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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

Jane Sandall¹, Hora Soltani², Simon Gates³, Andrew Shennan⁴, Declan Devane⁵

¹Division of Women's Health, King's College, London, Women's Health Academic Centre, King's Health Partners, London, UK. ²Centre for Health and Social Care Research, Sheffield Hallam University, Sheffield, UK. ³Warwick Clinical Trials Unit, Division of Health Sciences, Warwick Medical School, The University of Warwick, Coventry, UK. ⁴Women's Health Academic Centre, King's College London, London, UK. ⁵School of Nursing and Midwifery, National University of Ireland Galway, Galway, Ireland

Contact address: Jane Sandall, Division of Women's Health, King's College, London, Women's Health Academic Centre, King's Health Partners, 10th Floor, North Wing, St. Thomas' Hospital, Westminster Bridge Road, London, SE1 7EH, UK. jane.sandall@kcl.ac.uk.

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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 (31 May 2015) 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All published and unpublished trials in which pregnant women are randomly allocated to midwife-led continuity models of care or other models of care during pregnancy and birth.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

Two review authors independently assessed trials for inclusion and risk of bias, extracted data and checked them for accuracy.

Main results

We included 15 trials involving 17,674 women. We assessed the quality of the trial evidence for all primary outcomes (i.e., regional analgesia (epidural/spinal), caesarean birth, instrumental vaginal birth (forceps/vacuum), spontaneous vaginal birth, intact perineum, preterm birth (less than 37 weeks) and overall fetal loss and neonatal death (fetal loss was assessed by gestation using 24 weeks as the cut-off for viability in many countries) using the GRADE methodology: All primary outcomes were graded as of high quality.

For the primary outcomes, women who had midwife-led continuity models of care were less likely to experience regional analgesia (average risk ratio (RR) 0.85, 95% confidence interval (CI) 0.78 to 0.92; participants = 17,674; studies = 14; high quality), instrumental vaginal birth (average RR 0.90, 95% CI 0.83 to 0.97; participants = 17,501; studies = 13; high quality), preterm birth less than 37 weeks (average RR 0.76, 95% CI 0.64 to 0.91; participants = 13,238; studies = 8; high quality) and less overall fetal/neonatal death (average RR 0.84, 95% CI 0.71 to



0.99; participants = 17,561; studies = 13; *high quality evidence*). Women who had midwife-led continuity models of care were more likely to experience spontaneous vaginal birth (average RR 1.05, 95% CI 1.03 to 1.07; participants = 16,687; studies = 12; *high quality*). There were no differences between groups for caesarean births or intact perineum.

For the secondary outcomes, women who had midwife-led continuity models of care were less likely to experience amniotomy (average RR 0.80, 95% CI 0.66 to 0.98; participants = 3253; studies = 4), episiotomy (average RR 0.84, 95% CI 0.77 to 0.92; participants = 17,674; studies = 14) and fetal loss/neonatal death before 24 weeks (average RR 0.81, 95% CI 0.67 to 0.98; participants = 15,645; studies = 11). Women who had midwife-led continuity models of care were more likely to experience no intrapartum analgesia/anaesthesia (average RR 1.21, 95% CI 1.06 to 1.37; participants = 10,499; studies = 7), have a longer mean length of labour (hours) (mean difference (MD) 0.50, 95% CI 0.27 to 0.74; participants = 3328; studies = 3) and more likely to be attended at birth by a known midwife (average RR 7.04, 95% CI 4.48 to 11.08; participants = 6917; studies = 7). There were no differences between groups for fetal loss or neonatal death more than or equal to 24 weeks, induction of labour, antenatal hospitalisation, antepartum haemorrhage, augmentation/artificial oxytocin during labour, opiate analgesia, perineal laceration requiring suturing, postpartum haemorrhage, breastfeeding initiation, low birthweight infant, five-minute Apgar score less than or equal to seven, neonatal convulsions, admission of infant to special care or neonatal intensive care unit(s) or in mean length of neonatal hospital stay (days).

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 midwife-led continuity models of care. Similarly, there was a trend towards a cost-saving effect for midwife-led continuity care compared to other care models.

Authors' conclusions

This review suggests that women who received midwife-led continuity models of care were less likely to experience intervention and more likely to be satisfied with their care with at least comparable adverse outcomes for women or their infants than women who received other models of care.

Further research is needed to explore findings of fewer preterm births and fewer fetal deaths less than 24 weeks, and overall fetal loss/neonatal death associated with midwife-led continuity models of care.

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. Midwife-led continuity models aim to support women to experience a healthy pregnancy and birth, and provide care from a known and trusted midwife during the pregnancy, birth and early parenting journey. 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.

We identified 15 studies involving 17,674 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, and to lose their baby overall, although there were no differences in the risk of losing the baby after 24 weeks. All trials included licensed midwives, and none included lay or traditional midwives. No trial included models of care that offered out of hospital birth.

We used reliable methods to assess the quality of the trial evidence for seven key outcomes: Preterm birth < 37 weeks, overall fetal loss and neonatal death, spontaneous vaginal birth, caesarean birth, instrumental vaginal birth, intact perineum and regional analgesia. All of the evidence for these outcomes was considered to be of high quality. Good-quaity trials contributed enough data to each outcome to give us a reliable estimate of the effect of midwifery care versus other types of care. We can be reasonably confident that future trials would also find similar results for these key outcomes.

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.



Summary of findings for the main comparison. Midwife-led compared with other models of care for childbearing women and their infants (all) for childbearing women

Midwife-led compared with other models of care for childbearing women and their infants (all) for childbearing women

Patient or population: Pregnant women **Settings:** Australia, Canada, Ireleand, UK **Intervention:** Midwife-led models of care

Comparison: All other models of care for childbearing women and their infants

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Par- ticipants	Qual- ity of	Comments
	Assumed risk	Corresponding risk	(50 % 5.)	(studies)	the evi- dence	
	other models of care for child- bearing women and their in- fants (all)	Midwife-led			(GRADE)	
Preterm birth (less than 37 weeks)	Study population		RR 0.76 - (0.64 to 0.91)	13238 (8 RCTs)	⊕⊕⊕⊕ HIGH	None of the included tri-
than 37 weeks)	63 per 1000	48 per 1000 (41 to 58)	(0.04 to 0.31)	(o Ne 13)		als in this review had adequate blinding. We have not
	Moderate					
	59 per 1000	45 per 1000 (38 to 54)				downgrad- ed evidence (-1) for risk of bias due to lack of blinding.
Overall fetal loss and neonatal death	Study population		RR 0.84 - (0.71 to 0.99)	17561 (13 RCTs)	⊕⊕⊕⊕ High	
	34 per 1000	29 per 1000 (24 to 34)	(0.11 to 0.33)	(15 11515)	6	
	Moderate					
	20 per 1000	17 per 1000 (14 to 20)				

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Spontaneous vaginal birth (as defined by tri- al authors)	Study population		RR 1.05 — (1.03 to 1.07)	16687 (12 RCTs)	⊕⊕⊕⊕ HIGH
	658 per 1000	691 per 1000 (677 to 704)	(1.03 to 1.07)	(121(013)	111011
	Moderate				
	693 per 1000	727 per 1000 (713 to 741)			
Caesarean birth	Study population		RR 0.92 — (0.84 to 1.00)	17674 (14 RCTs)	⊕⊕⊕⊕ HIGH
	155 per 1000	143 per 1000 (130 to 155)	(0.0110 1.00)	(211(013)	
	Moderate				
	156 per 1000	144 per 1000 (131 to 156)			
Instrumental vaginal birth (forceps/vacuum)	Study population		RR 0.90 (0.83 to 0.97)	17501 (13 RCTs)	⊕⊕⊕⊕ HIGH
bital (toreeps) vacuum,	143 per 1000	129 per 1000 (119 to 139)	(0.00 to 0.01)	(0.05 to 0.51) (15 Ke15) THEF	
	Moderate				
	179 per 1000	161 per 1000 (149 to 174)			
Intact perineum	Study population		RR 1.04 — (0.95 to 1.13)	13186 (10 RCTs)	⊕⊕⊕⊕ HIGH ¹
	269 per 1000	279 per 1000 (255 to 304)	(0.33 to 1.13)	(10 11013)	THOIT-
	Moderate				
	333 per 1000	346 per 1000 (316 to 376)			
Regional analgesia (epidural/spinal)	Study population		RR 0.85 (0.78 to 0.92)	17674 (14 RCTs)	⊕⊕⊕⊕ HIGH ²
(epidaray spiriar)	270 per 1000	229 per 1000	(0.10 to 0.32)	(111013)	111011-

	(211 to 248)
Moderate	
287 per 1000	244 per 1000 (224 to 264)

^{*}The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; RR: risk ratio

GRADE Working Group grades of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

 1 Statistical heterogeneity, $I^{2} = 54\%$. We did not downgrade the evidence for heterogeneity with $I^{2} < 60\%$.

²Statistical heterogeneity, I² = 57%.



BACKGROUND

Description of the condition

In many parts of the world, midwives are the primary providers of care for childbearing women (ten Hoope-Bender 2014). There are, however, considerable variations in the organisation of midwifery services and in the education and role of midwives (UNFPA 2014). 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). 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). 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).

Description of the intervention

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. 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 well being of the woman and family throughout the childbearing cycle; providing the woman with individualised education, counselling and antenatal care; attendance during labour, birth and the immediate postpartum period by a known midwife; ongoing support during the postnatal period; minimising unnecessary technological interventions; and identifying, referring and co-ordinating care for 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).

Midwife-led continuity models of care

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, midwifeled 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).

Other models of care

Other models of care include the following.(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.

How the intervention might work

Continuity of care is a means of delivering care in a way which acknowledges that a woman's health needs are not isolated events, and should be managed over time (Reid 2002). This longitudinal aspect allows a relationship to develop between patients and their providers of care, and contributes to the patients' perception of



having a provider who has knowledge of their medical history, and similarly an expectation that a known provider will care for them in the future (Haggerty 2003). Continuity refers to a 'coordinated and smooth progression of care from the patient's point of view' (Freeman 2007) and therefore woman-centredness is an important aspect in the delivery of continuity of care.

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 2003; Saultz 2004; Saultz 2005). It has been argued that neither management nor informational continuity can compensate for lack of an ongoing relationship (Guthrie 2008). Midwife-led continuity models of care have generally aimed to improve continuity of care over a period of time. 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.

Why it is important to do this review

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.

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 clusterrandomisation methods. We also included quasi-randomised 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)
- 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
- 33. Breastfeeding on hospital discharge (not prespecified)
- 34. Maternal satisfaction (not prespecified)
- 35.Cost (not prespecified)

Search methods for identification of studies

The following methods section of this review is based on a standard template used by the Cochrane Pregnancy and Childbirth Group.

Electronic searches

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting the Trials Search Co-ordinator (31 May 2015).

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

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

Details of the search strategies for CENTRAL, MEDLINE, Embase and CINAHL, 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 Coordinator searches the register for each review using the topic list rather than keywords.

For search methods used in an earlier 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 or date restrictions.

Data collection and analysis

For methods used in the previous version of this review, see (Sandall 2013).

For this update, the following methods were used for assessing the two reports that were identified as a result of the updated search.

The following methods section of this review is based on a standard template used by the Cochrane Pregnancy and Childbirth Group.

Selection of studies

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

Data extraction and management

We designed a form to extract data. For eligible studies, two review authors extracted the data using the agreed form. We resolved discrepancies through discussion or, if required, we consulted the third review author. Data were entered into Review Manager software (RevMan 2014) and checked for accuracy.

When information regarding any of the above was unclear, we planned to contact 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 risk of bias for each study using the criteria outlined in the *Cochrane Handbook* for Systematic Reviews of Interventions (Higgins 2011). Any disagreement was resolved 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 nonopaque envelopes, alternation; date of birth);
- · unclear risk of bias.

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

We described for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We considered that studies were at low risk of bias if they were blinded, or if we judged that the lack of blinding unlikely to affect results. We assessed blinding separately for different outcomes or classes of outcomes.

We assessed the methods as:

- low, high or unclear risk of bias for participants;
- low, high or unclear risk of bias for personnel.

(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 participant received. We assessed blinding separately for different outcomes or classes of outcomes.

We assessed methods used to blind outcome assessment as:

• low, high or unclear risk of bias.

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

We described for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We stated whether attrition and exclusions were reported and the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information was reported, or could be supplied by the trial authors, we planned to re-include missing data in the analyses which we undertook.

We assessed methods as:

- low risk of bias (e.g. no missing outcome data; missing outcome data balanced across groups);
- high risk of bias (e.g. numbers or reasons for missing data imbalanced across groups; 'as treated' analysis done with substantial departure of intervention received from that assigned at randomisation);
- unclear risk of bias.

(5) Selective reporting (checking for reporting bias)

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

We assessed the methods as:

- low risk of bias (where it is clear that all of the study's prespecified outcomes and all expected outcomes of interest to the review have been reported);
- high risk of bias (where not all the study's pre-specified outcomes have been reported; one or more reported primary outcomes were not pre-specified; outcomes of interest are reported incompletely and so cannot be used; study fails to include results of a key outcome that would have been expected to have been reported);
- · unclear risk of bias.

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

We described for each included study any important concerns we had about other possible sources of bias.

(7) Overall risk of bias

We made explicit judgements about whether studies were at high risk of bias, according to the criteria given in the *Handbook* (Higgins 2011). With reference to (1) to (6) above, assessed the likely magnitude and direction of the bias and whether we considered it is likely to impact on the findings. In future updates, we will explore the impact of the level of bias through undertaking sensitivity analyses - see Sensitivity analysis.

Assessment of the quality of the evidence

For this update we assessed the quality of the evidence using the GRADE approach (Schunemann 2009). In order to assess the quality of the body of evidence relating to the following outcomes for the main comparisons of midwife-led versus all other models of care for childbearing women and their infants.

- 1. Preterm birth (less than 37 weeks)
- Overall fetal loss and neonatal death (fetal loss was assessed by gestation using 24 weeks as the cut-off for viability in many countries)
- 3. Spontaneous vaginal birth (as defined by trial authors)
- 4. Caesarean birth
- 5. Instrumental vaginal birth (forceps/vacuum)
- 6. Intact perineum
- 7. Regional analgesia (epidural/spinal)

We used GRADE profiler (GRADEpro 2014) to import data from Review Manager 5.3 (RevMan 2014) in order to create a 'Summary of findings' table. A summary of the intervention effect and a measure of quality for each of the above outcomes was produced using the GRADE approach. The GRADE approach uses five considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of the body of evidence for each outcome. The evidence can be downgraded from 'high quality' by one level for serious (or by two levels for very serious) limitations, depending on assessments for risk of bias, indirectness of evidence, serious inconsistency, imprecision of effect estimates or potential publication bias. We have not downgraded evidence for heterogeneity with an $I^2 < 60\%$. We have not downgraded for risk of bias due to lack of blinding.



Measures of treatment effect

Dichotomous data

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

Continuous data

We used the mean difference if outcomes were measured in the same way between trials. In future updates, as appropriate, we will use the standardised mean difference to combine trials that measure the same outcome, but used different methods.

Unit of analysis issues

Cluster-randomised trials

We included a cluster-randomised trial in the analyses along with individually-randomised trials (North Stafford 2000). This trial found a negative ICC so no adjustment was made for clustering. We considered it reasonable to combine the results from cluster-randomised trials and individually-randomised trials if there was little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomisation unit was considered to be unlikely.

Other unit of analysis issues

Multiple pregnancies were included and both infants included in the denominator.

Dealing with missing data

For included studies, we noted levels of attrition. In future updates, if more eligible studies are included, we will explore the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis.

For all outcomes, analyses were carried out, as far as possible, on an intention-to-treat basis i.e. we attempted to include all participants randomised to each group in the analyses. 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 Tau², I² and Chi² statistics. We regarded heterogeneity as substantial if an I² was greater than 30% and either a Tau² was greater than zero, or there was a low P value (less than 0.10) in the Chi² test for heterogeneity. If we identified substantial heterogeneity (above 30%), we planned to explore it by prespecified subgroup analysis.

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.

Data synthesis

We carried out statistical analysis using the Review Manager software (RevMan 2014).

As there was clinical heterogeneity sufficient to expect that the underlying treatment effects differed between trials, or where substantial statistical heterogeneity was detected, we used random-effects meta-analysis to produce an overall summary, if an average treatment effect across trials was considered clinically meaningful. 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. If the average treatment effect had not been clinically meaningful, we would not have combined trials. The results were presented as the average treatment effect with 95% confidence intervals, and the estimates of Tau² and I².

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, we used random-effects analysis to produce it.

We carried out the following subgroup analyses.

- 1. Caseload versus team models of midwifery care
- 2. Low-risk versus mixed-risk status

The following outcomes were used in subgroup analyses.

- 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
- 6. Preterm birth (< 37 weeks)
- 7. Overall fetal loss and neonatal death

We assessed subgroup differences by interaction tests available within RevMan (RevMan 2014). We reported the results of subgroup analyses quoting the Chi² statistic and P value, and the interaction test I² value.

Sensitivity analysis

We carried out sensitivity analyses to explore the effect of trial quality assessed by concealment of allocation, high attrition rates, or both, with poor quality studies being excluded from the analyses in order to assess whether this made any difference to the overall result

RESULTS

Description of studies

Results of the search

Our search strategy identified 88 citations relating to 38 studies in total. The updated search in May 2015 identified 11 new reports. Four were additional reports of an already included study McLachlan 2012; three new reports were included as Tracy 2013; two reports were excluded (Famuyide 2014 and Gu 2013); and one was an additional reports of an excluded study (Walker 2012). A final report, Allen 2013, was eligible for the review and included, though this trial was a feasibility study and presents no usable data.

Included studies

We included 15 trials involving 17,674 randomised women in total (Allen 2013; Begley 2011; Biro 2000; Flint 1989; Harvey 1996;



Hicks 2003; Homer 2001; Kenny 1994; MacVicar 1993; McLachlan 2012; North Stafford 2000; Rowley 1995; Tracy 2013; Turnbull 1996; Waldenstrom 2001) *See* Characteristics of included studies table.

Included studies were conducted in the public health systems in Australia, Canada, Ireland 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).

Four studies offered a caseload team model of care (McLachlan 2012; North Stafford 2000; Tracy 2013; 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 with 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 with medical-led models of care (Harvey 1996; MacVicar 1993; Turnbull 1996), and three 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; Tracy 2013; Waldenstrom 2001).

Participating women received ante-, intra- and postpartum care in 13 studies (Begley 2011; Biro 2000; Flint 1989; Harvey 1996; Hicks 2003; Homer 2001; Kenny 1994; McLachlan 2012; North Stafford 2000; Rowley 1995; Tracy 2013; 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 based on the development of complications (Hicks 2003; Tracy 2013; 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 six studies (Biro 2000; Homer 2001; Kenny 1994; North Stafford 2000; Rowley 1995; Tracy 2013).

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; Tracy 2013; 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 anteand 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).

Excluded studies

We excluded 22 studies Berglund 1998; Berglund 2007; Bernitz 2011; Chambliss 1991; Chapman 1986; Famuyide 2014; Giles 1992; Gu 2013; 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).

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.

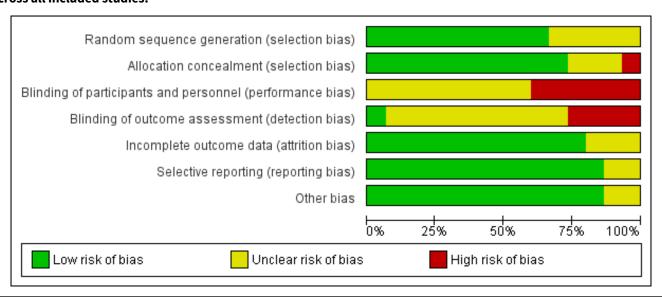




Figure 2. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Allen 2013	?	?	?	?	?	?	?
Begley 2011	•	•	•	•	•	•	•
Biro 2000	•	•	?	?	•	•	•
Flint 1989	?	?	?	?	•	•	•
Harvey 1996	•	•	?	?	•	•	•
Hicks 2003	•	•	?	?	•	•	•
Homer 2001	•	•	•	•	•	•	•
Kenny 1994	?	•	?	?	•	•	•
MacVicar 1993	•	•		?	?	•	•
McLachlan 2012	•	•	?	•	•	•	•
North Stafford 2000	?	•	•	?	•	•	•
Rowley 1995	•	?	•	•	?	•	•
Tracy 2013	•	•	•	•	•	?	?
Turnbull 1996	•	•	?	?	•	•	•
Waldenstrom 2001	?	•	?	?	•	•	•



Allocation

Ten 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; Tracy 2013; Turnbull 1996). Five gave no or insufficient information to form a clear judgement (Allen 2013, Flint 1989; Kenny 1994; North Stafford 2000; Waldenstrom 2001).

Allocation concealment was judged low risk of bias for 11 studies (Begley 2011; Biro 2000; Harvey 1996, Hicks 2003; Homer 2001; Kenny 1994; MacVicar 1993; McLachlan 2012; Tracy 2013; Turnbull 1996; Waldenstrom 2001). Three studies were judged unclear risk of bias: Rowley 1995 and Allen 2013 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

Six 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; Tracy 2013) and nine studies were of unclear risk of bias (Allen 2013; 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), four were judged as high risk of bias (Begley 2011; Homer 2001; Rowley 1995; Tracy 2013), and 10 studies were at unclear risk of bias (Allen 2013; Biro 2000; Flint 1989; Harvey 1996; Hicks 2003; Kenny 1994; MacVicar 1993; North Stafford 2000; Turnbull 1996; Waldenstrom 2001).

Incomplete outcome data

Twelve 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; Tracy 2013; 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. A feasibility study was also judged as unclear (Allen 2013).

Selective reporting

All outcomes stated in the methods section were adequately reported in the results in 13 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). Two trials were judged to be of unclear risk of bias due to reporting: Allen 2013, a feasibility recruiting just one woman to the intervention and Tracy 2013, where we emailed the trial authors for clarification of data and additional data.

Other potential sources of bias

No other potential sources of bias were identified in most included studies. A feasibility study (Allen 2013) was considered of unclear risk, as was Tracy 2013, where a small proportion of women were crossed-over from each arm.

Effects of interventions

See: Summary of findings for the main comparison Midwife-led compared with other models of care for childbearing women and their infants (all) for childbearing women

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 . Because our subgroup analyses (reported below) did not generally explain heterogeneity found in specific primary outcomes, we discuss additional sources of heterogeneity below and in the discussion section of the review.

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) 0.85, 95% confidence interval (CI) 0.78 to 0.92; participants = 17,674; studies = 14; I² = 57%) (Analysis 1.1);
- instrumental vaginal birth (forceps/vacuum) (average RR 0.90, 95% CI 0.83 to 0.97; participants = 17,501; studies = 13) (Analysis 1.3);
- preterm birth < 37 weeks (average RR 0.76, 95% CI 0.64 to 0.91; participants = 13,238; studies = 8; I² = 33%) (Analysis 1.6).

We conducted prespecified subgroup analysis to investigate heterogeneity in the above outcomes of regional analgesia and preterm birth. Assumed differences between caseload or team models of care versus other models of care could not explain the heterogeneity for these outcomes, and neither could potential differences between low-risk and mixed-risk groups of pregnant women (See analyses for regional analgesia Analysis 2.1 and Analysis 3.1 and for preterm birth Analysis 2.6 and Analysis 3.6).

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 1.07; participants = 16,687; studies = 12) (Analysis 1.4);

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

- caesarean birth (average RR 0.92, 95% CI 0.84 to 1.00; participants = 17,674; studies = 14) (Analysis 1.2);
- intact perineum (average RR 1.04, 95% CI 0.95 to 1.13; participants = 13,186; studies = 10) (Analysis 1.5); There was moderate heterogeneity for this outcome (Heterogeneity: Tau² = 0.01; I² = 54%), and this could not be attributed to differences in the prespecified subgroups (see below and Analysis 2.5 and Analysis 3.5).

There were borderline statistically significant differences between groups for the following outcome:



overall fetal loss and neonatal death (average RR 0.84, 95% CI 0.71 to 0.99; participants = 17,561; studies = 13) (Analysis 1.7).

Secondary outcomes

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

- amniotomy (average RR 0.80, 95% CI 0.66 to 0.98; participants = 3253; studies = 4; l² = 75%) (Analysis 1.11);
- episiotomy (average RR 0.84, 95% CI 0.77 to 0.92; participants = 17,674; studies = 14; l² = 47%) (Analysis 1.16);
- fetal loss/neonatal death before 24 weeks (average RR 0.81, 95% CI 0.67 to 0.98; participants = 15,645; studies = 11) (Analysis 1.27).

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

- no intrapartum analgesia/anaesthesia (RR 1.21, 95% CI 1.06 to 1.37; participants = 10,499; studies = 7; I² = 49%) (Analysis 1.13);
- a longer mean length of labour (hours) (mean difference (MD) 0.50, 95% CI 0.27 to 0.74; participants = 3328; studies = 3) (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 midwife (RR 7.04, 95% CI 4.48 to 11.08; participants = 6917; studies = 7). However, the effect estimates for individual studies are highly variable, as reflected in substantial statistical heterogeneity (Tau² = 0.31; I² = 94%; Analysis 1.15)

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

- antenatal hospitalisation (average RR 0.95, 95% CI 0.85 to 1.05; participants = 7731; studies = 7; I² = 40%) (Analysis 1.8);
- antepartum haemorrhage (average RR 0.89, 95% CI 0.57 to 1.40; participants = 3654; studies = 4; l² = 31%) (Analysis 1.9);
- induction of labour (average RR 0.93, 95% CI 0.86 to 1.01; participants = 17,501; studies = 13; I² = 47%) (Analysis 1.10);
- augmentation/artificial oxytocin during labour (average RR 0.88, 95% CI 0.78 to 0.99; participants = 15,194; studies = 12; I² = 76%) (Analysis 1.12);
- opiate analgesia (average RR 0.90, 95% CI 0.80 to 1.01; participants = 11,997; studies = 10; I² = 77%) (Analysis 1.14);
- perineal laceration requiring suturing (average RR 1.02, 95% CI 0.96 to 1.10; participants = 15,104; studies = 10; I² = 53%) (Analysis 1.17);
- postpartum haemorrhage (average RR 0.94, 95% CI 0.84 to 1.05; participants = 14,214; studies = 10) (Analysis 1.19);

- breastfeeding initiation (average RR 1.12, 95% CI 0.81 to 1.53; participants = 2050; studies = 2; I² = 81%) (Analysis 1.20);
- mean length of postnatal hospital stay (days) (MD -0.10, 95% CI -0.29 to 0.09, participants = 3593; studies = 3; Tau² = 0.02, I² = 58%) (Analysis 1.21);
- low birthweight infant (RR 0.96, 95% CI 0.82 to 1.13; participants = 11,458; studies = 7) (Analysis 1.22);
- five-minute Apgar score less than or equal to seven (RR 0.98, 95% CI 0.73 to 1.32; participants = 12,546; studies = 11; I² = 32%) (Analysis 1.23);
- neonatal convulsions (average RR 0.91, 95% CI 0.14 to 5.74; participants = 2923; studies = 2) (Analysis 1.24);
- admission of infant to special care or neonatal intensive care unit(s) (RR 0.90, 95% CI 0.78 to 1.04; participants = 17,561; studies = 13; I² = 43%) (Analysis 1.25);
- mean length of neonatal hospital stay (days) (MD -3.63, 95% CI -7.57 to 0.30, participants = 1979; studies = 2; Tau² = 6.69, I² = 80%) (Analysis 1.26);
- fetal loss or neonatal death more than or equal to 24 weeks (RR 1.00, 95% CI 0.67 to 1.49; participants = 17,359; studies = 12; I² = 0%) (Analysis 1.28).

There was substantial statistical heterogeneity in many of the analyses. The I² 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). It is likely that heterogeneity could be due to the nature of the complexity of the intervention of a model of care, with variation in case mix and organisational setting.

Investigation of publication bias

Visual inspection of funnel plots for analyses where there were 10 or more studies (Analysis 1.1, Analysis 1.2, Analysis 1.3, Analysis 1.4, Analysis 1.5, Analysis 1.7, Analysis 1.10, Analysis 1.12, Analysis 1.14, Analysis 1.16, Analysis 1.17, Analysis 1.19, Analysis 1.23, Analysis 1.25, Analysis 1.27 and Analysis 1.28) 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 (Harvey 1996 and Hicks 2003, see 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).

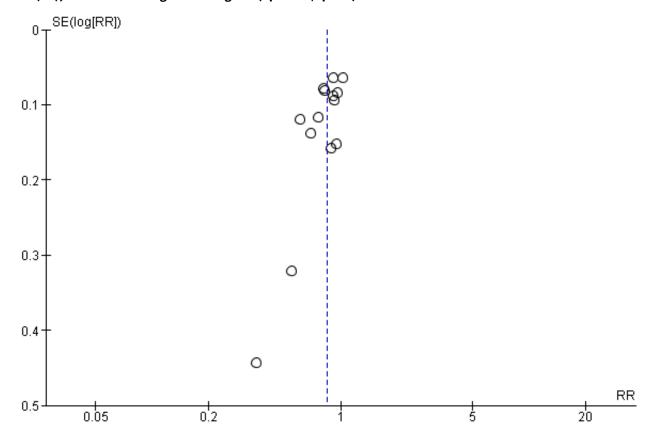




Figure 4. Funnel plot of comparison: 1 Midwife-led versus other models of care for childbearing women and their infants (all), outcome: 1.2 Caesarean birth.

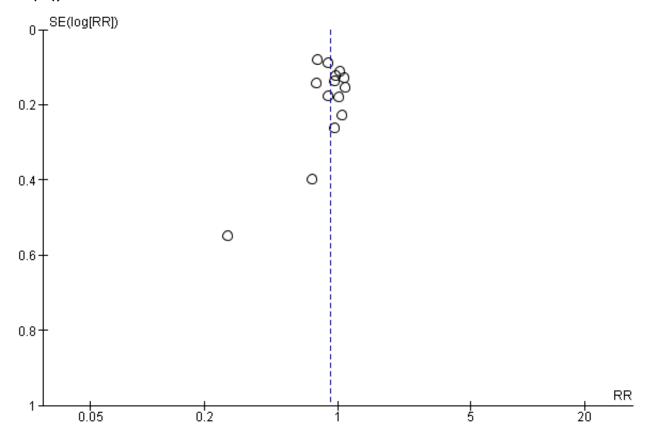
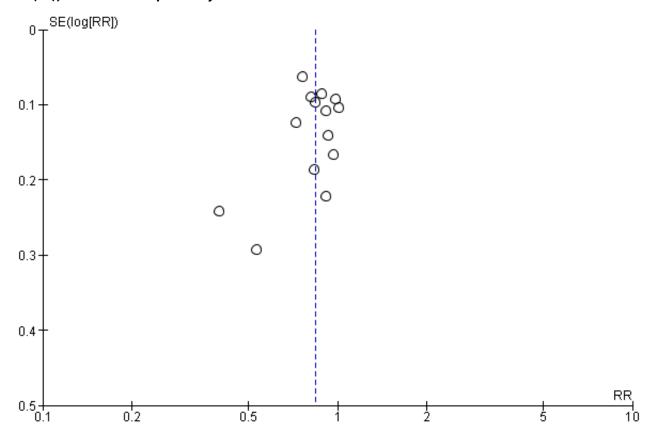




Figure 5. Funnel plot of comparison: 1 Midwife-led versus other models of care for childbearing women and their infants (all), outcome: 1.16 Episiotomy.



Outcomes reported in single trials or not at all

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, breastfeeding on discharge 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)

Four trials randomised 6782 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; Tracy 2013; Turnbull 1996). Caseload size was reported to be 45 women per midwife per year (McLachlan 2012), 35 to 40 women (North Stafford 2000), 40 women (Tracy 2013) and 32.4 women per midwife (Turnbull 1996). Ten trials randomised 11,183 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).

On the whole, 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 (RR 0.76, 95% CI 0.64 to 0.91) (Analysis 2.6); and overall fetal loss and neonatal death: caseload (RR 0.69, 95% CI 0.48 to 0.99); team (RR 0.89, 95% CI 0.73 to 1.07) (Analysis 2.7).

There were no significant subgroup differences found for either preterm birth or overall fetal loss, or for any outcome. There were borderline differences between subgroups for the outcome of regional analgesia (Test for subgroup differences: (P = 0.10), I² = 63.4%). Both caseload and team care (average RR 0.92, 95% CI 0.82 to 1.04; participants = 6782; studies = 4; I² = 56%) and other models of care (average RR 0.81, 95% CI 0.73 to 0.89; participants = 10,892; studies = 10; I² = 44%) had substantial heterogeneity. Due to heterogeneity and to the small number of trials in each subgroup, we would advise caution when interpreting this result (Analysis 2.1).

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). Six trials randomised over 6578 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; Tracy 2013;). 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 or previous history of a classical caesarean or more than two caesareans (Homer 2001), or women 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 (See Analysis 3.1 to 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. Ten studies reported maternal satisfaction with various components of the childbirth experiences (Biro 2000; Flint 1989; Harvey 1996; Hicks 2003; Kenny 1994; MacVicar 1993; McLachlan 2012; 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. Six 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; Tracy 2013; 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 (GBP 19,360 versus GBP 31,460).

Kenny 1994 examined the costs of care in detail. The average cost/client in the antenatal period was AUD 158 midwife-led continuity of care and AUD 167 control. For high-risk women the average cost/client was AUD 390 midwife-led continuity of care and AUD 437 control, and for low-risk women AUD 119 midwife-led continuity of care and AUD 123 control. The average cost per woman for intrapartum care was AUD 219 midwife-led continuity of care and AUD 220 control and for postnatal care was AUD 745 midwife-led continuity of care and AUD 833 control. The total cost/woman was AUD 1122 for midwife-led continuity of care and AUD 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 (AUD 3475) compared to the team-midwifery group (AUD 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 AUD 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.

Tracy 2013 calculated cost outcomes per woman on the basis of activity-based funding codes (Australian-refined Diagnosis-Related Group classification [DRG] codes). Expenditure data were obtained from the hospital financial systems, which provided detailed information about inpatient contacts for the mother and baby. The per-woman cost of care calculated included both direct and indirect costs for each full episode of maternity care, taking account of the length of hospital stay for each woman. Direct and indirect costs were calculated for midwifery and obstetric clinical time; use of operating theatres, laboratory tests, imaging, wards, allied health, pharmacy; capital depreciation; and clinical overheads. Costs for each full episode of maternity care we recalculated from the sum of the services provided to the woman for the duration of her stay. Neonatal costs were not reported. Caseload midwifery care for unassisted vaginal birth cost significantly less than standard maternity care. This difference contributed to a significant difference in the overall median cost of birth per woman of AUD 566.74 (95% CI 106.17 to 1027.30) P = 0.02). However, the cost



data showed several high-cost outliers greater than \$30 000, which were due to serious medical disorders, surgical complications, or accidental causes. The largest outlier, which cost more than \$40 000, was due to a motor vehicle accident. The total cost of care per woman was AUD 566.74 (95% CI 106.17 to 1027.30); P = 0.02) less for caseload midwifery than for standard maternity care.

Young 1997 (cost analysis, Turnbull 1996) 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: GPD 346 versus GPD 384, P = 0.05), but the postnatal care cost remained higher in the former group (GPD 444 versus GPD 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 (GPD 280 versus GPD 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: AUD 2579 versus AUD 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 midwifeled 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

Summary of main results

This review summarises 15 trials involving 17,674 women that took place in four 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 regional analgesia, episiotomy, and instrumental birth. 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, with 95% confidence interval (CI) 0.71 to 0.99 (participants = 17561; studies = 13). Given that (i) the 95% CI just reaches 0.99 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%.

We conducted prespecified subgroup analysis to investigate heterogeneity in the above outcomes of regional analgesia and preterm birth. 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. It is possible that the complexity of the intervention in a range of settings and populations may influence the heterogeneity found.

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), although 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 10 trials, care was provided on the labour ward, suggesting a separate effect of birth setting. To what extent the observed benefits can be attributed to the model of midwifery care, midwifery philosophy, 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 of the mechanisms through which midwife-led care might work.

The possible effects on fetal loss and the substantive 24% reduction in 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 carers 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

Overall completeness and applicability of evidence

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.

Quality of the evidence

We assessed the quality of trial evidence for the following outcomes using the GRADE methodology: preterm birth < 37 weeks, overall fetal loss and neonatal death, spontaneous vaginal birth (as defined by trialists), caesarean birth, instrumental vaginal birth, intact perineum and regional analgesia. All outcomes were graded as of high quality. Multiple trials of low risk of bias contributed to each outcome, and there were precise estimates with no heterogeneity greater than 60%. No trial included in this review had adequate blinding of participants, staff or outcomes assessors. We did not downgrade trial evidence for risk of bias due to lack of blinding. However, we understand that other authors might choose to do so.

We would not expect blinding to affect the outcomes of preterm birth or overall fetal loss, but the argument could be made that blinding matters for mode of birth, intact perineum and use of analgesia.

Potential biases in the review process

We searched for further studies in the reference list of the studies identified, and did not apply any language or date restrictions. We made explicit judgements about whether studies were at high risk of bias using the GRADE approach. We carried out sensitivity analyses to explore the effect of trial quality assessed by concealment of allocation, high attrition rates, or both, with poor quality studies being excluded from the analyses in order to assess whether this made any difference to the overall result. No other potential sources of bias were identified in any of the included studies. There was 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.

Agreements and disagreements with other studies or reviews

Studies of qualitative data can add understanding on why women experience fewer birth interventions within this model of care. One meta-synthesis (Walsh 2012), suggests that lower rates of interventions could be linked to the "greater agency experienced by women and midwives within midwife-led models", and that these effects are mediated, in part, by the smallness of scale in these settings. A review of reviews (Sutcliffe 2012), compared midwife-led care during pregnancy and birth with physician-led care resulted in similar findings to this review.

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 continuity through pregnancy and childbirth. Not all areas of the world have health systems where midwives are able to provide midwife-led continuity models of care, 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 midwifeled 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, philosophy, or to the quality and degree of relationship between the care provider and women. 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. 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. Others provide care to socially vulnerable women with promising results but further trials are required (Rayment-Jones 2015).

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). All trials should provide greater description of intervention and standard models of care being assessed (Hoffman 2014) and include process evaluations of how they are being implemented (Moore 2014), using reporting guidelines for complex interventions. Future research in this area would benefit from exploring the theoretical underpinnings of these complex interventions and their associations with processes and outcomes and implementation reviews are helpful.

Questions remain about the mechanisms regarding why fetal loss is reduced, and why there are fewer preterm births 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 well being 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 well being in pregnant and childbearing women. All trials should include an assessment of maternal and fetal well being. 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) data set, such as that by Devane 2007, and a validated measure of maternal quality of life and well being would be useful not only within multicentre 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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CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Allen 2013

Methods	Study design: RCT.
	Duration of study: 2010-2011.
Participants	Setting: Inner city tertiary maternity hospital and associated community based clinic, Australia. Inclusion criteria: women were eligible for trial entry if they were: (a) aged between 13-17 years of age (b) booked for public maternity care at the study hospital c) 23 weeks pregnant or less, d) single live fetus at time of recruitment. Exclusion criteria: maternal age 18 years or older, inability to provide consent (e.g. serious mental illness or lack of English fluency), residence outside of the hospital catchment area (because of the requirement for home visiting), 24 weeks gestation or greater, and multiple pregnancy Participants randomised: 1 midwife-led care, 0 to standard care.
Interventions	Experimental: Women randomised to the intervention received antenatal, intrapartum and postnatal care from a known midwife.

^{*} Indicates the major publication for the study



Αl	len	20	13	(Continued)
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Control: Women randomised to the control group were able to select any other available model of antenatal care including YWC, care with a general practitioner, or a community- or hospital-based antenatal clinic.

Outcomes

Outcomes considered in the review and reported in or extracted from the study:

Preterm birth

Gestation Birth weight

Mode of birth

Apgar score less than 7 at 5 minutes

Breastfeeding initiation

Breastfeeding at hospital discharge

Admission to a separate neonatal nursery Length of maternal and neonatal stay

Notes

This study was a feasibility study for a proposed randomised trial. Only one woman was recruited to receive the intervention, and the study was not continued. Authors concluded that an RCT with pregnant adolescents was not feasible according to specifications of the protocol.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Methods of randomisation not described.
Allocation concealment (selection bias)	Unclear risk	Allocation concealment not described.
Blinding of participants and personnel (perfor- mance bias) All outcomes	Unclear risk	Blinding not described.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding not described.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	This study was a feasibility study. Only one woman received the intervention. This study contributed no data to the review.
Selective reporting (reporting bias)	Unclear risk	This study was a feasibility study. Only one woman received the intervention and no outcome data were reported.
Other bias	Unclear risk	This study was a feasibility study, and the study authors concluded that recruitment was not feasible according to the specifications outlined in the study protocol.



Beg	lev	20	11

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)'

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: women 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)



Begl	ey 2011	(Continued))
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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 (perfor- mance 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 plans.

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.'



Biro 2000 (Continued)		
Blinding of participants and personnel (perfor- mance 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 = 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		



F	lint	1989	(Continued)
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Intact perineum

Instrumental vaginal birth(forceps/vacuum)

Low birthweight (< 2500 g)

No intrapartum analgesia/anaesthesia

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 (perfor- mance 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.



Harve	y 1996	(Continued)
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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).

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 hos-

Outcomes Outcomes considered in the review and reported in or extracted from the study:

pitals following usual process.

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)

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

Notes

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'computer-generated random allocation.'
Allocation concealment (selection bias)	Low risk	'using a series of consecutively numbered, sealed, opaque envelopes'



Harvey 1996 (Continued)		
Blinding of participants and personnel (perfor- mance 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)			
Notes	71% of experimental group and 14% of standard group had previously met midwife attending labour.			
Risk of bias				



Hicks 2003 (Continued)

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 (perfor- mance 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			



Homer 2001 (Continued)

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 (perfor- mance bias) All outcomes	High risk	No (states 'unblinded').
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.



Kenny 1994 (Continued)	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			
	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.			



Kenny 1994 (Continued)

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 (perfor- mance 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.
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

-tuerieur 2000		
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.	



MacVicar 1993 (Continued)

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)

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.

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'by a random sequence'
Allocation concealment (selection bias)	Low risk	'sealed envelopecards could not be read through the envelopes. Each envelope was numbered, and unused envelopes were not reallocated'
Blinding of participants and personnel (perfor- mance 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.



MacVicar 1993 (Continued)		
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information given on losses to follow-up.
Selective reporting (re- porting bias)	Low risk	Outcome reporting: all outcomes stated in the methods section were adequately reported in results.

McLachlan 2012

Methods	Study design: RCT.
MELIIUUS	Study design. Non.

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



McLachlan 2012 (Continued)

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."

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 (perfor- mance 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.	



North Stafford 2000 (Continued)

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 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.

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'Randomisation was undertaken by one of the principal investigatorswho had no prior knowledge of the area or medical and midwifery staff involved three pairs, one of eachrandomised 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 (perfor- mance 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.'



North Stafford 2000 (Continued	1)	
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: 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			



Rowley 1995 (Continued)

Allocation concealment

Incomplete outcome data

Tracy 2013

(selection bias)

Perineal laceration requiring suturing

Preterm birth (< 37 weeks)

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:'

'The women were allocated at random to team care or routine care....'

Blinding of participants and personnel (performance bias)	High risk	"the unblinded nature of the study could have led to differences in practice and measurement of outcomes"
All outcomes		

Unclear risk

Unclear risk

Blinding of outcome as-	High risk	"the unblinded nature of the study could have led to differences in practice
sessment (detection bias)		and measurement of outcomes'
All outcomes		

Loss to follow-up not reported (appears minimal).

(attrition bias) All outcomes		
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.
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Methods	Study took place in two Australian centres (site 1: Royal Hospital for Women, Randwick; and site 2: Mater Mother's Hospital, Brisbane). The randomised trial compared caseload midwifery with standard care. Women were recruited to the study from site 1 between December 2008 and May 2011, and from site 2 between June 2010 and May 2011.
Participants	Women were included if they were less than 24 weeks pregnant at the booking visit, and aged 18 years and older. Women were excluded if they had planned to have an elective caesarean section, had a multiple pregnancy, or were planning to book with another care provider (e.g., a general practitioner, caseload midwife, or private obstetrician).
Interventions	Intervention: Caseload midwifery care (receiving care through antenatal, intrapartum and postpartum, in hospital and in the community) from a named caseload midwife working in a small group of midwives known as a midwifery group practice (4 full-time MWs). Each midwife provides care to 40 women a year as named midwife. The named midwife was on call for labour and birth. The caseload midwives were backed up when necessary by other caseload colleagues and by hospital staff during women's



Tracy 2013 (Continued)

stay in the postnatal ward. Community postnatal care was provided for up to 6 weeks. An obstetrician was allocated to each midwifery practice for consultation and referral using national guidelines. Total number randomised to intervention: 871

Comparison: Standard care, which involved shared antenatal care from a GP and hospital midwives, labour and birth and postnatal hospital care from hospital midwives. It was unclear whether community postnatal care was provided in standard care. Total number randomised to standard care: 877.

Data were collected at recruitment, at 36 weeks gestation and at 6 weeks and 6 months postpartum

Outcomes

Primary Outcomes:

Caesarean section (main PO), instrumental vaginal birth, unassisted vaginal birth, epidural analgesia, Apgar scores ≤ 7 at 5 min, admission to SCBU, preterm birth (GA < 37 weeks)

Secondary outcomes:

Antenatal admission to hospital; induction or augmentation of labour; perineal status after birth; blood loss after birth; gestational ages and birthweights of the infants; breastfeeding at hospital discharge, 6 weeks and 6 months postnatally; and perinatal and maternal mortality, Hospital cost by mode of birth (cost of birth per woman).

Notes

- 1. Denominator = total randomised minus loss to follow-up, but including fetal loss before 20 weeks. Intervention = 871 31 + 11 = 951; Standard care = 877 50 + 14 = 841.
- 2. 19 (2%) women crossed over from caseload to standard care and 65 (7%) crossed over from standard to caseload care.
- 3. 70% of participants were first time mothers
- 4. The two groups were statistically different in terms of their BMI, which was judged as clinically not significant by authors.
- 5. An interesting observation was an overall reduction in caesarean sections for both groups from the pre-trial from 29% (at site 1) to 22% in the study population. This decrease could be seen as a limitation of the trial and the result of the Hawthorn effect.
- 6. Participants' satisfaction data and long-term cost analysis will be reported elsewhere
- 7. Cost calculation: The per-woman cost of care calculated includes both direct and indirect costs for each full episode of maternity care, taking account of the length of hospital stay for each woman. These were calculated for midwifery and obstetric clinical time; use of operating theatres, laboratory tests, imaging, wards, allied health, pharmacy; capital depreciation; and clinical overheads. Further comprehensive cost analyses, including neonatal costs, will be reported elsewhere, as will the results of a survey to assess the participants' experiences and satisfaction with the different models of care
- 8. For the outcome of PPH, we have added together women who had between 500 and 1000 mL blood loss with those who had > 1000 mL.

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Women were randomly assigned by a telephone-based computer randomisation service provided by ANHMRC clinical trials randomisation centre to each group.
Allocation concealment (selection bias)	Low risk	As above, centralised allocation.
Blinding of participants and personnel (perfor- mance bias) All outcomes	High risk	Due to the nature of the study it is not possible to blind participants or clinicians



Tracy 2013 (Continued)		
Blinding of outcome assessment (detection bias) All outcomes	High risk	Due to the nature of the study it is not possible to blind participants or clinicians
Incomplete outcome data (attrition bias)	Low risk	Withdrawls and losses outlined in a trial profile in Tracy 2013.
All outcomes		20/871 lost or withdrew from caseload care; 36 lost or withdrew from standard care. Pregnancies lost before 20 weeks and terminations of pregnancy have been added back in (see Notes above).
Selective reporting (reporting bias)	Unclear risk	Authors were emailed for length of neonatal stay and antepartum haemor- rhage; these were mentioned in the protocol and were not included in publica- tions. Answer expected 9.3.15.
		Authors emailed for gestational age of the 2 terminations of pregnancy for lethal abnormalities. Authors asked to clarify if length of stay outcome is for infants or women.
Other bias	Unclear risk	19 (2%) women crossed over from caseload to standard care and 65 (7%) crossed over from standard to caseload care.

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		



Turnbull 1996 (Continued)

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.

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.'
Blinding of participants and personnel (perfor- mance bias) All outcomes	Unclear risk	Participants: not 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.



Turnbull 1996 (Continued)

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		



Waldenstrom	2001 (Continued	ed)
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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 (perfor- mance 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

GA: gestational age GP: general practitioner

IUGR: intrauterine growth restriction MDU: midwifery development unit

MLU: midwife-led unit

NICU: neonatal intensive care unit PET: positron emissions tomography PPH: postpartum haemorrhage RCT: randomised controlled trial SCBU: special care baby unit

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.		
Famuyide 2014	This study did not provide continuity of care from antenatal through to intrapartum period.		
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.		
Gu 2013	This study did not provide continuity of care from antenatal through to intrapartum period.		
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.		
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 reduci postnatal depression in women with a past history of depression. Thus midwife-led care is not be ing 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.		



Study	Reason for exclusion	
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. Abstract only available.	

RCT: randomised controlled trial

vs: versus

Characteristics of ongoing studies [ordered by study ID]

Nagle 2011

Magic 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 ≥ 30 who are less than 17 weeks' gestation, recruited from materni 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.	



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)

No. of studies	No. of partici- pants	Statistical method	Effect size
14	17674	Risk Ratio (M-H, Random, 95% CI)	0.85 [0.78, 0.92]
14	17674	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.84, 1.00]
13	17501	Risk Ratio (M-H, Random, 95% CI)	0.90 [0.83, 0.97]
12	16687	Risk Ratio (M-H, Random, 95% CI)	1.05 [1.03, 1.07]
10	13186	Risk Ratio (M-H, Random, 95% CI)	1.04 [0.95, 1.13]
8	13238	Risk Ratio (M-H, Random, 95% CI)	0.76 [0.64, 0.91]
13	17561	Risk Ratio (M-H, Random, 95% CI)	0.84 [0.71, 0.99]
7	7731	Risk Ratio (M-H, Random, 95% CI)	0.95 [0.85, 1.05]
4	3654	Risk Ratio (M-H, Random, 95% CI)	0.89 [0.57, 1.40]
13	17501	Risk Ratio (M-H, Random, 95% CI)	0.93 [0.86, 1.01]
4	3253	Risk Ratio (M-H, Random, 95% CI)	0.80 [0.66, 0.98]
12	15194	Risk Ratio (M-H, Random, 95% CI)	0.88 [0.78, 0.99]
7	10499	Risk Ratio (M-H, Random, 95% CI)	1.21 [1.06, 1.37]
10	11997	Risk Ratio (M-H, Random, 95% CI)	0.90 [0.80, 1.01]
7	6917	Risk Ratio (M-H, Random, 95% CI)	7.04 [4.48, 11.08]
14	17674	Risk Ratio (M-H, Random, 95% CI)	0.84 [0.77, 0.92]
10	15104	Risk Ratio (M-H, Random, 95% CI)	1.02 [0.96, 1.10]
3	3328	Mean Difference (IV, Random, 95% CI)	0.50 [0.27, 0.74]
	14 14 13 12 10 8 13 7 4 13 4 12 7 10 7 10 7	studies participants 14 17674 14 17674 13 17501 12 16687 10 13186 8 13238 13 17561 7 7731 4 3654 13 17501 4 3253 12 15194 7 10499 10 11997 7 6917 14 17674 10 15104	studies participants 14 17674 Risk Ratio (M-H, Random, 95% CI) 14 17674 Risk Ratio (M-H, Random, 95% CI) 13 17501 Risk Ratio (M-H, Random, 95% CI) 12 16687 Risk Ratio (M-H, Random, 95% CI) 10 13186 Risk Ratio (M-H, Random, 95% CI) 8 13238 Risk Ratio (M-H, Random, 95% CI) 13 17561 Risk Ratio (M-H, Random, 95% CI) 7 7731 Risk Ratio (M-H, Random, 95% CI) 4 3654 Risk Ratio (M-H, Random, 95% CI) 13 17501 Risk Ratio (M-H, Random, 95% CI) 14 3253 Risk Ratio (M-H, Random, 95% CI) 7 10499 Risk Ratio (M-H, Random, 95% CI) 7 10499 Risk Ratio (M-H, Random, 95% CI) 10 11997 Risk Ratio (M-H, Random, 95% CI) 14 17674 Risk Ratio (M-H, Random, 95% CI) 10 15104 Risk Ratio (M-H, Random, 95% CI)

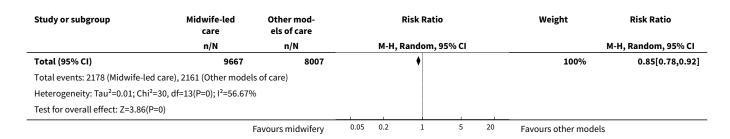


Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
19 Postpartum haemorrhage (as defined by trial authors)	10	14214	Risk Ratio (M-H, Random, 95% CI)	0.94 [0.84, 1.05]
20 Breastfeeding initiation	2	2050	Risk Ratio (M-H, Random, 95% CI)	1.12 [0.81, 1.53]
21 Duration of postnatal hospital stay (days)	3	3593	Mean Difference (IV, Random, 95% CI)	-0.10 [-0.29, 0.09]
22 Low birthweight (< 2500 g)	7	11458	Risk Ratio (M-H, Random, 95% CI)	0.96 [0.82, 1.13]
23 5-minute Apgar score below or equal to 7	11	12546	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.73, 1.32]
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	13	17561	Risk Ratio (M-H, Random, 95% CI)	0.90 [0.78, 1.04]
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	11	15645	Risk Ratio (M-H, Random, 95% CI)	0.81 [0.67, 0.98]
28 Fetal loss/neonatal death equal to/after 24 weeks	12	17359	Risk Ratio (M-H, Random, 95% CI)	1.00 [0.67, 1.49]

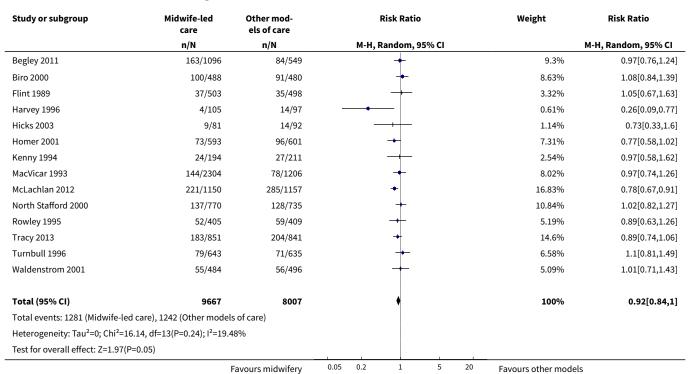
Analysis 1.1. Comparison 1 Midwife-led versus other models of care for childbearing women and their infants (all), Outcome 1 Regional analgesia (epidural/spinal).

Study or subgroup	Midwife-led care	Other mod- els of care	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H, Random, 95% CI		M-H, Random, 95% CI
Begley 2011	295/1096	183/549	+	9.76%	0.81[0.69,0.94]
Biro 2000	100/488	129/480	+	7%	0.76[0.61,0.96]
Flint 1989	88/503	143/498	+	6.81%	0.61[0.48,0.77]
Harvey 1996	13/105	22/97		1.61%	0.55[0.29,1.02]
Hicks 2003	6/81	19/92		0.89%	0.36[0.15,0.85]
Homer 2001	157/593	172/601	+	8.54%	0.93[0.77,1.11]
Kenny 1994	52/194	64/211	-	4.9%	0.88[0.65,1.2]
MacVicar 1993	326/2304	208/1206		9.51%	0.82[0.7,0.96]
McLachlan 2012	326/1150	358/1157	+	10.9%	0.92[0.81,1.04]
North Stafford 2000	80/770	110/735	+	5.83%	0.69[0.53,0.91]
Rowley 1995	69/405	73/409	+	5.13%	0.95[0.71,1.29]
Tracy 2013	314/851	304/841	+	10.91%	1.02[0.9,1.16]
Turnbull 1996	194/643	198/635	+	9.29%	0.97[0.82,1.14]
Waldenstrom 2001	158/484	178/496	+	8.94%	0.91[0.76,1.08]
	- 1	Favours midwifery	0.05 0.2 1 5 20	Favours other mode	ls





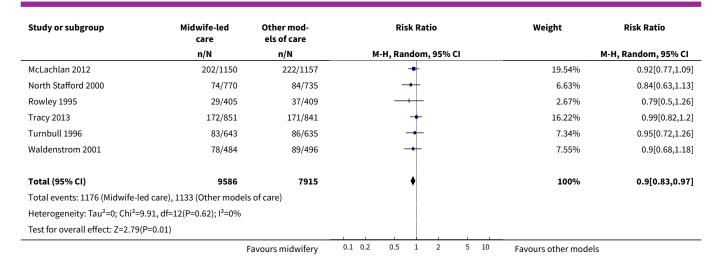
Analysis 1.2. Comparison 1 Midwife-led versus other models of care for childbearing women and their infants (all), Outcome 2 Caesarean birth.



Analysis 1.3. Comparison 1 Midwife-led versus other models of care for childbearing women and their infants (all), Outcome 3 Instrumental vaginal birth (forceps/vacuum).

Study or subgroup	Midwife-led care	Other mod- els of care	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H, Random, 95% CI		M-H, Random, 95% CI
Begley 2011	139/1096	79/549	-+	8.81%	0.88[0.68,1.14]
Biro 2000	67/488	86/480	-+ 	6.73%	0.77[0.57,1.03]
Flint 1989	56/503	66/498	-+ 	5.2%	0.84[0.6,1.17]
Harvey 1996	6/105	7/97		0.52%	0.79[0.28,2.27]
Homer 2001	71/593	63/601	+	5.67%	1.14[0.83,1.57]
Kenny 1994	12/194	29/211		1.4%	0.45[0.24,0.86]
MacVicar 1993	187/2304	114/1206	-+	11.73%	0.86[0.69,1.07]
	F	avours midwifery	0.1 0.2 0.5 1 2 5 10	Favours other model	S





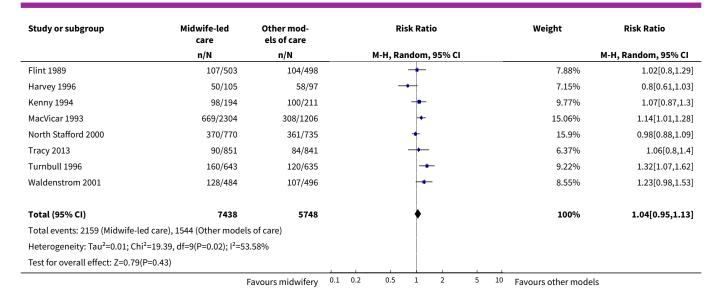
Analysis 1.4. Comparison 1 Midwife-led versus other models of care for childbearing women and their infants (all), Outcome 4 Spontaneous vaginal birth (as defined by trial authors).

Study or subgroup	Midwife-led care	Other mod- els of care	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H, Random, 95% CI		M-H, Random, 95% CI
Begley 2011	761/1096	372/549	+	8.83%	1.02[0.96,1.1]
Biro 2000	282/488	262/480	+-	3.69%	1.06[0.95,1.18]
Flint 1989	386/503	372/498	+-	8.74%	1.03[0.96,1.1]
Harvey 1996	89/105	71/97		2.21%	1.16[1,1.34]
Homer 2001	402/593	374/601		6.38%	1.09[1,1.18]
Kenny 1994	158/194	155/211		4.11%	1.11[1,1.23]
MacVicar 1993	1847/2304	931/1206	-	25.13%	1.04[1,1.08]
McLachlan 2012	719/1150	637/1157	-	9.1%	1.14[1.06,1.22]
North Stafford 2000	542/770	509/735	-	9.63%	1.02[0.95,1.09]
Tracy 2013	487/851	454/841	+	6.12%	1.06[0.97,1.15]
Turnbull 1996	450/643	440/635	+	8.26%	1.01[0.94,1.09]
Waldenstrom 2001	362/484	360/496	+	7.78%	1.03[0.96,1.11]
Total (95% CI)	9181	7506	•	100%	1.05[1.03,1.07]
Total events: 6485 (Midwife-le	ed care), 4937 (Other model	s of care)			
Heterogeneity: Tau ² =0; Chi ² =	12.16, df=11(P=0.35); l ² =9.57	7%			
Test for overall effect: Z=4.38	(P<0.0001)				
	Fav	ours other models	1	Favours midwifery	

Analysis 1.5. Comparison 1 Midwife-led versus other models of care for childbearing women and their infants (all), Outcome 5 Intact perineum.

Study or subgroup	Midwife-led care	Other mod- els of care		Risk Ratio					Weight	Risk Ratio	
	n/N	n/N		M-H, Random, 95% CI							M-H, Random, 95% CI
Begley 2011	421/1096	225/549		+					14.37%	0.94[0.83,1.06]	
Biro 2000	66/488	77/480					1	5.73%	0.84[0.62,1.14]		
		Favours midwifery	0.1	0.2	0.5	1	2	5	10	Favours other models	s





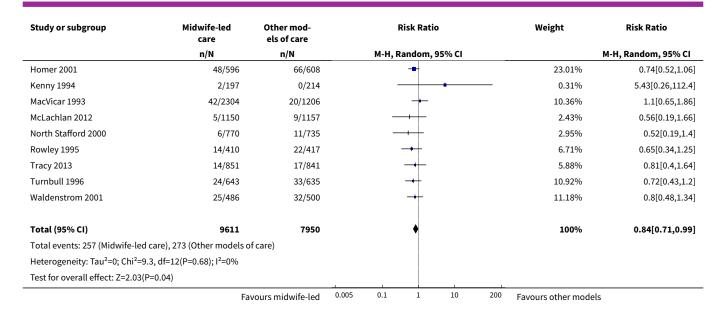
Analysis 1.6. Comparison 1 Midwife-led versus other models of care for childbearing women and their infants (all), Outcome 6 Preterm birth (< 37 weeks).

Study or subgroup	Midwife-led care	Other mod- els of care	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H, Random, 95% CI		M-H, Random, 95% CI
Begley 2011	48/1096	48/549		13.73%	0.5[0.34,0.74]
Biro 2000	36/500	42/493		12%	0.85[0.55,1.3]
MacVicar 1993	110/2304	70/1206		19.06%	0.82[0.61,1.1]
McLachlan 2012	29/1150	48/1157		11.04%	0.61[0.39,0.96]
Rowley 1995	52/410	54/417	+	15.25%	0.98[0.69,1.4]
Tracy 2013	39/851	51/841	-+ 	12.88%	0.76[0.5,1.13]
Turnbull 1996	30/643	42/635		10.97%	0.71[0.45,1.11]
Waldenstrom 2001	16/486	12/500	-	5.06%	1.37[0.66,2.87]
Total (95% CI)	7440	5798	•	100%	0.76[0.64,0.91]
Total events: 360 (Midwife-lec	d care), 367 (Other models o	f care)			
Heterogeneity: Tau ² =0.02; Chi	i ² =10.42, df=7(P=0.17); l ² =32	.85%			
Test for overall effect: Z=2.96(P=0)				
	F	avours midwifery	0.05 0.2 1 5	20 Favours other mode	els

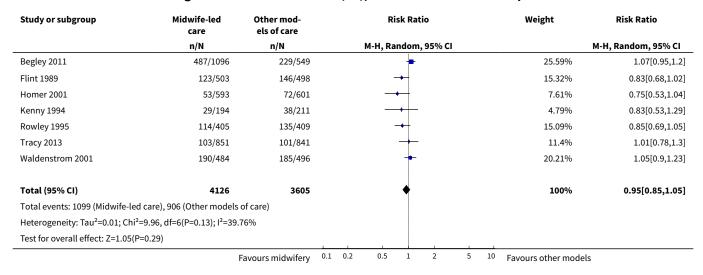
Analysis 1.7. Comparison 1 Midwife-led versus other models of care for childbearing women and their infants (all), Outcome 7 Overall fetal loss and neonatal death.

Study or subgroup	Midwife-led care	Other mod- els of care		Risk Ratio				Weight	Risk Ratio
	n/N	n/N		M-H, Random, 95% CI					M-H, Random, 95% CI
Begley 2011	20/1096	7/549			+			3.95%	1.43[0.61,3.36]
Biro 2000	35/500	40/493			+			15.17%	0.86[0.56,1.33]
Flint 1989	18/503	12/498			+			5.57%	1.49[0.72,3.05]
Harvey 1996	4/105	4/97	1	-	+			1.57%	0.92[0.24,3.59]
	Fav	vours midwife-led	0.005	0.1	1	10	200	Favours other models	<u> </u>





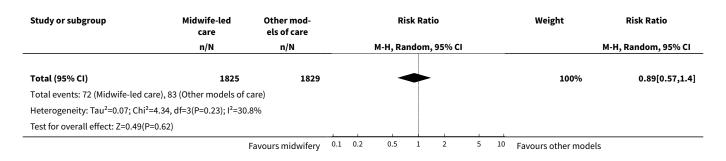
Analysis 1.8. Comparison 1 Midwife-led versus other models of care for childbearing women and their infants (all), Outcome 8 Antenatal hospitalisation.



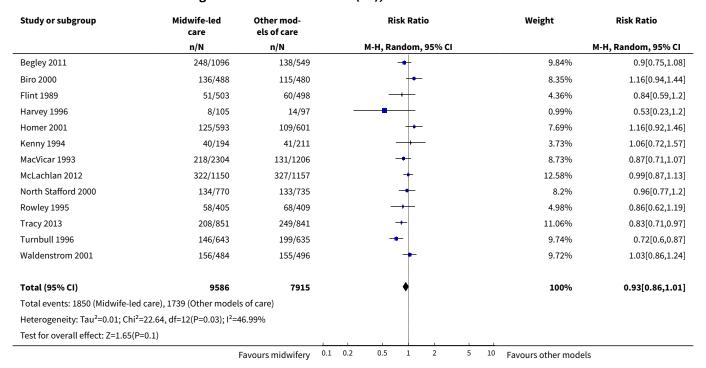
Analysis 1.9. Comparison 1 Midwife-led versus other models of care for childbearing women and their infants (all), Outcome 9 Antepartum haemorrhage.

Study or subgroup	Midwife-led care	Other mod- els of care		Risk Ratio				Weight	Risk Ratio		
	n/N	n/N			M-H, Raı	ndom	, 95% CI				M-H, Random, 95% CI
Harvey 1996	4/105	5/97		_	-	+				10.42%	0.74[0.2,2.67]
Homer 2001	9/593	14/601				+	-			21.03%	0.65[0.28,1.49]
Turnbull 1996	45/643	57/635			-	-				49.87%	0.78[0.54,1.13]
Waldenstrom 2001	14/484	7/496				+	+			18.68%	2.05[0.83,5.03]
	1	avours midwifery	0.1	0.2	0.5	1	2	5	10	Favours other models	<u> </u>





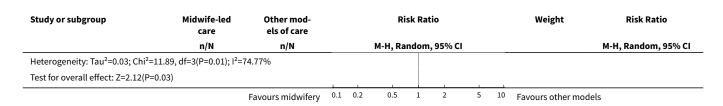
Analysis 1.10. Comparison 1 Midwife-led versus other models of care for childbearing women and their infants (all), Outcome 10 Induction of labour.



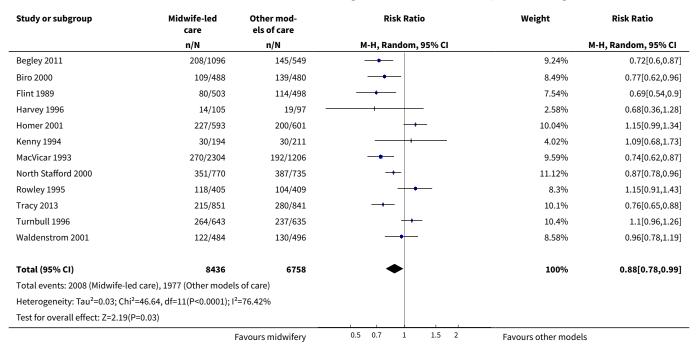
Analysis 1.11. Comparison 1 Midwife-led versus other models of care for childbearing women and their infants (all), Outcome 11 Amniotomy.

Study or subgroup	Midwife-led care	Other mod- els of care		Risk Ratio					Weight	Risk Ratio
	n/N	n/N			M-H, Rando	m, 95% C	I			M-H, Random, 95% CI
Begley 2011	228/1096	169/549			-				29.57%	0.68[0.57,0.8]
Flint 1989	247/503	270/498			-				33.05%	0.91[0.8,1.02]
Harvey 1996	17/105	28/97							10.37%	0.56[0.33,0.96]
Kenny 1994	90/194	102/211			+	-			27%	0.96[0.78,1.18]
Total (95% CI)	1898	1355			•				100%	0.8[0.66,0.98]
Total events: 582 (Midwife-le	d care), 569 (Other models o	f care)								
	F	avours midwifery	0.1	0.2	0.5 1	2	5	10	Favours other model	s





Analysis 1.12. Comparison 1 Midwife-led versus other models of care for childbearing women and their infants (all), Outcome 12 Augmentation/artificial oxytocin during labour.



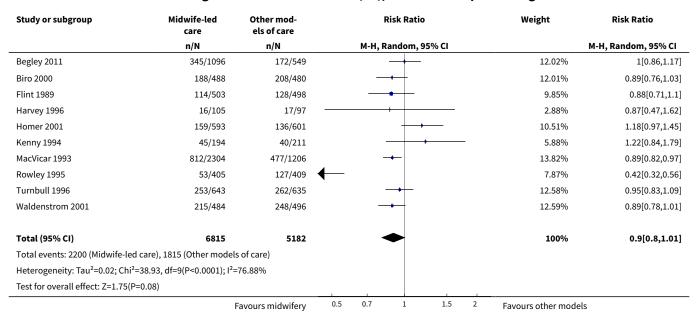
Analysis 1.13. Comparison 1 Midwife-led versus other models of care for childbearing women and their infants (all), Outcome 13 No intrapartum analgesia/anaesthesia.

Study or subgroup	Midwife-led care	Other mod- els of care	Risk Ratio	Weight	Risk Ratio M-H, Random, 95% CI	
	n/N	n/N	M-H, Random, 95% CI			
Begley 2011	136/1096	57/549	+-	11.62%	1.2[0.89,1.6]	
Biro 2000	62/488	57/480		9.63%	1.07[0.76,1.5]	
Flint 1989	246/503	180/498		21.64%	1.35[1.17,1.57]	
Kenny 1994	53/194	62/211		10.74%	0.93[0.68,1.27]	
MacVicar 1993	270/2304	127/1206	 	17.39%	1.11[0.91,1.36]	
Tracy 2013	216/851	140/841		18.08%	1.52[1.26,1.84]	
Turnbull 1996	76/643	69/635	+	10.9%	1.09[0.8,1.48]	
Total (95% CI)	6079	4420	•	100%	1.21[1.06,1.37]	
Total events: 1059 (Midwife-le	ed care), 692 (Other models	of care)				
Heterogeneity: Tau ² =0.01; Ch	ii ² =11.86, df=6(P=0.07); I ² =49	.4%				
	Favo	ours other models 0.1	0.2 0.5 1 2 5	10 Favours midwifery		



Study or subgroup	Midwife-led care	Other mod- els of care		Risk Ratio				Weight	Risk Ratio		
	n/N	n/N			M-H, Ra	ndom	, 95% CI				M-H, Random, 95% CI
Test for overall effect: Z=2.93(P=0)											
		Favours other models	0.1	0.2	0.5	1	2	5	10	Favours midwifery	

Analysis 1.14. Comparison 1 Midwife-led versus other models of care for childbearing women and their infants (all), Outcome 14 Opiate analgesia.

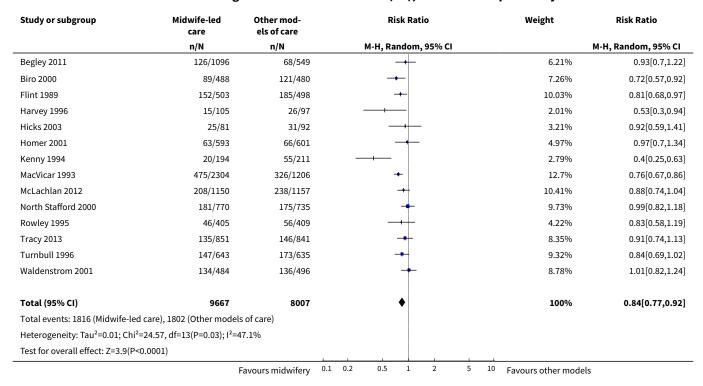


Analysis 1.15. Comparison 1 Midwife-led versus other models of care for childbearing women and their infants (all), Outcome 15 Attendance at birth by known midwife.

Study or subgroup	up Midwife-led Other mod- Risk Ratio care els of care		Ratio	Weight	Risk Ratio	
	n/N	n/N	M-H, Rand	om, 95% CI		M-H, Random, 95% CI
Biro 2000	329/488	1/480)	4.08%	323.61[45.63,2294.85]
Hicks 2003	57/81	13/92			14.05%	4.98[2.95,8.4]
Homer 2001	204/593	68/601			16.43%	3.04[2.37,3.9]
Kenny 1994	186/194	27/211		-	15.64%	7.49[5.26,10.67]
North Stafford 2000	696/770	52/735			16.34%	12.78[9.82,16.62]
Tracy 2013	759/851	123/841		-	16.9%	6.1[5.17,7.19]
Waldenstrom 2001	336/484	67/496		-+-	16.55%	5.14[4.08,6.47]
Total (95% CI)	3461	3456		•	100%	7.04[4.48,11.08]
Total events: 2567 (Midwife-le	d care), 351 (Other models	of care)				
Heterogeneity: Tau ² =0.31; Chi	² =94.98, df=6(P<0.0001); I ² =	93.68%				
Test for overall effect: Z=8.45(I	P<0.0001)					
	Fav	ours other models	0.05 0.2	1 5 20	Favours midwifery	



Analysis 1.16. Comparison 1 Midwife-led versus other models of care for childbearing women and their infants (all), Outcome 16 Episiotomy.



Analysis 1.17. Comparison 1 Midwife-led versus other models of care for childbearing women and their infants (all), Outcome 17 Perineal laceration requiring suturing.

Study or subgroup	Midwife-led care	Other mod- els of care	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H, Random, 95% CI		M-H, Random, 95% CI
Begley 2011	484/1096	247/549	+	13.9%	0.98[0.88,1.1]
Biro 2000	143/488	133/480	+	7.85%	1.06[0.87,1.29]
Kenny 1994	107/194	115/211	—	9.11%	1.01[0.85,1.21]
MacVicar 1993	1389/2304	743/1206	+	19.4%	0.98[0.93,1.03]
McLachlan 2012	394/1150	326/1157	+	13.18%	1.22[1.08,1.37]
North Stafford 2000	197/770	180/735	+	9.23%	1.04[0.88,1.24]
Rowley 1995	141/405	126/409	+	7.98%	1.13[0.93,1.38]
Tracy 2013	38/851	30/841	+-	2%	1.25[0.78,2]
Turnbull 1996	218/643	216/635	+	10.71%	1[0.86,1.16]
Waldenstrom 2001	100/484	135/496		6.63%	0.76[0.61,0.95]
Total (95% CI)	8385	6719	•	100%	1.02[0.96,1.1]
Total events: 3211 (Midwife-led car	re), 2251 (Other model	s of care)			
Heterogeneity: Tau ² =0.01; Chi ² =19	.18, df=9(P=0.02); l ² =53	3.06%			
Test for overall effect: Z=0.68(P=0.5	5)				



Analysis 1.18. Comparison 1 Midwife-led versus other models of care for childbearing women and their infants (all), Outcome 18 Mean labour length (hrs).

Study or subgroup	Midw	fe-led care		ner mod- s of care	Mean Difference	Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI		Random, 95% CI
Begley 2011	1096	4.6 (3.3)	549	4 (2.4)	-	71.49%	0.6[0.32,0.88]
Kenny 1994	194	6.1 (3.9)	211	5.7 (4)	+	9.47%	0.4[-0.37,1.17]
Turnbull 1996	643	7.9 (4.9)	635	7.7 (5)	+	19.04%	0.2[-0.34,0.74]
Total ***	1933		1395		•	100%	0.5[0.27,0.74]
Heterogeneity: Tau ² =0; Chi ² =	=1.73, df=2(P=0.4	2); I ² =0%					
Test for overall effect: Z=4.18	3(P<0.0001)						
			Favo	urs midwiferv	-2 -1 0 1 2	Favours oth	er models

Analysis 1.19. Comparison 1 Midwife-led versus other models of care for childbearing women and their infants (all), Outcome 19 Postpartum haemorrhage (as defined by trial authors).

Study or subgroup	Midwife-led care	Other mod- els of care		Risk Ratio	Weight	Risk Ratio	
	n/N	n/N		M-H, Random, 95% CI		M-H, Random, 95% CI	
Begley 2011	144/1096	75/549		+	19.52%	0.96[0.74,1.25]	
Flint 1989	22/503	29/498			4.51%	0.75[0.44,1.29]	
Harvey 1996	6/105	3/97			- 0.71%	1.85[0.48,7.19]	
Homer 2001	31/593	26/601		+	5.08%	1.21[0.73,2.01]	
Kenny 1994	13/194	12/211			2.28%	1.18[0.55,2.52]	
MacVicar 1993	118/2304	63/1206		-	14.84%	0.98[0.73,1.32]	
McLachlan 2012	53/1150	65/1157		-+	10.53%	0.82[0.58,1.17]	
Tracy 2013	149/851	168/841		-	33.26%	0.88[0.72,1.07]	
Turnbull 1996	36/643	34/635			6.34%	1.05[0.66,1.65]	
Waldenstrom 2001	17/484	16/496			2.92%	1.09[0.56,2.13]	
Total (95% CI)	7923	6291		•	100%	0.94[0.84,1.05]	
Total events: 589 (Midwife-led care),	491 (Other models o	f care)					
Heterogeneity: Tau ² =0; Chi ² =4.44, df=	9(P=0.88); I ² =0%						
Test for overall effect: Z=1.11(P=0.27)							
		Favours midwifery	0.1 0	.2 0.5 1 2 5	10 Favours other mode	ls	

Analysis 1.20. Comparison 1 Midwife-led versus other models of care for childbearing women and their infants (all), Outcome 20 Breastfeeding initiation.

Study or subgroup	Midwife-led care	Other mod- els of care		Risk Ratio			Weight	Risk Ratio
	n/N	n/N		M-H, Random, 95	% CI			M-H, Random, 95% CI
Begley 2011	616/1096	317/549		<u> </u>			57.77%	0.97[0.89,1.06]
Kenny 1994	78/194	63/211		-			42.23%	1.35[1.03,1.76]
Total (95% CI)	1290	760		•			100%	1.12[0.81,1.53]
Total events: 694 (Midwife-led	care), 380 (Other models of	care)						
Heterogeneity: Tau ² =0.04; Chi ²	=5.18, df=1(P=0.02); I ² =80.6	58%					1	
	Favo	ours other models	0.1 0.2	0.5 1	2	5 1	Favours midwifery	



Study or subgroup	Midwife-led care	Other mod- els of care		Risk Ratio				Weight	Risk Ratio	
	n/N	n/N		M-H, Ra	ndom	, 95% CI				M-H, Random, 95% CI
Test for overall effect: Z=0.68(P=0.5)										
			0.1 0.2	0.5	1	2	-	10		

Analysis 1.21. Comparison 1 Midwife-led versus other models of care for childbearing women and their infants (all), Outcome 21 Duration of postnatal hospital stay (days).

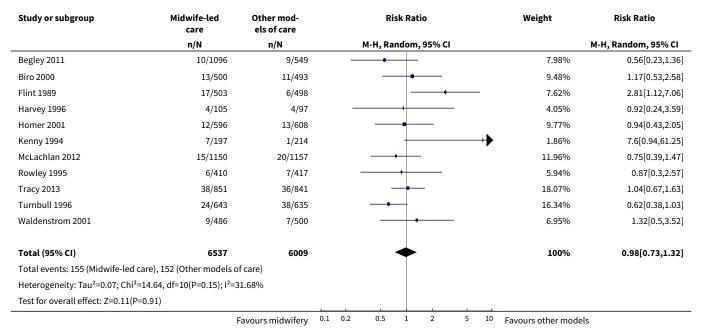
Study or subgroup	Midw	fe-led care		ner mod- s of care	Mean Difference	Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI		Random, 95% CI
Begley 2011	1096	2.6 (1.4)	549	2.7 (1.3)	-	44.67%	-0.08[-0.22,0.06]
Biro 2000	488	4.3 (1.8)	480	4.6 (1.9)		30.85%	-0.3[-0.53,-0.07]
Waldenstrom 2001	484	3.8 (2.6)	496	3.7 (2)		24.48%	0.1[-0.19,0.39]
Total ***	2068		1525		•	100%	-0.1[-0.29,0.09]
Heterogeneity: Tau ² =0.02; Ch	ni ² =4.72, df=2(P=	0.09); I ² =57.64%	ı				
Test for overall effect: Z=1.07	(P=0.28)						
			Favo	urs midwifery	-0.5 -0.25 0 0.25 0.5	Favours oth	er models

Analysis 1.22. Comparison 1 Midwife-led versus other models of care for childbearing women and their infants (all), Outcome 22 Low birthweight (< 2500 g).

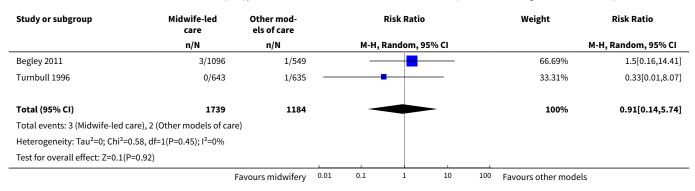
Study or subgroup	Midwife-led care	Other mod- els of care		Risk Ratio	Weight	Risk Ratio
	n/N	n/N		M-H, Random, 95% CI		M-H, Random, 95% CI
Begley 2011	29/1096	16/549		-+-	7.08%	0.91[0.5,1.66]
Flint 1989	31/503	38/498			12.23%	0.81[0.51,1.28]
MacVicar 1993	112/2304	59/1206		-	27.12%	0.99[0.73,1.35]
North Stafford 2000	52/770	51/735			18.45%	0.97[0.67,1.41]
Rowley 1995	28/410	24/417			9.2%	1.19[0.7,2.01]
Tracy 2013	26/851	31/841			9.77%	0.83[0.5,1.38]
Turnbull 1996	46/643	44/635		-	16.15%	1.03[0.69,1.54]
Total (95% CI)	6577	4881		•	100%	0.96[0.82,1.13]
Total events: 324 (Midwife-led	d care), 263 (Other models o	f care)				
Heterogeneity: Tau ² =0; Chi ² =1	1.69, df=6(P=0.95); I ² =0%					
Test for overall effect: Z=0.45(P=0.65)					
	F	avours midwifery	0.1 0.2	0.5 1 2	5 10 Favours other mode	ls



Analysis 1.23. Comparison 1 Midwife-led versus other models of care for childbearing women and their infants (all), Outcome 23 5-minute Apgar score below or equal to 7.



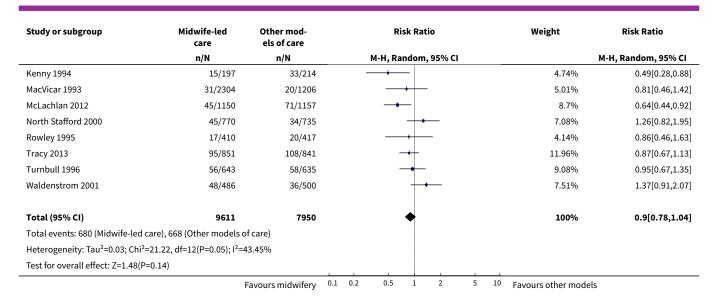
Analysis 1.24. Comparison 1 Midwife-led versus other models of care for childbearing women and their infants (all), Outcome 24 Neonatal convulsions (as defined by trial authors).



Analysis 1.25. Comparison 1 Midwife-led versus other models of care for childbearing women and their infants (all), Outcome 25 Admission to special care nursery/neonatal intensive care unit.

Study or subgroup	Midwife-led care	Other mod- els of care					Weight	Risk Ratio			
	n/N	n/N			M-H, Ran	dom	, 95% CI				M-H, Random, 95% CI
Begley 2011	128/1096	60/549			-	+	-			10.93%	1.07[0.8,1.43]
Biro 2000	89/500	87/493			-	+				11.63%	1.01[0.77,1.32]
Flint 1989	23/503	21/498				+				4.75%	1.08[0.61,1.93]
Harvey 1996	8/105	18/97			-	-				2.9%	0.41[0.19,0.9]
Homer 2001	80/596	102/608			, -+	+				11.57%	0.8[0.61,1.05]
	F	avours midwifery	0.1	0.2	0.5	1	2	5	10	Favours other models	;





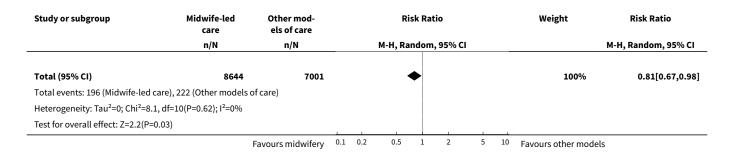
Analysis 1.26. Comparison 1 Midwife-led versus other models of care for childbearing women and their infants (all), Outcome 26 Mean length of neonatal hospital stay (days).

Study or subgroup	Midwi	fe-led care		ner mod- s of care		Mea	n Difference		Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)		Ran	dom, 95% CI			Random, 95% CI
Biro 2000	500	6.8 (0.5)	493	8.8 (0.5)					60.17%	-2[-2.06,-1.94]
Waldenstrom 2001	486	11.1 (23.2)	500	17.2 (34)			-		39.83%	-6.1[-9.72,-2.48]
Total ***	986		993				•		100%	-3.63[-7.57,0.3]
Heterogeneity: Tau ² =6.69; Ch	i ² =4.91, df=1(P=0	0.03); I ² =79.65%								
Test for overall effect: Z=1.81	(P=0.07)									
			Favo	urs midwifery	-40	-20	0 20	40	Favours oth	er models

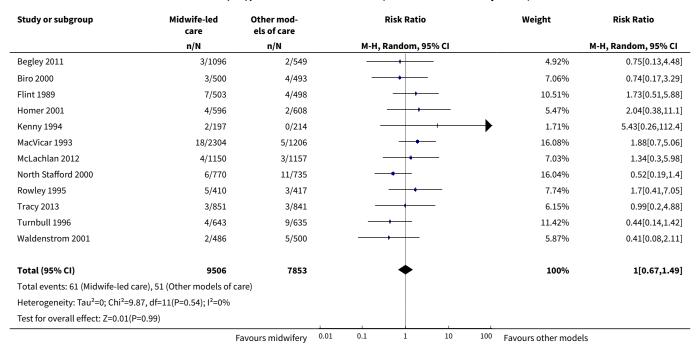
Analysis 1.27. Comparison 1 Midwife-led versus other models of care for childbearing women and their infants (all), Outcome 27 Fetal loss/neonatal death before 24 weeks.

Study or subgroup	Midwife-led care	Other mod- els of care	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H, Random, 95% CI		M-H, Random, 95% CI
Begley 2011	17/1096	5/549		3.73%	1.7[0.63,4.59]
Biro 2000	32/500	36/493	+ -	17.39%	0.88[0.55,1.39]
Flint 1989	11/503	8/498	- +	4.51%	1.36[0.55,3.36]
Harvey 1996	4/105	4/97		1.99%	0.92[0.24,3.59]
Homer 2001	44/596	64/608		27.3%	0.7[0.49,1.01]
MacVicar 1993	24/2304	15/1206		8.93%	0.84[0.44,1.59]
McLachlan 2012	1/1150	6/1157	+	0.82%	0.17[0.02,1.39]
Rowley 1995	9/410	19/417		6.02%	0.48[0.22,1.05]
Tracy 2013	11/851	14/841		5.98%	0.78[0.35,1.7]
Turnbull 1996	20/643	24/635		10.8%	0.82[0.46,1.47]
Waldenstrom 2001	23/486	27/500	· · · · · · · · · · · · · · · · · · ·	12.51%	0.88[0.51,1.51]
	F	avours midwifery	0.1 0.2 0.5 1 2 5	10 Favours other mode	ls





Analysis 1.28. Comparison 1 Midwife-led versus other models of care for childbearing women and their infants (all), Outcome 28 Fetal loss/neonatal death equal to/after 24 weeks.



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 partici- pants	Statistical method	Effect size
1 Regional analgesia (epidur- al/spinal)	14		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
1.1 Caseload	4	6782	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.82, 1.04]
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	14	17658	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.84, 1.00]

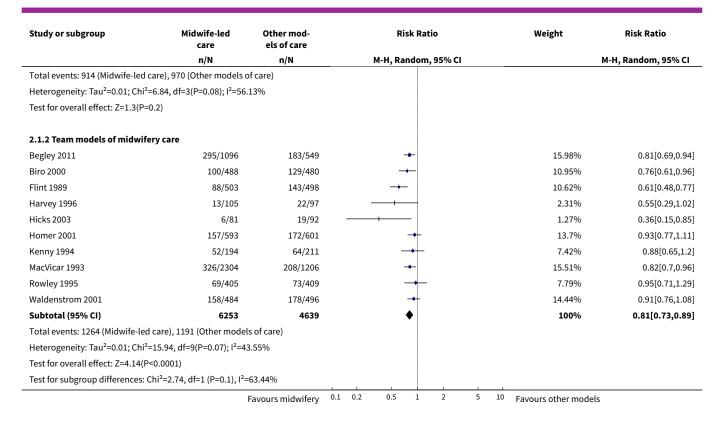


Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size	
2.1 Caseload	4	6782	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.79, 1.05]	
2.2 Team models of midwifery care	10	10876	Risk Ratio (M-H, Random, 95% CI)	0.94 [0.84, 1.05]	
3 Instrumental vaginal birth (for- ceps/vacuum)	13	17965	Risk Ratio (M-H, Random, 95% CI)	0.90 [0.84, 0.97]	
3.1 Caseload	4	6782	Risk Ratio (M-H, Random, 95% CI)	0.94 [0.84, 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)	12	16687	Risk Ratio (M-H, Random, 95% CI)	1.05 [1.03, 1.07]	
4.1 Caseload	4	6782	Risk Ratio (M-H, Random, 95% CI)	1.05 [1.00, 1.12]	
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	10	13186	Risk Ratio (M-H, Random, 95% CI)	1.04 [0.95, 1.13]	
5.1 Caseload	3	4475	Risk Ratio (M-H, Random, 95% CI)	1.10 [0.90, 1.34]	
5.2 Team	7	8711	Risk Ratio (M-H, Random, 95% CI)	1.01 [0.91, 1.13]	
6 Preterm birth (< 37 weeks)	8	13238	Risk Ratio (M-H, Random, 95% CI)	0.76 [0.64, 0.91]	
6.1 Caseload	3	5277	Risk Ratio (M-H, Random, 95% CI)	0.69 [0.54, 0.89]	
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	13	17527	Risk Ratio (M-H, Random, 95% CI)	0.84 [0.71, 0.99]	
7.1 Caseload	4	6782	Risk Ratio (M-H, Random, 95% CI)	0.69 [0.48, 0.99]	
7.2 Team	9	10745	Risk Ratio (M-H, Random, 95% CI)	0.89 [0.73, 1.07]	

Analysis 2.1. Comparison 2 Midwife-led versus other models of care: variation in midwifery models of care (caseload/one-to-one or team), Outcome 1 Regional analgesia (epidural/spinal).

Study or subgroup	Midwife-led care	Other mod- els of care	Risk Ratio			Weight	Risk Ratio
	n/N	n/N	M-H	, Random, 95% CI			M-H, Random, 95% CI
2.1.1 Caseload							
McLachlan 2012	326/1150	358/1157		-		30.68%	0.92[0.81,1.04]
North Stafford 2000	80/770	110/735				13.89%	0.69[0.53,0.91]
Tracy 2013	314/851	304/841		+		30.72%	1.02[0.9,1.16]
Turnbull 1996	194/643	198/635		+		24.72%	0.97[0.82,1.14]
Subtotal (95% CI)	3414	3368				100%	0.92[0.82,1.04]
		Favours midwiferv	0.1 0.2 0	.5 1 2	5 10	Favours other models	S

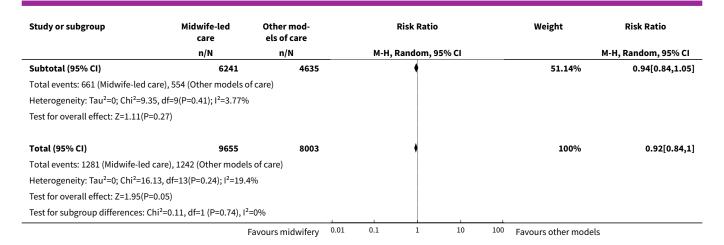




Analysis 2.2. Comparison 2 Midwife-led versus other models of care: variation in midwifery models of care (caseload/one-to-one or team), Outcome 2 Caesarean birth.

Study or subgroup	Midwife-led care	Other mod- els of care	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H, Random, 95% CI		M-H, Random, 95% CI
2.2.1 Caseload					
McLachlan 2012	221/1150	285/1157	+	16.84%	0.78[0.67,0.91]
North Stafford 2000	137/770	128/735	+	10.83%	1.02[0.82,1.27]
Tracy 2013	183/851	204/841	+	14.6%	0.89[0.74,1.06]
Turnbull 1996	79/643	71/635	+	6.58%	1.1[0.81,1.49]
Subtotal (95% CI)	3414	3368	♦	48.86%	0.91[0.79,1.05]
Total events: 620 (Midwife-led	d care), 688 (Other models o	f care)			
Heterogeneity: Tau ² =0.01; Chi	i ² =6.17, df=3(P=0.1); I ² =51.3	6%			
Test for overall effect: Z=1.26(P=0.21)				
2.2.2 Team models of midwi	fery care				
Begley 2011	163/1096	84/549	+	9.3%	0.97[0.76,1.24]
Biro 2000	100/488	91/480	+	8.63%	1.08[0.84,1.39]
Flint 1989	37/503	35/498	+	3.31%	1.05[0.67,1.63]
Harvey 1996	4/105	14/97		0.61%	0.26[0.09,0.77]
Hicks 2003	9/81	14/92		1.14%	0.73[0.33,1.6]
Homer 2001	73/593	96/601	-+ 	7.31%	0.77[0.58,1.02]
Kenny 1994	24/194	27/211	+	2.54%	0.97[0.58,1.62]
MacVicar 1993	144/2304	78/1206	+	8.02%	0.97[0.74,1.26]
Rowley 1995	52/393	59/405	 -	5.2%	0.91[0.64,1.28]
Waldenstrom 2001	55/484	56/496	. + .	5.08%	1.01[0.71,1.43]
	1	Favours midwifery	0.01 0.1 1 10	100 Favours other model	s





Analysis 2.3. Comparison 2 Midwife-led versus other models of care: variation in midwifery models of care (caseload/one-to-one or team), Outcome 3 Instrumental vaginal birth (forceps/vacuum).

Study or subgroup	Midwife-led care	Other mod- els of care	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H, Random, 95% CI		M-H, Random, 95% CI
2.3.1 Caseload					
McLachlan 2012	202/1150	222/1157	-+	18.66%	0.92[0.77,1.09]
North Stafford 2000	74/770	84/735	-+ 	6.33%	0.84[0.63,1.13]
Tracy 2013	172/851	171/841	+	15.5%	0.99[0.82,1.2]
Turnbull 1996	83/643	86/635	-	7.01%	0.95[0.72,1.26]
Subtotal (95% CI)	3414	3368	•	47.51%	0.94[0.84,1.04]
Total events: 531 (Midwife-led care),	563 (Other models o	f care)			
Heterogeneity: Tau ² =0; Chi ² =0.97, df=	=3(P=0.81); I ² =0%				
Test for overall effect: Z=1.21(P=0.22)					
2.3.2 Team models of midwifery car	re				
Begley 2011	139/1096	79/549	-+	8.42%	0.88[0.68,1.14]
Biro 2000	67/488	86/480		6.43%	0.77[0.57,1.03]
Flint 1989	56/503	66/498	-+	4.97%	0.84[0.6,1.17]
Harvey 1996	6/105	7/97		0.5%	0.79[0.28,2.27]
Homer 2001	71/593	63/601	- 	5.42%	1.14[0.83,1.57]
Kenny 1994	12/194	29/211		1.34%	0.45[0.24,0.86]
MacVicar 1993	187/2304	114/1206	-+ 	11.21%	0.86[0.69,1.07]
Rowley 1995	83/643	86/635		7.01%	0.95[0.72,1.26]
Waldenstrom 2001	78/484	89/496	-+	7.21%	0.9[0.68,1.18]
Subtotal (95% CI)	6410	4773	♦	52.49%	0.88[0.79,0.97]
Total events: 699 (Midwife-led care),	619 (Other models o	f care)			
Heterogeneity: Tau ² =0; Chi ² =8.06, df=	=8(P=0.43); I ² =0.78%				
Test for overall effect: Z=2.51(P=0.01)					
Total (95% CI)	9824	8141	•	100%	0.9[0.84,0.97]
Total events: 1230 (Midwife-led care)	, 1182 (Other model	s of care)	ĺ		
Heterogeneity: Tau ² =0; Chi ² =9.77, df=	=12(P=0.64); I ² =0%				
Test for overall effect: Z=2.66(P=0.01)			ĺ		
Test for subgroup differences: Chi ² =0	.73, df=1 (P=0.39), I ²	=0%			
	I	avours midwifery 0.1	0.2 0.5 1 2 5	10 Favours other mode	els



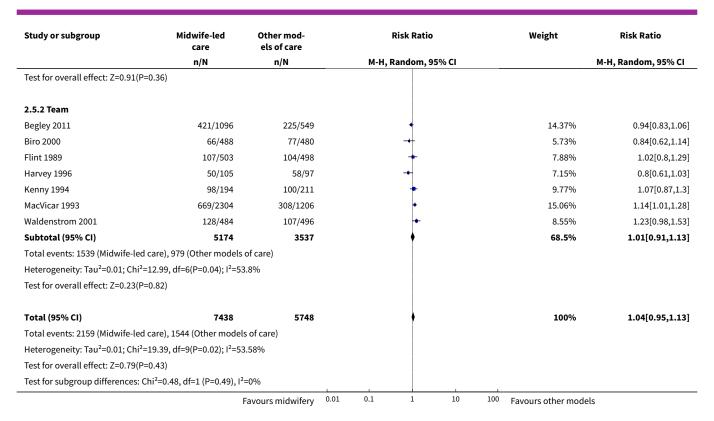
Analysis 2.4. Comparison 2 Midwife-led versus other models of care: variation in midwifery models of care (caseload/one-to-one or team), Outcome 4 Spontaneous vaginal birth (as defined by trial authors).

Study or subgroup	Mide- ife-led care	Other mod- els of care	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H, Random, 95% CI		M-H, Random, 95% CI
2.4.1 Caseload					
McLachlan 2012	719/1150	637/1157	*	9.1%	1.14[1.06,1.22]
North Stafford 2000	542/770	509/735	+	9.63%	1.02[0.95,1.09]
Tracy 2013	487/851	454/841	+	6.12%	1.06[0.97,1.15]
Turnbull 1996	450/643	440/635	<u>+</u>	8.26%	1.01[0.94,1.09]
Subtotal (95% CI)	3414	3368	•	33.12%	1.05[1,1.12]
Total events: 2198 (Mideife-led ca	are), 2040 (Other models	of care)			
Heterogeneity: Tau ² =0; Chi ² =7.16	5, df=3(P=0.07); I ² =58.129	6			
Test for overall effect: Z=1.85(P=0	0.06)				
2.4.2 Team models of midwifer	y care				
Begley 2011	761/1096	372/549	+	8.83%	1.02[0.96,1.1]
Biro 2000	282/488	262/480	+	3.69%	1.06[0.95,1.18]
Flint 1989	386/503	372/498	+	8.74%	1.03[0.96,1.1]
Harvey 1996	89/105	71/97	+	2.21%	1.16[1,1.34]
Homer 2001	402/593	374/601	+	6.38%	1.09[1,1.18]
Kenny 1994	158/194	155/211	+	4.11%	1.11[1,1.23]
MacVicar 1993	1847/2304	931/1206	•	25.13%	1.04[1,1.08]
Waldenstrom 2001	362/484	360/496	+	7.78%	1.03[0.96,1.11]
Subtotal (95% CI)	5767	4138	•	66.88%	1.05[1.02,1.07]
Total events: 4287 (Mideife-led ca	are), 2897 (Other models	of care)			
Heterogeneity: Tau ² =0; Chi ² =4.91	., df=7(P=0.67); I ² =0%				
Test for overall effect: Z=3.67(P=0))				
Total (95% CI)	9181	7506		100%	1.05[1.03,1.07]
Total events: 6485 (Mideife-led ca	are), 4937 (Other models	of care)			
Heterogeneity: Tau ² =0; Chi ² =12.1	.6, df=11(P=0.35); l ² =9.57	" %			
Test for overall effect: Z=4.38(P<0	0.0001)				
Test for subgroup differences: Ch	ii ² =0.06, df=1 (P=0.81), I ²	=0%			

Analysis 2.5. Comparison 2 Midwife-led versus other models of care: variation in midwifery models of care (caseload/one-to-one or team), Outcome 5 Intact perineum.

Study or subgroup	Midwife-led care	Other mod- els of care		Risk Ratio				Weight	Risk Ratio
	n/N	n/N		М-Н,	Random, 95%	CI			M-H, Random, 95% CI
2.5.1 Caseload									
North Stafford 2000	370/770	361/735			+			15.9%	0.98[0.88,1.09]
Tracy 2013	90/851	84/841			+			6.37%	1.06[0.8,1.4]
Turnbull 1996	160/643	120/635			+			9.22%	1.32[1.07,1.62]
Subtotal (95% CI)	2264	2211			•			31.5%	1.1[0.9,1.34]
Total events: 620 (Midwife-le	d care), 565 (Other models of	f care)							
Heterogeneity: Tau ² =0.02; Ch	i ² =6.42, df=2(P=0.04); I ² =68.8	33%			ĺ				
	F	avours midwifery	0.01	0.1	1	10	100	Favours other models	;

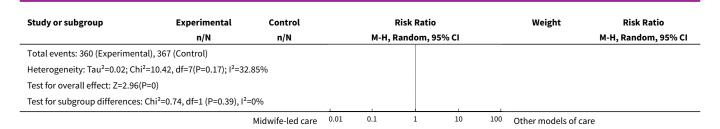




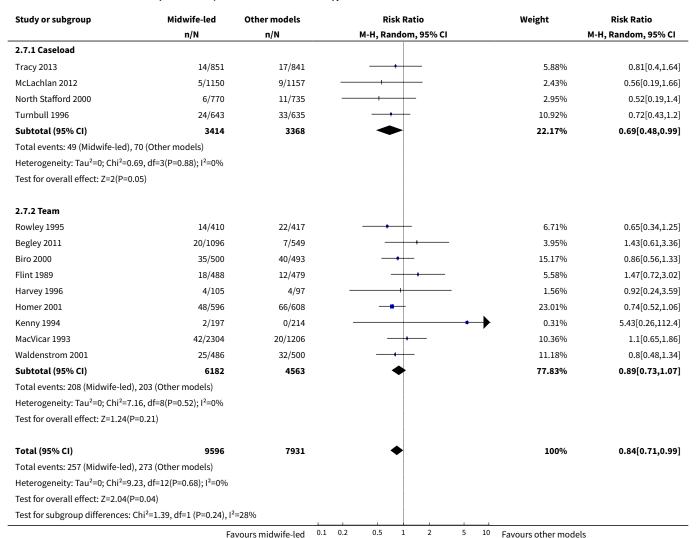
Analysis 2.6. Comparison 2 Midwife-led versus other models of care: variation in midwifery models of care (caseload/one-to-one or team), Outcome 6 Preterm birth (< 37 weeks).

Study or subgroup	Experimental	Control	Risk Ratio	Weight	Risk Ratio
	n/N n/N		M-H, Random, 95% CI		M-H, Random, 95% CI
2.6.1 Caseload					
McLachlan 2012	29/1150	48/1157		11.04%	0.61[0.39,0.96]
Tracy 2013	39/851	51/841	-+ 	12.88%	0.76[0.5,1.13]
Turnbull 1996	30/643	42/635	-+ 	10.97%	0.71[0.45,1.11]
Subtotal (95% CI)	2644	2633	•	34.89%	0.69[0.54,0.89]
Total events: 98 (Experimental),	141 (Control)				
Heterogeneity: Tau²=0; Chi²=0.5	, df=2(P=0.78); I ² =0%				
Test for overall effect: Z=2.86(P=	0)				
2.6.2 Team					
Begley 2011	48/1096	48/549	→	13.73%	0.5[0.34,0.74]
Biro 2000	36/500	42/493		12%	0.85[0.55,1.3]
MacVicar 1993	110/2304	70/1206		19.06%	0.82[0.61,1.1]
Rowley 1995	52/410	54/417	+	15.25%	0.98[0.69,1.4]
Waldenstrom 2001	16/486	12/500	+-	5.06%	1.37[0.66,2.87]
Subtotal (95% CI)	4796	3165	•	65.11%	0.81[0.62,1.07]
Total events: 262 (Experimental)), 226 (Control)				
Heterogeneity: Tau²=0.05; Chi²=	9.02, df=4(P=0.06); I ² =55.6	7%			
Test for overall effect: Z=1.47(P=	0.14)				
Total (95% CI)	7440	5798	•	100%	0.76[0.64,0.91]





Analysis 2.7. Comparison 2 Midwife-led versus other models of care: variation in midwifery models of care (caseload/one-to-one or team), Outcome 7 Overall fetal loss and neonatal death.



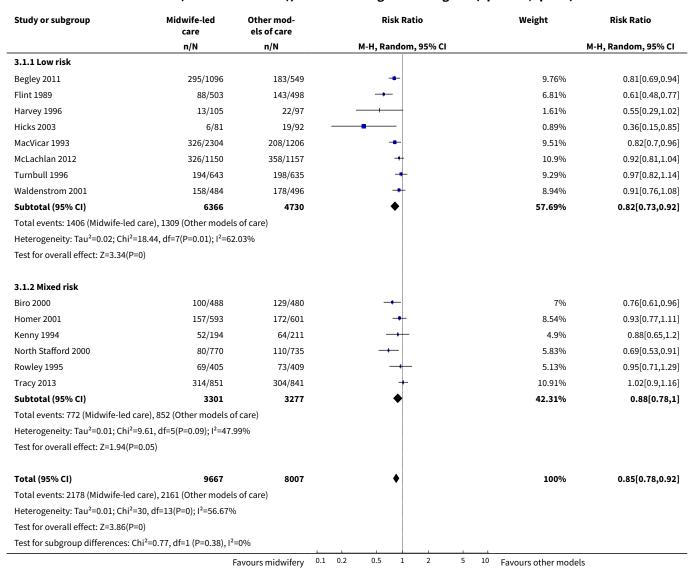


Comparison 3. Midwife-led versus other models of care: variation in risk status (low versus mixed)

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Regional analgesia (epidur- al/spinal)	14	17674	Risk Ratio (M-H, Random, 95% CI)	0.85 [0.78, 0.92]
1.1 Low risk	8	11096	Risk Ratio (M-H, Random, 95% CI)	0.82 [0.73, 0.92]
1.2 Mixed risk	6	6578	Risk Ratio (M-H, Random, 95% CI)	0.88 [0.78, 1.00]
2 Caesarean birth	14	17674	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.84, 1.00]
2.1 Low risk	8	11096	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.79, 1.06]
2.2 Mixed risk	6	6578	Risk Ratio (M-H, Random, 95% CI)	0.93 [0.84, 1.03]
3 Instrumental vaginal birth (forceps/vacuum)	13	17501	Risk Ratio (M-H, Random, 95% CI)	0.90 [0.83, 0.97]
3.1 Low risk	7	10923	Risk Ratio (M-H, Random, 95% CI)	0.89 [0.81, 0.99]
3.2 Mixed risk	6	6578	Risk Ratio (M-H, Random, 95% CI)	0.87 [0.73, 1.04]
4 Spontaneous vaginal birth (as defined by trial authors)	12	16687	Risk Ratio (M-H, Random, 95% CI)	1.05 [1.03, 1.07]
4.1 Low risk	7	10923	Risk Ratio (M-H, Random, 95% CI)	1.05 [1.02, 1.08]
4.2 Mixed risk	5	5764	Risk Ratio (M-H, Random, 95% CI)	1.06 [1.02, 1.10]
5 Intact perineum	10	13186	Risk Ratio (M-H, Random, 95% CI)	1.04 [0.95, 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	4	4570	Risk Ratio (M-H, Random, 95% CI)	0.99 [0.91, 1.08]
6 Preterm birth (< 37 weeks)	8	13238	Risk Ratio (M-H, Random, 95% CI)	0.76 [0.64, 0.91]
6.1 Low risk	5	9726	Risk Ratio (M-H, Random, 95% CI)	0.71 [0.54, 0.92]
6.2 Mixed risk	3	3512	Risk Ratio (M-H, Random, 95% CI)	0.87 [0.69, 1.09]
7 Overall fetal loss and neonatal death	13	17527	Risk Ratio (M-H, Random, 95% CI)	0.84 [0.71, 0.99]
7.1 Low risk	7	10895	Risk Ratio (M-H, Random, 95% CI)	0.94 [0.73, 1.20]
7.2 Mixed risk	6	6632	Risk Ratio (M-H, Random, 95% CI)	0.76 [0.61, 0.96]



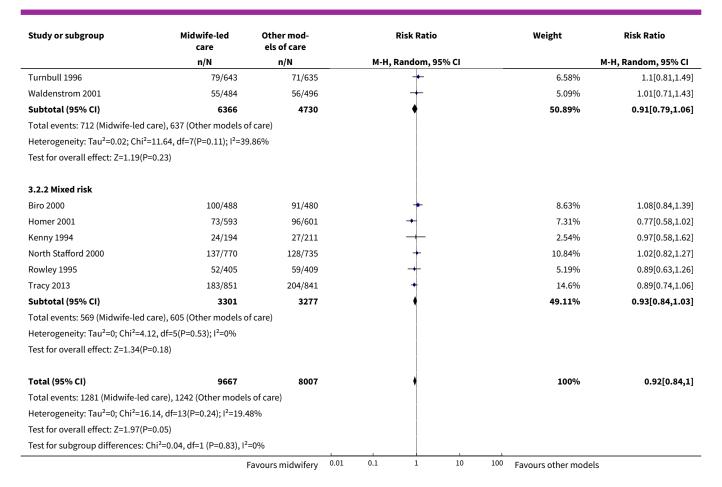
Analysis 3.1. Comparison 3 Midwife-led versus other models of care: variation in risk status (low versus mixed), Outcome 1 Regional analgesia (epidural/spinal).



Analysis 3.2. Comparison 3 Midwife-led versus other models of care: variation in risk status (low versus mixed), Outcome 2 Caesarean birth.

Study or subgroup	Midwife-led care	Other mod- els of care			Risk Ratio			Weight	Risk Ratio
	n/N	n/N		М-Н	, Random, 95	% CI			M-H, Random, 95% CI
3.2.1 Low risk									
Begley 2011	163/1096	84/549			+			9.3%	0.97[0.76,1.24]
Flint 1989	37/503	35/498			+			3.32%	1.05[0.67,1.63]
Harvey 1996	4/105	14/97			•—			0.61%	0.26[0.09,0.77]
Hicks 2003	9/81	14/92						1.14%	0.73[0.33,1.6]
MacVicar 1993	144/2304	78/1206			+			8.02%	0.97[0.74,1.26]
McLachlan 2012	221/1150	285/1157			*			16.83%	0.78[0.67,0.91]
	F	avours midwifery	0.01	0.1	1	10	100	Favours other models	5

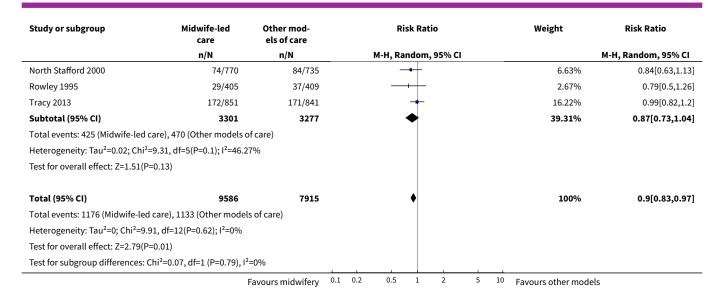




Analysis 3.3. Comparison 3 Midwife-led versus other models of care: variation in risk status (low versus mixed), Outcome 3 Instrumental vaginal birth (forceps/vacuum).

Study or subgroup	Midwife-led care	Other mod- els of care	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H, Random, 95% CI		M-H, Random, 95% CI
3.3.1 Low risk					
Begley 2011	139/1096	79/549	-+	8.81%	0.88[0.68,1.14]
Flint 1989	56/503	66/498		5.2%	0.84[0.6,1.17]
Harvey 1996	6/105	7/97		0.52%	0.79[0.28,2.27]
MacVicar 1993	187/2304	114/1206	-+ 	11.73%	0.86[0.69,1.07]
McLachlan 2012	202/1150	222/1157		19.54%	0.92[0.77,1.09]
Turnbull 1996	83/643	86/635	-	7.34%	0.95[0.72,1.26]
Waldenstrom 2001	78/484	89/496	-+	7.55%	0.9[0.68,1.18]
Subtotal (95% CI)	6285	4638	•	60.69%	0.89[0.81,0.99]
Total events: 751 (Midwife-led	d care), 663 (Other models o	of care)			
Heterogeneity: Tau ² =0; Chi ² =0	0.6, df=6(P=1); I ² =0%				
Test for overall effect: Z=2.25((P=0.02)				
3.3.2 Mixed risk					
Biro 2000	67/488	86/480		6.73%	0.77[0.57,1.03]
Homer 2001	71/593	63/601	+-	5.67%	1.14[0.83,1.57]
Kenny 1994	12/194	29/211		1.4%	0.45[0.24,0.86]
		Favours midwifery 0.1	1 0.2 0.5 1 2 5	Favours other mode	ls





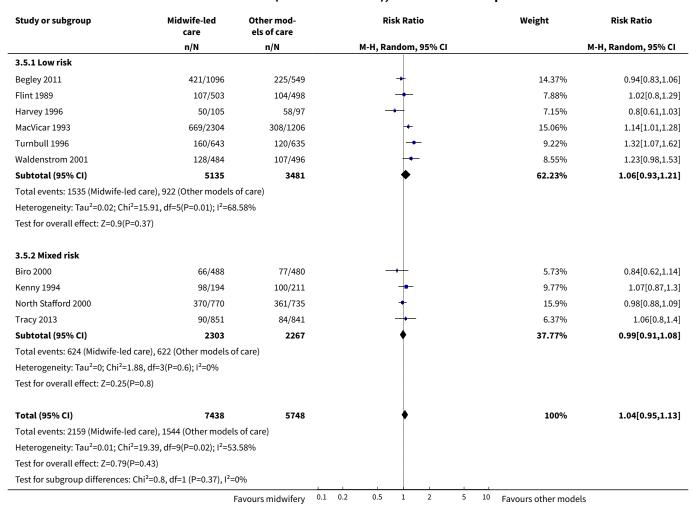
Analysis 3.4. Comparison 3 Midwife-led versus other models of care: variation in risk status (low versus mixed), Outcome 4 Spontaneous vaginal birth (as defined by trial authors).

Study or subgroup	Midwife-led care	Other mod- els of care	Risk Ratio	Weight	Risk Ratio	
	n/N	n/N	M-H, Random, 95% CI		M-H, Random, 95% CI	
3.4.1 Low risk						
Begley 2011	761/1096	372/549	+	8.83%	1.02[0.96,1.1]	
Flint 1989	386/503	372/498	+	8.74%	1.03[0.96,1.1]	
Harvey 1996	89/105	71/97	+	2.21%	1.16[1,1.34]	
MacVicar 1993	1847/2304	931/1206	•	25.13%	1.04[1,1.08]	
McLachlan 2012	719/1150	637/1157	+	9.1%	1.14[1.06,1.22]	
Turnbull 1996	450/643	440/635	+	8.26%	1.01[0.94,1.09]	
Waldenstrom 2001	362/484	360/496	<u>+</u>	7.78%	1.03[0.96,1.11]	
Subtotal (95% CI)	6285	4638	•	70.06%	1.05[1.02,1.08]	
Total events: 4614 (Midwife-le	ed care), 3183 (Other model	s of care)				
Heterogeneity: Tau ² =0; Chi ² =9	9.33, df=6(P=0.16); I ² =35.68 ⁰	%				
Test for overall effect: Z=2.89(P=0)					
3.4.2 Mixed risk						
Biro 2000	282/488	262/480	+	3.69%	1.06[0.95,1.18]	
Homer 2001	402/593	374/601	+	6.38%	1.09[1,1.18]	
Kenny 1994	158/194	155/211	+	4.11%	1.11[1,1.23]	
North Stafford 2000	542/770	509/735	+	9.63%	1.02[0.95,1.09]	
Tracy 2013	487/851	454/841	+	6.12%	1.06[0.97,1.15]	
Subtotal (95% CI)	2896	2868	•	29.94%	1.06[1.02,1.1]	
Total events: 1871 (Midwife-le	ed care), 1754 (Other model	s of care)				
Heterogeneity: Tau ² =0; Chi ² =2	2.63, df=4(P=0.62); I ² =0%					
Test for overall effect: Z=2.85(P=0)					
Total (95% CI)	9181	7506		100%	1.05[1.03,1.07]	
Total events: 6485 (Midwife-le	ed care), 4937 (Other model	s of care)				
Heterogeneity: Tau ² =0; Chi ² =1	12.16, df=11(P=0.35); l ² =9.57	7%				
Test for overall effect: Z=4.38(P<0.0001)					



Study or subgroup	Midwife-led care	Other mod- els of care		Risk Ratio				Weight	Risk Ratio		
	n/N	n/N			M-H, Ra	ndom	ı, 95% CI				M-H, Random, 95% CI
Test for subgroup differences: Chi ² =0.11, df=1 (P=0.74), I ² =0%											
	Favours other models			0.2	0.5	1	2	5	10	Favours midwifery	

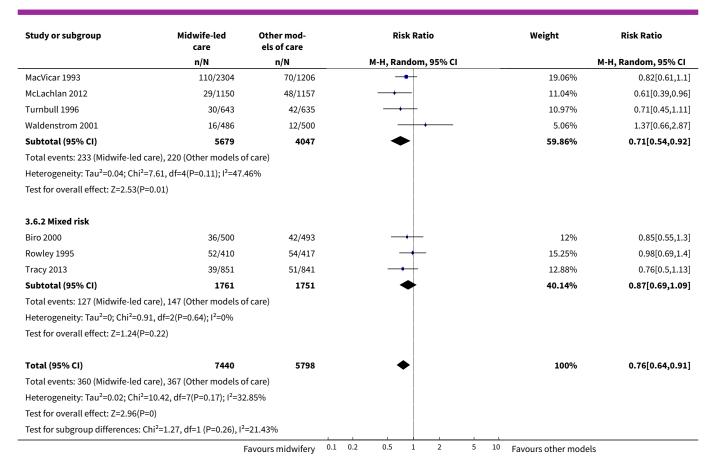
Analysis 3.5. Comparison 3 Midwife-led versus other models of care: variation in risk status (low versus mixed), Outcome 5 Intact perineum.



Analysis 3.6. Comparison 3 Midwife-led versus other models of care: variation in risk status (low versus mixed), Outcome 6 Preterm birth (< 37 weeks).

Study or subgroup	Midwife-led care	Other mod- els of care	Risk Ratio						Weight	Risk Ratio	
	n/N	n/N			M-H, Raı	ndom	, 95% CI				M-H, Random, 95% CI
3.6.1 Low risk											
Begley 2011	48/1096	48/549			-					13.73%	0.5[0.34,0.74]
	F	avours midwifery	0.1	0.2	0.5	1	2	5	10	Favours other models	5

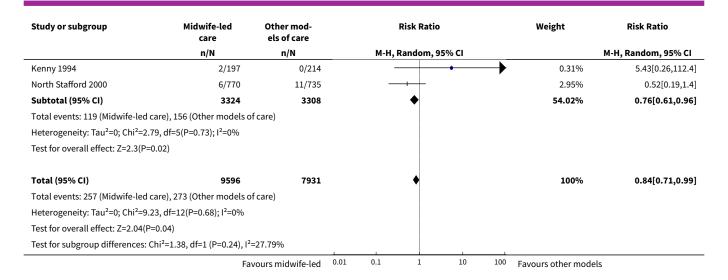




Analysis 3.7. Comparison 3 Midwife-led versus other models of care: variation in risk status (low versus mixed), Outcome 7 Overall fetal loss and neonatal death.

Study or subgroup	Midwife-led care	Other mod- els of care	Risk Ratio	Weight	Risk Ratio	
	n/N n/N		M-H, Random, 95% CI		M-H, Random, 95% CI	
3.7.1 Low risk						
McLachlan 2012	5/1150	9/1157		2.43%	0.56[0.19,1.66]	
Begley 2011	20/1096	7/549	- + -	3.95%	1.43[0.61,3.36]	
Flint 1989	18/488	12/479	+	5.58%	1.47[0.72,3.02]	
Harvey 1996	4/105	4/97		1.56%	0.92[0.24,3.59]	
MacVicar 1993	42/2304	20/1206	+	10.36%	1.1[0.65,1.86]	
Turnbull 1996	24/643	33/635	+	10.92%	0.72[0.43,1.2]	
Waldenstrom 2001	25/486	32/500	+	11.18%	0.8[0.48,1.34]	
Subtotal (95% CI)	6272	4623	*	45.98%	0.94[0.73,1.2]	
Total events: 138 (Midwife-led care), 1	117 (Other models o	f care)				
Heterogeneity: Tau ² =0; Chi ² =5.05, df=	6(P=0.54); I ² =0%					
Test for overall effect: Z=0.52(P=0.61)						
3.7.2 Mixed risk						
Rowley 1995	14/410	22/417	-+	6.71%	0.65[0.34,1.25]	
Tracy 2013	14/851	17/841		5.88%	0.81[0.4,1.64]	
Biro 2000	35/500	40/493	-+	15.17%	0.86[0.56,1.33]	
Homer 2001	48/596	66/608		23.01%	0.74[0.52,1.06]	
	Fa	vours midwife-led 0.0.	1 0.1 1 10 1	.00 Favours other model	S	





ADDITIONAL TABLES

Table 1. Women's experiences of care

Satisfaction	Inter- vention (n/N)	Con- trol (n/ N)	Rela- tive rate	95% CI	Sta- tis- tical test	P val- ue
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		
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	Differ- ence			
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
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	2.72-6.5	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	1.22-7.2	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		
Turnbull 1996	n/N	n/N	Mean differ- ence - sat- isfac-			



Table 1. Warranta ayrayingan of age (c.)					
Table 1. Women's experiences of care (Continued)			tion 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 differ- ence?		0.0000
Care and sensitivity of staff (labour and delivery)	1.26	1.58	Mean differ- ence?		0.008
Care and sensitivity of staff (postpartum at home)	1.24	1.57	Mean differ- ence?		0.0000
Harvey 1996					
Labour and Delivery Satisfaction Index +	211	185	26	18.8-33.1	0.001
Labour and Delivery Satisfaction mack :					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



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

APPENDICES

Appendix 1. Search methods used in previous versions of this review

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting the Trials Search Co-ordinator (January 2008).

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

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

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

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

In addition, we searched the Cochrane Effective Practice and Organisation of Care Group's Trials Register (January 2008), Current Contents (1994 to January 2008), CINAHL (1982 to August 2006), Web of Science, BIOSIS Previews, ISI Proceedings, (1990 to 2008), and the WHO Reproductive Health Library (WHO-RHL), No. 9. Through WHO-RHL we obtained unpublished studies from the System for Information on Grey Literature In Europe (SIGLE). We used the search strategy detailed below, modifying it for each database as appropriate by checking each thesaurus for relevant subject headings and replacing them with text-word search terms when a subject heading was not available.

We did not apply any language restrictions.

- 1 exp Pregnancy/
- 2 exp Prenatal Care/
- 3 exp Intrapartum Care/
- 4 exp Obstetric Care/
- 5 exp Postnatal Care/
- 6 exp Midwifery/
- 7 exp Midwifery Service/
- 8 exp Obstetric Service/
- 9 exp Home Childbirth/
- 10 exp Alternative Birth Centers/
- 11 or/1-10
- 12 exp Continuity of Patient Care/
- 13 exp Nursing Care Delivery Systems/
- 14 (midwif\$ adj2 team\$).tw.
- 15 (midwif\$ adj model\$).tw.
- 16 (multidisciplinary adj team\$).tw.
- 17 (share\$ adj care).tw.
- 18 (midwif\$ adj led).tw.
- 19 (midwif\$ adj manag\$).tw.
- 20 (medical\$ adj led).tw.
- 21 (medical adj manag\$).tw.
- 22 or/12-21

^{*: 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.



23 exp Clinical Trials/ 24 11 and 22 and 23

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

Blake, 19 November 2013

Summary

The Society of Obstetricians and Gynaecologists of Canada (SOGC) is the longest established national organization for women's reproductive care in North America, with membership made up of obstetricians, gynaecologists, nurses, midwives, family physicians and scientists. We have long supported a woman's right to choose the care provider of her preference for obstetrical care, and we actively support and promote collaborative models of care.

We were therefore very interested to read the review of midwifery-led care that you published in August of this year. We were not surprised by the main findings cited in the abstract: less use of epidural or intra-partum analgesia, fewer instrumental deliveries and, in consequence, fewer episiotomies, longer length of labour. These differences would be expected with the different model of care; for some women an unmediated delivery is a goal. However, for others, access to analgesia is a key consideration; we cannot conclude from this difference that the midwifery-led model is better for all women.

We were interested by the findings of fewer preterm births, fewer deaths <24weeks, findings which are unexplained, and for which it is unlikely that we could identify an explanation based on who was providing the care, given that there are few, if any, clinical interventions by any provider prior to 24 weeks which can affect these outcomes.

Beyond these matters, however, we are primarily contacting you because the abstract failed to list the important outcomes which do not differ with provider: perineal trauma, induction of labour, oxytocin augmentation of labour, caesarean section, antenatal hospitalisation, post-partum haemorrhage, length of hospital stay, initiation of breast feeding, neonatal Apgar score, admission to neonatal nursery, fetal loss or death >24 weeks.

Our greatest concern is that, although the abstract failed to list or consider these fundamentally important clinical outcomes that were equivalent, the authors still asserted that "most women should be offered midwifery-led continuity models of care and women should be encouraged to ask for this option..."

We believe this conclusion received, and continues to receive, the bulk of media and lay attention. In fact, those who do not actually read the review but only the abstract will come away with an incorrect understanding that is not supported by the results, an outcome that appears to be self-serving and misleading.

We expect better from the Cochrane Collaboration. This was an opportunity to provide women with reassurance that they have healthful options for their pregnancy care, and that they can feel confident that, regardless of their choice, the outcomes will be similar with respect to a safe and healthy pregnancy and delivery. Instead, the way this issue has been positioned, and by the selective use of the data, the Cochrane appears to advocate for a particular model of care, a disservice to women and the many other health care professionals who care for them.

Comment received from Jennifer Blake, Society of Obstetricians and Gynaecologists of Canada, November 2013.

Reply

We are pleased to see the SOGC's interest in our review and thank them for their comments.



We agree that findings of fewer preterm births and fewer deaths less than 24weeks are interesting. Midwife-led continuity of care is a complex intervention, and it is impossible to unpick the relative importance of philosophy and continuity of care. We note in our review that questions remain about the mechanisms underlying these findings.

Our abstract is reported in original format in an effort to present information on multiple outcomes in as clear a manner as possible. Further to your comments, in the updated review, we have reformatted the presentation of outcomes in the abstract such that all primary outcomes are presented initially followed by all secondary outcomes. This will, we believe provide the reader with the totality of information on which to inform their health care decisions. Similarly, we have revised the conclusion to summarise the findings of the review and key areas for further research.

We trust this addresses your concerns.

Regards

Jane Sandall, August 2015

Contributors

Jane Sandall

WHAT'S NEW

Date	Event	Description
23 September 2015	Amended	Correction to abstract. Clarification of results for the outcomes "No intrapartum analgesia/anaesthesia" and "Attendance at birth by known midwife".

HISTORY

Protocol first published: Issue 1, 2004 Review first published: Issue 4, 2008

Date	Event	Description
31 May 2015	New citation required but conclusions have not changed	Two new studies included (Allen 2013; Tracy 2013); two studies excluded (Famuyide 2014; Gu 2013). The conclusions remain the same.
31 May 2015	New search has been performed	Search updated. A 'Summary of findings' table has been incorporated.
19 November 2013	Feedback has been incorporated	Feedback 2 received from Jennifer Blake.
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 breastfeeding initiation.
28 January 2013	New search has been performed	Search updated. Methods updated.
29 April 2009	Amended	In response to feedback, we have clarified what is meant by mid- wife-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



Date	Event	Description
		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. Declan and Jane were not involved in assessing or data extraction for these studies.



SOURCES OF SUPPORT

Internal sources

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

External sources

- · National Institute for Health Research, UK.
 - 2013 update. NIHR Programme of centrally-managed pregnancy and childbirth systematic reviews of priority to the NHS and users of the NHS: 10/4001/02
- UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP), Department of Reproductive Health and Research (RHR), World Health Organization, Switzerland.
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 Sheffield Hallam University. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the
 Department of Health, UK.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Breastfeeding on hospital discharge, maternal satisfaction were added as outcomes for this update (2015).

INDEX TERMS

Medical Subject Headings (MeSH)

Amnion [surgery]; Continuity of Patient Care [*organization & administration]; Infant Mortality; Midwifery [economics] [*methods] [organization & administration]; Models, Organizational; Patient Satisfaction; 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; Infant, Newborn; Pregnancy