but there are no studies comparing outcomes for the use of different water temperatures.

The studies collected a wide range of data, but the specific outcome measures collected were very variable, and collected in different formats. For example, some studies did not consider neonatal wellbeing. Use of Apgar scores was also variable; some used them as continuous data, others as dichotomous, making comparison across studies challenging, and resulting in the reporting of many variables based on the results from one study.

#### Results of the search

We identified a total of 20 studies (some described in more than one report/paper) for consideration for inclusion in the review. Of these, we have now included 12 and excluded six; two await further assessment while we seek additional information from the authors. For more information see Characteristics of excluded studies.

**Included studies**—Of the 12 trials included in this review, eight related to the first stage of labour only; one related to early versus late immersion in the first stage of labour; two involved immersion during the first and second stages of labour; and one involved women in the second stage of labour only. There were no studies evaluating the use of different types of baths/pools at any stage of labour or the effects of water immersion on the third stage of labour. We identified no trials that evaluated immersion versus no immersion during pregnancy (i.e. not in labour).

For further details, see Characteristics of included studies.

**Excluded studies**—We excluded the two studies by Cluett (Cluett 2001; Cluett 2004), primarily because all the women were nulliparous who had been diagnosed as having dystocia in the first stage of labour, and the comparison (control) group all received augmentation of labour. Hence comparison and inclusion in any meta-analysis with women at low risk of complications is inappropriate. In addition, Cluett 2001 was a feasibility study and only involved four women in each arm. Cluett 2004 suggested that in nulliparous

women who have been classified as having slow progress in the first stage of labour, labouring in water reduced the incidents of epidural analgesia, although this did not reach statistical significance (P=0.056). The pain scores were significantly lower, but as the comparison group received augmentation of labour, it could be argued that this was to be expected. This further supports the rationale for not including these women in this review, as doing so would not represent the situation when water immersion would be used, namely in a low-risk labour and birth.

One pilot study (Calvert 2000) compared the use of essential oil of ginger with the use of essential oil of lemon grass. The data from this pilot are not in an appropriate form for analysis and so we excluded the study from the review. Use of other additives, such as salt, has not yet been evaluated in an RCT.

We excluded Benfield 2001 because of inadequate allocation concealment and the nature of the intervention.

#### Risk of bias in included studies

See details under Characteristics of included studies, Figure 1; Figure 2.

Allocation—Randomisation processes varied; those of the best quality used computer-generated, sequentially numbered opaque envelopes containing the group allocation (Eriksson 1997; Rush 1996; Woodward 2004) or a clear description of concealment (Cammu 1994; Eriksson 1997; Nikodem 1999; Ohlsson 2001; Taha 2000). Others were less transparent (Chaichian 2009; Kuusela 1998). Nikodem 1999 and Taha 2000 used allocation in blocks, which is not ideal as this has the potential for breaking concealment at the end of the block.

**Blinding**—None of the trials cite any blinding of outcome assessment, and this is likely to be difficult to achieve, as use of water during labour is usually clearly documented in case records.

As an intervention, it is not possible to blind participants or carers to water immersion. Not all participants and/or carers will be in a state of equipoise between immersion or non-immersion, that is being equally comfortable and confident about water immersion. This may positively or negatively influence outcomes such as pain perception and hence subsequent analgesia use, maternal satisfaction, self-esteem and postpartum depression. An example of this is Woodward 2004, which reports that some midwives were apparently not supportive of women using water, suggesting a positive bias within the women, and in this case a negative bias within the midwives. Conversely Rush 1996 reports practitioners as maintaining a interest in low-intervention labour practice, suggesting a positive bias towards water immersion. Water immersion, however, is as much a psychological choice as a physical pain management strategy, and as such pragmatic clinical trials are assessing the effect of the whole package.

Incomplete outcome data: Compliance with trial allocation was variable across the trials. Of the trials that involved water immersion in the first stage of labour, Rush 1996 reported that 46% of women allocated to water immersion did not actually enter the water, while Woodward 2004 planned a 2:1 ratio allocation to water anticipating that about 50% of women would not use water, but of the 40 allocated to use water, only 24 used the pool. Four (of 58) women in Da Silva 2006 did not receive the water intervention due to medical/obstetric reasons. Another five trials (Cammu 1994; Eckert 2001; Eriksson 1997; Ohlsson 2001; Woodward 2004) reported some crossover between groups. Kuusela 1998 and Chaichian 2009 did not provide information on this.

Rush 1996 and Da Silva 2006 referred to post-randomisation exclusion. For Rush 1996 this was 41 (of 785) women who were ineligible for the trial but recruited and allocated to a trial arm. They indicate that these 41 women were included in the analysis as it was on an intention-to-treat basis, but they also supply subgroup analysis with these women excluded.

<u>Selective reporting:</u> From the methods indicated, all the outcomes were reported. This was particularly hard to assess in the translated paper (Kuusela 1998), however, the risk of bias from selective reporting could be greater as in all trials there was an absence of a full study protocol.

Other potential sources of bias: The trials adopted a variety of definitions for water immersion, with different size baths/pools containing different volumes of water. To date, there is no evidence as to whether different degrees of immersion, or the amount of mobility possible within the bath/pool, affect outcomes. Schorn 1993 refers to a tub with a moulded seat, which may restrict mobility and the freedom to adopt different positions while immersed. Likewise, Rush 1996 used a pool where the woman could not change position. Schorn 1993 and Rush 1996 used a whirlpool (hot tub with jets) and the effect of moving water during immersion may be different to the effect of still water. Kuusela 1998 refers to a tub that is 70 cm deep and holds 730 litres; Da Silva 2006 indicates tub volume as 194 litres; Eckert 2001 and Eriksson 1997 cite tub depths of 54 cm and 40 cm, respectively. Differences as to what constitutes water immersion makes comparisons of outcomes across trials difficult.

Most of the included trials have small sample sizes and therefore a high risk of bias. These factors limit comparison across trials and the reliability and validity of the trial findings.

**Effects of interventions**—This section considers the results from the included trials and overall conclusions.

<u>Immersion versus no immersion in the first stage of labour:</u> Eight trials reported on this comparison.

<u>Maternal outcomes:</u> The following maternal outcomes were not reported in the trials: mortality; post-traumatic stress disorder; temperature; satisfaction with childbirth experience; maternal self-esteem; satisfaction with pain relief; sense of control in labour; effect on mother/baby interaction.

Blood loss during labour (first, second, third stage, and immediate postnatal period): One trial (Eckert 2001) reported on the postpartum haemorrhage rate in each group and there was no difference between groups (risk ratio (RR) 1.58; 95% confidence interval (CI) 0.80 to 3.13), Analysis 1.13. Two trials (Kuusela 1998; Taha 2000) reported on the mean blood loss (ml) in each group and there was no difference between groups (mean difference (MD) –14.33; 95% CI –63.03 to 34.37), Analysis 1.14.

<u>Infection during labour/postnatal period:</u> There were no significant differences in the incidence of maternal infection (Cammu 1994; Eckert 2001; Kuusela 1998; Rush 1996; Schorn 1993), (15/647 versus 15/648; RR 0.99; 95% CI 0.50 to 1.96), Analysis 1.26.

Perineal trauma: There were no significant differences between the benefits and risks associated with the use of water immersion during labour on outcomes such as perineal trauma: intact perineum (236/678 versus 200/659; RR 1.16; 95% CI 0.99 to 1.35) (Da Silva 2006; Eckert 2001; Rush 1996; Taha 2000; Woodward 2004); episiotomy (207/644 versus 219/628; RR 0.93; 95% CI 0.80 to 1.08), second-degree tears (110/658 versus 112/628; RR

0.94; 95% CI 0.74 to 1.20) and third-/fourth-degree tears (40/1202 versus 29/1199; RR 1.37; 95% CI 0.86 to 2.17) (Eckert 2001; Ohlsson 2001; Rush 1996; Taha 2000; Woodward 2004), Analysis 1.15.

<u>Postpartum depression:</u> Two trials (Eckert 2001; Taha 2000) reported on postpartum depression, which was defined as a score of more than 11 on the Edinburgh Postnatal Depression Scale (EPDS). There was no difference between groups in the incidence of postpartum depression, (RR 1.38; 95% 0.85 to 2.24), Analysis 1.28.

Augmentation of labour (artificial rupture of membranes and/or oxytocic administration): There has been some concern that water immersion may slow labour, therefore we analysed data on augmentation. There were no differences in the incidence of amniotomy (240/465 versus 233/461; RR 1.02; 95% CI 0.90 to 1.16) (Da Silva 2006; Kuusela 1998; Rush 1996), Analysis 1.19. There were no differences in the use of oxytocin infusion (RR 0.64; 95% CI 0.32 to 1.28), Analysis 1.22. However, considerable heterogeneity was detected within Analysis 1.22, which was not apparent with the exclusion of the Chaichian 2009 study, (heterogeneity:  $I^2 = 79\%$ ,  $T^2 = 0.41$ ,  $Chi^2$  test for heterogeneity P = 0.0008) and so we used a random-effects meta-analysis.

**Pain intensity:** Four trials (Da Silva 2006; Kuusela 1998; Nikodem 1999; Taha 2000) reported on pain intensity. Nikodem 1999 only reported the results narratively, "More (75% versus 40%) mothers in the water group experienced less pain than they expected" and so these data could not be included in an analysis. Two trials (Da Silva 2006: Kuusela 1998) reported mean visual analogue pain scores (VAS) at the start of assessment and then 30 minutes (Da Silva 2006) and one hour after (Kuusela 1998) the start of assessment and found no difference between groups in pain assessment at the different time points (start of assessment (MD –0.01; 95% CI –0.54 to 0.52), up to one hour after start assessment (MD –0.81; 95% CI –1.34 to –0.28), Analysis 1.17.

One trial (Taha 2000) assessed pain using three ordinal scales: pain reported on a VAS scale, where 1 is no pain and 10 is worst pain imaginable; feelings indicated by means of faces on a scale of 0 to 5; description in words the pain they experience, from no pain at all to unbearable pain. They did not use the McGill Pain Questionnaire. The data were reported at six different time points (before randomisation and then 30 minutes, one hour, two hours, three hours and 24 hours after randomisation) and was dichotomised giving the proportion of patients at different points on the scales. We have included only the data after randomisation in an analysis, Analysis 1.6. Moderate to severe pain according to all three ordinal scales was significantly less in those labouring in water than those not labouring in water when assessed 30 minutes after randomisation (RR 0.75; 95% CI 0.62 to 0.9, Analysis 1.6.1; RR 0.72; 95% CI 0.58 to 0.90, Analysis 1.6.2; RR 0.67; 95% CI 0.51 to 0.90, Analysis 1.6.3), and 24 hours after randomisation (RR 0.64; 95% CI 0.50 to 0.82, Analysis 1.6.13; RR 0.62; 95% CI 0.49 to 0.80, Analysis 1.6.14; RR 0.69; 95% CI 0.54 to 0.87). It was significantly less when assessed at one hour and two hours after randomisation for two out of the three ordinal scales (one hour - RR 0.76; 95% CI 0.63 to 0.91, Analysis 1.6.4; RR 0.68; 95% CI 0.53 to 0.86; Analysis 1.6.6) (two hours - RR 0.76; 95% CI 0.59 to 0.98, Analysis 1.6.7; RR 0.72; 95% CI 0.52 to 0.98, Analysis 1.6.9). However, there was no significant difference between those labouring in water and those not labouring in water when pain was assessed using the VAS 1 to 10 ordinal scale at one or two hours after randomisation (one hour -RR 1.21; 95% CI 0.69 to 2.11, Analysis 1.6.5; two hours - RR 0.83; 95% CI 0.66 to 1.05, Analysis 1.6.8). There was no significant difference between groups at three hours after randomisation on any of the three ordinal scales (Analysis 1.6.10, 1.6.11, 1.6.12), Analysis 1.6.

<u>Use of non-pharmacological analgesia:</u> Two trials (Rush 1996; Woodward 2004) provided data on the use of transcutaneous nerve stimulation (TENS) and there was no significant difference in the use of TENS between groups (RR 1.05; 95% CI 0.37 to 2.94), Analysis 1.3.

Use of pharmacological analgesia (including regional and general anaesthesia) duration of any stage of labour: Six trials (Cammu 1994; Eckert 2001; Kuusela 1998; Ohlsson 2001; Rush 1996; Woodward 2004) provided data on epidural/spinal analgesia/ anaesthesia use and there was a significant reduction in the incidence of epidural/spinal/ paracervical analgesia/anaesthesia amongst women allocated to immersion in water during the first stage of labour compared to controls (478/1254 versus 529/1245; RR 0.90; 95% CI 0.82 to 0.99), Analysis 1.1. Of these trials, Rush 1996 and Woodward 2004 reported women were allocated to water immersion who did not use water. In Rush 1996, 183 (46%) of the water group did not immerse, but none of the control group immersed. Based on clinical experience, Woodward 2004 anticipated that up to 50% of women allocated to labour in water, would not do so, and this was planned into the recruitment strategy, where the water to control recruitment ratio was 2:1. There was no significant difference in narcotic/ pethidine use from the four trials that provide this data (RR 0.85; 95% CI 0.46 to 1.56) (Eckert 2001; Rush 1996; Taha 2000; Woodward 2004), Analysis 1.2. However, substantial heterogeneity was detected (heterogeneity:  $I^2 = 58\%$ ,  $T^2 = 0.20$ , Chi<sup>2</sup> test for heterogeneity P = 0.07) and so we used a random-effects meta-analysis. The inclusion of Chaichian 2009, who only documented 'any analgesia', also resulted in a non-significant difference for the overall analgesia outcome of 'any analgesia used' (RR 0.72; 95% CI 0.46 to 1.12), Analysis 1.4. However, considerable heterogeneity was again detected (heterogeneity:  $I^2 = 93\%$ ,  $T^2 =$ 0.19,  $\text{Chi}^2$  test for heterogeneity P < 0.00001) and so we used a random-effects metaanalysis.

There was no significant difference for any pharmacological analgesia used from two trials that provide this data (RR 1.05; 95% CI 0.80 to 1.39), Analysis 1.5 (Eckert 2001; Taha 2000).

Seven studies provide data on mode of birth (Cammu 1994; Eckert 2001; Kuusela 1998; Ohlsson 2001; Rush 1996; Taha 2000; Woodward 2004). These showed no significant difference for either the assisted delivery rate (water/land 156/1313 versus 181/1315, (RR

Mode of delivery (spontaneous birth, assisted vaginal births and caesarean sections):

difference for either the assisted delivery rate (water/land 156/1313 versus 181/1315, (RR 0.86; 95% CI 0.71 to 1.05)) or caesarean section (water/land 72/1358 versus 58/1354, (RR 1.21; 95% CI 0.87 to 1.68)). Chaichian 2009 only indicates the normal birth rate which was significantly higher in the water group (100% compared to 79.2%, (RR 1.26; 95% CI 1.09 to 1.45)), Analysis 1.7.

Duration of labour (first, second and third stage): Seven trials (Cammu 1994; Chaichian 2009; Eckert2001; Kuusela 1998; Rush 1996; Schorn 1993; Woodward 2004) provided data on duration of the first stages of labour. These showed a significant difference in favour of a shorter labour for the immersion group (MD -32.4 minutes; 95% CI -58.67 minutes to -6.13 minutes), Analysis 1.8. Seven trials (Cammu 1994; Da Silva 2006; Eckert 2001; Kuusela 1998; Rush 1996; Schorn 1993; Woodward 2004) reported on the duration of the second stage of labour; there was no statistical difference (MD 0.47 minutes; 95% CI -3.45 minutes to 4.38 minutes), Analysis 1.9. Three trials (Chaichian 2009; Eckert 2001; Rush 1996) reported on the duration of the third stage of labour; there was no statistical difference (MD -0.52 minutes; 95% CI -1.84 minutes to 0.79 minutes), and moderate heterogeneity was detected (heterogeneity:  $I^2 = 41\%$ ,  $T^2 = 0.54$ ,  $Chi^2$  test for heterogeneity P = 0.18), Analysis 1.10.

Pulse and blood pressure (first, second and third stage): One study (Taha 2000) reported the biophysiological effect of immersion in water on the effect of blood pressure changes: systolic (mean 120.3 mmHg versus 127.5 mmHg; MD −7.20; 95% CI −13.12 to −1.28), Analysis 1.23; diastolic (mean 62.8 mmHg versus 73 mmHg; MD −10.20; 95% CI −13.70 to −6.70), Analysis 1.24; and mean arterial pressure (mean 83.7 versus 94.2; MD −10.50, 95% CI −14.68 to −6.32), Analysis 1.25, were statistically significantly reduced in the immersion group.

Preference for care in subsequent labour: One study (Taha 2000) reported the number of women who would not wish to use immersion during labour with a subsequent labour and delivery and there were significantly fewer women in the immersion group who expressed this wish when compared to the control group (RR 0.38; 95% CI 0.14 to 0.98), Analysis 1.18.

#### **Fetal outcomes**

Abnormal heart rate pattern: Three trials (Eckert 2001; Schorn 1993; Taha 2000) provided data on abnormal fetal heart rate patterns and there was no significant difference amongst women allocated to immersion in water during the first stage of labour compared to controls (RR 0.75; 95% CI 0.34 to 1.67), Analysis 1.30, and substantial heterogeneity was detected (heterogeneity:  $I^2 = 57\%$ ,  $T^2 = 0.22$ ,  $Chi^2$  test for heterogeneity P = 0.13) and so we used a random-effects meta-analysis.

Meconium liquor: Five trials (Da Silva 2006; Eckert 2001; Kuusela 1998; Rush 1996; Woodward 2004) provided data on the presence of meconium-stained liquor and there was no significant difference amongst women allocated to immersion in water during the first stage of labour compared to controls (RR 0.95; 95% CI 0.76 to 1.19), Analysis 1.21.

Gestational age at birth/birthweight: There were no differences in gestational age at birth (MD –0.01; 95% CI –0.82 to 0.80), Analysis 1.40 or birthweight (MD –22.74; 95% CI –66.44 to 20.96) (Cammu 1994; Da Silva 2006; Eckert 2001; Kuusela 1998; Ohlsson 2001; Rush 1996; Schorn 1993; Taha 2000; Woodward 2004), Analysis 1.41.

**Neonatal outcomes**—The following neonatal outcomes were not reported in the trials: mortality; respiratory support (oxygen/ventilation required); lung hypoplasia; neurological pathology, e.g. seizures, cerebral palsy; snapped cord; birth injury; poor infant outcomes at long-term follow-up (as defined by trialists).

Apgar score less than seven at five minutes: Five trials reported when the Apgar score was less than seven at five minutes (Cammu 1994; Eckert 2001; Ohlsson 2001; Schorn 1993; Taha 2000), and there was no significant difference (10/907 versus 6/927; RR 1.58; 95%CI 0.63 to 3.93), Analysis 1.31. Another two studies provided the mean Apgar score at five minutes (Da Silva 2006; Rush 1996) and again there was no difference (MD –0.03 95%CI –0.11 to 0.06), Analysis 1.32.

Cord pH immediately after birth (arterial and or venous cord blood): One trial reported on umbilical artery pH less than 7.20 (Cammu 1994) and found no difference amongst women allocated to immersion in water during the first stage of labour compared to controls (RR 5.18; 95% CI 0.25 to 105.51), Analysis 1.33.

Admission to special care baby unit/neonatal intensive care unit: There was no significant difference in the three trials that reported admissions to the neonatal intensive

care unit (48/789 versus 45/782; RR 1.06; 95% CI 0.71 to 1.57) (Eckert 2001; Ohlsson 2001; Woodward 2004), Analysis 1.35.

Infection, including markers of infection such as pyrexia and raised white cell count: Infection rates were very low (6/647 versus 3/648) and reported in five trials (RR 2.00; 95% CI 0.50 to 7.94) (Cammu 1994; Eckert 2001; Kuusela 1998; Rush 1996; Schorn 1993), Analysis 1.36, although in three trials there were no infections in either group (Cammu 1994; Kuusela 1998; Schorn 1993), as might be hoped, as all three had small sample sizes. Chaichian 2009 indicates there were no statistically significant outcomes. One trial reported temperature greater than 37.8°C as an indicator of infection (Eckert 2001) and found no difference between groups (RR 1.00; 95% CI 0.06 to 15.83), Analysis 1.34

**Breastfeeding (at specified time points):** Two trials reported on the number of women not breastfeeding after six weeks post delivery (Eckert 2001; Taha 2000) and found no difference amongst women allocated to immersion in water during the first stage of labour compared to controls (RR 1.17; 95% CI 0.64 to 2.15), Analysis 1.29.

Caregiver outcomes: No trial describes any injuries or satisfaction outcomes for caregivers.

Other outcomes: No trial describes the costs associated with immersion in water in labour and birth.

Immersion versus no immersion in the second stage of labour: Three trials reported on this comparison. One trial evaluated immersion during the second stage of labour (Nikodem 1999) and two trials measured outcomes across the first and second stages (Chaichian 2009; Woodward 2004). We have entered data for these trials in both the first and second stage sections of this review where there are data to compare, although it should be noted that only 10 (25%) of the 40 women allocated to birth in water actually did so in Woodward 2004. All the women birthed in the water in the trial by Chaichian 2009 which is somewhat surprising.

**Maternal outcomes**—The following maternal outcomes were not reported in the trials: mortality; infection during labour/postnatal period; postpartum depression; post-traumatic stress disorder; augmentation of labour (artificial rupture of membranes and/or oxytoxic administration); use of non-pharmacological analgesia; use of pharmacological analgesia (including regional and general anaesthesia) duration of any stage of labour; pulse and blood pressure (first, second and third stage); maternal self-esteem; satisfaction with pain relief (as defined by trialists); sense of control in labour (as defined by trialists); effect (negative) on mother/baby interaction.

Blood loss during labour (first, second, third stage, and immediate postnatal period): One trial reported on the postpartum haemorrhage rate in each group (Nikodem 1999) and there was no difference between groups (RR 0.14; 95% CI 0.01 to 2.71), Analysis 2.7.

**Perineal trauma:** There were no significant differences in incidence of trauma to the perineum; episiotomy (12/100 versus 10/79, RR 0.75; 95% CI 0.35 to 1.60); and second-degree tears (21/100 versus 14/79, RR 1.21; 95% CI 0.65 to 2.24); and third- or fourth-degree tears (RR 1.54; 95% CI 0.07 to 36.11) (Nikodem 1999; Woodward 2004), Analysis 2.4.

<u>Pain intensity (first and second stage, as defined by trialists):</u> One trial reported on the proportion of women experiencing moderate to severe pain (Nikodem 1999), and found no difference between groups (RR 1.06; 95% CI 0.73 to 1.53), Analysis 2.1.

Mode of delivery (spontaneous birth, assisted vaginal births and caesarean sections): There were no significant differences in the mode of delivery; assisted vaginal birth (RR 0.73; 95%CI 0.21 to 2.54); caesarean section rate (RR 0.33; 95% CI 0.07 to 1.52) (Nikodem

1999; Woodward 2004), Analysis 2.6.

<u>Duration of labour (first, second and third stage)</u>: Three trials reported on the duration of the second stage of labour (Chaichian 2009; Nikodem 1999; Woodward 2004) and there was no statistical difference between groups (MD –1.24 minutes; 95% CI –8.05 minutes to 5.56 minutes), Analysis 2.5.

<u>Temperature (first and second stage):</u> One trial reported on maternal temperature (Woodward 2004) and found no difference between groups, (MD 0.20; 95% CI –0.18 to 0.58), Analysis 2.17.

Satisfaction with childbirth experience (as defined by trialists): Nikodem 1999 demonstrated a significantly higher level of satisfaction with the birth experience (RR 0.24; 95% CI 0.07 to 0.80), Analysis 2.2, with fewer women in the immersion group feeling that they did not cope satisfactorily with their pushing efforts (3/60 versus 12/57). However, another trial (Woodward 2004) which measured satisfaction with labour and birth on a scale of 0-6 where 0 is not at all satisfied, found that both groups were reasonably satisfied, but there were no significant differences between groups (MD 0.03; 95% CI –0.64 to 0.70), Analysis 2.16.

<u>Preference for care in subsequent labour:</u> One trial (Nikodem 1999) reported the number of women who would not wish to use immersion during labour with a subsequent labour and delivery and found there was no difference between groups (RR 0.57; 95% CI 0.18 to 1.55), Analysis 2.3.

**<u>Fetal outcomes:</u>** The following fetal outcomes were not reported in the trials: abnormal heart rate pattern; birthweight.

**Meconium liquor:** Two trials (Nikodem 1999; Woodward 2004) provided data on the presence of meconium-stained liquor and there was no significant difference amongst women allocated to immersion in water during labour compared to controls (RR 1.32; 95%CI 0.63 to 2.80), Analysis 2.8

<u>Gestational age at birth:</u> Two trials (Nikodem 1999; Woodward 2004) provided data on gestational age at birth in days and found no significant difference amongst women allocated to immersion in water during labour compared to controls (MD –1.00; 95% CI –5.13 to 3.13), Analysis 2.21.

**Neonatal outcomes**—The following neonatal outcomes were not reported in the trials: respiratory support (oxygen/ventilation required); lung hypoplasia; neurological pathology, e.g. seizures, cerebral palsy; snapped cord; birth injury; poor infant outcomes at long-term follow-up (as defined by trialists).

<u>Mortality:</u> One trial provided data on perinatal deaths (Nikodem 1999) and found no difference between groups (RR 3.00; 95% CI 0.12 to 72.20), Analysis 2.15.

<u>Apgar score less than seven at five minutes:</u> Two trials reported on Apgar score; neither Nikodem 1999 nor Woodward 2004 found any significant difference in the incidence of low Apgar score (RR 4.92; 95% CI 0.24 to 100.31, Analysis 2.9), (RR 1.54; 95% CI 0.07 to

36.11, Analysis 2.10), although each used slightly different parameters. Nikodem 1999 reported the number of women in each group with Apgar less than seven at five minutes and Woodward 2004 reported the number of women in each group with Apgar less than eight at five minutes.

Cord pH immediately after birth (arterial and or venous cord blood): Two trials reported on cord pH; neither Nikodem 1999 nor Woodward 2004 found any significant difference in umbilical artery pH (RR 0.89; 95% CI 0.45 to 1.75, Analysis 2.12) or cord pH immediately after birth (values not estimable) (Analysis 2.13), although each used slightly different parameters.

Admission to special care baby unit/neonatal intensive care unit: There was no significant difference in the two trials that reported admissions to the neonatal intensive care unit (RR 0.79; 95% CI 0.25 to 2.49) (Nikodem 1999; Woodward 2004), Analysis 2.14.

Infection, including markers of infection such as pyrexia and raised white cell count: Nikodem 1999 found no significant difference in the incidence of raised neonatal temperature at birth greater than 37.5° C (8/55 versus 3/54; RR 2.62; 95% CI 0.73 to 9.35), Analysis 2.11. Woodward 2004 found no significant difference in antibiotics given to neonates (RR 1.50; 95% CI 0.17 to 13.52), Analysis 2.19 or in positive neonatal swabs of ear, mouth or umbilicus (RR 1.89; 95% CI 0.90 to 3.96), Analysis 2.20.

<u>Breastfeeding (at specified time points):</u> Woodward 2004 found no significant difference in the number of women breastfeeding at birth between groups (RR 0.86; 95% CI 0.69 to 1.08), Analysis 2.18.

<u>Caregiver outcomes:</u> No trial describes any injuries or satisfaction outcomes for caregivers.

<u>Other outcomes:</u> No trial describes the costs associated with immersion in water in labour and birth.

**Early versus late immersion:** One trial compared early versus late immersion during the first stage of labour (Eriksson 1997).

**Maternal outcomes**—The following maternal outcomes were not reported in the trials: mortality; blood loss during labour (first, second, third stage, and immediate postnatal period); infection during labour/postnatal period; perineal trauma; postpartum depression; post-traumatic stress disorder; pain intensity (first and second stage, as defined by trialists); use of non-pharmacological analgesia; mode of delivery (spontaneous birth, assisted vaginal births and caesarean sections); duration of labour (first, second and third stage); temperature (first and second stage); pulse and blood pressure (first, second and third stage); satisfaction with childbirth experience (as defined by trialists); maternal self-esteem; preference for care in subsequent labour; satisfaction with pain relief (as defined by trialists); sense of control in labour (as defined by trialists); effect (negative) on mother/baby interaction.

<u>Augmentation of labour (artificial rupture of membranes and/or oxytocic</u> <u>administration):</u> Eriksson 1997 found an increased incidence of augmentation of labour in the early group (57/100 versus 30/100; RR 1.90; 95% CI 1.35 to 2.68), Analysis 5.2.

<u>Use of pharmacological analgesia (including regional and general anaesthesia)</u> <u>duration of any stage of labour:</u> Eriksson 1997 found significantly higher epidural

analgesia rates in the early group (42/100 versus 19/100; RR 2.21; 95% CI 1.39 to 3.52), Analysis 5.1.

**<u>Fetal outcomes:</u>** The following fetal outcomes were not reported in the trials: abnormal heart rate pattern; meconium liquor; gestational age at birth.

**<u>Birthweight:</u>** Eriksson 1997 found no significant difference in neonatal birthweight in grams between the early and late groups (MD –66.00; 95% CI –189.34 to 57.34), Analysis 5.8.

Neonatal outcomes: The following neonatal outcomes were not reported in the trials: mortality; Apgar score less than seven at five minutes; cord pH immediately after birth (arterial and or venous cord blood); admission to special care baby unit/neonatal intensive care unit; respiratory support (oxygen/ventilation required); lung hypoplasia; neurological pathology, e.g. seizures, cerebral palsy; snapped cord; birth injury; poor infant outcomes at long-term follow-up (as defined by trialists); wellbeing markers; breastfeeding (at specified time points).

<u>Infection, including markers of infection such as pyrexia and raised white cell count:</u> Eckert 2001 found no difference in neonatal infection rate between early and late groups, (RR 3.00; 95% CI 0.12 to 72.77), Analysis 5.6

<u>Caregiver outcomes:</u> No trial describes any injuries or satisfaction outcomes for caregivers.

<u>Other outcomes:</u> No trial describes the costs associated with immersion in water in labour and birth.

#### DISCUSSION

This review showed that immersion in water during labour significantly reduced the epidural/spinal analgesia rate based on data from six trials. There was also a significant reduction in the duration of the first stage of labour in the immersion group (seven trials, immersion versus no immersion). However, there was a high level of heterogeneity for some of these outcomes and so these results should therefore be examined with caution. The only other statistically significant results were for experience of moderate to severe pain; wish to use water for a subsequent labour, and a reduction in blood pressure, all of which were measured in one trial (Taha 2000), during the first stage of labour.

These results are consistent with observational studies. However, these conclusions need to be considered in the context of small sample sizes (range 33 to 1237); only two trials achieved a total sample size of greater than 300; blinding to the intervention is not possible; and many outcomes were only considered in one or two trials. These factors limit the interpretation of the results. An equivalence study is required to explore whether or not labour and/or birth in water is as safe as labour/birth without immersion in water, in a comparable group of women. It is recognised, however, that as use of water in labour and birth is now widely considered a matter of maternal choice, it is increasingly unlikely that conducting a large, multicentred, randomised controlled trial needed to gain the required evidence will be feasible or acceptable. Large audits and cohort studies should be undertaken in units which provide a pool facility to provide evidence for practice (Geissbuehler 2000; Zanetti-Daellenbach 2007).

The trials reported using different sized pools (only five trials provide information on bath/pool size: Cammu 1994; Da Silva 2006; Eckert 2001; Eriksson 1997; Kuusela 1998);

various durations in the water; and still or moving water, each of which had an impact on the outcomes. These factors limit the validity of the findings.

Rush 1996 and Woodward 2004 reported respectively that 46% (n = 183) and 40% (n = 16) of women allocated to water immersion did not actually use water, although in the case of Woodward 2004 this was expected and a recruitment ratio of 2:1 had been adopted. In both studies, analysis was by intention to treat, and they did not report outcomes by actual use. It is possible that subgroup analysis excluding women who did not use the water might have increased the difference between water users and non-users, in favour of less epidural analgesia for those who used water immersion. This would be consistent with the study by Chaichian 2009. This is pertinent, as the authors reported that the main reasons for non-use of the water included early request for epidural, identification of complication precluding water use, as well as non-availability of the pool and change of mind (numbers for each are provided by Woodward 2004 but not by Rush 1996).

Another confounding factor is that the gestational age at which water immersion is permissible varies across the trials, from greater than 34 weeks' gestation (Eriksson 1997) through 35 weeks (Ohlsson 2001) and 36 weeks (Schorn 1993; Taha 2000; Woodward 2004) to greater than 37 weeks (Cammu 1994; Chaichian 2009; Da Silva 2006; Eckert 2001; Kuusela 1998; Rush 1996). This is due to variations in the definition of 'preterm' adopted by different countries. However the baseline characteristics of participants in the included studies showed no difference (*see* Effects of interventions, Neonatal outcomes for immersion during the first stage of labour).

Although all the trials involved women defined as 'in labour', this was interpreted differently, from trials including all women with contractions, or about to have labour induced with a cervical dilatation of as little as 1 cm (Eckert 2001), to trials including only women in active labour with a cervical dilatation of greater than 6 cm (Da Silva 2006). This variability makes comparisons across trials problematic.

Another variation is that the length of the first stage of labour for women in the trial by Cammu 1994 was shorter (mean of 244 minutes) and less variable (small standard deviation of 139 minutes), compared to a first stage length of 846 minutes (standard deviation 432 minutes) in the trial by Schorn 1993. This suggests that the samples may have met different inclusion criteria or experienced a different management protocol during labour, although this was not explicit in the papers. The length of the second stage of labour for the women in the immersion group is much longer than might be expected in the trial by Schorn 1993, which involved nulliparae only, compared to Kuusela 1998 and Chaichian 2009 where the second stage duration was reported as 21 and 20 minutes respectively. This may again relate to different management strategies, in particular definition of the onset of the second stage and the use or not of directed pushing, but again this is not detailed within the papers.

Only one trial investigated early (before a cervical dilatation of 5 cm) versus late (after a cervical dilatation of 5 cm) immersion in water during the first stage of labour, which investigated a higher rate of augmentation and use of pharmacological analgesia in the early immersion group (Eriksson 1997). The main issue arising from this trial is whether or not women in the trial were actually in active labour, and therefore could reasonably be expected to progress spontaneously. Alternatively women may have been in the latent phase, which might have been augmented by mobilisation and other activity within a labour room, compared to relaxation and latent phase contractions ceasing in the water group. It is not possible to preclude that some women may have entered a birthing pool in the latent phase of labour, which could predispose them requiring augmentation. The trial did not consider this possibility.

Although all participants across the included trials were considered at low risk of complications, and trials were excluded where this was not so (Cluett 2001; Cluett 2004), Eckert 2001 reported the inclusion of women whose labour was induced. Rush 1996 indicated that 41 women who did not meet the inclusion criteria had been randomised. When these women were removed from the analysis the P value for epidural analgesia use changes to 0.044 from 0.069, whilst that for instrumental vaginal delivery changes to 0.011 from 0.055. Therefore, when ineligible women are excluded the results indicate that, for women at low risk of complications, labouring in water reduced the likelihood of epidural/narcotic use and of needing an instrumental vaginal delivery (Rush 1996). The definitions adopted for 'labour' were varied and may have influenced outcomes. In particular, Cammu 1994 required that the amniotic membranes were ruptured, although there is no indication as to whether this occurred spontaneously or artificially. In contrast the membranes were intact in all participants in the trial by Schorn 1993. Participants in other trials had a mixture of intact and ruptured membranes (Ohlsson 2001; Rush 1996; Taha 2000; Woodward 2004). These differences may affect pain perception, and hence influence analgesia uptake, maternal satisfaction, and possibly labour progress, which makes comparison across trials difficult. There is little or no information about the presence of one-to-one care or not in the trials evaluating first stage of labour outcomes, although Rush 1996 indicated that caregivers tended to be more continuously present with the water immersion participants. As one-toone care in labour is known to affect outcomes (Hodnett 2007), if this was not balanced across trial arms, this could account for any differences found.

The main conclusion of this review is that labouring in water significantly reduces the incidence of epidural/spinal. It is not possible to conclude whether the differences identified, in particular the reduction in epidural/spinal analgesia, are due to water alone, or the water/pool environment. Water immersion is a care package which includes the actual water and the associated environment, together with the interactions of the woman and her caregivers.

It may be that this last factor, linking midwives/caregivers who support the tranquil, no-obstetric-intervention, salutogenic philosophy espoused by labour and birth in water with like-minded women is the most important component. This would be consistent with the evidence on one-to-one care in labour (Hodnett 2007). It could be argued that, if water immersion facilitates the adoption of a woman-centred approach to care, facilitating normalisation of labour and birth, as many now seek (Maternity Care Working Party 2007; RCM 2008), then immersion in water should be promoted.

### **AUTHORS' CONCLUSIONS**

#### Implications for practice

Despite limitations in the validity and reliability of the randomised controlled trial evidence to date due to trial design, the statistically significant reduction in rate of epidural/spinal/paracervical analgesia indicates that water immersion during the first stage of labour reduces the need for this invasive, pharmacological pain mode of analgesia, which disturbs the physiology of labour and is associated with iatrogenic interventions. We found no evidence that this was associated with poorer outcomes for neonates, longer labours or more complex births. The other significant findings come from data from one study only and therefore have to be read with caution. Women can be advised that the use of water immersion in the first stage of labour may reduce the incidence of epidural/spinal/paracervical analgesia, and midwives and other birth attendants can suggest water immersion as part of labour pain management strategy.

There is insufficient evidence about the use of water immersion during second stage of labour and therefore clear implications cannot be stated.

Overall, the evidence indicates that immersion in water during the first stage decreases maternal uptake of epidural/spinal analgesia, and that water immersion during the first stage of labour can be supported for women at low risk of complications.

Immersion during the second stage of labour needs further investigation, but at present there is no clear evidence to support or not to support a woman's decision to give birth in water.

#### Implications for research

There is some evidence that immersion in water during the first stage of labour reduces the need for analgesia, but the limited reliability and validity of the studies means that this would benefit from further research, in particular from a study of an appropriate size to assess equivalence. There is a lack of clarity as to what constitutes water immersion, and further evaluation of the relative merits of different shaped/sized pools is required, and of still versus moving water, and the relative merits of water immersion during early labour (latent phase). There is insufficient information to support or not to support the use of immersion during the second stage of labour (birth), or the third stage. The safety regarding infection and neonatal outcomes are not addressed, and large collaborative trials are needed to answer these critical issues. It has been suggested that maternal satisfaction increases with water immersion, although there is a need for a large trial to evaluate this.

There are no data on caregiver outcomes and this warrants investigation.

#### PLAIN LANGUAGE SUMMARY

Immersion in water in labour and birth

This review includes 12 trials (3243 women). Water immersion during the first stage of labour significantly reduced epidural/spinal analgesia requirements, without adversely affecting labour duration, operative delivery rates, or neonatal wellbeing. One trial showed that immersion in water during the second stage of labour increased women's reported satisfaction with their birth experience. Further research is needed to assess the effect of immersion in water on neonatal and maternal morbidity. No trials could be located that assessed the immersion of women in water during the third stage of labour, or evaluating different types of pool/bath.

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SOURCES OF SUPPORT

#### Internal sources

- OCHRAD Oxford Brookes University, UK.
- School of Health Sciences, UK.

University Of Southampton

#### External sources

• National Institute for Health Research, UK.

UK NIHR Programme of centrally-managed pregnancy and childbirth systematic reviews of priority to the NHS and users of the NHS: 10/4001/02

## **Appendix**

## **CHARACTERISTICS OF STUDIES**

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

Cammu 1994

Methods	Randomisation by sealed opaque envelopes containing method indicator card Methodological qualities:		
	1 selection bias: low risk: adequate concealment at time of randomisation;		
		oias: high risk of bias could have been introduced because researcher d to group allocation after randomisation;	
	3 exclusion bias: moderate risk of bias: 57 were randomly allocated to bath, 3 refused to bathe and their results were not included in analyses		
	4 bias conclusio about the result	n: moderate bias: 1 or more criteria partially met. May raise some doublts	
Participants	Study group: n = 54. Control group: n = 56. Inclusion criteria: gestation > 36 weeks; low risk; nulliparous; singleton; cephalic presentation; active labour between 4-5 cm cervical dilatation; ruptured membranes with clear liquor on entry; scalp electrodes used for all participants; ambulation and analgesics were allowed.		
Interventions	The use of an oval-shaped hot tub during labour. Bath temperature not exceeding 37 degrees celsius. No chemicals added.  Control group: no water immersion during labour.  First stage of labour study, women in both groups received 'personalised' care but it is not clear if this is 1-to-1 care or not, although care overseen by obstetricians and all births conducted by house officers (doctors)		
Outcomes	Maternal outcomes:  *use of analgesia/anaesthesia;  *augmentation of labour; cervical dilatation;  *duration of labour and birth;  *mode of delivery;  *maternal infection. Fetal outcomes: abnormal FHR patterns needing intervention. Neonatal outcomes:  *neonatal condition;  *admittance to NICU or high dependency care unit;  *neonatal infection rates.		
Notes	Academic hospital, Brusse	els, Belgium.	
Risk of bias			
Bias	Authors' judgement	Support for judgement	
Random sequence generation (selection bias)	Unclear risk	No indication of how random sequence was generated.	
Allocation concealment (selection bias)	Low risk	Sealed opaque envelopes containing method indicator card.	



Blinding (performance bias and detection bias) All outcomes	High risk	High risk of bias could have been introduced because women, carers and researcher cannot be blind to group allocation after randomisation due to the nature of the intervention
Incomplete outcome data (attrition bias) All outcomes	Low risk	Information available on number of participants asked (water –57/control –56) to number who gave consent (water –53/control –56) to outcome data - no attrition
Selective reporting (reporting bias)	Low risk	All outcome detailed in methods are reported on.
Other bias	Unclear risk	All women had 1-to-1 care, which is known to affect outcomes, but is common for water immersion care

## Chaichian 2009

Methods	Randomised control trial; no information on how randomisation was achieved women laboured and delivered in water, or not.		
Participants	Water group - n = 53; control group - n = 53. Gestational age 37-42 weeks. No previous CS. Intact membranes. No malpresentations. No placenta abruption or praevia. Well fetus.		
Interventions	Information given to women in pregnancy, then randomised to experimental or control group in labour. Water group labour and birth in warm water pool, but no description of pool size or care protocol given. Control group conventional care at the hospital, but not detailed		
Outcomes	Data provided on baseline characteristics or age, gravida, parity, previous abortion, and prolonged rupture of membranes  Data provided on outcomes, *normal birth rate, *duration of labour, *use of oxytocin and *analgesia (not stated what type)  Data collected on *episiotomy/perineal trauma, *neonatal weight, *Apgar score, gender and breastfeeding initiation but data not given		
Notes	Study undertaken in Iranian hospital affiliated to Iran University of Medical Sciences, between June 2006 and September 2007 Authors contacted twice for further information but no reply		
Risk of bias			
Bias	Authors' judgement	Support for judgement	
Random sequence generation (selection bias)	Unclear risk	No information given on randomisation processes.	
Allocation concealment (selection bias)	Unclear risk	No information given on randomisation processes.	
Blinding (performance bias and detection bias) All outcomes	High risk	High risk of bias could have been introduced because women, carers and researcher cannot be blind to group allocation after randomisation due to the nature of the intervention	
Incomplete outcome data (attrition bias) All outcomes	Low risk	No indication that women withdrew from study, or that data was lost/incomplete	
Selective reporting (reporting bias)	High risk	Outcomes not detailed on perineal trauma, neonatal weight, Apgars, gender and breastfeeding initiation although data collected and described as not significantly different	

	It is surprising that all the women that went to water gave birth in the water. Normally one would expect some who laboured in water to choose to get out for birth, but no evidence of this as number in each group is the same. This calls into question if all who got into the pool are included in study or just those who remained in for birth as well
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## Da Silva 2006

Methods	Randomisation was computer generated, and then recorded on a list (paper copy), where the next allocation was concealed from the research until the next woman had provided consent, was recruited and thus being allocated.  Methodological qualities:			
	1 selection b	ias: none apparent;		
	2 performance bias: high risk of bias could have been introduced because researcher cannot be blind to group allocation after randomisation;			
	3 exclusion bias: low risk of bias 4 of 58 in water group did not get water as required CS prior to immersion, and 2 of 56 in control group also required CS prior to reaching cervical dilation of 6cm. Analysed according to intention to treat;			
		usion: high risk of bias, where 1 or more criteria are not met may cause bias that seriously weakens confidence in the results		
Participants	Power calculation undertaken.  Water n = 58.  Control n = 56.  Full term, nulliparous, live, cephalic presentation, no complications, cervical dilation of 6 cm or less in established labour			
Interventions	Control group received standard care, including cardiotocography on admission, ambulation, amniotomy and oxytocin augmentation if now cervical progress over 3 hours, intermittent auscultation during labour  Intervention group as above with immersion in water when cervix had reached 6-7 cm dilated, for 60 minutes  First stage of labour study, all women received 1-to-1 care from the researcher Pool was 194 litres, equipped with a heater. Water temperature ranged from 27 to 38 degrees Celsius			
Outcomes	Pain score on 5-point behavioural scale and numerical pain score from 0 to 10, at 6-7 cm dilated and again 1 hour later  In addition the following data were collected: use of augmentation, amniotic liquor conditions, duration of labour, perineal condition, gestational age, Apgar score at 1 and 5 minutes, maternal and water temperature			
Notes	Study done in Sao Pau	lo, Brazil.		
Risk of bias				
Bias	Authors' judgement	Support for judgement		
Random sequence generation (selection bias)	Low risk	Computer generated random list.		
Allocation concealment (selection bias)	High risk	Each allocation on the list was covered with a tab, which was removed by the researcher after consent form signed by next participant. This description suggests the process could be ope to tampering		
Blinding (performance bias and detection bias) All outcomes	High risk	High risk of bias could have been introduced because women, carers and researcher cannot be blind to group allocation after randomisation due to the nature of the intervention		
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow chart detailed participants from eligibility to completion no attrition after instigation of allocated care		



Selective reporting (reporting bias)	Low risk	All the data mentioned in the methods, and that would reasonably be expected of this study are reported
Other bias	Unclear risk	All women had 1-to-1 care, which is known to affect outcomes, but is common for water immersion care. In this study the care was from the researcher, regardless of group
-		

## Eckert 2001

Bias	Authors' judgement Support for judgement		
Risk of bias			
Notes	Tertiary referral hospital in Adelaide, Australia. May 1995 - Sept 1998. Some of the results are not in an appropriate format. Further information needed		
Outcomes	Maternal outcomes:  *maternal experience and satisfaction of labour;  *use of analgesia/anaesthesia;  *augmentation of labour;  *presence of meconium-stained liquor;  *duration of labour and birth;  *mode of delivery;  *trauma to the birth canal requiring suturing;  *blood loss;  *postpartum depression;  breastfeeding.  Fetal outcomes:  *abnormal FHR patterns, needing intervention.  Neonatal outcomes:  *neonatal condition;  *admittance to NICU or high dependency care unit;  *temperature at birth;  *neonatal infection rates.		
Interventions	Women were allocated to a delivery suite with a bath or to a general delivery suite without a bath. The bath group was allowed to use the bath as long as each woman wished, but they had to get out during second stage of labour (first stage only). The bath tub was 120 cm × 160 cm × 54 cm and the maximum water temperature was 37 degrees Celsius. Control group was allowed to use a shower. First stage only study women received care from same midwives but no mention of 1-to-1 second care or not		
Participants	Study group n = 137. Control group n = 137.  Inclusion criteria: gestation > 36 weeks; low risk; singleton; cephalic presentation.  Exclusion criteria: planned CS; history of Group B streptococcal infection; epidural anaesthesia; continuous FHR monitoring needed		
	<ul> <li>bias conclusion: high risk of bias, where 1 or more criteria are not met may cause plausible bias that seriously weakens confidence in the results</li> </ul>		
	3 exclusion bias: high risk of bias 37/134 of women allocated to bath group did not bathe and 34/134 of women allocated to the control group did bathe. Analysed according to intention to treat:		
	2 performance bias: high risk of bias could have been introduced because researcher cannot be blind to group allocation after randomisation;		
	1 selection bias: none;		
	Randomisation by sealed opaque, sequentially numbered envelopes that were kept in the admission ward. Prepared in random blocks of 10, stratified for parity.  Methodological qualities:		

Random sequence generation (selection bias)	Low risk	Random table of numbers, using variable blocks of 10, by a clerk independent of the study. Stratification was by place of birth, hospital or midwifery birth centre	
Allocation concealment (selection bias)	Low risk	On recruitment midwife telephoned an independent clerk for allocation	
Blinding (performance bias and detection bias) All outcomes	High risk	High risk of bias could have been introduced because women, carers and researcher cannot be blind to group allocation after randomisation due to the nature of the intervention. Study says where appropriate the data analyst was blinded to group; however bias is likely to be at point of care	
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data analysed on intention-to-treat basis. Flow chart reports on participants from eligibility to completion. From randomisation similar numbers (water 58 (42%)/control 53 (39%)) became ineligible or did not use the allocated care option as might be expected in a study of this size which respected women's right to choice care options; however, this is a high percentage	
Selective reporting (reporting bias)	Low risk	All the data mentioned in the methods and that would reasonably be expected of this study are reported	
Other bias	Unclear risk	No mention of 1-to-1 care or not, but no other issue apparent	

## Eriksson 1997

Methods	Randomisation by sealed opaque, sequentially numbered envelopes containing the code. Methodological qualities:		
	1 selection bias: none;		
	2 performance bias: high risk of bias could have been introduced because researcher cannot be blind to group allocation after randomisation;		
	3 exclusion bias: low risk of bias as only 8/200 did not enter bath. Analysed according to intention to treat;		
	4 bias conclusion: moderate bias. 1 or more criteria partially met. May raise some doubt about the results		
Participants	Group 1: n = 100: the "early bath group". Group 2: n = 100: the "late bath group".  Regional referral hospital in the west of Sweden.  Inclusion criteria: gestation > 34 weeks; low risk; singleton; cephalic presentation; spontaneous labour; contractions 3/10 minutes and/or ruptured membranes with cervical dilatation less than 3 cm.  Normal FHR pattern. Ambulation and analgesics were allowed.		
Interventions	All women used an oval tub that was 1.5 m long and 40 cm deep. It contained 300 L of waters at a temperature not more than 38 degrees Celsius. Group 1: the "early bath group" had a cervical dilatation of less than 5 cm when immersed in water. Group 2: the "late bath group" had a cervical dilation of 5 cm or more when immersed in water No mention of 1-to-1 care or not.		
Outcomes	Maternal outcomes:  *use of analgesia/anaesthesia;  *augmentation of labour; duration of labour in the state of the state		

\*neonatal infection rates (studies that describe additional outcomes that may be of importance will be mentioned in the text);
parity;
maternal age;
birthweight;
Bishop score before randomisation.

Duration of labour not in acceptable format. Early group 9.80 hours and late group 8.
48 hours P < 0.004.
Primipara: 72/100 in early group and 60/100 in late group.
Maternal mean age: 26.3 early group; 27.2 late group.
Mean birthweight: 3550 g early group; 3616 g late group.
Performance bias: caregivers were not blind to group allocation. Not recorded if results were analysed blind.
Exclusion bias: \*women did not enter bath - groups not mentioned.
Thus moderate rate of bias may be present.

#### Risk of bias

Notes

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated.
Allocation concealment (selection bias)	Low risk	Sealed opaque envelopes containing allocation.
Blinding (performance bias and detection bias) All outcomes	High risk	High risk of bias could have been introduced because women, carers and researcher cannot be blind to group allocation after randomisation due to the nature of the intervention
Incomplete outcome data (attrition bias) All outcomes	Low risk	1 woman in early bath group did not use water, compared to 7 in late bath group; however, this might be expected as a result of different degrees of progression in labour
Selective reporting (reporting bias)	Low risk	All outcomes identified in methods are reported.
Other bias	Unclear risk	Percentage of primigravida higher in early group, but likely to be due to chance No mention of 1-to-1 care or not.

#### Kuusela 1998

Methods	Randomisation stated but only described as 'by lots'.  Methodological qualities:		
	1 selection bias: no information.		
	2 performance bias: high risk of bias could have been introduced because researcher cannot be blind to group allocation after randomisation.		
	3 exclusion bias: low risk of bias as no drop-outs reported.		
	4 bias conclusion: moderate bias. 1 or more criteria partially met. May raise some doubt about the results		
Participants	33 women, 18 water, 15 control. In labour (cervix 4 cm dilated). Low risk - term, 1 fetus, no complications in current or any previous pregnancy/birth		
Interventions	Intervention was use of bath for max of 60 minutes.  Bath was thermally insulted, oval, size 150 cm by 110 cm, by 70 cm deep. Volume was 730 litres Water temperature 37 degree Celsius.  No pharmacological analgesia available to either control or intervention group during study hour		

	After use of bath labou No mention of 1-to-1 s First stage only study.	r care as normal and could access 'usual' pain relief methods, positions econd care or not.
Outcomes	Duration of first and second stage of labour.  Pain relief used, pain score before and after study period (1 hour), own assessment in postnatal questionnaire on day 2 postpartum  Blood loss, perineal trauma, Apgars.  Maternal pulse, temperature, blood pressure.	
Notes	Undertaken in Finland - 1 hospital.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Randomised 'by lots' in translation.
Allocation concealment (selection bias)	High risk	Described as randomised but translation does not indicate how concealed
Blinding (performance bias and detection bias) All outcomes	High risk	High risk of bias could have been introduced because women, carers and researcher cannot be blind to group allocation after randomisation due to the nature of the intervention
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not reported.
Selective reporting (reporting bias)	Unclear risk	Unable to assess this from translation.
Other bias	Unclear risk	Full translation not available, just extracts as requested on Cochrane Pregnancy and Childbirth Group translation sheet

## Nikodem 1999

Methods	Randomisation by sealed opaque, sequentially numbered envelopes containing the code. Prepared in random blocks of 10, stratified for parity. Methodological qualities:		
	1 selection bias: none;		
	2 performance bias: high risk of bias could have been introduced because researcher cannot be blind to group allocation after randomisation		
	3 exclusion bias: low risk of bias as all women received their allocated treatment. Analysed according to intention to treat. 1 lost to follow-up;		
	4 bias conclusion: moderate bias. 1 or more criteria partially met. May raise some doubt about the results. Women were randomised at full dilatation of bearing down efforts		
Participants	Study group: n = 60. Control group: n = 60. Academic teaching hospital, Johannesburg, South Africa. Inclusion criteria: gestation > 36 weeks; low risk; singleton; cephalic presentation; active phase of labour; normal FHR pattern; ambulation and analgesics were allowed; able to read and understand English. No immersion of water was used during the first stage of labour		

Interventions	Study group: allocated to oval bath tub which contained about 220 L of water. Temperature 34-38 degrees Celsius. Women were allowed to use different postures in the bath. Control group: care the same as study group but they were not allowed to use a bath for birth. All care was the same. Consent obtained early in labour but randomisation took place at full second stage.  Same main caregivers for all women.		
Outcomes	*pain; *use of analgesia/anaes *augmentation of labou *blood pressure; *pulse; *duration of labour and *mode of delivery; *trauma to the birth cat *blood loss; maternal infection; *postpartum depression Fetal outcomes: *abnormal FHR pattern Neonatal outcomes: *neonatal condition;	th birth; nal requiring suturing; n. ns needing intervention. or high dependency care unit;	
Notes	Done in South Africa.	1999.	
Risk of bias			
Bias	Authors' judgement	Support for judgement	
Random sequence generation (selection bias)	High risk	Not stated only says prepared in random blocks of 10, stratified for parity. Blocks of 10 have potential for breaking concealment for at least participant in each block	
Allocation concealment (selection bias)	Low risk	Sealed opaque, sequentially numbered envelopes containing the code	
Blinding (performance bias and detection bias) All outcomes	High risk	High risk of bias could have been introduced because women, carers and researcher cannot be blind to group allocation after randomisation due to the nature of the intervention	
Incomplete outcome data (attrition bias) All outcomes	Low risk	Information from approach to women (133) to allocation (60+60); all women completed trial but 3 in control group to not complete follow-up questionnaire	
Selective reporting (reporting bias)	Low risk	All outcomes identified in methods are reported. Thesis made available with very detailed reporting	
Other bias	Unclear risk	All women regardless of group had 1-to-1 care from researcher	

### Ohlsson 2001

Methods Randomised when regular contractions and eligible.

Sealed opaque envelopes. Methodological qualities:

selection bias: low risk; adequate concealment at time of randomisation;

2 performance bias: high risk of bias; could have been introduced because researcher cannot be blind to group allocation after randomisation;

- 3 exclusion bias: moderate risk of bias; 46 were excluded and 11.1% (KH) and 4.4% (LH) did not use tub:
- 4 bias conclusion: moderate bias; 1 or more criteria partially met. May raise some doubt about the results

Participants	Inclusion criteria: gestation > 35 weeks; previous CS included ( twins included; active labour > 3 cm or ruptured membranes o Ambulation, analgesic	53; total = 612. = 376; OH: n = 97; LH: n =152; total = 625. (VBAC); ervical dilatation;
Interventions	on water temperature of Control group: shower	
Outcomes	Additional outcomes:	
Notes	3 obstetric units in Sw	eden - 1992-1995.
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not indicated.
Allocation concealment (selection bias)	Low risk	Sealed opaque envelopes.
Blinding (performance bias and detection bias) All outcomes	High risk	High risk of bias could have been introduced because women, carers and researcher cannot be blind to group allocation after randomisation due to the nature of the intervention
Incomplete outcome data (attrition bias) All outcomes	Low risk	From a total of 1279 women, 42 were excluded across both groups and all centres for obstetric reasons
Selective reporting (reporting bias)	Low risk	All outcomes mentioned in methods are reported, although detailed results only given for main outcomes, others just stated as not significant in the text
Other bias	Low risk	Study was started in 1 unit then after 2 years 2 further obstetric units were involved to achieve the required sample size. Nil else noted

Rush 1996

Methods	Randomisation by consecutively numbered, computer generated random allocation in sealed opaque envelopes.  Methodological qualities:			
	1 selection bias: low ris	sk; adequate concealment at time of randomisation;		
		gh risk of bias could have been introduced because researcher bup allocation after randomisation;		
	3 exclusion bias: high r	risk of bias;		
		risk of bias. Where 1 or more criteria are not met may cause riously weakens confidence in the results		
Participants	Nearly half (46%) of the women	atation; o eligible. sthesia were allowed. were withdrawn 8 from study group and 7 from control group. in the study group did NOT use the bath but were still considered tent to treat. 41 of the women did not meet eligibility criteria but ere analysed.		
Interventions	Study group: n = 393. The use of a Parker whirlpool hot tub with jets during labour. Bath temperature between 38-39 degrees celsius. Mean total time in tub was 54 minutes. No births in tub Control group: n = 392. No water immersion during labour. Refer to care being provided by assigned nurse, and all had be trained to care for women using immersion, but not clear if this is 1-to-1 second care First stage only.			
Outcomes	Maternal outcomes: *use of analgesia/anaesthesia; *augmentation of labour; *presence of meconium-stained lead that it is a compared to the com	iquor;		
Notes	Data table 1 incorrect. No respon	se from authors.		
Risk of bias				
Bias	Authors' judgement	Support for judgement		
Random sequence generation (selection bias)	Low risk	Computer generated.		
Allocation concealment (selection bias)	Low risk	Consecutively numbered sealed opaque envelopes.		
Blinding (performance bias and detection bias) All outcomes	High risk	High risk of bias could have been introduced because women, carers and researcher cannot be blind to group allocation after randomisation due to the nature of the intervention		
Incomplete outcome data	Low risk	All participants are accounted for, and 15 withdraws were detailed, as were 41 who did not meet criteria		



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expected as women had choice, and sample size was planned for this

## Schorn 1993

Cluett and Burns

Methods	Randomisation by packets containing random computer-generated codes.  Methodological qualities:		
	1 selection bias: high risk - the researcher knew group allocation before obtaining informed consent;		
	2 performance bias: high risk of bias could have been introduced because researcher cannot be blind to group allocation after randomisation;		
	3 exclusion bias: low risk of bias - no exclusions. Main outcome not stated. Determine safety and effect of water immersion on women in labour. Most women stayed in the tub for 30-45 minutes.		
	4 Bias conclusion: moderate bias. 1 or more criteria partially met. May raise some dout about the results		
Participants	Study group: n = 45.  Control group: n = 48. Inclusion criteria: gestation between 36-41 weeks; no major obstetric or medical complication; active labour between 4-7 cm cervical dilatation; intact membranes on entry; normal FHR patterns; ambulation and analgesics were allowed.		
Interventions	Study group: The use of a hot tub with air jets and with a moulded seat during labour. Bath temperature between 32-41 degrees Celsius. Control group: no water immersion during labour. Showers were allowed First stage of labour.		
Outcomes	Maternal age; gestational age; ethnicity; parity; water temperature; duration in bath; *use of analgesia; *augmentation; cervical dilatation; *duration of first stage of labour; *duration of second stage of labour; duration of admission to delivery; duration of ruptured membranes; blood pressure; pulse; maternal temperature; *method of delivery; *FHR patterns; Apgar score at 1 minute; *Apgar score at 5 minutes; neonatal weight; *postnatal maternal infections; re-admissions to hospital.		
Notes	Academic hospital, Houston, Texas, USA. December 1990 to December 1991		
Risk of bias			
Bias	Authors' judgement Support for judgement		

Random sequence generation (selection bias)	Low risk	Computer-generated code.
Allocation concealment (selection bias)	High risk	Midwife know the allocation at the time of recruitment, and risk of bias acknowledged but women apparently would not be recruited if they did not know which allocation they had
Blinding (performance bias and detection bias) All outcomes	High risk	High risk of bias could have been introduced because women, carers and researcher cannot be blind to group allocation after randomisation due to the nature of the intervention
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants are accounted for throughout study with no withdrawals
Selective reporting (reporting bias)	Low risk	All outcomes mentioned in method are reported, and seem appropriate for the study and topic
Other bias	Unclear risk	There were significantly more primigravid women in water group, which could affect outcomes, and is a confounding variable

#### Taha 2000

Methods	Randon	nisation	into	sequential	lly	numbered	sealed	opaque envelopes	containing the code.

Prepared in variable random blocks stratified for parity.

Randomised when in active birth labour and met inclusion and exclusion criteria.

Methodological qualities:

1 selection bias: none;

- performance bias: high risk of bias could have been introduced because researcher 2 cannot be blind to group allocation after randomisation;
- exclusion bias: low risk of bias all women received their allocated treatment. Analysed 3 according to intention to treat. 1 lost to follow-up;
- bias conclusion: moderate bias. 1 or more criteria partially met. May raise some doubt about the results

#### Participants Study group: n = 59. Control group: n = 61. Inclusion criteria: in active labour;

primiparous women with cervical dilatation of 4-7 cm;

multiparous women with cervical dilatation of 4-6 cm;

low-risk women;

read/understand English.

Exclusion criteria: poor obstetric history;

previous CS; medical disorders; pre-eclampsia; multiple pregnancy;

First stage study.

intrauterine growth impairment;

< 36 weeks and > 42 weeks;

pyrexia;

meconium-stained liquor;

prolonged ruptured of membranes.

Interventions Study group: labour in water; water temperature 34-38 degrees Celsius; analgesia as required; exit for second stage; not out of the water for more than 30 minutes.

Control group: encouraged ambulation; if lie down use side analgesia as required. Same midwife for all women (so 1-to-1 second stage care assumed) also same observer/assessor of pain for all

Outcomes Outcomes reported:

maternal outcomes;

\*pain;

\*use of analgesia/anaesthesia;

\*augmentation of labour;

\*blood pressure;

\*pulse;

\*duration of labour and birth;

\*mode of delivery;

\*trauma to the birth canal requiring suturing;

\*blood loss;

\*postpartum depression;

\*breastfeeding;

fetal outcomes

\*abnormal FHR patterns needing intervention.

Additional outcomes:

studies which describe additional outcomes that may be of importance will bementioned in the

text:

gestational age; maternal age;

gravida;

parity;

cervical dilatation;

duration in tub; meconium-stained liquor.

Academic hospital, South Africa. Notes Risk of bias Bias Authors' judgement Support for judgement Random Unclear risk Random list compiled in different block size of 6 and 8 but not clear how this was sequence generation achieved or by whom (selection bias) Allocation Low risk Sequentially numbered sealed opaque envelopes containing the allocation concealment (selection bias) Blinding High risk High risk of bias could have been introduced because women, carers and (performance researcher cannot be blind to group allocation after randomisation due to bias and the nature of the intervention detection bias) All outcomes Incomplete Low risk All participants are accounted for throughout study with no withdrawals outcome data (attrition bias) All outcomes All outcomes mentioned in method are reports, and seem appropriate for Low risk Selective reporting the study and topic (reporting bias)

#### Woodward 2004

Unclear risk

Other bias

#### Methods

Randomisation schedule provided by National Perinatal Epidemiology Unit, Oxford. A person unconnected to study prepared by consecutively numbered, computer-generated random allocation in sealed opaque envelopes.

Methodological qualities:

Researcher recruited and cared for all women and provided 1-to-1 care

- 1 selection bias: low risk; adequate concealment at time of randomisation;
- 2 performance bias: high risk of bias could have been introduced because researcher cannot be blind to group allocation after randomisation;
- 3 exclusion bias: moderate risk as, although expected and 2:1 randomisation undertaken, 16 of 40 women in water arm and 2 of 20 in control arm did not receive their allocated treatment. Analysed according to intention to treat. 1 woman withdrew;

4 bias conclusion: moderate risk of bias. Where 1 or more criteria are not met may cause plausible bias that seriously weakens confidence in the results

Participants	2 groups in RCT part of study. Water $n=40$ . Land $n=20$ (2:1 ratio as about local experience was 50% of women choose not to use water) Women recruited through community midwife, posters in clinics, and media promotions and interested women contacted researcher or gave permission to own midwife to pass on information Aged 18-50. Low risk.
Interventions	Women could use pool in first and second stages of labour - results do not distinguish which of the women allocated to pool, did not use pool (16 of 40 women), used pool for first stage only (13 of 40 women), used pool in second stage but not for birth (1 woman), or gave birth in the pool (10 women) (no subgroup analysis)  Data entered into both 'immersion in water versus no immersion during first stage of labour' AND 'immersion in water versus no immersion during second stage of labour' DATA and ANALYSIS section  Waterbirth pool - dimensions/volume not described, temperature described as recorded but data not provided  No mention of 1-to-1 second care or not.
Outcomes	Intention-to-treat analysis done.  Maternal: age, social history, pulse, temperature, maternal satisfaction on scale of 0-6 immediately post birth and in 6 week postal questionnaire  Labour: length of first, second stages; analgesia used; augmentation; mode of birth  Fetus/neonate: cord arterial and venous gases, Apgar score at 1, 5 and 10 mins, time to first respiration, rectal temperature at birth, ear swabs, method of feeding, date and time of first feed, admission to neonatal unit (plus any interventions needed) infection, any mortality/morbidity  Water; duration in water, water temperature, microbiological analysis at end of labour/use
Notes	Non-randomised, preference arm data not included although additional 20 participants in this part of study 16 (40%) of water women did not use water. UK study.

Rick	of bias	
nun	oj vius	

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated independent of study.
Allocation concealment (selection bias)	Low risk	Consecutively numbered in sealed opaque envelopes.
Blinding (performance bias and detection bias) All outcomes	High risk	High risk of bias could have been introduced because women, carers and researcher cannot be blind to group allocation after randomisation due to the nature of the intervention
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants are accounted for throughout study with no withdrawals
Selective reporting (reporting bias)	Low risk	All outcomes mentioned in method are reported, and seem appropriate for the study and topic
Other bias	Unclear risk	40% or water group did not use water, which is consistent with choice and other papers on this topic

prespecified outcomes

CS: caesarean section

FHR: fetal heart rate KH: Karlskrona Hospital LH: Lund hospital

NICU: neonatal intensive care unit

OH: Osterund Hospital
OP: occipito posterior

VBAC: vaginal birth after caesarean section

# Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Bastide 1990	Unpublished data from 1990 available only. Inadequate data for assessment at this time. We contacted the author for further information, but nothing was provided
Benfield 2001	Only 18 women, 9 in each group. Randomsied by drawing slips of paper from a total of 52 paper slips in a bag which is inadequate allocation concealment. Women were in a limited depth of water; were asked to adopt a semi recumbent positions on a partially inflated air raft with attached head pillow (authors description) for 1 hour, and had cannulation to facilitate repeat blood samples. All of which limits mobility and is not consistent with water immersion in normal labour
Calvert 2000	Results of this pilot study (22 women) are not given in a format that can be used in the review. The aim was to compare the effect of the essential oil of ginger compared to essential oil of lemon grass on the progress of labour. The pilot study showed no differences on frequency of contractions, cervical dilatation or duration of first stage of labour between the 2 groups
Cluett 2001	Feasibility study: only 4 women in each of the 3 trial arms. Women had all been diagnosed as having dystocia in the first stage of labour (less than 1 cm/hr progress after established labour)
Cluett 2004	Women had all been diagnosed as having dystocia in the first stage of labour (less than 1 cm/hr progress after established labour) and the comparison group was women receiving augmentation of labour
Labrecque 1999	The method does not meet the inclusion criteria for this review. It is impossible to disentangle the effects of immersion in water. The aim of the trial was to compare 3 non-pharmacological approaches to relieve back pain. A total of 34 women were randomly allocated to receive 1 of 3 treatments: (1) intracutaneous sterile water injections, (2) transcutaneous electrical nerve stimulation and (3) standard care that included back massage, whirlpool bath and liberal mobilisation. The sample size is small and results should be interpreted within the setting only. Women in the ISW group experienced a decrease in the intensity and unpleasantness of their backache, but they would not like to use this method in a future labour

ISW: intracutaneous sterile water injection

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

Malarewicz 2005

Methods	Not clear; paper refer to 'the analysis of 205 deliveries including 100 in control group' however, this could have been subgroups within a cohort. There is no reference to any randomisation
Participants	Primiparous women, full-term uncomplicated pregnancy, in first stage of labour with a cervical dilation of between 2-6 cm, with fetus in a longitudinal lie, vertex presentation, and presented part engaged
Interventions	Women in the first stage of labour were immersed in a whirlpool bath for duration of no more than 40 minutes
Outcomes	Cervical dilation prior to immersion and at end of immersion period. Duration of first stage of labour. Uterine activity before and after intervention
Notes	Abstract in English with limited translation of other parts of paper; however, we were not able to determine with any certainty that this study is a RCT. We have contacted the main author for clarification

Torkamani 2010

Methods	Clinical trial of women equally divided into 2 groups of 50 of delivery in water and normal delivery. It is not clear from this if there was any randomisation. The fact that all 50 women in the intervention (water) group all achieved a water birth suggests they were a cohort of women who consecutively achieved a water birth rather than a randomised group allocated to water immersion. Clarification has been sought from the main author					
Participants	100 gravida 1 and to women; aged 16-28 years; gestational age of 38-42 weeks					
Interventions	Immersion in water during the active phase of delivery (not clear if this is first or second stage)					
Outcomes	Outcomes Amount of analgesia, pain score, oxytocin use, duration of labour fist and second stage, Apgar score, admission to neonatal unit, satisfaction with mode of delivery					
Notes	We have sought clarification from the main author on whether or not randomisation was used; if so, what measure were taken to conceal the allocation; and for clarity on the nature of the intervention					

RCT: randomised controlled trial

# **DATA AND ANALYSES**

## Comparison 1

Immersion in water versus no immersion during first stage of labour

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Use of epidural/spinal analgesia/paracervical block	6	2499	Risk Ratio (M-H, Fixed, 95% CI)	0.90 [0.82, 0.99]
2 Pethidine/narcotic used	4	1240	Risk Ratio (M-H, Random, 95% CI)	0.85 [0.46, 1.56]
3 Use of transcutaneous nerve stimulation (TENS)	2	845	Risk Ratio (M-H, Fixed, 95% CI)	1.05 [0.37, 2.94]
4 Use of any analgesia	5	653	Risk Ratio (M-H, Random, 95% CI)	0.72 [0.46, 1.12]
5 Any pharmacological analgesia	2	394	Risk Ratio (M-H, Fixed, 95% CI)	1.05 [0.80, 1.39]
6 Experience of moderate to severe pain	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
6.1 Ordinal description as moderate to severe, 30 mins after randomisation	1	120	Risk Ratio (M-H, Fixed, 95% CI)	0.75 [0.62, 0.91]
6.2 VAS scale 8 to 10, 30 mins after randomisation	1	120	Risk Ratio (M-H, Fixed, 95% CI)	0.72 [0.58, 0.90]
6.3 Ordinal scale pain faces 4 to 5, 30 mins after randomisation	1	120	Risk Ratio (M-H, Fixed, 95% CI)	0.67 [0.51, 0.90]
6.4 Ordinal description as moderate to severe, 1 hr after randomisation	1	117	Risk Ratio (M-H, Fixed, 95% CI)	0.76 [0.63, 0.91]
6.5 VAS scale 8 to 10, 1 hr after randomisation	1	117	Risk Ratio (M-H, Fixed, 95% CI)	1.21 [0.69, 2.11]
6.6 Ordinal scale pain faces 4 to 5, 1 hr after randomisation	1	117	Risk Ratio (M-H, Fixed, 95% CI)	0.68 [0.53, 0.86]
6.7 Ordinal description as moderate to severe, 2 hrs after randomisation	1	57	Risk Ratio (M-H, Fixed, 95% CI)	0.76 [0.59, 0.98]
6.8 VAS scale 8 to 10, 2 hrs after randomisation	1	57	Risk Ratio (M-H, Fixed, 95% CI)	0.83 [0.66, 1.05]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
6.9 Ordinal scale pain faces 4 to 5, 2 hrs after randomisation	1	57	Risk Ratio (M-H, Fixed, 95% CI)	0.72 [0.52, 0.98]
6.10 Ordinal description as moderate to severe, 3 hrs after randomisation	1	32	Risk Ratio (M-H, Fixed, 95% CI)	0.52 [0.23, 1.16]
6.11 VAS scale 8 to 10, 3 hrs after randomisation	1	32	Risk Ratio (M-H, Fixed, 95% CI)	0.69 [0.39, 1.23]
6.12 Ordinal scale pain faces 4 to 5, 3 hrs after randomisation	1	32	Risk Ratio (M-H, Fixed, 95% CI)	0.57 [0.25, 1.27]
6.13 Ordinal description as moderate to severe, 24 hrs after randomisation	1	119	Risk Ratio (M-H, Fixed, 95% CI)	0.64 [0.50, 0.82]
6.14 VAS scale 8 to 10, 24 hrs after randomisation	1	119	Risk Ratio (M-H, Fixed, 95% CI)	0.62 [0.49, 0.80]
6.15 Ordinal scale pain faces 4 to 5, 24 hrs after randomisation	1	119	Risk Ratio (M-H, Fixed, 95% CI)	0.69 [0.54, 0.87]
7 Instrumental/surgical delivery	9		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
7.1 Assisted vaginal deliveries	7	2628	Risk Ratio (M-H, Fixed, 95% CI)	0.86 [0.71, 1.05]
7.2 Caesarean section	8	2712	Risk Ratio (M-H, Fixed, 95% CI)	1.21 [0.87, 1.68]
7.3 Normal versus operative birth	1	106	Risk Ratio (M-H, Fixed, 95% CI)	1.26 [1.09, 1.45]
8 Duration of first stage (minutes)	7	1461	Mean Difference (IV, Fixed, 95% CI)	-32.40 [-58.67, -6.13]
9 Duration of second stage (minutes)	8	1569	Mean Difference (IV, Fixed, 95% CI)	0.47 [-3.45, 4.38]
10 Duration of third stage (minutes)	3	1165	Mean Difference (IV, Random, 95% CI)	-0.52 [-1.84, 0.79]
11 Duration of labour from randomisation till delivery	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
12 Duration of total labour (all three stages)	1	120	Mean Difference (IV, Fixed, 95% CI)	-27.5 [-133.05, 78.05]
13 Postpartum haemorrhage	1	274	Risk Ratio (M-H, Fixed, 95% CI)	1.58 [0.80, 3.13]
14 Blood loss	2	153	Mean Difference (IV, Fixed, 95% CI)	-14.33 [-63.03, 34.37]
15 Perineal trauma after vaginal birth	6		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
15.1 Intact	5	1337	Risk Ratio (M-H, Fixed, 95% CI)	1.16 [0.99, 1.35]
15.2 Episiotomy	5	1272	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.80, 1.08]
15.3 Second-degree tear	5	1286	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.74, 1.20]
15.4 Third- or fourth-degree tears	5	2401	Risk Ratio (M-H, Fixed, 95% CI)	1.37 [0.86, 2.17]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
16 Satisfication with labour	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
16.1 Labour and delivery satisfaction index	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
16.2 Dissatisfied measured using ordinal scale	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
17 Self reports pain score on visual analogue scale of 0-10	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
17.1 Pain score at start of assessment period (time zero)	2	141	Mean Difference (IV, Fixed, 95% CI)	-0.01 [-0.54, 0.52]
17.2 Pain score up to 60 minutes later	2	141	Mean Difference (IV, Fixed, 95% CI)	-0.81 [-1.34, -0.28]
18 Does not wish to use bath with next labour/delivery	1	119	Risk Ratio (M-H, Fixed, 95% CI)	0.38 [0.14, 0.98]
19 Artificial rupture of membranes	3	926	Risk Ratio (M-H, Fixed, 95% CI)	1.02 [0.90, 1.16]
20 Amniotic fluid index	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
21 Presence of meconium stained liquor	5	1260	Risk Ratio (M-H, Fixed, 95% CI)	0.95 [0.76, 1.19]
22 Use of oxytocin for augmentation of labour	5	1125	Risk Ratio (M-H, Random, 95% CI)	0.64 [0.32, 1.28]
23 Systolic blood pressure	1	120	Mean Difference (IV, Fixed, 95% CI)	-7.20 [-13.12, -21.28]
24 Diastolic blood pressure	1	120	Mean Difference (IV, Fixed, 95% CI)	-10.20 [-13.70, -6.70]
25 Mean arterial blood pressure	1	120	Mean Difference (IV, Fixed, 95% CI)	-10.5 [-14.68, -6.32]
26 Maternal infection (perineal, systemic, uterine or increase in temperature)	5	1295	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.50, 1.96]
27 Low self-esteem	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
28 Postpartum depression EPDS more than 11	2	370	Risk Ratio (M-H, Fixed, 95% CI)	1.38 [0.85, 2.24]
29 Not breastfeeding after six weeks postdelivery	2	363	Risk Ratio (M-H, Fixed, 95% CI)	1.17 [0.64, 2.15]
30 Abnormal fetal heart rate patterns	3	487	Risk Ratio (M-H, Random, 95% CI)	0.75 [0.34, 1.67]
31 Apgar score less than seven (five minutes)	5	1834	Risk Ratio (M-H, Fixed, 95% CI)	1.58 [0.63, 3.93]
32 Apgar score at five minutes	2	893	Mean Difference (IV, Fixed, 95% CI)	-0.03 [-0.11, 0.06]
33 Umbilical artery pH less than 7.20	1	110	Risk Ratio (M-H, Fixed, 95% CI)	5.18 [0.25, 105.51]
34 Neonate temperature	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
than 7.20		110	Fixed, 95% CI) Risk Ratio (M-H,	

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
34.1 Temperature less than 36.2 degrees C at birth	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
34.2 Temperature greater than 37.5 degrees C at birth	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
34.3 Temperature greater than 37.8 degrees C as an indicator for infection	1	274	Risk Ratio (M-H, Fixed, 95% CI)	1.0 [0.06, 15.83]
35 Admission to neonatal intensive care unit	3	1571	Risk Ratio (M-H, Fixed, 95% CI)	1.06 [0.71, 1.57]
36 Neonatal infection	5	1295	Risk Ratio (M-H, Fixed, 95% CI)	2.00 [0.50, 7.94]
37 Lung hypoplasia present	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
38 Perinatal deaths	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
39 Caregiver injuries	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
40 Neonatal gestational age at birth	9	2820	Mean Difference (IV, Fixed, 95% CI)	-0.01 [-0.82, 0.80]
41 Birthweight in grams	9	2820	Mean Difference (IV, Fixed, 95% CI)	-22.74 [-66.44, 20.96]

Comparison 2

Immersion in water versus no immersion during second stage of labour

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Experience of moderate to severe pain	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1 Ordinal description as moderate to severe	1	117	Risk Ratio (M-H, Fixed, 95% CI)	1.06 [0.73, 1.53]
1.2 Labour Agentry scale	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.3 Line scale	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2 Satisfied with labour	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.1 Labour and delivery satisfaction index	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2.2 Little or not satisfied with coping experience	1	117	Risk Ratio (M-H, Fixed, 95% CI)	0.24 [0.07, 0.80]
3 Does not wish to use bath next delivery	1	117	Risk Ratio (M-H, Fixed, 95% CI)	0.57 [0.22, 1.47]
4 Perineal trauma after vaginal birth	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
4.1 Episiotomy	2	179	Risk Ratio (M-H, Fixed, 95% CI)	0.75 [0.35, 1.60]
4.2 Second-degree tear	2	179	Risk Ratio (M-H, Fixed, 95% CI)	1.21 [0.65, 2.24]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.3 Third- or fourth-degree tears	1	60	Risk Ratio (M-H, Fixed, 95% CI)	1.54 [0.07, 36.11]
5 Duration of second stage (minutes)	3	286	Mean Difference (IV, Fixed, 95% CI)	-1.24 [-8.05, 5.56]
6 Instrumental/surgical delivery	3		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
6.1 Assisted vaginal deliveries	2	180	Risk Ratio (M-H, Fixed, 95% CI)	0.73 [0.21, 2.54]
6.2 Caesarean section	2	180	Risk Ratio (M-H, Fixed, 95% CI)	0.33 [0.07, 1.52]
6.3 Any operative versus normal birth	1	106	Risk Ratio (M-H, Fixed, 95% CI)	0.04 [0.00, 0.72]
7 Postpartum haemorrhage more than 500 ml	1	120	Risk Ratio (M-H, Fixed, 95% CI)	0.14 [0.01, 2.71]
8 Presence of meconium-stained liquor	2	180	Risk Ratio (M-H, Fixed, 95% CI)	1.32 [0.63, 2.80]
9 Apgar score less than seven (five minutes)	1	119	Risk Ratio (M-H, Fixed, 95% CI)	4.92 [0.24, 100.31]
10 Apgar less than eight at five minutes	1	60	Risk Ratio (M-H, Fixed, 95% CI)	1.54 [0.07, 36.11]
11 Neonate temperature	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
11.1 Temperature less than 36.2 degrees C at birth	1	109	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.30, 3.20]
11.2 Temperature greater than 37.5 degrees C at birth	1	109	Risk Ratio (M-H, Fixed, 95% CI)	2.62 [0.73, 9.35]
11.3 Temperature greater 37.8 degrees C as an indicator for infection	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
12 Umbilical artery pH less than 7.20	1	116	Risk Ratio (M-H, Fixed, 95% CI)	0.89 [0.45, 1.75]
13 Cord arterial pH	1	48	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
14 Admission to neonatal intensive care unit	2	180	Risk Ratio (M-H, Fixed, 95% CI)	0.79 [0.25, 2.49]
15 Perinatal deaths	1	120	Risk Ratio (M-H, Fixed, 95% CI)	3.0 [0.12, 72.20]
16 Satisfaction with labour and birth on scale of 0-6 where 0 is not at all satisfied	1	60	Mean Difference (IV, Fixed, 95% CI)	0.03 [-0.64, 0.70]
17 Maternal temperature	1	60	Mean Difference (IV, Fixed, 95% CI)	0.20 [-0.18, 0.58]
18 Breastfeeding	1	60	Risk Ratio (M-H, Fixed, 95% CI)	0.86 [0.69, 1.08]
19 Antibiotics given to neonate	1	60	Risk Ratio (M-H, Fixed, 95% CI)	1.5 [0.17, 13.52]
20 Positive neonatal swab of ear, mouth or umbilicus	1	154	Risk Ratio (M-H, Fixed, 95% CI)	1.89 [0.90, 3.96]
21 Neonatal gestational age at birth in days	2	180	Mean Difference (IV, Fixed, 95% CI)	-1.0 [-5.13, 3.13]

#### Comparison 5

Early versus late immersion in water

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Epidural/spinal analgesia/paracervical block	1	200	Risk Ratio (M-H, Fixed, 95% CI)	2.21 [1.39, 3.52]
2 Use of oxytocin	1	200	Risk Ratio (M-H, Fixed, 95% CI)	1.9 [1.35, 2.68]
3 Instrumental or surgical delivery	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
4 Abnormal fetal heart rate patterns	1	200	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
5 Apgar score less than seven at one minute	1	200	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
6 Neonatal infection	1	200	Risk Ratio (M-H, Fixed, 95% CI)	3.0 [0.12, 72.77]
7 Admission to neonatal special care unit	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
8 Neonatal birthweight in grams	1	200	Mean Difference (IV, Fixed, 95% CI)	-66.0 [-189.34, 57.34]

## **FEEDBACK**

## Wein, December 2006

**Summary**—How can the review authors conclude "Overall, the evidence indicates that immersion in water decreases maternal reported pain levels and the uptake of pharmacological analgesia" when their analysis reports the odds ratio for pharmacological analgesia as 1.08 (95% CI 0.71 to 1.65)?

(Summary of comment from Peter Wein, December 2006)

Reply—In the authors' conclusions section of the previous update of this review (Cluett 2002), the statement "immersion in water decreases maternal reported pain levels" was based on the one trial (Taha 2000) that reported this outcome (OR 0.23, 95% CI 0.08 to 0.63). The limitation of only one study is indicated in the maternal outcome section of the review. The reference to a decrease in maternal 'uptake of pharmacological analgesia' was based on the outcome 'use of epidural/spinal/paracervical block' (OR 0.84, 95% CI 0.71 to 0.99), which included data from four trials, not the outcome 'any pharmacological analgesia' which include data from two trials and is the one cited by Wein above. We accept the wording was ambiguous, and have clarified it in the current update.

Interestingly, in this update data for these outcomes have altered minimally: use of epidural/spinal/paracervical block is now OR 0.82, 95% CI 0.70 to 0.98, with data from six trials; 'any pharmacological analgesia', remains unchanged, as do the data for maternal pain experience.

(Response from Elizabeth Cluett, October 2008)

Contributors—Peter Wein

## **WHAT'S NEW**

Last assessed as up-to-date: 23 August 2011.

Date	Event	Description
14 December 2011	Amended	Corrected error in Abstract and in Analysis 1.17.

## **HISTORY**

Protocol first published: Issue 3, 1996

Review first published: Issue 3, 1997

Date	Event	Description
30 June 2011	New search has been performed	Papers from June 2011 search reviewed and data incorporated as appropriate. I new study included (Chaichian 2009) and 2 added to Characteristics of studies awaiting classification pending more information from the authors. Risk of bias tables generated. Text updated, although no change in overall conclusions
5 January 2009	New citation required but conclusions have not changed	Change in authorship.
20 November 2008	New search has been performed	Search updated. New trials identified, appraised and data are included Title changed to reflect focus on water immersion in labour and birth, so pregnancy removed from title, and outcomes updated accordingly Background information updated.  Results and discussion sections updated but no change to overall conclusions
20 November 2008	Feedback has been incorporated	Response from authors to feedback from Wein incorporated.
29 October 2008	Amended	Converted to new review format.
25 April 2004	New search has been performed	Search updated. Five new trials are included (Eckert 2001; Eriksson 1997; Nikodem 1999; Ohlsson 2001; Taha 2000).
25 April 2004	New citation required and conclusions have changed	The inclusion of the new trials has resulted in a change in the implications for practice, which now indicates that immersion in water during the first stage of labour reduces reported maternal pain and the use of analgesia.  The outcome measures have been modified to ensure clarity. Neonatal outcomes have been added to reflect current methods of wellbeing assessment Change in authorship for this update.

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\* Indicates the major publication for the study

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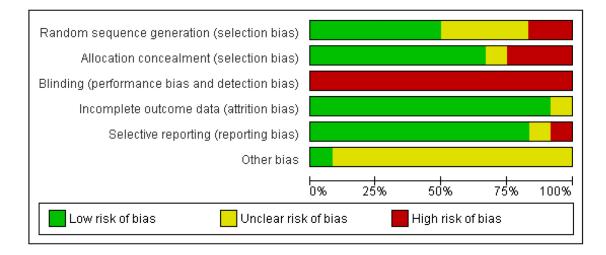
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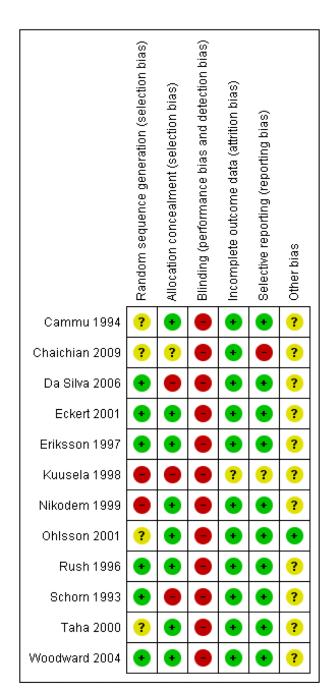
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**Figure 1.**Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.



**Figure 2.** Risk of bias summary: review authors' judgements about each risk of bias item for each included study.