# Continuous support for women during childbirth (Review)

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## [Intervention Review]

# Continuous support for women during childbirth

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#### ABSTRACT

## Background

Historically, women have been attended and supported by other women during labour. However in hospitals worldwide, continuous support during labour has become the exception rather than the routine.

## **Objectives**

Primary: to assess the effects of continuous, one-to-one intrapartum support compared with usual care. Secondary: to determine whether the effects of continuous support are influenced by: (1) routine practices and policies; (2) the provider's relationship to the hospital and to the woman; and (3) timing of onset.

## Search strategy

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (31 December 2010).

#### Selection criteria

All published and unpublished randomized controlled trials comparing continuous support during labour with usual care.

## Data collection and analysis

We used standard methods of the Cochrane Collaboration Pregnancy and Childbirth Group. Two authors independently evaluated methodological quality and extracted the data. We sought additional information from the trial authors. We used random-effects analyses for comparisons in which high heterogeneity was present, and we reported results using the risk ratio for categorical data and mean difference for continuous data.

#### Main results

Twenty-one trials involving 15061 women met inclusion criteria and provided usable outcome data. Results are of random-effects analyses, unless otherwise noted. Women allocated to continuous support were more likely to have a spontaneous vaginal birth (RR 1.08, 95% CI 1.04 to 1.12) and less likely to have intrapartum analgesia (RR 0.90, 95% CI 0.84 to 0.97) or to report dissatisfaction (RR 0.69, 95% CI 0.59 to 0.79). In addition their labours were shorter (mean difference -0.58 hours, 95% CI -0.86 to -0.30), they were less likely to have a caesarean (RR 0.79, 95% CI 0.67 to 0.92) or instrumental vaginal birth (fixed-effect, RR 0.90, 95% CI

0.84 to 0.96), regional analgesia (RR 0.93, 95% CI 0.88 to 0.99), or a baby with a low 5-minute Apgar score (fixed-effect, RR 0.70, 95% CI 0.50 to 0.96). There was no apparent impact on other intrapartum interventions, maternal or neonatal complications, or on breastfeeding. Subgroup analyses suggested that continuous support was most effective when provided by a woman who was neither part of the hospital staff nor the woman's social network, and in settings in which epidural analgesia was not routinely available. No conclusions could be drawn about the timing of onset of continuous support.

#### Authors' conclusions

Continuous support during labour has clinically meaningful benefits for women and infants and no known harm. All women should have support throughout labour and birth.

## PLAIN LANGUAGE SUMMARY

## Continuous support for women during childbirth

Continuous support in labour increased the chance of a spontaneous vaginal birth, had no harm, and women were more satisfied.

Historically women have been attended and supported by other women during labour and birth. However in many countries, as more women are giving birth in hospital rather than at home, continuous support during labour has become the exception rather than the norm. This may contribute to the dehumanization of women's childbirth experiences. Modern obstetric care frequently subjects women to institutional routines, which may have adverse effects on the progress of labour. Supportive care during labour may involve emotional support, comfort measures, information and advocacy. These may enhance physiologic labour processes as well as women's feelings of control and competence, and thus reduce the need for obstetric intervention. The review of studies included 21 trials, from 15 countries, involving more than 15,000 women in a wide range of settings and circumstances. The continuous support was provided either by hospital staff (such as nurses or midwives), women who were not hospital employees and had no personal relationship to the labouring woman (such as doulas or women who were provided with a modest amount of guidance), or by companions of the woman's choice from her social network (such as her husband, partner, mother, or friend). Women who received continuous labour support were more likely to give birth 'spontaneously', i.e. give birth with neither caesarean nor vacuum nor forceps. In addition, women were less likely to use pain medications, were more likely to be satisfied, and had slightly shorter labours. Their babies were less likely to have low 5-minute Apgar Scores. No adverse effects were identified. We conclude that all women should have continuous support during labour. Continuous support from a person who is present solely to provide support, is not a member of the woman's social network, is experienced in providing labour support, and has at least a modest amount of training, appears to be most beneficial. Support from a chosen family member or friend appears to increase women's satisfaction with their childbearing experience.

## BACKGROUND

The first version of this Cochrane Review was published in 1995 (Hodnett 2003) when the first systematic reviews in the Cochrane Collaboration Pregnancy and Childbirth Group Module were converted to the Cochrane Review format. Thus a formal Cochrane Protocol was not initially published. Subsequently the Review author, Ellen Hodnett, completed a trial of labour support (Hodnett 2002) with a sample size larger than the entire sample in the prior version of the original Review. As a protection against bias, she sought co-authors who were blind to the results of the new trial and who had special expertise that would enhance the quality of the Review. Discussions among the authors led to decisions to modify the background and methods. The authors de-

cided that the best approach would be to write a new Protocol for the Review. The new Protocol was submitted through the peer review process of the Cochrane Pregnancy and Childbirth Group and has subsequently evolved into a Review that has been updated.

Historically and cross-culturally, women have been attended and supported by other women during labour and birth. However, since the middle of the 20th century, in many countries as the majority of women gave birth in hospital rather than at home, continuous support during labour has become the exception rather than the routine. Concerns about dehumanization of women's birth experiences (in high-, middle-, and low income countries) have led to calls for a return to continuous, one-to-one support by women

for women during labour (Klaus 2002). Common elements of this care include emotional support (continuous presence, reassurance and praise), information about labour progress and advice regarding coping techniques, comfort measures (such as comforting touch, massage, warm baths/showers, promoting adequate fluid intake and output) and advocacy (helping the woman articulate her wishes to others).

Two complementary theoretical explanations have been offered for the effects of labour support on childbirth outcomes. Both explanations hypothesize that labour support enhances labour physiology and mothers' feelings of control and competence, reducing reliance on medical interventions. The first theoretical explanation considers possible mechanisms when companionship during labour is used in stressful, threatening and disempowering clinical birth environments (Hofmeyr 1991). During labour women may be uniquely vulnerable to environmental influences; modern obstetric care frequently subjects women to institutional routines, high rates of intervention, unfamiliar personnel, lack of privacy and other conditions that may be experienced as harsh. These conditions may have an adverse effect on the progress of labour and on the development of feelings of competence and confidence; this may in turn impair adjustment to parenthood and establishment of breastfeeding, and increase the risk of depression. The provision of support and companionship during labour may to some extent buffer such stressors.

The second theoretical explanation does not focus on a particular type of birth environment. Rather, it describes two pathways enhanced passage of the fetus through the pelvis and soft tissues, as well as decreased stress response - by which labour support may reduce the likelihood of operative birth and subsequent complications, and enhance women's feelings of control and satisfaction with their childbirth experiences (Hodnett 2002a). Enhanced fetopelvic relationships may be accomplished by encouraging mobility and effective use of gravity, supporting women to assume their preferred positions and recommending specific positions for specific situations. Studies of the relationships among fear and anxiety, the stress response and pregnancy complications have shown that anxiety during labour is associated with high levels of the stress hormone epinephrine in the blood, which may in turn lead to abnormal fetal heart rate patterns in labour, decreased uterine contractility, a longer active labour phase with regular well-established contractions and low Apgar scores (Lederman 1978; Lederman 1981). Emotional support, information and advice, comfort measures and advocacy may reduce anxiety and fear and associated adverse effects during labour.

Continuous support has been viewed by some as a form of pain relief, specifically, as an alternative to epidural analgesia (Dickinson 2002), because of concerns about the deleterious effects of epidural analgesia on labour progress (Anim-Somuah 2005). Many labour and birth interventions routinely involve, or increase the likelihood of, co-interventions to monitor, prevent or treat adverse

effects, in a "cascade of interventions". Continuous, one-to-one support has the potential to limit this cascade and therefore to have a broad range of different effects, in comparison to usual care. For example, if continuous support leads to reduced use of epidural analgesia, it may in turn involve less use of electronic fetal monitoring, intravenous drips, synthetic oxytocin, drugs to combat hypotension, bladder catheterization, vacuum extraction or forceps, episiotomy and less morbidity associated with these, and may increase mobility during labour and spontaneous birth (Caton 2002).

A systematic review examining factors associated with women's satisfaction with the childbirth experience suggests that continuous support can make a substantial contribution to this satisfaction. When women evaluate their experience, four factors predominate: the amount of support from caregivers, the quality of relationships with caregivers, being involved with decision-making and having high expectations or having experiences that exceed expectations (Hodnett 2002a).

Clarification of the effects of continuous support during labour, overall and within specific circumstances, is important in light of public and social policies and programs that encourage this type of care. For example, the Congress in Uruguay passed a law in 2001 decreeing that all women have the right to companionship during labour. In several low- and middle-income countries (including China, South Africa, Tanzania and Zimbabwe), the Better Births Initiative promotes labour companionship as a core element of care for improving maternal and infant health (WHO 2010). In many low income countries, women are not permitted to have anyone with them during labour and birth. Efforts to change policies in these settings have led to questions about the effectiveness of support from husbands/partners or other support people of the woman's own choosing, particularly in settings where the cost of paid companions would be prohibitive.

In North America, the services of women with special training in labour support have become available. Most commonly known as doula (a Greek word for 'handmaiden'), this new member of the caregiver team may also be called a labour companion, birth companion, labour support specialist, labour assistant or birth assistant. A number of North American organizations offer doula training, certification and professional support; according to one estimate more than 50,000 people have received this training to date (P Simkin, personal communication). Some North American hospitals have begun to sponsor doula services. In recent national surveys of childbearing women in the United States, 3% to 5% of respondents indicated that they had used doula services during their most recent labours (Declercq 2002; Declercq 2006). An association for doulas has been established in the UK (McGinnis 2001). Maternal healthcare systems in dozens of high- and lowto middle-income countries throughout the world are developing new traditions for supportive female companionship during labour (Pascali-Bonaro 2010).

Questions have arisen about the ability of employees (such as nurses or midwives) to provide effective labour support, in the context of modern institutional birth environments (Hodnett 1997). For example, nurses and midwives often have simultaneous responsibility for more than one labouring woman, spend a large proportion of time managing technology and keeping records, and begin or end work shifts in the middle of women's labours. They may lack labour support skills or may work in short-staffed environments. Companions, such as husbands/partners and female relatives, usually have little experience in providing labour support and are themselves in need of support when with a loved one during labour and birth. In addition to questions about the impact of the type of provider of labour support, there are other questions about the effectiveness of support, including its impact under a variety of environmental conditions, and whether its effects are mediated by when continuous support begins (early versus active labour).

Childbearing women, policy-makers, payers of health services, health professionals and facilities and those who provide labour support all need evidence about the effects of continuous support, overall and under specific conditions.

The current update includes new trials and major revisions to all aspects of the Review, to align it with current Cochrane methodological guidelines (Higgins 2009).

## **OBJECTIVES**

The primary objective was to assess the effects, on mothers and their babies, of continuous, one-to-one intrapartum support compared with usual care, in any setting. Secondary objectives were to determine whether the effects of continuous support are influenced by:

- (1) routine practices and policies in the birth environment that may affect a woman's autonomy, freedom of movement and ability to cope with labour, including:
- (a) policies about the presence of support people of the woman's own choosing;
- (b) epidural analgesia; and
- (c) continuous electronic fetal monitoring;
- (2) whether the provider is a) a member of the staff of the institution (and thus has additional loyalties or responsibilities), b) not a staff member but not part of the woman's social network, or c) or a person chosen by the woman from family members and friends; and
- (3) whether the continuous support begins early or later in labour.

## Criteria for considering studies for this review

## Types of studies

All controlled trials comparing continuous labour support by either a familiar or unfamiliar person (with or without healthcare professional qualifications) with usual care, in which there was random allocation to treatment and control groups, were considered for inclusion in the Review.

## Types of participants

Pregnant women, in labour.

## Types of interventions

The form of care that was evaluated was continuous presence and support during labour and birth. The person providing the support could have qualifications as a healthcare professional (nurse, midwife) or training as a doula or childbirth educator, or be a family member, spouse/partner, friend or stranger with little or no special training in labour support. The control group received usual care, as defined by the trialists. In all cases, 'usual care' did not involve continuous intrapartum support, but it could involve other measures, such as routine epidural analgesia, to help women to cope with labour.

## Types of outcome measures

Theoretically continuous support can have many diverse physiological and psychosocial effects (both short- and long-term), and therefore a larger than usual number of outcomes were considered.

## Primary outcomes

## Mother

- 1. Any analgesia/anaesthesia (pain medication)
- 2. Synthetic oxytocin during labour
- 3. Spontaneous vaginal birth
- 4. Postpartum depression (defined using a pre-specified cutoff score on a validated instrument)
- 5. Negative rating of/negative feelings about the birth experience

## Baby

- 1. Admission to special care nursery
- 2. Breastfeeding at 1-2 months postpartum

## Secondary outcomes

#### Labour events

- 1. Regional analgesia/anaesthesia
- 2. Labour length

## METHODS

3. Severe labour pain (postpartum report)

#### Birth

- 1. Caesarean birth
- 2. Instrumental vaginal birth
- 3. Perineal trauma (defined as episiotomy or laceration requiring suturing)

#### Newborn

- 1. Low five-minute Apgar score (as defined by trial authors)
- 2. Prolonged newborn hospital stay

## Longer-term maternal outcomes

- 1. Difficulty mothering
- 2. Low self-esteem in the postpartum period

## Search methods for identification of studies

#### **Electronic searches**

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting the Trials Search Co-ordinator (31 December 2010).

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

- 1. quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
  - 2. weekly searches of MEDLINE;
- 3. handsearches of 30 journals and the proceedings of major conferences;
- 4. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

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

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

We did not apply any language restrictions.

## Data collection and analysis

For this update we re-assessed all trials (both those already in the review and the reports identified by the updated search), using the following methods.

#### Selection of studies

For the current update, two review authors (EH and JW) independently assessed for inclusion all potentially eligible studies. Had any disagreement occurred, we would have resolved it through discussion or, if required, we would have consulted a third member of the review team.

#### Data extraction and management

We designed a form to extract data. For eligible studies, two review authors (EH, JW) extracted the data using the agreed form. We resolved discrepancies through discussion. We entered data into Review Manager software (RevMan 2008) and checked for accuracy.

When information regarding any of the above was unclear, we attempted to contact authors of the original reports to provide further details.

#### Assessment of risk of bias in included studies

Two review authors (EH, JW) independently assessed risk of bias for each study using the criteria outlined in the *Cochrane Handbook* for Systematic Reviews of Interventions (Higgins 2009). We would have resolved any disagreement by discussion or by involving a third assessor.

# (I) 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:

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

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

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

We assessed the methods as:

- adequate (e.g. telephone or central randomization; consecutively numbered sealed opaque envelopes);
- inadequate (open random allocation; unsealed or nonopaque envelopes, alternation; date of birth);
  - unclear.

## (3) Blinding (checking for possible performance bias)

We described for each included study the methods used, if any, to blind personnel from knowledge of which intervention a participant received. Since women and care providers cannot be blinded as to whether continuous support was given, we considered blinding adequate if outcomes were recorded by outcome assessors who had no knowledge of the woman's group assignment. We judged studies at low risk of bias if they were blinded, or if we judged that the lack of blinding could not have affected the results. We assessed blinding separately for different outcomes or classes of outcomes.

# 4) Incomplete outcome data (checking for possible attrition bias through withdrawals, dropouts, protocol deviations)

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, the numbers included in the analysis at each stage (compared with the total randomized participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. To be included in the review, data on a given outcome had to be available for at least 80% of those who were originally randomized. For outcomes collected post hospital discharge, we recognize that follow-up, particularly in low-income countries, can be very difficult. Therefore, we included data if the response rate was higher than 75% and there was no obvious imbalance in groups. Where sufficient information was reported, or could be supplied by the trial authors, we planned to include missing data in the analyses. We assessed methods as:

- adequate;
- inadequate;
- unclear.

## (5) Selective 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:

- adequate (where it is clear that all of the study's prespecified outcomes and all expected outcomes of interest to the review have been reported);
- inadequate (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.

## (6) Other sources of bias

We planned to describe for each included study any important concerns we had about other possible sources of bias, including, for example, whether the trial was stopped early due to a datadependent process, there was evidence of extreme baseline imbalance, or there had been claims of fraud.

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

- yes;
- no;
- unclear.

#### (7) Overall risk of bias

We made explicit judgements about whether studies are at high risk of bias, according to the criteria given in the *Handbook* (Higgins 2009). With reference to (1) to (6) above, we assessed the likely magnitude and direction of the bias and whether we considered it is likely to impact on the findings. We explored the impact of the level of bias through undertaking sensitivity analyses - *see* 'Sensitivity analysis'

#### Measures of treatment effect

#### Dichotomous data

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

## Continuous data

All but one pre-specified outcome involved dichotomous data. For labour length, we used the mean difference because it was measured in the same way in the trials.

#### Unit of analysis issues

## Cluster-randomized trials

Had we found cluster-randomized trials, we would have included them in the analyses along with individually randomized trials. Our plan was as follows: we would adjust their sample sizes or standard errors using the methods described in the *Handbook* (Section 16.3.4 or 16.3.6) using an estimate of the intracluster correlation co-efficient (ICC) derived from the trial (if possible), from a similar trial or from a study of a similar population. If we use ICCs from other sources, we will report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. If we identify both cluster-randomized trials and individually-randomized trials, we plan to synthesize the relevant information. We will

consider it reasonable to combine the results from both if there is little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomization unit is considered to be unlikely. We will also acknowledge heterogeneity in the randomization unit and perform a separate meta-analysis.

## Dealing with missing data

For included studies, we noted levels of attrition. We included data for a given outcome which occurred prior to hospital discharge only if the data were available for at least 80% of those originally randomized. For outcomes collected post-hospital discharge we included data if the response rate was higher than 75% and there was no obvious imbalance in groups.

For all outcomes we have carried out analyses, as far as possible, on an intention-to-treat basis, i.e. we attempted to include all participants randomized to each group in the analyses. The denominator for each outcome in each trial was the number randomized minus any participants whose outcomes were known to be missing.

#### Assessment of heterogeneity

We assessed statistical heterogeneity in each meta-analysis using the  $T^2$ ,  $I^2$  and  $Chi^2$  statistics. We regarded heterogeneity as substantial if  $T^2$  was greater than zero and either  $I^2$  was greater than 30% or there was a low P value (less than 0.10) in the  $Chi^2$  test for heterogeneity. In such cases we took the following steps:

- a sensitivity analysis, in which methodological weak trials were removed from the analyses and results compared for the primary outcomes:
- 2. visual inspection of the forest plots for evidence of inconsistency in results; and
- 3. comparison of the results of fixed-effect and random-effects analyses.

#### Assessment of reporting biases

Had we suspected reporting bias, we would have attempted to contact study authors asking them to provide missing outcome data. If this were not possible, and the missing data were thought to introduce serious bias, we would not have included the outcome data from that trial.

## **Data synthesis**

We carried out statistical analysis using the Review Manager soft-ware (RevMan 2008). We used fixed-effect Mantel-Haenszel meta-analysis for combining data. We defined heterogeneity as substantial if a given meta-analysis resulted in an I<sup>2</sup> value greater than 30%, and there was inconsistency among trials in the direction or magnitude of effects (judged visually in the forest plot), or a low (less than 0.10) P value in the Chi<sup>2</sup> test for heterogeneity.

We excluded from analyses data for any outcome in which data were missing for more than 20% of those originally randomized.

## Subgroup analysis and investigation of heterogeneity

We planned the following subgroup analyses.

# A) Three subgroup analyses that concern characteristics of the childbirth environment

- (1) Trials in settings in which women were permitted to be accompanied by one or more support persons of their own choosing compared with trials in which accompaniment was not permitted; (2) trials conducted in settings in which epidural analgesia was available compared with trials in settings in which it was unavailable:
- (3) trials in which there was a policy of routine electronic fetal heart rate monitoring compared with trials in settings in which continuous electronic fetal monitoring was not routine.

## (B) One subgroup analysis that concerns characteristics of the providers of labour support

(4) Trials in which the caregivers were employees of the institution, compared with trials in which the caregivers were not employees and were not members of the woman's social network, compared to trials in which the providers were not employees and were lay people chosen by the participants (e.g. husband/partner, friend, close relative).

# (C) One subgroup analysis that concerns differences in the timing of onset of continuous support

(5) Trials in which continuous labour support began prior to or during early labour (as defined by trial authors), compared with trials in which continuous support began in active labour.

Because few of the trial reports contained all of the information needed for the above subgroup analyses, we contacted the trial authors in an attempt to verify the presence/absence of routine electronic fetal monitoring (EFM), the presence/absence of epidural analgesia and timing of onset of continuous support. We excluded some studies included in the primary comparisons from the subgroup analyses concerning the use of EFM because their status regarding EFM use was unknown. For tests of differences between these subgroups, we recalculated the overall analysis by including only the studies in which EFM use was known.

The seven primary outcomes and one secondary outcome were used in the subgroup analyses. While normally subgroup analyses are restricted to primary outcomes, we also included the outcome of caesarean delivery, because there is widespread concern about escalating caesarean rates worldwide, and subgroup analyses could be helpful to policy makers in decisions about the provision of continuous labour support. Thus the outcomes in the subgroup

analyses were: any analgesia/anaesthesia, synthetic oxytocin during labour, spontaneous vaginal birth, caesarean birth, postpartum depression, negative ratings of the birth experience, admission to special care nursery, and breastfeeding at 1-2 months postpartum. When I<sup>2</sup> levels were high but the amount of heterogeneity in treatment effects was low (as happens when there are a large number of big trials and thus the amount of variation due to sampling error is extremely low), we compared the results of random-effects and fixed-effect analyses. In instances in which the conclusions were not materially different in both methods of analysis, we reported the results of fixed-effect, inverse variance meta-analysis, in order to be able to calculate a Chi<sup>2</sup> for the purpose of exploring differences based on pre-specified subgroups. As a consequence the totals in the subgroup analysis tables are sometimes slightly different from those in the main comparison, since the main comparisons used the Mantel-Haenszel rather than the inverse variance method.

### Sensitivity analysis

We performed sensitivity analyses, for the primary outcomes, in instances in which there was a high risk of bias associated with the quality of included trials.

#### RESULTS

## **Description of studies**

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

Please see Characteristics of included studies table. While 22 trials met inclusion criteria, one trial (Thomassen 2003) provided no usable outcome data. We do not describe it here, but provide details in the Characteristics of included studies table.

All 21 trials (n = 15,061) that provided usable outcome data were conducted in hospitals. The trials were conducted in Australia, Belgium, Botswana, Brazil, Canada, Chile, Finland, France, Greece, Guatemala, Mexico, Nigeria, South Africa, Sweden and the United States, under widely disparate hospital conditions, regulations and routines. There was remarkable consistency in the descriptions of continuous support across all trials. In all instances the intervention included continuous or nearly continuous presence, at least during active labour. Nineteen of the 21 trials that provided usable outcome data (all except Cogan 1988 and Dickinson 2002) also included specific mention of comforting touch and words of praise and encouragement.

In 11 trials (Breart - Belgium 1992; Breart - France 1992; Campbell 2006; Cogan 1988; Dickinson 2002; Gagnon 1997;

Hemminki 1990a; Hemminki 1990b; Hodnett 1989; Hodnett 2002; McGrath 2008), hospital policy permitted women to be accompanied by their husbands/partners or other family members during labour, while in the other 10 trials, no additional support people were allowed. Epidural analgesia was not routinely available in six trials (Breart - Greece 1992; Hofmeyr 1991; Kashanian 2010; Klaus 1986; Madi 1999; Morhason-Bello 2009). We were unsuccessful in obtaining information about availability of epidural analgesia in one trial (Cogan 1988). Epidural analgesia was routinely available in the other 14 trials. Electronic fetal heart rate monitoring was not routine in seven trials (Bruggemann 2007; Hofmeyr 1991; Kashanian 2010; Klaus 1986; Langer 1998; Madi 1999; Morhason-Bello 2009). In nine trials (Campbell 2006; Dickinson 2002; Gagnon 1997; Hemminki 1990a; Hemminki 1990b; Hodnett 1989; Hodnett 2002; Kennell 1991; McGrath 2008) electronic fetal monitoring was used routinely. We were unsuccessful in obtaining information about the use of electronic fetal monitoring in five trials (Breart - Greece 1992; Breart - Belgium 1992; Breart - France 1992; Cogan 1988; Torres 1999).

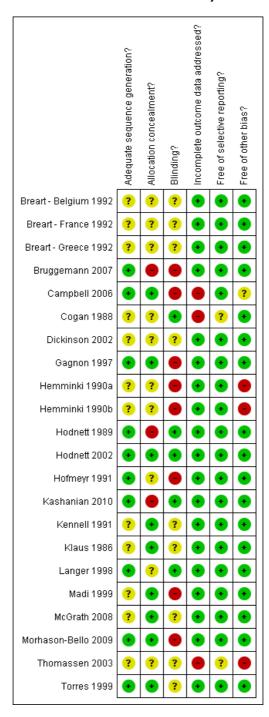
It was not possible to categorize most of the trials according to the pre-specified subgroups of early versus active labour. In four trials (Cogan 1988; Hodnett 1989; Klaus 1986; Madi 1999), the support began in early labour. In the other 17 trials, the timing of onset of support was much more heterogenous, as were definitions of early and active labour, in instances in which these were defined. Women were in varying phases of labour, from elective induction to active labour.

In addition, the persons providing the support intervention varied in their experience, qualifications and relationship to the labouring women. In nine trials (Breart - Belgium 1992; Breart - France 1992; Breart - Greece 1992; Dickinson 2002; Gagnon 1997; Hemminki 1990a; Hemminki 1990b; Hodnett 2002; Kashanian 2010), the support was provided by a member of the hospital staff, for example, a midwife, student midwife or nurse. In seven trials the providers were not members of the hospital staff and were not part of the woman's social network; they were women with or without special training, such as doulas or women who had given birth before (Hodnett 1989; Hofmeyr 1991; Kennell 1991; Klaus 1986; McGrath 1999): a childbirth educator (Cogan 1988), or retired nurses (Langer 1998). In five trials they were companions of the woman's choice from her social network, with or without brief training -- a female relative or friend or the woman's husband/partner (Bruggemann 2007; Campbell 2006; Madi 1999; Morhason-Bello 2009; Torres 1999).

## Risk of bias in included studies

The trials were of generally good quality (Figure 1; Figure 2), although the risk of selection bias was high in three small trials (Bruggemann 2007; Hodnett 1989; Kashanian 2010).

Figure 1. Methodological quality summary: review authors' judgements about each methodological quality item for each included study.



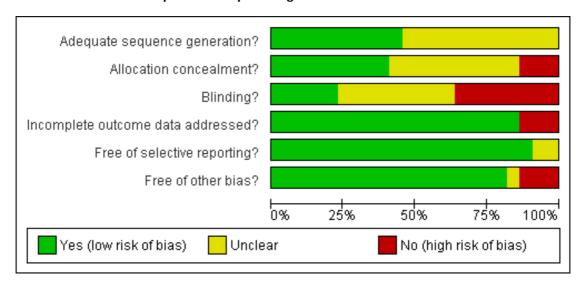


Figure 2. Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all included studies

Allocation concealment: Hodnett 2002 used a central, computerized randomization service accessed by telephone. In 17 trials (Breart - Belgium 1992; Breart - France 1992; Breart - Greece 1992; Campbell 2006; Dickinson 2002; Gagnon 1997; Hemminki 1990a; Hemminki 1990b; Hofmeyr 1991; Kashanian 2010; Kennell 1991; Klaus 1986; Langer 1998; Madi 1999; McGrath 2008; Morhason-Bello 2009; Torres 1999) randomization was by sealed, opaque envelopes. In Bruggemann 2007 women picked their treatment allocation from an opaque container. Two trials used methods that were centrally controlled but not concealed (Cogan 1988; Hodnett 1989). One trial (Thomassen 2003) did not describe the method of random assignment.

Performance bias: neither those providing nor receiving care could be blinded to the presence/absence of a person providing continuous support. Hodnett 2002 provided evidence to discount contamination and co-intervention as serious threats to validity.

Attrition bias: we did not include data for outcomes assessed in hospital in a comparison if there was more than 20% loss to follow-up; we did not include longer-term outcome data if there was more than 25% loss to follow-up; based on this criterion, one trial (Thomassen 2003) provided no usable outcome data.

Detection bias: in the trials which sought participants' evaluations of their birth experiences (Breart - Belgium 1992; Breart - France 1992; Hofmeyr 1991; Hodnett 2002; Kennell 1991), ef-

forts were made to reduce response bias, through use of an interviewer blinded to the woman's group allocation or self-administered questionnaires.

## **Effects of interventions**

# Main comparison: continuous support versus usual care - all trials

We considered 17 outcomes. Between one and 21 trials contributed to the analyses of each outcome. Sensitivity analyses, conducted by removing the trials (all of which were small) with a high likelihood of selection bias (Bruggemann 2007, Hodnett 1989; Kashanian 2010) did not alter the conclusions. According to our pre-specified criteria, there was substantial statistical heterogeneity in all but four outcomes (instrumental vaginal birth, low 5minute Apgar score, low postpartum self-esteem and postpartum depression). Inspection of the forest plots did not suggest sources of heterogeneity. Comparisons of fixed-effect and random-effects analyses did not yield substantive differences nor alter conclusions. We report results of average random-effects analyses for all comparisons, for all outcomes except instrumental vaginal birth, low 5-minute Apgar score, low postpartum self-esteem data, and postpartum depression. (Each of the latter two comparisons only contain data from one trial.) We have noted in the text the three instances in which fixed-effect analysis was used.

## **Primary outcomes**

Women who had continuous, one-to-one support during labour were:

more likely to have

• a spontaneous vaginal birth (18 trials, n = 14,005, RR 1.08, 95% CI 1.04 to 1.12, I<sup>2</sup> 48%, Ñ,<sup>2</sup> 0.00);

less likely to have

- any intrapartum analgesia/anaesthesia (13 trials, n = 12,169, RR 0.90, 95% CI 0.84 to 0.97, I<sup>2</sup> 76%, Ñ,<sup>2</sup> 0.01);
- reported negative rating of/negative feelings about childbirth experience (11 trials, n = 11,133, RR 0.69, 95% CI 0.59 to 0.79,  $I^2$  63%,  $\tilde{N}$ ,  $^2$  0.03);

and there was no apparent impact of continuous support on

- use of synthetic oxytocin during labour (14 trials, n = 12,506; RR 0.97, 95% CI 0.90 to 1.04, I<sup>2</sup> 67%, Ñ,<sup>2</sup> 0.01);
- admission to the special care nursery (7 trials; n = 8897; RR 0.97, 95% CI 0.76 to 1.25,  $I^2$  37%,  $\tilde{N}$ ,  $^2$  0.03);
- breastfeeding at 1-2 months postpartum (3 trials, n = 5363, RR 1.01, 95% CI 0.94 to 1.09, I<sup>2</sup> 52%, Ñ,<sup>2</sup> 0.00); and
- postpartum depression (1 trial, n = 5567; RR = 0.86, 95% CI 0.73 to 1.02, fixed-effect).

## Secondary outcomes

Women who had continuous, one-to-one support were: more likely to have

• shorter labours (11 trials; n = 5269; mean difference -0.58 hours, 95% CI -0.86 to -0.30,  $I^2$  50%,  $\tilde{N}$ ,  $\tilde{V}$ , 0.09);

less likely to have

- regional analgesia/anaesthesia (9 trials; n = 11,444, RR 0.93, 95% CI 0.88 to 0.99,  $I^2$  81%,  $\tilde{N}$ ,  $\tilde{V}$  0.01);
- an instrumental vaginal birth (18 trials; n = 14,004; RR 0.90, 95% CI 0.84 to 0.96, fixed-effect);
- a caesarean birth (21 trials; n = 15,061; RR 0.79, 95% CI 0.67 to 0.92, I<sup>2</sup> 55%, Ñ,<sup>2</sup> 0.05);
- a baby with a low 5-minute Apgar score (12 trials; n = 12,401; RR 0.70, 95% CI 0.50 to 0.96, fixed-effect);

and there was no apparent impact of continuous labour support on

- the likelihood of serious perineal trauma (4 trials; n = 8120; RR 0.97, 95% CI 0.92 to 1.01, I<sup>2</sup> 44%, Ñ,<sup>2</sup> 0.00);
- severe labour pain (4 trials; n = 2456; RR 1.00, 95% CI 0.83 to 1.12, I<sup>2</sup> 78%, Ñ, 2 0.03);
- difficulty mothering (3 trials; n = 6308, RR 0.60, 95% CI 0.35 to 1.02,  $I^2$  94%,  $\tilde{N}$ ,  $\tilde{V}$  0.19);
- low postpartum self-esteem (1 trial; n = 652; RR 1.00, 95% CI 0.77 to 1.30, fixed-effect); and
- prolonged neonatal hospital stay (3 trials; n = 1098, RR 0.83, 95% CI 0.42 to 1.65, I<sup>2</sup> 62%, N̄, 2 0.15).

## Subgroup comparisons

For the first time, the Review includes trials of support by companions of the woman's own choosing, i.e. husband/partner, relative, or friend from her existing social network. Therefore we grouped the trials according to the following provider characteristics: 1) staff members of the hospital; 2) neither hospital employees nor part of the woman's social network; and 3) chosen by the woman from her social network.

We have presented the results of the subgroup analyses below. While we made every effort to obtain the required information from trial authors, none of the subgroup comparisons are based on the total number of included trials for which usable data were available. Thus results must be interpreted with caution. The text below does not present the results for postpartum depression or breastfeeding at 1-2 months postpartum, because too few trials provided data. Only one trial contributed data about postpartum depression (Hodnett 2002) and three about breastfeeding (Hodnett 2002; Hofmeyr 1991; Langer 1998).

We were unable to conduct the planned subgroup comparison based on timing of onset of labour support. It was not possible to categorize most of the trials according to the pre-specified subgroups of early versus active labour. In four trials (Cogan 1988; Hodnett 1989; Klaus 1986; Madi 1999), the support began in early labour. In the other 17 trials, the timing of onset of support was much more heterogenous, as were definitions of early and active labour, in instances in which these were defined. Women were in varying phases of labour, from elective induction to active labour.

As noted in Subgroup analysis and investigation of heterogeneity, totals in the subgroup analysis figures may differ slightly from those in the main comparisons, because a different method of analysis had to be used. All subgroup comparisons used fixed-effect, to allow computation of tests for differences between subgroups.

#### Outcome: any intrapartum analgesia/anaesthesia

- 1. Policies about the presence of companions during labour and birth: In seven trials (n = 9752) companions were permitted; RR 0.97, 95% CI 0.96 to 0.99, while in six trials (n = 2484) companions were not permitted; RR 0.91, 95% CI 0.85 to 0.96.  $\text{Chi}^2$  for the subgroup comparison = 4.98, P = 0.03.
- 2. Availability of epidural analgesia: In nine trials (n = 10.888), epidural analgesia was routinely available; RR 0.97, 95% CI 0.96 to 0.98. In four trials (n = 1348) epidural analgesia was not routinely available; RR 0.83, 95% CI 0.69 to 0.99. Chi<sup>2</sup> for the subgroup comparison = 2.89, P = 0.09.
- 3. Routine use of EFM: in six trials (n = 8580), EFM was routine; RR 0.97, 95% CI 0.96 to 0.99. In five trials (n = 2072), EFM was not routine; RR 0.96, 95% CI 0.90 to 1.03. In two trials (n = 1579), the policy about routine EFM was unknown; RR 0.89, 95% CI 0.80 to 0.99.  $Chi^2$  for the subgroup comparison = 2.31, P = 0.32.

4. Provider characteristics: in six trials (n = 9152) the support was provided by a member of the hospital staff; RR 0.97, 95% CI 0.95 to 0.98. In four trials (n = 1790), the support was provided by a woman who was not a member of the staff and was not part of the woman's social network; RR 0.91, 95% CI 0.86 to 0.97. In three trials (n = 1294) the support was provided by a member of the woman's social network; RR 0.94, 95% CI 0.88 to 1.00. Chi² for the subgroup comparison = 4.76, P = 0.09. Thus, the effects of continuous support on use of any intrapartum analgesia/anaesthesia appeared to be stronger in settings where companions were not permitted, but did not appear to be influenced by the availability of epidural analgesia, the use of routine EFM, or provider characteristics.

#### Outcome: synthetic oxytocin during labour

- 1. Policies about the presence of companions: in five trials (n = 9495) companions were permitted; RR 1.04, 95% CI 0.99 to 1.10. In nine trials (n = 3011) companions were not permitted; RR 0.99, 95% CI 0.97 to 1.01.  $\text{Chi}^2$  for the subgroup comparison = 3.16, P = 0.08.
- 2. Availability of epidural analgesia: in eight trials (n = 10,568) epidural analgesia was routinely available; RR 1.00, 95% CI 0.98 to 1.02. In six trials (n = 1952), epidural analgesia was not routinely available; RR 1.02, 95% CI 0.93 to 1.11. Chi $^2$ for the subgroup comparison = 0.17, P = 0.68.
- 3. Use of routine EFM: in four trials (n = 8340) EFM was routine; RR 1.04, 95% CI 0.98 to 1.11. In six trials (n = 1612) EFM was not routine; RR 0.99, 95% CI 0.96 to 1.01. In 4 trials (n = 2568) it is not known whether EFM was routine; RR 1.02, 95% CI 0.97 to 1.08.  $\text{Chi}^2$  for the subgroup comparison = 3.32, P = 0.19.
- 4. Provider characteristics: in six trials (n = 9561), the support was provided by a member of the hospital staff; RR 1.06, 95% CI 1.01 to 1.11. In three trials (n = 1018), the support was provided by a woman who was not a member of the staff and was not part of the woman's social network; RR 0.69, 95% CI 0.50 to 0.94. In five trials (n = 1927), the support was provided by a member of the woman's social network; RR 0.99, 95% CI 0.96 to 1.01. Chi² for the subgroup comparison = 11.51, P = 0.003. Thus the effects of continuous support on use of synthetic oxytocin during labour did not appear to be influenced by policies about the presence of companions, use of routine EFM, or availability of epidural analgesia. The effectiveness of continuous support in reducing the likelihood of intrapartum oxytocin seemed to be strongest when the provider was neither a staff member nor part of the woman's social network.

## Outcome: spontaneous vaginal birth

1. Policies about companions: In nine trials (n = 10,889) companions were permitted; RR 1.03, 95% CI 1.00 to 1.05. In

- nine trials (n = 3215) companions were not permitted; RR1.12, 95% CI 1.07 to 1.16. Chi<sup>2</sup> for the subgroup comparison = 12.04, P = 0.005.
- 2. Availability of epidural analgesia: In 13 trials (n = 12,672), epidural analgesia was routinely available; RR 1.04, 95% CI 1.01 to 1.06). In five trials (n = 1432) epidural analgesia was not routinely available; RR 1.12, 95% CI 1.06 to 1.17.  $\rm Chi^2$  for the subgroup comparison = 6.82,  $\rm P = 0.009$ .
- 3. Routine use of EFM: In eight trials (n = 9717) EFM was routine; RR 1.03, 95% CI 1.01 to 1.06. In six trials (n = 1799) EFM was not routine; RR 1.12, 95% CI 1.06 to 1.17. In 4 trials (n = 2561), the policy about routine EFM is not known; RR 1.07, 95% CI 1.01 to 1.13.  $\text{Chi}^2$  for the subgroup comparison = 8.78, P = 0.01.
- 4. Provider characteristics: in nine trials (n = 10,813) the support was provided by a member of the hospital staff; RR 1.03, 95% CI 1.01 to 1.06. In five trials (n = 1935) the support was provided by a woman who was not part of the hospital staff nor part of the woman's social network; RR 1.12, 95% CI 1.07 to 1.17. In four trials (n = 1356), the support was provided by a member of the woman's social network; RR 1.07, 95% CI 0.99 to 1.15. Chi<sup>2</sup> for the subgroup comparison = 10.00, P = 0.007. Thus the effectiveness of continuous support in increasing the likelihood of spontaneous vaginal birth appeared to be stronger when hospital policies did not permit companions, when epidural analgesia was not available, when EFM was not routine, and when the support provider was neither a staff member nor part of the woman's social network.

## Outcome: caesarean birth

- 1. Policies about companions: in 11 trials (n = 11,326) companions were permitted; RR 0.94, 95% CI 0.85 to 1.03. In 10 trials (n = 3735) companions were not permitted; RR 0.75, 95% CI 0.65 to 0.87.  $\text{Chi}^2$  for the subgroup comparison = 6.10, P = 0.01.
- 2. Availability of epidural analgesia: in 14 trials (n = 13,064), epidural analgesia was routinely available; RR 0.93, 95% CI 0.86 to 1.02. In six trials (n = 1963), epidural analgesia was not routinely available; RR 0.52, 95% CI 0.41 to 0.67. In one very small trial (n = 34), we were unable to determine if epidural analgesia was routinely available; RR 1.40, 95% CI 0.14 to 13.98. Chi² for the subgroup comparison = 19.40, P < 0.0001.
- 3. Routine use of EFM: in nine trials (n = 10,123), EFM was routine; RR 0.92, 95% CI 0.83 to 1.01. In seven trials (n = 2343) EFM was not routine; RR 0.66, 95% CI 0.55 to 0.80. In five trials (n = 2595), it is not known whether EFM was routine; RR 1.06, 95% CI 0.84 to 1.33.  $Chi^2$  for the subgroup comparison = 12.38, P = 0.002.
- 4. Provider characteristics: in nine trials (n = 10,786), the support was provided by a member of the hospital staff; RR 0.95, 95% CI 0.85 to 1.05. In seven trials (n = 2330), the support was

provided by a woman who was not a member of the hospital staff and not part of the woman's social network; RR 0.72, 95% CI 0.60 to 0.86. In five trials (n = 1945), the support was provided by a member of the woman's social network; RR 0.84, 95% CI 0.69 to 1.03. Chi<sup>2</sup> for the subgroup comparison = 6.75, P = 0.03. Thus the effectiveness of continuous support in reducing the likelihood of caesarean birth appeared to be stronger in settings where companions were not permitted, epidural analgesia was not routinely available and EFM was not routine, and when the provider was neither a staff member nor part of the woman's social network.

#### Outcome: admission to special care nursery

- 1. Policies about companions: in two trials (n = 7328), companions were permitted; RR 0.99, 95% CI 0.84 to 1.17. In five trials (n = 1569), companions were not permitted; RR 0.91, 95% CI 0.71 to 1.17.  $\text{Chi}^2$  for the subgroup comparison = 0.28, P = 0.60.
- 2. Availability of epidural analgesia: in five trials (n = 8380) epidural analgesia was routinely available; RR 0.98, 95% CI 0.85 to 1.13. In two trials (n = 517) epidural analgesia was not routinely available; RR 0.26, 95% CI 0.08 to 0.88. Chi<sup>2</sup> for the subgroup comparison = 4.51, P = 0.03.
- 3. Routine use of EFM: in three trials (n = 7740) EFM was routine; RR 0.97, 95% CI 0.84 to 1.11. In three trials (n = 729) EFM was not routine; RR 0.48, 95% CI 0.21 to 1.12. In one trial (n = 428), it is not known whether EFM was routine; RR 1.98, 95% CI 0.76 to 5.18. Chi<sup>2</sup> for the subgroup comparison = 4.76, P = 0.09.
- 4. Provider characteristics: in three trials (n = 7428), the support was provided by a member of the hospital staff; RR 0.99, 95% CI 0.84, 1.17. In two trials (n = 829), the support was provided by a woman who was not a member of the hospital staff and not part of the woman's social network; RR 0.86, 95% CI 0.66 to 1.12. In two trials (n = 640) the support was provided by a member of the woman's social network; RR 1.40, 95% CI 0.67 to 2.93. Chi² for the subgroup comparison = 1.74, P = 0.42. Thus the effectiveness of continuous support in reducing the likelihood of admission of the newborn to a special care nursery appeared to be stronger in settings in which epidural analgesia was not routinely available, but effectiveness did not appear to be influenced by policies about companions or routine EFM, or by provider characteristics.

# Outcome: negatives ratings of/negative views about the birth experience

1. Policies about companions: in five trials (n = 8639) companions were permitted; RR 0.70, 95% CI 0.62 to 0.78. In six trials (n = 2539) companions were not permitted; RR 0.62, 95%CI 0.56 to 0.69. Chi<sup>2</sup> for the subgroup comparison = 2.03, P = 0.15.

- 2. Availability of epidural analgesia: in nine trials (n = 10,404) epidural analgesia was routinely available; RR 0.70, 95% CI 0.64 to 0.77. In two trials (n = 774) epidural analgesia was not routinely available; RR 0.55, 95% CI 0.48 to 0.63. Chi<sup>2</sup> for the subgroup comparison = 7.92, P 0.0005.
- 3. Routine use of EFM: four trials (n = 7467) were conducted in settings with routine EFM; RR 0.67, 95% CI 0.60 to 0.76. Four trials (n = 1710) were conducted in settings in which EFM was not routine; RR 0.60, 95% CI 0.53 to 0.68. Three trials (n = 1977) were in settings in which the use of routine EFM is not known; RR 0.84, 95% CI 0.65 to 1.08.  $\text{Chi}^2$  for the subgroup comparison = 5.55, P = 0.06.
- 4. Provider characteristics: in four trials (n = 8145) support providers were hospital staff; RR 0.87, 95% CI 0.73 to 1.03. In three trials (n = 1325) the providers were not hospital staff and not part of the woman's social network; RR 0.66, 95% CI 0.57 to 0.77. In four trials (n = 1708), providers were part of the woman's social network; RR 0.57, 95% CI 0.51 to 0.64. Chi² for the subgroup comparison = 16.47, P = 0.0003.

Thus the effectiveness of continuous support in reducing the likelihood of dissatisfaction with or negative views of the childbirth experience appeared to be stronger in settings in which epidural analysesia was not routinely available, and when the provider was neither a staff member nor part of the woman's social network.

## DISCUSSION

This Review summarizes results of 21 trials involving 15,061 women, conducted in 15 countries under a wide variety of circumstances. Continuous one-to-one support was given by providers with a variety of experiences, through having given birth themselves and/or through education and practice as nurses, midwives, doulas or childbirth educators, or by the woman's husband or partner, female relative or close friend. The methodological quality of the trials was generally good to excellent. Much of the heterogeneity in the trials appears to be due to wide variations in the size of the trials; comparisons of fixed-effect and random-effects analyses did not yield material differences in the results. Thus neither the risk of bias nor heterogeneity should be of concern when interpreting results.

In the primary comparison, women who were allocated to continuous one-to-one support were more likely to have a spontaneous vaginal birth (RR 1.08, 95% CI 1.04 to 1.12) and less likely to have intrapartum analgesia (RR 0.90, 95% CI 0.84 to 0.97) or to report dissatisfaction (RR 0.69, 95% CI 0.59 to 0.79). In addition their labours were shorter (mean difference -0.58 hours, 95% CI -0.86 to -0.30), they were less likely to have a caesarean (RR 0.79, 95% CI 0.67 to 0.92) or instrumental vaginal birth (RR 0.90, 95% CI 0.84 to 0.96), regional analgesia (RR 0.93, 95% CI 0.88 to 0.99), or a baby with a low five-minute Apgar

score (RR 0.70, 95% CI 0.50 to 0.96). The trial reports do not list any adverse effects. This form of care appears to confer important benefits without attendant risks. The results of earlier versions of this Review prompted organizations in Canada, the UK and the USA to issue practice guidelines, advocating continuous support (AWHONN 2002; NICE Intrapartum Care 2007; MIDIRS 1999; SOGC 1995). The results of the primary comparison in the current Review offer continued justification for such practice guidelines.

The subgroup analyses should be interpreted with caution. Individually each should be considered exploratory and hypothesis-generating, particularly when the sample size in one subgroup was much smaller than in another. However, taken in their totality, the consistency of the patterns suggests that the effectiveness of continuous intrapartum support may be enhanced or reduced by policies and practices in the birth setting and by the nature of the relationship between the provider and labouring woman.

We chose three aspects of the birth environment - routine use of electronic fetal monitoring, availability of epidural analgesia and policies about the presence of additional support people of the woman's own choosing - as proxies for environmental conditions that may mediate the effectiveness of labour support. This Review cannot answer questions about the mechanisms whereby settings with epidural analgesia limit the effectiveness of labour support. The impact of epidural analgesia may be direct (Anim-Somuah 2005) or indirect, as part of the 'cascade of interventions' described in the Background. The effects of a policy of routine EFM are less clear, most likely because we were unable to obtain information about EFM policies for several of the trials. However continuous labour support in settings without routine EFM was associated with greater likelihood of spontaneous vaginal birth and lower likelihood of a caesarean birth. These results raise questions about the ability of labour support to act as a buffer against adverse aspects of routine medical interventions. Labour support appears to be effective in reducing the adverse consequences of the fear and distress associated with labouring alone in an unfamiliar environment. A report of a qualitative component of one of the included trials (Langer 1998), aptly titled "Alone, I wouldn't have known what to do", provides further justification for this argument.

Effects of continuous labour support appear to vary by provider characteristics. Divided loyalties, additional duties besides labour support, self-selection and the constraints of institutional policies and routine practices may all have played a role in the apparently limited effectiveness of members of the hospital staff. Childbirth environments influence the healthcare professionals who work in them as well as labouring women and their support people. Furthermore, while women want and benefit from the presence of selected members of their social network, the support of partners and others with whom they have a longstanding relationship is qualitatively different and more complex than that of a woman who is experienced and often trained to provide labour support

and who has no other role other than to provide it. An early trial of labour support with partners present found that women received more support from their partners when a doula was present to guide them, and the partners themselves reported more support (Hodnett 1989). While continuous labour support appears to be more effective when it is provided by caregivers who are not employees of an institution (and thus have no obligation to anyone other than the labouring woman) and who have an exclusive focus on this task, the trials of husband/partner/relative/friend support in this update to the Review demonstrate that support from a member of the woman's social network is also effective in improving women's satisfaction with their birth experiences.

There remains relatively little information about the effects of continuous intrapartum support on mothers' and babies' health and well-being in the postpartum period.

#### AUTHORS' CONCLUSIONS

## Implications for practice

Continuous support during labour should be the norm, rather than the exception. Hospitals should permit and encourage women to have a companion of their choice during labour and birth, and hospitals should implement programs to offer continuous support during labour. Policy makers and hospital administrators in high-income countries who wish to effect clinically important reductions in inappropriately high caesarean rates should be cautioned that continuous support by nurses or midwives may not achieve this goal, in the absence of other changes to policies and routines. In many settings, the labour ward functions according to a risk-oriented, technology-dominated approach to care. Institutional staff are unlikely to be able to offer labouring women benefits comparable to non-staff members, in the absence of fundamental changes in the organization and delivery of maternity care. Changes to the content of health professionals' education and to the core identity of professionals may also be important. Policy makers and administrators must look at system reform and rigorous attention to evidence-based use of interventions that were originally developed to diagnose or treat problems and are now used routinely during normal labours. Given the clear benefits and absence of adverse effects of continuous labour support, policy makers should consider including it as a covered service for all women

Every effort should be made to ensure that women's birth environments are empowering, non-stressful, afford privacy, communicate respect and are not characterized by routine interventions that add risk without clear benefit. In most areas of the world, childbearing women have limited or no access to trained doulas. Where available, costs of doula services are frequently borne by childbearing families and may be a barrier to access. In areas where doulas are not available, a comprehensive guidebook for designation.

nated companions is available for those with good English literacy (Simkin 2007). The 'Better Births Initiative' is a structured motivational program which promotes humane, evidence-based care during labour. The program focuses on promoting labour companionship and avoiding unproven interventions such as routine starvation, supine position and routine episiotomy. The educational materials for the Better Births Initiative include a video presentation on childbirth companions which is available in the World Health Organization Reproductive Health Library (WHO 2010). It can be accessed free of charge on the internet in Arabic, Chinese, French, English, Spanish, Russian and Vietnamese and is distributed on CD to health workers in resource-poor countries. The selection of Cochrane Reviews in the Reproductive Health Library includes this Review of continuous labour support.

#### Implications for research

There remains relatively little information about the effects of continuous intrapartum support on mothers' and babies' health and well-being in the postpartum period, and thus trials across all types of settings, which include a focus on longer-term outcomes for mother and baby, would be helpful. The trials in resource-constrained countries were relatively small, and additional, large trials may be required in such settings, where the cost of providing continuous support may compete with other resource priorities. Particular attention should be paid to outcomes that have

been under-researched in resource-poor settings, but are causes of significant morbidity, including urinary and faecal incontinence, pain during intercourse, prolonged perineal pain and depression.

Trials of different models of training providers of labour support would help to inform decision makers about the most effective models in the context of their settings. All trials should include economic analyses of the relative costs and benefits.

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\* Indicates the major publication for the study

# CHARACTERISTICS OF STUDIES

# Characteristics of included studies [ordered by study ID]

# Breart - Belgium 1992

| Methods   | RCT   |   |  |  |  |  |  |  |  |
|---|---|---|--|--|--|--|--|--|--|
| Participants                                    | 3 trials are reported separately, within 1 publication. Participants were nulliparous, healthy, in spontaneous labour, term, with singleton vertex presentations. Trial in Belgium: n = 264 (133 permanent support; 131 control). |   |  |  |  |  |  |  |  |
| Interventions                                   | Permanent presence of a midwife compared to varying degrees of presence. Fathers were allowed to be present.  |   |  |  |  |  |  |  |  |
| Outcomes  | Oxytocin, epidural analgesia, labour length, mode of birth, Apgar scores, mothers' views of their experiences.  |   |  |  |  |  |  |  |  |
| Notes   | Epidural analgesia was available and it is not known whether electronic fetal monitoring was used routinely.  |   |  |  |  |  |  |  |  |
| Risk of bias                                    |   |   |  |  |  |  |  |  |  |
| Bias  | Authors' judgement  | Support for judgement   |  |  |  |  |  |  |  |
| Adequate sequence generation?                   | Unclear risk  | Women were 'randomly assigned'. The envelopes were prepared by the coordinating centre. No mention of the process of sequence generation.   |  |  |  |  |  |  |  |
| Allocation concealment?                         | Unclear risk  | Sealed envelopes. No mention if they were opaque or consecutively numbered. The process of how the envelopes were opened was not described. |  |  |  |  |  |  |  |
| Blinding?<br>All outcomes                       | Unclear risk  | No details given.   |  |  |  |  |  |  |  |
| Incomplete outcome data addressed? All outcomes | Low risk  | Completion rate for medical record data and in-hospital questionnaire were 99.2% and 91.0% respectively.                                    |  |  |  |  |  |  |  |
| Free of selective reporting?                    | Low risk  | All outcomes were reported.   |  |  |  |  |  |  |  |
| Free of other bias?                             | Low risk  | No other sources of bias noted.   |  |  |  |  |  |  |  |

# Breart - France 1992

| Methods       | See Breart - Belgium.   |  |  |  |  |  |  |
|---------------|---|--|--|--|--|--|--|
| Participants  | See Breart - Belgium.  Trial in France: n = 1320 (656 continuous support; 664 control). |  |  |  |  |  |  |
| Interventions | See Breart - Belgium. Fathers were allowed to be present.                               |  |  |  |  |  |  |
| Outcomes      | See Breart - Belgium.   |  |  |  |  |  |  |
| Notes         | Epidural analgesia was available and it is unknown whether EFM was routine.             |  |  |  |  |  |  |

# Risk of bias

| Bias  | Authors' judgement | Support for judgement   |
|---|--------------------|---|
| Adequate sequence generation?                   | Unclear risk       | Women were 'randomly assigned'. The envelopes were prepared by the coordinating centre. No mention of the process of sequence generation.   |
| Allocation concealment?                         | Unclear risk       | Sealed envelopes. No mention if they were opaque or consecutively numbered. The process of how the envelopes were opened was not described.   |
| Blinding?<br>All outcomes                       | Unclear risk       | No details given.   |
| Incomplete outcome data addressed? All outcomes | Low risk           | Completion rate for medical record data and in-hospital questionnaire was > 95%. There were some discrepancies in the total number enrolled. Two reports show 656 in the permanent support group and 664 in the control group for a total of 1320. The table of results in one report shows 654 in the permanent support and 666 in control. The in-hospital questionnaire results are shown for 654 and 664 women (total 1318) but the authors state this is 95% of the sample meaning the total is 1386. The n reported with each outcome was the one used in the data tables in this review. |
| Free of selective reporting?                    | Low risk           | All outcomes were reported.   |
| Free of other bias?                             | Low risk           | No other sources of bias noted.   |

## Breart - Greece 1992

| Methods       | See Breart - Belgium.  |  |  |  |  |  |  |
|---------------|--|--|--|--|--|--|--|
| Participants  | See Breart - Belgium. Trial in Greece: n = 569 (295 permanent support; 274 control). |  |  |  |  |  |  |
| Interventions | See Breart - Belgium. Fathers/family members were not permitted to be present.       |  |  |  |  |  |  |

## Breart - Greece 1992 (Continued)

| Outcomes  | See Breart - Belgium, except that mothers' views were not reported.                                 |   |  |  |  |  |  |  |  |  |
|---|---|---|--|--|--|--|--|--|--|--|
| Notes   | Epidural analgesia was not available. Not stated if electronic fetal monitoring was used routinely. |   |  |  |  |  |  |  |  |  |
| Risk of bias                                    |   |   |  |  |  |  |  |  |  |  |
| Bias  | Authors' judgement  | Support for judgement   |  |  |  |  |  |  |  |  |
| Adequate sequence generation?                   | Unclear risk  | Women were 'randomly assigned'. The envelopes were prepared by the coordinating centre. No mention of the process of sequence generation.   |  |  |  |  |  |  |  |  |
| Allocation concealment?                         | Unclear risk  | Sealed envelopes. No mention if they were opaque or consecutively numbered. The process of how the envelopes were opened was not described. |  |  |  |  |  |  |  |  |
| Blinding?<br>All outcomes                       | Unclear risk  | No details given.   |  |  |  |  |  |  |  |  |
| Incomplete outcome data addressed? All outcomes | Low risk  | Completion rate for medical record data was 97%. No in-hospital questionnaire data were available.  |  |  |  |  |  |  |  |  |
|   |   |   |  |  |  |  |  |  |  |  |

All medical record outcomes were reported.

No other sources of bias noted.

Low risk

Low risk

# Bruggemann 2007

Free of other bias?

Free of selective reporting?

| Methods       | RCT.  |
|---------------|---|
| Participants  | 212 nulliparous women in active labour at term (105 support group, 107 control group) at a University-affiliated hospital in Sao Paulo Brazil. To be eligible a companion of the woman's choosing had to be available. 49.5% of the companions were present at enrolment and the others were phoned and asked to come to the hospital (4 failed to make it before delivery).  |
| Interventions | Support was 'presence of a chosen companion during labour and delivery'. 'The companions received verbal and written information on the activities involved in providing support, expected behaviour when confronted with signs of tiredness, anxiety, concern, crying, screaming and/or the woman's feelings of inability to cope, compliance with regulations and the possibility of requesting information from staff'. in 47.6% of the sample the woman's companion was her partner, for 29.5% it was her mother. The control group received usual care where a companion during labour and delivery was not permitted.  For both groups labour and delivery care was provided 'according to the routine protocol including active management of labour (early amniotomy, use of oxytocin, intermittent electronic fetal monitoring and systematic analgesia)'. |

# Bruggemann 2007 (Continued)

| Outcomes | Satisfaction with labour and delivery, perinatal and breastfeeding outcome in the 12 hours post delivery.   |
|----------|---|
| Notes    | All women in labour at this hospital received epidural analgesia as a routine practice. Therefore we did not include epidural analgesia data in the Review. Electronic fetal monitoring was not used routinely. |

# Risk of bias

| Bias   | Authors' judgement | Support for judgement   |
|--|--------------------|---|
| Adequate sequence generation?                      | Low risk           | "Computer generated sequence of random numbers'.  |
| Allocation concealment?                            | High risk          | 'Individual assignment numbers were all placed in an opaque container to assure the concealment. The eligible women who had agreed to participate selected one of the numbers once, and were therefore allocated to either intervention group or control according to the list.'  This process was open to selection bias as women could have repicked another number from the container. No audit process is possible with this system of randomization. |
| Blinding?<br>All outcomes                          | High risk          | Data collection by author, who knew group allocation.   |
| Incomplete outcome data addressed?<br>All outcomes | Low risk           | Medical record data were collected and in-hospital question-<br>naires were completed for 100% of sample.   |
| Free of selective reporting?                       | Low risk           | All outcomes were reported.   |
| Free of other bias?                                | Low risk           | No other sources of bias noted.   |

# Campbell 2006

| Methods       | RCT.   |
|---------------|--|
| Participants  | 600 nulliparous, low-income, under-insured pregnant women (300 doula group, 300 control group) booked for delivery at a hospital in New Jersey, USA were enrolled between 12 and 38 weeks' gestation. They were considered low risk, with no contraindications to labour and had a female friend or relative willing to act as their lay doula. The doula was in addition to support people of their own choosing. |
| Interventions | Intervention: continuous support by a female friend or relative who had had 2, 2-hour sessions about labour support. The training sessions were conducted for nearly all of the lay caregivers when the participants were 34-36 weeks' gestation. Control group: support people of their own choosing.   |

# Campbell 2006 (Continued)

| Outcomes   | Labour length, epidural analgesia, oxytocin augmentation, cervical dilation at epidural insertion, length of second stage labour, caesarean birth, 1-min Apgar score > 6, 5-min Apgar score > 6. |   |
|--|--|---|
| Notes  | Epidural analgesia was available and electronic fetal monitoring was used routinely.   |   |
| Risk of bias                                       |  |   |
| Bias   | Authors' judgement   | Support for judgement   |
| Adequate sequence generation?                      | Low risk   | 'Computer generated randomization scheme'.  |
| Allocation concealment?                            | Low risk   | Consecutively-numbered, sealed opaque envelopes contained treatment assignmentsAfter obtaining consent, a research assistant opened the next envelope. It was unclear whether the research assistant enrolling the woman was the same one that opened the envelope.   |
| Blinding?<br>All outcomes                          | High risk  | Medical record abstraction was done by the author who was not blinded. The six-week questionnaire data collection was not blinded.  |
| Incomplete outcome data addressed?<br>All outcomes | High risk  | Medical record information was completed for 97.7% of the sample (82.3% in the intervention group and 94.3% in the control group). The differential rates are due to withdrawals from the intervention group for doula related reasons (incomplete training and not being present during labour). The 6-week questionnaire was completed for 82.3% of the sample. Only those women included in the study at delivery had the opportunity to complete the questionnaire and thus the differential completion rate between groups remained (76.3% in the intervention group and 88.3% in the control group). The differential withdrawals could introduce selection bias. |
| Free of selective reporting?                       | Low risk   | All outcomes were reported.   |
| Free of other bias?                                | Unclear risk   | The training of the doulas giving the intervention was done<br>by the research assistant, who was herself a doula. This same<br>research assistant enrolled all study participants.   |

| Methods      | RCT.  |
|--------------|---|
| Participants | 34 women (primigravidas and multigravidas) at 26-37 weeks' gestation in 2 Texas hospitals (20 to supported group and 14 to usual care). They were in early, uncomplicated preterm labour. |

## Cogan 1988 (Continued)

| Interventions                 | included continuous p<br>tion, and teaching rela | Intervention: support provided by a Lamaze childbirth preparation instructor. Support included continuous presence, acting as a liaison with hospital staff, providing information, and teaching relaxation and breathing measures.  Usual care: intermittent nursing care. Family members allowed to be present. |  |
|-------------------------------|--|---|--|
| Outcomes                      | Fetal distress, caesarea intensive care.         | Fetal distress, caesarean birth, artificial oxytocin, labour length, Apgar scores, neonatal intensive care.   |  |
| Notes                         | Not stated if epidural routinely.                | Not stated if epidural analgesia was available or if electronic fetal monitoring was used routinely.  |  |
| Risk of bias                  |  |   |  |
| Bias                          | Authors' judgement                               | Authors' judgement Support for judgement  |  |
| Adequate sequence generation? | Unclear risk                                     | 'Randomly assigned'. No further details provided.   |  |
| Allocation concealment?       | Unclear risk                                     | Admitting nurse telephoned research assistant to obtain treatment allocation. No details about whether the research assistant had foreknowledge of the treatment allocation scheme.   |  |
|                               |  |   |  |
| Blinding?<br>All outcomes     | Low risk   | Medical record information collected by 'research assistants who did not know the group membership of the women'.   |  |

group, i.e. some women were withdrawn because of an event that occurred *before the support person arrived*. Women in the control group with the same event were not withdrawn. We were able to re-create the original study groups for one outcome only, caesarean birth, and therefore it is included in the analysis table.

No outcomes were stated a priori.

No other sources of bias noted.

## Dickinson 2002

Free of other bias?

Free of selective reporting?

| Methods       | RCT, stratified by induced or spontaneous labour at trial entry.  |
|---------------|---|
| Participants  | 992 nulliparous women at term (499 to continuous support and 493 to control), cephalic fetal presentation, cervical dilatation < 5 cm, in a hospital in Perth, Western Australia. |
| Interventions | Group 1: continuous physical and emotional support by midwifery staff, and women were encouraged to use pharmacologic and nonpharmacologic alternatives to epidural analgesia.    |

Unclear risk

Low risk

## Dickinson 2002 (Continued)

|          | Group 2: continuous midwifery support was not provided and women were encouraged to have epidural analgesia as their primary method of pain relief in labour.  |
|----------|--|
| Outcomes | Labour length (expressed as median and interquartile range), epidural analgesia, mode of delivery, 5 min Apgar score < 7, arterial cord pH.  |
| Notes    | The stated purpose was to compare the effects of intrapartum analgesic techniques on labour outcomes. Continuous midwifery support was conceptualized as an analgesic technique. Both groups had access to opioids and nitrous oxide. No data were presented about the number of women who used no pharmacologic analgesia. Because the type of analgesia used was a measure of compliance rather than an outcome, no data on analgesic outcomes are included in this Review.  It was not stated if other support person was allowed. epidural analgesia was available and electronic fetal monitoring was used routinely. |

# Risk of bias

| Bias   | Authors' judgement | Support for judgement   |
|--|--------------------|---|
| Adequate sequence generation?                      | Unclear risk       | No details about how the blocks of treatment allocations were produced.   |
| Allocation concealment?                            | Unclear risk       | Randomization on presentation in the labour and delivery unit, "by selection from a blocked group of eight sealed opaque envelopes, replenished from blocks of 12". No further details about process. |
| Blinding?<br>All outcomes                          | Unclear risk       | Not noted.  |
| Incomplete outcome data addressed?<br>All outcomes | Low risk           | There was 100% follow-up for medical record data and in-hospital survey. A 6-month questionnaire was completed by 64.7% of the sample and these data were not used.                                   |
| Free of selective reporting?                       | Low risk           | All main outcomes were reported. Effects on breastfeeding were not analyzed by treatment group and thus the results could not be included in the review.  |
| Free of other bias?                                | Low risk           | No other sources of bias noted.   |

# Gagnon 1997

| Methods   | RCT.   |  |  |
|---|--|--|--|
| Participants                                    | 413 women admitted to an intrapartum unit at a tertiary care teaching hospital in Montreal, Canada, were randomly allocated to experimental (n = 209) or control (n = 204) groups. All but 3 in the experimental group and 6 in the control group were accompanied by a spouse, relative or friend during labor. All participants were nulliparous, with singleton fetuses, > 37 weeks' gestation, and in labour.  |  |  |
| Interventions                                   | Experimental: one-to-one nursing care from randomization until 1 hour postbirth. Care was provided by on-call nurses who were hired specifically for the study and had received a 30-hour training program and quarterly refresher workshops. The training program included critical reviews of the literature concerning the effects of intrapartum medical and nursing practices, as well as discussions of stress and pain management techniques. The nurse provided the usual nursing care plus physical comfort, emotional support, and instruction on relaxation and coping techniques. The nurse took meal breaks and brief rest breaks.  Women in the comparison group received usual nursing care by the regular unit staff, consisting of intermittent support and monitoring. |  |  |
| Outcomes  | Caesarean birth, caesarean birth for cephalopelvic disproportion or failure to progress, post-randomization artificial oxytocin augmentation, post-randomization analgesia/ anaesthesia, instrumental vaginal delivery (forceps or vacuum extraction), NICU admission, perineal trauma, mean duration of labour post-randomization, postpartum urinary catheterization.  |  |  |
| Notes   | The participants had been admitted to the unit for an average of 5 hours (SD = 4 hours) prior to randomization. 36 women in the experimental group and 41 in the control group had epidural analgesia prior to randomization. 55 women in the experimental group and 45 in the control group had intravenous oxytocin augmentation of labour prior to randomization. Mean duration of labour post-randomization was 9.2 hours (SD = 4.3).  Epidural analgesia was available but it was not stated if electronic fetal monitoring was used routinely.   |  |  |
| Risk of bias                                    |  |  |  |
| Bias  | Authors' judgement   | Support for judgement  |  |
| Adequate sequence generation?                   | Low risk   | 'Randomized using a list of computer generated random numbers'.  |  |
| Allocation concealment?                         | Low risk   | 'Randomized in blocks of eight'. 'Group assignments were placed in sequentially numbered, sealed, opaque envelopes'. |  |
| Blinding?<br>All outcomes                       | High risk  | Data collectors were not blinded as they read nurses notes to collect data.  |  |
| Incomplete outcome data addressed? All outcomes | Low risk   | 100% follow-up.  |  |

# Gagnon 1997 (Continued)

| Free of selective reporting?  | Low risk   | All outcomes were reported.   |
|-------------------------------|--|---|
| Free of other bias?           | Low risk   | No other sources of bias noted.   |
| Hemminki 1990a                |  |   |
| Methods                       | Two RCTs reported in the same publication. The Zelen method was used: only those participants randomized to the experimental group were told the true purpose of the trial and asked for consent. The participants in the control group were told about the study in the introduction letter for the postpartum questionnaire and they were told it was 'a study on factors influencing birth'.                                      |   |
| Participants                  | Healthy nulliparous and parous women in labour at a hospital in Finland. 86 women were enrolled in Trial A. The actual number enrolled to each group was not noted but medical record data were collected for 79 women (41 in the support group and 38 in the control group). These 79 women represented 91.9% of the total sample.  |   |
| Interventions                 | Trial A: in 1987, the intervention was 1:1 support by midwifery students from enrolment until transfer to the postpartum ward. The midwifery students volunteered, were not specially trained in support and responsible for the other routine intrapartum care. The control group 'was cared for according to the normal routine of the midwife and by a medical student, if s(he) was on duty'.  Over 70% of fathers were present. |   |
| Outcomes                      | Labour length, medical interventions, complications (mother and baby), pharmacologic pain relief, method of birth, mothers' evaluations of their experiences.  |   |
| Notes                         | Not stated if epidural analgesia was available or if electronic fetal monitoring was used routinely.   |   |
| Risk of bias                  |  |   |
| Bias                          | Authors' judgement   | Support for judgement   |
| Adequate sequence generation? | Unclear risk   | No mention of how the allocation sequence was produced.   |
| Allocation concealment?       | Unclear risk   | 'Randomization coding was done in blocks of 6 and put into non-transparent envelopes. The envelope was opened at the reception ward when it was decided to transfer mother to labour ward.' It was not stated if the envelopes were consecutively numbered. |
| Blinding?<br>All outcomes     | High risk  | Medical record outcome were collected unblinded.  |

## Hemminki 1990a (Continued)

| Incomplete outcome data addressed?<br>All outcomes | Low risk  | Medical record data were collected on 91.9% of the sample. A questionnaire was administered at 2-3 days postpartum. This was completed by only 70% of the sample and thus the data were not used. |
|--|-----------|---|
| Free of selective reporting?                       | Low risk  | All outcomes were reported.   |
| Free of other bias?                                | High risk | Mothers were told the purpose of the study differentially (see methods for Trial A above).  |

# Hemminki 1990b

| Methods       | See Hemminki 1990a.  |
|---------------|--|
| Participants  | See Hemminki 1990a. 161 women were enrolled in Trial B (81 in the support group and 80 in control).  |
| Interventions | Trial B: in 1988, the intervention was support by a new group of midwifery students. All students were involved in the trial, not just volunteers. The students were permitted to leave their participants to witness other interventions and deliveries. The control group 'was cared for according to the normal routine of the midwife' and by a medical student as enrolment was limited to days when medical students were on duty. Slightly less than 70% of fathers were present. |
| Outcomes      | See Hemminki 1990a.  |
| Notes         | Not stated if epidural analgesia was available or if electronic fetal monitoring was used routinely.   |

# Risk of bias

| ·                             |                    |   |
|-------------------------------|--------------------|---|
| Bias                          | Authors' judgement | Support for judgement   |
| Adequate sequence generation? | Unclear risk       | No details provided.  |
| Allocation concealment?       | Unclear risk       | The block size was reduced from the first study. 'To lessen the frustration resulting from opening a code for a control mother, randomization envelopes contained a maximum of two similar codes in sequence (not told in advance)'. 'Put into nontransparent envelopes'. The envelope was opened in the labour ward. It was not stated if the envelopes were consecutively numbered. |
| Blinding?<br>All outcomes     | High risk          | Medical record outcome were collected unblinded.  |

## Hemminki 1990b (Continued)

| Incomplete outcome data addressed?<br>All outcomes | Low risk  | Medical record data were collected on 100% of the sample. A questionnaire was administered at 2-3 days postpartum and completed by 93.7% of the sample. |
|--|-----------|---|
| Free of selective reporting?                       | Low risk  | All outcomes were reported.   |
| Free of other bias?                                | High risk | Mothers were told the purpose of the study differentially (see methods for Trial A above).  |

## Hodnett 1989

| Methods       | RCT, stratified by type of prenatal classes (Lamaze versus general).  |
|---------------|---|
| Participants  | 145 nulliparous women (72 to support group and 73 to control) in the last trimester of a healthy pregnancy, booked for delivery at a Toronto, Canada, hospital.   |
| Interventions | Support provided by a monitrice (community 'lay' midwife or midwifery apprentice) compared to usual hospital care, defined as the intermittent presence of a nurse. Support described as including physical comfort measures, continuous presence, information, emotional support, and advocacy. The monitrice met with the woman twice in the latter weeks of pregnancy, to discuss her birth plans.  Comparable prenatal attention was provided to the controls.  All but 1 woman also had husbands or partners present during labour. Support began in early labour at home or in hospital and continued through delivery. |
| Outcomes      | Intrapartum interventions, perceived control, method of delivery.   |
| Notes         | Epidural analgesia was available and EFM was used routinely.  |

# Risk of bias

| Bias                          | Authors' judgement | Support for judgement  |
|-------------------------------|--------------------|--|
| Adequate sequence generation? | Low risk           | Computer-generated table of random numbers.  |
| Allocation concealment?       | High risk          | Randomization done over the phone by a third party who had no knowledge of the participant, but used the open table of random numbers  |
| Blinding?<br>All outcomes     | Low risk           | All participants blinded to the intervention. Control participants received prenatal and postpartum support (after the end of data collection); experimental participants received prenatal and intrapartum support. Initial collection of medical record data |

## Hodnett 1989 (Continued)

|   |          | was not blinded. 'Duplicate abstraction was done by a second research assistant blind to the subject's study group assignment, on a random sample of 20 records. Interrater agreement of over 95% was obtained for all categories of intervention and physical outcomes.' In-home interview at 2-4 weeks postpartum was blinded. |
|---|----------|--|
| Incomplete outcome data addressed? All outcomes | Low risk | Method of delivery outcome available on 88.3% of sample. Other outcomes collected on only 71% of the sample and thus not used.   |
| Free of selective reporting?                    | Low risk | All outcomes were reported.  |
| Free of other bias?                             | Low risk | No other sources of bias noted.  |

# Hodnett 2002

| Bias          | Authors' judgement   | Support for judgement |
|---------------|--|-----------------------|
| Risk of bias  |  |                       |
| Notes         | Other support person(s) were allowed, epidural analgesia was available and electronic fetal monitoring was used routinely.   |                       |
| Outcomes      | Intrapartum interventions, method of birth, immediate complications (mother or baby) , complications (mother or baby) in the first 6-8 weeks postpartum, perceived control, postpartum depression, breastfeeding at 6-8 weeks, relationship with partner and with baby, likes and dislikes about birth experience and future preferences for labour support.   |                       |
| Interventions | Experimental: continuous support from staff labour and delivery nurses who had volunteered for and received a 2-day training workshop in labour support. Prior to the trial, the support nurses had opportunities to practice their skills. They also had opportunities to continue learning from each other and the labour support trainer, throughout the trial. The nurses with training were part of the regular staffing complement of the unit and they provided care to the continuous support group but not to the usual care group. Usual care: intermittent support from a nurse who had not received labour support training. |                       |
| Participants  | 6915 nulliparous and parous women in labour at 13 hospitals in the USA and Canada (3454 to continuous labour support and 3461 to usual care). Eligibility criteria: live singleton fetus or twins, no contraindications to labour, in labour. Women were excluded if gestational age was < 34 weeks or if they were so high risk that a 1:1 patient-nurse ratio was medically necessary.   |                       |
| Methods       | Multi-centre RCT with prognostic stratification for parity and hospital.   |                       |

## Hodnett 2002 (Continued)

| Adequate sequence generation?                   | Low risk | Computerized randomization program.   |
|---|----------|---|
| Allocation concealment?                         | Low risk | 'Randomization was centrally controlled with the use of a computerized randomization program at the data coordinating centre, accessible by means of a touch-tone telephone.'               |
| Blinding?<br>All outcomes                       | Low risk | Data collectors were not blinded as they read nurses' notes to collect data about type of nursing care provided. However random chart audits yielded no errors in reporting study outcomes. |
| Incomplete outcome data addressed? All outcomes | Low risk | Medical record data were collected on 100% of the sample. In-hospital questionnaires were completed by 96.4% and 6-8 week questionnaires by 81% of the sample.                              |
| Free of selective reporting?                    | Low risk | All outcomes were reported.   |
| Free of other bias?                             | Low risk | No other sources of bias noted.   |

# Hofmeyr 1991

| Methods       | RCT.   |                       |
|---------------|--|-----------------------|
| Participants  | 189 nulliparous women (92 to support and 97 to control) in active labour at a community hospital serving low-income women in South Africa.   |                       |
| Interventions | Intervention group: support by carefully trained, volunteer lay women, for at least several hours (supporters not expected to remain after dark).  Control group: intermittent care on a busy ward. Husbands/family members were not permitted.  |                       |
| Outcomes      | Intrapartum interventions, method of birth, complications (mother and baby), anxiety, pain, mothers' perceptions of labour, breastfeeding.   |                       |
| Notes         | Epidural analgesia was not available and electronic fetal monitoring was not used routinely. While scores on an instrument measuring postpartum depression were reported in categories of "low", "moderate," and 'high", the authors stated that categorization was not appropriate as a clinical diagnostic definition of depression. To achieve the latter, the change in score must be reported, and these data were not collected. |                       |
| Risk of bias  |  |                       |
| Bias          | Authors' judgement   | Support for judgement |

## Hofmeyr 1991 (Continued)

| Adequate sequence generation?                   | Low risk     | Random.  |
|---|--------------|--|
| Allocation concealment?                         | Unclear risk | "Randomly ordered cards in sealed opaque envelopes". Not stated if consecutively numbered.   |
| Blinding?<br>All outcomes                       | High risk    | Data collectors were not blinded as they asked questions about support received in labour.   |
| Incomplete outcome data addressed? All outcomes | Low risk     | Medical record data were collected on 100% of the sample and questionnaires within 24 hours postpartum were completed by 99%. The 6-week follow-up interviews were completed by 78.8% of the sample, no imbalances existed between groups and thus the data were included in the analysis. At 1-year interviews were complete for 46% of the sample and data from these were not used. Nikodem reported on a larger sample of women with 1-year follow-ups but the completion rate was still only 50% of the original number enrolled. |
| Free of selective reporting?                    | Low risk     | All outcomes were reported.  |
| Free of other bias?                             | Low risk     | No other sources of bias noted.  |

#### Kashanian 2010

| Methods       | RCT.  |
|---------------|---|
| Participants  | 100 nulliparous women at term (50 to support and 50 to routine care) in active labour at a university hospital in Tehran, Iran from March to September 2003.  |
| Interventions | 'Women allocated to the intervention group were shown to an isolated room and were supported by an experienced midwife. The women were free to choose their position, and able to eat and walk about freely. During labor, the midwife explained the process of labor and the importance of body relaxation. Midwife-led support included close physical proximity, touch, and eye contact with the laboring women, and teaching, reassurance, and encouragement. The midwife remained with the woman throughout labor and delivery, and applied warm or cold packs to the woman's back, abdomen, or other parts of the body, as well as performing massage according to each woman's request.  'Women allocated to the routine care group were admitted to the labor ward (where 5-7 women labour in the same room), did not receive continuous support, and followed the routine orders of the ward. They did not have a private room, did not receive one-to-one care,were not permitted food, and did not receive education and explanation about the labor process. The only persons allowed in the delivery room were nurses, midwives, and doctors.' |
| Outcomes      | Duration of labour, caesarean delivery, oxytocin use, Apgar score at 5 minutes  |

#### Kashanian 2010 (Continued)

| Notes   | Electronic fetal monitoring was not used routinely and epidural analgesia was not available.  |   |  |
|---|---|---|--|
| Risk of bias                                    |   |   |  |
| Bias  | Authors' judgement  | Support for judgement   |  |
| Adequate sequence generation?                   | Low risk  | From personal communication - equal numbers of envelopes were produced for each letter (see below) and put into a box. No list of treatment allocations was created.  |  |
| Allocation concealment?                         | High risk   | 'Allocated to one of two groups using 4-part, block randomization'. Used 'sealed envelopes labelled A, B, C, and D: envelopes A and C (intervention group) and B and D (routine care group). Patients then chose an envelope, which was opened by the investigator'.  Further details from personal communication - the women picked from all the envelopes produced. Once an envelope was picked it was discarded.  This process was open to selection bias as women previously in the trial may have shared knowledge of which envelope contained which group with women not yet enrolled in the study. |  |
| Blinding?<br>All outcomes                       | Low risk  | From personal communication - 'The co worker of investigator collected the outcome data and she was blind for the study group.'   |  |
| Incomplete outcome data addressed? All outcomes | Low risk  | Medical record information was collected on 100% of the sample.   |  |
| Free of selective reporting?                    | Low risk  | All outcomes were reported.   |  |
| Free of other bias?                             | Low risk  | No other sources of bias noted.   |  |
| Kennell 1991                                    |   |   |  |
| Methods   | RCT of continuous support vs usual care with an 'inconspicuous observer' plus a retrospective non-random control group. This review is restricted to comparisons of the outcomes of the participants who were randomly assigned.  |   |  |
| Participants                                    | 412 nulliparous women (212 in support group and 200 in observed group) were part of the RCT. They were aged 13-34, with singleton, term, healthy pregnancies, many not English-speaking, in active labour at a public hospital in Texas which provides care for low-income patients . |   |  |
| Interventions                                   | The description of the setting, the participants, and the type of care echo developing world conditions. All women laboured in a large 12-bed room. For the women in the support group a doula stayed by their bedside and gave continuous  |   |  |

#### Kennell 1991 (Continued)

|          | support. For those in the observed group they had the routine intermittent presence of a nurse and continuous presence of an 'inconspicuous observer' who 'kept a record of staff contact, interaction and procedures'. The observer was away from the beside and never spoke to the labouring woman.   |
|----------|---|
| Outcomes | Analgesia/anaesthesia, labour length, artificial oxytocin use, method of birth, complications (mother and baby), neonatal health, number of women who rated their experience as negative.   |
| Notes    | In instances in which outcome data (such as analgesia/anaesthesia use) in the published report were only provided for subgroups, the primary author was contacted and he provided complete outcome data for all women who were originally randomized. Family members were not allowed to be present. Epidural analgesia was available and electronic fetal monitoring was used routinely. |

| Bias  | Authors' judgement | Support for judgement  |
|---|--------------------|--|
| Adequate sequence generation?                   | Unclear risk       | Described as random.   |
| Allocation concealment?                         | Low risk           | 'Randomly assigned' is stated in the report. In the protocol for the trial it states 'numbered opaque envelopes' would be used. The envelopes 'would contain the random assignments of the women to control or treatment groups and would be numbered sequentially'.   |
| Blinding?<br>All outcomes                       | Unclear risk       | Not stated.  |
| Incomplete outcome data addressed? All outcomes | Low risk           | There is some discrepancy in the number of women enrolled in the study. The report states 412 were enrolled and reports outcome data on all 412 women. But it also states that '14 women that agreed to participate were not included in the study.' The reasons for not including them seem to be events that would happen after randomization - e.g. transferred due to staffing limitations, withdrew, undetected breech, interrupted observations, etc., and thus the sample appears to have numbered 426. Data are reported for 412 women (96.7% of 426). |
| Free of selective reporting?                    | Low risk           | All outcomes were reported.  |

#### Kennell 1991 (Continued)

| Free of other bias?                             | Low risk   | No other sources of bias noted.  |  |
|---|--|--|--|
| Klaus 1986                                      |  |  |  |
| Methods   | RCT. Purposefully enrolled more wor below.   | RCT. Purposefully enrolled more women to the control group. See risk of bias table below.  |  |
| Participants                                    |  | 465 healthy nulliparous women (186 to support group and 279 to control) in labour at the Social Security Hospital in Guatemala.  |  |
| Interventions                                   |  | Support group: continuous emotional and physical support by a doula.  Control group: usual hospital routines (described as no consistent support).   |  |
| Outcomes  | Labour length, use of artificial oxytocial birth, fetal distress, Apgar scores, transfer | n, method of birth, problems during labour and fer to neonatal intensive care nursery.   |  |
| Notes   | No family members permitted to be pelectronic fetal monitoring was not use               | present. epidural analgesia was not available and ed routinely.  |  |
| Risk of bias                                    |  |  |  |
| Bias  | Authors' judgement   | Support for judgement  |  |
| Adequate sequence generation?                   | Unclear risk   | 'Enrolled using randomised design'. 'Pool of envelopes contained more control group to ensure similar sized groups with uncomplicated labours and deliveries.' They anticipated more complications in control group based on an earlier study (Sosa 1980). No information on how allocation sequence was generated.  |  |
| Allocation concealment?                         | Low risk   | 'Randomly assigned according to contents of a sealed opaque envelope. Each envelope was numbered sequentially.'  |  |
| Blinding?<br>All outcomes                       | Unclear risk   | Not noted.   |  |
| Incomplete outcome data addressed? All outcomes | Low risk   | 'Mother-infant pairs were excluded when the mother developed a complication during labour, delivery, or post partum that required special care, if the baby's weight was below 5.5 lbs or above 8 lbs, if there were twins or congenital malformations.' This occurred for about 10% of cases in both groups resulting in reported outcomes for 89.6% of those randomized. Unpublished |  |

#### Klaus 1986 (Continued)

|                              |          | data on the excluded women were provided<br>by the author.<br>Labour length data were only available for<br>48.4% of the sample (225 of 465) and thus<br>not included. |
|------------------------------|----------|--|
| Free of selective reporting? | Low risk | All outcomes were reported on.   |
| Free of other bias?          | Low risk | No other sources of bias noted.  |

## Langer 1998

| Methods       | RCT.   |
|---------------|--|
| Participants  | 724 women (361 to support and 363 to control) admitted for delivery at a large social security hospital in Mexico City, who met the following criteria: singleton fetus, no previous vaginal delivery, < 6 cm cervical dilatation, and no indications for an elective caesarean delivery.  |
| Interventions | Support group: continuous support from 1 of 10 women who had received doula training (6 were retired nurses), throughout labour, birth, and the immediate postpartum period. Support included: emotional support, information, physical comfort measures, social communication, ensuring immediate contact between mother and baby after birth, and offering advice about breastfeeding during a single brief session postnatally. Control group: women received 'routine care'. |
| Outcomes      | The main outcomes were exclusive and full breastfeeding at 1 month postpartum. Other outcomes included labour length, epidural anaesthesia, forceps birth, caesarean birth, meconium staining, and Apgar scores, as well as mothers' perceived control during childbirth, anxiety, pain, satisfaction, and self-esteem.  |
| Notes         | Partners and family members were not permitted. Epidural analgesia was available but it was not stated if electronic fetal monitoring was used routinely.  |

| Bias                          | Authors' judgement | Support for judgement  |
|-------------------------------|--------------------|--|
| Adequate sequence generation? | Low risk           | 'Computer generated random number list'. 'The treatment sequence was kept at a central level.'   |
| Allocation concealment?       | Unclear risk       | 'Opaque envelopes with the assignment were locked in a cabinet to which only a social worker exclusively in charge of randomisation and the principal investigator had access. An envelope with a paper inside showing to which group each woman was assigned was opened by the social worker immediately after recruitment in the labour and delivery unit. Not stated if envelopes were sequentially numbered. |

## Langer 1998 (Continued)

| Blinding?<br>All outcomes                          | Low risk | Data were collected by 2 'blinded social workers'.   |
|--|----------|--|
| Incomplete outcome data addressed?<br>All outcomes | Low risk | Medical record data and in-hospital interview data were collected for 100% of the sample. A in-home interview was completed at one month postpartum for 92.2% of the sample. |
| Free of selective reporting?                       | Low risk | All outcomes were reported.  |
| Free of other bias?                                | Low risk | No other sources of bias noted.  |

## Madi 1999

| 109 Black women from Botswana (53 in support group and 56 in usual care group) , mean age 19 years, 80% unmarried, mostly students, who had met the following criteria: nulliparous, in labour, pregnancy at term, no history of pregnancy complications, cephalic presentation, normal spontaneous labour with cervical dilation 1-6 cm, female relative present who was willing to remain with the woman for the duration of labour. |
|--|
| Support group: continuous presence of female relative (usually her mother) in addition to usual hospital care  Congrol group: usual hospital care, which involved staff:patient ratios of 1:4, and no companions permitted during labour.  |
| Spontaneous vaginal birth, vacuum extraction, caesarean birth, analgesia, amniotomy, artificial oxytocin during labour, Apgar scores (1- and 5-min).   |
| Epidural analgesia was not available and it was not stated whether electronic fetal monitoring was used routinely.   |
|  |

| Bias                          | Authors' judgement | Support for judgement  |
|-------------------------------|--------------------|--|
| Adequate sequence generation? | Unclear risk       | 'Randomly allocated.' No other details provided.   |
| Allocation concealment?       | Low risk           | 'Selection of an opaque, numbered, sealed envelope from a box of envelopes that were shuffled in the woman's presence. When opened the envelope revealed a code indicating her group.' An assistant that was not involved in the recruitment process shuffled the envelopes. |
| Blinding?<br>All outcomes     | High risk          | The researcher, who was involved in the recruitment of participants, collected the medical record data.  |

#### Madi 1999 (Continued)

| Incomplete outcome data addressed? All outcomes | Low risk | Medical record data were collected on 100% of the sample. |
|---|----------|---|
| Free of selective reporting?                    | Low risk | All outcomes were reported.                               |
| Free of other bias?                             | Low risk | No other sources of bias noted.                           |

## McGrath 2008

| Methods       | RCT. Enrollment occurred at childbirth education classes and randomization occurred when the woman arrived at hospital in labour.   |
|---------------|---|
| Participants  | 420 nulliparous middle and upper class women (224 on doula group and 196 in control group) were enrolled in the third trimester of an uncomplicated pregnancy in Cleveland, Ohio. All women expected to be accompanied during labor by their male partner.  |
| Interventions | Experimental group: A doula met the couple at the hospital as soon as possible after random assignment (typically within an hour of their arrival at the hospital) and remained with them throughout labor and delivery. The central component of doula support was the doula's continuous bedside presence during labor and delivery, although her specific activities were individualized to the needs of the labouring woman. Doula support included close physical proximity, touch, and eye contact with the labouring woman, and teaching, reassurance, and encouragement of the woman and her male partner. All doulas completed training requirements that were equivalent to the DONA International doula certification.  Control group: routine obstetric and nursing care which included the presence of a male partner or other support person. |
| Outcomes      | Caesarean delivery, epidural anaesthesia, oxytocin use, labour length, mode of delivery, fever during labour, satisfaction at 6 weeks postpartum.   |
| Notes         | Epidural analgesia was available and electronic fetal monitoring was used routinely. The author has been contacted for data split by study group and questionnaire data for the control group.  |

| Bias                          | Authors' judgement | Support for judgement  |
|-------------------------------|--------------------|--|
| Adequate sequence generation? | Unclear risk       | No details stated.   |
| Allocation concealment?       | Low risk           | 'When the research coordinator was informed that an enrolled woman had arrived at the hospital in early active labor, she opened the next sequentially numbered opaque envelope to determine random assignment to the doula or control group'. |

#### McGrath 2008 (Continued)

|   |              | The research coordinator was off-site and called by the staff or the study participant.   |
|---|--------------|---|
| Blinding?<br>All outcomes                       | Unclear risk | Not stated.   |
| Incomplete outcome data addressed? All outcomes | Low risk     | Medical record data were collected on 100% of the sample. The in-hospital and 6-week questionnaires were completed by 87.9% and 87.5% of the doula group. No information was provided for the control group.  |
| Free of selective reporting?                    | Low risk     | The primary outcomes of caesarean birth and epidural anaesthesia were reported for each study group. Other labour and delivery outcomes were reported for the full sample only (not split by group). The in-hospital and 6-week questionnaire data were only reported for the doula group. The author has been contacted for these missing details. |
| Free of other bias?                             | Low risk     | No other sources of bias noted.   |

## Morhason-Bello 2009

| Methods       | RCT.   |
|---------------|--|
| Participants  | 603 women from Ibadan, Nigeria with anticipated vaginal delivery were enrolled between 30 and 32 weeks' gestation at an antenatal clinic (305 to intervention and 298 to control) from November 2006 to March 2007.  |
| Interventions | Those in the experimental group were informed to bring someone of their choice to act as a companion during labour. On arrival in labour the accompanying companions were provided with an information leaflet that explained their responsibilities. These included: gentle massage of the woman's back during contraction, reassuring words, spiritual support inform of prayers and also acting as intermediary between the woman and healthcare team. After studying the leaflets, they were allowed to seek clarifications. The information leaflet was also interpreted for those that are not literate. The attending midwife allowed and ensured companions performed their expected duties throughout. The companions were told to offer continuous support - they were to be by the patient's side except for feeding and use of toilet until two hours after childbirth. Husbands were the most common support person (65.4%).  The women in the control group had only routine care where relatives of patients are usually barred from the labour ward. |

#### Morhason-Bello 2009 (Continued)

| Outcomes | Caesarean section rate, active phase of labour duration, pain score, need for analgesia, need for oxytocin augmentation, time from delivery to initiation of breastfeeding and the emotional experience during labour.  |
|----------|---|
| Notes    | Epidural analgesia was not available and it was not stated whether electronic fetal monitoring was used routinely. We have requested further details from the authors. The randomization process was well done, but resulted in an imbalance in socioeconomic status between the groups. Women in the experimental group tended to be more educated (82% vs 48% with tertiary level) and skilled workers (78% vs 39%). This imbalance was noted and discussed by the authors. |

| Bias  | Authors' judgement | Support for judgement  |
|---|--------------------|--|
| Adequate sequence generation?                   | Low risk           | 'The randomisation sequence was generated using a table of random numbers'.  |
| Allocation concealment?                         | Low risk           | 'Random permuted blocks of size four were used to ensure a balanced design.' 'Based on the sequence of treatments generated using this method, treatment groups (A and B) were written on pieces of cardboard paper and put into sealed opaque envelopes. Each of the opaque envelopes had a serial number on it.' 'Two trained research assistants (RAs) non-medical staff, supervised the randomisation procedure at every clinic. On each clinic day, consented women that met the inclusion criteria were given serial numbers with allotted treatment group based on their arrival time. Only the statistician and RAs had access to the list of numbers used to prevent clinicians' influence on the randomisation. Each participant opened the opaque envelope in the presence of an RA, and the assigned treatment group was recorded on the woman's medical record file.' |
| Blinding?<br>All outcomes                       | High risk          | How data collection was done was not noted. The treatment group was noted in the chart so it is likely that the data collectors were unblinded.  |
| Incomplete outcome data addressed? All outcomes | Low risk           | Follow up was completed for 97% of the sample.   |
| Free of selective reporting?                    | Low risk           | All outcomes were reported.  |
| Free of other bias?                             | Low risk           | No other sources of bias noted.  |

#### Thomassen 2003

| Methods       | RCT, no details regarding method of random assignment.  |
|---------------|---|
| Participants  | 144 'healthy' women having their first baby booked for delivery at a Swedish hospital (72 to doula group and 72 to usual care). Participants were enrolled at 36 weeks' gestation.  |
| Interventions | Continuous presence by a doula who had met the woman during pregnancy, compared to usual care.  |
| Outcomes      | Emergency caesarean birth and epidural analgesia.   |
| Notes         | The trial author reported that the information about randomization method and outcomes of those lost to follow-up are no longer available.  Epidural analgesia was available. It was not stated if other support person(s) were allowed or if electronic fetal monitoring was used routinely. |

| Bias  | Authors' judgement | Support for judgement  |
|---|--------------------|--|
| Adequate sequence generation?                   | Unclear risk       | "Randomized' - no further details provided or available.   |
| Allocation concealment?                         | Unclear risk       | No details provided or obtained.   |
| Blinding?<br>All outcomes                       | Unclear risk       | Not noted.   |
| Incomplete outcome data addressed? All outcomes | High risk          | Medical record data collected on 70.1% of sample. No usable outcome data, due to serious risk of attrition bias. Outcomes are reported for 55/72 (76%) of the intervention group and 46/72 (64%) of the control group. Reason for the 41 "dropouts" were preterm birth, induction, or caesarean section "for medical reasons", and participant withdrawal. No numbers are given for individual reasons, or by group, but it is clear that some "dropouts" were prior to labour and others were during labour. Numbers in the report show the number of dropouts was actually 43. |
| Free of selective reporting?                    | Unclear risk       | Sample size was based on caesarean section rate. The only outcome reported was emergency caesarean.  |
| Free of other bias?                             | High risk          | Trial was stopped early for 'a range of largely organizational issues' when only 1/4 of the original sample size had been enrolled.  |

## Torres 1999

| Methods  | RCT  | RCT   |  |
|--|--|---|--|
| Participants                                       |  | 435 women (217 in companion group, 218 in control group) with a singleton pregnancy and considered to be low-risk at University Hospital in Santiago, Chile. Enrolled at 34-36 weeks' gestation.  |  |
| Interventions                                      | the pregnant woman. support, promote physwith the activities of th continuously from adr who had experienced a Control group did not | Intervention group: psychosocial support during labour from a companion chosen by the pregnant woman. The companions were trained by trial staff to provide emotional support, promote physical comfort and encourage progress of labor, without interfering with the activities of the obstetricians or midwives. They were with the labouring woman continuously from admission to delivery. Women were encouraged to pick a companion who had experienced a vaginal birth.  Control group did not have companion.  Both groups laboured in a room with other women where curtains were pulled for privacy. |  |
| Outcomes   | oxytocics, presence of 1   | Caesarean section, exclusive breastfeeding, duration of labour, mode of delivery, use of oxytocics, presence of meconium, regional anaesthesia, birth asphyxia, Apgar scores, level of neonatal care, maternal satisfaction.  |  |
| Notes  |  | Epidural analgesia was available. It was not stated if electronic fetal monitoring was used routinely. Authors have been contacted for further details.   |  |
| Risk of bias                                       |  |   |  |
| Bias   | Authors' judgement   | Support for judgement   |  |
| Adequate sequence generation?                      | Low risk   | Computer generated list of random numbers.  |  |
| Allocation concealment?                            | Low risk   | Used blocks of 6. Group assignment used sealed opaque envelopes numbered consecutively. A member of the trial team enrolled women and did not know in advance the content of each envelope.   |  |
| Blinding?<br>All outcomes                          | Unclear risk   | Not stated.   |  |
| Incomplete outcome data addressed?<br>All outcomes | Low risk   | Medcial record data were collected for 100% of the sample and in-hospital surveys were completed by 95.8%. A 6-week phone interview was completed for 71.2% of the sample and thus these data were not used.  |  |
| Free of selective reporting?                       | Low risk   | All outcomes were reported.   |  |
| Free of other bias?                                | Low risk   | No other sources of bias noted.   |  |

EFM: electronic fetal monitoring

min: minutes

NICU: neonatal intensive care unit RCT: randomized controlled trial

SD: standard deviation

vs: versus

# Characteristics of excluded studies [ordered by study ID]

| Study          | Reason for exclusion   |
|----------------|--|
| Bender 1968    | 2 studies are reported, $n = 12$ in the first study and $n = 30$ in the second. Neither one was an RCT. Both employed alternate allocation that was neither centrally controlled nor concealed. The researcher delivered the intervention and collected outcome data. In the first study the researcher also enrolled participants. No usable outcome data are reported.   |
| Bochain 2000   | The intervention was not continuous labour support. It was a short nursing intervention (taking approximately 1 hour) administered in early labour for women undergoing Misoprostol induction.   |
| Brown 2007     | The intervention was not continuous labour support. It was an educational intervention to promote childbirth companions in hospital deliveries. A cluster RCT was done at 10 South African state maternity hospitals.  |
| Dalal 2006     | Not an RCT. 100 randomly-selected mothers who had a birth companion were compared to 50 randomly-selected mothers who did not have one. Mothers were matched for age and socioeconomic status.   |
| Gordon 1999    | 30% of those enrolled were excluded post-randomization, 73/232 in the doula group and 69/246 in the control group. A letter was sent to the first author, asking for data on the excluded participants that would permit an intent-to-treat analysis. If and when a response is received, we will evaluate the trial report again.   |
| Hemminki 1990c | Third study in the same report as Hemminki 1990a and 1990b. This was a small pilot RCT of support by laywoman that was 'stopped for economic and other practical reasons'. 31 women were enrolled but 7 dropped out (all from the intervention group). Very little data were reported and it was not separated by treatment group and thus unusable.   |
| Lindow 1998    | Support was not continuous, and was quite brief in duration. 16 women in active labour were randomized to either 1 hour with a supportive companion or 1 hour without. The only outcome was maternal oxytocin level for 16 minutes post-support or control period.   |
| McGrath 1999   | An abstract outlining a study of 531 women in Houston, Texas. Insufficient details to permit evaluation of the quality of the trial, and insufficient details regarding results. Thus far, attempts to locate a full report of the trial have been unsuccessful.   |
| Orenstein 1998 | Not a randomized trial. Women chose to either have a doula or have Lamaze preparation for childbirth.  |
| Pinheiro 1996  | An abstract of a paper presented at the Xth World Congress of Psychiatry in Madrid, 1996. Preliminary results were reported. Efforts to locate a published report of the full trial have been unsuccessful. The abstract provides insufficient details regarding methods, to permit evaluation of the quality of the trial. The purpose was to compare the effectiveness of female vs male doulas vs routine care without doulas. The doulas were medical and psychology students. |

#### (Continued)

| Ran 2005    | Not an RCT. Translated personal communication from the author stated "I randomly sampling allocated the patient, did not use any random tool".   |
|-------------|--|
| Scott 1999  | Not a trial. A review of selected studies of intrapartum support.  |
| Sosa 1980   | Strong evidence of selection bias. "A woman was removed from the study if labor was false or prolonged; if fetal distress necessitated an intervention such as oxytocin, caesarean delivery, or forceps"; or if the infant was asphyxiated or ill at birth, etc. "If a woman was removed, her group assignment was inserted at random into the pool of unused assignments. Women were enrolled in the study until there were 20 in the control group and 20 in the experimental group." The total study sample of 127 mothers includes 95 in the control group and 32 in the experimental group. Thus assignment was not random. |
| Trueba 2000 | Direct contact with investigator revealed that randomization was not used. On arrival at the hospital, women were asked if they wanted to have a doula. If they accepted, a doula was assigned to them. Also support was not continuous throughout active labour for most women, since admission to the labour ward (and assignment of a doula) did not usually occur until 8 cm.  |
| Tryon 1966  | Not an RCT. "After a random start, the matched groups were alternately assigned to experimental and control groups." Women who developed severe complications in labour (number not specified), such as fetal distress, were dropped from the study.   |
| Zhang 1996  | Not a trial of continuous one-to-one support. On admission to the labour ward, women received instruction about normal labour, non-pharmacological methods to ease pain, and how to push in second stage, from a team of physicians and nurses. Support was continuous, depending on the women's needs, but not one-to-one.  |

EFM: electronic fetal monitoring RCT: randomized controlled trial

vs: versus

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

## Huang 2003

| Methods       |   |
|---------------|---|
| Participants  |   |
| Interventions |   |
| Outcomes      |   |
| Notes         | Communication to author through Chinese Cochrane Centre regarding details of randomization process and information to allow classification for analysis sub groups. |

## DATA AND ANALYSES

Comparison 1. Continuous support versus usual care - all trials

| Outcome or subgroup title                                      | No. of studies | No. of participants | Statistical method                   | Effect size          |
|--|----------------|---------------------|--------------------------------------|----------------------|
| 1 Any analgesia/anaesthesia                                    | 13             | 12169               | Risk Ratio (M-H, Random, 95% CI)     | 0.90 [0.84, 0.97]    |
| 2 Regional analgesia/anaesthesia                               | 9              | 11444               | Risk Ratio (M-H, Random, 95% CI)     | 0.93 [0.88, 0.99]    |
| 3 Synthetic oxytocin during labour                             | 14             | 12506               | Risk Ratio (M-H, Random, 95% CI)     | 0.97 [0.90, 1.04]    |
| 4 Labour length  | 11             | 5269                | Mean Difference (IV, Random, 95% CI) | -0.58 [-0.86, -0.30] |
| 5 Spontaneous vaginal birth                                    | 18             | 14005               | Risk Ratio (M-H, Random, 95% CI)     | 1.08 [1.04, 1.12]    |
| 6 Instrumental vaginal birth                                   | 18             | 14004               | Risk Ratio (M-H, Fixed, 95% CI)      | 0.90 [0.84, 0.96]    |
| 7 Caesarean birth  | 21             | 15061               | Risk Ratio (M-H, Random, 95% CI)     | 0.79 [0.67, 0.92]    |
| 8 Perineal trauma  | 4              | 8120                | Risk Ratio (M-H, Random, 95% CI)     | 0.97 [0.92, 1.01]    |
| 9 Low 5-minute Apgar score                                     | 12             | 12401               | Risk Ratio (M-H, Fixed, 95% CI)      | 0.70 [0.50, 0.96]    |
| 10 Admission to special care nursery                           | 7              | 8897                | Risk Ratio (M-H, Random, 95% CI)     | 0.97 [0.76, 1.25]    |
| 11 Prolonged neonatal hospital stay                            | 3              | 1098                | Risk Ratio (M-H, Random, 95% CI)     | 0.83 [0.42, 1.65]    |
| 12 Postpartum report of severe labour pain                     | 4              | 2456                | Risk Ratio (M-H, Random, 95% CI)     | 1.00 [0.83, 1.21]    |
| 13 Negative rating of/negative feelings about birth experience | 11             | 11133               | Risk Ratio (M-H, Random, 95% CI)     | 0.69 [0.59, 0.79]    |
| 14 Difficulty mothering  | 3              | 6308                | Risk Ratio (M-H, Random, 95% CI)     | 0.60 [0.35, 1.02]    |
| 15 Breastfeeding at 1-2 months postpartum                      | 3              | 5363                | Risk Ratio (M-H, Random, 95% CI)     | 1.01 [0.94, 1.09]    |
| 16 Postpartum depression                                       | 1              | 5567                | Risk Ratio (M-H, Fixed, 95% CI)      | 0.86 [0.73, 1.02]    |
| 17 Low postpartum self-esteem                                  | 1              | 652                 | Risk Ratio (M-H, Fixed, 95% CI)      | 1.00 [0.77, 1.30]    |

Comparison 2. Continuous support versus usual care - policy regarding presence of companion

| Outcome or subgroup title          | No. of studies | No. of participants | Statistical method             | Effect size       |
|------------------------------------|----------------|---------------------|--------------------------------|-------------------|
| 1 Any analgesia/anaesthesia        | 13             |                     | Risk Ratio (IV, Fixed, 95% CI) | Subtotals only    |
| 1.1 Other support permitted        | 7              | 9752                | Risk Ratio (IV, Fixed, 95% CI) | 0.97 [0.96, 0.99] |
| 1.2 Other support not permitted    | 6              | 2484                | Risk Ratio (IV, Fixed, 95% CI) | 0.91 [0.85, 0.96] |
| 2 Synthetic oxytocin during labour | 14             |                     | Risk Ratio (IV, Fixed, 95% CI) | Subtotals only    |
| 2.1 Other support permitted        | 5              | 9495                | Risk Ratio (IV, Fixed, 95% CI) | 1.04 [0.99, 1.10] |
| 2.2 Other support not permitted    | 9              | 3011                | Risk Ratio (IV, Fixed, 95% CI) | 0.99 [0.97, 1.01] |
| 3 Spontaneous vaginal birth        | 18             |                     | Risk Ratio (IV, Fixed, 95% CI) | Subtotals only    |
| 3.1 Other support permitted        | 9              | 10889               | Risk Ratio (IV, Fixed, 95% CI) | 1.03 [1.00, 1.05] |
| 3.2 Other support not permitted    | 9              | 3215                | Risk Ratio (IV, Fixed, 95% CI) | 1.12 [1.07, 1.16] |

| 4 Caesarean birth                   | 21 |       | Risk Ratio (IV, Fixed, 95% CI) | Subtotals only    |
|-------------------------------------|----|-------|--------------------------------|-------------------|
| 4.1 Other support permitted         | 11 | 11326 | Risk Ratio (IV, Fixed, 95% CI) | 0.94 [0.85, 1.03] |
| 4.2 Other support not               | 10 | 3735  | Risk Ratio (IV, Fixed, 95% CI) | 0.75 [0.65, 0.87] |
| permitted                           |    |       |                                |                   |
| 5 Admission to special care nursery | 7  |       | Risk Ratio (IV, Fixed, 95% CI) | Subtotals only    |
| 5.1 Other support permitted         | 2  | 7328  | Risk Ratio (IV, Fixed, 95% CI) | 0.99 [0.84, 1.17] |
| 5.2 Other support not               | 5  | 1569  | Risk Ratio (IV, Fixed, 95% CI) | 0.91 [0.71, 1.17] |
| permitted                           |    |       |                                |                   |
| 6 Postpartum depression             | 1  |       | Risk Ratio (IV, Fixed, 95% CI) | Subtotals only    |
| 6.1 Other support permitted         | 1  | 5567  | Risk Ratio (IV, Fixed, 95% CI) | 0.86 [0.73, 1.02] |
| 6.2 Other support not               | 0  | 0     | Risk Ratio (IV, Fixed, 95% CI) | Not estimable     |
| permitted                           |    |       |                                |                   |
| 7 Negative rating of/negative       | 11 |       | Risk Ratio (IV, Fixed, 95% CI) | Subtotals only    |
| feelings about birth experience     |    |       |                                |                   |
| 7.1 Other support permitted         | 5  | 8639  | Risk Ratio (IV, Fixed, 95% CI) | 0.70 [0.62, 0.78] |
| 7.2 Other support not               | 6  | 2539  | Risk Ratio (IV, Fixed, 95% CI) | 0.62 [0.56, 0.69] |
| permitted                           |    |       |                                |                   |
| 8 Breastfeeding at 1-2 months       | 3  |       | Risk Ratio (IV, Fixed, 95% CI) | Subtotals only    |
| postpartum                          |    |       |                                | ·                 |
| 8.1 Other support permitted         | 1  | 4559  | Risk Ratio (IV, Fixed, 95% CI) | 0.97 [0.92, 1.02] |
| 8.2 Other support not               | 2  | 804   | Risk Ratio (IV, Fixed, 95% CI) | 1.05 [0.98, 1.13] |
| permitted                           |    |       |                                |                   |
|                                     |    |       |                                |                   |

Comparison 3. Continuous support versus usual care - availability of epidural analgesia

| Outcome or subgroup title                      | No. of studies | No. of participants | Statistical method             | Effect size       |
|--|----------------|---------------------|--------------------------------|-------------------|
| 1 Any analgesia/anaesthesia                    | 13             |                     | Risk Ratio (IV, Fixed, 95% CI) | Subtotals only    |
| 1.1 Epidural analgesia routinely available     | 9              | 10888               | Risk Ratio (IV, Fixed, 95% CI) | 0.97 [0.96, 0.98] |
| 1.2 Epidural analgesia not routinely available | 4              | 1348                | Risk Ratio (IV, Fixed, 95% CI) | 0.83 [0.69, 0.99] |
| 2 Synthetic oxytocin during labour             | 14             |                     | Risk Ratio (IV, Fixed, 95% CI) | Subtotals only    |
| 2.1 Epidural analgesia routinely available     | 8              | 10568               | Risk Ratio (IV, Fixed, 95% CI) | 1.00 [0.98, 1.02] |
| 2.2 Epidural analgesia not routinely available | 6              | 1952                | Risk Ratio (IV, Fixed, 95% CI) | 1.02 [0.93, 1.11] |
| 3 Spontaneous vaginal birth                    | 18             |                     | Risk Ratio (IV, Fixed, 95% CI) | Subtotals only    |
| 3.1 Epidural analgesia routinely available     | 13             | 12672               | Risk Ratio (IV, Fixed, 95% CI) | 1.04 [1.01, 1.06] |
| 3.2 Epidural analgesia not routinely available | 5              | 1432                | Risk Ratio (IV, Fixed, 95% CI) | 1.12 [1.06, 1.17] |
| 4 Caesarean birth                              | 21             |                     | Risk Ratio (IV, Fixed, 95% CI) | Subtotals only    |
| 4.1 Epidural analgesia routinely available     | 14             | 13064               | Risk Ratio (IV, Fixed, 95% CI) | 0.93 [0.86, 1.02] |
| 4.2 Epidural analgesia not routinely available | 6              | 1963                | Risk Ratio (IV, Fixed, 95% CI) | 0.52 [0.41, 0.67] |

| 4.3 Unknown availability of epidural analgesia                | 1  | 34    | Risk Ratio (IV, Fixed, 95% CI) | 1.4 [0.14, 13.98] |
|---|----|-------|--------------------------------|-------------------|
| 5 Admission to special care nursery                           | 7  |       | Risk Ratio (IV, Fixed, 95% CI) | Subtotals only    |
| 5.1 Epidural analgesia routinely available                    | 5  | 8380  | Risk Ratio (IV, Fixed, 95% CI) | 0.98 [0.85, 1.13] |
| 5.2 Epidural analgesia not routinely available                | 2  | 517   | Risk Ratio (IV, Fixed, 95% CI) | 0.26 [0.08, 0.88] |
| 6 Postpartum depression                                       | 1  |       | Risk Ratio (IV, Fixed, 95% CI) | Subtotals only    |
| 6.1 Epidural analgesia routinely available                    | 1  | 6915  | Risk Ratio (IV, Fixed, 95% CI) | 0.89 [0.75, 1.05] |
| 6.2 Epidural analgesia not routinely available                | 0  | 0     | Risk Ratio (IV, Fixed, 95% CI) | Not estimable     |
| 7 Negative rating of/negative feelings about birth experience | 11 |       | Risk Ratio (IV, Fixed, 95% CI) | Subtotals only    |
| 7.1 Epidural analgesia routinely available                    | 9  | 10404 | Risk Ratio (IV, Fixed, 95% CI) | 0.70 [0.64, 0.77] |
| 7.2 Epidural analgesia not routinely available                | 2  | 774   | Risk Ratio (IV, Fixed, 95% CI) | 0.55 [0.48, 0.63] |
| 8 Breastfeeding at 1-2 months postpartum                      | 3  |       | Risk Ratio (IV, Fixed, 95% CI) | Subtotals only    |
| 8.1 Epidural analgesia routinely available                    | 2  | 5214  | Risk Ratio (IV, Fixed, 95% CI) | 0.99 [0.95, 1.03] |
| 8.2 Epidural analgesia not routinely available                | 1  | 149   | Risk Ratio (IV, Fixed, 95% CI) | 1.15 [0.95, 1.40] |

Comparison 4. Continuous support versus usual care - policy about routine EFM

| Outcome or subgroup title              | No. of studies | No. of participants | Statistical method             | Effect size       |
|--|----------------|---------------------|--------------------------------|-------------------|
| 1 Any analgesia/anaesthesia            | 13             |                     | Risk Ratio (IV, Fixed, 95% CI) | Subtotals only    |
| 1.1 Setting had routine EFM            | 6              | 8580                | Risk Ratio (IV, Fixed, 95% CI) | 0.97 [0.96, 0.99] |
| 1.2 Setting did not have routine EFM   | 5              | 2072                | Risk Ratio (IV, Fixed, 95% CI) | 0.96 [0.90, 1.03] |
| 1.3 Policy about routine EFM not known | 2              | 1579                | Risk Ratio (IV, Fixed, 95% CI) | 0.89 [0.80, 0.99] |
| 2 Synthetic oxytocin during labour     | 14             |                     | Risk Ratio (IV, Fixed, 95% CI) | Subtotals only    |
| 2.1 Setting had routine EFM            | 4              | 8340                | Risk Ratio (IV, Fixed, 95% CI) | 1.04 [0.98, 1.11] |
| 2.2 Setting did not have routine EFM   | 6              | 1612                | Risk Ratio (IV, Fixed, 95% CI) | 0.99 [0.96, 1.01] |
| 2.3 Policy about routine EFM not known | 4              | 2568                | Risk Ratio (IV, Fixed, 95% CI) | 1.02 [0.97, 1.08] |
| 3 Spontaneous vaginal birth            | 18             |                     | Risk Ratio (IV, Fixed, 95% CI) | Subtotals only    |
| 3.1 Setting had routine EFM            | 8              | 9717                | Risk Ratio (IV, Fixed, 95% CI) | 1.03 [1.01, 1.06] |
| 3.2 Setting did not have routine EFM   | 6              | 1799                | Risk Ratio (IV, Fixed, 95% CI) | 1.12 [1.06, 1.17] |
| 3.3 Policy about routine EFM not known | 4              | 2561                | Risk Ratio (IV, Fixed, 95% CI) | 1.07 [1.01, 1.13] |
| 4 Caesarean birth                      | 21             |                     | Risk Ratio (IV, Fixed, 95% CI) | Subtotals only    |

| 4.1 Setting had routine EFM         | 9  | 10123 | Risk Ratio (IV, Fixed, 95% CI)          | 0.92 [0.83, 1.01]  |
|-------------------------------------|----|-------|---|--------------------|
| 4.2 Setting did not have            | 7  | 2343  | Risk Ratio (IV, Fixed, 95% CI)          | 0.66 [0.55, 0.80]  |
| routine EFM                         | ,  | 25 15 | rusk rutto (11,1 incu, 75/10 Ci)        | 0.00 [0.55, 0.00]  |
| 4.3 Policy about routine EFM        | 5  | 2595  | Risk Ratio (IV, Fixed, 95% CI)          | 1.06 [0.84, 1.33]  |
| not known                           |    | 2,,,, | 14011 141110 (11,1 1111ed, 75,70 G2)    | 1100 [010 1, 1133] |
| 5 Admission to special care nursery | 7  |       | Risk Ratio (IV, Fixed, 95% CI)          | Subtotals only     |
| 5.1 Setting had routine EFM         | 3  | 7740  | Risk Ratio (IV, Fixed, 95% CI)          | 0.97 [0.84, 1.11]  |
| 5.2 Setting did not have            | 3  | 729   | Risk Ratio (IV, Fixed, 95% CI)          | 0.48 [0.21, 1.12]  |
| routine EFM                         |    |       | , , , , , , ,                           |                    |
| 5.3 Policy about routine EFM        | 1  | 428   | Risk Ratio (IV, Fixed, 95% CI)          | 1.98 [0.76, 5.18]  |
| not known                           |    |       | , |                    |
| 6 Postpartum depression             | 1  |       | Risk Ratio (IV, Fixed, 95% CI)          | Subtotals only     |
| 6.1 Setting had routine EFM         | 1  | 6915  | Risk Ratio (IV, Fixed, 95% CI)          | 0.89 [0.75, 1.05]  |
| 6.2 Setting did not have            | 0  | 0     | Risk Ratio (IV, Fixed, 95% CI)          | Not estimable      |
| routine EFM                         |    |       |   |                    |
| 7 Negative rating of /negative      | 11 |       | Risk Ratio (IV, Fixed, 95% CI)          | Subtotals only     |
| views about birth experience        |    |       |   | ·                  |
| 7.1 Setting had routine EFM         | 4  | 7467  | Risk Ratio (IV, Fixed, 95% CI)          | 0.67 [0.60, 0.76]  |
| 7.2 Setting did not have            | 4  | 1710  | Risk Ratio (IV, Fixed, 95% CI)          | 0.60 [0.53, 0.68]  |
| routine EFM                         |    |       |   |                    |
| 7.3 Policy about routine EFM        | 3  | 1977  | Risk Ratio (IV, Fixed, 95% CI)          | 0.84 [0.65, 1.08]  |
| not known                           |    |       |   |                    |
| 8 Breastfeeding at 1-2 months       | 3  |       | Risk Ratio (IV, Fixed, 95% CI)          | Subtotals only     |
| postpartum                          |    |       |   |                    |
| 8.1 Setting had routine EFM         | 1  | 4559  | Risk Ratio (IV, Fixed, 95% CI)          | 0.97 [0.92, 1.02]  |
| 8.2 Setting did not have            | 2  | 804   | Risk Ratio (IV, Fixed, 95% CI)          | 1.05 [0.98, 1.13]  |
| routine EFM                         |    |       |   |                    |

Comparison 5. Continuous support versus usual care - variations in provider characteristics

| Outcome or subgroup title   | No. of studies | No. of participants | Statistical method             | Effect size       |  |
|---|----------------|---------------------|--------------------------------|-------------------|--|
| 1 Any analgesia/anaesthesia   | 13             |                     | Risk Ratio (IV, Fixed, 95% CI) | Subtotals only    |  |
| 1.1 Support people were hospital staff  | 6              | 9152                | Risk Ratio (IV, Fixed, 95% CI) | 0.97 [0.96, 0.99] |  |
| 1.2 Support people were not hospital staff and not chosen                     | 4              | 1790                | Risk Ratio (IV, Fixed, 95% CI) | 0.91 [0.86, 0.97] |  |
| by woman  1.3 Support people were not hospital staff and were chosen by woman | 3              | 1294                | Risk Ratio (IV, Fixed, 95% CI) | 0.94 [0.88, 1.00] |  |
| 2 Synthetic oxytocin during labour  | 14             |                     | Risk Ratio (IV, Fixed, 95% CI) | Subtotals only    |  |
| 2.1 Support people were hospital staff  | 6              | 9561                | Risk Ratio (IV, Fixed, 95% CI) | 1.06 [1.01, 1.11] |  |
| 2.2 Support people were not hospital staff and not chosen by woman            | 3              | 1018                | Risk Ratio (IV, Fixed, 95% CI) | 0.69 [0.50, 0.94] |  |

| 2.3 Support people were not hospital staff and were chosen          | 5   | 1927  | Risk Ratio (IV, Fixed, 95% CI) | 0.99 [0.96, 1.01] |
|---|-----|-------|--------------------------------|-------------------|
| by woman  | 1.0 |       | D' 1 D ' (D/ E' 1 050/ CT)     | 0.1 1 1           |
| 3 Spontaneous vaginal birth   | 18  |       | Risk Ratio (IV, Fixed, 95% CI) | Subtotals only    |
| 3.1 Support people were hospital staff                              | 9   | 10813 | Risk Ratio (IV, Fixed, 95% CI) | 1.03 [1.01, 1.06] |
| 3.2 Support people were not hospital staff and not chosen by woman  | 5   | 1935  | Risk Ratio (IV, Fixed, 95% CI) | 1.12 [1.07, 1.17] |
| 3.3 Support people were not hospital staff and were chosen by woman | 4   | 1356  | Risk Ratio (IV, Fixed, 95% CI) | 1.07 [0.99, 1.15] |
| 4 Caesarean birth   | 21  |       | Risk Ratio (IV, Fixed, 95% CI) | Subtotals only    |
|   |     | 10786 |                                |                   |
| 4.1 Support people were hospital staff                              | 9   |       | Risk Ratio (IV, Fixed, 95% CI) | 0.95 [0.85, 1.05] |
| 4.2 Support people were not hospital staff and not chosen by woman  | 7   | 2330  | Risk Ratio (IV, Fixed, 95% CI) | 0.72 [0.60, 0.86] |
| 4.3 Support people were not hospital staff and were chosen by woman | 5   | 1945  | Risk Ratio (IV, Fixed, 95% CI) | 0.84 [0.69, 1.03] |
| 5 Admission to special care nursery                                 | 7   |       | Risk Ratio (IV, Fixed, 95% CI) | Subtotals only    |
| 5.1 Support people were hospital staff                              | 3   | 7428  | Risk Ratio (IV, Fixed, 95% CI) | 0.99 [0.84, 1.17] |
| 5.2 Support people were not hospital staff and not chosen by woman  | 2   | 829   | Risk Ratio (IV, Fixed, 95% CI) | 0.86 [0.66, 1.12] |
| 5.3 Support people were not hospital staff and were chosen by woman | 2   | 640   | Risk Ratio (IV, Fixed, 95% CI) | 1.40 [0.67, 2.93] |
| 6 Postpartum depression   | 1   |       | Risk Ratio (IV, Fixed, 95% CI) | Subtotals only    |
| 6.1 Support people were hospital staff                              | 1   | 5567  | Risk Ratio (IV, Fixed, 95% CI) | 0.86 [0.73, 1.02] |
| 6.2 Support people were not hospital staff and not chosen by woman  | 0   | 0     | Risk Ratio (IV, Fixed, 95% CI) | Not estimable     |
| 6.3 Support people were not hospital staff and were chosen by woman | 0   | 0     | Risk Ratio (IV, Fixed, 95% CI) | Not estimable     |
| 7 Negative rating of/negative feelings about birth experience       | 11  |       | Risk Ratio (IV, Fixed, 95% CI) | Subtotals only    |
| 7.1 Support people were hospital staff                              | 4   | 8145  | Risk Ratio (IV, Fixed, 95% CI) | 0.87 [0.73, 1.03] |
| 7.2 Support people were not hospital staff and not chosen by woman  | 3   | 1325  | Risk Ratio (IV, Fixed, 95% CI) | 0.66 [0.57, 0.77] |
| 7.3 Support people were not hospital staff and were chosen by woman | 4   | 1708  | Risk Ratio (IV, Fixed, 95% CI) | 0.57 [0.51, 0.64] |
| 8 Breastfeeding at 1-2 months postpartum                            | 3   |       | Risk Ratio (IV, Fixed, 95% CI) | Subtotals only    |

| 8.1 Support people were hospital staff                              | 1 | 4559 | Risk Ratio (IV, Fixed, 95% CI) | 0.97 [0.92, 1.02] |
|---|---|------|--------------------------------|-------------------|
| 8.2 Support people were not hospital staff and not chosen by woman  | 2 | 804  | Risk Ratio (IV, Fixed, 95% CI) | 1.05 [0.98, 1.13] |
| 8.3 Support people were not hospital staff and were chosen by woman | 0 | 0    | Risk Ratio (IV, Fixed, 95% CI) | Not estimable     |

Analysis I.I. Comparison I Continuous support versus usual care - all trials, Outcome I Any analgesia/anaesthesia.

Comparison: I Continuous support versus usual care - all trials

Outcome: I Any analgesia/anaesthesia

| Continuous support<br>n/N         | Usual care<br>n/N   | Risk Ratio<br>M-H,Random,95% CI  | Weight  | Risk Ratio<br>M-H,Random,95% CI          |
|-----------------------------------|---|--|---------|--|
| 84/293                            | 89/292  | -  | 5.2 %   | 0.94 [ 0.73, 1.21 ]                      |
| 247/291                           | 260/295   | -  | 14.0 %  | 0.96 [ 0.90, 1.03 ]                      |
| 3077/3454                         | 3159/3461   | •  | 15.8 %  | 0.98 [ 0.96, 0.99 ]                      |
| 28/53                             | 41/56   |  | 4.0 %   | 0.72 [ 0.53, 0.97 ]                      |
| 295/361                           | 302/363   | •  | 13.8 %  | 0.98 [ 0.92, 1.05 ]                      |
| 141/209                           | 142/204   | +  | 10.1 %  | 0.97 [ 0.85, 1.10 ]                      |
| 55/133                            | 62/128  | -+   | 4.6 %   | 0.85 [ 0.65, 1.12 ]                      |
| 281/652                           | 319/666   | -  | 10.8 %  | 0.90 [ 0.80, 1.01 ]                      |
| 52/92                             | 56/97   | +  | 5.2 %   | 0.98 [ 0.76, 1.25 ]                      |
| 93/212                            | 150/200   | •  | 8.0 %   | 0.58 [ 0.49, 0.69 ]                      |
| 25/41                             | 23/38   | +  | 3.1 %   | 1.01 [ 0.71, 1.44 ]                      |
| 45/81                             | 52/80   | -  | 5.1 %   | 0.85 [ 0.66, 1.10 ]                      |
| 2/168                             | 10/249  | -  | 0.2 %   | 0.30 [ 0.07, 1.34 ]                      |
| 6040                              | 6129  | •  | 100.0 % | 0.90 [ 0.84, 0.97 ]                      |
| support), 4665 (Usual care        | e)  |  |         |  |
| $i^2 = 50.70$ , $df = 12$ (P<0.00 | 0001); I <sup>2</sup> =76%  |  |         |  |
| (P = 0.0032)                      |   |  |         |  |
| (P = 0.0032)                      |   |  |         |  |
| i                                 | n/N<br>84/293<br>247/291<br>3077/3454<br>28/53<br>295/361<br>141/209<br>55/133<br>281/652<br>52/92<br>93/212<br>25/41<br>45/81<br>2/168<br><b>6040</b><br>support), 4665 (Usual care 2 = 50.70, df = 12 (P<0.00 | n/N n/N  84/293 89/292  247/291 260/295  3077/3454 3159/3461  28/53 41/56  295/361 302/363  141/209 142/204  55/133 62/128  281/652 319/666  52/92 56/97  93/212 150/200  25/41 23/38  45/81 52/80  2/168 10/249  6040 6129  support), 4665 (Usual care)  2 = 50.70, df = 12 (P<0.00001); l² = 76% | n/N     | n/N n/N M-H,Random,95% CI  84/293 89/292 |

0.1 0.2 0.5 | 2 5 10 Favours support Favours usual care

Analysis 1.2. Comparison I Continuous support versus usual care - all trials, Outcome 2 Regional analgesia/anaesthesia.

Comparison: I Continuous support versus usual care - all trials

Outcome: 2 Regional analgesia/anaesthesia

| Study or subgroup                         | Continuous support Usual car        |               | Risk Ratio        | Weight  | Risk Ratio          |
|---|-------------------------------------|---------------|-------------------|---------|---------------------|
|   | n/N                                 | n/N           | M-H,Random,95% CI |         | M-H,Random,95% CI   |
| McGrath 2008                              | 145/224                             | 149/196       | -                 | 10.3 %  | 0.85 [ 0.75, 0.96 ] |
| Campbell 2006                             | 247/291                             | 260/295       | -                 | 14.6 %  | 0.96 [ 0.90, 1.03 ] |
| Hodnett 2002                              | 2349/3454                           | 2436/3461     | -                 | 16.6 %  | 0.97 [ 0.94, 1.00 ] |
| Torres 1999                               | 202/217                             | 195/218       | -                 | 15.0 %  | 1.04 [ 0.98, 1.10 ] |
| Langer 1998                               | 295/335                             | 302/346       | +                 | 15.2 %  | 1.01 [ 0.95, 1.07 ] |
| Gagnon 1997                               | 139/209                             | 142/204       |                   | 9.8 %   | 0.96 [ 0.84, 1.09 ] |
| Breart - Belgium 1992                     | 55/133                              | 62/131        |                   | 4.1 %   | 0.87 [ 0.67, 1.15 ] |
| Breart - France 1992                      | 281/652                             | 319/666       |                   | 10.7 %  | 0.90 [ 0.80, 1.01 ] |
| Kennell 1991                              | 47/212                              | 94/200        | <b>←</b>          | 3.7 %   | 0.47 [ 0.35, 0.63 ] |
| Total (95% CI)                            | 5727                                | 5717          | •                 | 100.0 % | 0.93 [ 0.88, 0.99 ] |
| otal events: 3760 (Continuo               | ous support), 3959 (Usual care      | e)            |                   |         |                     |
| leterogeneity: Tau <sup>2</sup> = 0.01; ( | $Chi^2 = 41.66$ , $df = 8$ (P<0.000 | 001); 12 =81% |                   |         |                     |
| est for overall effect: $Z = 2$ .         | 16 (P = 0.031)                      |               |                   |         |                     |

0.5 0.7 | 1.5 2
Favours support Favours usual care

Analysis I.3. Comparison I Continuous support versus usual care - all trials, Outcome 3 Synthetic oxytocin during labour.

Comparison: I Continuous support versus usual care - all trials

Outcome: 3 Synthetic oxytocin during labour

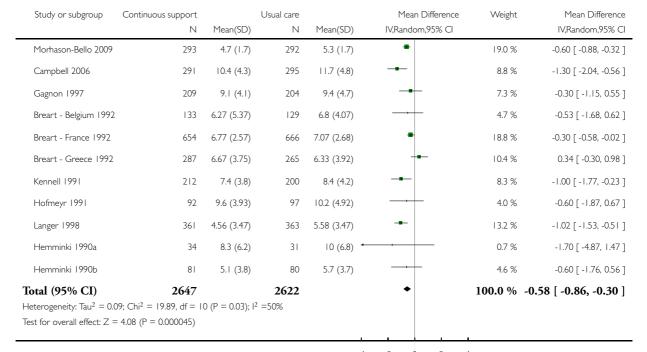
| Study or subgroup     | ,  |          | Risk Ratio<br>M-H,Random,95% Cl | Weight  | Risk Ratio<br>M-H,Random,95% Cl |  |
|-----------------------|--|----------|---------------------------------|---------|---------------------------------|--|
| Kashanian 2010        | 11/50  | 19/50    |                                 | 1.1 %   | 0.58 [ 0.31, 1.09 ]             |  |
| Morhason-Bello 2009   | 51/293   | 56/292   |                                 | 3.3 %   | 0.91 [ 0.64, 1.28 ]             |  |
| Bruggemann 2007       | 104/105  | 107/107  | •                               | 17.2 %  | 0.99 [ 0.96, 1.02 ]             |  |
| Campbell 2006         | 133/291  | 144/295  | +                               | 8.4 %   | 0.94 [ 0.79, 1.11 ]             |  |
| Hodnett 2002          | 1040/3454  | 942/3461 | -                               | 14.6 %  | 1.11 [ 1.03, 1.19 ]             |  |
| Madi 1999             | 7/53   | 17/56    |                                 | 0.7 %   | 0.44 [ 0.20, 0.96 ]             |  |
| Torres 1999           | 167/217  | 172/218  | +                               | 12.9 %  | 0.98 [ 0.88, 1.08 ]             |  |
| Gagnon 1997           | 82/209   | 96/204   | -                               | 6.2 %   | 0.83 [ 0.67, 1.04 ]             |  |
| Breart - Belgium 1992 | 55/132   | 64/129   |                                 | 4.9 %   | 0.84 [ 0.64, 1.10 ]             |  |
| Breart - France 1992  | 383/654  | 371/666  | +                               | 13.3 %  | 1.05 [ 0.96, 1.15 ]             |  |
| Breart - Greece 1992  | 224/287  | 193/265  | +                               | 13.1 %  | 1.07 [ 0.97, 1.18 ]             |  |
| Hofmeyr 1991          | 16/92  | 17/97    |                                 | 1.2 %   | 0.99 [ 0.53, 1.85 ]             |  |
| Kennell 1991          | 36/212   | 46/200   |                                 | 2.6 %   | 0.74 [ 0.50, 1.09 ]             |  |
| Klaus 1986            | 4/168  | 37/249   | <b></b>                         | 0.5 %   | 0.16 [ 0.06, 0.44 ]             |  |
| ,                     | 6217 is support), 2281 (Usual care thi <sup>2</sup> = 39.59, df = 13 (P = 0.8) | <i>'</i> | •                               | 100.0 % | 0.97 [ 0.90, 1.04 ]             |  |

0.2 0.5 | 2 5
Favours support Favours usual care

Analysis I.4. Comparison I Continuous support versus usual care - all trials, Outcome 4 Labour length.

Comparison: I Continuous support versus usual care - all trials

Outcome: 4 Labour length



-4 -2 0 2 4
Favours support Favours usual care

Analysis 1.5. Comparison I Continuous support versus usual care - all trials, Outcome 5 Spontaneous vaginal birth.

Comparison: I Continuous support versus usual care - all trials

Outcome: 5 Spontaneous vaginal birth

| Study or subgroup                         | Continuous support                 | **           |                   | Weight  | Risk Ratio          |
|---|------------------------------------|--------------|-------------------|---------|---------------------|
|   | n/N                                | n/N          | M-H,Random,95% CI |         | M-H,Random,95% CI   |
| Kashanian 2010                            | 46/50                              | 38/50        |                   | 3.3 %   | 1.21 [ 1.02, 1.44 ] |
| Bruggemann 2007                           | 41/105                             | 38/107       | <del>-    </del>  | 1.0 %   | 1.10 [ 0.78, 1.56 ] |
| Campbell 2006                             | 223/291                            | 220/295      | +                 | 7.5 %   | 1.03 [ 0.94, 1.13 ] |
| Hodnett 2002                              | 2481/3454                          | 2463/3461    | <del>†</del>      | 13.3 %  | 1.01 [ 0.98, 1.04 ] |
| Dickinson 2002                            | 280/499                            | 239/493      |                   | 5.6 %   | 1.16 [ 1.03, 1.30 ] |
| Madi 1999                                 | 48/53                              | 40/56        |                   | 3.0 %   | 1.27 [ 1.05, 1.53 ] |
| Torres 1999                               | 110/217                            | 101/218      | +-                | 2.8 %   | 1.09 [ 0.90, 1.33 ] |
| Langer 1998                               | 260/357                            | 247/357      | +                 | 7.4 %   | 1.05 [ 0.96, 1.16 ] |
| Gagnon 1997                               | 132/209                            | 127/204      | +                 | 4.2 %   | 1.01 [ 0.87, 1.18 ] |
| Breart - Belgium 1992                     | 97/133                             | 85/129       | +                 | 3.7 %   | 1.11 [ 0.94, 1.30 ] |
| Breart - France 1992                      | 451/654                            | 425/665      | -                 | 8.8 %   | 1.08 [ 1.00, 1.17 ] |
| Breart - Greece 1992                      | 202/282                            | 183/263      | +                 | 6.3 %   | 1.03 [ 0.92, 1.15 ] |
| Hofmeyr 1991                              | 74/92                              | 76/97        | <del></del>       | 4.4 %   | 1.03 [ 0.89, 1.19 ] |
| Kennell 1991                              | 179/212                            | 137/200      |                   | 6.2 %   | 1.23 [ 1.10, 1.38 ] |
| Hemminki 1990a                            | 38/41                              | 34/38        | <del></del>       | 4.6 %   | 1.04 [ 0.90, 1.19 ] |
| Hemminki 1990b                            | 76/81                              | 72/80        | -                 | 7.5 %   | 1.04 [ 0.95, 1.14 ] |
| Hodnett 1989                              | 47/72                              | 42/73        | <del></del>       | 1.7 %   | 1.13 [ 0.88, 1.47 ] |
| Klaus 1986                                | 154/168                            | 196/249      | -                 | 8.6 %   | 1.16 [ 1.08, 1.26 ] |
| Total (95% CI)                            | 6970                               | 7035         | •                 | 100.0 % | 1.08 [ 1.04, 1.12 ] |
| Total events: 4939 (Continuo              | ous support), 4763 (Usual can      | e)           |                   |         |                     |
| Heterogeneity: Tau <sup>2</sup> = 0.00; ( | $Chi^2 = 32.63, df = 17 (P = 0.1)$ | 01); 12 =48% |                   |         |                     |
| Test for overall effect: $Z = 4.2$        | 29 (P = 0.000018)                  |              |                   |         |                     |
|   | ,                                  |              |                   |         |                     |

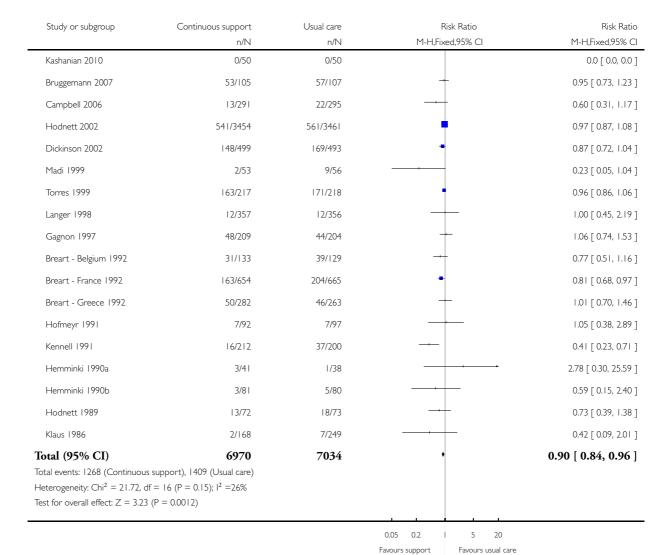
0.5 0.7 | 1.5 2

Favours usual care Favours support

Analysis I.6. Comparison I Continuous support versus usual care - all trials, Outcome 6 Instrumental vaginal birth.

Comparison: I Continuous support versus usual care - all trials

Outcome: 6 Instrumental vaginal birth

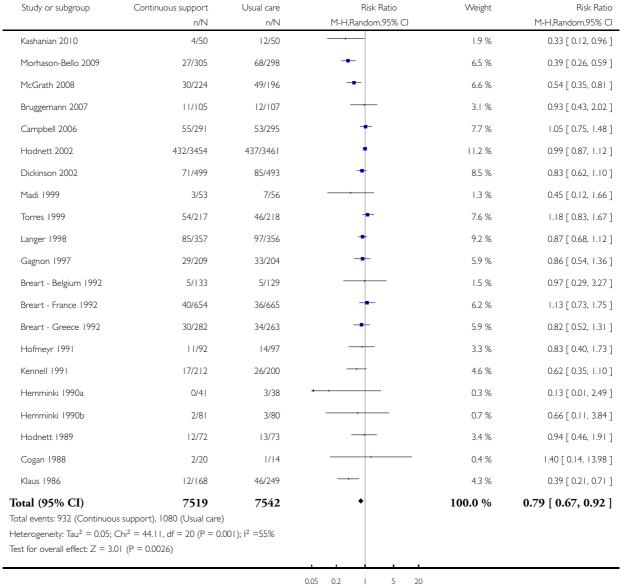


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Analysis I.7. Comparison I Continuous support versus usual care - all trials, Outcome 7 Caesarean birth.

Comparison: I Continuous support versus usual care - all trials

Outcome: 7 Caesarean birth



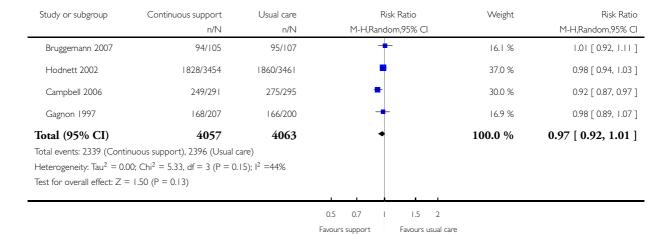
Favours support Favours usual care

#### Analysis I.8. Comparison I Continuous support versus usual care - all trials, Outcome 8 Perineal trauma.

Review: Continuous support for women during childbirth

Comparison: I Continuous support versus usual care - all trials

Outcome: 8 Perineal trauma



Analysis 1.9. Comparison I Continuous support versus usual care - all trials, Outcome 9 Low 5-minute Apgar score.

Comparison: I Continuous support versus usual care - all trials

Outcome: 9 Low 5-minute Apgar score

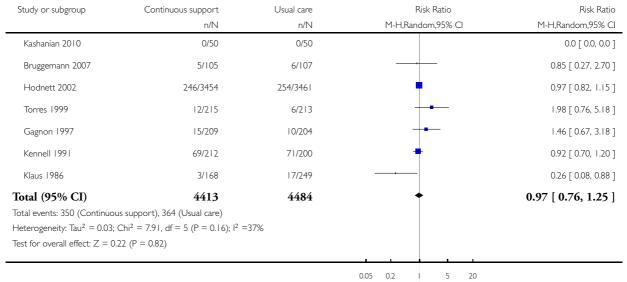
| Study or subgroup  | r subgroup Continuous support Usual care Risk Ratio n/N n/N M-H,Fixed,95% CI |         |   |         | Risk Ratio<br>M-H,Fixed,95% CI |  |
|--|--|---------|---|---------|--------------------------------|--|
| Kashanian 2010   | 0/50   | 1/50    |   | 1.7 %   | 0.33 [ 0.01, 7.99 ]            |  |
| McGrath 2008   | 4/224  | 6/196   |   | 7.3 %   | 0.58 [ 0.17, 2.04 ]            |  |
| Bruggemann 2007  | 3/105  | 2/107   |   | 2.3 %   | 1.53 [ 0.26, 8.96 ]            |  |
| Campbell 2006  | 1/291  | 9/295   | - | 10.2 %  | 0.11 [ 0.01, 0.88 ]            |  |
| Hodnett 2002   | 30/3454  | 25/3461 | - | 28.4 %  | 1.20 [ 0.71, 2.04 ]            |  |
| Dickinson 2002   | 4/499  | 8/493   |   | 9.2 %   | 0.49 [ 0.15, 1.63 ]            |  |
| Torres 1999  | 1/217  | 5/218   |   | 5.7 %   | 0.20 [ 0.02, 1.71 ]            |  |
| Breart - Belgium 1992  | 3/132  | 4/128   |   | 4.6 %   | 0.73 [ 0.17, 3.19 ]            |  |
| Breart - France 1992   | 4/651  | 11/664  | - | 12.4 %  | 0.37 [ 0.12, 1.16 ]            |  |
| Breart - Greece 1992   | 6/295  | 8/274   | _ | 9.4 %   | 0.70 [ 0.24, 1.98 ]            |  |
| Hofmeyr 1991   | 4/89   | 6/96    |   | 6.6 %   | 0.72 [ 0.21, 2.46 ]            |  |
| Kennell 1991   | 1/212  | 2/200   |   | 2.3 %   | 0.47 [ 0.04, 5.16 ]            |  |
| Total (95% CI)   | 6219   | 6182    | • | 100.0 % | 0.70 [ 0.50, 0.96 ]            |  |
| otal events: 61 (Continuous<br>leterogeneity: $Chi^2 = 11.05$ ,<br>est for overall effect: $Z = 2.2$ | $df = 11 (P = 0.44); I^2 = 0\%$  |         |   |         |                                |  |

0.02 0.1 | 10 50
Favours support Favours usual care

Analysis 1.10. Comparison I Continuous support versus usual care - all trials, Outcome 10 Admission to special care nursery.

Comparison: I Continuous support versus usual care - all trials

Outcome: 10 Admission to special care nursery



Favours support

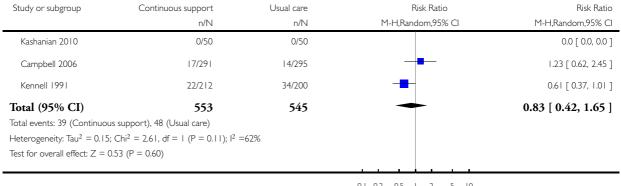
Favours usual care

# Analysis I.II. Comparison I Continuous support versus usual care - all trials, Outcome II Prolonged neonatal hospital stay.

Review: Continuous support for women during childbirth

Comparison: I Continuous support versus usual care - all trials

Outcome: II Prolonged neonatal hospital stay



0.1 0.2 0.5 | 2 5 10 Favours support | Favours usual care

# Analysis 1.12. Comparison I Continuous support versus usual care - all trials, Outcome 12 Postpartum report of severe labour pain.

Review: Continuous support for women during childbirth

Comparison: I Continuous support versus usual care - all trials

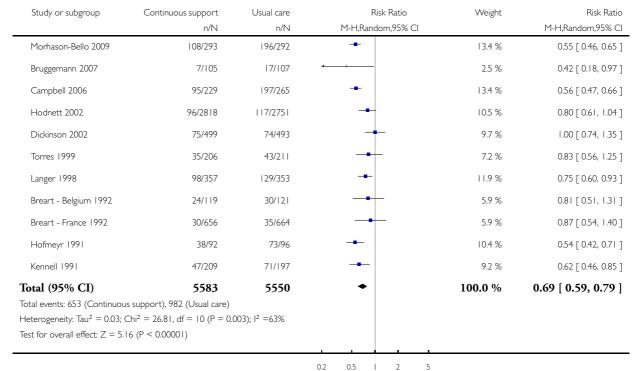
Outcome: 12 Postpartum report of severe labour pain

| Study or subgroup                  | Continuous support                  | Usual care               |         | F       | Risk Ratio |           | Weight  | Risk Ratio          |
|------------------------------------|-------------------------------------|--------------------------|---------|---------|------------|-----------|---------|---------------------|
|                                    | n/N                                 | n/N                      |         | M-H,Ran | dom,95% CI |           |         | M-H,Random,95% CI   |
| Langer 1998                        | 261/356                             | 248/352                  |         | -       | -          |           | 31.1 %  | 1.04 [ 0.95, 1.14 ] |
| Breart - Belgium 1992              | 61/119                              | 53/121                   |         | _       | -          |           | 20.2 %  | 1.17 [ 0.90, 1.53 ] |
| Breart - France 1992               | 157/656                             | 139/664                  |         | -       | -          |           | 24.4 %  | 1.14 [ 0.93, 1.40 ] |
| Hofmeyr 1991                       | 53/92                               | 76/96                    |         |         |            |           | 24.3 %  | 0.73 [ 0.59, 0.89 ] |
| <b>Total</b> (95% CI)              | 1223                                | 1233                     |         | ~       | _          |           | 100.0 % | 1.00 [ 0.83, 1.21 ] |
| Total events: 532 (Continuou       | s support), 516 (Usual care)        |                          |         |         |            |           |         |                     |
| Heterogeneity: $Tau^2 = 0.03$ ; (  | $Chi^2 = 13.35$ , $df = 3$ (P = 0.0 | 04); I <sup>2</sup> =78% |         |         |            |           |         |                     |
| Test for overall effect: $Z = 0.0$ | 00 (P = 1.0)                        |                          |         |         |            |           |         |                     |
|                                    |                                     |                          |         | i       |            |           |         |                     |
|                                    |                                     |                          | 0.5     | 0.7     | 1 1.5      | 2         |         |                     |
|                                    |                                     |                          | Favours | support | Favours u  | sual care |         |                     |

Analysis 1.13. Comparison I Continuous support versus usual care - all trials, Outcome 13 Negative rating of/negative feelings about birth experience.

Comparison: I Continuous support versus usual care - all trials

Outcome: 13 Negative rating of/negative feelings about birth experience

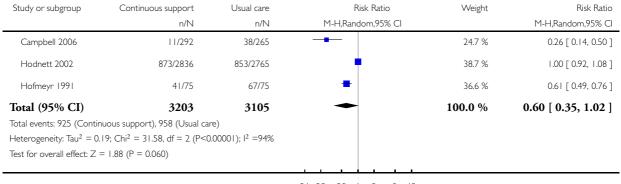


Favours support Favours usual care

Analysis 1.14. Comparison I Continuous support versus usual care - all trials, Outcome 14 Difficulty mothering.

Comparison: I Continuous support versus usual care - all trials

Outcome: 14 Difficulty mothering



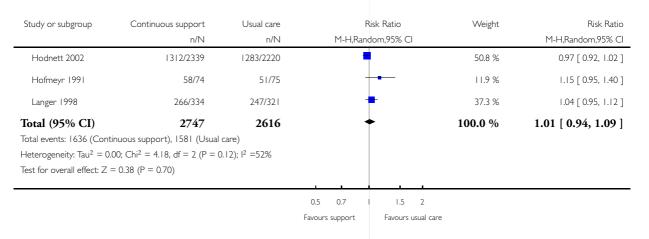
0.1 0.2 0.5 | 2 5 10 Favours support Favours usual care

Analysis 1.15. Comparison I Continuous support versus usual care - all trials, Outcome 15 Breastfeeding at I-2 months postpartum.

 $\label{eq:Review:Continuous support} Review: \quad Continuous support for women during childbirth$ 

Comparison: I Continuous support versus usual care - all trials

Outcome: 15 Breastfeeding at 1-2 months postpartum



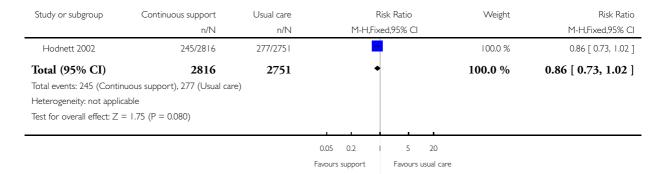
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# Analysis 1.16. Comparison I Continuous support versus usual care - all trials, Outcome 16 Postpartum depression.

Review: Continuous support for women during childbirth

Comparison: I Continuous support versus usual care - all trials

Outcome: 16 Postpartum depression

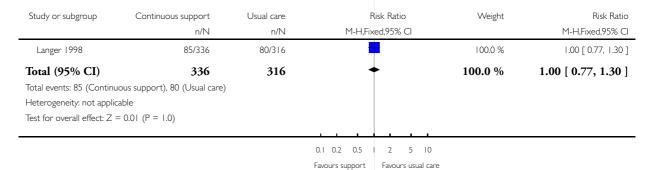


# Analysis 1.17. Comparison I Continuous support versus usual care - all trials, Outcome 17 Low postpartum self-esteem.

Review: Continuous support for women during childbirth

Comparison: I Continuous support versus usual care - all trials

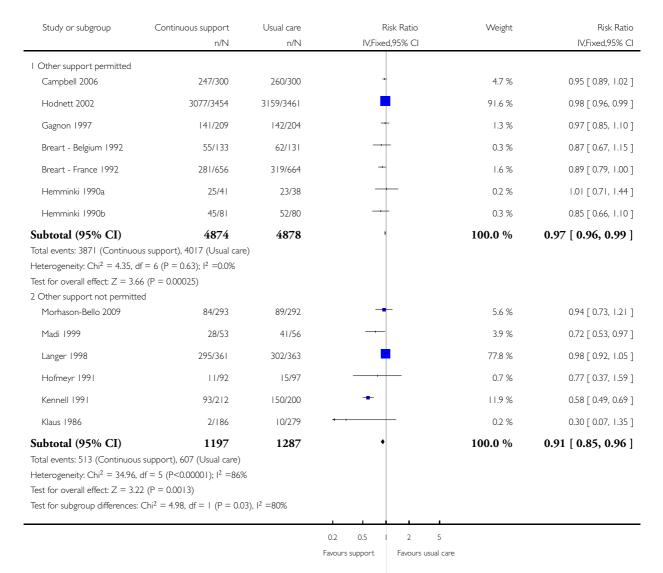
Outcome: 17 Low postpartum self-esteem



Analysis 2.1. Comparison 2 Continuous support versus usual care - policy regarding presence of companion, Outcome I Any analgesia/anaesthesia.

Comparison: 2 Continuous support versus usual care - policy regarding presence of companion

Outcome: I Any analgesia/anaesthesia

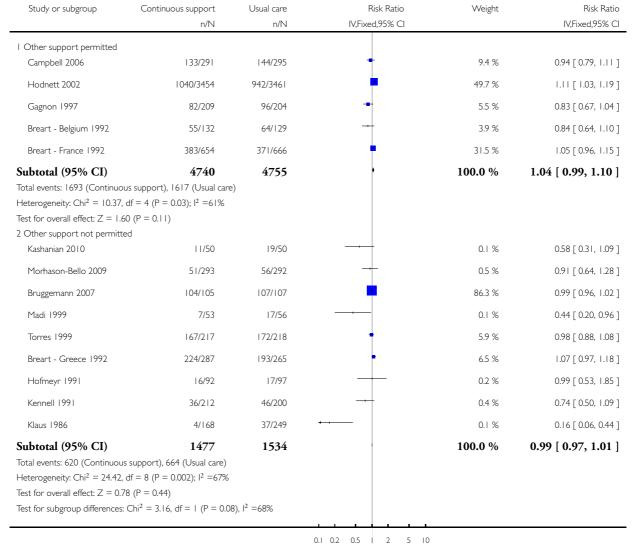


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Analysis 2.2. Comparison 2 Continuous support versus usual care - policy regarding presence of companion, Outcome 2 Synthetic oxytocin during labour.

Comparison: 2 Continuous support versus usual care - policy regarding presence of companion

Outcome: 2 Synthetic oxytocin during labour

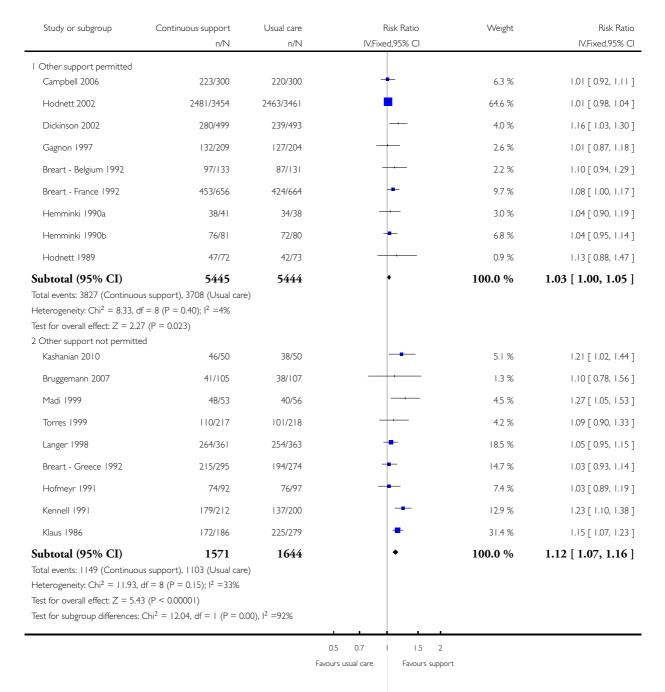


Favours support Favours usual care

Analysis 2.3. Comparison 2 Continuous support versus usual care - policy regarding presence of companion, Outcome 3 Spontaneous vaginal birth.

Comparison: 2 Continuous support versus usual care - policy regarding presence of companion

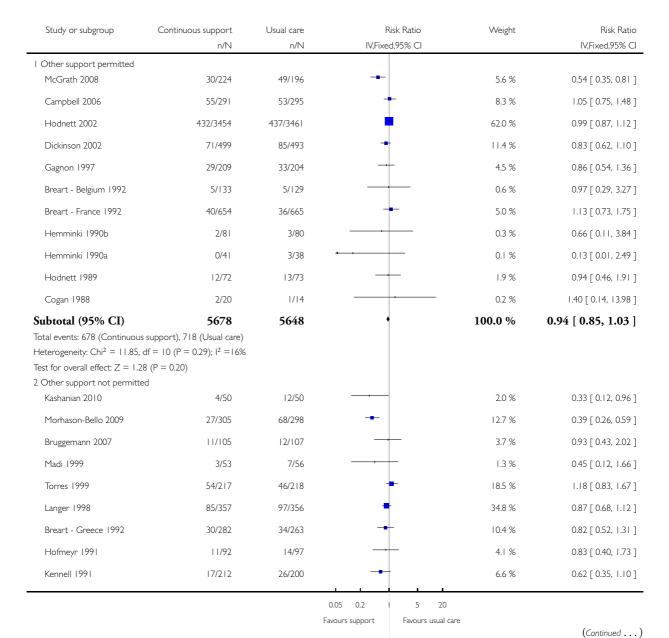
Outcome: 3 Spontaneous vaginal birth

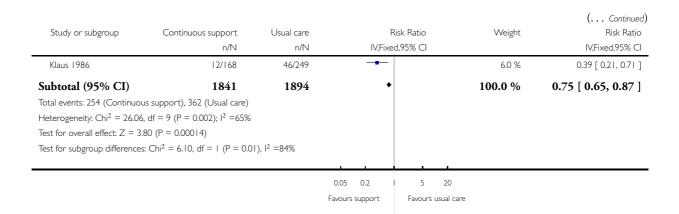


Analysis 2.4. Comparison 2 Continuous support versus usual care - policy regarding presence of companion, Outcome 4 Caesarean birth.

Comparison: 2 Continuous support versus usual care - policy regarding presence of companion

Outcome: 4 Caesarean birth

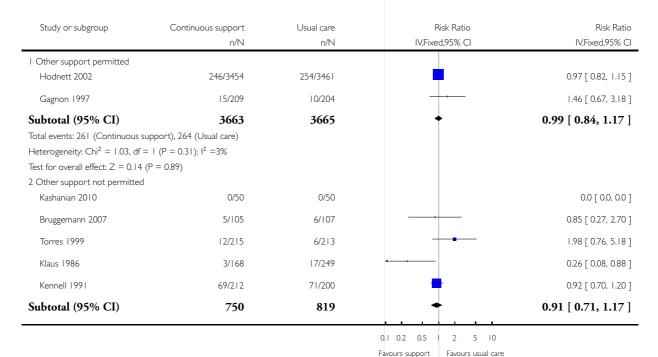




Analysis 2.5. Comparison 2 Continuous support versus usual care - policy regarding presence of companion,
Outcome 5 Admission to special care nursery.

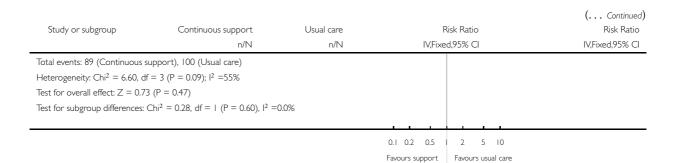
Comparison: 2 Continuous support versus usual care - policy regarding presence of companion

Outcome: 5 Admission to special care nursery



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(Continued . . . )



# Analysis 2.6. Comparison 2 Continuous support versus usual care - policy regarding presence of companion, Outcome 6 Postpartum depression.

Review: Continuous support for women during childbirth

Comparison: 2 Continuous support versus usual care - policy regarding presence of companion

Outcome: 6 Postpartum depression

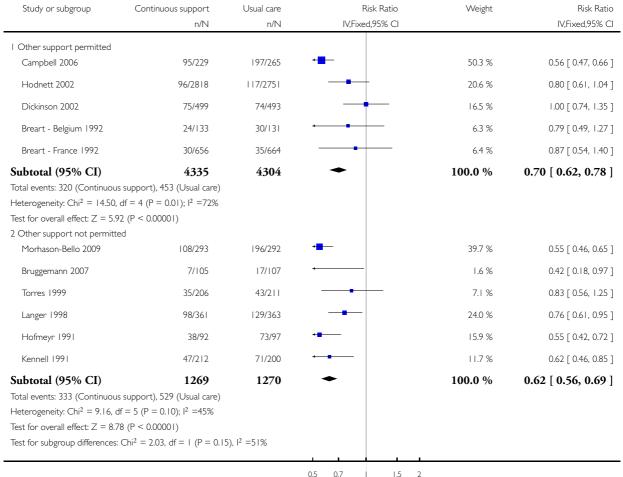
| Weight  | Risk Ratio<br>IV,Fixed,95% CI | Usual care<br>n/N                 | Continuous support<br>n/N     | Study or subgroup  |
|---------|-------------------------------|-----------------------------------|-------------------------------|--|
|         |                               |                                   |                               | I Other support permitted  |
| 100.0 % | -                             | 277/2751                          | 245/2816                      | Hodnett 2002   |
| 100.0 % | -                             | 2751                              | 2816                          | Subtotal (95% CI)  |
|         |                               |                                   | s support), 277 (Usual care)  | Total events: 245 (Continuou   |
|         |                               |                                   |                               | Heterogeneity: not applicable  |
|         |                               |                                   | 75 (P = 0.080)                | Test for overall effect: $Z = 1$ .   |
|         |                               |                                   | ed                            | 2 Other support not permit   |
| 0.0 %   |                               | 0                                 | 0                             | Subtotal (95% CI)  |
|         |                               |                                   | upport), 0 (Usual care)       | Total events: 0 (Continuous s  |
|         |                               |                                   |                               | Heterogeneity: not applicable  |
|         |                               |                                   | blicable                      | Test for overall effect: not ap  |
|         | 100.0 %<br>100.0 %            | IV,Fixed,95% CI  100.0 %  100.0 % | n/N IV,Fixed,95% CI  277/2751 | 245/2816 277/2751 100.0 %  2816 2751 100.0 %  us support), 277 (Usual care) e 75 (P = 0.080) ted  0 0 0  0.0 %  support), 0 (Usual care) e |

0.5 0.7 | 1.5 2
Favours support Favours usual care

Analysis 2.7. Comparison 2 Continuous support versus usual care - policy regarding presence of companion,
Outcome 7 Negative rating of/negative feelings about birth experience.

Comparison: 2 Continuous support versus usual care - policy regarding presence of companion

Outcome: 7 Negative rating of/negative feelings about birth experience



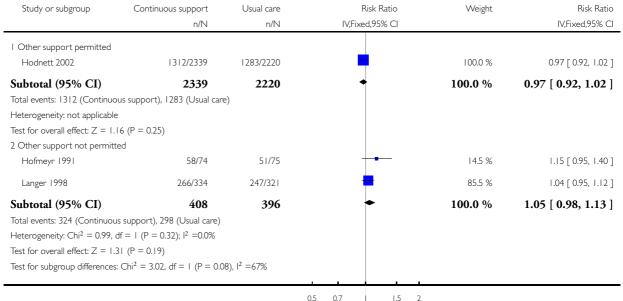
0.5 0.7 1.5 2

Favours support Favours usual care

Analysis 2.8. Comparison 2 Continuous support versus usual care - policy regarding presence of companion,
Outcome 8 Breastfeeding at 1-2 months postpartum.

Comparison: 2 Continuous support versus usual care - policy regarding presence of companion

Outcome: 8 Breastfeeding at 1-2 months postpartum

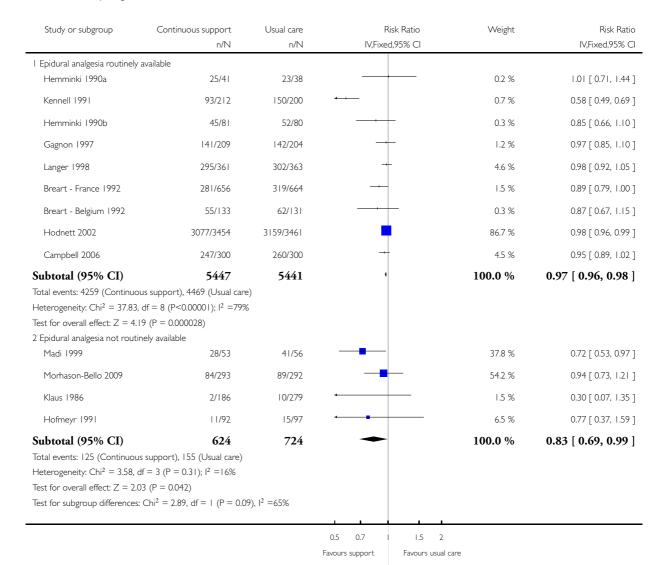


Favours support Favours usual care

Analysis 3.1. Comparison 3 Continuous support versus usual care - availability of epidural analgesia, Outcome I Any analgesia/anaesthesia.

Comparison: 3 Continuous support versus usual care - availability of epidural analgesia

Outcome: I Any analgesia/anaesthesia

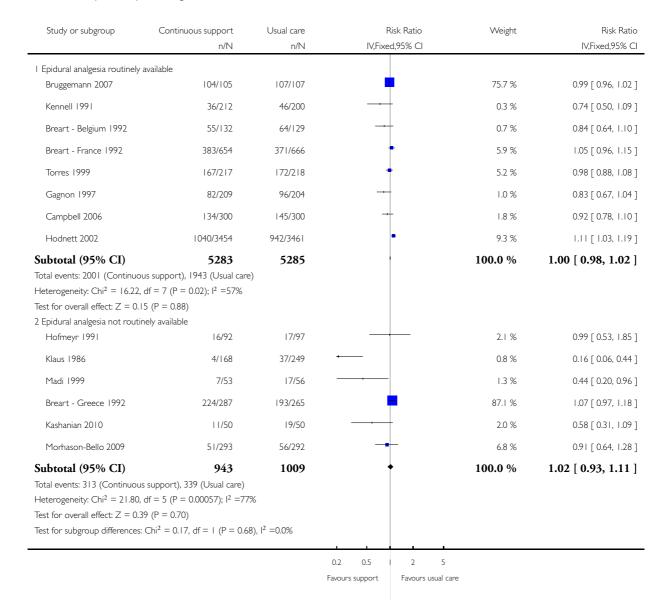


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Analysis 3.2. Comparison 3 Continuous support versus usual care - availability of epidural analgesia, Outcome 2 Synthetic oxytocin during labour.

Comparison: 3 Continuous support versus usual care - availability of epidural analgesia

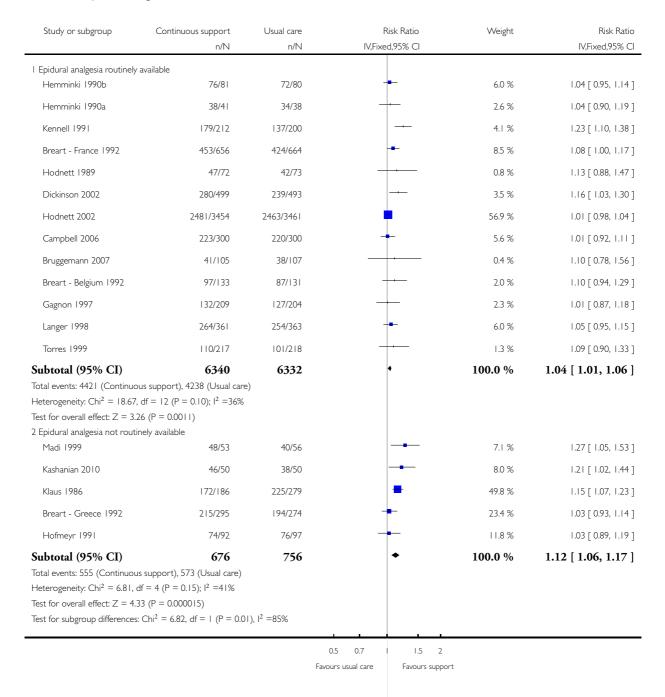
Outcome: 2 Synthetic oxytocin during labour



Analysis 3.3. Comparison 3 Continuous support versus usual care - availability of epidural analgesia, Outcome 3 Spontaneous vaginal birth.

Comparison: 3 Continuous support versus usual care - availability of epidural analgesia

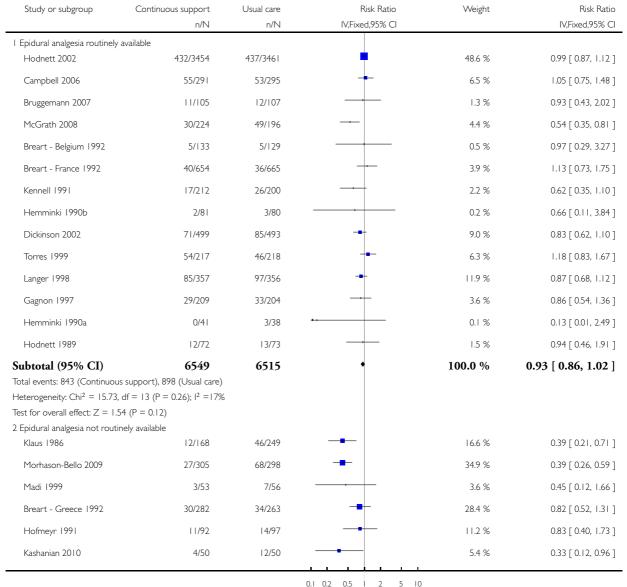
Outcome: 3 Spontaneous vaginal birth



Analysis 3.4. Comparison 3 Continuous support versus usual care - availability of epidural analgesia, Outcome 4 Caesarean birth.

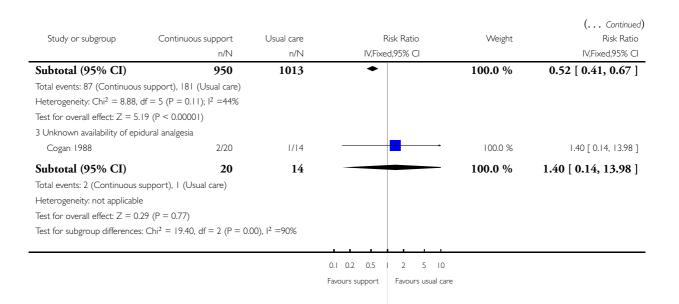
Comparison: 3 Continuous support versus usual care - availability of epidural analgesia

Outcome: 4 Caesarean birth



Favours support Favours usual care

(Continued  $\dots$ )



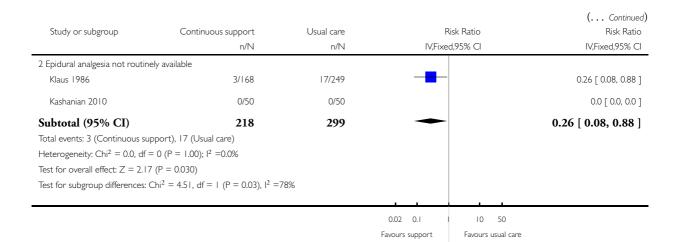
Analysis 3.5. Comparison 3 Continuous support versus usual care - availability of epidural analgesia,
Outcome 5 Admission to special care nursery.



Comparison: 3 Continuous support versus usual care - availability of epidural analgesia

Outcome: 5 Admission to special care nursery

| Study or subgroup                  | Continuous support              | Usual care |                 | Risk Ratio         | Risk Ratio          |
|------------------------------------|---------------------------------|------------|-----------------|--------------------|---------------------|
|                                    | n/N                             | n/N        | IV,Fixe         | ed,95% CI          | IV,Fixed,95% CI     |
| l Epidural analgesia routinely a   | available                       |            |                 |                    |                     |
| Kennell 1991                       | 69/212                          | 71/200     | •               | _                  | 0.92 [ 0.70, 1.20 ] |
| Torres 1999                        | 12/215                          | 6/213      |                 |                    | 1.98 [ 0.76, 5.18 ] |
| Gagnon 1997                        | 15/209                          | 10/204     | -               | <u> </u>           | 1.46 [ 0.67, 3.18 ] |
| Bruggemann 2007                    | 5/105                           | 6/107      |                 |                    | 0.85 [ 0.27, 2.70 ] |
| Hodnett 2002                       | 246/3454                        | 254/3461   |                 | -                  | 0.97 [ 0.82, 1.15 ] |
| Subtotal (95% CI)                  | 4195                            | 4185       |                 | <b>†</b>           | 0.98 [ 0.85, 1.13 ] |
| Total events: 347 (Continuous      | support), 347 (Usual care)      |            |                 |                    |                     |
| Heterogeneity: $Chi^2 = 3.39$ , d  | $f = 4 (P = 0.49); I^2 = 0.0\%$ |            |                 |                    |                     |
| Test for overall effect: $Z = 0.2$ | 7 (P = 0.79)                    |            |                 |                    |                     |
|                                    |                                 |            |                 |                    |                     |
|                                    |                                 |            | 0.02 0.1        | 10 50              |                     |
|                                    |                                 |            | Favours support | Favours usual care |                     |
|                                    |                                 |            |                 |                    | (Continued )        |



# Analysis 3.6. Comparison 3 Continuous support versus usual care - availability of epidural analgesia, Outcome 6 Postpartum depression.

 $\label{eq:Review:Continuous support} Review: \quad Continuous support for women during childbirth$ 

Comparison: 3 Continuous support versus usual care - availability of epidural analgesia

Outcome: 6 Postpartum depression

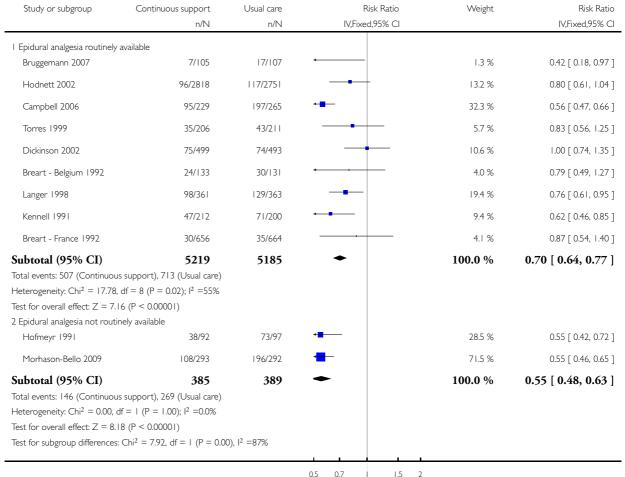
| Study or subgroup                  | Continuous support            | Usual care<br>n/N | Risk Ratio<br>IV,Fixed,95% CI | Weight  | Risk Ratio<br>IV,Fixed,95% CI |
|------------------------------------|-------------------------------|-------------------|-------------------------------|---------|-------------------------------|
| I Epidural analgesia routinely     | v available                   |                   |                               |         |                               |
| Hodnett 2002                       | 245/3454                      | 277/3461          | =                             | 100.0 % | 0.89 [ 0.75, 1.05 ]           |
| Subtotal (95% CI)                  | 3454                          | 3461              | •                             | 100.0 % | 0.89 [ 0.75, 1.05 ]           |
| Total events: 245 (Continuo        | us support), 277 (Usual care) |                   |                               |         |                               |
| Heterogeneity: not applicable      | e                             |                   |                               |         |                               |
| Test for overall effect: $Z = 1$ . | .43 (P = 0.15)                |                   |                               |         |                               |
| 2 Epidural analgesia not rout      | inely available               |                   |                               |         |                               |
| Subtotal (95% CI)                  | 0                             | 0                 |                               | 0.0 %   | 0.0 [ 0.0, 0.0 ]              |
| Total events: 0 (Continuous :      | support), 0 (Usual care)      |                   |                               |         |                               |
| Heterogeneity: not applicable      | e                             |                   |                               |         |                               |
| Test for overall effect: not ap    | plicable                      |                   |                               |         |                               |
|                                    |                               |                   |                               |         |                               |

0.05 0.2 5 20
Favours support Favours usual care

Analysis 3.7. Comparison 3 Continuous support versus usual care - availability of epidural analgesia, Outcome 7 Negative rating of/negative feelings about birth experience.

Comparison: 3 Continuous support versus usual care - availability of epidural analgesia

Outcome: 7 Negative rating of/negative feelings about birth experience



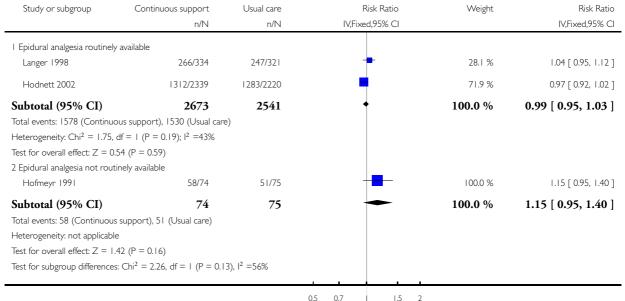
Favours support

Favours usual care

Analysis 3.8. Comparison 3 Continuous support versus usual care - availability of epidural analgesia,
Outcome 8 Breastfeeding at 1-2 months postpartum.

Comparison: 3 Continuous support versus usual care - availability of epidural analgesia

Outcome: 8 Breastfeeding at 1-2 months postpartum



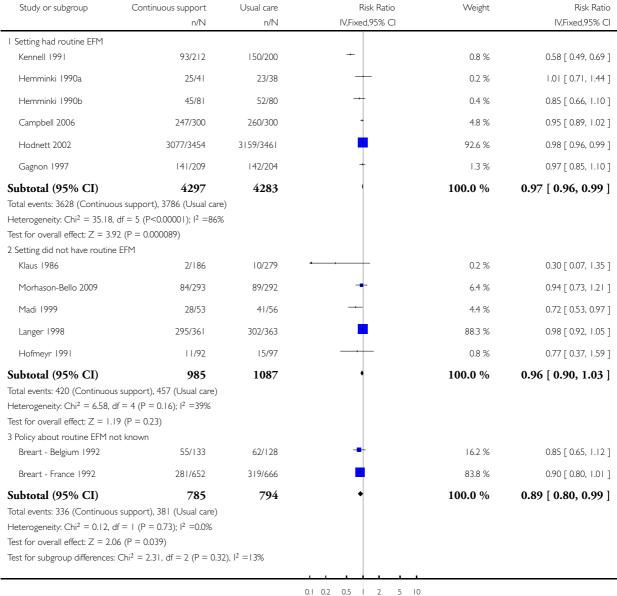
Favours support Favours usual care

Analysis 4.1. Comparison 4 Continuous support versus usual care - policy about routine EFM, Outcome I

Any analgesia/anaesthesia.

Comparison: 4 Continuous support versus usual care - policy about routine EFM

Outcome: I Any analgesia/anaesthesia



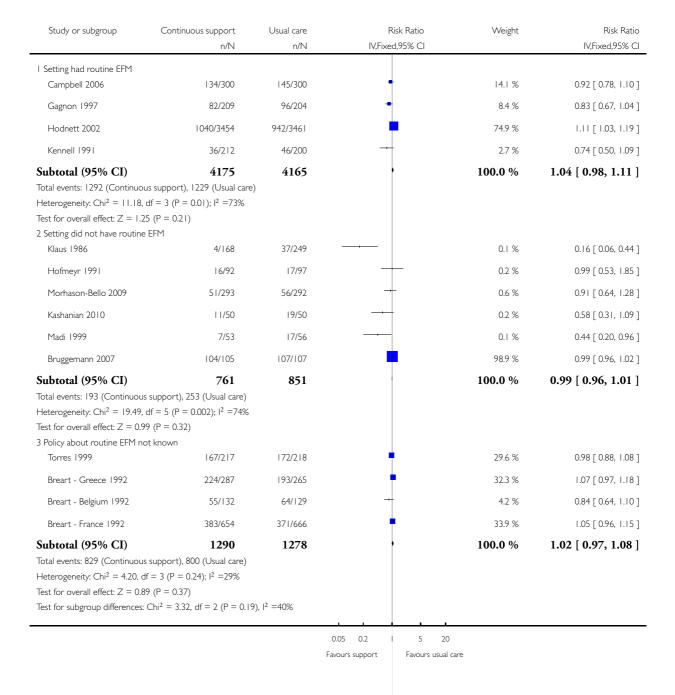
Favours support Favours usual care

Analysis 4.2. Comparison 4 Continuous support versus usual care - policy about routine EFM, Outcome 2

Synthetic oxytocin during labour.

Comparison: 4 Continuous support versus usual care - policy about routine EFM

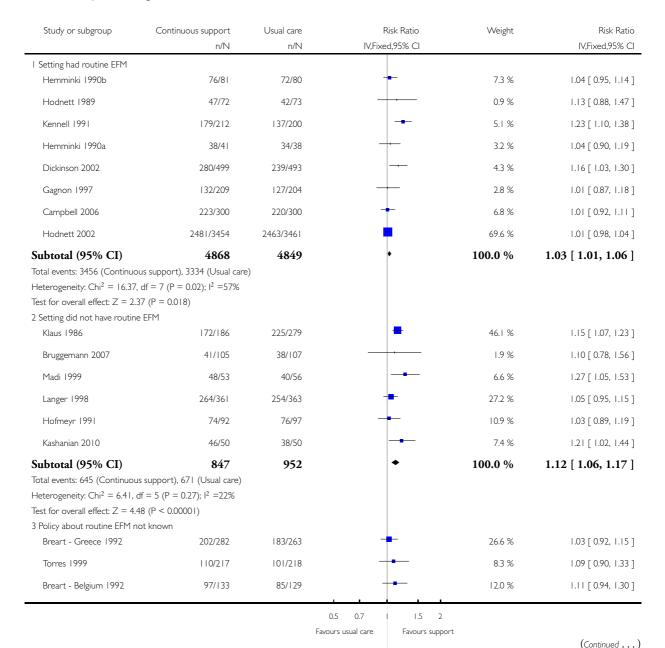
Outcome: 2 Synthetic oxytocin during labour



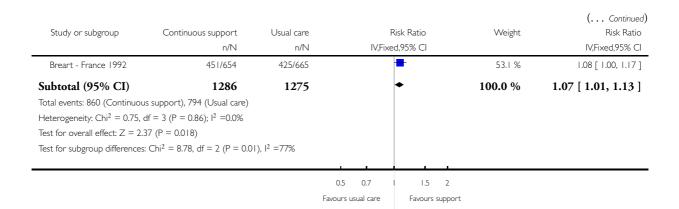
Analysis 4.3. Comparison 4 Continuous support versus usual care - policy about routine EFM, Outcome 3 Spontaneous vaginal birth.

Comparison: 4 Continuous support versus usual care - policy about routine EFM

Outcome: 3 Spontaneous vaginal birth



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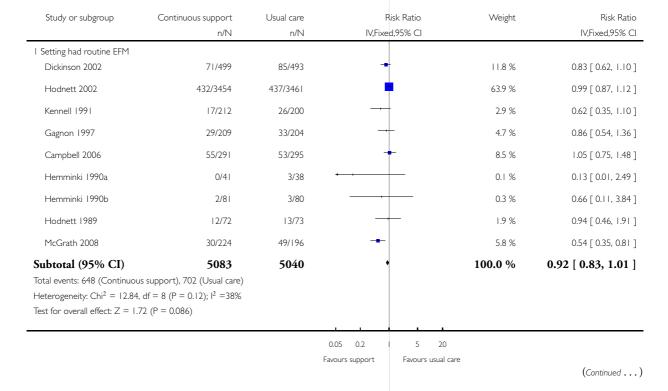


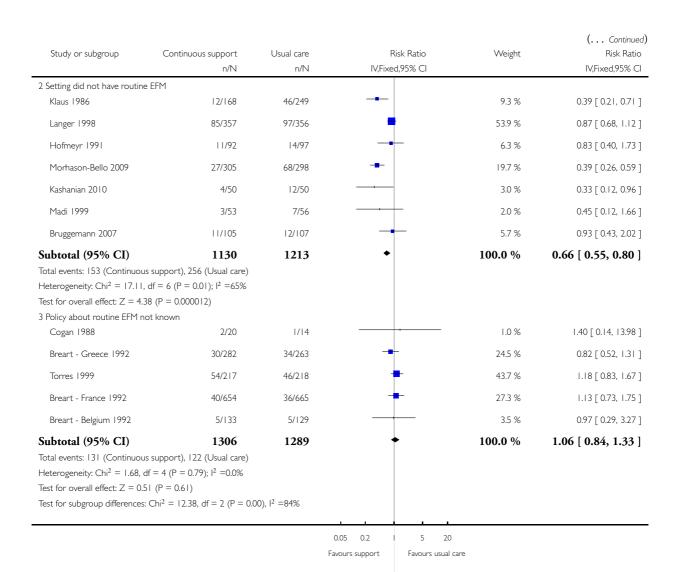
Analysis 4.4. Comparison 4 Continuous support versus usual care - policy about routine EFM, Outcome 4

Caesarean birth.

Comparison: 4 Continuous support versus usual care - policy about routine EFM

Outcome: 4 Caesarean birth





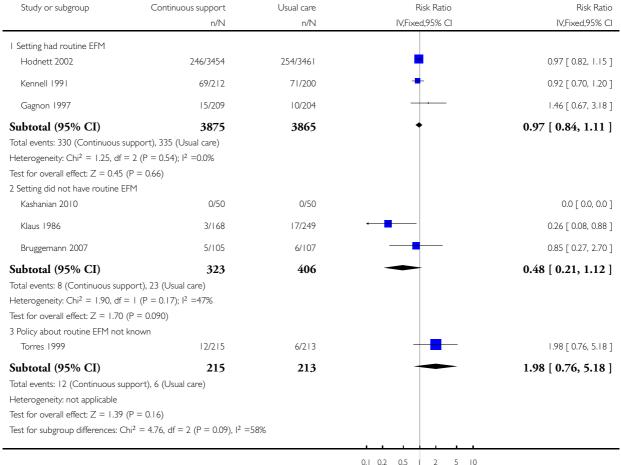
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Analysis 4.5. Comparison 4 Continuous support versus usual care - policy about routine EFM, Outcome 5

Admission to special care nursery.

Comparison: 4 Continuous support versus usual care - policy about routine EFM

Outcome: 5 Admission to special care nursery



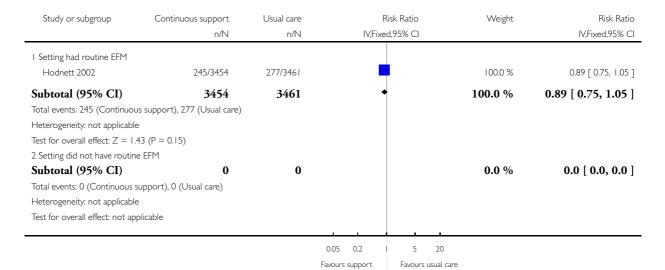
Favours support Favours usual care

# Analysis 4.6. Comparison 4 Continuous support versus usual care - policy about routine EFM, Outcome 6 Postpartum depression.

Review: Continuous support for women during childbirth

Comparison: 4 Continuous support versus usual care - policy about routine EFM

Outcome: 6 Postpartum depression

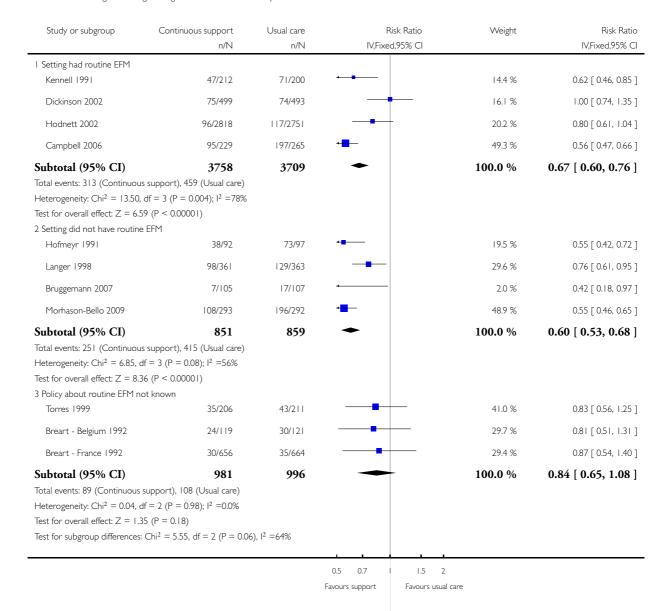


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Analysis 4.7. Comparison 4 Continuous support versus usual care - policy about routine EFM, Outcome 7 Negative rating of /negative views about birth experience.

Comparison: 4 Continuous support versus usual care - policy about routine EFM

Outcome: 7 Negative rating of /negative views about birth experience

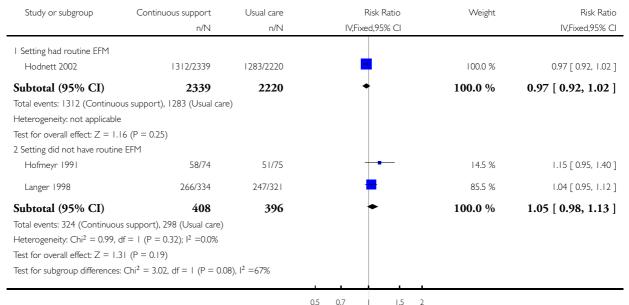


Analysis 4.8. Comparison 4 Continuous support versus usual care - policy about routine EFM, Outcome 8

Breastfeeding at I-2 months postpartum.

Comparison: 4 Continuous support versus usual care - policy about routine EFM

Outcome: 8 Breastfeeding at 1-2 months postpartum

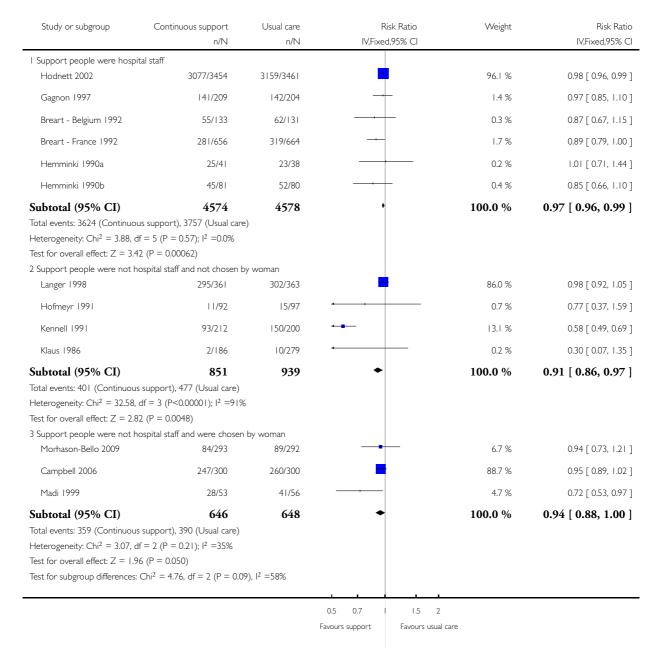


Favours support Favours usual care

Analysis 5.1. Comparison 5 Continuous support versus usual care - variations in provider characteristics, Outcome I Any analgesia/anaesthesia.

Comparison: 5 Continuous support versus usual care - variations in provider characteristics

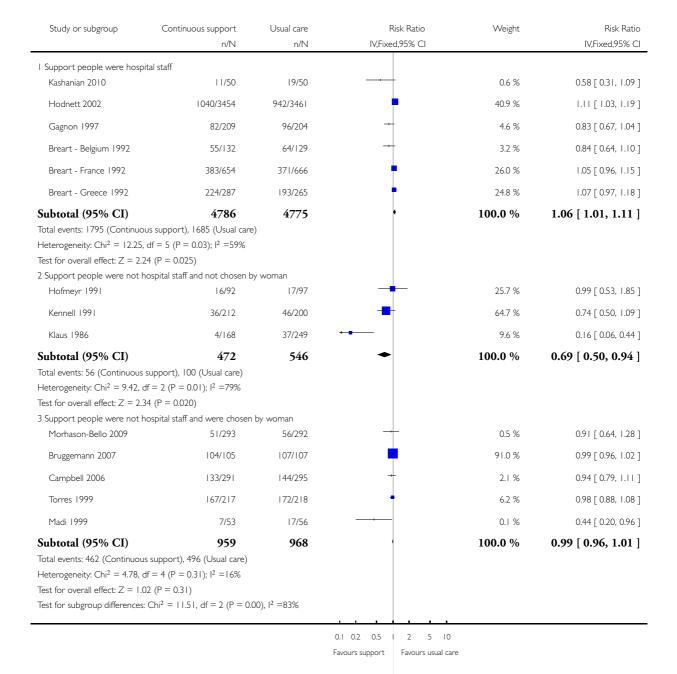
Outcome: I Any analgesia/anaesthesia



Analysis 5.2. Comparison 5 Continuous support versus usual care - variations in provider characteristics, Outcome 2 Synthetic oxytocin during labour.

Comparison: 5 Continuous support versus usual care - variations in provider characteristics

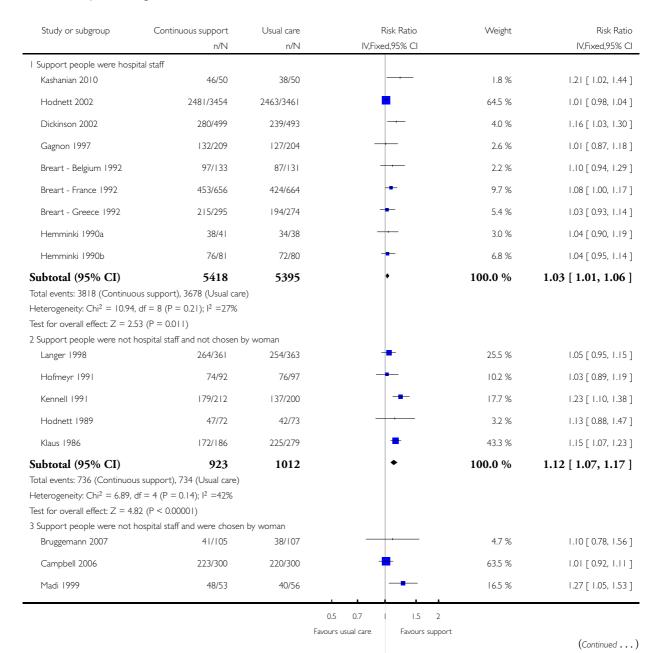
Outcome: 2 Synthetic oxytocin during labour

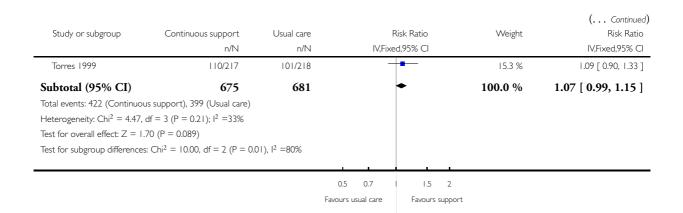


Analysis 5.3. Comparison 5 Continuous support versus usual care - variations in provider characteristics,
Outcome 3 Spontaneous vaginal birth.

Comparison: 5 Continuous support versus usual care - variations in provider characteristics

Outcome: 3 Spontaneous vaginal birth

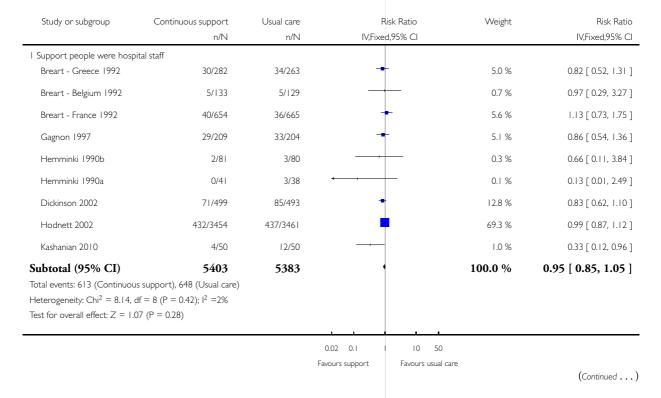


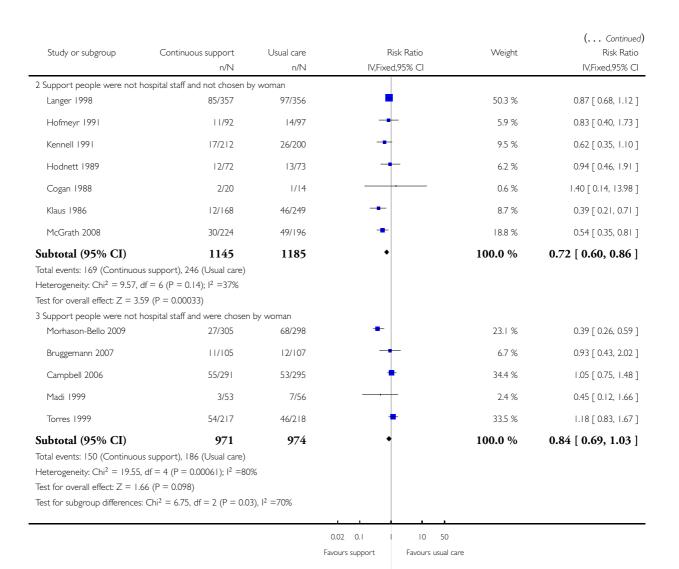


Analysis 5.4. Comparison 5 Continuous support versus usual care - variations in provider characteristics,
Outcome 4 Caesarean birth.

Comparison: 5 Continuous support versus usual care - variations in provider characteristics

Outcome: 4 Caesarean birth

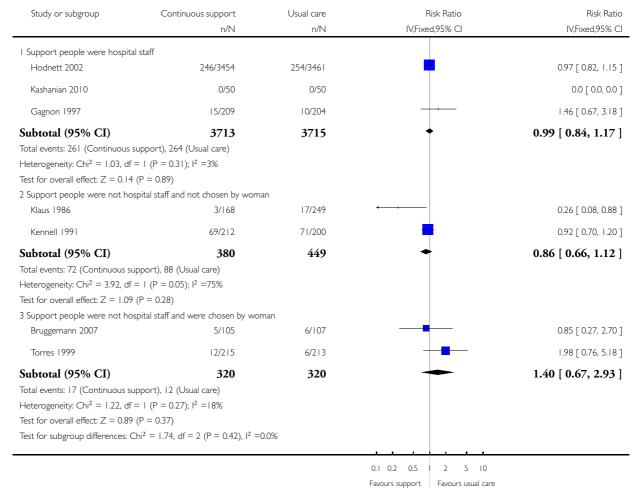




Analysis 5.5. Comparison 5 Continuous support versus usual care - variations in provider characteristics, Outcome 5 Admission to special care nursery.

Comparison: 5 Continuous support versus usual care - variations in provider characteristics

Outcome: 5 Admission to special care nursery



ravours support Favours usual care

# Analysis 5.6. Comparison 5 Continuous support versus usual care - variations in provider characteristics, Outcome 6 Postpartum depression.

Review: Continuous support for women during childbirth

Comparison: 5 Continuous support versus usual care - variations in provider characteristics

Outcome: 6 Postpartum depression

| Study or subgroup                  | Continuous support              | Usual care | Risk Ratio      | Weight  | Risk Ratio          |
|------------------------------------|---------------------------------|------------|-----------------|---------|---------------------|
|                                    | n/N                             | n/N        | IV,Fixed,95% CI |         | IV,Fixed,95% CI     |
| I Support people were hosp         | oital staff                     |            |                 |         |                     |
| Hodnett 2002                       | 245/2816                        | 277/2751   | -               | 100.0 % | 0.86 [ 0.73, 1.02 ] |
| Subtotal (95% CI)                  | 2816                            | 2751       | •               | 100.0 % | 0.86 [ 0.73, 1.02 ] |
| Total events: 245 (Continuou       | is support), 277 (Usual care)   |            |                 |         |                     |
| Heterogeneity: not applicable      | 2                               |            |                 |         |                     |
| Test for overall effect: $Z = 1.7$ | 75 (P = 0.080)                  |            |                 |         |                     |
| 2 Support people were not h        | nospital staff and not chosen b | oy woman   |                 |         |                     |
| Subtotal (95% CI)                  | 0                               | 0          |                 | 0.0 %   | 0.0 [ 0.0, 0.0 ]    |
| Total events: 0 (Continuous s      | support), 0 (Usual care)        |            |                 |         |                     |
| Heterogeneity: not applicable      |                                 |            |                 |         |                     |
| Test for overall effect: not app   | plicable                        |            |                 |         |                     |
| 3 Support people were not h        | nospital staff and were chosen  | by woman   |                 |         |                     |
| Subtotal (95% CI)                  | 0                               | 0          |                 | 0.0 %   | 0.0 [ 0.0, 0.0 ]    |
| Total events: 0 (Continuous s      | support), 0 (Usual care)        |            |                 |         |                     |
| Heterogeneity: not applicable      |                                 |            |                 |         |                     |
| Test for overall effect: not app   | plicable                        |            |                 |         |                     |
|                                    |                                 |            |                 | 1       |                     |
|                                    |                                 |            | 0.05 0.2   5    | 20      |                     |

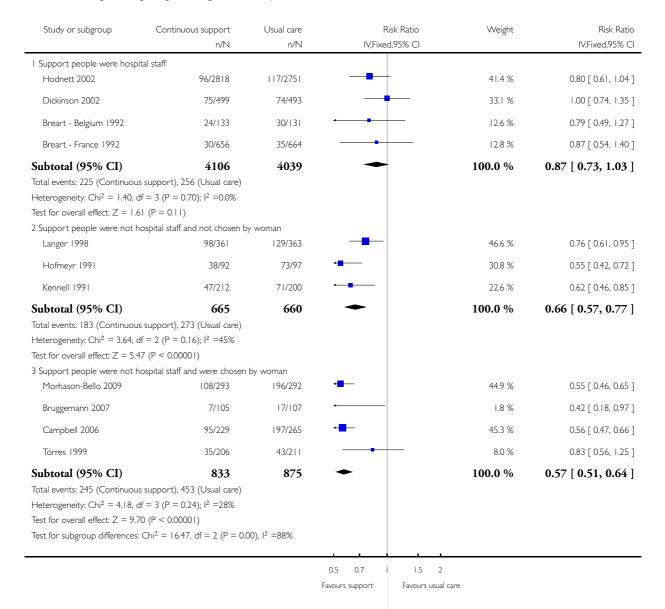
Favours support Favours usual care

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Analysis 5.7. Comparison 5 Continuous support versus usual care - variations in provider characteristics, Outcome 7 Negative rating of/negative feelings about birth experience.

Comparison: 5 Continuous support versus usual care - variations in provider characteristics

Outcome: 7 Negative rating of/negative feelings about birth experience

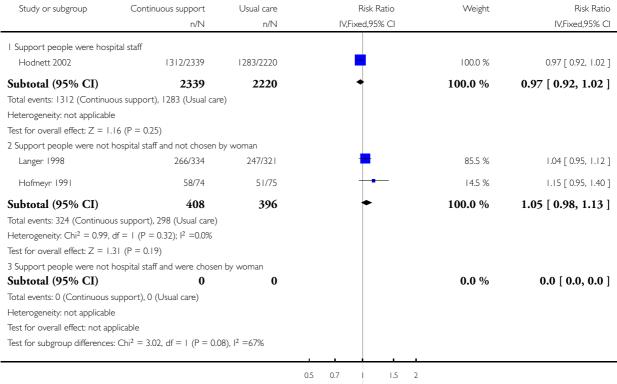


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Analysis 5.8. Comparison 5 Continuous support versus usual care - variations in provider characteristics,
Outcome 8 Breastfeeding at 1-2 months postpartum.

Comparison: 5 Continuous support versus usual care - variations in provider characteristics

Outcome: 8 Breastfeeding at 1-2 months postpartum



# Favours support

Favours usual care

### WHAT'S NEW

Last assessed as up-to-date: 9 January 2011.

| Date             | Event                         | Description  |
|------------------|-------------------------------|--|
| 31 December 2010 | New search has been performed | Search updated. We evaluated and added new trials. We obtained additional information from trial authors. Other revisions included numerous changes to bring the entire Review up-to-date in terms of current methodological guidelines. We altered the acceptable follow-up rate for long term outcomes, and we expanded the number of outcomes to be included in |

#### (Continued)

|                 |  | the planned subgroup analyses.                          |
|-----------------|--|---|
| 25 October 2010 | New citation required but conclusions have not changed | New author joined the review team to update the review. |

#### HISTORY

Protocol first published: Issue 3, 2002

Review first published: Issue 3, 2003

| Date            | Event                         | Description   |
|-----------------|-------------------------------|---|
| 12 May 2008     | Amended                       | Converted to new review format.   |
| 18 April 2007   | New search has been performed | Search updated in February 2007. Two new trials identified. We excluded one (Dalal 2006) and included the other (Campbell 2006). The Results section was updated accordingly. With the exception of the outcome of labour length, there were no substantive changes in results or conclusions of the Review. Minor edits were made throughout. Additional text was added to the Discussion. |
| 30 October 2006 | New search has been performed | Search updated. One 'awaiting assessment' trial was assessed and included (Thomassen 2003).   |

#### **CONTRIBUTIONS OF AUTHORS**

Ellen Hodnett wrote the initial draft of the protocol. Carol Sakala wrote the initial draft of the Discussion in the previous version of the Review. Simon Gates wrote the initial draft of the statistical methods and provided statistical advice for the Protocol and each update of the Review. Julie Weston entered the data for the current update. All review authors participated in all aspects of the preparation of the protocol and in writing the text of the Review. All authors participated in the update of the Review.

### **DECLARATIONS OF INTEREST**

Ellen Hodnett was the principal investigator for two labour support trials. Justus Hofmeyr was the principal investigator for one labour support trial. Julie Weston was the Trial Coordinator for the Hodnett 2002 trial.

## SOURCES OF SUPPORT

#### Internal sources

- University of Toronto, Canada.
- University of the Witwatersrand, South Africa.
- Fort Hare University, South Africa.
- East London Hospital Complex, South Africa.
- National Perinatal Epidemiology Unit, Oxford, UK.
- Childbirth Connection (formerly Maternity Center Association), USA.
- Warwick Clinical Trials Unit, University of Warwick, UK.

#### **External sources**

• No sources of support supplied

## INDEX TERMS

### **Medical Subject Headings (MeSH)**

\*Delivery, Obstetric [methods; nursing]; \*Labor, Obstetric; Midwifery; Obstetrical Nursing; Perinatal Care [\*methods; standards]; Randomized Controlled Trials as Topic

#### MeSH check words

Female; Humans; Pregnancy