Midwife-led continuity models versus other models of care for childbearing women (Review)

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[Intervention Review]

Midwife-led continuity models versus other models of care for childbearing women

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ABSTRACT

Background

Midwives are primary providers of care for childbearing women around the world. However, there is a lack of synthesised information to establish whether there are differences in morbidity and mortality, effectiveness and psychosocial outcomes between midwife-led continuity models and other models of care.

Objectives

To compare midwife-led continuity models of care with other models of care for childbearing women and their infants.

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (28 January 2013) and reference lists of retrieved studies.

Selection criteria

All published and unpublished trials in which pregnant women are randomly allocated to midwife-led continuity models of care or other models of care during pregnancy and birth.

Data collection and analysis

All review authors evaluated methodological quality. Two review authors checked data extraction.

Main results

We included 13 trials involving 16,242 women. Women who had midwife-led continuity models of care were less likely to experience regional analgesia (average risk ratio (RR) 0.83, 95% confidence interval (CI) 0.76 to 0.90), episiotomy (average RR 0.84, 95% CI 0.76 to 0.92), and instrumental birth (average RR 0.88, 95% CI 0.81 to 0.96), and were more likely to experience no intrapartum analgesia/anaesthesia (average RR 1.16, 95% CI 1.04 to 1.31), spontaneous vaginal birth (average RR 1.05, 95% CI 1.03 to 1.08), attendance at birth by a known midwife (average RR 7.83, 95% CI 4.15 to 14.80), and a longer mean length of labour (hours) (mean

difference (hours) 0.50, 95% CI 0.27 to 0.74). There were no differences between groups for caesarean births (average RR 0.93, 95% CI 0.84 to 1.02).

Women who were randomised to receive midwife-led continuity models of care were less likely to experience preterm birth (average RR 0.77, 95% CI 0.62 to 0.94) and fetal loss before 24 weeks' gestation (average RR 0.81, 95% CI 0.66 to 0.99), although there were no differences in fetal loss/neonatal death of at least 24 weeks (average RR 1.00, 95% CI 0.67 to 1.51) or in overall fetal/neonatal death (average RR 0.84, 95% CI 0.71 to 1.00).

Due to a lack of consistency in measuring women's satisfaction and assessing the cost of various maternity models, these outcomes were reported narratively. The majority of included studies reported a higher rate of maternal satisfaction in the midwifery-led continuity care model. Similarly there was a trend towards a cost-saving effect for midwife-led continuity care compared to other care models.

Authors' conclusions

Most women should be offered midwife-led continuity models of care and women should be encouraged to ask for this option although caution should be exercised in applying this advice to women with substantial medical or obstetric complications.

PLAIN LANGUAGE SUMMARY

Midwife-led continuity models versus other models of care for childbearing women

In many parts of the world, midwives are the main providers of care for childbearing women. Elsewhere, it may be obstetricians or family physicians that have the main responsibility for care; or the responsibility may be shared. The philosophy behind midwife-led continuity models is normality, continuity of care and being cared for by a known, trusted midwife during labour. The emphasis is on the natural ability of women to experience birth with minimum intervention. Midwife-led continuity of care can be provided through a team of midwives who share the caseload, often called 'team' midwifery. Another model is 'caseload midwifery', which aims to ensure that the woman receives all her care from one midwife or her or his practice partner. Midwife-led continuity of care is provided in a multi-disciplinary network of consultation and referral with other care providers. This contrasts with medical-led models of care where an obstetrician or family physician is primarily responsible for care. In shared-care models, responsibility is shared between different healthcare professionals.

In this review we included models of care where midwives provided care throughout the pregnancy, and during labour and after birth. We identified 13 studies involving 16,242 women both at low and increased risk of complications. Midwife-led continuity of care was associated with several benefits for mothers and babies, and had no identified adverse effects compared with models of medical-led care and shared care. The main benefits were a reduction in the use of epidurals, with fewer episiotomies or instrumental births. Women's chances of being cared for in labour by a midwife she had got to know, and having a spontaneous vaginal birth were also increased. There was no difference in the number of caesarean births. Women who received midwife-led continuity of care were less likely to experience preterm birth, or lose their baby before 24 weeks' gestation, although there were no differences in the risk of losing the baby after 24 weeks, or overall. All trials included licensed midwives, and none included lay or traditional midwives. No trial included models of care that offered out of hospital birth.

The review concludes that most women should be offered midwife-led continuity models of care, although caution should be exercised in applying this advice to women with substantial medical or obstetric complications.

BACKGROUND

In many parts of the world, midwives are the primary providers of care for childbearing women (Koblinsky 2006). There are, however, considerable variations in the organisation of midwifery services and in the education and role of midwives (WHO 2006). Furthermore, in some countries, e.g. in North America, medical doctors are the primary care providers for the vast majority of childbearing women, while in other countries, e.g. Australia,

New Zealand, the Netherlands, the United Kingdom and Ireland, various combinations of midwife-led continuity, medical-led, and shared models of care are available. Childbearing women are often faced with different opinions as to which option might be best for them (De Vries 2001). The midwife-led continuity model of care is based on the premise that pregnancy and birth are normal life events. The midwife-led continuity model of care includes: continuity of care; monitoring the physical, psychological, spiritual and social wellbeing of the woman and family throughout the childbearing cycle; providing the woman with individualised education, counselling and antenatal care; continuous attendance during labour, birth and the immediate postpartum period; ongoing support during the postnatal period; minimising technological interventions; and identifying and referring women who require obstetric or other specialist attention. Differences between midwife-led continuity and other models of care often include variations in philosophy, relationship between the care provider and the pregnant woman, use of interventions during labour, care setting (home, home-from-home or acute setting) and in the goals and objectives of care (Rooks 1999). In addition, there is much debate about the clinical and cost effectiveness of the different models of maternity care (Ryan 2013) and hence continuing debate on the optimal model of care for routine ante, intra and postnatal care for healthy pregnant women (Sutcliffe 2012; Walsh 2012). There has been a lack of a single source of synthesised evidence on the effectiveness of midwife-led continuity models of care when compared with other models of care. This review attempts to provide this evidence.

Midwife-led continuity models of care have generally aimed to improve continuity of care over a period of time. However, the general literature on continuity notes that a lack of clarity in definition and measurement of different types of continuity has been one of the limitations in research in this field (Haggerty 2003). Continuity has been defined by Freeman 2007 as having three major types - management, informational and relationship. Management continuity involves the communication of both facts and judgements across team, institutional and professional boundaries, and between professionals and patients. Informational continuity concerns the timely availability of relevant information. Relationship continuity means a therapeutic relationship of the service user with one or more health professionals over time. Relationship/personal continuity over time has been found to have a greater effect on user experience and outcome (Saultz 2004; Saultz 2005). Some models of midwife-led care offer continuity with a group of midwives, and others offer personal or relational continuity, and thus the models of care that are the foci of this review are defined as follows.

(1) Midwife-led continuity models of care

Whilst it is difficult to categorise maternity models of care exclusively due to the influence of generic policies and guidelines, it is assumed that the underpinning philosophy of a midwife-led model of care is normality and the natural ability of women to experience birth without routine intervention. Midwife-led continuity of care has been defined as care where "the midwife is the lead professional in the planning, organisation and delivery of care given to a woman from initial booking to the postnatal period" (RCOG 2001). Some antenatal and/or intrapartum and/or postpartum care may be provided in consultation with medical staff as appropriate. Within these models, midwives are, however, in partnership with the woman, the lead professional with responsibility for assessment of her needs, planning her care, referral to other professionals as appropriate, and for ensuring provision of maternity services. Thus, midwife-led continuity models of care aim to provide care in either community or hospital settings, normally to healthy women with uncomplicated or 'low-risk' pregnancies. In some models, midwives provide continuity of midwifery care to all women from a defined geographical location, acting as lead professional for women whose pregnancy and birth is uncomplicated, and continuing to provide midwifery care to women who experience medical and obstetric complications in partnership with other professionals.

Some models of midwife-led continuity of care provide continuity of care to a defined group of women through a team of midwives sharing a caseload, often called 'team' midwifery. Thus, a woman will receive her care from a number of midwives in the team, the size of which can vary. Other models, often termed 'caseload midwifery', aim to offer greater relationship continuity, by ensuring that childbearing women receive their ante, intra and postnatal care from one midwife or her/his practice partner (McCourt 2006). There is continuing debate about the risks, benefits, and costs of team and caseload models of midwife-led continuity of care (Ashcroft 2003; Benjamin 2001; Green 2000; Johnson 2005; Waldenstrom 1998).

(2) Other models of care

Other models of care include:

(a) Obstetrician-provided care. This is common in North America, where obstetricians are the primary providers of antenatal care for most childbearing women. An obstetrician (not necessarily the one who provides antenatal care) is present for the birth, and nurses provide intrapartum and postnatal care.

(b) Family doctor-provided care, with referral to specialist obstetric care as needed. Obstetric nurses or midwives provide intrapartum and immediate postnatal care but not at a decision-making level, and a medical doctor is present for the birth.

(c) Shared models of care, where responsibility for the organisation and delivery of care, throughout initial booking to the postnatal period, is shared between different health professionals.

At various points during pregnancy, childbirth, and the postnatal period, responsibility for care can shift to a different provider or group of providers. Care is often shared by family doctors and midwives, by obstetricians and midwives, or by providers from all three groups. In some countries (e.g. Canada and the Netherlands), the midwifery scope of practice is limited to the care of women experiencing uncomplicated pregnancies, while in other countries (e.g. United Kingdom, France, Australia and New Zealand), midwives provide care to women who experience medical and obstetric complications in collaboration with medical colleagues. In addition, maternity care in some countries (e.g. Republic of Ireland, Iran and Lebanon), is predominantly provided by a midwife but is obstetrician-led, in that the midwife might provide the actual care, but the obstetrician assumes overall responsibility for the care provided to the woman throughout her ante-, intra- and postpartum periods.

This review complements other work on models of maternity care and attributes thereof, specifically, the work of Hodnett (Hodnett 2012) and Olsen (Olsen 2012) in which the relationships between the various birth settings and pregnancy outcomes were evaluated systematically. This review also subsumes the Cochrane review, 'Continuity of caregivers during pregnancy, childbirth, and the postpartum period' (Hodnett 2000).

OBJECTIVES

The primary objective of this review is to compare the effects of midwife-led continuity models of care with other models of care for childbearing women and their infants.

We also explore whether the effects of midwife-led continuity of care are influenced by: 1) models of midwife-led care that provide differing levels of relationship continuity; 2) varying levels of obstetrical risk.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised trials including trials using individual or cluster randomisation methods. We also included trials where allocation may not have been truly random (e.g. where allocation was alternate or not clear).

Types of participants

Pregnant women.

Types of interventions

Models of care are classified as midwife-led continuity of care, and other or shared care on the basis of the lead professional in the antepartum and intrapartum periods. In midwife-led continuity models of care, the midwife is the woman's lead professional, but one or more consultations with medical staff are often part of routine practice. Other models of care include a) where the physician/obstetrician is the lead professional, and midwives and/or nurses provide intrapartum care and in-hospital postpartum care under medical supervision; b) shared care, where the lead professional changes depending on whether the woman is pregnant, in labour or has given birth, and on whether the care is given in the hospital, birth centre (free standing or integrated) or in community setting(s); and c) where the majority of care is provided by physicians or obstetricians.

Types of outcome measures

Primary outcomes

Birth and immediate postpartum

1. Regional analgesia (epidural/spinal)
2. Caesarean birth
3. Instrumental vaginal birth (forceps/vacuum)
4. Spontaneous vaginal birth (as defined by trial authors)
5. Intact perineum

Neonatal

1. Preterm birth (less than 37 weeks)
2. Overall fetal loss and neonatal death (fetal loss was assessed by gestation using 24 weeks as the cut-off for viability in many countries)

Secondary outcomes

1. Antenatal hospitalisation
2. Antepartum haemorrhage
3. Induction of labour
4. Amniotomy
5. Augmentation/artificial oxytocin during labour
6. No intrapartum analgesia/anaesthesia
7. Opiate analgesia
8. Attendance at birth by known midwife
9. Episiotomy

10. Perineal laceration requiring suturing
11. Mean labour length (hours)
12. Postpartum haemorrhage
13. Breastfeeding initiation
14. Duration of postnatal hospital stay (days)
15. Low birthweight (less than 2500 g)
16. Five-minute Apgar score less than or equal to seven
17. Neonatal convulsions
18. Admission to special care nursery/neonatal intensive care unit
19. Mean length of neonatal hospital stay (days)
20. Fetal loss and neonatal death less than 24 weeks
21. Fetal loss and neonatal death equal to/after 24 weeks
22. Perceptions of control during labour and childbirth
23. Mean number of antenatal visits
24. Maternal death
25. Cord blood acidosis
26. Postpartum depression
27. Any breastfeeding at three months
28. Prolonged perineal pain
29. Pain during sexual intercourse
30. Urinary incontinence
31. Faecal incontinence
32. Prolonged backache

Search methods for identification of studies

Electronic searches

We contacted the Trials Search Co-ordinator to search the Cochrane Pregnancy and Childbirth Group's Trials Register (28 January 2013).

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

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

Details of the search strategies for CENTRAL, MEDLINE and Embase, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service 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.

For search methods used in the previous update of this review (Hatem 2008), *see* Appendix 1.

Searching other resources

We searched for further studies in the reference list of the studies identified.

We did not apply any language restrictions.

Data collection and analysis

For the methods used when assessing the trials identified in the previous version of this review, *see* Appendix 2. For this update we used the following methods.

Selection of studies

Two review authors independently assessed for inclusion all the potential studies we identified as a result of the search strategy. We resolved any disagreement through discussion or, if required, we consulted a third person.

Data extraction and management

We designed a form to extract data. For eligible studies, at least two review authors extracted the data using the agreed form. We resolved discrepancies through discussion or, if required, we consulted a third person. One review author entered data into Review Manager software (RevMan 2012) and this was independently checked by a second review author.

When information regarding any of the above was unclear, we contacted authors of the original reports to provide further details. One of the review authors (D Devane) is a co-author of one of the included studies (Begley 2011) so was not involved in data extraction or in the 'Risk of bias' assessment for this study.

Assessment of risk of bias in included studies

Two review authors independently assessed the risk of bias for each included study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We resolved any disagreement by discussion or by involving a third assessor.

(1) Random sequence generation (checking for possible selection bias)

We described for each included study the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.

We assessed the method as:

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

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

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

- low risk of bias (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
- high risk of bias (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear risk of bias.

(3.1) Blinding of participants and personnel (checking for possible performance bias)

We viewed it unlikely that it would be possible to blind participants or personnel in these trials to the group to which women were randomised because the model of care that women are allocated to determines from whom and where they receive maternity care services. Nevertheless, we recognised that some authors may have attempted to blind control group participants or personnel. Therefore, we assessed the methods as:

- low risk of bias;
- high risk of bias;
- unclear risk of bias.

(3.2) Blinding of outcome assessment (checking for possible detection bias)

We described for each included study the methods used, if any, to blind outcome assessors from knowledge of which intervention a woman received. We assessed blinding separately for different outcomes or classes of outcomes. We assessed the risk of bias for blinding of outcome assessment as:

- low risk;
- high risk;
- unclear risk.

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

We described for each included study the completeness of data including attrition and exclusions from the analysis. We stated whether attrition and exclusions were reported and the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes.
We assessed methods as:

- low risk of bias (if attrition rate was less than 20% for all outcomes);
- high risk of bias (e.g. numbers or reasons for missing data imbalanced across groups; 'as treated' analysis done with substantial departure of intervention received from that assigned at randomisation);
- unclear risk of bias.

(5) Selective reporting (checking for reporting bias)

We described for each included study how we investigated the possibility of selective outcome reporting bias and what we found.
We assessed the methods as:

- low risk of bias (where it was clear that all outcomes stated in the methods section were adequately reported or explained in results);
- high risk of bias (where not all the outcomes stated in the methods section were adequately reported or explained in result);
- unclear risk of bias.

(6) Other bias (checking for bias due to problems not covered by (1) to (5) above)

We described for each included study any important concerns we have about other possible sources of bias such as considerable deviation from protocol, limitations in study design or significant imbalances in baseline characteristics.
We assessed whether each study was free of other problems that could put it at risk of bias:

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

Measures of treatment effect

We conducted statistical analysis using the Review Manager software (RevMan 2012).

Dichotomous data

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

Continuous data

For continuous data, we used the mean difference if outcomes were measured in the same way between trials. If necessary, we planned to use the standardised mean difference to combine trials that measured the same outcome, but used different methods.

Unit of analysis issues

Cluster-randomised trials

We included one cluster-randomised trial in the analyses along with individually-randomised trials (North Stafford 2000). We adjusted the sample size using the methods described by Gates 2005 using an estimate of the intracluster correlation coefficient (ICC) derived from the trial. This trial estimated the ICC to be zero, so for the main analysis we used this estimate and did not adjust the sample sizes.

Dealing with missing data

For included studies, we noted levels of attrition. We explored the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis based on the 'Risk of bias' assessment.

For all outcomes, we carried out analyses, as far as possible, on an intention-to-treat basis, i.e. we included all participants randomised to each group in the analyses, and all participants were analysed in the group to which they were allocated, regardless of whether or not they received the allocated intervention. The denominator for each outcome in each trial was the number randomised minus any participants whose outcomes were known to be missing.

Assessment of heterogeneity

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

Assessment of reporting biases

Where there were 10 or more studies in the meta-analysis, we investigated reporting biases (such as publication bias) using funnel plots. We assessed funnel plot asymmetry visually. Where asymmetry was suggested by a visual assessment, we performed exploratory analyses to investigate it.

Data synthesis

We carried out statistical analysis using the Review Manager software (RevMan 2012). Due to the nature of this complex intervention it was agreed that there was sufficient clinical heterogeneity to expect that the underlying treatment effects differed between trials and, therefore, we used a random-effect meta-analysis for combining data to produce an overall summary of the average treatment effect across trials. The random-effects summary was treated as the average of the range of possible treatment effects and we discussed the clinical implications of treatment effects differing between trials. Where the average treatment effect was not clinically meaningful, we did not combine trials.

The results are presented as the average treatment effect with 95% confidence intervals, and the estimates of T^2 and I^2.

Subgroup analysis and investigation of heterogeneity

Where we identified substantial heterogeneity, we investigated it using subgroup analyses and sensitivity analyses. We considered whether an overall summary was meaningful, and if it was, used random-effects analysis to produce it.

We carried out the following subgroup analyses:

1. variation in levels of personal continuity (caseload or team);
2. variation in levels of obstetric risk (low versus mixed).

Subgroup analyses were performed on primary outcomes. The following outcomes were used in subgroup analysis.

Delivery and immediate postpartum

1. Regional analgesia (epidural/spinal)
2. Caesarean birth
3. Instrumental vaginal birth (forceps/vacuum)
4. Spontaneous vaginal birth (as defined by trial authors)
5. Intact perineum

Neonatal

1. Overall fetal loss and neonatal death
2. Preterm birth (less than 37 weeks)

We assessed subgroup differences by interaction tests within RevMan (RevMan 2012). We reported the results of subgroup analyses quoting the χ^2 statistic and P value, and the interaction test I^2 value.

Sensitivity analysis

We carried out sensitivity analysis based on the quality of the included trials to identify the impact of the methodological quality on the overall results. For the purpose of this review, we defined "high quality" as a trial having adequate sequence generation, allocation concealment and an attrition rate of less than 20%.

RESULTS

Description of studies

See Characteristics of included studies table.

Our search strategy identified 55 citations relating to 33 studies for potential inclusion.

Of those, we included 13 trials involving 16,242 randomised women in total (Begley 2011; Biro 2000; Flint 1989; Harvey 1996; Hicks 2003; Homer 2001; Kenny 1994; MacVicar 1993; McLachlan 2012; North Stafford 2000; Rowley 1995; Turnbull 1996; Waldenstrom 2001) and excluded 20 studies (Berglund 1998; Berglund 2007; Bernitz 2011; Chambliss 1991; Chapman 1986; Giles 1992; Heins 1990; Hildingsson 2003; Hundley 1994; James 1988; Kelly 1986; Klein 1984; Law 1999; Marks 2003; Runnerstrom 1969; Slome 1976; Stevens 1988; Tucker 1996; Waldenstrom 1997; Walker 2012 (*see* Characteristics of excluded studies).

Included studies were conducted in the public health systems in Australia, Canada, Ireland, New Zealand and the United Kingdom with variations in model of care, risk status of participating women and practice settings. The Zelen method was used in three trials (Flint 1989; Homer 2001; MacVicar 1993) and one trial used cluster randomisation (North Stafford 2000).

Three studies offered a caseload team model of care (McLachlan 2012; North Stafford 2000; Turnbull 1996) and 10 studies provided a team model of care: (Begley 2011; Biro 2000; Flint 1989; Harvey 1996; Hicks 2003; Homer 2001; Kenny 1994; MacVicar 1993; Rowley 1995; Waldenstrom 2001). The composition and modus operandi of the teams varied among trials. Levels of continuity (measured by the percentage of women who were attended during birth by a known carer varied between 63% to 98% for midwife-led continuity models of care to 0.3% to 21% in other models of care).

Eight studies compared a midwife-led continuity model of care to a shared model of care (Begley 2011; Biro 2000; Flint 1989; Hicks 2003; Homer 2001; Kenny 1994; North Stafford 2000; Rowley 1995), three studies compared a midwife-led continuity model of care to medical-led models of care (Harvey 1996; MacVicar 1993; Turnbull 1996) and two studies compared midwife-led continuity of care with various options of standard care including midwife-led (with varying levels of continuity), medical-led and shared care (McLachlan 2012; Waldenstrom 2001).

Participating women received ante-, intra- and postpartum care in 12 studies (Begley 2011; Biro 2000; Flint 1989; Harvey 1996; Hicks 2003; Homer 2001; Kenny 1994; McLachlan 2012; North Stafford 2000; Rowley 1995; Turnbull 1996; Waldenstrom 2001) and antenatal and intrapartum care in one study (MacVicar 1993).

Some midwife-led continuity models included routine visits to the obstetrician or family physicians (GPs), or both. The frequency of such visits varied. Such visits were dependent on women's risk status during pregnancy (Biro 2000); routine for all women (one to three visits) (Flint 1989; Harvey 1996; Kenny 1994; MacVicar 1993; McLachlan 2012; Rowley 1995; Waldenstrom 2001) or determined based on the development of complications (Hicks 2003; Turnbull 1996) or antenatal care from midwives and, if desired by the woman, from the woman's general practitioner (Begley 2011).

Women were classified as being at low risk of complications in eight studies (Begley 2011; Flint 1989; Harvey 1996; Hicks 2003; MacVicar 1993; McLachlan 2012; Turnbull 1996; Waldenstrom 2001) and as 'low and high' and 'high' in five studies (Biro 2000; Homer 2001; Kenny 1994; North Stafford 2000; Rowley 1995).

The midwifery models of care were hospital-based in four studies (Biro 2000; MacVicar 1993; Rowley 1995; Waldenstrom 2001) or offered (i) antenatal care in an outreach community-based clinic and intra- and postpartum care in hospital (Homer 2001); (ii) ante- and postpartum community-based care with intrapartum hospital-based care (Hicks 2003; North Stafford 2000; Turnbull 1996) (iii) antenatal and postnatal care in the hospital and community settings with intrapartum hospital-based care or (iv) postnatal care in the community with hospital-based ante- and intrapartum care (Flint 1989; Harvey 1996; Kenny 1994; McLachlan 2012).

Four studies offered intrapartum care in homelike settings, either to all women in the trial (Waldenstrom 2001), or to women receiving midwife-led continuity of care only (Begley 2011; MacVicar 1993; Turnbull 1996).

Risk of bias in included studies

See Figure 1; Figure 2 for summary of 'Risk of bias' assessments.

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

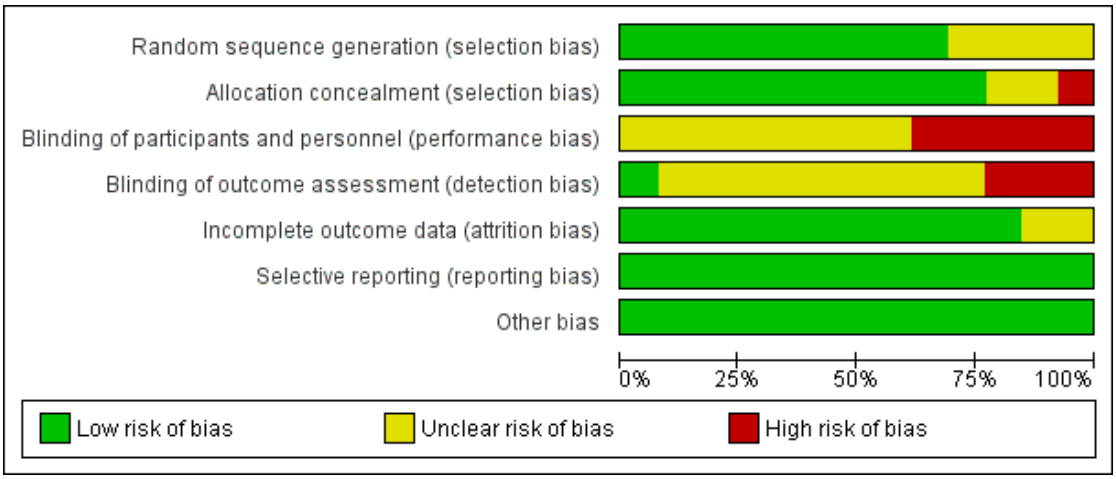
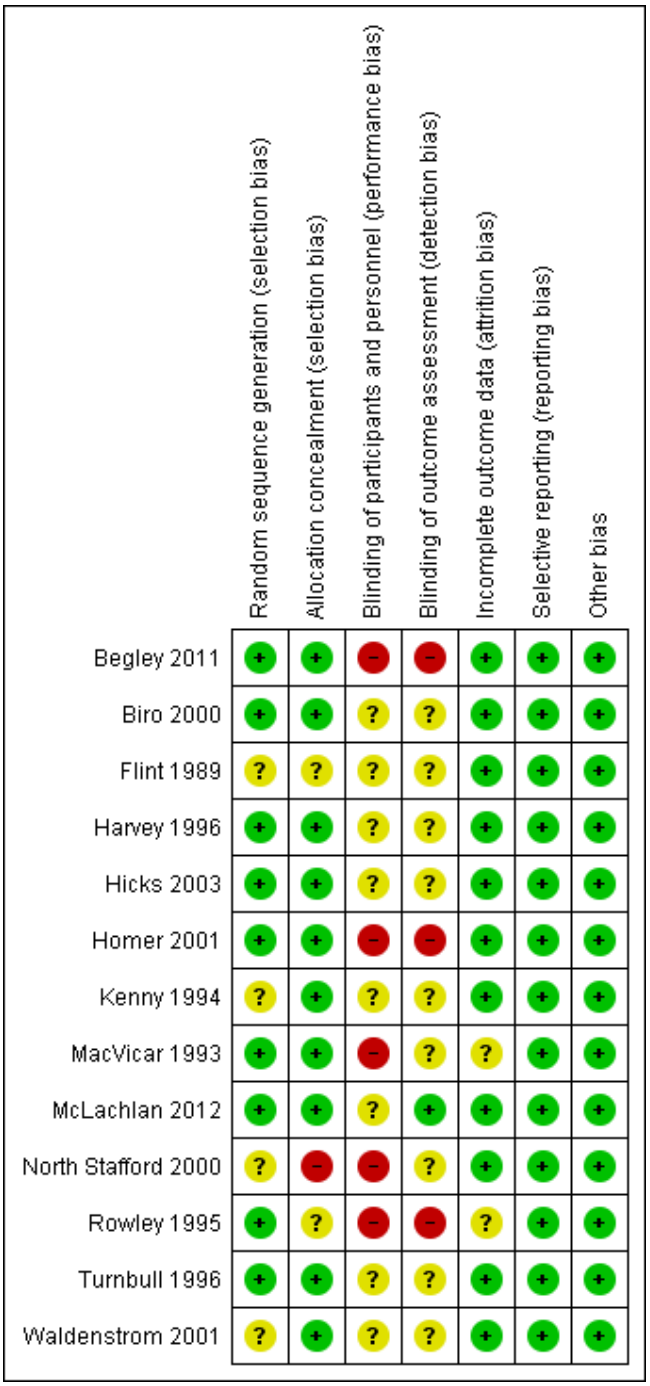


Figure 2. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.



Allocation

Nine studies reported genuine random methods of generation of the randomisation sequence (Begley 2011; Biro 2000; Harvey 1996; Hicks 2003; Homer 2001; MacVicar 1993; McLachlan 2012; Rowley 1995; Turnbull 1996). Four gave no or insufficient information to form a clear judgement (Flint 1989; Kenny 1994; North Stafford 2000; Waldenstrom 2001). Allocation concealment was judged low risk of bias for 10 studies (Begley 2011; Biro 2000; Harvey 1996, Hicks 2003; Homer 2001; Kenny 1994; MacVicar 1993; McLachlan 2012; Turnbull 1996; Waldenstrom 2001). Two studies were judged unclear risk of bias (Rowley 1995 gave no information about the process of random allocation, and Flint 1989 used sealed opaque envelopes but did not specify any numbering). The North Stafford 2000 trial was a cluster-randomised trial, whereby allocation concealment was not possible and it was judged high risk of bias for allocation concealment.

Blinding

Five of the included studies were judged as high risk in blinding of participants and personnel (Begley 2011; Homer 2001; MacVicar 1993; North Stafford 2000; Rowley 1995) and eight studies were at unclear risk of bias (Biro 2000; Flint 1989; Harvey 1996; Hicks 2003; Kenny 1994; McLachlan 2012; Turnbull 1996; Waldenstrom 2001).

One study was at low risk of bias for blinding of outcome assessment (McLachlan 2012), three were judged as high risk of bias (Begley 2011; Homer 2001; Rowley 1995) and nine studies were at unclear risk of bias (Biro 2000; Flint 1989; Harvey 1996; Hicks 2003; Kenny 1994; MacVicar 1993; North Stafford 2000; Turnbull 1996; Waldenstrom 2001).

Incomplete outcome data

Eleven of the included studies were judged at low risk of bias for incomplete outcome data on the basis that attrition rate was less than 20% for all outcomes (other than satisfaction) or missing outcome data were balanced across groups (Begley 2011; Biro 2000; Flint 1989; Harvey 1996; Hicks 2003; Homer 2001; Kenny 1994; McLachlan 2012; North Stafford 2000; Turnbull 1996; Waldenstrom 2001). Two of the studies (MacVicar 1993; Rowley 1995) did not provide sufficient information on loss to follow-up and were judged as unclear.

Selective reporting

All outcomes stated in the methods section were adequately reported in results in all included studies (Begley 2011; Biro 2000; Flint 1989; Harvey 1996; Hicks 2003; Homer 2001; Kenny 1994; MacVicar 1993; McLachlan 2012; North Stafford 2000; Rowley 1995; Turnbull 1996; Waldenstrom 2001).

Other potential sources of bias

No other potential sources of bias were identified in any of the included studies.

Effects of interventions

We used random-effects for all analyses - where we identified statistical heterogeneity (I^2 > 30%) we have reported the values of both Tau^2 and I^2.

Comparison 1 (main comparison): midwife-led continuity models of care versus other models of care for childbearing women and their infants - all trials

Primary outcomes

Women randomised to midwife-led continuity models of care were, on average, less likely to experience:

- **regional analgesia (epidural/spinal)** (average risk ratio (RR) 0.83, 95% confidence interval (CI) 0.76 to 0.90, 13 trials, n = 15,982, Tau^2 = 0.01, I^2 = 48%) (Analysis 1.1);
- **instrumental vaginal birth (forceps/vacuum)** (average RR 0.88, 95% CI 0.81 to 0.96,12 trials, n = 15,809) (Analysis 1.3);
- **preterm birth** (average RR 0.77, 95% CI 0.62 to 0.94, seven trials, n = 11,546, Tau^2 = 0.03, I^2 = 42%) (Analysis 1.6).

Women randomised to midwife-led continuity models of care were on average more likely to experience:

- **a spontaneous vaginal birth** (average RR 1.05, 95% CI 1.03 to 1.08, 11 trials, n = 14,995) (Analysis 1.4);

There were no statistically significant differences between groups for the following outcomes:

- **caesarean birth** (average RR 0.93, 95% CI 0.84 to 1.02, 13 trials, n = 15,982) (Analysis 1.2);
- **intact perineum** (average RR 1.03, 95% CI 0.94 to 1.13, nine trials, n = 11,494, Tau^2 = 0.01, I^2 = 59%) (Analysis 1.5);
- **overall fetal loss and neonatal death** (average RR 0.84, 95% CI 0.71 to 1.00, 12 trials, n = 15,869) (Analysis 1.7)

Secondary outcomes

Women randomised to midwife-led continuity models of care were, on average, less likely to experience:

- **amniotomy** (average risk ratio (RR) 0.80, 95% CI 0.66 to 0.98, four trials, n = 3253, Tau² = 0.03, I² = 75%) (Analysis 1.11);
- **episiotomy** (average RR 0.84, 95% CI 0.76 to 0.92,13 trials, n = 15,982, Tau² = 0.01, I² = 50%) (Analysis 1.16);
- **fetal loss/neonatal death before 24 weeks** (average RR 0.81, 95% CI 0.66 to 0.99, 10 trials, n = 13,953) (Analysis 1.27).

Women randomised to midwife-led continuity models of care were on average more likely to experience:

- **no intrapartum analgesia/anaesthesia** (average RR 1.16, 95% CI 1.04 to 1.31, six trials, n = 8807) (Analysis 1.13);
- a**longer mean length of labour** (hours) (mean difference (MD) 0.50, 95% CI 0.27 to 0.74, three trials, n = 3328) (Analysis 1.18); However, there was evidence of skewness in the data from one of the trials in the analyses of length of labour (Turnbull 1996);
- women allocated to midwife-led continuity models of care were more likely to be **attended at birth by a known carer** (average RR 7.83, 95% CI 4.15 to 14.80, six trials, n = 5225). However, the effect estimates for individual studies are highly variable (as reflected in substantial statistical heterogeneity, i.e., Tau² = 0.54; Chi² = 100.76, df = 5 (P < 0.00001), I² = 95%) (see Analysis 1.15)

There were no statistically significant differences between groups for the following outcomes:

- **antenatal hospitalisation** (average RR 0.93, 95% CI 0.83 to 1.05, six trials, n = 6039, Tau² = 0.01, I² = 50%) (Analysis 1.8);
- **antepartum haemorrhage** (average RR 0.89, 95% CI 0.57 to 1.40, four trials, n = 3654, Tau² = 0.07, I² = 31%) (Analysis 1.9);
- **induction of labour** (average RR 0.95, 95% CI 0.86 to 1.03, 12 trials, n = 15,809, Tau² = 0.01, I² = 45%) (Analysis 1.10);
- **augmentation/artificial oxytocin during labour** (average RR 0.89, 95% CI 0.79 to 1.01, 11 trials, n = 13,502, Tau² = 0.03, I² = 76% (Analysis 1.12);
- **opiate analgesia** (average RR 0.90, 95% CI 0.80 to 1.01, 10 trials, n = 11,997, Tau² = 0.02, I² = 77% (Analysis 1.14);
- **perineal laceration requiring suturing** (average RR 1.02, 95% CI 0.95 to 1.10, nine trials, n = 13,412, Tau² = 0.01, I² = 56%) (Analysis 1.17);
- **postpartum haemorrhage** (average RR 0.97, 95% CI 0.84 to 1.11, nine trials, n = 12,522) (Analysis 1.19);
- **breastfeeding initiation** (average RR 1.12, 95% CI 0.81 to 1.53, two trials, n = 2050, Tau² = 0.04, I² = 81%) (Analysis 1.20);
- **mean length of postnatal hospital stay** (days) (MD -0.10, 95% CI -0.29 to 0.09, three trials, n = 3593, Tau² = 0.02, I² = 58%) (Analysis 1.21);
- **low birthweight infant** (average RR 0.98, 95% CI 0.83 to 1.16, six trials, n = 9766) (Analysis 1.22);
- **five-minute Apgar score less than or equal to seven** (average RR 0.99, 95% CI 0.70 to 1.41, 10 trials, n = 10,854,Tau² = 0.11, I² = 38%) (Analysis 1.23);
- **neonatal convulsions** (average RR 0.91, 95% CI 0.14 to 5.74, two trials, n = 2923) (Analysis 1.24);
- **admission of infant to special care or neonatal intensive care unit(s)** (average RR 0.90, 95% CI 0.76 to 1.06, 12 trials, n = 15,869, Tau² = 0.04, I² = 48%) (Analysis 1.25);
- **mean length of neonatal hospital stay** (days) (MD -3.63, 95% CI -7.57 to 0.30, two trials, n = 1979, Tau² = 6.69, I² = 80%) (Analysis 1.26);
- **fetal loss or neonatal death more than or equal to 24 weeks** (average RR 1.00, 95% CI 0.67 to 1.51, 11 trials, n = 15,667) (Analysis 1.28).

The difference in the average treatment effect in overall fetal loss and neonatal death across included trials between women allocated to midwife-led continuity models of care and women allocated to other models has a RR of 0.84 and a 95% CI of 0.71 to 1.00 (12 trials, n = 15,869, average RR 0.84, 95% CI 0.71 to 1.00) (Analysis 1.7). Given that (i) the 95% CI just reaches 1.00 and (ii) the absence of measurable heterogeneity in this outcome analysis, the probability is that midwife-led continuity models of care are associated with a reduction in overall fetal loss and neonatal death by approximately 16%.

There was substantial statistical heterogeneity in many of the analyses. The I^2 value was greater than 50% for 10 outcomes (antenatal hospitalisation, amniotomy, augmentation, opiate analgesia, attendance at birth by known carer, intact perineum, perineum requiring suturing, duration of postnatal hospital stay, duration of neonatal stay, breastfeeding initiation, and greater than 30% for a further six (antepartum haemorrhage, induction of labour, episiotomy, five-minute Apgar score less than seven, preterm birth, admission to neonatal care).

Visual inspection of funnel plots for analyses where there were 10 or more studies (Analysis 1.10, Analysis 1.12, Analysis 1.14, Analysis 1.1, Analysis 1.2, Analysis 1.3, Analysis 1.4, Analysis 1.16, Analysis 1.23, Analysis 1.25, Analysis 1.27, Analysis 1.28 and Analysis 1.7) suggested little evidence of asymmetry for most analyses. For three analyses (Analysis 1.1 regional analgesia, Analysis 1.2 caesarean delivery and Analysis 1.16 episiotomy) there was a some suggestion of asymmetry, though in all cases this was due to two small trials with large treatment effects in the same direction (Figure 3; Figure 4; Figure 5). There is therefore no strong evidence of reporting bias, though this is difficult to detect with the number of studies in this review, and whether it exists and the extent to which it affects the results may be clarified when more studies have been conducted.

Figure 3. Funnel plot of comparison: 1 Midwife-led versus other models of care for childbearing women and their infants (all), outcome: 1.1 Regional analgesia (epidural/spinal).

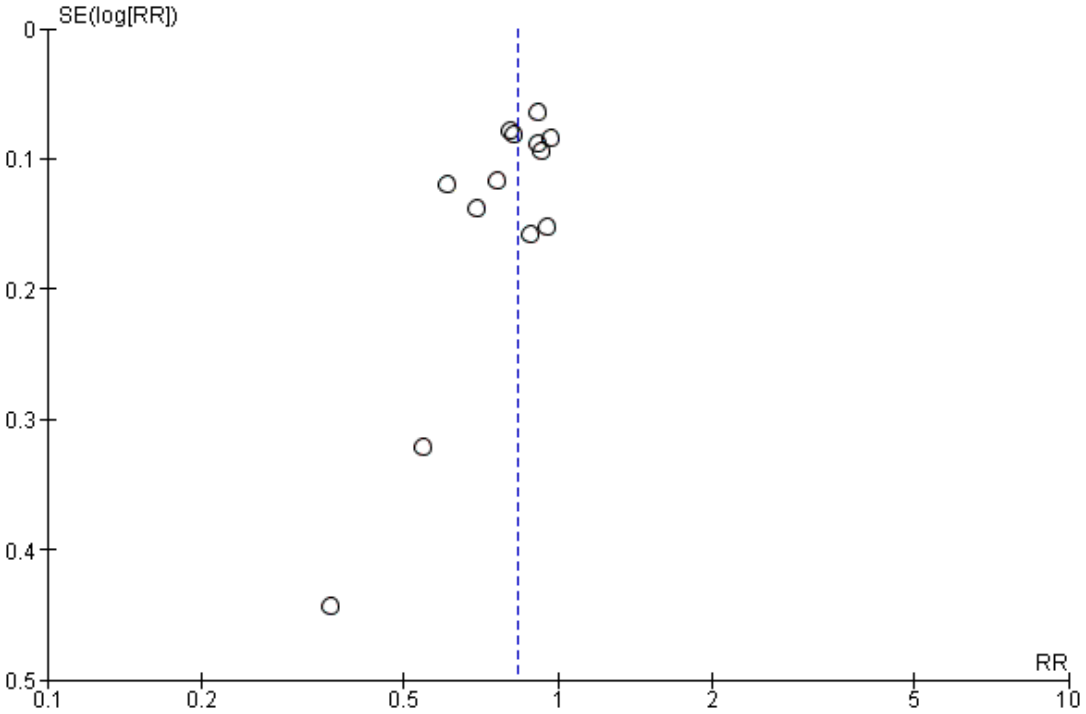


Figure 4. Funnel plot of comparison: 1 Midwife-led versus other models of care for childbearing women and their infants (all), outcome: 1.2 Caesarean birth.

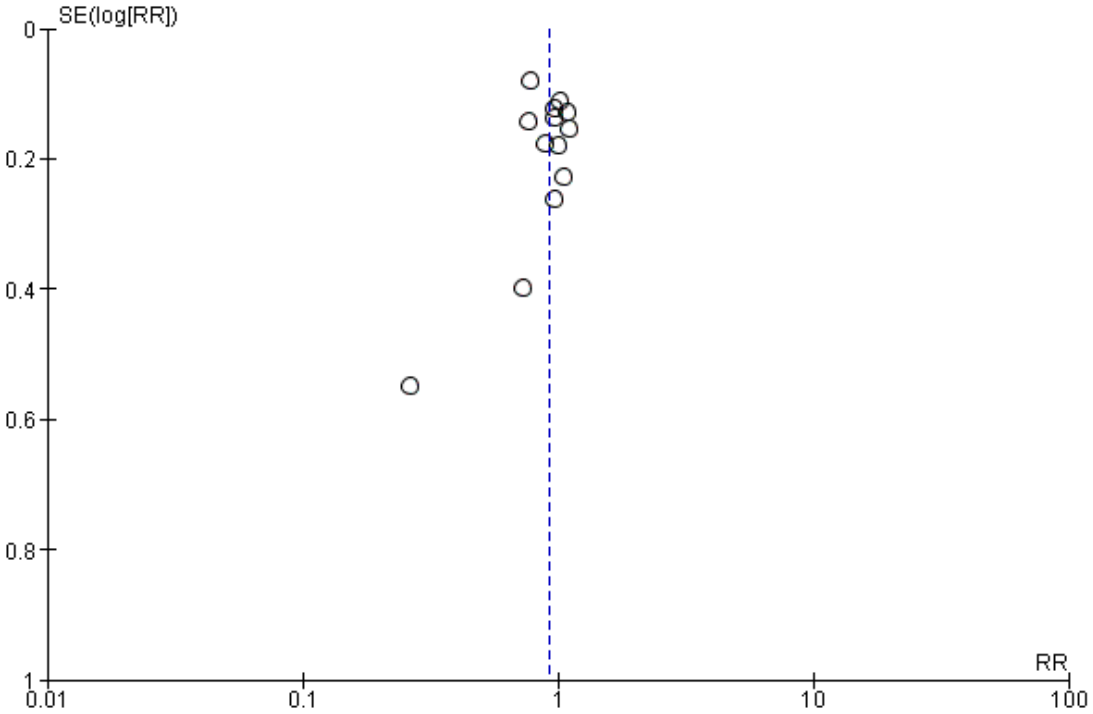
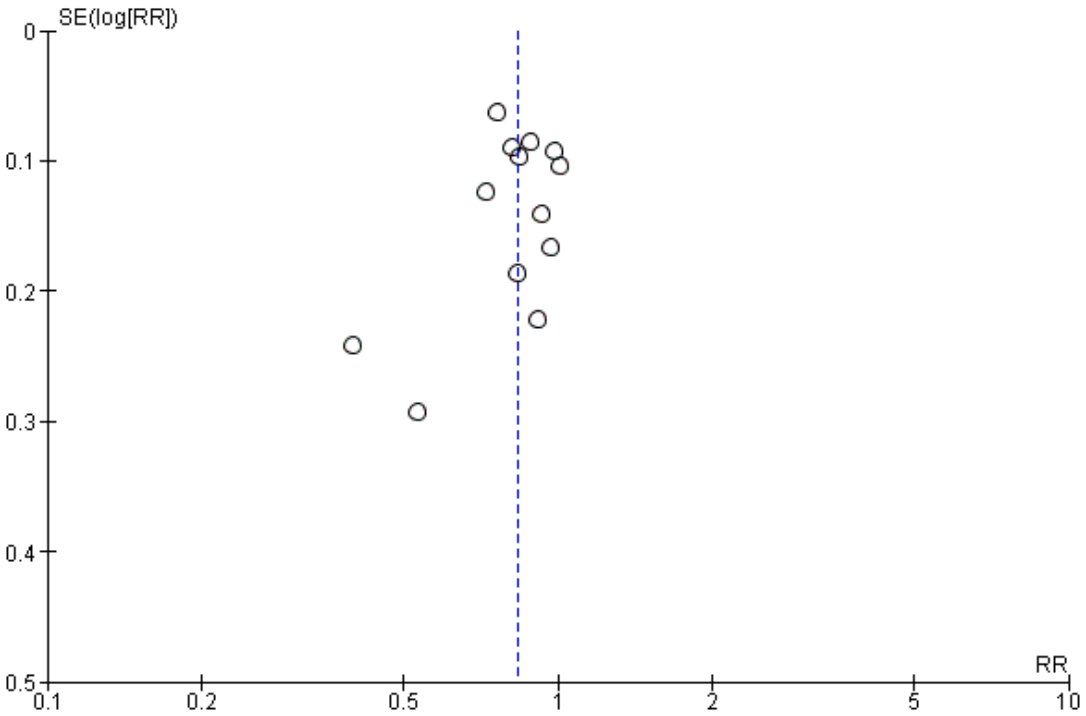


Figure 5. Funnel plot of comparison: 1 Midwife-led versus other models of care for childbearing women and their infants (all), outcome: 1.16 Episiotomy.



It was not possible to analyse the following outcomes, either because data were not reported by any studies or they were reported in a way that did not allow extraction of the necessary data for meta-analysis, or losses and exclusions were more than 20% of the randomised participants. No maternal deaths were reported. Only one trial reported the following outcomes: mean number of antenatal visits, perceptions of control, and postpartum depression and so results were not included in a meta-analysis. No trials reported on longer-term outcomes: any breastfeeding at three months; prolonged perineal pain; pain during sexual intercourse; urinary incontinence; faecal incontinence; and prolonged backache.

Subgroup analyses

Comparison 2: variation in midwifery models of care (caseload or one-to-one versus team)

Three trials randomised 5118 women to compare a caseload model of care (defined as one midwife carrying responsibility for a defined caseload of women in partnership with a midwife partner) with other models of care (McLachlan 2012; North Stafford 2000; Turnbull 1996). Caseload size was reported to be 45 women per midwife per year (McLachlan 2012), 35 to 40 women (North Stafford 2000) and 32.4 women per midwife (Turnbull 1996). Ten trials randomised 11,124 women to compare team models of midwifery (defined as a group of midwives sharing responsibility for a caseload of women) with other models of care (Begley 2011; Biro 2000; Flint 1989; Harvey 1996; Hicks 2003; Homer 2001; Kenny 1994; MacVicar 1993; Rowley 1995; Waldenstrom 2001). There was no evidence of a difference between the caseload and team subgroups for any of the outcomes included in the subgroup analysis. Differences between the average treatment effects for the subgroups were generally small. The largest differences were for preterm birth: caseload (average RR 0.65, 95% CI 0.47 to 0.90); team (average RR 0.81, 95% CI 0.62 to 1.07) (Analysis 2.6); and overall fetal loss and neonatal death: caseload (RR 0.65, 95% CI 0.43 to 0.99); team (average RR 0.89 95% CI 0.73 to 1.07) (Analysis 2.7).

Comparison 3: variation in risk status (low risk versus mixed)

Eight trials randomised 11,195 women to compare midwife-led continuity models of care versus other models of care in women defined to be at low risk by trial authors (Begley 2011; Flint 1989; Harvey 1996; Hicks 2003; MacVicar 1993; McLachlan 2012; Turnbull 1996; Waldenstrom 2001). Five trials randomised 5047 women to compare midwife-led continuity models of care with other models of care in women defined to be at mixed risk of complications by trial authors (Biro 2000; Homer 2001; Kenny 1994; North Stafford 2000; Rowley 1995). Of these, two trials excluded women who booked late - after 24 weeks' gestation (Biro 2000; Homer 2001) and 16 weeks' gestation (Kenny 1994). Two trials excluded women with a substance misuse problem (Kenny 1994; Rowley 1995) and two trials excluded women with significant medical disease/previous history of a classical or more than two caesareans (Homer 2001), or requiring admission to the maternal fetal medicine unit (Biro 2000).

There was no evidence of differences in treatment effect between the low risk and mixed risk subgroups for any of the outcomes included. Differences in treatment effect were very small, except for preterm birth: low risk (average RR 0.71, 95% CI 0.54 to 0.92); mixed risk (average RR 0.92, 95% CI 0.70 to 1.21) (Analysis 3.6); and overall fetal loss: low risk (average RR 0.94, 95% CI 0.73, to 1.20); mixed risk (average RR 0.76 95% CI 0.59 to 0.97) (Analysis 3.7).

Maternal satisfaction

Due to the lack of consistency in conceptualisation and measurement of women's experiences and satisfaction of care, a narrative synthesis of such data is presented. Nine studies reported maternal satisfaction with various components of the childbirth experiences (Biro 2000; Flint 1989; Harvey 1996; Hicks 2003; Kenny 1994; MacVicar 1993; Rowley 1995; Turnbull 1996; Waldenstrom 2001).

Given the ambiguity surrounding the concept of satisfaction, it was not surprising to find inconsistency in the instruments, scales, timing of administration and outcomes used to 'measure' satisfaction across studies. Because of such heterogeneity and as might be expected, response rates of lower than 80% for most of these studies, meta-analysis for the outcome of satisfaction was considered inappropriate and was not conducted.

Satisfaction outcomes reported in the included studies included maternal satisfaction with information, advice, explanation, venue of delivery, preparation for labour and birth, as well as giving choice for pain relief and behaviour of the carer. One study assessed perceptions of control in labour (Flint 1989) using a three-point scale. For convenience and ease of understanding, tabulated results of the overall satisfaction or indicators which directly relate to staff attitude, or both, are presented in Table 1. In brief, the majority of the included studies, showed a higher level of satisfaction in various aspects of care in the midwife-led continuity compared to the other models of care.

Sensitivity analyses

We performed a sensitivity analysis excluding the cluster-randomised North Staffordshire trial from all outcomes in the primary comparison (comparison 1) for which it had contributed data (North Stafford 2000). This did not alter the findings for any outcome, which remained consistent with overall findings with all trials included. Similarly, a sensitivity analysis for the primary outcomes including only the studies rated at low risk of bias (Begley 2011; Biro 2000; Harvey 1996; Hicks 2003; Homer 2001; McLachlan 2012; Turnbull 1996) found that there were only minor differences from the overall analyses. The main consequence was that confidence intervals were slightly wider, because of the smaller number of trials in the analysis. In no case were the conclusions of the analysis different. The primary outcome with the largest difference in this sensitivity analysis was preterm birth, where an analysis restricted to trials with lower risk of bias suggested a larger treatment effect: RR 0.64, (95% CI 0.51 to 0.81) compared with RR 0.77, (95% CI 0.62 to 0.94) in the overall analysis.

Economic analysis

Findings from economic analyses will vary depending on the structure of health care in a given country, and what factors are included in the modelling. Due to the lack of consistency in measurement of economic evaluations, a narrative synthesis of such data is presented. Five studies presented economic analysis in which various measures and items were included in the final cost estimation (Flint 1987; Homer 2001; Kenny 1994; Rowley 1995; Young 1997).

Flint 1989 examined the costs for a subgroup of women (n = 49) and estimated costs for antenatal admission and antenatal care, and found antenatal care was 20% to 25% cheaper for women in the midwife-led continuity of care group due to differences in staff costs. Women in the midwife-led continuity of care group had fewer epidurals (£19,360 versus £31,460).

Kenny 1994 examined the costs of care in detail. The average cost/client in the antenatal period was $158 midwife-led continuity of care and $167 control. For high-risk women the average cost/client was $390 midwife-led continuity of care and $437 control, and for low-risk women $119 midwife-led continuity of care and $123 control. The average cost per woman for intrapartum care was $219 midwife-led continuity of care and $220 control and for postnatal care was $745 midwife-led continuity of care and $833 control. The total cost/woman was $1122 for midwife-led continuity of care and $1220 control.

Rowley 1995 used the Australian national cost weights for diagnostic related groups (AN-DRGs) to estimate maternity care in each study group. The average cost per delivery was higher in the standard care group ($3475) compared to the team-midwifery group ($3324). This method was limited to the acute inpatient and did not include antenatal or postnatal care cost estimations. An assessment of midwife salaries from the first antenatal visit up

to and including labour and delivery care resulted in a cost of $653 for each team care woman and $688 for each routine care woman. The amount of sick leave taken by team care midwives was half that taken by standard care midwives.

Young 1997 used the "individual patient-based costing" approach, in which an assumption was made about the number of caseloads per midwife. When the assumption was based on a median caseload of 29 women per midwife, the cost of midwife managed care was not significantly different from the shared-care group in the antenatal and intrapartum periods, but it was higher in the postpartum period. The authors also used an alternative assumption including a caseload of 39 women per midwife. A lower cost in the antenatal period for the midwife-managed care was shown in comparison with the shared-care group (mean: £346 versus £384, P = 0.05), but the postnatal care cost remained higher in the former group (£444 versus £397, respectively, P < 0.01). The authors did not recalculate the cost of intrapartum care for the second assumption, and used the same estimation as for the 29 caseload per midwife (since they indicated that the main effects were in the unit costs of clinic and home visits). They reported no significant differences between the midwifery and shared-care group, in the cost of intrapartum care (£280 versus £276, P = 0.4).

Homer 2001 calculated the costs of all aspects of care from the healthcare provider's perspective, including salaries and wages; goods and services; and repair, maintenance and renewal (RMR). The associated costs for all stages of antenatal, intrapartum and postnatal care were calculated and presented as the mean cost per woman per group. The results showed a cost-saving effect in the team midwifery group compared with the standard care arm of the study (mean cost per woman: $2579 versus $3483, respectively).

In summary, five studies presented cost data using different economic evaluation methods. All studies suggest a cost-saving effect in intrapartum care. One study suggests a higher cost, and one study no differences in cost of postnatal care when midwife-led continuity of care is compared with medical-led maternity care. There is a lack of consistency in estimating maternity care cost among the available studies; however, there seems to be a trend towards the cost-saving effect of midwife-led continuity of care in comparison with medical-led care.

DISCUSSION

This review summarises 13 trials involving 16,242 women that took place in five countries in a wide variety of settings and health systems. All trials involved midwife-led continuity models of care that included either team or caseload midwifery, and women classified as at low or mixed risk. All trials included licensed midwives, and none included lay or traditional midwives. The review includes trials that compared midwife-led continuity of care given both during the antepartum and the intrapartum period with other models of care which included obstetricians or family physicians, or both, collaborating with nurses and midwives in a variety of organisational settings.No trial included models of care that offered out of hospital birth.

In the primary comparison, the results consistently show less use of some interventions for women who were randomised to receive midwife-led continuity of care compared to women randomised to receive other models of care without detriment to outcomes. Specifically, women were on average less likely to experience amniotomy, the use of regional analgesia, episiotomy, and instrumental delivery. Women were on average more likely to experience spontaneous vaginal birth, a longer mean length of labour, and to be attended at birth by a known midwife, however, there were no differences in caesarean birth rates.

Stillbirth is not reported specifically due to differing gestational definitions, but is included within the outcome 'Fetal loss/neonatal death equal to/after 24 weeks'. Women who were randomised to receive midwife-led continuity of care compared to women randomised to receive other models of care were, on average, less likely to experience fetal loss before 24 weeks' gestation and preterm birth before 37 weeks. The difference in the average treatment effect in overall fetal loss and neonatal death across included trials between women allocated to midwife-led continuity models of care and women allocated to other models has an average risk ratio (RR) of 0.84 and a 95% confidence interval (CI) of 0.71 to 1.00 (12 trials, n = 15,869, RR 0.84, 95% CI 0.71 to 1.00, random-effects). Given that (i) the 95% CI just reaches 1.00 and (ii) the absence of measurable heterogeneity in this outcome analysis, the probability is that midwife-led continuity models of care are associated with a reduction in overall fetal loss and neonatal death by approximately 16%. For a number of outcomes (induction of labour, augmentation, opiate analgesia, caesarean birth), the point estimate was less than 1 and the upper limit of the 95% confidence interval just exceeded 1. These outcomes therefore did not show a formally statistically significant effect using the conventional P = 0.05 cut-off, but are suggestive that midwife-led care may, on average, be beneficial. Further data may clarify the effects of the intervention on these outcomes.

The subgroup analyses of models of midwife-led continuity of care and risk status did not find any significant subgroup interaction tests, indicating that there is no observable subgroup effect.

Overall, we did not find any increased likelihood for any adverse outcome for women or their infants associated with having been randomised to a midwife-led continuity model of care. These results were moderate in magnitude and generally consistent across all the trials.

It is possible that practice settings such as midwife-led units can be a confounding influence on outcomes of midwife-led continuity of care Brocklehurst 2011, and home birth was not offered in any of the trials. Four trials offered care in midwife-led units (Begley 2011; MacVicar 1993; Turnbull 1996; Waldenstrom 2001), which

was available to women in both arms of one trial (Waldenstrom 2001) and only women in the midwife-led group in three trials (Begley 2011; MacVicar 1993; Turnbull 1996). The increased likelihood of spontaneous vaginal birth in women randomised to midwife-led continuity models of care may be a function of increased mobility due to less use of a range of analgesics, a much greater likelihood of attendance at birth by a known midwife, and the philosophy of care on offer. Midwife-led continuity of care is a complex intervention, and it is impossible to unpick the relative importance of philosophy and continuity of care. However, in nine trials, care was provided on the labour ward, suggesting a separate effect to birth setting. To what extent the observed benefits can be attributed to the model of midwifery care or to the quality and degree of relationship between the care provider and women was outside the scope of this review and requires an in depth exploration.

The possible effects on fetal loss prior to 24 weeks and preterm birth are important. Aetiology of both these events are complex but potentially influenced by models of care. Medical interventions to prevent fetal loss prior to 24 weeks do exist, as this is mostly due to spontaneous miscarriage, (and are dependent on quick access to care potentially influenced by continuity), such as cerclage and progesterone. These interventions are targeted to 'at risk' women, and may explain why mixed risk populations (with the improved access to care and appropriate referral) have the effect. Low-risk women may not be referred or when referred the interventions not used due to lack of evidence in low-risk women. There is insufficient detail in the trials to elucidate reasons for loss (e.g. intrauterine death or spontaneous miscarriage) and this would be important in future research.

Government and hospital policies affect how midwives are 'allowed' to practise, and/or the institutional structure within which midwives practise, and would thus affect practices and outcomes by limiting the potential of midwife-led continuity of care in some settings. This is in contrast to models of health care which offer relationship continuity over time, which have been found to prevent clients falling through 'gaps in care' (Cook 2000). Women's experiences of care reported in the original studies include maternal satisfaction with information, advice, explanation, venue of delivery and preparation for labour and birth, as well as perceptions of choice for pain relief and evaluations of carer's behaviour. In the majority of the included studies, satisfaction with various aspects of care appears to be higher in the midwife-led continuity of care compared to the other models of care.

Although there were limitations in the way that satisfaction related outcomes were assessed and reported, the majority of the included studies showed a higher level of satisfaction with various aspects of care in the midwife-led continuity of care compared to the other models of care. Estimates of cost and resource use employed different economic evaluation methods. Results generally suggest a cost-saving effect in intrapartum care; one study suggests a higher cost of postnatal care when midwife-led continuity of care is compared with medical-led care. However, there is a lack of consistency in estimating maternity care cost among the available studies, and there seems to be a trend towards a cost-saving effect of midwife-led continuity of care in comparison with medical-led care.

AUTHORS' CONCLUSIONS

Implications for practice

Midwife-led continuity of care confers important benefits and shows no adverse outcomes. However, due to the exclusion of women with significant maternal disease and substance abuse from some trials of women at mixed risk, caution should be exercised in applying the findings of this review to women with substantial medical or obstetric complications. Policy makers and healthcare providers should be aware that such benefits are conferred when midwives provide intrapartum care in hospital settings and also where midwives provide antenatal care in hospital or community settings. Not all areas of the world have health systems where midwives are able to provide midwife-led continuity models of care (De Vries 2001) and health system financing is a potential barrier to implementation. Policy makers who wish to achieve clinically important improvements in maternity care, particularly around normalising and humanising birth, and preventing preterm birth should consider midwife-led continuity models of care and consider how financing of midwife-led services can be reviewed to support this.

Implications for research

Questions remain about the best way to organise midwife-led continuity of care under varying conditions, and further comparisons of different models of midwife-led continuity of care would be helpful. Further research should explore whether the observed benefits can be attributed to the model of continuity of midwifery care or to the quality and degree of relationship between the care provider. Further research is needed on more recently developed midwife-led continuity models of care that include home birth and greater levels of relationship continuity in community settings to women classified at low and high risk of complications (Haggerty 2003; Saultz 2003; Saultz 2004; Saultz 2005). One such model that should be evaluated is the community-based caseload model of midwife-led continuity of care. These models offer continuity of carer, with a named midwife working in partnership with associate midwives (usually two). They provide community-based outreach and locally accessible services, in association with other care providers as necessary, with the option of intrapartum care provided at home, in a midwife-led unit or in a hospital setting as appropriate.

All trials should provide greater description of intervention and standard models of care being assessed and how they are being delivered. Little is known about the interface between midwife-

led continuity models of care and the multi-disciplinary network of support. Although continuity of care has been identified as a core component of a model of midwife-led care, there is wide variation in the definition and measurement of continuity of care which will require greater sophistication in future studies. Future research should also assess acceptability to midwives of different models of midwife-led continuity of care that offer relational continuity. Future trials in this area would benefit from drawing on a framework for trials of complex interventions which explicitly requires theoretical modelling between processes and outcomes in the pre-trial stage, and a process evaluation of the trial (Anderson 2008). Future research in this area would benefit from exploring the theoretical underpinnings of these complex interventions and their associations with processes and outcomes. Questions remain about why fetal loss is reduced for babies under 24 weeks' gestation, and why there are fewer preterm births and likely fewer overall fetal losses and neonatal deaths in midwife-led continuity models of care.

There remains relatively little information about the effects of midwife-led continuity models of care on mothers' and babies' health and wellbeing in the longer postpartum period. Future research should pay particular attention to outcomes that have been under-researched, but are causes of significant morbidity, including postpartum depression, urinary and faecal incontinence, duration of caesarean incision pain, pain during intercourse, prolonged perineal pain and birth injury (to the baby). We will add these to the review outcomes when the review is updated as available, if not already specified in this review.

There were no trials in resource-constrained countries and additional trials may be required in such settings.

Little is known about whether women feel they are part of the decision making process; sense of control; maternal self-confidence; post-traumatic stress disorder, coping after the birth. There is wide variation in the instruments used to measure women's views of and experiences of care. There is a need to develop meaningful, robust, valid and reliable methods to assess psychosocial outcomes and wellbeing in pregnant and childbearing women. All trials should include an assessment of maternal and fetal wellbeing. There is a lack of consistency in estimating maternity care cost, and further research using standard approaches of cost estimation is required which also includes cost to women and families. All trials should include economic analyses of the relative costs and benefits.

Given the heterogeneity in the choice of outcome measures routinely collected and reported in randomised evaluations of models of maternity care, a core (minimum) dataset, such as that by Devane 2007, and a validated measure of maternal quality of life and wellbeing would be useful not only within multi-centre trials and for comparisons between trials, but might also be a significant step in facilitating useful meta-analyses of similar studies. In addition, future trials should include measures of optimal outcomes for mothers and babies in addition to measures of morbidity.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Begley 2011

Methods	**Study design:** RCT. **Duration of study:** 2004-2007.
Participants	**Setting:** Health Service Executive, Dublin North-East, Republic of Ireland. **Inclusion criteria:** women were eligible for trial entry if they were: (a) healthy with an absence of risk factors for complications for labour and delivery as identified in the *'Midwifery-led Unit (Integrated) Guidelines for Practitioners'* (at http://www.nehb.ie/midu/guidelines.htm); (b) aged between 16 and 40 years of age; and (c) within 24 completed weeks of pregnancy. **Exclusion criteria:** women with risk factors. **Participants randomised:** 1101 midwife-led care, 552 to CLC.
Interventions	**Experimental:** women randomised to CLU received standard care: antenatal care provided by obstetricians supported by the midwifery and medical team; intrapartum and postpartum care (2 to 3 days in hospital) provided by midwives, overseen by consultants. Women were discharged into the care of Public Health Nurses **Control: w**omen randomised to MLU received antenatal care from midwives and, if desired, from their GPs for some visits. Where complications arose, women were transferred to CLU based on agreed criteria. Intrapartum care was provided by midwives in a MLU with transfer to CLU if necessary. Postnatal care was by midwives in the MLU for up to 2 days, with transfer of women or neonates to CLU if necessary (and back, as appropriate). On discharge, MLU midwives visited at home, and/or provided telephone support, up to the seventh postpartum day
Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/NICU Amniotomy Antenatal hospitalisation Antepartum haemorrhage Augmentation/artificial oxytocin during labour Breastfeeding initiation Caesarean birth Duration of postnatal hospital stay (days) Episiotomy Fetal loss/neonatal death before 24 weeks Fetal loss/neonatal death equal to/after 24 weeks Induction of labour Instrumental vaginal birth (forceps/vacuum) Intact perineum Low birthweight (< 2500 g) Mean labour length Mean length of neonatal hospital stay (days) Neonatal convulsions (as defined by trial authors)

Begley 2011 (*Continued*)

	No intrapartum analgesia/anaesthesia Opiate analgesia Overall fetal loss and neonatal death Perineal laceration requiring suturing Preterm birth (< 37 weeks) Postpartum haemorrhage (as defined by trial authors) Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial authors)
Notes	Women were randomised to MLU or CLU in a 2:1 ratio.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	'Random integers were obtained using a random number generator…'
Allocation concealment (selection bias)	Low risk	'…an independent telephone randomisation service.'
Blinding of participants and personnel (performance bias) All outcomes	High risk	'...lack of blinding of participants and carers...'
Blinding of outcome assessment (detection bias) All outcomes	High risk	'Assessors for certain outcomes, such as laboratory tests, were blinded to study group. '
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up = 5 midwife-led care, 3 CLC.
Selective reporting (reporting bias)	Low risk	**Outcome reporting:** all outcomes stated in the methods section were adequately reported or explained in results
Other bias	Low risk	No other bias identified.

Biro 2000

Methods	**Study design:** RCT. **Duration of study:** 1996-1998.
Participants	**Setting:** public tertiary hospital, Monash Medical Centre, Melbourne, Australia. **Inclusion criteria:** participants included women at low and high risk of complications. **Exclusion criteria:** women who requested shared obstetric care, needed care in the maternal-fetal medicine unit, were > 24 weeks' gestation, did not speak English. **Participants randomised:** 502 team midwifery, 498 to standard care.

Biro 2000 (*Continued*)

Interventions	**Experimental:** team of 7 full-time midwives who provided antenatal, intrapartum, and some postnatal care in hospital in consultation with medical staff. Doctors and team midwife jointly saw women at 12-16, 28, 36, 41 weeks. Women at high risk of complications had individual care plan. **Control:** various options of care including shared care between GPs in the community and hospital obstetric staff, shared care between midwives in a community health centre and hospital obstetric staff, care by hospital obstetric staff only, and less commonly, care by hospital midwives in collaboration with obstetric staff. Women within these options experienced a variable level of continuity of care during their pregnancy, from seeing the same midwife or doctor at most visits to seeing several doctors and midwives
Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/NICU Attendance at birth by known midwife Augmentation/artificial oxytocin during labour Duration of postnatal hospital stay (days) Episiotomy Fetal loss/neonatal death before 24 weeks Fetal loss/neonatal death equal to/after 24 weeks Induction of labour Intact perineum Instrumental vaginal birth(forceps/vacuum) Mean length of neonatal hospital stay (days) No intrapartum analgesia/anaesthesia Overall fetal loss and neonatal death Perineal laceration requiring suturing Preterm birth (< 37 weeks) Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial authors)
Notes	2 groups similar at baseline. 80% of experimental group and 0.3% of standard group had previously met midwife attending labour

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	'Allocations were computer generated...'
Allocation concealment (selection bias)	Low risk	'...the research team member telephoned the medical records staff and asked them to select an envelope with the randomized treatment allocation.'
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not stated but unlikely.

Biro 2000 (*Continued*)

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated but unlikely.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up = 14 team care, 18 standard care.
Selective reporting (reporting bias)	Low risk	**Outcome reporting:** all outcomes stated in the methods section were adequately reported in results
Other bias	Low risk	No other bias identified.

Flint 1989

Methods	**Study design:** RCT, Zelen design. **Duration of study:** 1983-1985.
Participants	**Setting:** tertiary hospital and community settings, St George's Hospital, London, UK. **Inclusion criteria:** low risk of complications who booked at the study hospital and were likely to receive all their antenatal care at that hospital. **Exclusion criteria:** under 5 feet tall, serious medical problems, previous uterine surgery, past obstetric history of > 2 miscarriages/TOP/SB/NND, Rh antibodies. **Participants randomised:** 503 team-midwifery, 498 to standard care (shared care).
Interventions	**Experimental:** team of 4 midwives who provided antenatal, intrapartum and postnatal care in hospital, and postnatal care in the community for women in predefined geographic area. Obstetrician seen at 36 and 41 weeks as appropriate. **Control:** standard antenatal, intrapartum and postpartum care provided by assortment of midwives and obstetricians
Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/NICU Amniotomy Antenatal hospitalisation Augmentation/artificial oxytocin during labour Caesarean birth Episiotomy Fetal loss/neonatal death before 24 weeks Fetal loss/neonatal death equal to/after 24 weeks High perceptions of control during labour and childbirth Induction of labour Intact perineum Instrumental vaginal birth(forceps/vacuum) Low birthweight (< 2500 g) No intrapartum analgesia/anaesthesia

Flint 1989 (*Continued*)

	Opiate analgesia Overall fetal loss and neonatal death Postpartum haemorrhage (as defined by trial authors) Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial authors)
Notes	At baseline, more Asian women in control group (18% vs 10%) and more smokers in experimental group (30% vs 22%). Sub-analysis of case notes found that 98% of experimental group and 20% of standard group had previously met midwife attending labour. Discrepancy in instrumental birth data. Date taken from report and not published paper

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not stated.
Allocation concealment (selection bias)	Unclear risk	'...randomised into two groups by pinning sealed envelopes on their notes containing either the motto KNOW YOUR MIDWIFE or CONTROL GROUP' (Does not state if envelopes were number consecutively.)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not stated but unlikely.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated but unlikely.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up = 15 team care, 19 standard care.
Selective reporting (reporting bias)	Low risk	**Outcome reporting:** all outcomes stated in the methods section were adequately reported in results
Other bias	Low risk	No other bias identified.

Harvey 1996

Methods	**Study design:** RCT. **Duration of study:** 1992-1994.
Participants	**Setting:** range of city hospitals and community settings in Alberta, Canada. **Inclusion criteria:** women at low risk of complications who requested and qualified for nurse-midwife-led care. **Exclusion criteria:** past history of caesarean section, primigravidas < 17 or > 37, > 24 weeks' gestation at time of entry to study. **Participants randomised:** 109 team-midwife-led care, 109 to standard care (Physician care)
Interventions	**Experimental:** team of 7 nurse-midwives who provided antenatal and intrapartum care in the hospital and postnatal care in the community. Obstetrician seen at booking and at 36 weeks. **Control:** physician care (family practice or obstetrician) which women chose from a range of city hospitals following usual process
Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/NICU Amniotomy Antepartum haemorrhage Attendance at birth by known midwife Augmentation/artificial oxytocin during labour Caesarean birth Episiotomy Fetal loss/neonatal death before 24 weeks Induction of labour Instrumental vaginal birth (forceps/vacuum) Intact perineum Opiate analgesia Overall fetal loss and neonatal death Postpartum haemorrhage (as defined by trial authors) Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial author)
Notes	At baseline, more women in experimental group had longer period in education (16 years vs 15.23 years). Level of continuity not reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'...computer-generated random allocation.'

Harvey 1996 (*Continued*)

Allocation concealment (selection bias)	Low risk	'...using a series of consecutively numbered, sealed, opaque envelopes...'
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not stated but unlikely.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated but unlikely.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up = 4 team care and 12 standard care.
Selective reporting (reporting bias)	Low risk	**Outcome reporting:** all outcomes stated in the methods section were adequately reported in results
Other bias	Low risk	No other bias identified.

Hicks 2003

Methods	**Study design:** RCT. **Duration of study:** not stated.
Participants	**Setting:** tertiary hospital and community, City not stated but UK. **Inclusion criteria:** women at low risk of complications. **Exclusion criteria:** not stated. **Participants randomised:** 100 team-midwife-led care, 100 to standard care (shared care)
Interventions	**Experimental:** team of 8 midwives who provided antenatal, intrapartum and postnatal care 24 hours a day, 7 days a week in both hospital and community. The team was attached to a GP practice. Referral to obstetrician as necessary. **Control:** shared care between community and hospital midwives and GPs and obstetricians when necessary. Women delivered by hospital midwife or community midwife if under domino scheme (1 midwife provides care for a woman throughout pregnancy, accompanies her into hospital for birth and returns home with her and baby a few hours after the birth, and care in postnatal period)
Outcomes	Outcomes considered in the review and reported in or extracted from the study: Induction of labour Instrumental vaginal birth (forceps/vacuum) Intact perineum Opiate analgesia Overall fetal loss and neonatal death Postpartum haemorrhage (as defined by trial authors) Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial authors)

Hicks 2003 (*Continued*)

Notes	71% of experimental group and 14% of standard group had previously met midwife attending labour	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Envelopes '...had been shuffled previously by an individual not involved in the recruitment process, and then numbered consecutively.'
Allocation concealment (selection bias)	Low risk	'Allocation was undertaken by giving each woman a sealed envelope containing one of the care options.'
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not stated but unlikely.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated but unlikely.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up = 19 team care and 8 standard. Due to non-response to questionnaires
Selective reporting (reporting bias)	Low risk	**Outcome reporting:** all outcomes stated in the methods section were adequately reported in results
Other bias	Low risk	No other bias identified.

Homer 2001

Methods	**Study design:** RCT, Zelen method. **Duration of study:** 1997-1998.
Participants	**Setting:** public tertiary hospital and community, Sydney, Australia. **Inclusion criteria:** women at low and high risk of complications. **Exclusion criteria:** women more than 24 weeks' gestation at their first visit to the hospital, women with an obstetric history of 2 previous caesareans or a previous classical caesarean and medical history of significant maternal disease. **Participants randomised:** 640 team-midwife-led care, 643 to standard care (shared care)

Interventions	**Experimental:** 2 teams of 6 midwives sharing a caseload of 300 women a year/team. Antenatal care in outreach community-based clinics. Intrapartum and postpartum hospital and community care. Obstetrician or obstetric registrar did not see women routinely, but acted as a consultant and reviewed women only as necessary. Women who developed complications during their pregnancy continued to receive care from the same group of carers. **Control:** standard care provided by hospital midwives and doctors in hospital-based antenatal clinic, delivery suite and postnatal ward. Woman at high risk of complications were seen by obstetrician or registrar. Low-risk women were seen by midwives and shared care with GPs in a shared model of care
Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/NICU Antenatal hospitalisation Antepartum haemorrhage Attendance at birth by known midwife Augmentation/artificial oxytocin during labour Caesarean birth Episiotomy Fetal loss/neonatal death before 24 weeks Fetal loss/neonatal death equal to/after 24 weeks Induction of labour Instrumental vaginal birth (forceps/vacuum) Opiate analgesia Overall fetal loss and neonatal death Postpartum haemorrhage (as defined by trial authors) Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial authors)
Notes	63% of experimental group and 21% of standard group had previously met midwife attending labour

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	'...computer-generated random numbers...'
Allocation concealment (selection bias)	Low risk	'...group allocation was not revealed until the woman's details were recorded by the administrative assistant.'
Blinding of participants and personnel (performance bias) All outcomes	High risk	No (states 'unblinded').

Homer 2001 (*Continued*)

Blinding of outcome assessment (detection bias) All outcomes	High risk	No (states 'unblinded').
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up: team care 46, standard care 42.
Selective reporting (reporting bias)	Low risk	**Outcome reporting:** all outcomes stated in the methods section were adequately reported in results
Other bias	Low risk	No other bias identified.

Kenny 1994

Methods	**Study design:** RCT. **Duration of study:** 1992-199.
Participants	**Setting:** Westmead public hospital, NSW, Australia. **Inclusion criteria:** women at low and high risk of complications. **Exclusion criteria:** women requiring use of the 'Drug use in pregnancy service' or booked after 16' weeks' gestation. **Participants randomised:** 213 team-midwife-led care, 233 to standard care (shared care)
Interventions	**Experimental:** team of 6.8 WTE midwives sharing a caseload. Provided antenatal and intrapartum care in hospital and postnatal care in hospital and community. Obstetrician saw all women at first visit and 32 weeks, and after 40 weeks, and as appropriate. Team midwife was on call for out-of-hours care **Control:** low-risk women seen in midwives' hospital antenatal clinics, and all other women seen by medical staff. Women received intrapartum care from delivery suite midwives, and postnatal care from midwives on postnatal ward and community postnatal care
Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/NICU Amniotomy Antenatal hospitalisation Attendance at birth by known midwife Augmentation/artificial oxytocin during labour Breastfeeding initiation Caesarean birth Episiotomy Fetal loss/neonatal death equal to/after 24 weeks Induction of labour Instrumental vaginal birth (forceps/vacuum) Intact perineum

Kenny 1994 (*Continued*)

	Mean labour length Mean number of antenatal visits No intrapartum analgesia/anaesthesia Opiate analgesia Overall fetal loss and neonatal death Perineal laceration requiring suturing Postpartum haemorrhage (as defined by trial authors) Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial authors)
Notes	96% of experimental group and 13% of standard group had previously met midwife attending labour Randomisation before consent to participate.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	'...allocated a numbered randomisation envelope (the number was recorded by the booking-in midwife on a list of women booked in the session).'
Allocation concealment (selection bias)	Low risk	'Allocated a numbered randomisation envelope (the number was recorded by the booking-in midwife on a list of women booked in the session). When each woman returned for her first visit to the doctor at the antenatal clinic she was approached in the waiting room by a program midwife, reminded about the research and asked to sign a consent form. If the woman agreed to join the study, the randomisation envelope was opened and the woman informed of the type of care she was to receive and the appropriate future appointments made.'
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not stated but unlikely.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated but unlikely.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up = 19 team care and 22 standard who either moved or had a miscarriage

Kenny 1994 (*Continued*)

Selective reporting (reporting bias)	Low risk	**Outcome reporting:** all outcomes stated in the methods section were adequately reported in results
Other bias	Low risk	No other bias identified.

MacVicar 1993

Methods	**Study design:** RCT, Zelen method. **Duration of study:** 1989-1991.
Participants	**Setting:** tertiary hospital and community in Leicester, UK. **Inclusion criteria:** women at low risk of complications. **Exclusion criteria:** women who had a previous caesarean section or difficult vaginal delivery, a complicating general medical condition, a previous stillbirth or neonatal death, or a previous small-for-gestational-age baby, multiple pregnancy, Rhesus antibodies, and a raised level of serum alpha-feto protein. **Participants randomised:** 2304 team midwifery, 1206 to standard care (shared care).
Interventions	**Experimental:** team of 2 midwifery sisters assisted by 8 staff midwives provided hospital-based antenatal, intrapartum (in hospital-based 3 room home-from-home unit (no EFM or epidural) and hospital postnatal care only. All the staff were volunteers. Antenatal midwife-led hospital clinic with scheduled visits at 26, 36 and 41 weeks' gestation. Intervening care shared with GPs and community midwives. Referral to obstetrician as appropriate. At 41 weeks mandatory referral to consultant. Postnatal care in community provided by community midwife and GP. **Control group:** shared antenatal care with GP and midwife. Intrapartum care provided by hospital staff
Outcomes	Outcomes considered in the review and reported in or extracted from the study: Admission to special care nursery/NICU Augmentation/artificial oxytocin during labour Caesarean birth Episiotomy Fetal loss/neonatal death before 24 weeks Fetal loss/neonatal death equal to/after 24 weeks Induction of labour Intact perineum Instrumental vaginal birth (forceps/vacuum) Low birthweight (< 2500 g) No intrapartum analgesia/anaesthesia Opiate analgesia Overall fetal loss and neonatal death Perineal laceration requiring suturing Postpartum haemorrhage(as defined by trial authors) Preterm birth (< 37 weeks) Regional analgesia (epidural/spinal)

MacVicar 1993 (*Continued*)

	Spontaneous vaginal birth (as defined by trial authors)
Notes	2:1 randomisation ratio in favour of midwife-led care. 189/2304 (8%) women opted out of team-midwife care post-randomisation. Analysis by intention-to-treat analysis Level of continuity not reported.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	'...by a random sequence...'
Allocation concealment (selection bias)	Low risk	'...sealed envelope...cards could not be read through the envelopes. Each envelope was numbered, and unused envelopes were not reallocated...'
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not stated re participants but not possible to have achieved. Clinical staff were unaware whether a particular woman was in the control group or was not in the study. No information given re blinding of women in intervention arm
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated but unlikely.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information given on losses to follow-up.
Selective reporting (reporting bias)	Low risk	**Outcome reporting:** all outcomes stated in the methods section were adequately reported in results
Other bias	Low risk	No other bias identified.

McLachlan 2012

Methods	**Study design:** RCT. **Duration of study:** 2007-2010.
Participants	**Setting:** Royal Women's Hospital (RWH), Melbourne, Australia. **Inclusion criteria:** low-risk pregnant women; fewer than 24 completed weeks' gestation; a singleton pregnancy; and considered low obstetric risk at recruitment including an uncomplicated obstetric history. **Exclusion criteria:** previous caesarean section, history of stillbirth or neonatal death, 3

	or more consecutive miscarriages, previous fetal death in utero, previous preterm birth (< 32 weeks), previous midtrimester loss/cervical incompetence/cone biopsy/known uterine anomaly, previous early onset of pre-eclampsia (< 32 weeks' gestation), or rhesus iso-immunisation; complications during the current pregnancy (such as multiple pregnancy or fetal abnormality); medical conditions (such as cardiac disease, essential hypertension, renal disease, pre-existing diabetes, previous gestational diabetes, epilepsy, severe asthma, substance use, significant psychiatric disorders and obesity [BMI > 35] or significantly underweight [BMI < 17]). **Participants randomised:** 1156 caseload, 1158 standard care.
Interventions	**Experimental:** majority of care from a 'primary' caseload midwife at the hospital. The primary midwife collaborated with obstetricians and other health professionals and continued to provide caseload care if complications arose. Women saw an obstetrician at booking, at 36 weeks' gestation and postdates if required, and usually had 1 or 2 visits with a 'back-up' midwife. Intrapartum care was provided in the hospital birthing suite. Where possible, primary midwife was on call for the woman's labour and birth. The primary midwife (or a back-up) attended the hospital on most days to provide some postnatal care and provided domiciliary care following discharge from hospital. Fulltime midwives had a caseload of 45 women per annum. During the trial there were 7.5 (at commencement) to 12 full-time equivalent midwives employed in caseload care, equating to 10-14 midwives **Control:** options included midwifery-led care with varying levels of continuity, obstetric trainee care and community-based care 'shared' between a general medical practitioner (GP) and the hospital, where the GP provided the majority of antenatal care. In the midwife and GP-led models women saw an obstetrician at booking, 36 weeks' gestation and postdates if required, with other referral or consultation as necessary. In all standard-care options, women were cared for by whichever midwives and doctors were rostered for duty when they came into the hospital for labour, birth and postnatal care
Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/NICU Caesarean birth Duration of postnatal hospital stay (days) Episiotomy Fetal loss/neonatal death before 24 weeks Fetal loss/neonatal death equal to/after 24 weeks Induction of labour Instrumental vaginal birth (forceps/vacuum) Low birthweight (< 2500 g) Overall fetal loss and neonatal death Preterm birth (< 37 weeks) Postpartum haemorrhage (as defined by trial authors) Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial authors)
Notes	'...around 90% of the women had a known carer in labour.'

McLachlan 2012 (*Continued*)

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	'...using stratified permuted blocks of varying size.'
Allocation concealment (selection bias)	Low risk	'Randomisation was undertaken using an interactive voice response system activated by telephone...'
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not stated but unlikely.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	'Obstetric and medical outcome data (including type of birth) were obtained directly from the electronic obstetric database, blinded to treatment allocation. Data not available this way (e.g. continuity of carer) were manually abstracted (unblinded) from the medical record.'
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up = 6 caseload and 1 standard care.
Selective reporting (reporting bias)	Low risk	**Outcome reporting:** all outcomes stated in the methods section were adequately reported in results
Other bias	Low risk	No other bias identified.

North Stafford 2000

Methods	**Study design:** RCT, cluster randomisation. **Duration of study:** not stated.
Participants	**Setting:** tertiary hospital and community, UK. **Inclusion criteria:** 'all-risks'. **Exclusion criteria:** not stated. **Participants randomised:** 770 midwife-led caseload care, 735 standard care (shared care)
Interventions	**Experimental:** caseload midwife-led care. 3 geographic areas with 21 WTE midwives working in 3 practices offering a caseload model of care. Each midwife was attached to 2-3 GP practices and cared for 35-40 women. Midwives worked in pairs/threesomes. Caseload midwives were existing community midwives, plus new midwives recruited from community and hospital resulting in a mix of senior and junior staff. Monthly

North Stafford 2000 (*Continued*)

	antenatal care in the community, intrapartum and postnatal care in hospital and postnatal care in the community provided **Control:** shared care in the community between GPs, community midwives and obstetricians. Each community midwife cared for 100/150 women each
Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/NICU Attendance at birth by known midwife Augmentation/artificial oxytocin during labour Caesarean birth Episiotomy Fetal loss/neonatal death equal to/after 24 weeks Induction of labour Instrumental vaginal birth (forceps/vacuum) Intact perineum Low birthweight (< 2500 g) Overall fetal loss and neonatal death Perineal laceration requiring suturing Preterm birth (< 37 weeks) Regional analgesia (epidural/spinal)
Notes	95% of experimental group and 7% of standard group had previously met midwife attending labour

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	'Randomisation was undertaken by one of the principal investigators...who had no prior knowledge of the area or medical and midwifery staff involved.... three pairs, one of each...randomised to receive caseload care and the other to traditional care.'
Allocation concealment (selection bias)	High risk	No information given about allocation concealment.
Blinding of participants and personnel (performance bias) All outcomes	High risk	'It was not possible to mask allocation and both women and professionals were aware of the allocated type of midwifery care.'
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated but unlikely.

North Stafford 2000 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up: not reported but appears complete.
Selective reporting (reporting bias)	Low risk	**Outcome reporting:** all outcomes stated in the methods section were adequately reported or explained in results
Other bias	Low risk	No other bias identified.

Rowley 1995

Methods	**Study design:** RCT. **Duration of study:** 1991-1992.
Participants	**Setting:** John Hunter hospital, Newcastle, NSW, Australia. **Inclusion criteria:** women booked for delivery at hospital of low and high risk. **Exclusion criteria:** women who had chosen shared antenatal care with their GP or had a substance abuse problem. **Participants randomised:** 405 team care, 409 standard care (shared care).
Interventions	**Experimental:** team of 6 experienced and newly graduated midwives provided antenatal care, intrapartum care, and postnatal care in hospital. Women at low risk had scheduled consultations with an obstetrician at 12-16, 36, 41 weeks and additional consultations as needed. Women at high risk had consultations with an obstetrician at a frequency determined according to their needs. **Control:** antenatal care from hospital physicians and intrapartum and postnatal care from midwives and doctors working in the delivery suite, and the postnatal ward. Women were usually seen by a doctor at each visit. Control-group midwives were also a mix of experienced and newly qualified midwives
Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/NICU Antenatal hospitalisation Augmentation/artificial oxytocin during labour Caesarean birth Episiotomy Fetal loss/neonatal death before 24 weeks Fetal loss/neonatal death equal to/after 24 weeks Induction of labour Instrumental vaginal birth(forceps/vacuum) Low birthweight (< 2500 g) Opiate analgesia Overall fetal loss and neonatal death Perineal laceration requiring suturing Preterm birth (< 37 weeks)

Rowley 1995 (*Continued*)

	Regional analgesia(epidural/spinal) Spontaneous vaginal birth (as defined by trial authors)
Notes	Degree of continuity not reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'Allocation to either team care or routine care was done by computer-generated random assignments:'
Allocation concealment (selection bias)	Unclear risk	'The women were allocated at random to team care or routine care....'
Blinding of participants and personnel (performance bias) All outcomes	High risk	'...the unblinded nature of the study could have led to differences in practice and measurement of outcomes...'
Blinding of outcome assessment (detection bias) All outcomes	High risk	'...the unblinded nature of the study could have led to differences in practice and measurement of outcomes...'
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Loss to follow-up not reported (appears minimal).
Selective reporting (reporting bias)	Low risk	**Outcome reporting:** all outcomes stated in the methods section were adequately reported or explained in result
Other bias	Low risk	No other bias identified.

Turnbull 1996

Methods	**Study design:** RCT. **Duration of study:** 1993-1994.
Participants	**Setting:** Glasgow Royal Maternity Hospital, Scotland, United Kingdom. **Inclusion criteria:** women at low risk of complications. **Exclusion criteria:** women booking after 16 weeks of pregnancy, not living in catchment area or with medical/obstetric complications. **Participants randomised:** 648 caseload, 651 standard care (shared care).
Interventions	**Experimental:** caseload midwifery provided by 20 midwives who volunteered to join the MDU. Each pregnant woman had a named midwife whom she met at her first booking visit who aimed to provide the majority of care. When the named midwife was not available, care was provided by up to 3 associate midwives. Women were not seen

	by medical staff at booking. Antenatal care was provided at home, community-based clinics or hospital clinics. Intrapartum care was in hospital (MDU - 3 rooms with fewer monitors and homely surroundings) or main labour suite. Postnatal care was provided in designated 8-bed MDU ward and community. A medical visit was scheduled where there was a deviation from normal. **Control:** all women seen by medical staff at booking. Shared antenatal care with from midwives, hospital doctors and GPs/family doctors. Intrapartum care from labour ward midwife on labour suite. Postnatal care on postnatal ward and community by community midwife
Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/NICU Antepartum haemorrhage Augmentation/artificial oxytocin during labour Caesarean birth Episiotomy Fetal loss/neonatal death before 24 weeks Fetal loss/neonatal death equal to/after 24 weeks Induction of labour Instrumental vaginal birth(forceps/vacuum) Intact perineum Low birthweight (< 2500 g) Mean labour length Neonatal convulsions (as defined by trial authors) No intrapartum analgesia/anaesthesia Opiate analgesia Overall fetal loss and neonatal death Perineal laceration requiring suturing Postpartum depression Postpartum haemorrhage (as defined by trial authors) Preterm birth (< 37 weeks) Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial authors)
Notes	Women in the intervention group saw 7 fewer care providers across antenatal, labour and postnatal periods and 2 fewer providers during labour

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	'...random number tables...'
Allocation concealment (selection bias)	Low risk	'The research team telephoned a clerical officer in a separate office for care allocation for each woman.'

Turnbull 1996 (*Continued*)

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	**Participants: n**ot stated. **Personnel:** clinical staff were unaware whether a particular woman was in the control group or was not in the study. No information given for women in intervention arm
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	'Clinical data were gathered through a retrospective review of records by the research team who were not involved in providing care.'
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up: 5 team care and 16 shared care.
Selective reporting (reporting bias)	Low risk	**Outcome reporting:** all outcomes stated in the methods section were adequately reported or explained in result
Other bias	Low risk	No other bias identified.

Waldenstrom 2001

Methods	**Study design:** RCT. **Duration of study:** 1996-1997.
Participants	**Setting:** Royal Women's Hospital, Melbourne, Australia. **Inclusion criteria:** women at low risk of complications. **Exclusion criteria:** non-English speaking women, women > 25 weeks' gestation at booking, women with high-risk criteria including previous obstetric complications, preterm delivery, IUGR, PET, previous fetal loss, significant medical disease, > 3 abortions, substance addiction, infertility > 5 years. **Participants randomised:** 495 team-midwife care, 505 standard care (combination of different models of care)
Interventions	**Experimental:** team-midwife care provided by team of 8 midwives who provided hospital-based antenatal, intrapartum (delivery suite or family birth centre) and some postnatal care in collaboration with medical staff **Control:** standard care included different options of care being provided mostly by doctors, care mainly by midwives in collaboration with doctors (midwives clinics), birth centres and shared care between general practitioners and hospital doctors
Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/NICU Antenatal hospitalisation Antepartum haemorrhage

	Attendance at birth by known midwife Augmentation/artificial oxytocin during labour Caesarean birth Duration of postnatal hospital stay(days) Episiotomy Fetal loss/neonatal death before 24 weeks Fetal loss/neonatal death equal to/after 24 weeks Induction of labour Instrumental vaginal birth (forceps/vacuum) Intact perineum Mean length of neonatal hospital stay (days) Opiate analgesia Overall fetal loss and neonatal death Perineal laceration requiring suturing Postpartum haemorrhage (as defined by trial authors) Preterm birth (< 37 weeks) Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial authors)
Notes	65% and 9% of experimental (team) and control (standard) group participants had previously met midwife attending labour

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No information given.
Allocation concealment (selection bias)	Low risk	'The research midwife rang a clerk at the hospital's information desk who opened an opaque, numbered envelope that contained information about the allocated group.'
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not stated but unlikely.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated but unlikely.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Lost to follow-up: 11 team care and 9 standard-care group.
Selective reporting (reporting bias)	Low risk	**Outcome reporting:** all outcomes stated in the methods section were adequately reported or explained in result

Other bias	Low risk	No other bias identified.

BMI: body mass index
CLC: consultant-led care
CLU: consultant-led unit
EFM: electronic fetal monitoring
GP: general practitioner
IUGR: intrauterine growth restriction
MDU: midwifery development unit
MLU: midwife-led care
NICU: neonatal intensive care unit
PET: positron emissions tomography
RCT: randomised controlled trial
vs: versus
WTE: whole time equivalent

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Berglund 1998	This study was a retrospective study comparing outcomes for 2 groups of women who gave birth in 1990 and 1992
Berglund 2007	This study compared risk assessment by physicians with midwives reporting new mothers to the doctor. It does not compare midwife-led with other models of care
Bernitz 2011	This study compared women giving birth in three different birth units: the special unit for high risk women; the normal unit; and the midwife-led unit. It does not compare midwife-led with other models of care throughout pregnancy and birth
Chambliss 1991	Women admitted in labour were assigned to either midwife-led or a resident physician and antenatal care was not part of the intervention
Chapman 1986	This study compares similar models of care occurring in 2 different birth environments rather than comparing 2 different models of care. The same group of community midwives cared for the women in both groups. Method of randomisation is not stated
Giles 1992	The study compares 2 models of antenatal care, i.e. antenatal care by midwives and obstetricians or antenatal care by midwives only. Intrapartum and postpartum care are not part of the intervention
Heins 1990	The study presents a randomised trial of nurse-midwifery prenatal care to reduce low birthweight: intrapartum and postpartum care are not part of the intervention

(*Continued*)

Hildingsson 2003	The aim of the study was to determine women's interest in home birth and in-hospital birth centre care in Sweden and to describe the characteristics of these women. It did not compare the models of care in these 2 settings
Hundley 1994	The main objective was to compare care and delivery of low-risk women in a midwife-managed delivery unit with care and delivery in the consultant-led labour ward. It is not indicated if women in the birth centre group had antenatal midwifery-led care
James 1988	This study compared a schematic approach to antenatal care only and conventional shared care.There are no data available
Kelly 1986	Study protocol only, search strategy did not reveal any evidence that the trial was conducted and completed
Klein 1984	The intervention involved the comparison of 2 birthing environments
Law 1999	In this study, the randomisation took place on the admission to labour ward, thus the study compared intrapartum care only
Marks 2003	This study aimed to compare continuity of midwifery care with standard midwifery care in reducing postnatal depression in women with a past history of depression. Thus midwife-led care is not being compared to another model of care
Runnerstrom 1969	The primary reason for exclusion is the fact that the study did not compare a midwifery model of care to another model. The purpose of the investigation was to study the effectiveness or non-effectiveness of nurse-midwives in a supervised hospital environment. The population of the study comprised student nurse-midwives and compared their services to those of MD residents in the same unit. Moreover, there are not enough comparable data
Slome 1976	Large loss to follow-up after randomisation. A total of 66.5% in the treatment group and 63.5% in the control group were excluded or lost to the study
Stevens 1988	The care was not midwifery-led. Both groups received shared care. 1 group received most of their care at a satellite clinic in their neighbourhood, which was an inner-city, socio-economically deprived area. The other group received care at the hospital clinic. Women receiving satellite clinic care also had additional social support from link workers during pregnancy. It was a comparison of the same model of care at different settings
Tucker 1996	The study compares a shared care model vs a medical-led model. The primary analyses are not included
Waldenstrom 1997	This study compared birth centre care - characterised by comprehensive antenatal, intrapartum and postpartum care, on the same premises with a home-like environment and the same team of midwives - to the standard obstetric care divided into antenatal care at neighbourhood antenatal clinics, intrapartum care in hospital delivery wards, and postpartum care in hospital postpartum wards. In the standard obstetric care, a woman usually meets with the same midwife, at the antenatal clinic, throughout pregnancy. In the delivery ward she meets a new staff team, and in the hospital postpartum ward, yet another staff team. Thus, the study compares continuous midwifery-led caseload model of care to team midwifery-led care
Walker 2012	This study compared care provided by general physicians, obstetric nurses and professional midwives in a cluster RCT in Mexico. It does not compare midwife-led with other models of care throughout pregnancy and birth.

(*Continued*)

	Abstract only available

RCT: randomised controlled trial
vs: versus

Characteristics of ongoing studies *[ordered by study ID]*

Nagle 2011

Trial name or title	Continuity of midwifery care and gestational weight gain in obese women: a randomised controlled trial
Methods	A 2-arm unblinded randomised controlled trial.
Participants	Primigravid women with a BMI $\geq$ 30 who are less than 17 weeks' gestation, recruited from maternity services in Victoria, Australia
Interventions	Women allocated to the intervention arm will be cared for in a midwifery continuity of care model and receive an informational leaflet on managing weight gain in pregnancy. Women allocated to the control group will receive routine care in addition to the same informational leaflet
Outcomes	The primary outcome is the proportion of women with a gestational weight gain within IOM guidelines Secondary outcomes: Provision of care in line with the standards within the UK guidelines, Women's satisfaction with care
Starting date	Unclear.
Contact information	cate.nagle@deakin.edu.au, School of Nursing and Midwifery, Deakin University, Geelong Waterfront campus, 1 Gheringhap St, Geelong Victoria, 3217, Australia
Notes	Trial Registration: Australian New Zealand Clinical Trials Registry ACTRN12610001078044

Tracy 2008

Trial name or title	The M@NGO Study (Midwives at New Group practice Options): A randomised controlled trial of caseload midwifery care
Methods	2-arm unblinded randomised controlled trial.
Participants	Women at low risk (as defined by trial authors) over 18 years booking at the participating hospital at or less than 24 weeks pregnant with a single, live fetus
Interventions	Caseload midwifery care compared with standard maternity care
Outcomes	Primary outcome measures: caesarean section rates; instrumental birth rates; rates of admission to neonatal intensive care

Tracy 2008 (*Continued*)

Starting date	
Contact information	Sally Tracy Sydney Nursing School, University of Sydney, Sydney [sally.tracy@sydney.edu.au]
Notes	NHRMC grant 510207

BMI: body mass index
IOM: Institute of Medicine

DATA AND ANALYSES

Comparison 1. Midwife-led versus other models of care for childbearing women and their infants (all)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Regional analgesia (epidural/ spinal)	13	15982	Risk Ratio (M-H, Random, 95% CI)	0.83 [0.76, 0.90]
2 Caesarean birth	13	15982	Risk Ratio (M-H, Random, 95% CI)	0.93 [0.84, 1.02]
3 Instrumental vaginal birth (forceps/vacuum)	12	15809	Risk Ratio (M-H, Random, 95% CI)	0.88 [0.81, 0.96]
4 Spontaneous vaginal birth (as defined by trial authors)	11	14995	Risk Ratio (M-H, Random, 95% CI)	1.05 [1.03, 1.08]
5 Intact perineum	9	11494	Risk Ratio (M-H, Random, 95% CI)	1.03 [0.94, 1.13]
6 Preterm birth (< 37 weeks)	7	11546	Risk Ratio (M-H, Random, 95% CI)	0.77 [0.62, 0.94]
7 Overall fetal loss and neonatal death	12	15869	Risk Ratio (M-H, Random, 95% CI)	0.84 [0.71, 1.00]
8 Antenatal hospitalisation	6	6039	Risk Ratio (M-H, Random, 95% CI)	0.93 [0.83, 1.05]
9 Antepartum haemorrhage	4	3654	Risk Ratio (M-H, Random, 95% CI)	0.89 [0.57, 1.40]
10 Induction of labour	12	15809	Risk Ratio (M-H, Random, 95% CI)	0.95 [0.86, 1.03]
11 Amniotomy	4	3253	Risk Ratio (M-H, Random, 95% CI)	0.80 [0.66, 0.98]
12 Augmentation/artificial oxytocin during labour	11	13502	Risk Ratio (M-H, Random, 95% CI)	0.89 [0.79, 1.01]
13 No intrapartum analgesia/ anaesthesia	6	8807	Risk Ratio (M-H, Random, 95% CI)	1.16 [1.04, 1.31]
14 Opiate analgesia	10	11997	Risk Ratio (M-H, Random, 95% CI)	0.90 [0.80, 1.01]
15 Attendance at birth by known midwife	6	5225	Risk Ratio (M-H, Random, 95% CI)	7.83 [4.15, 14.80]
16 Episiotomy	13	15982	Risk Ratio (M-H, Random, 95% CI)	0.84 [0.76, 0.92]
17 Perineal laceration requiring suturing	9	13412	Risk Ratio (M-H, Random, 95% CI)	1.02 [0.95, 1.10]
18 Mean labour length (hrs)	3	3328	Mean Difference (IV, Random, 95% CI)	0.50 [0.27, 0.74]
19 Postpartum haemorrhage (as defined by trial authors)	9	12522	Risk Ratio (M-H, Random, 95% CI)	0.97 [0.84, 1.11]
20 Breastfeeding initiation	2	2050	Risk Ratio (M-H, Random, 95% CI)	1.12 [0.81, 1.53]
21 Duration of postnatal hospital stay (days)	3	3593	Mean Difference (IV, Random, 95% CI)	-0.10 [-0.29, 0.09]
22 Low birthweight (< 2500 g)	6	9766	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.83, 1.16]
23 5-minute Apgar score below or equal to 7	10	10854	Risk Ratio (M-H, Random, 95% CI)	0.99 [0.70, 1.41]
24 Neonatal convulsions (as defined by trial authors)	2	2923	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.14, 5.74]
25 Admission to special care nursery/neonatal intensive care unit	12	15869	Risk Ratio (M-H, Random, 95% CI)	0.90 [0.76, 1.06]
26 Mean length of neonatal hospital stay (days)	2	1979	Mean Difference (IV, Random, 95% CI)	-3.63 [-7.57, 0.30]

27 Fetal loss/neonatal death before 24 weeks	10	13953	Risk Ratio (M-H, Random, 95% CI)	0.81 [0.66, 0.99]
28 Fetal loss/neonatal death equal to/after 24 weeks	11	15667	Risk Ratio (M-H, Random, 95% CI)	1.00 [0.67, 1.51]

Comparison 2. Midwife-led versus other models of care: variation in midwifery models of care (caseload/one-to-one or team)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Regional analgesia (epidural/spinal)	13	15982	Risk Ratio (M-H, Random, 95% CI)	0.83 [0.76, 0.90]
1.1 Caseload	3	5090	Risk Ratio (M-H, Random, 95% CI)	0.88 [0.76, 1.03]
1.2 Team models of midwifery care	10	10892	Risk Ratio (M-H, Random, 95% CI)	0.81 [0.73, 0.89]
2 Caesarean birth	13	15966	Risk Ratio (M-H, Random, 95% CI)	0.93 [0.84, 1.02]
2.1 Caseload	3	5090	Risk Ratio (M-H, Random, 95% CI)	0.93 [0.75, 1.17]
2.2 Team models of midwifery care	10	10876	Risk Ratio (M-H, Random, 95% CI)	0.94 [0.84, 1.05]
3 Instrumental vaginal birth (forceps/vacuum)	12	16273	Risk Ratio (M-H, Random, 95% CI)	0.89 [0.82, 0.96]
3.1 Caseload	3	5090	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.80, 1.04]
3.2 Team models of midwifery care	9	11183	Risk Ratio (M-H, Random, 95% CI)	0.88 [0.79, 0.97]
4 Spontaneous vaginal birth (as defined by trial authors)	11	14995	Risk Ratio (M-H, Random, 95% CI)	1.05 [1.03, 1.08]
4.1 Caseload	3	5090	Risk Ratio (M-H, Random, 95% CI)	1.05 [0.98, 1.14]
4.2 Team models of midwifery care	8	9905	Risk Ratio (M-H, Random, 95% CI)	1.05 [1.02, 1.07]
5 Intact perineum	9	11494	Risk Ratio (M-H, Random, 95% CI)	1.03 [0.94, 1.13]
5.1 Caseload	2	2783	Risk Ratio (M-H, Random, 95% CI)	1.12 [0.83, 1.50]
5.2 Team	7	8711	Risk Ratio (M-H, Random, 95% CI)	1.01 [0.91, 1.13]
6 Preterm birth (< 37 weeks)	7	11546	Risk Ratio (M-H, Random, 95% CI)	0.77 [0.62, 0.94]
6.1 Caseload	2	3585	Risk Ratio (M-H, Random, 95% CI)	0.65 [0.47, 0.90]
6.2 Team	5	7961	Risk Ratio (M-H, Random, 95% CI)	0.81 [0.62, 1.07]
7 Overall fetal loss and neonatal death	12	15835	Risk Ratio (M-H, Random, 95% CI)	0.84 [0.70, 1.00]
7.1 Caseload	3	5090	Risk Ratio (M-H, Random, 95% CI)	0.65 [0.43, 0.99]
7.2 Team	9	10745	Risk Ratio (M-H, Random, 95% CI)	0.89 [0.73, 1.07]

Comparison 3. Midwife-led versus other models of care: variation in risk status (low versus mixed)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Regional analgesia (epidural/ spinal)	13	15982	Risk Ratio (M-H, Random, 95% CI)	0.83 [0.76, 0.90]
1.1 Low risk	8	11096	Risk Ratio (M-H, Random, 95% CI)	0.82 [0.73, 0.92]
1.2 Mixed risk	5	4886	Risk Ratio (M-H, Random, 95% CI)	0.84 [0.75, 0.95]
2 Caesarean birth	13	15982	Risk Ratio (M-H, Random, 95% CI)	0.93 [0.84, 1.02]
2.1 Low risk	8	11096	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.79, 1.06]
2.2 Mixed risk	5	4886	Risk Ratio (M-H, Random, 95% CI)	0.96 [0.84, 1.09]
3 Instrumental vaginal birth (forceps/vacuum)	12	15809	Risk Ratio (M-H, Random, 95% CI)	0.88 [0.81, 0.96]
3.1 Low risk	7	10923	Risk Ratio (M-H, Random, 95% CI)	0.89 [0.81, 0.99]
3.2 Mixed risk	5	4886	Risk Ratio (M-H, Random, 95% CI)	0.82 [0.65, 1.03]
4 Spontaneous vaginal birth (as defined by trial authors)	11	14995	Risk Ratio (M-H, Random, 95% CI)	1.05 [1.03, 1.08]
4.1 Low risk	7	10923	Risk Ratio (M-H, Random, 95% CI)	1.05 [1.02, 1.08]
4.2 Mixed risk	4	4072	Risk Ratio (M-H, Random, 95% CI)	1.06 [1.01, 1.10]
5 Intact perineum	9	11494	Risk Ratio (M-H, Random, 95% CI)	1.03 [0.94, 1.13]
5.1 Low risk	6	8616	Risk Ratio (M-H, Random, 95% CI)	1.06 [0.93, 1.21]
5.2 Mixed risk	3	2878	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.90, 1.07]
6 Preterm birth (< 37 weeks)	7	11546	Risk Ratio (M-H, Random, 95% CI)	0.77 [0.62, 0.94]
6.1 Low risk	5	9726	Risk Ratio (M-H, Random, 95% CI)	0.71 [0.54, 0.92]
6.2 Mixed risk	2	1820	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.70, 1.21]
7 Overall fetal loss and neonatal death	12	15835	Risk Ratio (M-H, Random, 95% CI)	0.84 [0.70, 1.00]
7.1 Low risk	7	10895	Risk Ratio (M-H, Random, 95% CI)	0.94 [0.73, 1.20]
7.2 Mixed risk	5	4940	Risk Ratio (M-H, Random, 95% CI)	0.76 [0.59, 0.97]

ADDITIONAL TABLES

Table 1. Women's experiences of care

Satisfaction	Intervention (n/N)	Control (n/N)	Relative rate	95% CI	Statistical test	P value
Flint 1989*						
Staff in labour (very caring)	252/275 (92%)	208/256 (81%)	1.1	1.0-1.2		
Experience of labour (wonderful/enjoyable)	104/246 (42%)	72/223 (32%)	1.3	1.0-1.8		

Table 1. Women's experiences of care (*Continued*)

Satisfaction with pain relief (very satisfied)	121/209 (58%)	104/205 (51%)	1.1	0.9-1.4		
Very well prepared for labour	144/275 (52%)	102/254 (40%)	1.3	1.0-1.7		
MacVicar 1993	N = 1663	N = 826	Difference			
Very satisfied with antenatal care	52%	44%	8.3%	4.1-12.5		
Very satisfied with care during labour	73%	60%	12.9%	9.1-16.8		
Kenny 1994	N = 213	N = 233				
Carer skill, attitude and communication (antenatal care)	57.1/60	47.7/60			t = 12.4	0.0001
Convenience and waiting (antenatal care)	14.8/20	10.9/20			t = 10.1	0.0001
Expectation of labour/birth (antenatal care)	9.8/18	9.3/18			t = 1.4	0.16
Asking questions (antenatal care)	8.5/12	6.9/12			t = 6.6	0.0001
Information/ communication (labour and birth)	28.3/30	24.8/30			t = 7.48	0.0001
Coping with labour (labour and birth)	20.9/30	19.3/30			t = 2.83	0.005

Table 1. Women's experiences of care (*Continued*)

Midwife skill/ caring (labour and birth)	22.7/24	21.3/24			t = 3.44	0.0007
Help and advice (postnatal care)	21.0/24	19.7/24			t = 1.88	0.06
Midwife skill and communication (postnatal care)	16.6/18	15.4/18			t = 4.48	0.0001
Managing baby (postnatal care)	8.7/12	8.5/12			t = 0.77	0.77
Self-rated health (postnatal care)	7.5/12	7.1/12			t = 1.67	0.10
Rowley 1995			OR			
Encouraged to ask questions	N/A		4.22	2.72-6.55		
Given answers they could understand	N/A		3.03	1.33-7.04		
Able to discuss anxieties	N/A		3.60	2.28-5.69		
Always had choices explained to them	N/A		4.17	1.93-9.18		
Participation in decision making	N/A		2.95	1.22-7.27		
Midwives interested in woman as a person	N/A		7.50	4.42-12.80		
Midwives always friendly	N/A		3.48	1.92 - 6.35		

Table 1. Women's experiences of care (*Continued*)

Turnbull 1996	n/N	n/N	Mean difference - satisfaction score			
Antenatal care	534/648	487/651	0.48	0.55-0.41		
Intrapartum care	445/648	380/651	0.28	0.37-0.18		
Hospital-based postnatal care	445/648	380/651	0.57	0.70-0.45		
Home-based postnatal care	445/648	380/651	0.33	0.42-0.25		
Waldenstrom 2001	%	%	OR			
Overall antenatal care was very good (strongly agree)	58.2%	39.7%	2.22	1.66-2.95		< 0.001
Happy with the physical aspect of intrapartum care (strongly agree)	58.6%	42.5%	1.94	1.46-2.59		< 0.001
Happy with the emotional aspect of intrapartum care (strongly agree)	58.8%	44.0%	1.78	1.34-2.38		< 0.001
Overall postnatal care was very good (strongly agree)	37.6%	33.2%	1.27	0.97-1.67		0.08
Hicks 2003**						
Care and sensitivity of staff (antenatal)	1.32	1.77	Mean difference?			0.0000

Table 1. Women's experiences of care (*Continued*)

Care and sensitivity of staff (labour and delivery)	1.26	1.58	Mean difference?			0.008
Care and sensitivity of staff (postpartum at home)	1.24	1.57	Mean difference?			0.0000
Harvey 1996						
Labour and Delivery Satisfaction Index +	211	185	26	18.8-33.1		0.001
Biro 2000						
Satisfaction with antenatal care (very good)	195/344 (57%)	100/287 (35%)	1.24	1.13-1.36		0.001
Satisfaction with intrapartum care (very good)	215/241 (63%)	134/282 (47%)	1.11	1.03-1.20		0.01
Satisfaction with postpartum care in hospital (very good)	141/344 (41%)	102/284 (31%)	0.92	0.82-1.04		0.22

*: 99% Confidence interval (CI) for Flint study was reported
N/A: not available
**:Mean satisfaction scores are reported: lower scale indicates higher satisfaction. Satisfaction scores were calculated on a 5-point ordinal scale in which 1 = very satisfied and 5 = very dissatisfied.

FEEDBACK

Bacon, May 2004

Summary

Are you planning to include intrapartum foetal death rates for women delivering in different types of unit, and with different levels of risk, as one of your outcome measures? We have been unable to find comparative data for a local review.
(Summary of comment from Sallie Bacon, May 2004)

Reply

We have not looked at intrapartum deaths specifically, but have addressed this issue in the 'Discussion'.
(Summary of response from Jane Sandall, November 2007)

Contributors

Sallie Bacon

WHAT'S NEW

Last assessed as up-to-date: 22 July 2013.

Date	Event	Description
2 May 2013	New citation required and conclusions have changed	Two new studies included (Begley 2011; McLachlan 2012). In this update the evidence now suggests that women randomised to receive midwife-led continuity models of care were less likely to experience preterm birth. There is now no evidence of a difference between different models of care in terms of antenatal hospitalisation and breast-feeding initiation
28 January 2013	New search has been performed	Search updated. Methods updated.

HISTORY

Protocol first published: Issue 1, 2004

Review first published: Issue 4, 2008

Date	Event	Description
29 April 2009	Amended	In response to feedback, we have clarified what is meant by midwife-led care and have stressed the multi-disciplinary network of care providers; have added information to the Abstract about the lack of effect on caesarean section; and revised the Abstract's conclusions from "All women" to "Most women should be offered midwife-led models of care and women should be encouraged to ask for this option."
9 November 2008	Amended	Amended the graph labelling for control in childbirth (Analysis 1.32) and corrected a typographical error in the Results section
15 May 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

Declan Devane (DD)

DD contributed to the protocol by contributing to the design and writing.

DD contributed to the review by contributing to the design of the review, appraising the quality of and extracting data from selected papers, contributing to the interpretation of data, writing the review and providing a methodological and clinical perspective.

Simon Gates (SG)

SG provided methodological and statistical expertise in the development of the review, and assisted with analysis of data and interpretation of results.

Jane Sandall (JS)

JS contributed to the protocol by contributing to the design and writing. JS contributed to the design, screened retrieved papers against inclusion criteria and appraised quality of papers.

JS has been the contact author for the review since July 2006 and is first author of the review. Since 2006, she has co-ordinated the review process, written to authors for additional information, managed data for the review, re-extracted data from papers, re-entered data into Review Manager, re-entered data for the included studies section, analysed and interpreted data, and provided a clinical and policy perspective. She has rewritten the Plain Language Summary, Abstract, Background, Methods, Description of studies, Methodological quality, Results, Analysis, Discussion and wrote the final draft of the review.

JS revised the review in response to feedback from referees and the editor. When making the revisions, JS updated the search and identified four new reports, and contacted authors for additional data, which were assessed by JS and DD, and which she included in the revised version.

JS in the guarantor for the review.

Andrew Shennan (AS)

AS provided specialist obstetric expertise, and assisted with interpretation of results.

Hora Soltani (HS)

HS contributed to the design and commented on the first draft of the protocol.

HS contributed to the development of the protocol and review by contributing to the design, evaluation of the quality of the articles against the inclusion/exclusion criteria, data extraction, writing to authors for clarification of original article information, data interpretation, commenting on as well as writing the review.

DECLARATIONS OF INTEREST

Declan Devane is a co-author in one of the included trials in this review (Begley 2011) Jane Sandall was and is principal investigator for two studies evaluating models of midwife-led continuity of care (Sandall 2001), and co-investigator on the 'Birthplace in England Research Programme', an integrated programme of research designed to compare outcomes of births for women planned at home, in different types of midwifery units, and in hospital units with obstetric services.

SOURCES OF SUPPORT

Internal sources

- Women's Health Academic Centre, King's Health Partners, King's College, London, UK.
- Sheffield Hallam University, Seffield, UK.
- Health Services Executive, Dublin North East, Ireland.
- Trinity College, Dublin, Ireland.

External sources

- National Institute for Health Research, UK.

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

INDEX TERMS

Medical Subject Headings (MeSH)

*Continuity of Patient Care [organization & administration]; Infant, Newborn; Midwifery [economics; *methods; organization & administration]; Models, Organizational; Perinatal Care [*methods; organization & administration]; Postnatal Care [*methods; organization & administration]; Prenatal Care [*methods; organization & administration]; Randomized Controlled Trials as Topic

MeSH check words

Female; Humans; Infant; Pregnancy