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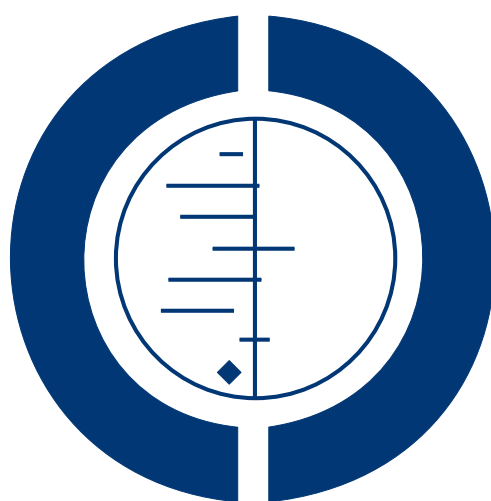
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Alternative versus conventional institutional settings for birth (Review)

Hodnett ED, Downe S, Walsh D, Weston J



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[Intervention Review]

Alternative versus conventional institutional settings for birth

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ABSTRACT

Background

Alternative institutional settings have been established for the care of pregnant women who prefer and require little or no medical intervention. The settings may offer care throughout pregnancy and birth, or only during labour; they may be part of hospitals or freestanding entities. Specially designed labour rooms include bedroom-like rooms, ambient rooms, and Snoezelen rooms.

Objectives

Primary: to assess the effects of care in an alternative institutional birth environment compared to care in a conventional institutional setting. Secondary: to determine if the effects of birth settings are influenced by staffing, architectural features, organizational models or geographical location.

Search strategy

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

Selection criteria

All randomized or quasi-randomized controlled trials which compared the effects of an alternative institutional maternity care setting to conventional hospital care.

Data collection and analysis

We used standard methods of the Cochrane Collaboration Pregnancy and Childbirth Group. Two review authors evaluated methodological quality. We performed double data entry and have presented results using risk ratios (RR) and 95% confidence intervals (CI).

Main results

Nine trials involving 10684 women met the inclusion criteria. We found no trials of freestanding birth centres or Snoezelen rooms. Allocation to an alternative setting increased the likelihood of: no intrapartum analgesia/anaesthesia (five trials, n = 7842; RR 1.17, 95% CI 1.01 to 1.35); spontaneous vaginal birth (eight trials; n = 10,218; RR 1.04, 95% CI 1.02 to 1.06); breastfeeding at six to eight weeks (one trial, n = 1147; RR 1.04, 95% CI 1.02 to 1.06); and very positive views of care (two trials, n = 1207; RR 1.96, 95% CI 1.78 to 2.15). Allocation to an alternative setting decreased the likelihood of epidural analgesia (seven trials, n = 9820; RR 0.82, 95% CI 0.75 to 0.89); oxytocin augmentation of labour (seven trials, n = 10,020; RR 0.78, 95% CI 0.66 to 0.91); and episiotomy (seven trials, n = 9944; RR 0.83, 95% CI 0.77 to 0.90). There was no apparent effect on serious perinatal or maternal morbidity/mortality.

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other adverse neonatal outcomes, or postpartum hemorrhage. No firm conclusions could be drawn regarding the effects of variations in staffing, organizational models, or architectural characteristics of the alternative settings.

Authors' conclusions

When compared to conventional settings, hospital-based alternative birth settings are associated with increased likelihood of spontaneous vaginal birth, reduced medical interventions and increased maternal satisfaction.

PLAIN LANGUAGE SUMMARY

Alternative versus conventional institutional settings for birth

In high- and moderate-income countries, labour wards have become the settings for childbirth for the majority of childbearing women. Routine medical interventions have also increased steadily over time, leading to many questions about benefits, safety, and risk for healthy childbearing women. The design of conventional hospital labour rooms is similar to the design of other hospital sick rooms, i.e. the hospital bed is a central feature of the room, and medical equipment is in plain view. In an effort to support normal labour and birth for healthy childbearing women, a variety of institutional maternity care settings have been constructed. Some are 'home-like' bedrooms within hospital labour wards. Others are 'home-like' birthing units adjacent to the labour wards. Others are freestanding birth centres. More recently, 'ambient' and 'Snoezelen' rooms have been constructed within labour wards; these rooms are not home-like but contain a variety of sensory stimuli and furnishings designed to promote feelings of calmness, control, and freedom of movement.

The primary aim of this review is to evaluate the effects, on labour and birth outcomes, of care in an alternative institutional birth setting compared to care in a conventional hospital labour ward. We included nine trials involving 10,684 women. We found no trials of freestanding birth centres. When compared to conventional institutional settings, alternative settings were associated with reduced likelihood of medical interventions, increased likelihood of spontaneous vaginal birth, increased maternal satisfaction, and greater likelihood of continued breastfeeding at one to two months postpartum, with no apparent risks to mother or baby. Unfortunately in several trials, the design features of the alternative setting were confounded by differences in the organizational models of care (including separate staff and more continuity of caregiver in the alternative setting), and thus it is not possible to draw conclusions about the independent effects of the design of the birth environment. We conclude that women and policy makers should be informed about the benefits of institutional settings which focus on supporting normal labour and birth.

BACKGROUND

In high- and moderate-income countries, labour wards have become the settings for labour and birth for the majority of childbearing women. Routine medical interventions have also increased steadily over time, leading to many questions about benefits, safety, and risk for healthy childbearing women. The design of conventional hospital labour rooms is similar to the design of other hospital patient rooms, i.e. the hospital bed is a central feature of the room, and medical equipment such as oxygen, suction, and intravenous equipment are in plain view.

As a critique of 'technological' approaches to childbirth, there has been a steady increase in interest in the impact of the care environment on the outcomes of labour and birth. Since the 1970s in many high-income countries, many hospitals have endeavoured to make their labour rooms or birthing units 'home-like,' although a more accurate term would be 'bedroom-like,' since the hospital

bed is still the prominent feature. Labour rooms are decorated and furnished to be like Western middle-class bedrooms, with medical equipment concealed from view (Fannin 2003). The bedroom-like rooms draw on notions of domesticity and the naturalness of birth, while hiding the technology behind curtains and wood cabinets (Fannin 2003). According to Fannin (Fannin 2003), these hybrid spaces send dual messages to birthing women and to the staff working in them, exemplifying the struggles over competing conceptualizations of safety, control, and family, and thus over the very meaning of birth itself (Fannin 2003). In a parallel trend, alternative locations for care which are geographically separate from the hospital labour and delivery unit have been gaining prominence in high-income countries. These 'freestanding' birth centres have evolved both out of concerns that routine hospital policies and practices may have spillover effects on birth centre care, and as a means of providing an alternative to home birth. While it may

appear that the freestanding units offer more scope for separation between 'technological' and 'social' models of birth, the evidence is mixed (Annandale 1987; Walsh 2004).

In recent years, in recognition that a bedroom (home-like or otherwise) may not be the optimum environment to support normal labour, other types of institutional birth settings have been constructed. While the new types of rooms share the same values (decreasing anxiety and fear, promoting mobility and personal control), they do not resemble home environments and do not contain hospital labour beds. One such room is the ambient room (Hodnett 2009), in which scenes from nature are projected on a wall, a variety of music is available, and other features encourage mobility during labour. Another type of room is the Snoezelen room, in which the user is exposed to multiple sensory stimulations including fibre-optic lights, auditory stimuli, and aromatherapy. A qualitative study of women's labour experiences in a Snoezelen room found that the users would choose it again in a future labour (Hauck 2008).

Alternative settings vary in location and staffing models. While some alternative settings have arisen as a re-configuration of previously existing facilities, others have been purpose built. Some in-hospital birth centres are adjacent to conventional labour wards, or on another floor of the same hospital. Others are freestanding centres that are not physically part of a hospital but may or may not have administrative linkages to a hospital. The organizational models of care delivery in birth centres vary. The model of care may or may not involve continuity of care provider, in which the same staff provide antenatal as well as intrapartum care. While the core staff of birth centres are usually midwives or nurse-midwives, they may be a separate staff or they may be part of the regular labour ward staff. If they are part of the regular labour ward staff, they provide care for women in the birthing centre as well as women in the traditional labour ward, necessitating a shift in philosophical orientation from one emphasizing normality and avoidance of interventions to one emphasizing detection/management of risk and use of routine interventions. Another common, though not universal, feature is that these units have no routine input by medical practitioners. In these cases, the core staff are usually midwives or nurse-midwives, sometimes with the addition of trained but non-professional assistants, and/or doulas.

The focus of this review is on alternative institutional environments for labour and birth. While the home-like, ambient, and Snoezelen settings vary in whether they also include antenatal care, continuity of care, and in their structural characteristics, they share a philosophical orientation towards promoting normal birth. Their philosophies and guidelines value minimal intervention in labour and the promotion of enhanced freedom and control in labour women, and booking is restricted to women deemed at low risk of obstetric emergency. All include labour rooms which do not look like hospital sick rooms. This review is complementary to two other Cochrane reviews, 'Midwifery-led versus other mod-

els of care delivery for childbearing women' (Hattem 2008) and 'Home versus hospital birth' (Olsen 2004).

OBJECTIVES

The primary objective is to evaluate the effects, on labour and birth outcomes, of care in an alternative institutional birth setting compared to care in a conventional hospital labour ward.

Secondary objectives were to determine if the effects of care in alternative birth settings were influenced by:

- (a) whether the staff in the alternative setting were also part of the conventional maternity care staff;
- (b) whether care in the alternative setting included more continuity of care provider than women experienced in the conventional hospital setting;
- (c) whether the alternative setting was in a building that was geographically separate from the hospital; and
- (d) the architectural characteristics of the alternative setting.

METHODS

Criteria for considering studies for this review

Types of studies

All randomized or quasi-randomized controlled trials which compared the effects of an alternative institutional birth environment to conventional maternity ward care.

Types of participants

Pregnant women at low risk of obstetric complications.

Types of interventions

We included trials if the intervention included care during labour and birth in an alternative institutional birth setting. Antenatal and postnatal care may also have occurred in the alternative setting. Care may have been provided by the same group of caregivers, or by separate groups of caregivers in the alternative versus conventional settings. We excluded trials comparing home birth to institutional birth; they are the subject of another Cochrane review (Olsen 2004).

Types of outcome measures

We identified the following pre-specified primary and secondary outcomes for mother and baby.

Primary outcomes

Mother

1. Spontaneous vaginal birth.
2. Maternal death or serious maternal morbidity, e.g. uterine rupture, admission to intensive care unit; septicemia.
3. No analgesia/anaesthesia for labour or birth.
4. Labour augmentation with artificial oxytocics.
5. Very positive views of intrapartum care. (This was a composite outcome, defined as the highest category of ratings (such as “very satisfied”), in whatever measure was used by trial authors. If trial authors used more than one measure of women’s views, we chose the one assessing satisfaction with intrapartum care.)

Baby

1. Perinatal death or serious perinatal morbidity. (Serious perinatal morbidity was a composite outcome which included birth asphyxia defined by trialists, neonatal encephalopathy, severe respiratory distress syndrome, and other conditions threatening life or predictive of long-term disability.) Perinatal and maternal morbidity are composite outcomes. This is not an ideal solution because some components are clearly less severe than others. It is possible for one intervention to cause more deaths but fewer babies with severe morbidity. All these outcomes are likely to be rare, and a modest change in their incidence is easier to detect if composite outcomes are presented.

Secondary outcomes

Mother

1. Instrumental vaginal birth (forceps or vacuum).
2. Caesarean delivery.
3. Postpartum hemorrhage.
4. Epidural analgesia.
5. Episiotomy.

Baby

1. Admission to neonatal intensive care unit.
2. Five-minute Apgar score less than seven.
3. Perinatal mortality.
4. Any breastfeeding at six to eight weeks of age.

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 May 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 two new trials), using the following methods.

Selection of studies

Two review authors (EH, JW) independently assessed the studies for eligibility. Two other review authors (SD, DW) assessed [Hodnett 2009](#) for eligibility. We would have resolved any disagreement 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. A third review author (DW) extracted data for [Hodnett 2009](#). We would have resolved discrepancies through discussion or, if required, by consulting another member of the review team. 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). A third review author (DW) assessed the risk of bias for Hodnett 2009. We would have resolved any disagreement by discussion or by involving a third assessor.

(1) 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 in sufficient detail 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 non-opaque 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 to type of institutional birth environment, 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. Where sufficient information was reported, or could be supplied by the trial authors, we included 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 was clear that all of the study's pre-specified 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 were reported incompletely and so cannot be used; study failed to include results of a key outcome that would have been expected to have been reported);
- unclear.

(6) Other sources of bias

We described 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 data-dependent process, there was evidence of extreme baseline imbalance, or there have 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 present results as summary risk ratio with 95% confidence intervals.

Continuous data

All pre-specified outcomes were dichotomous.

Unit of analysis issues

Cluster-randomized trials

We will include cluster-randomized trials in the analyses along with individually randomized trials. We will 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), or from another source. 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 synthesise the relevant information. We will consider it reasonable to combine the results from both if there is little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of 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 have noted levels of attrition. We included data for a given outcome only if the data were available for at least 80% of those originally randomized.

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 are 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.

Assessment of reporting biases

Where we suspect reporting bias (*see* 'Selective reporting bias' above), we planned to attempt to contact study authors asking them to provide missing outcome data. Where this is not possible, and the missing data are thought to introduce serious bias, we planned to not include the outcome data from that trial.

Data synthesis

We carried out statistical analysis using the Review Manager software ([RevMan 2008](#)). We used fixed-effect inverse variance meta-analysis for combining data. Had we suspected clinical or methodological heterogeneity between studies sufficient to suggest that treatment effects may differ between trials, we would have used random-effects meta-analysis.

If we identified substantial heterogeneity in a fixed-effect meta-analysis according to our pre-specified criteria, we repeated the analysis using a random-effects method. In such instances, we reported whether the two methods of analysis yielded important differences, and we reported the T^2 and I^2 .

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:

1. type of alternative institutional setting (bedroom-like, ambient, Snoezelen);
2. location of alternative setting (in-hospital or freestanding birth centre);
3. staffing model (separate staff for alternative setting or same staff who work in conventional labour ward setting);
4. whether continuity of caregiver was a component of the care in the alternative setting.

The outcomes which we used in subgroup analyses were chosen from the primary outcomes, on the basis of their importance from the perspective of parents, care providers, and policy makers. They were: spontaneous vaginal birth, serious maternal morbidity/mortality, serious perinatal morbidity/mortality, and very positive views of intrapartum care.

For fixed-effect meta-analyses, we conducted planned subgroup analyses classifying whole trials by interaction tests as described by [Deeks 2001](#). For random-effects meta-analyses we assessed differences between subgroups by inspection of the subgroups' confidence intervals; non-overlapping confidence intervals indicate a

statistically significant difference in treatment effect between the subgroups.

When we identified substantial heterogeneity, we investigated it using visual inspection of the forest plots and sensitivity analyses. We considered whether an overall summary was meaningful, and if it was, we used random-effects analysis to produce it, and we reported the T^2 and I^2 .

Sensitivity analysis

We conducted sensitivity analyses based on two conditions. We compared the results when studies with a high risk of bias were included versus excluded, and we compared fixed-effect versus random-effects analyses when evidence of statistical heterogeneity was present. We defined statistical heterogeneity as a) an I^2 value greater than 30% and b) inconsistency between trials in the direction or magnitude of effects (judged visually).

RESULTS

Description of studies

See: [Characteristics of included studies](#).

See table of [Characteristics of included studies](#).

Nine trials involving 10,684 women met inclusion criteria for the review, although eight trials involving 10,392 women provided data for this review. One trial ([Abdullahi 1990](#)) ($n = 292$) reported no data relevant to the review's pre-specified outcomes. If in the future the trial authors supply usable data, we will incorporate the data into the review. One trial ([Hodnett 2009](#)) was a small randomized controlled trial to assess feasibility and acceptability of an ambient labour room. We found no trials of freestanding units, Snoezelen rooms or other alternative labour room designs. All other trials compared bedroom-like settings with conventional institutional labour wards. Five trials included at least some antenatal care in the alternative setting ([Begley 2009](#); [Byrne 2000](#); [Hundley 1994](#); [MacVicar 1993](#); [Waldenstrom 1997](#)).

All of the alternative settings were characterized by a philosophical orientation towards labour and birth as fundamentally normal experiences. All restricted access to women who were experiencing normal pregnancies. However, there were differences in the scope of the interventions. The Stockholm trial ([Waldenstrom 1997](#)) enrolled 1860 women in an evaluation of care during pregnancy, childbirth, and the postpartum period by a team of 10 midwives at a hospital birth centre, compared to standard care by different midwives during the antenatal, intrapartum and postnatal periods, in which intrapartum care was in a conventional labour ward in the same hospital. The Aberdeen trial ([Hundley 1994](#)) enrolled 2844 women in an evaluation of care in an alternative, midwife-managed delivery unit compared to care in a consultant-led labour

ward; the same midwives also worked in both intrapartum settings. The London ([Chapman 1986](#)), Montreal ([Klein 1984](#)), Danish ([Abdullahi 1990](#)) and Toronto ([Hodnett 2009](#)) trials were smaller trials which compared care in alternative birth rooms within standard labour wards; the same staff cared for women in both groups. The Leicester trial ([MacVicar 1993](#)) enrolled 3510 women in an evaluation of intrapartum care in an alternative, midwife-managed unit compared to care in a standard labour ward in the same hospital; women allocated to the former group had up to three antenatal visits in a clinic run by the midwives in the birth centre, with the remainder of their antenatal care by their general practitioner or community midwife. The Australian trial ([Byrne 2000](#)) enrolled 201 women at 20 to 36 weeks' gestation. Birth centre care was provided by midwives who were 'committed to the normality of the birth process' and involved antenatal, intrapartum, and up to 12 hours of postnatal care. The Irish trial ([Begley 2009](#)) enrolled 1653 women prior to 24 weeks' gestation, in an evaluation of midwifery-led versus consultant-led care. One component of midwifery-led care was the setting for intrapartum and postpartum care - a home-like unit adjacent to the conventional labour ward.

Thus the trials varied considerably in the scope of the intervention (study groups which differed solely in intrapartum care versus study groups in which there were differences in antenatal and/or postnatal care as well as intrapartum care), and the length of time between randomization and onset of 'treatment', but all trials shared one common aspect of the intervention: intrapartum care in a setting that did not look like a conventional hospital patient room.

We found no randomized trials which compared care in a free-standing birth centre with hospital-based birth centres or conventional hospital care. All trials in which care in the alternative birth setting was by separate midwifery staff also involved increased continuity of caregiver.

Response rates to questionnaires seeking information about women's satisfaction with their birth experiences were at least 80% in only three trials ([Hodnett 2009](#); [Hundley 1994](#); [Waldenstrom 1997](#)). Although 1860 women were enrolled in the Stockholm trial ([Waldenstrom 1997](#)), data on maternal satisfaction outcomes were sought from, and reported on, the first 1230 women who were enrolled. Postpartum questionnaire data were only available for 22% of those enrolled in the Irish trial ([Begley 2009](#)). Of the three trials with usable outcome data, two ([Hodnett 2009](#); [Waldenstrom 1997](#)) employed the same measure of satisfaction (interest in the same birth setting in the future), while the third ([Hundley 1994](#)) reported on whether the woman's labour and delivery were managed as she liked.

Substantial numbers of women allocated to alternative settings were transferred to standard care either before or during labour, because they no longer met eligibility criteria for the alternative setting. The most common reasons for intrapartum transfer were: failure to progress in labour, fetal distress, and desire for pharma-

cologic analgesia. In the Australian trial (Byrne 2000) only 23/100 women allocated to birth centre care actually gave birth in the birth centre. In two UK trials (Hundley 1994; MacVicar 1993), 46% of women randomized to the birth centres actually gave birth in them. Thirty-four per cent of women in the Stockholm trial (Waldenstrom 1997) were transferred to standard care antenatally or intrapartum for medical reasons, and an additional 3% withdrew from birth centre care at their own request. In the Montreal trial (Klein 1984), 63% of nulliparous women and 19% of multiparous women were transferred intrapartum to standard care, for an overall transfer rate of 43%. In the London trial (Chapman 1986), 29% of 76 women were transferred from birth room to standard care. Transfers in the Toronto trial (Hodnett 2009) were for women's preference (n = 1) and at delivery if a caesarean delivery was to be performed (13% of 30 women). Permanent transfers from midwifery-led care in the Irish Trial (Begley 2009) included 505 women antenatally (most commonly for induction of labour), 144 during the intrapartum period (most commonly for

complications or slow progress), and five postnatally, for an overall transfer rate of 59%. However, wherever possible, the woman's midwife remained with her after an intrapartum transfer of care.

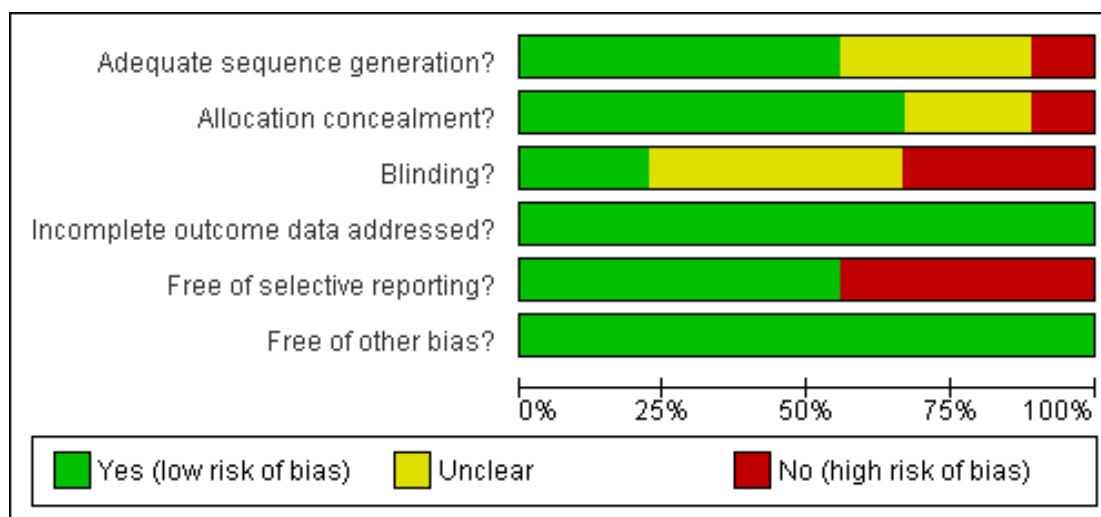
Risk of bias in included studies

With the exception of the quasi-random method (alternation) used in the smallest trial (Klein 1984), all trials used adequate methods of sequence generation. Concealment was adequate for all but two trials (Chapman 1986; Klein 1984); it was unclear in one trial (Abdullahi 1990). Selective reporting was a problem in three trials; Abdullahi 1990 only reported outcomes for primiparous women (55% of those randomized); Chapman 1986 mailed questionnaires only to those who had not been dropped from study analyses (61%); and Klein 1984 did not report results of postpartum questionnaires. Figure 1 and Figure 2 illustrate that the trials were of variable quality.

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

	Adequate sequence generation?	Allocation concealment?	Blinding?	Incomplete outcome data addressed?	Free of selective reporting?	Free of other bias?
Abdullahi 1990	?	?	?	+	-	+
Begley 2009	+	+	-	+	-	+
Byrne 2000	+	+	-	+	+	+
Chapman 1986	?	?	?	+	-	+
Hodnett 2009	+	+	+	+	+	+
Hundley 1994	+	+	?	+	+	+
Klein 1984	-	-	-	+	-	+
MacVicar 1993	+	+	+	+	+	+
Waldenstrom 1997	?	+	?	+	+	+

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



Effects of interventions

Main comparisons: alternative versus conventional institutional settings for birth

Primary outcomes

Women who were randomized to receive care in an alternative birth setting were more likely to labour and give birth without analgesia/anaesthesia (five trials, $n = 7842$; risk ratio (RR) 1.17, 95% confidence interval (CI) 1.01 to 1.35), and more likely to have a spontaneous vaginal birth (eight trials, $n = 10,218$; RR 1.04, 95% CI 1.02 to 1.06). Allocation to care in an alternative setting had no apparent effect on serious maternal morbidity/mortality (four trials, $n = 6334$; RR 1.11, 95% CI 0.23 to 5.36). In oxytocin augmentation of labour (Analysis 1.2), the I^2 was 65%, τ^2 was 0.03, and the P value for the χ^2 test of heterogeneity was 0.009. The majority of the observations came from very large trials, and visual inspection of the forest plots did not suggest inconsistency in the direction of effects. A sensitivity analysis, in which we removed the methodologically weakest trial (Klein 1984) had no effect on heterogeneity. We have therefore reported the results of random-effects analyses. Women allocated to an alternative birth setting were less likely to have oxytocin augmentation of labour (seven trials, $n = 10,020$; RR 0.78, 95% CI 0.66 to 0.91).

Three trials which measured women's views of their care had at least 80% follow up (Hodnett 2009; Hundley 1994; Waldenström 1997), as noted above under Description of studies; none of the questions in one trial (Hundley 1994) were conceptually similar to those used in the other two. Thus the meta-analysis results include only two trials (Hodnett 2009; Waldenström 1997), and the measure used was whether the woman would prefer the same setting for a subsequent birth ($n = 1207$; RR 1.96, 95% CI 1.78 to 2.15). Other measures of satisfaction with the childbirth experience reported in the trials included involvement in the process of birth, freedom to express feelings, support from midwives, and indicators of involvement in decision-making; all results either favoured those allocated to an alternative birth setting or suggested no differences.

Only five trials reported both perinatal mortality and serious perinatal morbidity (Begley 2009; Hodnett 2009; Hundley 1994; Klein 1984; Waldenström 1997). We noted evidence of substantial heterogeneity: the τ^2 was 0.35, I^2 was 66%, and the P value for the χ^2 test for heterogeneity was 0.05. We did not perform a sensitivity analysis, since the only trial which was methodologically weak (Klein 1984) contributed no adverse outcomes to the meta-analysis. Visual inspection of the forest plot showed that one large trial (Waldenström 1997) had effects in opposite directions to the other trials. Close examination of the trial reports failed to identify

a reason why their results should not be combined. Comparison of results using a fixed-effect and random-effects model indicated results were comparable. We report the results of the random-effects model (five trials, $n = 6385$; RR 1.17, 95% CI 0.51 to 2.67).

Secondary outcomes

Women allocated to alternative settings were less likely to have epidural analgesia (seven trials, $n = 9820$; RR 0.82, 95% CI 0.75 to 0.89), and episiotomy (seven trials, $n = 9944$; RR 0.83, 95% CI 0.77 to 0.90). Comparisons of instrumental vaginal and caesarean birth followed similar trends to that of spontaneous vaginal birth, indicating less medical intervention. For caesarean birth (eight trials, $n = 10,239$), the RR was 0.89, 95% CI 0.78 to 1.01. For instrumental vaginal birth (seven trials, $n = 10,091$), the RR was 0.89, 95% CI 0.79 to 1.00. Allocation to an alternative setting had no apparent effect on postpartum hemorrhage (five trials, $n = 9601$; RR 0.98, 95% CI 0.85 to 1.14).

Allocation to alternative birth settings had no apparent effect on babies' five-minute Apgar scores less than seven (six trials, $n = 6554$; RR 0.98, 95% CI 0.69 to 1.40); admission to a neonatal intensive care unit (six trials, $n = 9867$; RR 1.07, 95% CI 0.92 to 1.25); or perinatal deaths (seven trials, $n = 10,095$; RR 1.67, 95% CI 0.93 to 3.00).

Babies of women allocated to alternative settings were more likely to be breastfed at six to eight weeks (one trial; $n = 1147$; RR 1.04, 95% CI 1.02 to 1.06).

Subgroup analyses: care by the same versus separate staff

All trials, in which the staff of the alternative setting were separate from the staff of the conventional setting, also involved more continuity of caregiver in the alternative setting. Thus it was not possible to separate the effects of one staffing model from the other. We found no trials of freestanding birth centre care compared to conventional institutional settings, no trials of Snoezelen rooms, only one small ($n = 62$) trial (Hodnett 2009) of an ambient room, and no trials of other architectural designs for labour rooms. Therefore, the subgroup analyses were confined to comparisons of trials in which either the same or separate midwifery/nursing staff provided care in the two settings.

In the four outcomes of interest in the subgroup analysis, there were no apparent effects based on type of staffing on the likelihood of spontaneous vaginal birth (Analysis 2.1, Chi² test for subgroup differences 0.00, $P = 1.00$), serious perinatal morbidity/mortality (Analysis 2.2, Chi² test for subgroup differences 0.92, $P = 0.34$), or serious maternal morbidity/mortality (Analysis 1.13, Chi² test for subgroup differences 0.05, $P = 0.83$). It was not possible to draw conclusions in regard to women's views of their care, since the comparison involved one small trial ($n = 62$) in which the staff were the same (Hodnett 2009) with a large trial ($n = 1927$) in

which there was separate staffing of the two units (Waldenstrom 1997).

DISCUSSION

Summary of main results

The benefits of alternative institutional settings for birth include increased likelihood of spontaneous vaginal birth, labour and birth without analgesia/anaesthesia, breastfeeding at six to eight weeks postpartum, satisfaction with care, and decreased likelihood of oxytocin augmentation, assisted vaginal birth, caesarean birth, and episiotomy. The results are consistent with a growing body of research which has demonstrated the independent effects of physical attributes of the hospital room on caregivers' behavior and patients' health outcomes, including postsurgical complications and length of stay (Ulrich 2004). However, in several of the trials included in this review, the design features of the alternative setting were confounded by important differences in the organizational models for care (separate staff for the alternative setting, offering more continuity of caregiver), and thus it is difficult to draw inferences about the independent effects of the physical birth environment. Furthermore, the effects of an alternative environment may be overpowered by routine institutional policies and practices (Fannin 2003).

There were only three trials in which losses to follow up on questionnaires were low enough to permit inclusion of the data in this review (Hodnett 2009; Hundley 1994; Waldenstrom 1997), but similar results are reported in the other trials that measured satisfaction with care. Different measures were used in the trials, but the results pertaining to women's ratings of their birth experiences consistently favoured the group allocated to the alternative setting. Given the generally high rates of transfer from alternative settings to the conventional ward for intrapartum care, which presumably would create disappointment, these results strongly suggest higher levels of satisfaction in those allocated to alternative birth settings.

Overall completeness and applicability of evidence

Although more than 10,000 women have participated in randomized trials of alternative birth settings, the low number of women allocated to alternative settings who actually gave birth in their allocated setting serves to dilute both the potential benefits and risks of alternative settings. Other important factors that complicate interpretation of the results are the variations in organizational models of care in the trials, including the potential impact of antenatal care, continuity of caregiver, and midwifery-led versus consultant-led care.

AUTHORS' CONCLUSIONS

Implications for practice

Pregnant women should be informed that hospital birth centres are associated with lower rates of medical interventions during labour and birth and higher levels of satisfaction, without increasing risk to themselves or their babies. Decision-makers who wish to decrease rates of medical interventions for women experiencing normal pregnancies should consider developing birthing units with policies and practices to support normal labour and birth.

It was not possible to examine the separate influences of continuity of caregiver and whether the staff provided care in both the alternative and conventional settings, and there were no trials of freestanding birth centres. Thus those who wish to develop a alternative birth setting, and those who wish to use them, have little to go on when making decisions about staffing models, organization of care, autonomy of the setting, or its architectural features. These issues are critically important, in light of women's reports of greater satisfaction with alternative institutional birth settings, and the lower rates of interventions associated with alternative settings.

Implications for research

Future trials should measure and report serious perinatal morbidity as well as perinatal mortality. It would also be helpful to consider the importance of ensuring high-quality inter-professional working relationships, with clear protocols for consultation and transfer of care. Future trials should also address the potential confounding effects of differences in the extent of continuity of caregiver in the alternative versus conventional birth settings. It would be helpful to have full descriptions of both the alternative and usual care interventions. And trials should include evidence-based approaches to encourage high response rates to postal questionnaires, as well as cost-effectiveness analyses.

Given the growing awareness of the importance of the birth en-

vironment, the escalating caesarean delivery rates in many high-income countries, and the favourable results of large observational studies of freestanding birth centres (e.g. [Rooks 1989](#)), randomized trials of freestanding birth centres are warranted. Similarly, adequately-powered trials are needed, of architectural designs which promote freedom of mobility and enhance feelings of calmness and control.

Questions have arisen about: the impact of competing philosophical, political, and administrative pressures on the operation of alternative settings ([Annandale 1987](#)); these questions require qualitative investigation. Qualitative studies, examining what happens when women are transferred from alternative to conventional birth settings, would shed light on the impact of transfer on women, care providers, and decision-making processes regarding the need for intervention. Questions which can be answered quantitatively include: the effects of alternative settings on birth outcomes, women's preferences for traditional labour ward care compared to birth centre care, the pros and cons of freestanding versus hospital-based birth centres, and the optimum organizational models of birth centre care. Evidence from both qualitative and quantitative sources is needed, to provide a complete picture of the nature, benefits, and risks of birth centre care.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Abdullahi 1990

Methods	Randomized controlled trial; women consented at 33 weeks' gestation and were randomized when they arrived in labour.
Participants	292 nulliparous and multiparous low-risk women at term (38-42 weeks' gestation) (147 in experimental group and 145 in control group) at a hospital in Denmark. Exclusion criteria were: non-cephalic position.
Interventions	The experimental group was cared for in the 'green room'; an 'environmental' delivery room that included a large bed (2 m x 2 m), bath tub, curtains, plants, artwork, tape recorder and wall bar. The control group was cared for in the 'white room' which was the normal hospital labour room. Both rooms were in the same physical location and so it is assumed that the same staff cared for women in both study groups.
Outcomes	Spontaneous onset of labour, vacuum delivery, caesarean delivery, episiotomy, intervention rates, 5-minute Apgar score < 10, umbilical cord pH.
Notes	No information available at this time as to how many women remained in the 'green room' for delivery. Attempt to contact author met with no response. No data from the trial were usable (see Risk of Bias Table).

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Described as 'randomization-grouping' with no further details. Not stratified by parity.
Allocation concealment?	Unclear	No details provided.
Blinding? All outcomes	Unclear	No mention of blinding.
Incomplete outcome data addressed? All outcomes	Yes	No withdrawals from data collection were noted. However, all outcomes were not reported for all cases.
Free of selective reporting?	No	Results are reported only for subgroups, e.g. those whose labour onset was spontaneous, or primiparous women. The risk of reporting bias made all data unusable.

Abdullahi 1990 (Continued)

Free of other bias?	Yes	No other potential sources of bias were noted.
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Begley 2009

Methods	Randomized controlled trial. Eligible and consenting women were randomized at the time of booking for antenatal care.
Participants	1653 nulliparous and multiparous women (randomized in a 2:1 ratio -- 1102 in the midwifery-led care group and 551 to consultant-led care), booked for delivery at 2 hospitals in Ireland. Participants were < 24 weeks' gestation, judged to be low in obstetrical risk, aged 16-40 years, with singleton pregnancies.
Interventions	Midwifery-led care: shared antenatal care between midwives and family doctors. Intrapartum care by midwives, who (whenever possible) remained with women who were transferred to consultant-led care in the standard labour ward. Antenatal and intrapartum care were provided in a refurbished unit with a separate entrance, adjacent to the conventional labour ward. The unit contained two birthing rooms with home-like decor and a birthing pool. Medical equipment was concealed from view. Consultant-led care: the organization and delivery of care, from initial booking through the postnatal period, was led by a consultant-obstetrician, within either a public or private system of maternity care. General practitioners may also have been involved in antenatal care. Intrapartum care was provided by midwives, but consultants may have been present for the birth. No details about the conventional hospital labour wards were provided.
Outcomes	10 primary outcomes: induction of labour, continuous electronic fetal monitoring, augmentation of labour, episiotomy, caesarean birth, instrumental birth, postpartum hemorrhage, Apgar score < 7, initiation of breastfeeding; and umbilical cord pH. An extensive list of secondary outcomes (n > 60) included serious maternal and perinatal morbidity and mortality, health care costs, and medical interventions during pregnancy, childbirth, and the postnatal period.
Notes	

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Computerized random number generator.
Allocation concealment?	Yes	Central telephone randomization service.
Blinding? All outcomes	No	Neither women nor care providers could be blinded. Data collectors were unblinded.
Incomplete outcome data addressed? All outcomes	Yes	Medical record data were available for all but 9 of the 1653 who were randomized. Usable postpartum questionnaire data was

Begley 2009 (Continued)

		only obtained for 22% of those originally randomized.
Free of selective reporting?	No	Pre-specified neonatal outcomes included hypoxic ischemic encephalopathy, neonatal seizures, meconium aspiration, serious neonatal trauma but no outcome data were provided. Results were listed for all study outcomes.
Free of other bias?	Yes	No other potential sources of bias were noted.

Byrne 2000

Methods	Randomized controlled trial; women who consented were randomized between 20-36 weeks' gestation.
Participants	201 nulliparous and multiparous women booked for delivery at a hospital in Adelaide, Australia (100 in experimental group and 101 in control group). All were experiencing normal, uncomplicated pregnancies.
Interventions	Those allocated to birth centre care had antenatal, intrapartum, and up to 12 hours of intrapartum care from a staff of midwives who were "committed to the normality of the birth process". Intrapartum care may have been by midwives who were not known to the women. The women were also encouraged to attend 2 classes about the birthing centre. The birthing centre consisted of 2 bedroom-like rooms adjacent to the delivery suite, staffed by midwives. The control group received usual care antenatal care and their intrapartum care was in the conventional delivery suite; they were under the care of the staff there which included both a midwife and doctor.
Outcomes	Maternal satisfaction, intervention rates, method of infant feeding at 6 weeks postpartum, and costs.
Notes	Experimental group: 13 allocated to birth centre care did not receive it because of staffing problems, and 64 were transferred to delivery suite care for medical reasons. Control: 1 woman was lost to follow up, and 1 transferred to birthing centre at her request. The author has been contacted for additional information about perinatal morbidity, but no reply has been received.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Randomization scheme in balanced, variable-sized blocks prepared by off-site clerical officer not otherwise involved in the study.

Byrne 2000 (Continued)

Allocation concealment?	Yes	Sealed, opaque envelopes were opened by the off-site clerical officer.
Blinding? All outcomes	No	Both baseline and outcome medical record data were collected by the researcher, and the researcher telephoned the clerical officer to obtain the participant's allocation. Participants placed their questionnaires in sealed envelopes, which were collected by staff and delivered to the researcher.
Incomplete outcome data addressed? All outcomes	Yes	1 participant was lost to follow up when she moved and delivered at another hospital. Postpartum questionnaire data were obtained from < 80% of the participants and thus not used.
Free of selective reporting?	Yes	Results were listed for all study outcomes.
Free of other bias?	Yes	No other potential sources of bias were noted.

Chapman 1986

Methods	Randomized controlled trial; women enrolled at or before 30 weeks' gestation.
Participants	148 multiparous women booked for delivery at London, UK hospital were enrolled (76 in experimental group and 72 in control group). All were multiparous, had normal pregnancies and deliveries with previous babies, had asked for early discharge and lived within 5 miles of the hospital.
Interventions	All participants had routine antenatal care. During labour and birth the experimental group was cared for in an alternative birth room close to the labour ward. The control group was admitted to the labour ward. The same group of community midwives cared for both the experimental and control groups during labour.
Outcomes	Reason for withdrawal, intrapartum analgesia, perineal trauma, meconium staining, forceps delivery, caesarean delivery, breastfeeding, effect on relationship with baby, preferred birth setting for future pregnancies.
Notes	22 (29%) in the experimental group were withdrawn, 11 before labour. 13 (18%) were withdrawn in the standard care group, 10 in the antenatal period. Only mode of delivery was reported for the complete sample. No additional information was available when author was contacted.

Risk of bias

Item	Authors' judgement	Description
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Chapman 1986 (Continued)

Adequate sequence generation?	Unclear	Not described.
Allocation concealment?	Unclear	“Random envelope selection.” No mention if opaque or consecutively-numbered or centrally controlled.
Blinding? All outcomes	Unclear	No mention of blinding.
Incomplete outcome data addressed? All outcomes	Yes	Only mode of delivery data were usable as it was reported for the complete sample. The large numbers of withdrawals made all other data unusable.
Free of selective reporting?	No	Questionnaires were only mailed to those “remaining in the study”.
Free of other bias?	Yes	No other evidence of bias.

Hodnett 2009

Methods	Randomized controlled trial; women who consented were randomized on arrival at the hospital before admission to labour and delivery.
Participants	62 nulliparous and multiparous women were enrolled (31 in the experimental group and 31 in the control group) at 2 hospitals in Toronto, Canada. Inclusion criteria were: spontaneous onset of labour; about to be admitted to a labour room; singleton vertex fetus; no contraindications to vaginal birth. Exclusion criteria were: medical indications (such as complications or need for intravenous infusion) or preferences (such as desire for immediate epidural) that would limit mobility.
Interventions	Experimental: an ambient room which contained a double bed size mattress in the corner of the room (in place of the hospital bed); multiple pillows; dimmed lighting; projection of beaches and waterfalls on the wall; a closed door with a 'do not disturb' sign; iPods with a variety of music options; and, equipment to promote upright positioning (chair, poster). In the ambient room auscultation was used to monitor the fetal heart, medical equipment was hidden but within easy reach and there was limited use of technologies unless medically indicated. The hospital bed was returned to the room at the request of the patient or physician. Control: the usual labour room which included the labour bed as the main focus; a lounge chair; routine continuous fetal heart rate monitoring; visible medical equipment; bright overhead lighting and normal hospital noises. The same staff cared for women in both study groups.
Outcomes	Participant and staff evaluation of room; use of hospital bed; time hospital bed was in the room; use of ambient equipment; mode of delivery; rate of interventions; duration of labour events; Apgar score.

Hodnett 2009 (Continued)

Notes	This was a pilot trial to assess the feasibility and acceptability of the ambient room for women and caregivers.	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Computer-generated random numbers.
Allocation concealment?	Yes	Centralized touch tone phone randomization service.
Blinding? All outcomes	Yes	Research assistant was blinded to group allocation when collecting outcome data.
Incomplete outcome data addressed? All outcomes	Yes	1 woman withdrew consent for medical record data to be collected. An in-hospital questionnaire was completed by 29/31 women in the experimental group and 30/31 in the control group.
Free of selective reporting?	Yes	Results were listed for all study outcomes.
Free of other bias?	Yes	No other potential sources of bias were noted.

Hundley 1994

Methods	Randomized controlled trial, women were enrolled early in pregnancy at first booking appointment.
Participants	2844 nulliparous and multiparous women (1900 in experimental group and 944 in control group) who were low-risk at booking at a hospital in Aberdeen, Scotland. Exclusion criteria were: age > 35, height < 150 cm, pre-existing maternal disease, history of infertility or prior obstetric complications, multiple pregnancy.
Interventions	Experimental: antenatal care and delivery in a midwife-managed, alternative unit 20 yards from the hospital's delivery suite. Strict protocols were in place for booking, admission, and transfer of women. Labour was managed with minimal intervention and fetal monitoring by intermittent auscultation. Control: care in the consultant-led delivery suite. The midwives' unit was staffed by hospital midwives who also worked in the delivery suite.
Outcomes	Number transferred from care in the midwives' unit and reason for transfer, type of fetal heart rate monitoring, fetal distress, meconium staining in labour, shoulder dystocia, undiagnosed malpresentation, induction of labour, augmentation of labour, delay in 1st and 2nd stage labour, intrapartum analgesia, mobility in labour, perineal trauma, mode

Hundley 1994 (Continued)

	of delivery, neonatal resuscitation, neonatal intensive care unit admission, stillbirths and neonatal deaths, satisfaction with care, costs.	
Notes	54% of those allocated to the experimental group were not delivered in the midwives' unit. 1.5% were lost to follow up.	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Stated as 'simple unstratified'. 2:1 randomization scheme favouring the experimental group.
Allocation concealment?	Yes	Consecutively-numbered, sealed opaque envelopes.
Blinding? All outcomes	Unclear	Not stated if data collectors were blinded to allocation group.
Incomplete outcome data addressed? All outcomes	Yes	Outcome data collected on 96% of those randomized. Questionnaires completed by 87% of those randomized.
Free of selective reporting?	Yes	Results were listed for all study outcomes.
Free of other bias?	Yes	No other potential sources of bias were noted.

Klein 1984

Item 1984

Methods	A quasi-random study (see below), women were enrolled in labour on arrival at hospital.
Participants	114 nulliparous and multiparous women (56 allocated to the birth room and 58 to conventional care), at low risk for obstetric complications.
Interventions	Intrapartum care in a alternative birth room was compared to standard care in an adjacent labour ward in a tertiary care hospital in Montreal, Canada. The same medical and nursing staff provided care in both settings.
Outcomes	Oxytocin augmentation of labour, epidural analgesia, forceps delivery, episiotomy, perineal trauma, caesarean delivery, 1-minute Apgar score < 7, admission to special care nursery.
Notes	In the experimental group, transfer from the birth room for labour or delivery occurred in 39 of 62 (63%) primiparas and 11 of 59 (19%) multiparas.
<i>Risk of bias</i>	

Klein 1984 (Continued)

Item	Authors' judgement	Description
Adequate sequence generation?	No	"Strict alternation". Only 1 alternative birth room was available. When an eligible woman arrived, if the room was available, the nurse telephoned the trial coordinator, who gave out the next allocation.
Allocation concealment?	No	Centrally controlled but not randomized. Because of shift changes and low numbers of women enrolled, the authors felt the staff could not predict the next treatment allocation. But without randomization it was possible.
Blinding? All outcomes	No	Data collection was done by a research assistant, who was present during active labour and thus knew study group.
Incomplete outcome data addressed? All outcomes	Yes	Medical record outcomes were reported for all those originally enrolled in the study.
Free of selective reporting?	No	In-hospital postpartum questionnaire data were not reported.
Free of other bias?	Yes	No other evidence of bias.

MacVicar 1993

Methods	Randomized controlled trial. Envelopes containing random assignment were attached to the records of pregnant women by the secretary when they arrived for their first prenatal appointment. Their eligibility for the study was assessed during the appointment and the envelope was opened for those considered eligible. The Zelen method was used (i.e. women were randomized prior to seeking consent to participate, and consent was sought only from the experimental group). Envelopes were attached to the records of 7906 women and 3510 (44%) of those were considered eligible for the study. 8% of those randomized to the experimental group refused to participate in the trial.
Participants	3510 nulliparous and multiparous women (2304 in experimental group and 1206 in control group) in Leicester, UK. Exclusion criteria: previous caesarean delivery, maternal illness such as diabetes, epilepsy, and renal disease, previous stillbirth or neonatal death, previous small for gestational age baby, multiple pregnancy, Rhesus antibodies, and elevated serum alpha-feto protein level on 2 occasions.
Interventions	Experimental: antenatal care that included routine care by the general practitioner or community midwife except for 3 scheduled visits to the clinic staffed by hospital midwives, and intrapartum care in a 3-room, alternative unit adjacent to the delivery suite, staffed by 10 staff midwives who were not normally involved with the care of women

	in the delivery suite. Control: routine antenatal care and care in the delivery suite. The majority had antenatal care shared between a consultant and general practitioner or community midwife; a small number had antenatal care from the general practitioner and community midwife.	
Outcomes	Induction of labour, augmentation of labour, intrapartum bleeding, meconium staining, electronic fetal monitoring, fetal heart rate abnormality, delay in 1st or 2nd stage labour, intrapartum analgesia, mode of delivery, perineal trauma, postpartum haemorrhage, neonatal resuscitation, prolonged neonatal hospital stay, stillbirths, neonatal deaths, numbers of, and reasons for, transfers from the experimental form of care, woman's satisfaction.	
Notes	In the experimental group 45% of the women were transferred to specialist care in the delivery suite (23% during the antenatal period, 18% during first stage labour, and 4% in the second or third stage or after delivery). We contacted one of the authors for details about neonatal morbidity but none is available. The primary author is retired.	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Stated the allocation was done by 'random sequence' and envelopes were produced by the statistician who was not involved in the enrolment process. 2:1 randomization scheme favouring the experimental group.
Allocation concealment?	Yes	Consecutively numbered, sealed, opaque envelopes containing random assignment were attached to the records of pregnant women at booking. For those considered eligible for the study the envelopes were opened.
Blinding? All outcomes	Yes	Data collection done by research assistant blinded to the group allocation.
Incomplete outcome data addressed? All outcomes	Yes	Outcome data were obtained on 95% of those randomized. Completion rate for the 6-week maternal questionnaire was 71% and thus not used.
Free of selective reporting?	Yes	Results were listed for all study outcomes.
Free of other bias?	Yes	No other potential sources of bias were noted.

Waldenstrom 1997

Methods	Randomized controlled trial; women enrolled at first visit (mean 20 weeks' gestation).
Participants	1860 nulliparous and multiparous women (928 in the experimental group and 932 controls) who were: residents of Greater Stockholm, Sweden, and did not have any disease that might complicate the birth or jeopardize the baby's health, including diabetes, multiple pregnancy, pre-eclampsia, drug abuse, or smoking during the current pregnancy. A history of low birthweight, preterm birth, perinatal death or a difficult vaginal birth were not exclusion criteria. Women were enrolled between October 1989 and June 1993. The 1230 women who gave birth between October 1989 and January 1992 comprised the sample to assess birth satisfaction and breastfeeding.
Interventions	Experimental: antenatal, intrapartum, and postnatal care in a alternative birth centre located 1 floor below the ordinary labour ward at a Stockholm hospital, with 1:1 midwife-woman ratio during labour, and discharge within 24 hours of the birth. Control: antenatal care at neighbourhood antenatal clinics, intrapartum care in the hospital labour delivery suite (usually each midwife caring for more than 1 woman), and postnatal care for 3-4 days in the hospital postnatal ward. Staff working in the alternative birth centre did not work in the delivery suite.
Outcomes	Transfers to and reasons for standard care, intrapartum medical interventions, operative delivery, postpartum hemorrhage, 5-minute Apgar score < 7, transfer to NICU, perinatal mortality, serious perinatal morbidity, at least 1 postnatal home visit, breastfeeding, stopped breastfeeding within 2 months, sore nipples, engorgement, milk stasis, mastitis, satisfaction with care.
Notes	34% of birth centre group were transferred to standard care either antenatally or intrapartally, and an additional 2% were transferred in the postpartum period.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	No mention of the process of sequence generation. 100 envelopes prepared at a time, with a 50/50 split between groups. Envelopes were "mingled" in a box. A new batch of envelopes was added when "a few" remained.
Allocation concealment?	Yes	Opaque envelopes were used and participants picked their own from the box.
Blinding? All outcomes	Unclear	Not noted whether data collectors were blinded.
Incomplete outcome data addressed? All outcomes	Yes	Only 2 were lost to follow up for the main study outcomes. > 90% follow up in both groups for the postpartum questionnaire at 2 months.

Waldenstrom 1997 (Continued)

Free of selective reporting?	Yes	All outcomes were reported.
Free of other bias?	Yes	Earlier reports were of an n of 1230, because funding ended. Subsequently, additional funding permitted additional enrolment to increase statistical power for medical outcomes.

NICU: neonatal intensive care unit

DATA AND ANALYSES

Comparison 1. Alternative versus conventional birth settings - all trials

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 No analgesia/anaesthesia	5	7842	Risk Ratio (IV, Fixed, 95% CI)	1.17 [1.01, 1.35]
2 Oxytocin augmentation of labour	7	10020	Risk Ratio (IV, Random, 95% CI)	0.78 [0.66, 0.91]
3 Epidural analgesia	7	9820	Risk Ratio (IV, Fixed, 95% CI)	0.82 [0.75, 0.89]
4 Instrumental vaginal birth (forceps or ventouse)	7	10091	Risk Ratio (IV, Fixed, 95% CI)	0.89 [0.79, 1.00]
5 Caesarean birth	8	10239	Risk Ratio (IV, Fixed, 95% CI)	0.89 [0.78, 1.01]
6 Spontaneous vaginal birth	8	10218	Risk Ratio (IV, Fixed, 95% CI)	1.04 [1.02, 1.06]
7 Episiotomy	7	9944	Risk Ratio (IV, Fixed, 95% CI)	0.83 [0.77, 0.90]
8 Postpartum hemorrhage	5	9601	Risk Ratio (IV, Fixed, 95% CI)	0.98 [0.85, 1.14]
9 5-minute Apgar score < 7	6	6554	Risk Ratio (IV, Fixed, 95% CI)	0.98 [0.69, 1.40]
10 Admission to neonatal intensive care unit	6	9867	Risk Ratio (IV, Fixed, 95% CI)	1.07 [0.92, 1.25]
11 Serious perinatal morbidity or mortality	5	6385	Risk Ratio (IV, Random, 95% CI)	1.17 [0.51, 2.67]
12 Perinatal mortality	7	10095	Risk Ratio (IV, Fixed, 95% CI)	1.67 [0.93, 3.00]
13 Serious maternal morbidity or mortality	4	6334	Risk Ratio (IV, Fixed, 95% CI)	1.11 [0.23, 5.36]
14 Breastfeeding at 6-8 weeks	1	1147	Risk Ratio (IV, Fixed, 95% CI)	1.04 [1.02, 1.06]
15 Very positive views of care	2	1207	Risk Ratio (IV, Fixed, 95% CI)	1.96 [1.78, 2.15]

Comparison 2. Alternative versus conventional birth settings - same or separate staff

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Spontaneous vaginal birth	8	10218	Risk Ratio (IV, Fixed, 95% CI)	1.04 [1.02, 1.06]
1.1 Separate staff in birth centre	4	7182	Risk Ratio (IV, Fixed, 95% CI)	1.04 [1.01, 1.06]
1.2 Same staff in both settings	4	3036	Risk Ratio (IV, Fixed, 95% CI)	1.04 [1.00, 1.07]
2 Serious perinatal morbidity or mortality	5	6385	Risk Ratio (IV, Random, 95% CI)	1.17 [0.51, 2.67]
2.1 Separate staff in birth centre	2	3472	Risk Ratio (IV, Random, 95% CI)	1.51 [0.31, 7.43]
2.2 Same staff in both settings	3	2913	Risk Ratio (IV, Random, 95% CI)	0.86 [0.50, 1.48]
3 Serious maternal morbidity or mortality	4	6334	Risk Ratio (IV, Fixed, 95% CI)	1.11 [0.23, 5.36]
3.1 Separate staff in birth centre	2	3472	Risk Ratio (IV, Fixed, 95% CI)	1.00 [0.16, 6.15]
3.2 Same staff in both settings	2	2862	Risk Ratio (IV, Fixed, 95% CI)	1.50 [0.06, 36.88]

4 Very positive views of intrapartum care	2	1207	Risk Ratio (IV, Fixed, 95% CI)	1.96 [1.78, 2.15]
4.1 Separate staff in birth centre	1	1148	Risk Ratio (IV, Fixed, 95% CI)	1.95 [1.77, 2.14]
4.2 Same staff in both settings	1	59	Risk Ratio (IV, Fixed, 95% CI)	2.66 [1.31, 5.40]

Comparison 3. Alternative versus conventional birth settings - variations in continuity of caregiver

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Spontaneous vaginal birth	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.1 Greater continuity of caregiver in birth centre	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.2 No difference in extent of continuity of caregiver	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2 Serious perinatal morbidity or mortality	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
2.1 Greater continuity of caregiver in birth centre	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
2.2 No difference in extent of continuity of caregiver	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
3 Serious maternal morbidity or mortality	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
3.1 Greater continuity of caregiver in birth centre	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
3.2 No difference in extent of continuity of caregiver	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
4 Very positive views of intrapartum care	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
4.1 Greater continuity of caregiver in birth centre	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
4.2 No difference in extent of continuity of caregiver	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

Comparison 4. Alternative versus conventional birth settings - freestanding versus in-hospital

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Spontaneous vaginal birth	0	0	Risk Ratio (IV, Fixed, 95% CI)	Not estimable
1.1 Freestanding	0	0	Risk Ratio (IV, Fixed, 95% CI)	Not estimable
1.2 In-hospital	0	0	Risk Ratio (IV, Fixed, 95% CI)	Not estimable
2 Serious perinatal morbidity or mortality	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2.1 Freestanding	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

2.2 In-hospital	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
3 Serious maternal morbidity or mortality	0	0	Odds Ratio (IV, Fixed, 95% CI)	Not estimable
4 Very positive views of intrapartum care	0	0	Risk Ratio (IV, Fixed, 95% CI)	Not estimable
4.1 Freestanding	0	0	Risk Ratio (IV, Fixed, 95% CI)	Not estimable
4.2 In-hospital	0	0	Risk Ratio (IV, Fixed, 95% CI)	Not estimable

Comparison 5. Variations in alternative settings - bedroom-like, ambient, Snoezelen

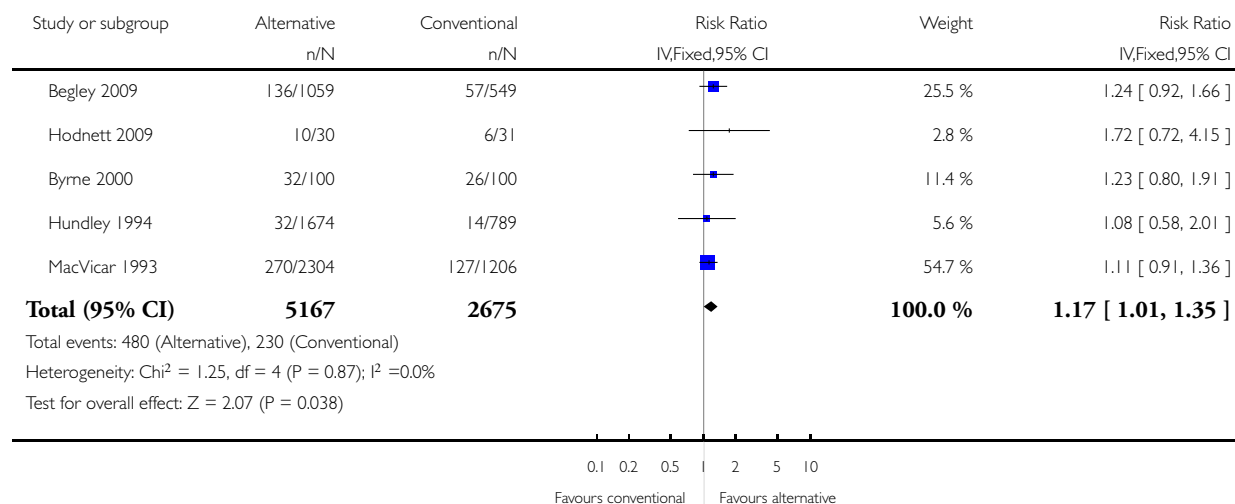
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Spontaneous vaginal birth	1	61	Risk Ratio (M-H, Fixed, 95% CI)	0.87 [0.65, 1.16]
1.1 Bedroom-like	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.2 Ambient	1	61	Risk Ratio (M-H, Fixed, 95% CI)	0.87 [0.65, 1.16]
1.3 Snoezelen	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2 Serious perinatal morbidity or mortality	1	61	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2.1 Bedroom-like	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2.2 Ambient	1	61	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2.3 Snoezelen	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
3 Serious maternal morbidity or mortality	1	61	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
3.1 Bedroom-like	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
3.2 Ambient	1	61	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
3.3 Snoezelen	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
4 Very positive views of intrapartum care	1	59	Risk Ratio (M-H, Fixed, 95% CI)	2.66 [1.31, 5.40]
4.1 Bedroom-like	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
4.2 Ambient	1	59	Risk Ratio (M-H, Fixed, 95% CI)	2.66 [1.31, 5.40]
4.3 Snoezelen	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

Analysis 1.1. Comparison 1 Alternative versus conventional birth settings - all trials, Outcome 1 No analgesia/anaesthesia.

Review: Alternative versus conventional institutional settings for birth

Comparison: 1 Alternative versus conventional birth settings - all trials

Outcome: 1 No analgesia/anaesthesia

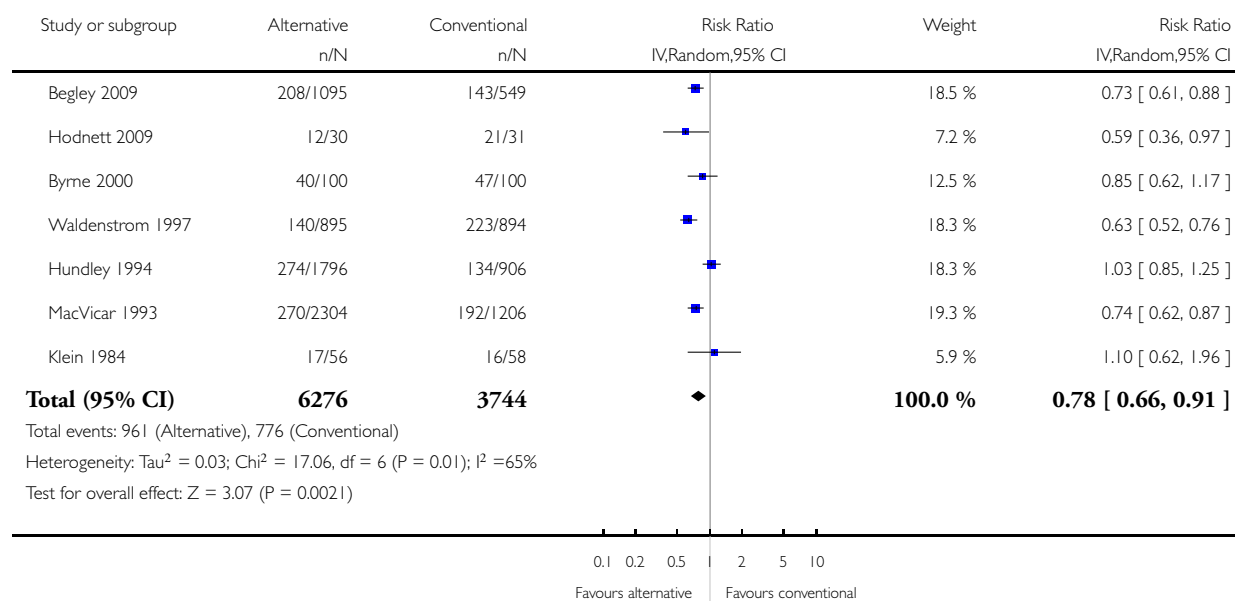


Analysis 1.2. Comparison 1 Alternative versus conventional birth settings - all trials, Outcome 2 Oxytocin augmentation of labour.

Review: Alternative versus conventional institutional settings for birth

Comparison: 1 Alternative versus conventional birth settings - all trials

Outcome: 2 Oxytocin augmentation of labour

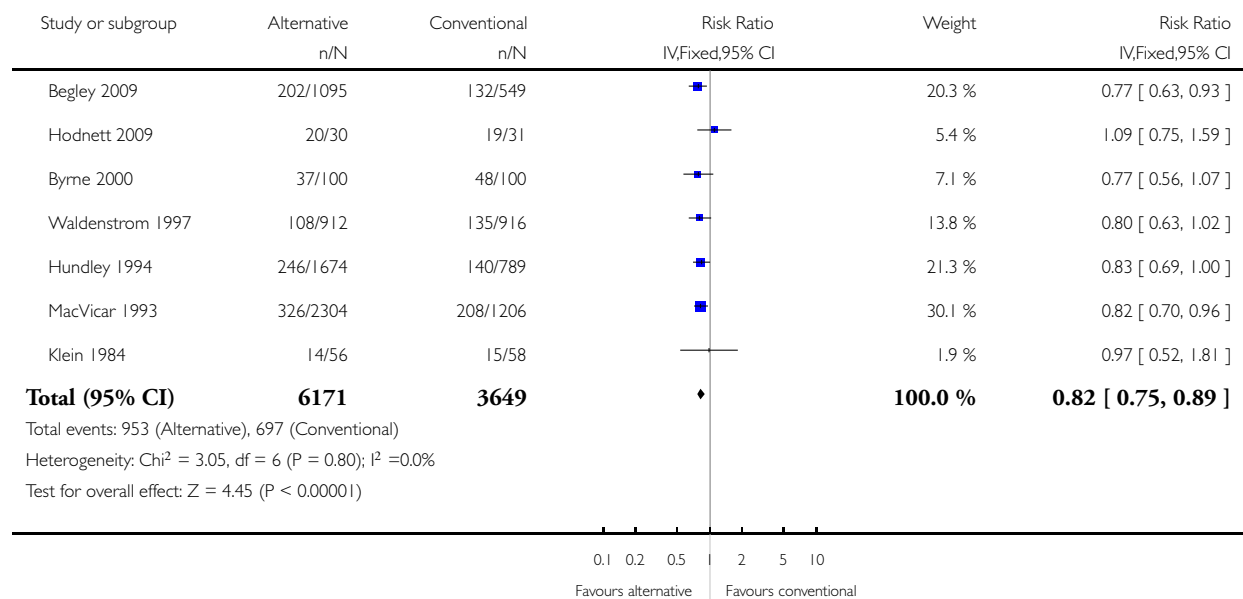


Analysis 1.3. Comparison 1 Alternative versus conventional birth settings - all trials, Outcome 3 Epidural analgesia.

Review: Alternative versus conventional institutional settings for birth

Comparison: 1 Alternative versus conventional birth settings - all trials

Outcome: 3 Epidural analgesia

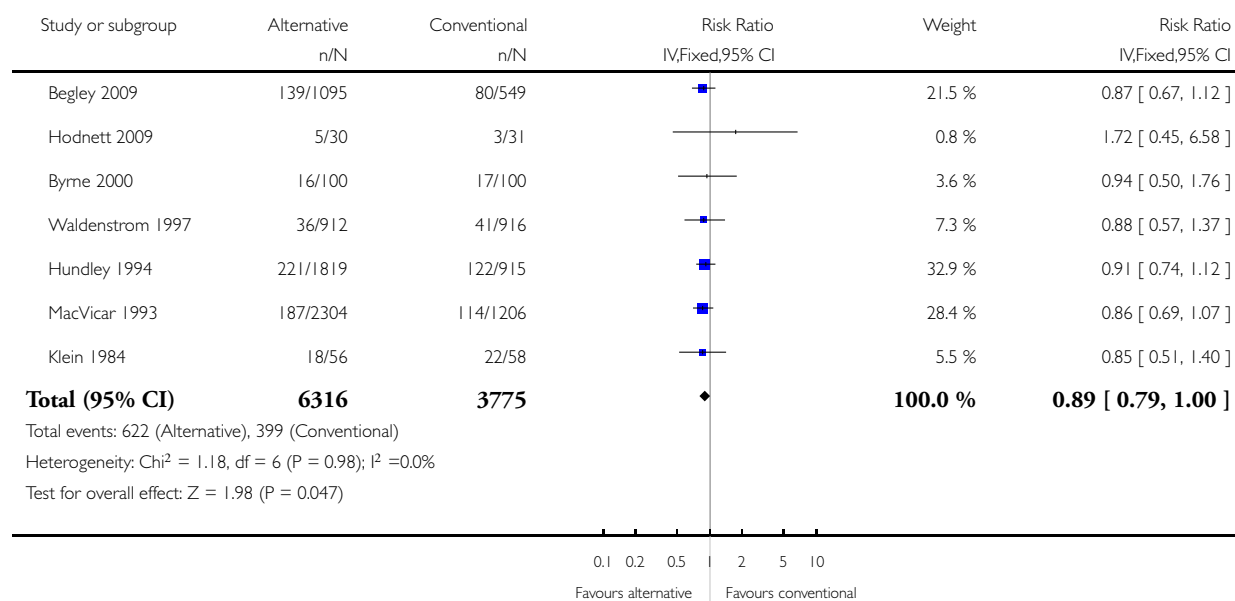


Analysis 1.4. Comparison 1 Alternative versus conventional birth settings - all trials, Outcome 4 Instrumental vaginal birth (forceps or ventouse).

Review: Alternative versus conventional institutional settings for birth

Comparison: 1 Alternative versus conventional birth settings - all trials

Outcome: 4 Instrumental vaginal birth (forceps or ventouse)

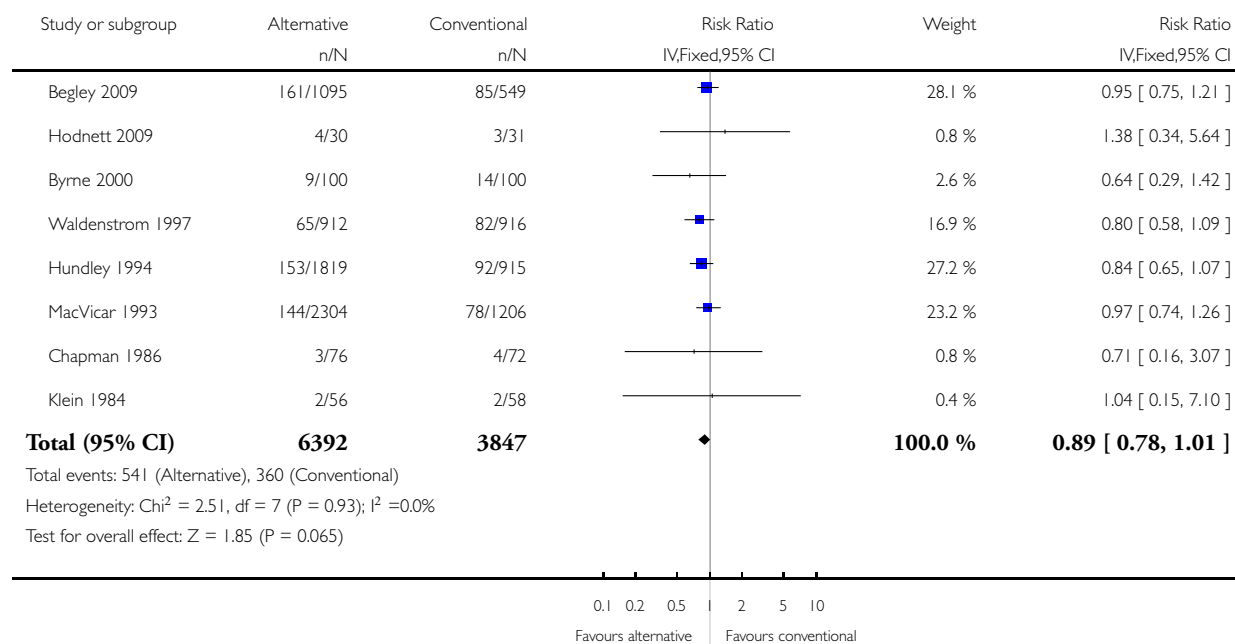


Analysis 1.5. Comparison 1 Alternative versus conventional birth settings - all trials, Outcome 5 Caesarean birth.

Review: Alternative versus conventional institutional settings for birth

Comparison: 1 Alternative versus conventional birth settings - all trials

Outcome: 5 Caesarean birth

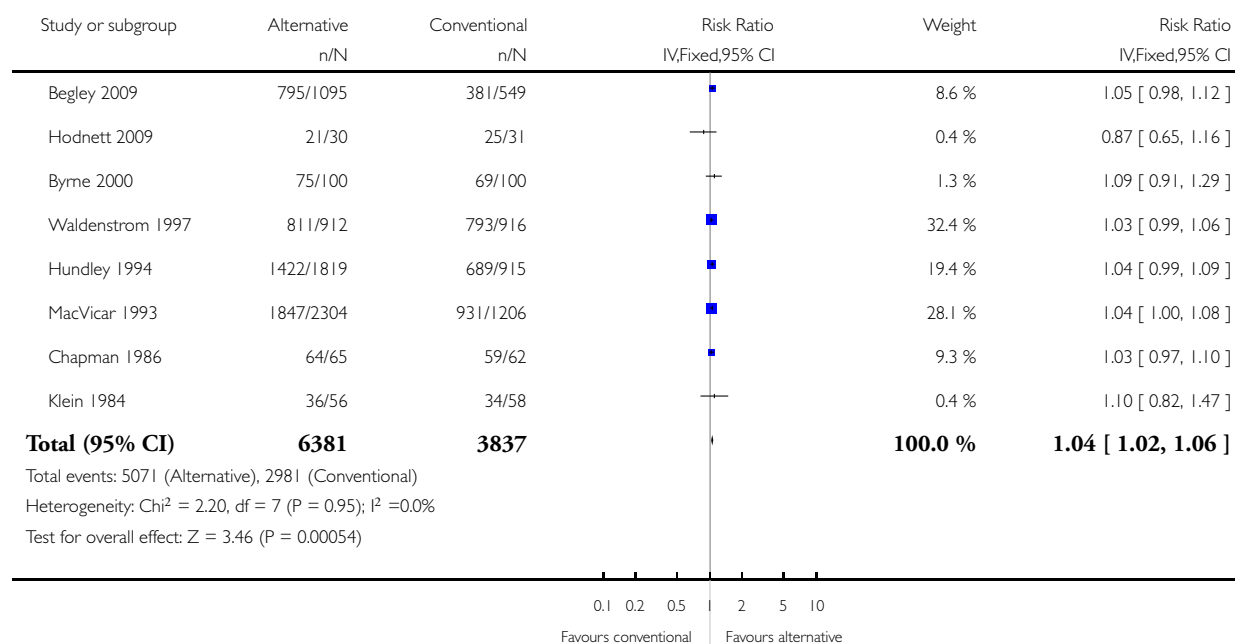


Analysis 1.6. Comparison 1 Alternative versus conventional birth settings - all trials, Outcome 6 Spontaneous vaginal birth.

Review: Alternative versus conventional institutional settings for birth

Comparison: 1 Alternative versus conventional birth settings - all trials

Outcome: 6 Spontaneous vaginal birth

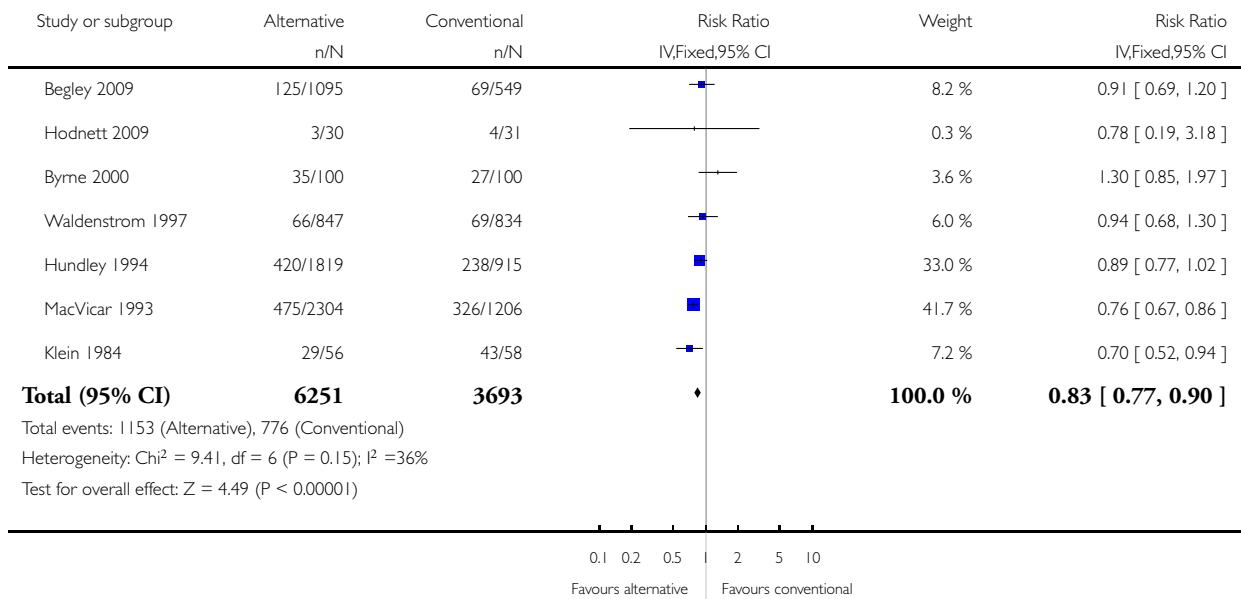


Analysis 1.7. Comparison 1 Alternative versus conventional birth settings - all trials, Outcome 7 Episiotomy.

Review: Alternative versus conventional institutional settings for birth

Comparison: 1 Alternative versus conventional birth settings - all trials

Outcome: 7 Episiotomy

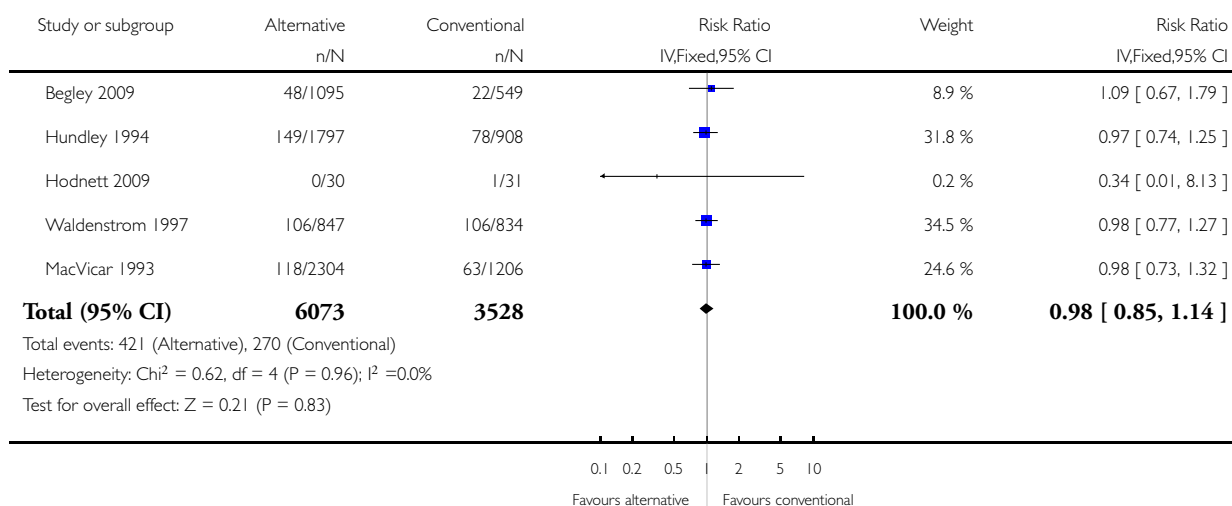


Analysis 1.8. Comparison 1 Alternative versus conventional birth settings - all trials, Outcome 8 Postpartum hemorrhage.

Review: Alternative versus conventional institutional settings for birth

Comparison: 1 Alternative versus conventional birth settings - all trials

Outcome: 8 Postpartum hemorrhage

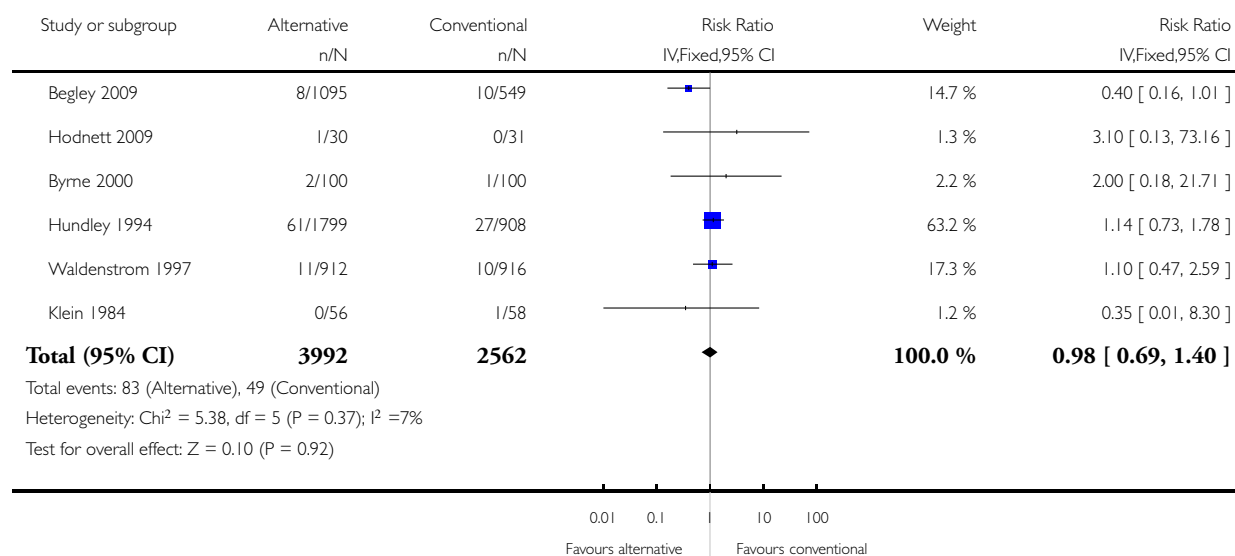


Analysis 1.9. Comparison 1 Alternative versus conventional birth settings - all trials, Outcome 9 5-minute Apgar score < 7.

Review: Alternative versus conventional institutional settings for birth

Comparison: 1 Alternative versus conventional birth settings - all trials

Outcome: 9 5-minute Apgar score < 7

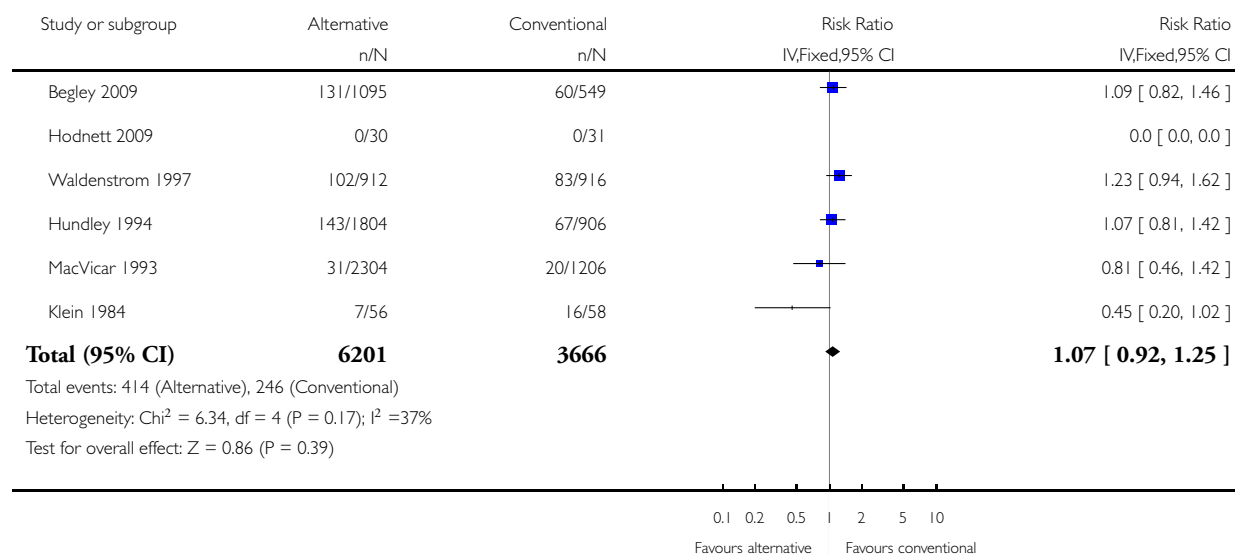


Analysis 1.10. Comparison 1 Alternative versus conventional birth settings - all trials, Outcome 10 Admission to neonatal intensive care unit.

Review: Alternative versus conventional institutional settings for birth

Comparison: 1 Alternative versus conventional birth settings - all trials

Outcome: 10 Admission to neonatal intensive care unit

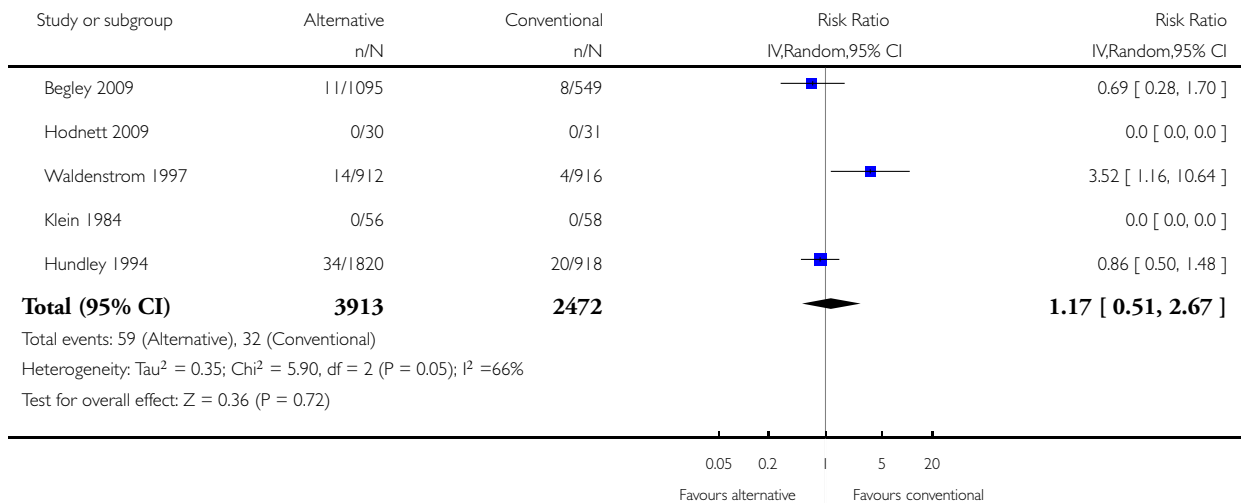


Analysis 1.11. Comparison 1 Alternative versus conventional birth settings - all trials, Outcome 11 Serious perinatal morbidity or mortality.

Review: Alternative versus conventional institutional settings for birth

Comparison: 1 Alternative versus conventional birth settings - all trials

Outcome: 11 Serious perinatal morbidity or mortality

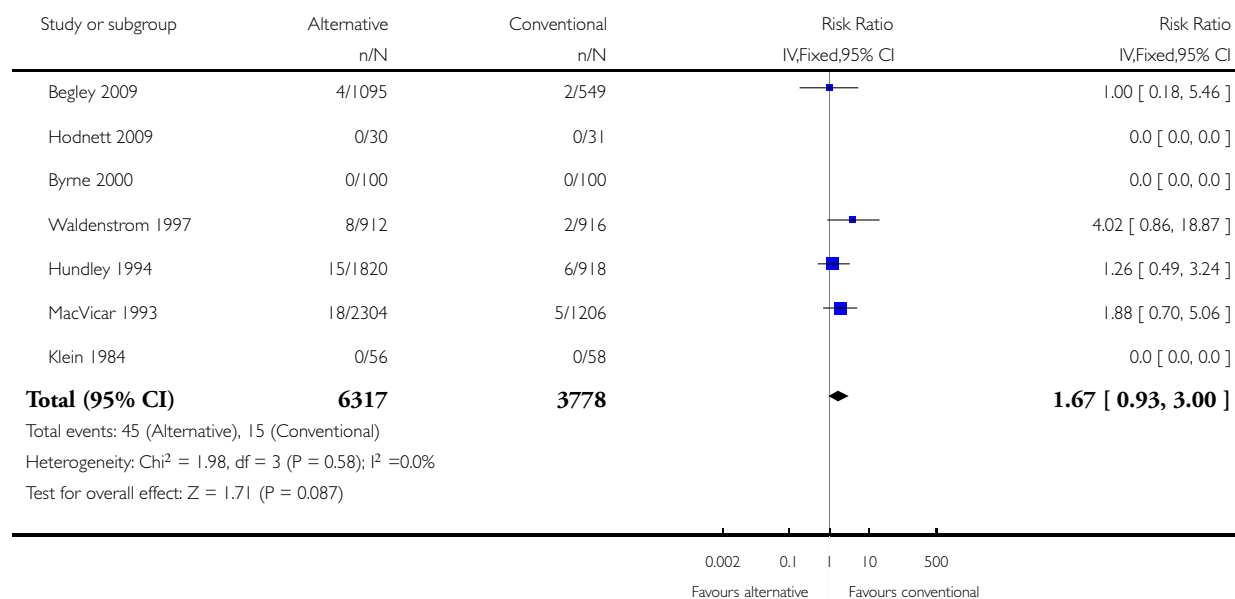


Analysis 1.12. Comparison 1 Alternative versus conventional birth settings - all trials, Outcome 12 Perinatal mortality.

Review: Alternative versus conventional institutional settings for birth

Comparison: 1 Alternative versus conventional birth settings - all trials

Outcome: 12 Perinatal mortality

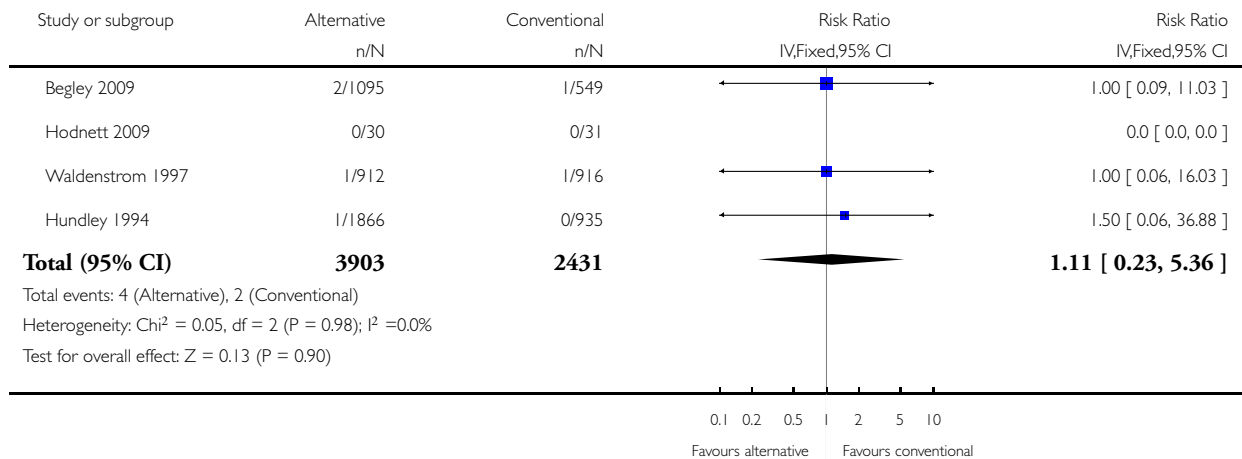


Analysis 1.13. Comparison 1 Alternative versus conventional birth settings - all trials, Outcome 13 Serious maternal morbidity or mortality.

Review: Alternative versus conventional institutional settings for birth

Comparison: 1 Alternative versus conventional birth settings - all trials

Outcome: 13 Serious maternal morbidity or mortality

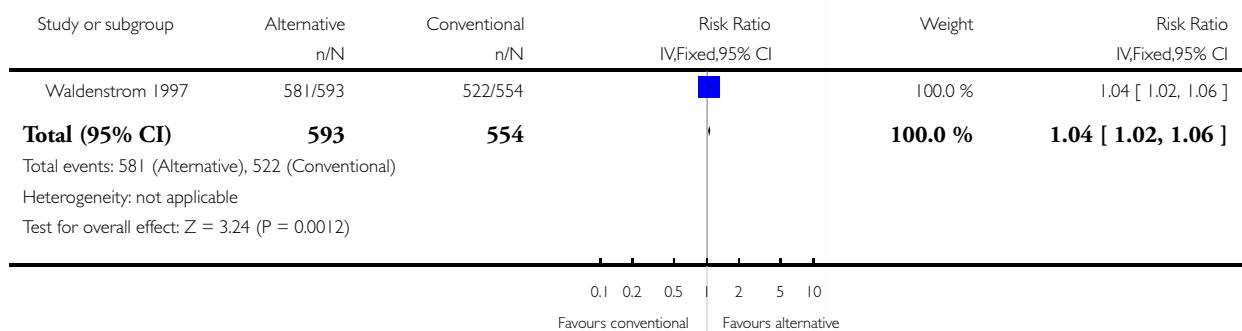


Analysis 1.14. Comparison 1 Alternative versus conventional birth settings - all trials, Outcome 14 Breastfeeding at 6-8 weeks.

Review: Alternative versus conventional institutional settings for birth

Comparison: 1 Alternative versus conventional birth settings - all trials

Outcome: 14 Breastfeeding at 6-8 weeks

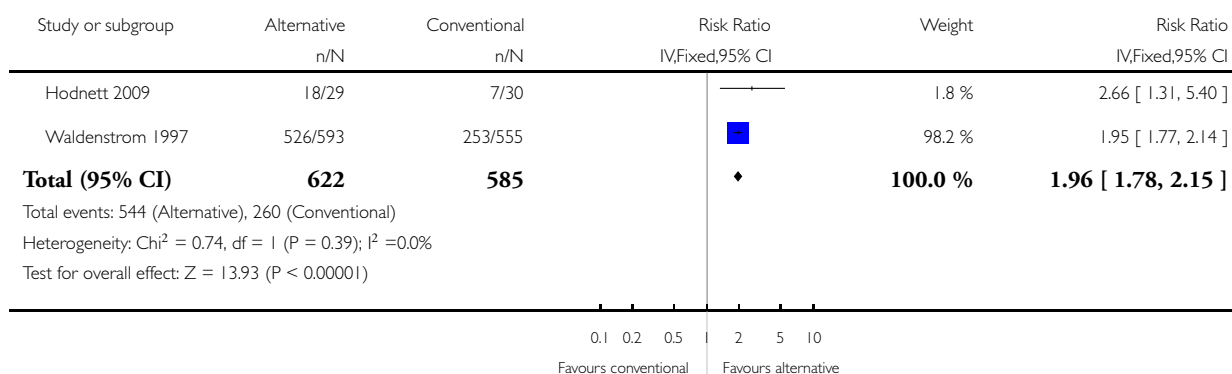


Analysis 1.15. Comparison 1 Alternative versus conventional birth settings - all trials, Outcome 15 Very positive views of care.

Review: Alternative versus conventional institutional settings for birth

Comparison: 1 Alternative versus conventional birth settings - all trials

Outcome: 15 Very positive views of care

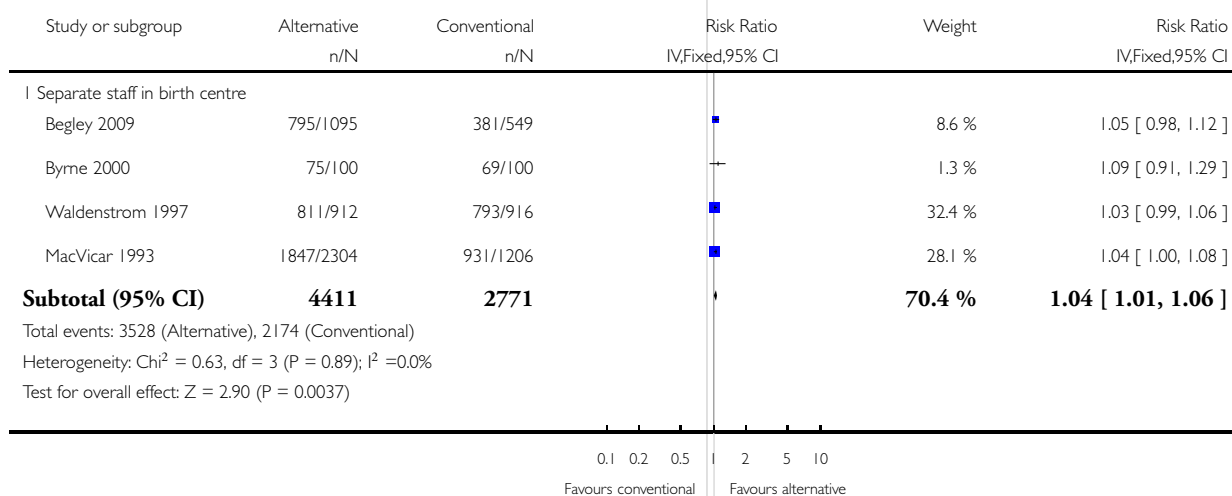


Analysis 2.1. Comparison 2 Alternative versus conventional birth settings - same or separate staff, Outcome 1 Spontaneous vaginal birth.

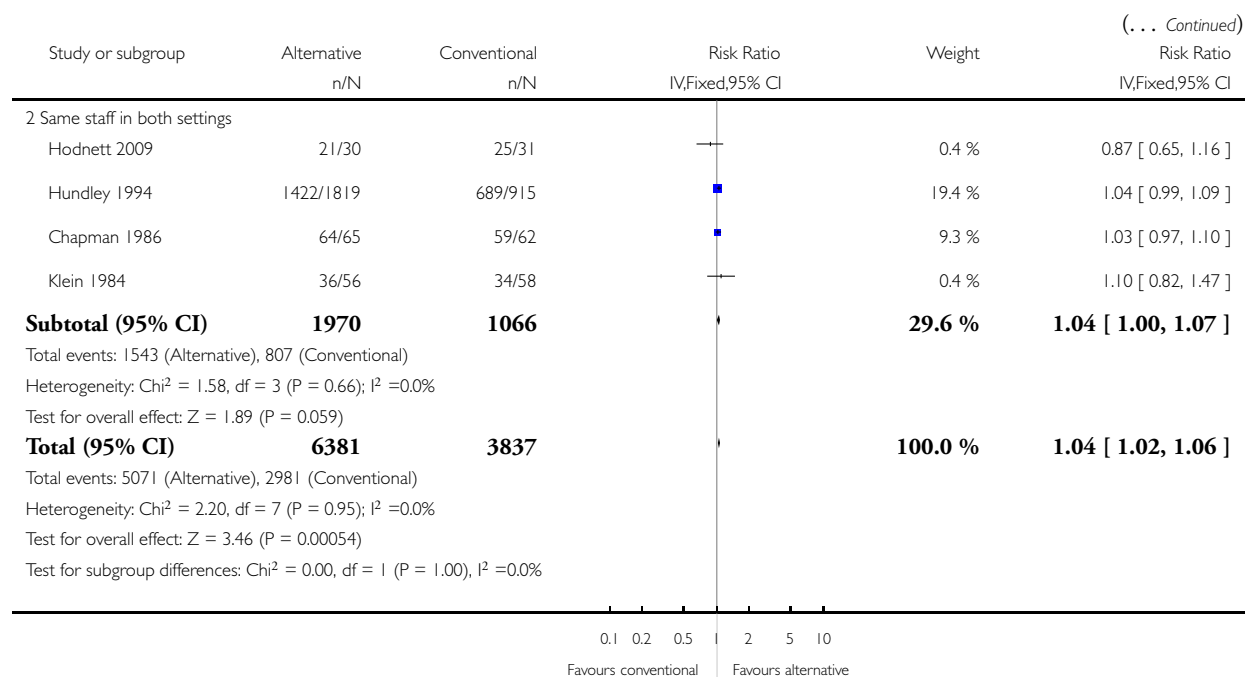
Review: Alternative versus conventional institutional settings for birth

Comparison: 2 Alternative versus conventional birth settings - same or separate staff

Outcome: 1 Spontaneous vaginal birth



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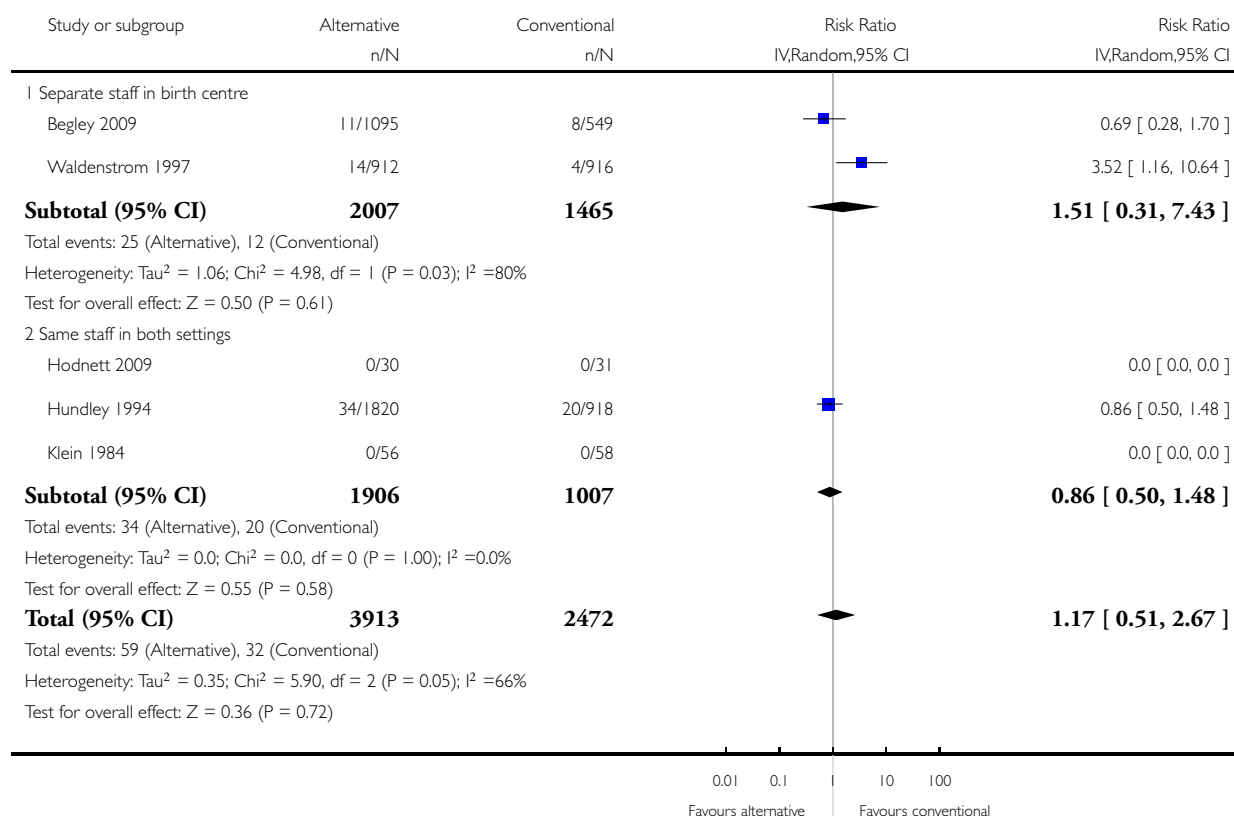


Analysis 2.2. Comparison 2 Alternative versus conventional birth settings - same or separate staff, Outcome 2 Serious perinatal morbidity or mortality.

Review: Alternative versus conventional institutional settings for birth

Comparison: 2 Alternative versus conventional birth settings - same or separate staff

Outcome: 2 Serious perinatal morbidity or mortality

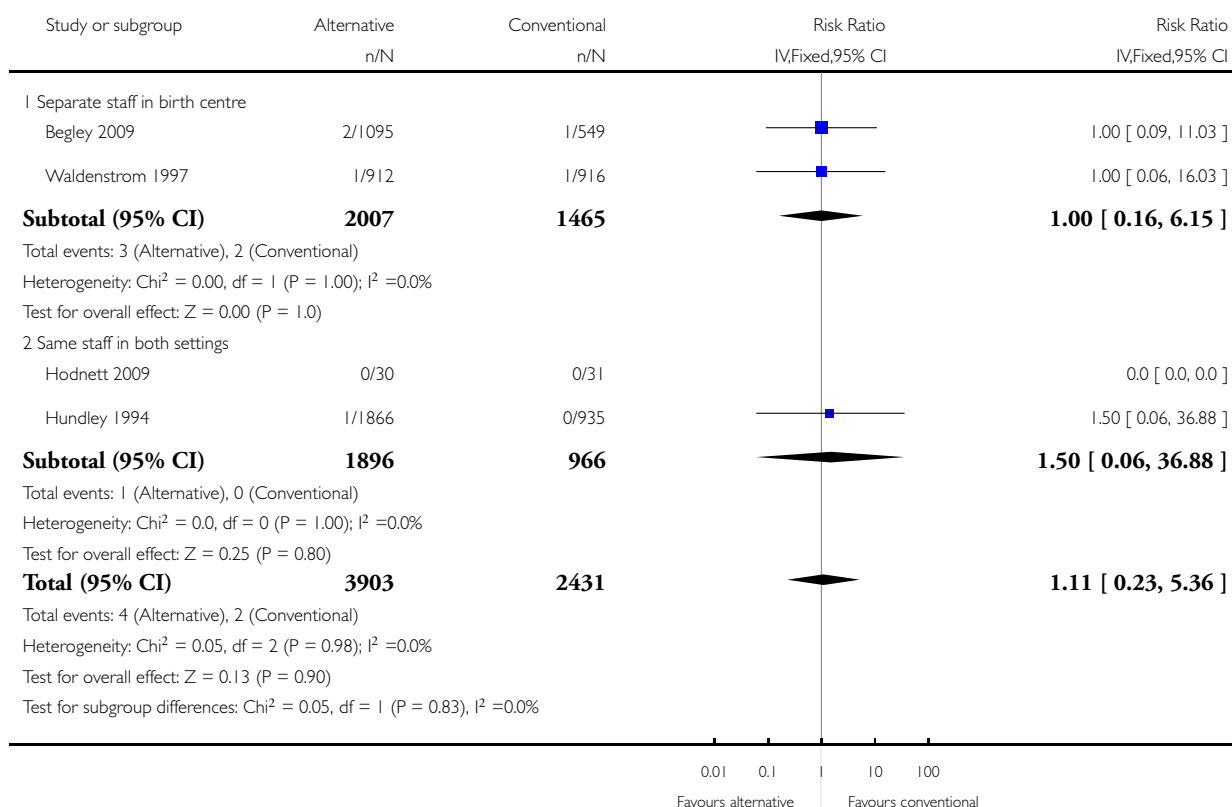


Analysis 2.3. Comparison 2 Alternative versus conventional birth settings - same or separate staff, Outcome 3 Serious maternal morbidity or mortality.

Review: Alternative versus conventional institutional settings for birth

Comparison: 2 Alternative versus conventional birth settings - same or separate staff

Outcome: 3 Serious maternal morbidity or mortality

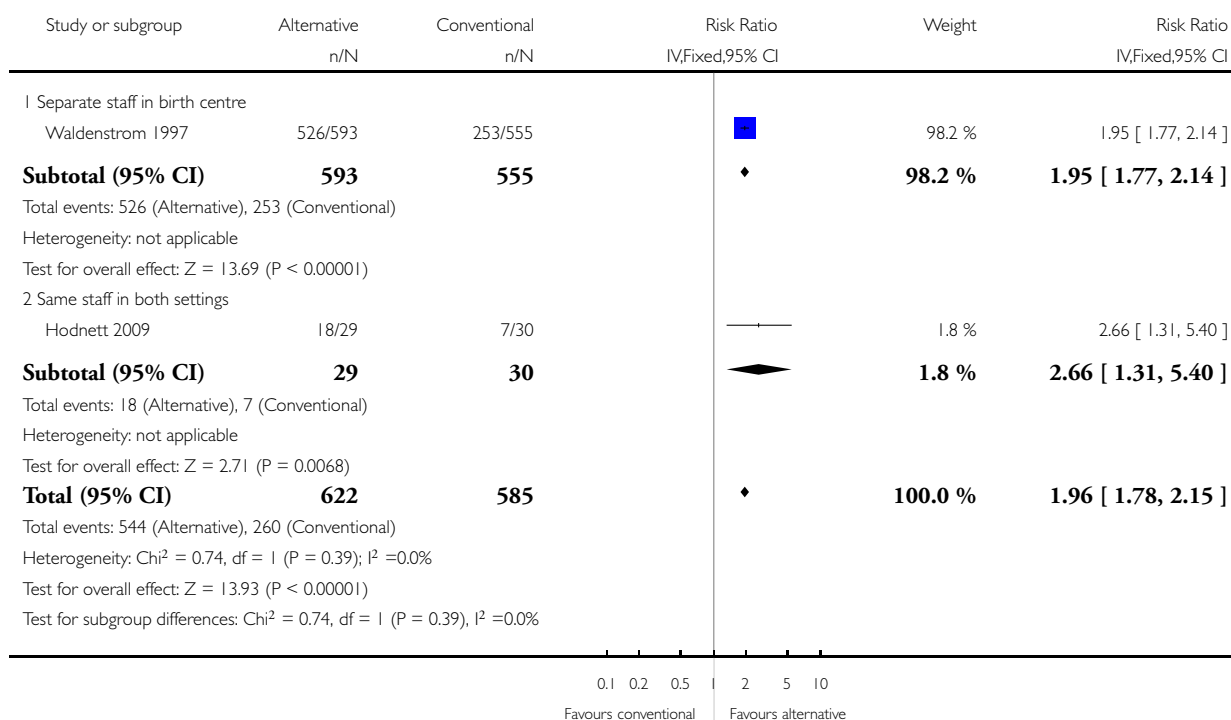


Analysis 2.4. Comparison 2 Alternative versus conventional birth settings - same or separate staff, Outcome 4 Very positive views of intrapartum care.

Review: Alternative versus conventional institutional settings for birth

Comparison: 2 Alternative versus conventional birth settings - same or separate staff

Outcome: 4 Very positive views of intrapartum care

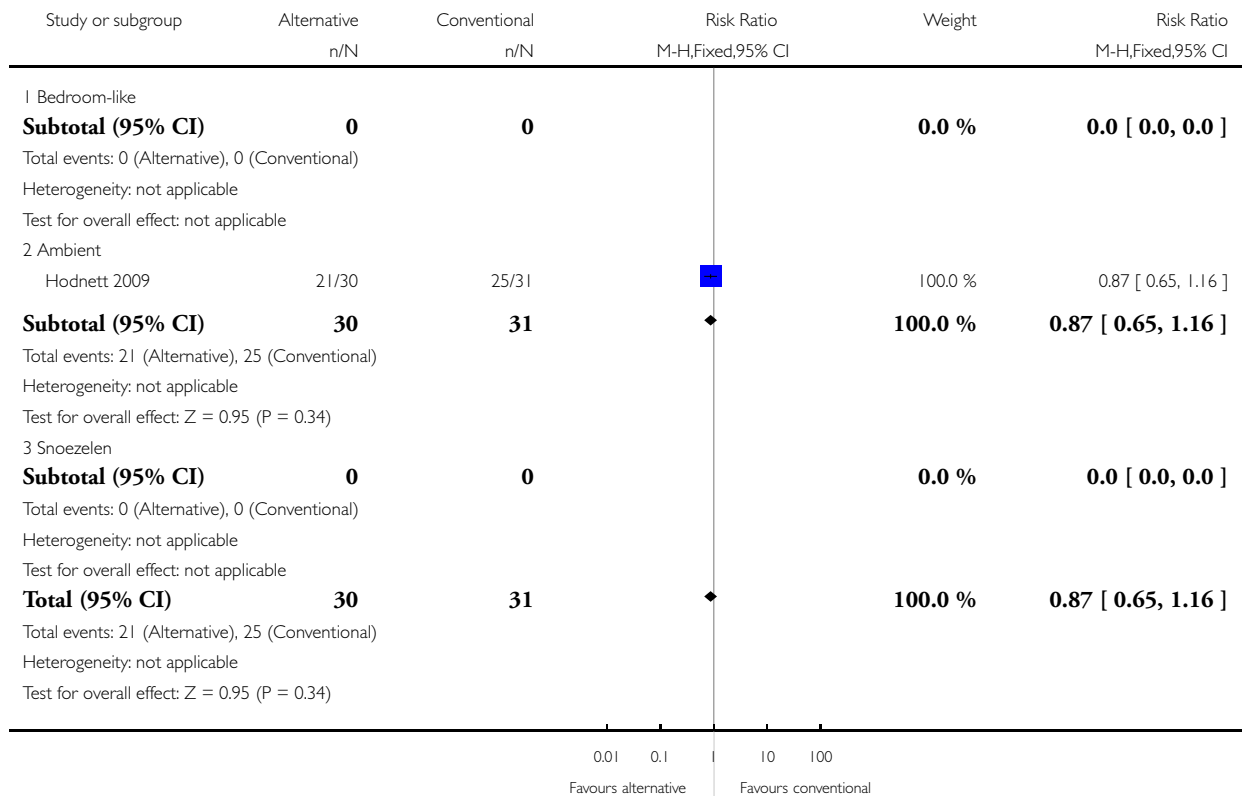


Analysis 5.1. Comparison 5 Variations in alternative settings - bedroom-like, ambient, Snoezelen, Outcome 1 Spontaneous vaginal birth.

Review: Alternative versus conventional institutional settings for birth

Comparison: 5 Variations in alternative settings - bedroom-like, ambient, Snoezelen

Outcome: 1 Spontaneous vaginal birth

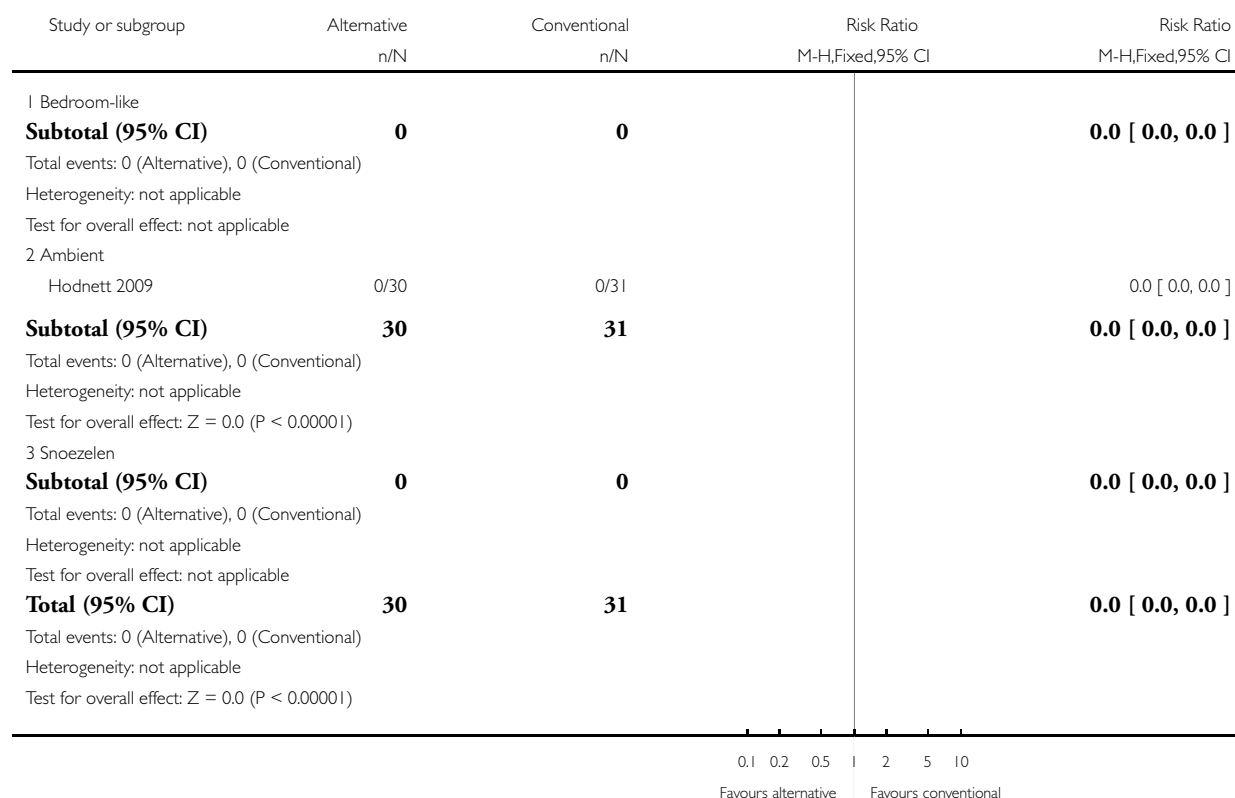


Analysis 5.2. Comparison 5 Variations in alternative settings - bedroom-like, ambient, Snoezelen, Outcome 2 Serious perinatal morbidity or mortality.

Review: Alternative versus conventional institutional settings for birth

Comparison: 5 Variations in alternative settings - bedroom-like, ambient, Snoezelen

Outcome: 2 Serious perinatal morbidity or mortality



Analysis 5.3. Comparison 5 Variations in alternative settings - bedroom-like, ambient, Snoezelen, Outcome 3 Serious maternal morbidity or mortality.

Review: Alternative versus conventional institutional settings for birth

Comparison: 5 Variations in alternative settings - bedroom-like, ambient, Snoezelen

Outcome: 3 Serious maternal morbidity or mortality

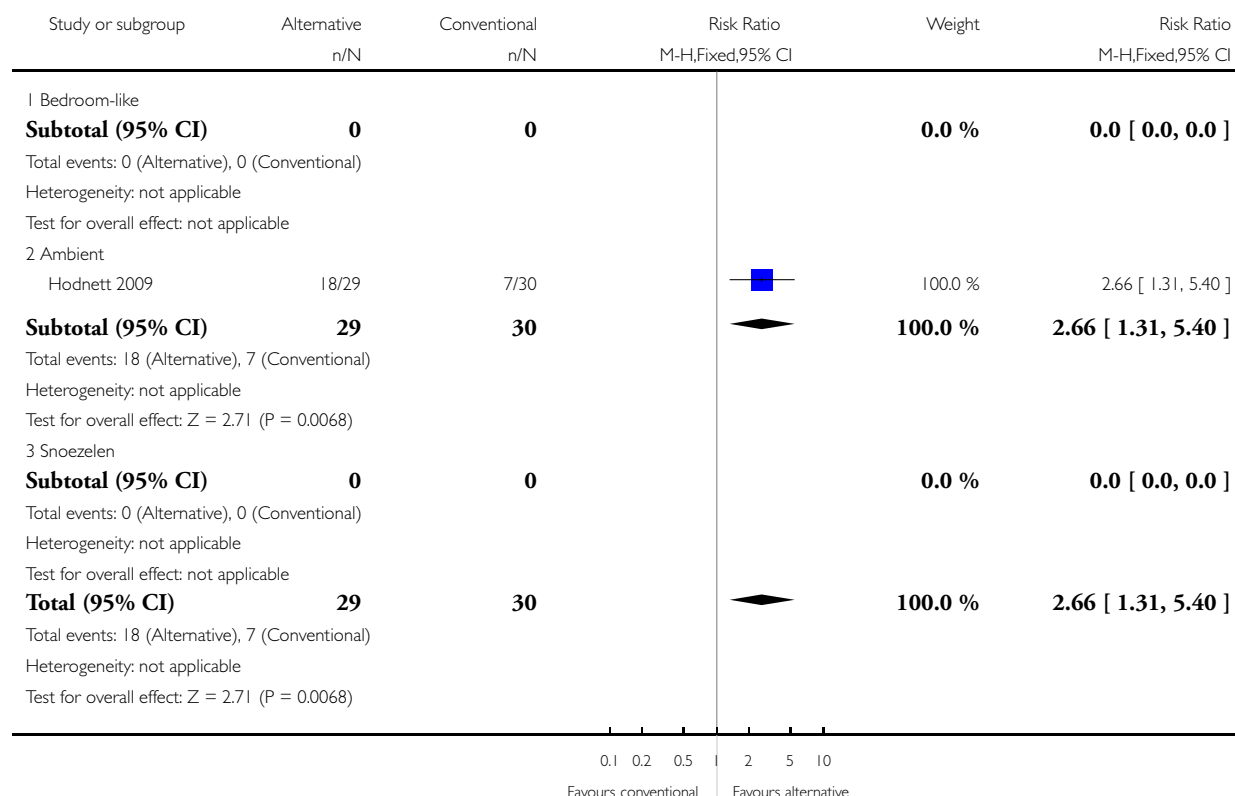
Study or subgroup	Alternative n/N	Conventional n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
1 Bedroom-like				
Subtotal (95% CI)	0	0		0.0 [0.0, 0.0]
Total events: 0 (Alternative), 0 (Conventional)				
Heterogeneity: not applicable				
Test for overall effect: not applicable				
2 Ambient				
Hodnett 2009	0/30	0/31		0.0 [0.0, 0.0]
Subtotal (95% CI)	30	31		0.0 [0.0, 0.0]
Total events: 0 (Alternative), 0 (Conventional)				
Heterogeneity: not applicable				
Test for overall effect: Z = 0.0 (P < 0.00001)				
3 Snoezelen				
Subtotal (95% CI)	0	0		0.0 [0.0, 0.0]
Total events: 0 (Alternative), 0 (Conventional)				
Heterogeneity: not applicable				
Test for overall effect: not applicable				
Total (95% CI)	30	31		0.0 [0.0, 0.0]
Total events: 0 (Alternative), 0 (Conventional)				
Heterogeneity: not applicable				
Test for overall effect: Z = 0.0 (P < 0.00001)				

Analysis 5.4. Comparison 5 Variations in alternative settings - bedroom-like, ambient, Snoezelen, Outcome 4 Very positive views of intrapartum care.

Review: Alternative versus conventional institutional settings for birth

Comparison: 5 Variations in alternative settings - bedroom-like, ambient, Snoezelen

Outcome: 4 Very positive views of intrapartum care



FEEDBACK

Fahy, January 2007

Summary

The review authors comment about a “trend towards higher rates of perinatal mortality in the alternative settings” has been reported elsewhere in support of claims that birth centres are less safe than conventional settings for labour (1). A possible explanation for any real increase in perinatal mortality could be delayed transfer from the birth centre. We examined reports of the six trials included in the review and, as in the Cochrane review, found 41 perinatal deaths amongst women allocated birth centres. Only six of these deaths, however, were of normally formed babies who reached term. It is only these babies who were eligible to be born in a birth centre. Three of these six deaths were of women who had been allocated birth centre care but actually received standard labour care.

This raises questions about the validity of the underlying randomised trials. These studies have an experimental design where researcher control should ensure that people receive the specific treatment that was planned for them (2). The Cochrane Handbook gives no

guidance on how to evaluate either the quality of the researchers' definition of the planned treatments, or the agreement between what treatment was actually provided and what the researcher planned (3). For the majority of the trials in this review the treatments are not adequately defined. Nor did they adequately control the treatments actually provided to each allocated group. It is not clear how any birth centre trial can sensibly be considered to have been scientifically controlled. The reviewers attempted to deal with this crucial point by claiming that they were only looking at the effect of the 'setting', but their objectives clearly state that they were examining the effect of "care within a setting".

In conclusion, this review is scientifically weak because of the weaknesses of the underlying trials.

References

1. Pesce A. (2005). Media Transcript: Discussion of Midwife-led birthing units - AMA's Dr Andrew Pesce on the Today Show. Retrieved July 9th, 2006, from <http://www.ama.com.au/web.nsf/doc/WEEN-6FS3EU>
2. Borelli B, Sepinwall D, Ernst D, Bellg A, Czajkowski S, Berger R. A new tool to assess treatment fidelity and evaluation of treatment fidelity across 10 years of health behavior research. *Journal of Consulting and Clinical Psychology* 2005 73:852-860.
3. Higgins J, Green S. *Cochrane Handbook for Systematic Reviews of Interventions* Version 4.2.5. 2005. Retrieved 10th July, 2006, from <http://www.cochrane.org/resources/handbook/>
(Summary of feedback from Kathleen Fahy and Sally Tracy, January 2007)

Reply

We acknowledge in our Review that place of birth is a complex amalgamation of setting and care (and, indeed, philosophies of care) within that setting. We did not, and never intended to, distinguish 'setting' from 'care within the setting'. On the contrary, the two are indistinguishable, involving not only architectural differences but also different policies and procedures (and frequently, different care providers), compared to a conventional hospital labour ward.

We agree that one reason for excess perinatal mortality (if indeed it is a "true" excess) could be delayed transfer. But there may be other factors, such as those we raise in our Discussion. Systematic reviews, and randomized trials, report what happened but cannot tell one why it happened. The fact that some of the babies who died were antenatal transfers and not at term does not invalidate the Review, as it included the outcomes of women and babies from the point of trial entry, which, in some of the included studies, was early in pregnancy. Intention-to-treat captures all the outcomes consequent on the initial place of booking, as those are the outcomes that are likely to pertain for women in 'real life' who make similar booking decisions.

We point out in the Discussion that the high rates of transfer out of alternative settings serve to dilute both the potential benefits and risks. The issue here is not one of validity, but of the precision of the results. It would be unethical to keep women in their allocated form of care, regardless of subsequent changes in risk factors or preferences. The important question for women and providers is whether choosing an alternative setting is likely to be better or worse than choosing a conventional hospital setting. Making this judgment will include an assessment of the rates of transfer between settings, and of fetal and infant wellbeing at various stages of gestation. The package of care provided in alternative settings needs to be examined in conjunction with that delivered in the referral unit(s), since this is what women are potentially signing up for when they make their booking decision.

In our view, none of the points raised threaten the internal validity of the Review, but they do illustrate the turmoil that can arise when results are used to support the arguments of one faction or another without regard to the full context of a study, especially in a highly contested area like place of birth. We acknowledge the difficulties faced by both those who want to maximize choice for childbearing women, and those who are concerned about safety issues. We hope that a close reading of our introduction, methods, and discussion will reveal that we share some of the concerns of both groups of protagonists, and we hope that the design of future research in this area can benefit from on-going debates like the one we are addressing here.

(Response from Ellen Hodnett and Soo Downe, May 2007)

Contributors

Kathleen Fahy and Sally Tracy

WHAT'S NEW

Last assessed as up-to-date: 12 July 2010.

Date	Event	Description
13 July 2010	New search has been performed	Search updated. Three new trials identified and included (Abdullahi 1990 ; Begley 2009 ; Hodnett 2009). Revision to every aspect of the Review, to expand the focus to incorporate new types of alternative birth settings, to bring it up-to-date in terms of current methodological guidelines, and to incorporate the three new trials.
13 July 2010	New citation required and conclusions have changed	This update has expanded the focus of the review to a variety of types of alternative institutional birth settings. The title has been changed to reflect the expansion of the focus.

HISTORY

Protocol first published: Issue 3, 1996

Review first published: Issue 3, 1996

Date	Event	Description
12 May 2008	Amended	Converted to new review format.
12 November 2004	New search has been performed	New search conducted in May 2004. We did not identify additional studies. Revisions to entire review, including background, objectives, methods, results, discussion, implications, and tables have been made.

CONTRIBUTIONS OF AUTHORS

Ellen Hodnett: all aspects of preparation of revised review.

Soo Downe: edited all aspects of revised review.

Denis Walsh: edited all aspects of revised review, assessed risk of bias in one trial.

Julie Weston: prepared new data entry forms and re-did all data entry; editing of tables; assessment of methodological quality of the studies; edited all aspects of revised review.

DECLARATIONS OF INTEREST

Ellen Hodnett has given talks and has written about the importance of the birth environment, and she was the Principal Investigator for one of the trials included in the review. Soo Downe and Denis Walsh have completed qualitative and quantitative reviews of birth settings. Julie Weston was the trial coordinator for one of the included trials.

SOURCES OF SUPPORT

Internal sources

- University of Toronto, Canada.
- University of Central Lancashire, UK.

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

This update has expanded the focus of the review to a variety of types of alternative institutional birth settings. The title has been changed to reflect the expansion of the focus.

The review was revised to align it with current methodological guidelines of the Pregnancy and Childbirth Group. This involved pre-specifying a limited number of primary and secondary outcomes, completing Risk of Bias tables, and a number of other methodological improvements.

INDEX TERMS

Medical Subject Headings (MeSH)

*Birthing Centers; *Delivery Rooms; Randomized Controlled Trials as Topic

MeSH check words

Female; Humans; Pregnancy