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Fetal movement counting for assessment of fetal wellbeing (Review)

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[Intervention Review]

Fetal movement counting for assessment of fetal wellbeing

Lindeka Mangesi[1], G Justus Hofmeyr[2], Valerie Smith[3], Rebecca MD Smyth[4]

[1]Epidemiological Research and Surveillance Management Directorate, Eastern Cape Department of Health, Bisho, South Africa. [2]Walter Sisulu University; Centre for Evidence-based Health Care, Faculty of Medicine and Health Sciences, Stellenbosch University; and Eastern Cape Department of Health, East London, South Africa. [3]School of Nursing and Midwifery, Trinity College Dublin, Dublin, Ireland. [4]School of Nursing, Midwifery and Social Work, The University of Manchester, Manchester, UK

Contact address: Lindeka Mangesi, Epidemiological Research and Surveillance Management Directorate, Eastern Cape Department of Health, Private Bag X0038, Bisho, 5605, South Africa. lin.mangesi@gmail.com.

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ABSTRACT

Background

Fetal movement counting is a method by which a woman quantifies the movements she feels to assess the condition of her baby. The purpose is to try to reduce perinatal mortality by alerting caregivers when the baby might be compromised. This method may be used routinely, or only in women who are considered at increased risk of complications affecting the baby. Fetal movement counting may allow the clinician to make appropriate interventions in good time to improve outcomes. On the other hand, fetal movement counting may cause unnecessary anxiety to pregnant women, or elicit unnecessary interventions.

Objectives

To assess outcomes of pregnancy where fetal movement counting was done routinely, selectively or was not done at all; and to compare different methods of fetal movement counting.

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (31 May 2015) and reference lists of retrieved studies.

Selection criteria

Randomised controlled trials (RCTs) and cluster-RCTs where fetal movement counting was assessed as a method of monitoring fetal wellbeing.

Data collection and analysis

Two review authors assessed studies for eligibility, assessed the methodological quality of included studies and independently extracted data from studies. Where possible the effects of interventions were compared using risk ratios (RR), and presented with 95% confidence intervals (CI). For some outcomes, the quality of the evidence was assessed using the GRADE approach.

Main results

Five studies (71,458 women) were included in this review; 68,654 in one cluster-RCT. None of these five trials were assessed as having low risk of bias on all seven risk of bias criteria. All included studies except for one (which included high-risk women as participants) included women with uncomplicated pregnancies.Two studies compared fetal movement counting with standard care, as defined by trial authors. Two included studies compared two types of fetal movement counting; once a day fetal movement counting (Cardiff count-to-10) with more than once a day fetal movement counting methods. One study compared fetal movement counting with hormone assessment.

(1) Routine fetal movement counting versus mixed or undefined fetal movement counting

No study reported on the primary outcome 'perinatal death or severe morbidity'. In one large cluster-RCT, there was no difference in mean stillbirth rates per cluster (standard mean difference (SMD) 0.23, 95% CI -0.61 to 1.07; participants = 52 clusters; studies = one, *low quality evidence*). The other study reported no fetal deaths. There was no difference in caesarean section rate between groups (RR 0.93, 95% CI 0.60 to 1.44; participants = 1076; studies = one,*low quality evidence*). Maternal anxiety was significantly reduced with routine fetal movement counting (SMD -0.22, 95% CI -0.35 to -0.10; participants = 1013; studies = one, *moderate quality evidence*). Maternal-fetal attachment was not significantly different (SMD -0.02, 95% CI -0.15 to 0.11; participants = 951; studies = one, *low quality evidence*). In one study antenatal admission after reporting of decreased fetal movements was increased (RR 2.72, 95% CI 1.34 to 5.52; participants = 123; studies = one). In another there was a trend to more antenatal admissions per cluster in the counting group than in the control group (SMD 0.38, 95% CI -0.17 to 0.93; participants = 52 clusters; studies = one, *low quality evidence*). Birthweight less than 10th centile was not significantly different between groups (RR 0.98, 95% CI 0.66 to 1.44; participants = 1073; studies = one, *low quality evidence*). The evidence was of low quality due to imprecise results and because of concerns regarding unclear risk of bias.

(2) Formal fetal movement counting (Modified Cardiff method) versus hormone analysis

There was no difference between the groups in the incidence of caesarean section (RR 1.18, 95% CI 0.83 to 1.69; participants = 1191; studies = one). Women in the formal fetal movement counting group had significantly fewer hospital visits than those randomised to hormone analysis (RR 0.26, 95% CI 0.20 to 0.35), whereas there were fewer Apgar scores less than seven at five minutes for women randomised to hormone analysis (RR 1.72, 95% CI 1.01 to 2.93). No other outcomes reported showed statistically significant differences. 'Perinatal death or severe morbidity' was not reported.

(3) Formal fetal movement counting once a day (count-to-10) versus formal fetal movement counting method where counting was done more than once a day (after meals)

The incidence of caesarean section did not differ between the groups under this comparison (RR 2.33, 95% CI 0.61 to 8.99; participants = 1400; studies = one). Perinatal death or severe morbidity was not reported. Women were more compliant in using the count-to-10 method than they were with other fetal movement counting methods, citing less interruption with daily activities as one of the reasons (non-compliance RR 0.25, 95% CI 0.19 to 0.32).

Except for one cluster-RCT, included studies were small and used different comparisons, making it difficult to measure the outcomes using meta-analyses. The nature of the intervention measured also did not allow blinding of participants and clinicians..

Authors' conclusions

This review does not provide sufficient evidence to influence practice. In particular, no trials compared fetal movement counting with no fetal movement counting. Only two studies compared routine fetal movements with standard antenatal care, as defined by trial authors. Indirect evidence from a large cluster-RCT suggested that more babies at risk of death were identified in the routine fetal monitoring group, but this did not translate to reduced perinatal mortality. Robust research by means of studies comparing particularly routine fetal movement counting with selective fetal movement counting is needed urgently, as it is a common practice to introduce fetal movement counting only when there is already suspected fetal compromise.

PLAIN LANGUAGE SUMMARY

Fetal movement counting for assessment of fetal wellbeing

Not enough evidence on counting the baby's movements in the womb to check for wellbeing.

Mothers can usually feel their babies moving in their wombs from around 16 to 20 weeks. Babies' activities in the womb can vary considerably, some being very active and some not so active. A decrease in a baby's normal pattern of movements may be a sign that the baby is struggling for some reason and it might be better for the baby to be born early. Hence, it has been suggested that if the mother counts her babies' movements each day, and there are several ways of doing this, she may be able to identify a decrease in her baby's normal movement patterns. It is further suggested that if the mother informs caregivers of this, then the caregivers can do additional tests and some babies can be prevented from dying before birth. However, sometimes fetal movement-counting tests can cause considerable anxiety for women and may not be easy for some women especially when a mother is busy at work or caring for other small children, so it is important to assess if these tests are helpful in identifying babies in difficulty with time then to intervene.

The review of trials found five studies, involving 71,458 women, comparing two fetal movement counting methods, fetal movement counting versus hormonal analysis and routine fetal movement counting compared with standard antenatal care, as defined by trial authors. In studies that compared routine counting of baby's movements in the womb with mixed or undefined counting, there was no difference in stillbirths, caesarean sections, birth weight less than 10th centile and mother-baby attachment; there was reduction in women's anxiety in the group counting the baby's movements. There was a tendency to more antenatal admissions. When counting of baby's movement was compared with hormonal analysis, there were fewer hospital visits among women who were counting and fewer babies in the hormonal analysis group had low Apgar scores, which assess the baby's condition after birth. There was no difference between

the groups in terms of caesarean sections done and other outcomes. 'Perinatal death or severe morbidity' was not reported. When different types of fetal movement counting methods (once a day compared to more than once a day) were compared, women were more compliant in using the once a day counting method, citing less interruption with daily activities as one of the reasons; the incidence of caesarean section did not differ and perinatal death or severe illness was not reported. The numbers and the methodological quality of studies were insufficient to assess stillbirths accurately. Further trials are suggested, and it would be very important to assess women's anxiety and views in addition to the ability of the counting to prevent stillbirths.

Summary of findings for the main comparison. Routine fetal movement counting compared with mixed or undefined fetal movement counting for assessment of fetal wellbeing

Routine fetal movement counting compared with mixed or undefined fetal movement counting for assessment of fetal wellbeing

Patient or population: Pregnant women who had reached the gestational age of fetal viability
Settings: High-income countries (Norway, United Kingdom, Ireland, Sweden, Belgium and the USA)
Intervention: Routine fetal movement counting
Comparison: Mixed or undefined fetal movement counting

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Mixed or undefined fetal movement counting	Routine fetal movement counting				
Perinatal death and or severe morbidity (neonatal intensive care unit admission, neonatal encephalopathy)	None of the included studies mentioned this composite outcome among their outcomes of interest. If in future updates we find a study that reports this composite outcome, we will include in the table					
Caesarean section	Study population		RR 0.93 (0.60 to 1.44)	1076 (1 RCT)	⊕⊕⊝⊝ LOW [1,2]	
	71 per 1000	66 per 1000 (43 to 103)				
Perinatal death	Study population		not estimable	1076 (1 RCT)	⊕⊕⊝⊝ LOW [1,2]	
	0 per 1000	0 per 1000 (0 to 0)				
Maternal anxiety	The mean maternal anxiety in the control group was 0.9	The mean maternal anxiety in the intervention group was 0.22 **standard deviations lower** (0.35 to 0.10 lower)	SMD-0.22; 95% CI -0.35, -0.10	1013 (1 RCT)	⊕⊕⊕⊝ MODERATE [1]	Cambridege Worry Scale was used to assess maternal anxiety. The difference was sta-

						tistically significant but would not be clinically important
Maternal-fetal attachment	The mean maternal-fetal attachment in the control group was 59.54	The mean maternal-fetal attachment in the intervention group was 0.2**standard deviations lower** (0.15 lower to .11 higher)	SMD -0.02; 95% CI -0.15, 0.11	951 (1 RCT)	⊕⊕⊖⊖ LOW [1,2]	
Antenatal hospital admission rate per cluster (mean)	The mean antenatal hospital admission rate per cluster (mean) in the control group was 24	The mean antenatal hospital admission rate per cluster (mean) in the intervention group was 0.38 **standard deviations lower** (3.61 lower to 21.61 higher)	SMD 0.38; 95% CI -0.17, 0.93	52 (1 RCT)	⊕⊕⊖⊖ LOW [1,2]	
Low birthweight (< 2500 g or < 10th centile)	Study population		RR 0.98 (0.66 to 1.44)	1073 (1 RCT)	⊕⊕⊖⊖ LOW [1,2]	
	87 per 1000	85 per 1000 (57 to 125)				

*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; **SMD:** standardised mean difference

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]The effect provided by one study with design limitations (-1)
[2]Wide CI crossing the line of no effect (-1)

BACKGROUND

The goal for care during pregnancy is a healthy baby and a satisfied mother. There are many ways of monitoring the baby's condition during pregnancy. Examples of these are auscultation of the fetal heart with the fetal stethoscope, cardiotocography (Alfirevic 2006; Grivell 2010; Pattison 2010), fetal acoustic (Tan 2013) or other stimulation, ultrasound for biophysical profile (Lalor 2008), umbilical artery waveform analysis (Alfirevic 2015), fetal echocardiography and colour flow mapping, fetal electrocardiography (Neilson 2013), fetal pulse oximetry (East 2014) and fetal movement counting. Fetal movement counting is the only method which can be used by the mother without the need for a clinician or equipment.

Description of the condition

Primigravidae usually feel fetal movements for the first time at 18 to 20 weeks and multipara start feeling fetal movements at 16 to 18 weeks (Cronje 1996). Fetal movements are maximal between 28 and 34 weeks and, although there is evidence to suggest that fetal movements do not decrease in late pregnancy (Rådestad 2010; Winje 2011), there is often a perceived decrease in fetal movements near term. This is because movements become more organised as pregnancy progresses with increased motor co-ordination resulting in slower, more powerful, gross movements (D'Elia 2001; Rayburn 1990). Fetal movements can occur without the mother recognising them, especially at term, when the mother recognises about 40% of fetal movements. Fetal movements in a healthy fetus can vary from four to 100 movements per hour (Cronje 1996).

When the fetus is compromised, movements may be decreased as the fetus reduces oxygen consumption in an effort to conserve energy supplies and movements may not be felt for one or more days. A period of decreased fetal movements commonly precedes fetal death, but the absence of perceived fetal movements does not necessarily indicate fetal death or fetal compromise. Decreased fetal movements may be due to decreased amniotic fluid, drugs, smoking habits, maternal overweight, sedatives, sleep state in the fetus and fetal compromise (Sellers 1993; Tveit 2010). External stimuli may either increase, decrease, or even arrest fetal movements (Cronje 1996). Some suggest that fetal movement counting should be performed in all high-risk women, whether they are admitted to hospital or not (Cronje 1996), but the evidence to support this needs to be assessed.

Description of the intervention

Fetal movement counting is a method used by the mother to quantify her baby's movements (for descriptions of formal fetal movement counting, *see* Table 1). When counting fetal movements at rest, a woman may be asked to empty her bladder, lie on her side, relax, put her hand on her abdomen and count the fetal movements over the period specified for the method used. Fetal movements may also be counted during normal activity. Patterns of fetal movements are considered an indicator of fetal wellbeing (Bennet 1999). According to Smith 1992, all participants in their study, comparing three different methods of fetal movement counting, saw monitoring of fetal movements as a necessary activity. They found a 'count-to-10' method more user-friendly than the other methods and higher rates of compliance with a 'count-to-10' method have been found (Christensen 2003; Gomez 2007a). The study by Liston 1994 found no deleterious side-effects in low-risk pregnant women monitoring their babies by fetal movement counting.

In the 'count-to-10' method, the woman is asked to count 10 fetal movements from a specific time each day. She is advised to report if the fetus takes longer than usual to achieve the 10 movements, or if there are fewer than 10 movements in 12 hours (Bennet 1999). This is taken as a warning sign that the fetus may be becoming compromised. In the Sadovsky method a woman counts fetal movements three times a day after meals (F).

In the fixed-period method, fetal movement counting may be done over a period of one hour, daily or, if a rapidly changing condition is anticipated, six-hourly. If fetal movements are fewer than four in one hour, movement counting is repeated in the next hour (Freda 1993). Fetal movement counting may be done in hospital or at home, and the chart brought to every antenatal visit.

How the intervention might work

A sudden decrease in the number of fetal movements is suggestive of fetal compromise (Cronje 1996). The rationale for fetal movement counting is that it is hoped that fetal death can be prevented by acting immediately when the woman reports decreased fetal movements.

When starting a woman on a fetal movement chart, it has been suggested that a clinician should go through the procedure with her and palpate her abdomen as she is counting fetal movements to see whether she can identify them (Tucker 2000). Providing uniform information aimed at increasing maternal awareness and vigilance to decreased fetal activity has been associated benefit in reducing stillbirth rates (Tveit 2009).

Sometimes the period between decreased movements and fetal death is too short for clinicians to intervene to prevent fetal death (Enkin 2000). If fetal movements are decreased from the normal pattern of the baby's movement, fetal wellbeing can be assessed with further tests such as cardiotocography (CTG - electronic measurement of the baby's heartbeat) (Nolte 1998; Tucker 2000). Most clinicians would agree that if the CTG pattern is reactive with normal fetal activity and no other complications of pregnancy, there is no need for other forms of assessment (Tucker 2000).

Why it is important to do this review

Fetal movement counting is simple, and can be done at home. It is economical as there are no human or material resources needed, but it does intrude on the woman's time and it may cause unnecessary anxiety to the mother. It may lead to staff overload as additional investigations may have to be done to exclude fetal compromise. It might increase antenatal admissions, obstetric interventions and prematurity. It is important to establish whether, in practice, benefits outweigh risks or vice versa, both as a routine procedure and in selected high-risk pregnancies.

A previous review of two randomised trials found that routine counting was associated with frequent reports of decreased fetal activity, increased use of other techniques, frequent antepartum admissions and increased caesarean sections on the basis of decreased fetal movements (Enkin 2000). Some authors have continued to highlight the importance of the method while others express concerns about the disadvantages of fetal

movement counting. Furthermore, survey research has revealed wide variation in clinical practice, internationally, with regard to fetal movement assessment (Heazell 2008; Smith 2014). It is important that this review be conducted to address whether this method is useful to identify fetal compromise in time for effective interventions. Although inexpensive, the test should not be performed unless it proves to do more good than harm.

The original version of this review did not provide any conclusive evidence as to whether fetal movement counting is beneficial or not. It recommended that robust research should be conducted to assess fetal movement counting for the assessment of fetal wellbeing.

OBJECTIVES

To compare the outcome of pregnancy when fetal movement counting is done routinely, selectively, or not at all, and using various methods.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised clinical trials or cluster-randomised trials in which fetal movement counting was assessed. We excluded quasi-randomised trials.

Types of participants

Pregnant women who had reached the gestational age of fetal viability, as defined in the trial setting.

Types of interventions

1. Routine fetal movement counting in all women
2. Selective fetal movement counting: fetal movement counting done by women considered to be at high risk of fetal compromise
3. Different methods of fetal movement counting: once a day or more than once a day fetal movement counting

Types of outcome measures

Primary outcomes

1. Perinatal death or severe morbidity (neonatal intensive care unit admission, neonatal encephalopathy)
2. Caesarean section

Secondary outcomes

Maternal outcomes

1. Maternal satisfaction as defined by trial authors
2. Maternal anxiety as defined by trial authors
3. Maternal-fetal attachment as defined by trial authors
4. Non-compliance (not pre-specified)

Pregnancy complications

1. Antenatal hospital admission
2. Other fetal testing
3. Stillbirths
4. Premature birth
5. Birthweight; less than 2500 g or less than 10th centile (not pre-specified)
6. Assisted birth
7. Operative birth
8. Number of hospital visit (not pre-specified)
9. Consultation for decreased fetal movements (not pre-specified)

Neonatal outcomes

1. Five-minute Apgar score less than seven
2. Umbilical arterial pH less than 7.2
3. Neonatal intensive care unit admission
4. Respiratory distress syndrome
5. Neonatal encephalopathy
6. Early neonatal death
7. Perinatal death
8. Childhood disability

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:

1. 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;
6. 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 Co-ordinator searches the register for each review using the topic list rather than keywords.

Searching other resources

We also searched the reference lists of relevant papers.

We did not apply any language or date restrictions.

Data collection and analysis

For the methods used when assessing the trials identified in the previous version of this review, *see* Mangesi 2007.

For this update we used the following methods when assessing the reports identified by the updated search. The methods are 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 we identified as a result of the search strategy. We resolved any disagreement through discussion and by involving one of the review authors. We requested assistance from the Cochrane Pregnancy and Childbirth Group for translation of one study that was not written in English.

Data extraction and management

We used standard Cochrane Pregnancy and Childbirth Group Data Extraction Template to extract data from studies. For eligible studies, two review authors extracted the data using the agreed form. We resolved discrepancies through discussion and involving one of the authors. We entered data into Review Manager software (RevMan 2014) and checked for accuracy.

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

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). We resolved any disagreement by discussion and by involving one of the authors. For individual randomised trials we assessed the risk of bias using the criteria (1) to (7) below. For cluster-randomised trials we had planned to assess the risk of bias using the criteria described in section 16.3.2 of the *Handbook* (i.e. recruitment bias, baseline imbalance, loss of clusters, incorrect analysis and comparability with individually-randomised trials); however, as the one included cluster trial (Grant 1989) had no loss of clusters and randomised participants at an individual participant level within multiple sites, we assessed this report as per the criteria outlined below.

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

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

We assessed the method as:

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

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

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

We assessed the methods as:

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

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

We 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 are at low risk of bias if they were blinded, or if we judged that the lack of blinding would be 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.

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. greater than 20% of missing data on primary outcomes, 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 pre-specified 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 have about other possible sources of bias.

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

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

(7) Overall risk of bias

We 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, we assessed the likely magnitude and direction of the bias and whether we considered it was likely to impact on the findings.

Assessment of the quality of evidence using GRADE

For this update the quality of the evidence was assessed using the GRADE approach as outlined in the GRADE handbook in order to assess the quality of the body of evidence relating to the following key outcomes for the comparison "routine fetal movement counting versus mixed or undefined fetal movement counting".

1. Perinatal death or severe morbidity (neonatal intensive care unit admission, neonatal encephalopathy)
2. Caesarean section
3. Perinatal death
4. Maternal anxiety as defined by trial authors
5. Maternal-fetal attachment as defined by trial authors
6. Antenatal hospital admission
7. Birthweight; < 2500 g or < 10th centile (not pre-specified)

We used GRADEpro Guideline Development Tool 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 was 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.

Measures of treatment effect

Dichotomous data

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

Continuous data

For continuous data, we used the mean difference if outcomes are measured in the same way between trials. We used the standardised mean difference to combine trials that measure the same outcome, but used different methods.

Unit of analysis issues

For all included trials, except one (Grant 1989), an individual woman, an individual fetus or an individual neonate was the unit of analysis. None of the studies included women with twin pregnancies. The Grant 1989 study used clusters as the unit of analysis.

Cluster-randomised trials

We included cluster-randomised trials in the analyses along with individually-randomised trials. We planned to adjust their sample sizes using the methods described in the *Handbook* [Section 16.3.4 or 16.3.6] using an estimate of the intracluster correlation co-efficient (ICC) derived from the trial (if possible), from a similar trial or from a study of a similar population. Where both cluster-randomised trials and individually-randomised trials, were identified, we had planned to synthesise the relevant information. This, however, was not possible due to the diverse nature of the interventions and lack of comparable data to perform a meta-analysis.

The one cluster-randomised trial included presented data by cluster, not individual, therefore sample size adjustment was not necessary.

We assessed qualitative data on women's views of the method in the discussion section.

Cross-over trials

We did not include any cross-over trials in this review and we do not intend to include them in the future because fetal movements depend on the age of the fetus and comparing fetal movements at different fetal ages will not be ideal.

Other unit of analysis issues

The unit of analysis was an individual woman in maternal outcomes and where outcomes measures were fetal or neonatal the unit of analysis was an individual fetus or an individual neonate respectively. All included studies excluded women with twin pregnancies.

Dealing with missing data

For included studies, we noted levels of attrition. Had we detected high levels of missing data in studies, we would have explored the impact of including these studies in the overall assessment of treatment effect by using sensitivity analysis. However, due to the differing nature of the interventions in the review and the absence/limited number of meta-analyses, this was not necessary.

For all outcomes, we carried out analyses, 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, and all participants were analysed in the group to which they were allocated, regardless of whether or not they received the allocated intervention. The denominator for each outcome in each trial was the number randomised minus any participants whose outcomes were known to be missing.

Assessment of heterogeneity

We had few studies, measuring different comparisons and different outcomes. We performed only one meta-analysis. We assessed statistical heterogeneity using the Tau^2, I^2 and Chi^2 statistics. We regarded heterogeneity as substantial if an I^2 was greater than 30% and either a Tau^2 was greater than zero, or there was a low P value (less than 0.10) in the Chi^2 test for heterogeneity.

Assessment of reporting biases

We conducted only one meta-analysis. If in future updates we have 10 or more studies in the meta-analysis, we will investigate reporting biases (such as publication bias) using funnel plots. We will assess funnel plot asymmetry visually. If asymmetry is suggested by a visual assessment, we will seek statistical support to perform exploratory analyses to investigate it.

Data synthesis

We carried out statistical analyses using the Review Manager software (RevMan 2014). Due to the differing nature of the interventions in the included studies, we were able to perform a meta-analysis on only one of the reported outcomes. We planned to use a fixed-effect meta-analysis for combining data where it was reasonable to assume that studies were estimating the same underlying treatment effect: i.e. where trials were examining the same intervention, and the trials' populations and methods were judged sufficiently similar. If there had been clinical heterogeneity sufficient to expect that the underlying treatment effects differ between trials, or if substantial statistical heterogeneity was detected, we would have 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 would have been treated as the average range of possible treatment effects and we would have discussed the clinical implications of treatment effects differing between trials. If the average treatment effect was not clinically meaningful, we would not have combined trials. This applied to the one meta-analysis we performed.

Subgroup analysis and investigation of heterogeneity

In future updates, if we identify substantial heterogeneity, we will investigate it using subgroup analyses and sensitivity analyses. We will consider whether an overall summary is meaningful, and if it is, use random-effects analysis to produce it.

In future updates we intend to carry out the following subgroup analyses for the primary outcomes.

1. Parity (primigravid women compared with parous women)
2. Obstetric risk (low-risk women compared with high-risk women) (not pre-specified at protocol stage)

We also intend to assess subgroup differences by interaction tests available within RevMan (RevMan 2014). We will report the results of subgroup analyses quoting the Chi^2 statistic and P value, and the interaction test I^2 value.

Sensitivity analysis

In this update we included too few studies, with limited contributions to the outcomes for us to carry out a sensitivity analysis. In future updates, we will carry out a sensitivity analysis to explore the effects of fixed-effect versus random-effects analyses for outcomes with statistical heterogeneity, as well as the effects of exclusion of studies with higher risk of bias and the effects of varying assumptions regarding the ICC of cluster-randomised trials.

RESULTS

Description of studies

Results of the search

The updated search of the Cochrane Pregnancy and Childbirth Group retrieved a further eight reports. Three of these are separate reports of one study (Saastad 2011a), which is included in the review. Three studies are ongoing (Delaram 2012; Flenady 2014; Helzlsouer 2013). One report (Gomez 2007b) is a subsequent report of a previously included study (Gomez 2003). This study is now renamed Gomez 2007a. The remaining new report (Abasi 2010) is a non-English language publication categorised as awaiting classification as further information has been requested from the authors and is pending before final decisions regarding inclusion or exclusion can be made.

One study previously excluded (Mikhail 1991) was reviewed and considered to be an additional report of an included study Freda 1993 for the following reasons.

1. The author lists, study populations and methodology were similar.
2. Freda 1993 describes a randomised trial with 125 participants, 63 allocated to group A (Sadovsky method) and 62 to Group B (Cardif method). Mikhail 1991 describes 213 women, 63 randomly allocated to Sadovsky method, 62 to Cardif and 88 Controls. They state that computer-generated randomisation was used but do not explain why there were 40% more women in the control group. In their abstract (Mikhail 1991a), which seems to be a presentation of earlier results with fewer participants they say "Women were randomised into those who completed fetal movements using the Sadovsky (n=35) or Cardiff (n=42) charts, and matched controls (n=49)". The term "matched" suggests that the controls were not randomised. Because of uncertainty as to whether the control group was randomised, we have included only the two randomised intervention groups in this review.

Both reports have been included under the study name Mikhail 1991.

This results in a total of five studies included in this update.

See Characteristics of included studies and Characteristics of excluded studies.

Included studies

Five included studies comprised of 71,458 women with singleton pregnancies (Gomez 2007a; Grant 1989; Mikhail 1991; Saastad 2011a; Thomsen 1990). All included studies except for Gomez 2007a (which included high-risk women as participants) included women with uncomplicated pregnancies. Most studies recruited women who were 28 to 32 weeks pregnant, with Gomez 2007a recruiting women at 30 weeks of pregnancy and Thomsen 1990 at 20 weeks of pregnancy. A total of 68,654 women were from the largest study in the review, a cluster-randomised trial (Grant 1989).

Three of the five included studies assessed a once a day fetal movement counting method with another intervention as a control as follows.

1. Count-to-10 fetal movement counting versus standard care (Grant 1989)
2. Modified count-to-10 fetal movement counting versus standard care (Saastad 2011a)
3. Modified count-to-10 fetal movement counting versus hormone assessment (Thomsen 1990)

Two studies compared two fetal movement counting methods as follows.

1. Cardiff count-to-10 method versus Sadovsky fetal movement counting method (Mikhail 1991)
2. Standard count-to-10 versus fetal movement counting method where fetal movements were counted four times a day (Gomez 2007a)

A broad range of interventions with studies contributing different outcomes and different comparisons resulted in us being unable to pool data and perform a meta-analysis except for one outcome. Details of women participating in the studies can be found in the Characteristics of included studies table.

Excluded studies

We excluded a total of eight studies. The exclusion of four studies was based on the study design. These studies (Christensen 2003; Leader 1980; Lobb 1985; Neldam 1983) were either not randomised controlled trials or not properly randomised. One study was excluded because of the intervention they measured. The study by Shafi 1979 assessed women's understanding of the two fetal movements counting charts. Three studies were excluded because of their presentation of findings and the authors could not be found to give adequate data (Gibby 1988; Liston 1994; Smith 1992). Some studies did not give the numerical values but only stated that one intervention was better than the other. In a future update we will review exclusions to determine whether those excluded for lack of data meet the other criteria for inclusion.

Risk of bias in included studies

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

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

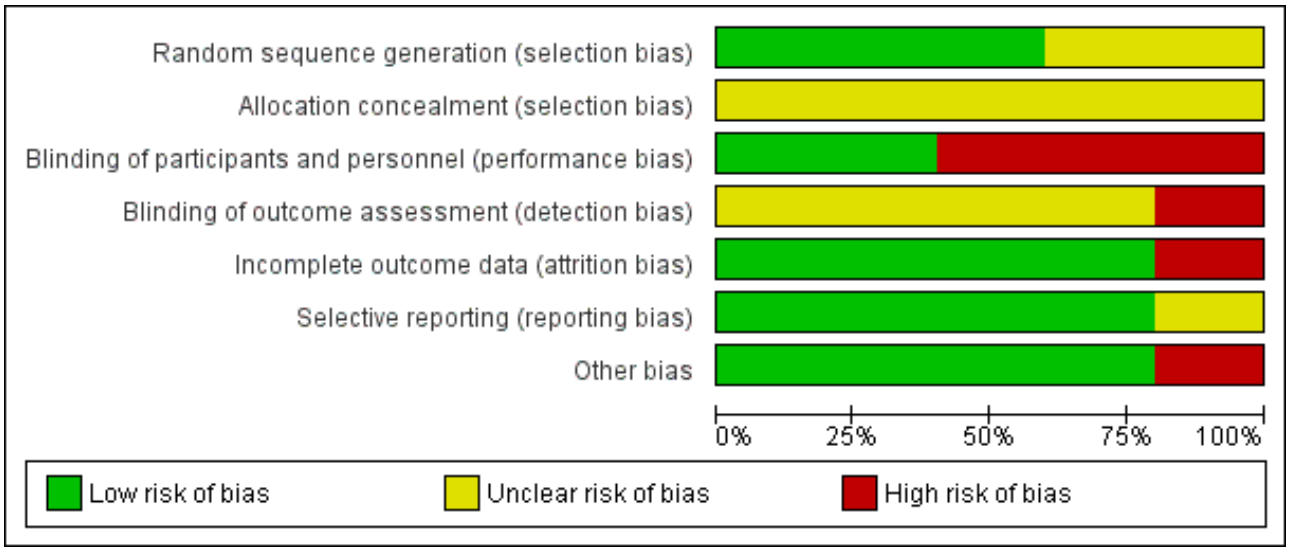
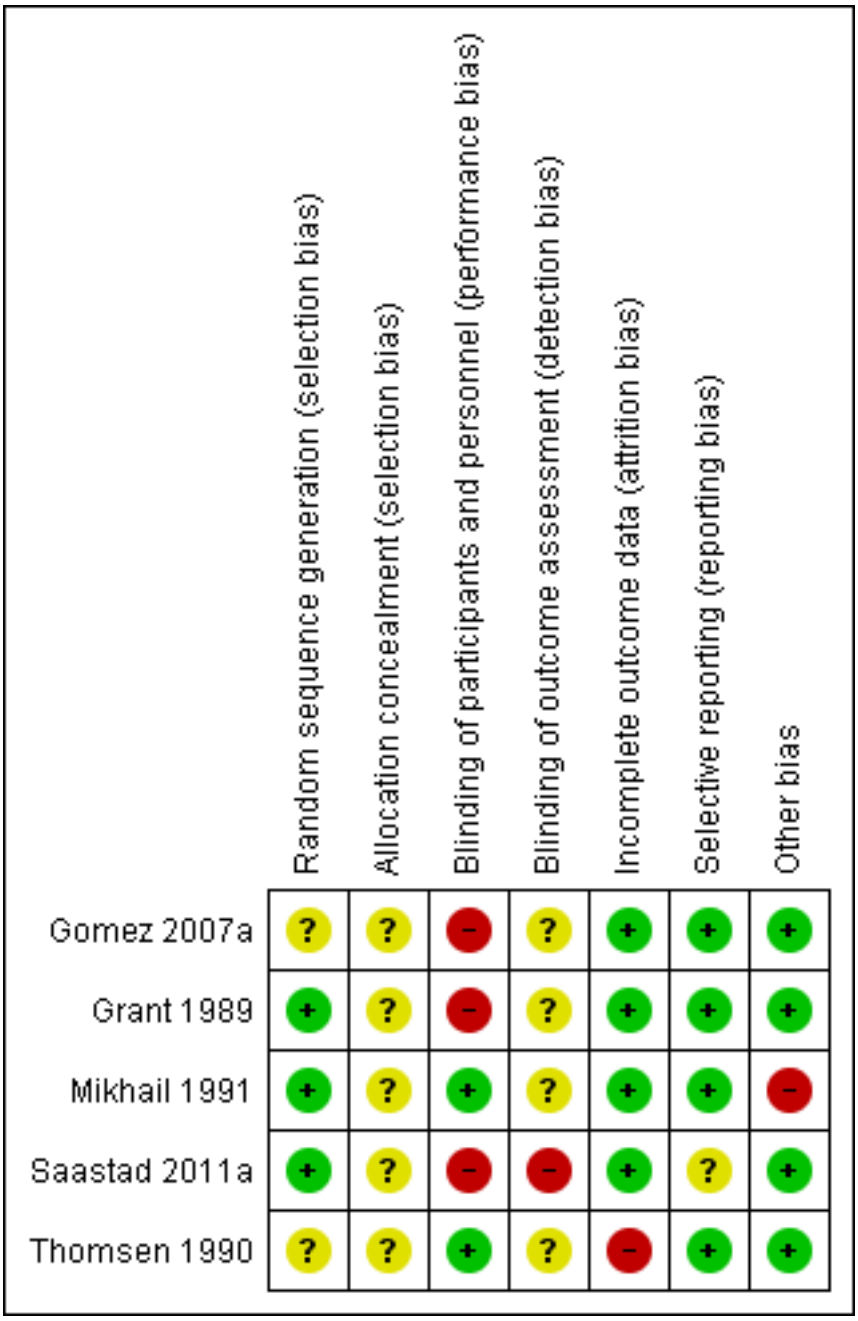


Figure 2. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.



Allocation

All the included studies were randomised controlled trials. Two studies did not explain how the randomisation sequence was generated (Gomez 2007a; Thomsen 1990) and two used a computer-generated number list (Mikhail 1991; Saastad 2011a). In Grant 1989, randomisation was by clusters. The clusters were paired based on estimates of the risks of late fetal death from previous records, and one of each pair was randomly allocated to each group. There were about 1000 women in each cluster. Data were presented with clusters as the units of analysis (n = 33 pairs). For some outcomes, data from only 26 pairs of clusters were available. The method of allocation concealment was not described in all included trials, therefore the studies were at unclear risk of bias for allocation concealment.

Blinding

In all the included studies, there is no mention of blinding for either the caregivers or the outcome assessors due to the nature of intervention. However, the studies were assessed as at high risk of bias if the outcomes were measured subjectively. When the inability to blind the participants was not likely to introduce bias because outcomes measure were not subjective outcomes, we assessed the studies as of having low risk of bias.

Incomplete outcome data

In Thomsen 1990, there were 22% post-enrolment exclusions in the treatment group and 24% in the control group.The analysis was not on an 'intention-to-treat' basis. In Saastad 2011a, loss to follow-up was similar across groups (20 intervention group; 27 control group); there was transparency on post randomisation exclusions. All other included studies reported on all outcomes of interest for all participants.

Selective reporting

In Saastad 2011a, a number of additional outcomes that were not pre-specified in the methods sections of the published reports, were reported. These were mode of birth, birthweight, gestation at birth and need for neonatal care. The findings on these outcomes, however, were all non-significant. All pre-specified outcomes were reported and no selective reporting noted for the remaining four included studies.

Other potential sources of bias

No other source of bias was noted in the included studies.

Effects of interventions

See: **Summary of findings for the main comparison** Routine fetal movement counting compared with mixed or undefined fetal movement counting for assessment of fetal wellbeing

(1) Routine fetal movement counting versus mixed or undefined fetal movement counting

One trial (Grant 1989), involving 68,654 women randomised in 33 clusters of about 1000 women each, compared formal fetal movement counting (Cardiff method) with no instructions to monitor fetal movements The results are given as rate per cluster mean. None of the review's primary outcomes were reported in the study.

One trial (Saastad 2011a), reported across three study publications (Saastad 2011; Saastad 2011; Saastad 2012), randomised individual women (n = 1076). Women in the intervention group were randomised to fetal movement counting from 28 weeks of pregnancy using a modified count-to-10 method previously tested in the Norwegian population. Women randomised to the control group received standard care as per the trial country's (Norway) national guidelines. A midwife or obstetrician from the participating hospitals or the research study group called women in the intervention group within two weeks after counting-start to support them in their interpretation of the counting method.

Primary outcomes

In Saastad 2011a, caesarean section (elective or combined) was no different between groups (risk ratio (RR) 0.93, 95% confidence interval (CI) 0.60 to 1.44; participants = 1076; studies = one) (Analysis 1.1).

No study reported on the other primary outcome, perinatal death or severe morbidity (neonatal intensive care unit admission, neonatal encephalopathy).

Secondary outcomes

In Grant 1989, there was a trend to more antenatal admissions in the counting group than in the control group (standardised mean difference (SMD) 0.38, 95% CI -0.17 to 0.93 participants = 52 clusters; studies = one, *low quality evidence*), but this was not statistically significant (Analysis 1.4). In Saastad 2011a, antenatal admission after reporting of decreased fetal movements was increased (RR 2.72, 95% CI 1.34 to 5.52; participants = 123; studies = one) (Analysis 1.5).

In Grant 1989, there was no significant difference between groups in the use of other fetal testing with cardiotocography (mean difference (MD) 20.00, 95% CI -7.72 to 47.72; participants = 52; studies = one) (Analysis 1.6). There were no significant differences in the number of stillbirths in each group (MD 0.23, 95% CI -0.61 to 1.07; participants = 52 clusters; studies = one, *low quality evidence*) (Analysis 1.9).

In Saastad 2011a the use of cardiotocography on presentation with decreased fetal movements was similar between groups (RR 1.05, 95% CI 0.95 to 1.16; participants = 124; studies = one) (Analysis 1.7) as was the use of ultrasound (RR 1.00, 95% CI 0.83 to 1.21) (Analysis 1.17).

None of the review's other pre-specified secondary outcomes were reported in the Grant 1989 study.

The following outcomes were not significantly different between groups in the Saastad 2011a study: consultation for decreased fetal movement (RR 1.22, 95% CI 0.88 to 1.69; participants = 1076; studies = one) Analysis 1.16; assisted vaginal delivery (RR 1.04, 95% CI 0.65 to 1.66; participants = 1076; studies = one) (Analysis 1.12); premature birth (RR 0.81, 95% CI 0.46 to 1.46; participants = 1076; studies = one) (Analysis 1.10); birthweight < 10th centile (RR 0.98, 95% CI 0.66 to 1.44; participants = 1073; studies = one) (Analysis 1.11); five-minute Apgar score less than four (RR 0.20, 95% CI 0.01 to 4.08; participants = 1078; studies = two) (Analysis 1.13); neonatal intensive care unit admission (RR 1.08, 95% CI 0.67 to 1.74; participants = 1076; studies = one) (Analysis 1.14); and no perinatal deaths were reported for either group (Analysis 1.15); maternal-fetal attachment as measured by the Prenatal Attachment Inventory scale at 35 weeks' gestation was not significantly different (SMD -0.02, 95% CI -0.15 to 0.11; participants = 951; studies = one) (Analysis 1.3). Maternal anxiety was significantly reduced with routine fetal movement counting (SMD -0.22, 95% CI -0.35 to -0.10; participants = 1013; studies = one) (Analysis 1.2). Compliance rates, as defined as recording more than 50% of the days during the period, in the fetal movement counting group, was 78%.

(2) Formal fetal movement counting (Modified Cardiff method) versus hormone analysis

Primary outcomes

One trial (Thomsen 1990), involving 1191 women, evaluated a modified Cardiff method versus hormone analysis. There was no difference between the groups in the incidence of caesarean section (RR 1.18, 95% CI 0.83 to 1.69; participants = 1191; studies = one) (Analysis 2.1). The outcome of perinatal death or severe morbidity was not reported in the study.

Secondary outcomes

Women in the formal fetal movement counting group had significantly fewer visits to the hospital antenatally than those women randomised to hormone analysis (RR 0.26, 95% CI 0.20 to

0.35; participants = 1191; studies = one) (Analysis 2.7). Operative deliveries were conducted in 24.3% of the formal fetal movement counting group and 20.2% in women having hormone assay (RR 1.20, 95% CI 0.97 to 1.49; participants = 1191; studies = one) (Analysis 2.6). There were no significant differences in the number of hospital admissions between the two groups (RR 0.87, 95% CI 0.55 to 1.37; participants = 1191; studies = one) (Analysis 2.3). A stillbirth occurred in one woman in the formal fetal movement counting group (RR 3.19, 95% CI 0.13 to 78.20; participants = 1191; studies = one) (Analysis 2.4). Fewer Apgar scores less than seven at five minutes were evident for women randomised to hormone analysis (RR 1.72, 95% CI 1.01 to 2.93; participants = 1112; studies = one) (Analysis 2.5). A trend was observed towards more women in the counting group than in the hormone analysis group reporting that counting caused insecurities both at 35 weeks and at birth (RR 3.55, 95% CI 0.98 to 12.82; participants = 1191; studies = one), (RR 2.13, 95% CI 0.87 to 5.24; participants = 1191; studies = one (Analysis 2.2). None of the review's other secondary outcomes were reported in the study.

(3) Formal fetal movement counting once a day (count-to-10) versus formal fetal movement counting method where counting was done more than once a day (after meals)

Two studies compared the Cardiff "count-to-10" method with the Sadovsky method in low-risk women (counting for one hour or four movements three times a day after meals Mikhail 1991) and a novel fetal movement chart proposed by the Latin American Centre for Perinatology (CLAP, Gomez 2007a).

The CLAP method required recording movements four times per day, for 30 minutes after each meal and at bedtime. Ten or more movements per day were considered reassuring.

Primary outcomes

In Gomez 2007a, data for the outcome caesarean section were reported only for women who presented at term with an absence of fetal movements and fetal viability confirmed by ultrasound. The numbers were small and the difference was not statistically significant (RR 2.33, 95% CI 0.61 to 8.99; participants = 1400; studies = one) (Analysis 3.1). The outcome of perinatal death or severe morbidity was not reported in the study.

Secondary outcomes

There was extreme heterogeneity in the comparisons of compliance (I^2 = 95%) (Analysis 3.7). For this reason, the results were not combined. In Mikhail 1991 there was no statistically significant difference in non-compliance in the two groups (Analysis 3.7) (RR 0.92, 95% CI 0.56 to 1.51). In Gomez 2007a, non-compliance was considerably less with the count-to-10 method (Analysis 3.7) (RR 0.25, 95% CI 0.19 to 0.32). This is not surprising as compliance required completion of one chart daily as compared to four charts.

In Gomez 2007a there was a trend to less preterm birth with the count-to-10 method (RR 0.75, 95% CI 0.55 to 1.01; participants = 1400; studies = one) (Analysis 3.5).

In Mikhail 1991, fewer women in the count-to-10 group felt nervous than women in the count three times daily group, but the numbers were small and not statistically significant (RR 0.11, 95% CI 0.01 to 2.05; participants = 125; studies = one) Analysis 3.2. Maternal fetal attachment was not different between groups (MD 0.02, 95% CI -0.12 to 0.16; participants = 125; studies = one) (Analysis 3.3).

In Gomez 2007a, perinatal death was reported as zero for both groups (Analysis 3.6).

In Gomez 2007a, other tests of fetal wellbeing were used less frequently in the count-to-10 group (RR 0.85, 95% CI 0.74 to 0.97; participants = 1400; studies = one) (Analysis 3.4).

The review's other secondary outcomes were not reported.

DISCUSSION

Summary of main results

None of the included studies compared the effects of fetal movement counting selectively or routinely with no fetal movement counting on perinatal outcome, which was the main objective of this review. The results neither confirm nor refute the effectiveness of fetal movement counting as a method of fetal surveillance.

The largest trial to date (Grant 1989), compared routine fetal movement counting with 'normal care', which included fetal movement counting at the discretion of the caregiver (8.9% in a subset of 'control' participants received a formal fetal movement counting chart). The potential effect on perinatal outcome may have been masked by contamination of the 'control' group. There was likely to be a heightened awareness of the importance of fetal movements at the control sites because of their participation in the study. This likelihood is supported by two observations: (1) the rate of antepartum late fetal deaths in the control groups were considerably lower than in data collected prior to the commencement of the study; (2) the only subgroups, in which there was a trend towards reduced rates of unexplained late fetal deaths in the study group, were those in which the clusters were paired between rather than within hospitals and those in which the control consultants chose not to inform the control participants about the study (in both cases less likelihood of contamination).

The potential effectiveness of routine over discretionary fetal movement counting is also suggested by the fact that, when fetal movements were formally counted, there were more babies with subsequent unexplained late fetal deaths who were alive when first admitted to hospital (11/59 versus 6/58). The reasons for admission were reduced or absent fetal movements in 35/59 versus 16/58 respectively. However, the warnings did not translate into fewer deaths, mainly because of falsely reassuring fetal testing, mainly cardiotocography, and clinical error.

There is heterogeneity in two studies that compared compliance in once a day versus more than once a day counting methods. In the Mikhail 1991 study, there was no significant difference in compliance between the 'count-to-10' and the Sadovsky method. In the Gomez 2003 study, women complied significantly better with the 'count-to-10' versus the Latin American Centre for Perinatology and human development (CLAP) fetal movement chart method because they thought it was easier. The study that carries more weight in this regard is the one by Gomez 2003 as it had a bigger sample size. Meta-analysis was not performed because of the degree of heterogeneity in these trials.

In Mikhail 1991, there was a high percentage of women in both groups who liked to count although the percentage was higher in the Sadovsky method than in the 'count-to-10' method. The high compliance rate in both groups, the acceptability of the method to the women, and the high number of women who liked to count fetal movements may indicate that there are few, if any, negative psychological factors associated with the method. However, this is a research area that needs to be explored further.

Overall completeness and applicability of evidence

None of the five included studies reported on the primary outcome of composite of perinatal death and neonatal morbidity. Stillbirth was reported separately in Grant 1989 and Thomsen 1990, and perinatal death was reported separately in Saastad 2011a and Gomez 2007a. The primary outcome of caesarean section was reported in three (Gomez 2007a; Saastad 2011a; Christensen 2003) of the included trials. Maternal anxiety and maternal fetal attachment was reported in three (Mikhail 1991; Saastad 2011a; Thomsen 1990) and two (Mikhail 1991; Saastad 2011a) of the included trials respectively. Other outcomes, such as other fetal testing, premature birth, birthweight < 2500 g, assisted delivery, five-minute Apgar score of less than seven and admission to the neonatal unit were variously reported by either three, two or one of the included trials. None of the included trials reported on the outcomes of maternal satisfaction, umbilical cord pH of less than 7.2, respiratory distress syndrome, neonatal encephalopathy, early neonatal death and childhood disability. This variation in outcome reporting is problematic for evidence synthesis as it reduces the ability to compare, combine and contrast outcomes from individual studies, resulting, ultimately, in less clinical applicability of the evidence when attempting to optimise decision-making on methods for assessing fetal wellbeing and on methods of fetal surveillance in practice.

Quality of the evidence

Five trials with 71,458 participants were included in the analyses in the review. None of these five trials were assessed as having low risk of bias on all seven risk of bias criteria. Other than in the Thomsen 1990 study, in which there were post-randomisation exclusions of 24% in the counting group and 22% in the hormone analysis group, there was a low level of missing data in the studies. Selective reporting of outcomes was also assessed as low risk of bias in all of the studies, other than Saastad 2011a, who reported additional outcomes not pre-specified in the methods sections of the study reports. Other than one large trial (Grant 1989), which contributed 68,654 women to the review, the numbers of participants in the trials were relatively small (ranging from 125 to 1400). In the one outcome of compliance where efforts to pool data from two studies (Gomez 2007a; Mikhail 1991) were made, a high level of heterogeneity was present (I^2 = 95%). For this reason the results for this outcome were presented separately.

The overall quality of the evidence was assessed using GRADEpro for the comparison "routine fetal movement counting compared to mixed or undefined fetal movement counting for assessment of fetal wellbeing." (Summary of findings for the main comparison). Evidence downgrading was based on including studies with unclear risk of bias and statistically non-significant results. None of the included trials reported the composite outcome perinatal death or neonatal morbidity, or caesarean section. Other than for the outcome of maternal anxiety, which was assessed to be of moderate quality, all of the other outcomes were assessed as being of low quality. This reduces the clinical applicability of these results.

Potential biases in the review process

We acknowledge that there is potential for bias in the review process as assessment of risk of bias, for example, is not an exact science and is subject to individual interpretation. We attempted to minimise this by: 1) having two review authors independently assess risk of bias and carry out data extraction; 2) contacting study authors if study methods or results were unclear; and 3) consulting a third party if we were unable to resolve dilemmas.

Agreements and disagreements with other studies or reviews

The review is an update of the previous version of the Cochrane review on fetal movement counting for assessing fetal wellbeing. One new study, (Saastad 2011a) that provided additional data to the review, was included. The addition of these new data does not alter the conclusions of this review, and at present, there is insufficient evidence on whether formal fetal movement counting is beneficial or risky for assessing fetal wellbeing. Four additional reports were identified (one awaiting classification (Abasi 2010) and three ongoing studies (Delaram 2012; Flenady 2014; Helzlsouer 2013)) and may be included in future updates, and have the potential to alter the current conclusions of the review.

AUTHORS' CONCLUSIONS

Implications for practice

There is insufficient evidence that formal fetal movement counting either for all women or for women at increased risk of problems with their babies is beneficial or not. The indirect evidence of the greater ability of formal rather than discretionary fetal movement counting to identify babies at risk of intrauterine death was not translated into reduced perinatal mortality, due to falsely reassuring fetal assessment tests and clinical error. Limited data suggest that women prefer daily counting to repeated counting periods throughout the day. Women in the fetal movement counting group identified growth restricted fetuses more than women who were not in the fetal movement counting group.

Implications for research

Because of indirect evidence from these studies that fetal movement counting may be beneficial, more research is needed in this area. Studies comparing fetal movement counting with no fetal movement counting would be difficult to implement because fetal movement counting, whether formal or informal, is widely practiced. More research should be conducted to determine the sensitivity and the specificity of fetal movement counting in detecting fetal compromise; its effectiveness in decreasing the perinatal mortality in high-risk and low-risk women; its effectiveness in low-resource settings with no acces to electronic fetal heart rate monitoring; its acceptability to women; how easy it is for women; and the best fetal movement counting method.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

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

Gomez 2007a

Methods	Randomised controlled trial. Reported as randomly assigned.
Participants	1400 gravid high-risk women with singleton pregnancies after 30 weeks of gestation presenting at high-risk obstetric outpatient clinic in a hospital in Lima, Peru.
Interventions	Novel FM counting (CLAP method) where fetal movements are counted for 30 minutes 4 times a day (after each meal and before bed time) versus the standard count-to-10 method where women were recording the time it takes for them to feel 10 fetal movements at a selected time each day; where reassuring reports recorded 10 movements in at least 2 hours.
Outcomes	Patient compliance (defined as use of assigned charting method for 5 or more days a week and for at least 4 consecutive weeks. Women were also allowed to miss 1 30-minute period and still considered to be compliant). Additional antepartum fetal tests. Obstetric interventions.
Notes	This is a subsequent published paper to the Gomez 2003 study included in the previous version of this review. Compliance was defined as use of assigned charting method for 5 or more days a week for at least 4 consecutive weeks. Women in the FMC were allowed to miss only 1 30-minute period to be considered compliant.

Gomez 2007a *(Continued)*

The reason given for high compliance in the count-to-10 group was lack of interference with daily life activities but those who complied with CLAP method cited positive approach towards pregnancy and enhancement of maternal-fetal bonding as a major advantage.

Reasons for non-compliance with the count-to-10 method were inability to understand the chart recording and for the CLAP method the main reason given was interference with daily life activities.

The authors state "No intrauterine fetal demises or neonatal deaths occurred during the study". This seems unlikely given that 1400 high-risk pregnancies were studied.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information to provide judgement.
Allocation concealment (selection bias)	Unclear risk	Insufficient information to provide judgement.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Insufficient information to provide judgement (but due to nature of intervention, blinding of participants and caregivers was unlikely). Subjective outcome of maternal fetal attachment measured.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to provide judgement.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data for primary outcome of compliance available for all participants.
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported.
Other bias	Low risk	There were no differences in the demographic characteristics of treatment and control groups (marital, socioeconomic and educational status); distribution of high-risk conditions was not significantly different between the groups. The intention-to-treat analysis was used for analysis.

Grant 1989

Methods	Randomised controlled trial with cluster allocation.
Participants	68,654 women were included (33 clusters randomised formal fetal movement counting (Cardiff) n = 31,993 women; 33 clusters randomised no instruction n = 36,661 women). Women with pregnancies between 28 and 32 weeks.
Interventions	Treatment group were women counting their fetal movements formally every day using a 'count-to-10' chart (Cardiff). Women were to contact the hospital if movements were reduced. Women in the control group were not told to monitor fetal movements but were asked about fetal movements on each antenatal visits and were allowed to raise concerns. Clinicians were asked to respond in any way appropriate to the concerns in both groups.
Outcomes	Antepartum late fetal deaths, hospital admissions, use of cardiotocograph.

Grant 1989 *(Continued)*

Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised controlled trial. Matched cluster pairs based on estimate of fetal death using data from previous 5 years.
Allocation concealment (selection bias)	Unclear risk	Insufficient information to make judgement.
Blinding of participants and personnel (performance bias) All outcomes	High risk	No details; however, due to nature of the intervention blinding of participant's and personnel not likely. Due to the nature of the clusters within sites there was the potential for 'contamination' across groups.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to make judgement.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Blinding of obstetrician to group for classification of fetal death; primary outcome data for all clusters reported.
Selective reporting (reporting bias)	Low risk	Reported on all outcomes of interest.
Other bias	Low risk	Baseline characteristics were similar between the groups.

Mikhail 1991

Methods	Randomised controlled trial (3 groups).
Participants	Normal uncomplicated, singleton pregnancies of gestational age between 28 and 32 weeks.
Interventions	Intervention 1. Sadovsky method; counting 3 times a day after meals, Intervention 2: Cardiff; counting the 1st 10 movements each morning compared with the control group where women were given standard care and not instructed to count fetal movements. It is not clear whether the control group were randomly allocated, thus only the two randmized groups are included in this review.
Outcomes	Maternal fetal attachment measured using the Cranley scale (a 24-item Likert scale describing baby-related thoughts and actions of expectant mothers).
Notes	Freda 1993 is an additional report to this study in which only 125 women were included (63 Sadovsky; 62 Cardiff). The outcomes assessed by Freda study were the psychological effects, acceptance, compliance and how user-friendly fetal movement counting methods.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated number list.

Mikhail 1991 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Insufficient information to make judgement.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	No details but due to nature of intervention, blinding of participants and caregivers was unlikely. Failure to blind participants is not likely to expose the findings to the risk of bias because the outcome is measured using a validated objective measurement scale.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to make judgement.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up reported (numbers in study are small).
Selective reporting (reporting bias)	Low risk	Outcome of MFA reported for all groups.
Other bias	High risk	Potential for contamination; There was increased awareness of fetal movement counting due to study in control group.

Saastad 2011a

Methods	Randomised controlled trial.
Participants	1076 singleton pregnancies, at least 28 weeks pregnant, Norwegian speaking. Exclusion: women with severe fetal anomalies, or other causes for considering termination.
Interventions	Intervention: fetal movement counting from 28 weeks of pregnancy using a modified count-to-10 method previously tested in the Norwegian population. A midwife or obstetrician from the participating hospitals or the research study group called women in the intervention group within two weeks after counting-start to support them in their interpretation of the counting method. Control: standard antenatal care according to Norwegien guidelines.
Outcomes	Primary outcomes: (i) fetal growth restriction < 2.5th centile, (ii) emergency caesarean section on fetal indication, (iii) oligohydramnios (as defined by the clinicians), (iv) pathological blood flow in arteria umbilicalis, (v) maternal perception of absent fetal movements for more than 24 hours before admission, (vi) perinatal death. Secondary outcomes: (i) Apgar scores < 4 at 1 and 5 minutes, (ii) fetal growth restriction < 2.5th centile unidentified prior to birth, (iii) total number of consultations for decreased fetal movements, (iv) use of health resources in evaluation of pregnancies, (v) intervention prior or during delivery. From associated publication (Birth 2012): (i) maternal concern, measured by the Cambridge Worry Scale, (ii) frequency of maternal reports of hospital examinations because of perceived decreased fetal movements, (iii) maternal perception of fetal activity, (iv) maternal experiences of using fetal movement counting chart. From associated publication (Birth 2011): (i) maternal-fetal attachment.
Notes	The growth restricted fetuses were more frequently identified prior to birth in the fetal movement counting group than in the control group 20 of 23 fetuses ((87.0%) versus 12 of 20 fetuses (60.0%) respectively).

Saastad 2011a *(Continued)*

This study was part of a more comprehensive piece of work evaluating fetal movement counting. The 2 other studies required a completed questionnaire in pregnancy week 22 for women to be eligible for allocation.

Recruitment from Sept 2007-Nov 2009.

Country: Norway.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated random allocation list.
Allocation concealment (selection bias)	Unclear risk	Paper reports 'the allocation sequence was concealed until participants were assigned to trial groups'. Method of allocation concealment was not described.
Blinding of participants and personnel (performance bias) All outcomes	High risk	After allocation, blinding for group assignment was not desirable neither for the participants nor their care providers. Blinding was left at high because some of the outcomes measured are subjective outcomes.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Analyses were performed by the researcher without blinding to group assignment.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up was similar across groups (20 intervention group; 27 control group). There was transparency on post randomisation exclusions.
Selective reporting (reporting bias)	Unclear risk	There were additional outcomes reported: mode of delivery, birthweight, gestation at birth, and need for neonatal care. All were non-statistically significant findings.
Other bias	Low risk	No additional bias evident.

Thomsen 1990

Methods	Randomised controlled trial. Method of allocation concealment not mentioned.
Participants	1191 women were included (577 modified Cardiff; 614 hormone analysis). Women without obstetric complications and medical diseases were recruited from 16 to 18 weeks of pregnancy in Denmark.
Interventions	Women started counting from 29 weeks. The fetal movement counting group were to count daily using the Modified Cardiff 'count-to-10' method. They were to count in the evening because the majority of them were working women and because fetal activity is thought to be at its peak in the early evening. A participant was to contact the hospital if she had fewer than 10 fetal movements in 5 hours, where physical examination, hormonal assessment and CTG were performed. Fetal movements charts were presented to staff for assessment at 33 weeks, 35 weeks, 39 weeks and 41 weeks. In the control group oestriol and human placental lactogen were measured by radio-immunoassay at 33 weeks, 36 weeks, 39 and 41 weeks. All women were asked to evaluate the monitoring procedures used for them at 35 weeks of pregnancy and 1 or 2 days after delivery.

Thomsen 1990 *(Continued)*

Outcomes	Number of hospital visits, hospital admissions, frequency of caesarean sections, intrauterine growth restriction, stillbirths, Apgar scores, umbilical artery pH.
Notes	Women who suffered pregnancy complications after enrolment were removed from the study. 180 women (24%) were removed from the counting group and 173 (22%) from the hormonal assay group. Intention-to-treat analysis was not used.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information on how random sequence generation was done.
Allocation concealment (selection bias)	Unclear risk	No information on allocation concealment.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Blinding of participants and personnel is not stated but not possible due to the nature of intervention. The inability to blind the participants is not likely to introduce bias because outcomes measure in this trial are not subjective outcomes.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessors not mentioned.
Incomplete outcome data (attrition bias) All outcomes	High risk	There are post-randomisation exclusion (24% in counting group and 22% in hormone analysis group) and intention-to-treat analysis was not done.
Selective reporting (reporting bias)	Low risk	Primary outcomes reported on.
Other bias	Low risk	The 2 groups did not differ regarding maternal age, parity, gestational age at delivery and smoking habits.

CLAP:
CTG: cardiotocography
FMC: fetal movement counting
MFA: maternal fetal attachment

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

Study	Reason for exclusion
Christensen 2003	Randomised controlled trial, cross-over design. At each weekly antenatal visit the participants were given a different chart. Data not presented in suitable format.
Gibby 1988	The authors did not give numerical values. Only mentioned that there were no significant differences between fetal movement counting group and the group, which did not record fetal movements. Information is sought from trial authors.
Leader 1980	Not a randomised controlled trial.
Liston 1994	Measures psychological effects of fetal movements counting using assessment scales and the results are given in means.

Study	Reason for exclusion
Lobb 1985	Not a randomised controlled trial.
Neldam 1983	Participants were not properly randomised. They were allocated according to their entry numbers. This trial showed significantly fewer deaths in the fetal movement count group in fetuses more than 1.500 g without major congenital malformation compared to the control group. In this study 1562 women were in the counting group and 1549 women were in the control group. Women in the counting group were given written information and instructions as to how to count and register their fetal movements and women in the control group were not instructed to count but were asked questions on fetal movement on each antenatal visit and were encouraged to report problems they encountered with fetal movements.
Shafi 1979	The study was not comparing different types of fetal movement counting methods but different types of fetal movements charts. They evaluated women's understanding of fetal movement counting, comparing a "Cardiff count-to-10" chart and their newly designed pictorial fetal movement, which explained the use and the importance of fetal movement counting in pictures.
Smith 1992	No numerical values were given for patient preference of each method. The study only mentions that women preferred the "Cardiff count-to-10" method because it took less time to monitor fetal movements than all the other methods.

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

Abasi 2010

Methods	Women selected through purposive sampling from pregnant women admitted to health centres of Sari in 2009.
Participants	This interventional study was conducted on 83 pregnant women selected through purposive sampling from pregnant women admitted to health centres of Sari in 2009.
Interventions	All cases received forms to record the number of foetal movement every morning after breakfast for 1 month. However, controls only received the routine pregnancy care.
Outcomes	The present study was conducted to determine the effect of counting foetal movement on maternal-fetal attachment.
Notes	Awaiting additional information from trial authors on the total numbers recruited in the 2 groups.

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

Delaram 2012

Trial name or title	The effect of fetal movement counting on general health, anxiety, and depression of mother and outcome of pregnancy.
Methods	The method of sampling will be random.
Participants	Inclusion criteria: singleton pregnancy; not having been terminated pregnancy; no previous abortion. Exlusion criteria: oligohydramnios; maternal smoking and drugs.
Interventions	Intervention group, fetal movement counting will be done from 28 to 37 weeks of gestation.

Delaram 2012 *(Continued)*

	Control group will not receive the intervention.
Outcomes	General health, antenatal depression, pregnancy outcome.
Starting date	Expected recruitment start date: 2012-08-22. Expected recruitment end date: 2013-08-23.
Contact information	Faculty of Nursing and Midwifery, Shahrekord University Of Medical Sciences, Shahrekord, Iran Shahrekord Chaharmahal & Bakhteeyari.
Notes	Irct registration number: IRCT201207103078N9. Date registered: December 6, 2012. Registration timing: registration while recruiting.

Flenady 2014

Trial name or title	My Baby's Movements: a stepped wedge cluster-randomised controlled trial to raise maternal awareness of fetal movements during pregnancy.
Methods	Cluster-randomisation in stepped-wedge design so that, by the end of the trial, all clusters have received the intervention.
Participants	Women with a singleton pregnancy attending for antenatal care at participating sites, and clinicians providing antenatal care at participating sites. Women at any stage of pregnancy are eligible for entry into the trial.
Interventions	My Baby's Movements (MBM): a package of interventions to raise awareness and promote early reporting and best-practice management of decreased fetal movements in the third-trimester of pregnancy, including a mobile phone application for pregnant women and e-learning program for clinicians.
Outcomes	Primary: stillbirth at 28 weeks' gestation or more (among all women in the trial). Secondary: adverse neonatal outcome - subset of 4377 babies only: composite measure of birth outcomes including Apgar score < 7 at 5 minutes; umbilical artery pH <7.0; intubation and ventilation at birth; hypoxic ischaemic encephalopathy; neonatal seizures; meconium aspiration syndrome; neonatal intensive care greater than 5 days; use of mechanical ventilation; neonatal death. Health service utilisation - subset of 4377 women only: assessed via audits of presentations for decreased fetal movements including the duration of decreased movement at presentation and details and outcome of any clinical assessments.
Starting date	1/01/2015.
Contact information	Vicki Flenady, Address: Mater Research Institute - The University of Queensland Level 2 Aubigny, Place Mater Health Services South Brisbane QLD 4101.
Notes	ACTRN12614000291684.

Helzlsouer 2013

Trial name or title	Promoting Fetal Movement Monitoring: Improving Birth Outcomes.
Methods	Allocation: randomised.
Participants	Inclusion criteria: 24-28 weeks pregnant, able to receive daily text messages or emails, 18 years of age or older, willing to sign informed consent.

Helzlsouer 2013 *(Continued)*	
	Exclusion criteria: unable to sign informed consent.
Interventions	Daily electronic reminders. Women in the intervention arm will be sent either daily text messages on the weekdays on their cell phone or emails on the weekdays reminding them to track kick counts on the chart. No Intervention: education only. All women enrolled in the trial will receive a paper-based kick count chart, will be educated in the use of the kick count chart, and will be instructed to keep track of their fetal movements on a daily basis.
Outcomes	Completion of kick count charts at follow-up prenatal visits, knowledge of kick counting post delivery, baseline questionnaire, including knowledge questions regarding monitoring baby's movement and kick count methods can be compared to post-education kick count knowledge questionnaire, week 36 questionnaire and end of study questionnaire.
Starting date	March 2013. Proposed finish date: December 2013 (final data collection date for primary outcome measure).
Contact information	No information provided.
Notes	ClinicalTrials.gov Identifier: NCT01844011.

DATA AND ANALYSES

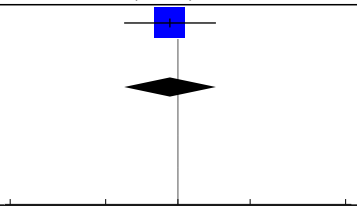
Comparison 1. Routine fetal movement counting versus mixed or undefined fetal movement counting

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Caesarean section	1	1076	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.60, 1.44]
2 Maternal anxiety	1	1013	Std. Mean Difference (IV, Fixed, 95% CI)	-0.22 [-0.35, -0.10]
3 Maternal-fetal attachment	1	951	Std. Mean Difference (IV, Fixed, 95% CI)	-0.02 [-0.15, 0.11]
4 Antenatal hospital admission rate per cluster (mean)	1	52	Std. Mean Difference (IV, Fixed, 95% CI)	0.38 [-0.17, 0.93]
5 Antenatal Admission after reporting DFM	1	123	Risk Ratio (M-H, Fixed, 95% CI)	2.72 [1.34, 5.52]
6 Other fetal testing (cardiotocogram) on presentation with DFM rate per cluster (mean)	1	52	Mean Difference (IV, Fixed, 95% CI)	20.0 [-7.72, 47.72]
7 Other fetal testing (cardiotocogram) on presentation with DFM	1	124	Risk Ratio (M-H, Fixed, 95% CI)	1.05 [0.95, 1.16]
8 Other fetal testing (ultrasound) on presentation with DFM	1	124	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.83, 1.21]
9 Stillbirth rate per cluster (mean)	1	66	Mean Difference (IV, Fixed, 95% CI)	0.23 [-0.61, 1.07]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
10 Premature birth	1	1076	Risk Ratio (M-H, Fixed, 95% CI)	0.81 [0.46, 1.46]
11 Low birthweight (< 2500 g or < 10th centile)	1	1073	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.66, 1.44]
12 Assisted birth (vaginal)	1	1076	Risk Ratio (M-H, Fixed, 95% CI)	1.04 [0.65, 1.66]
13 5 minute Apgar score < 4	1	1078	Risk Ratio (M-H, Fixed, 95% CI)	0.20 [0.01, 4.08]
14 Neonatal ICU admission	1	1076	Risk Ratio (M-H, Fixed, 95% CI)	1.08 [0.67, 1.74]
15 Perinatal death	1	1076	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
16 Consultation for DFM	1	1076	Risk Ratio (M-H, Fixed, 95% CI)	1.22 [0.88, 1.69]
17 Use of ultrasound (for foetal growth, amniotic fluid and foetal activity)	1	124	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.83, 1.21]

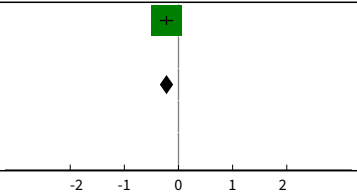
Analysis 1.1. Comparison 1 Routine fetal movement counting versus mixed or undefined fetal movement counting, Outcome 1 Caesarean section.

Study or subgroup	Routine FM Counting n/N	Mixed/undefined FMC n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Saastad 2011a	36/544	38/532		100%	0.93[0.6,1.44]
Total (95% CI)	**544**	**532**		**100%**	**0.93[0.6,1.44]**
Total events: 36 (Routine FM Counting), 38 (Mixed/undefined FMC)					
Heterogeneity: Tau^2=0; Chi^2=0, df=0(P<0.0001); I^2=100%					
Test for overall effect: Z=0.34(P=0.73)					

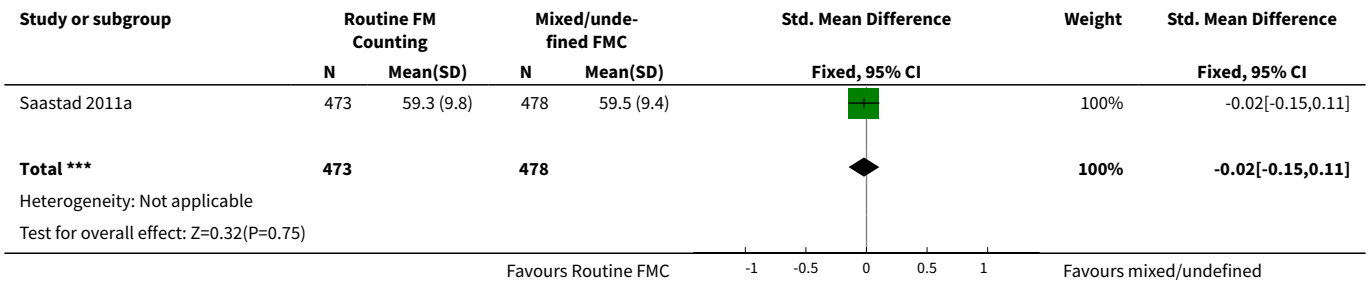


Analysis 1.2. Comparison 1 Routine fetal movement counting versus mixed or undefined fetal movement counting, Outcome 2 Maternal anxiety.

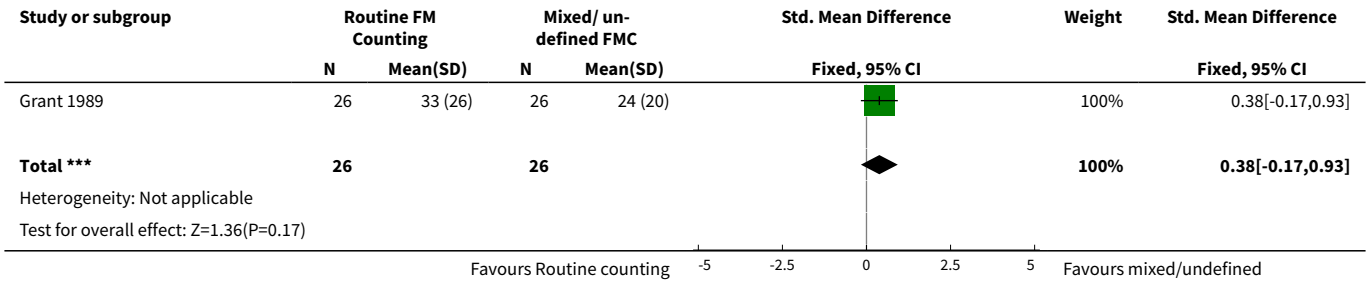
Study or subgroup	Routine FM Counting N	Routine FM Counting Mean(SD)	Mixed/undefined FMC N	Mixed/undefined FMC Mean(SD)	Std. Mean Difference Fixed, 95% CI	Weight	Std. Mean Difference Fixed, 95% CI
Saastad 2011a	503	0.8 (0.6)	510	0.9 (0.6)		100%	-0.22[-0.35,-0.1]
Total ***	**503**		**510**			**100%**	**-0.22[-0.35,-0.1]**
Heterogeneity: Not applicable							
Test for overall effect: Z=3.52(P=0)							



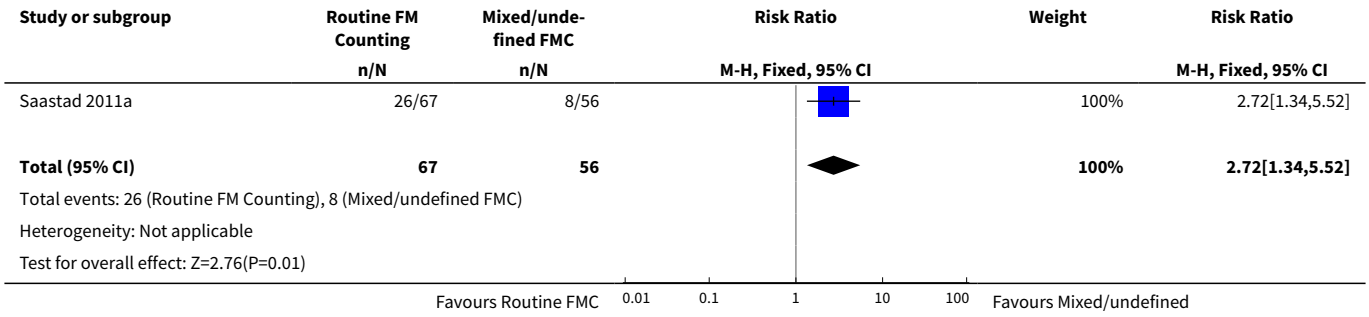
Analysis 1.3. Comparison 1 Routine fetal movement counting versus mixed or undefined fetal movement counting, Outcome 3 Maternal-fetal attachment.



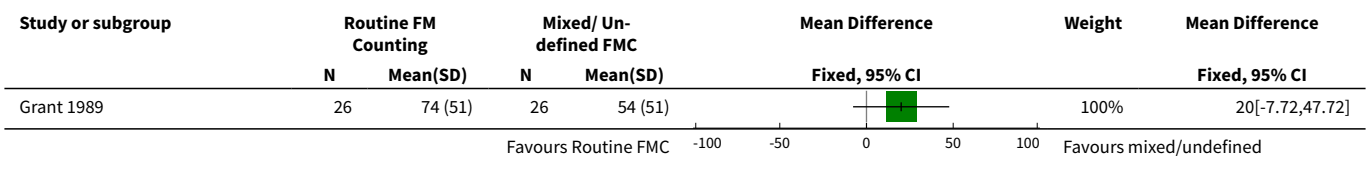
Analysis 1.4. Comparison 1 Routine fetal movement counting versus mixed or undefined fetal movement counting, Outcome 4 Antenatal hospital admission rate per cluster (mean).

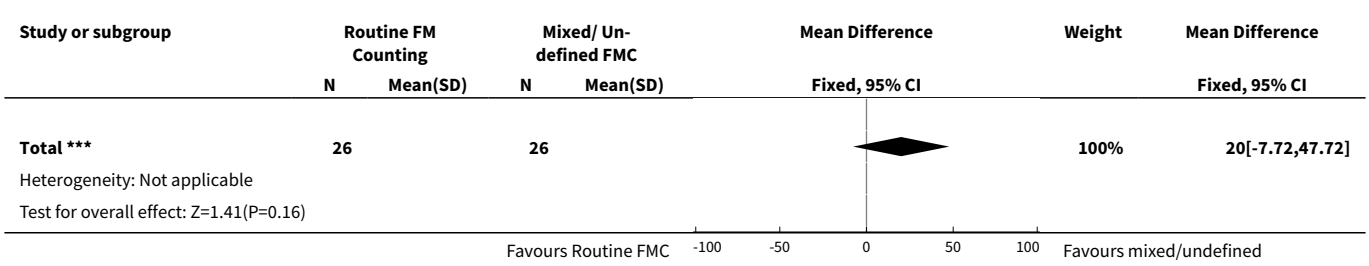


Analysis 1.5. Comparison 1 Routine fetal movement counting versus mixed or undefined fetal movement counting, Outcome 5 Antenatal Admission after reporting DFM.

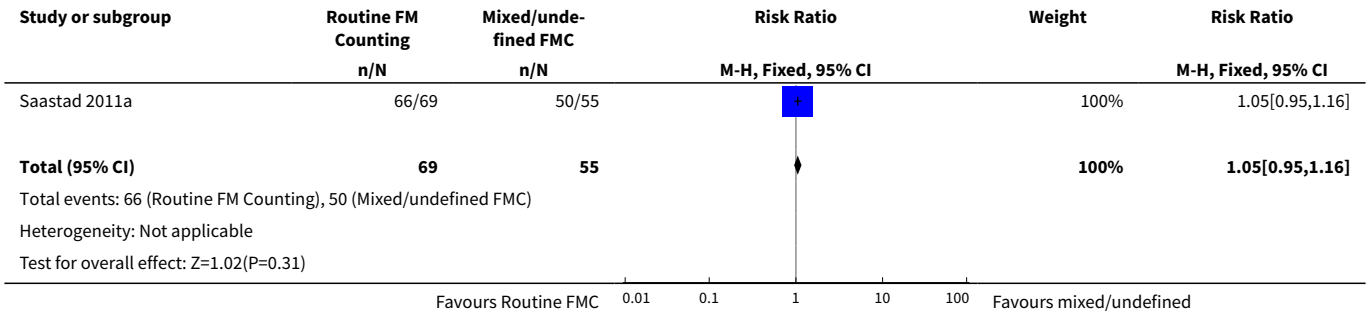


Analysis 1.6. Comparison 1 Routine fetal movement counting versus mixed or undefined fetal movement counting, Outcome 6 Other fetal testing (cardiotocogram) on presentation with DFM rate per cluster (mean).

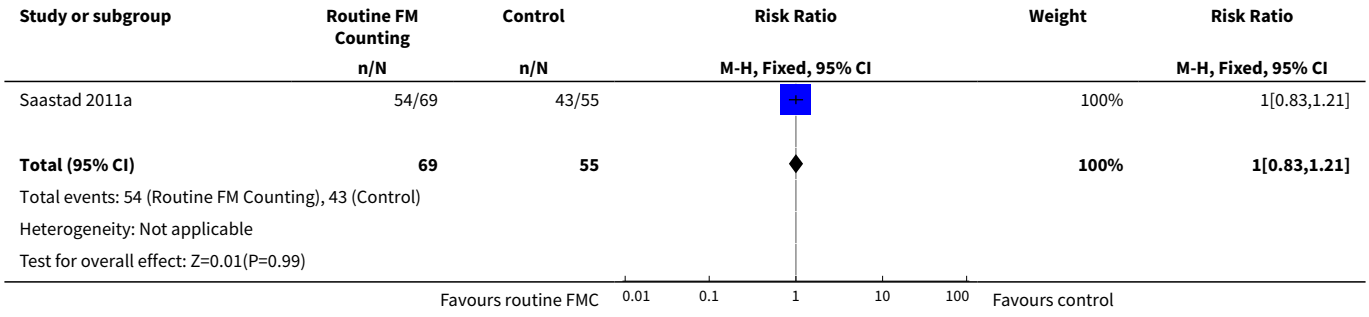




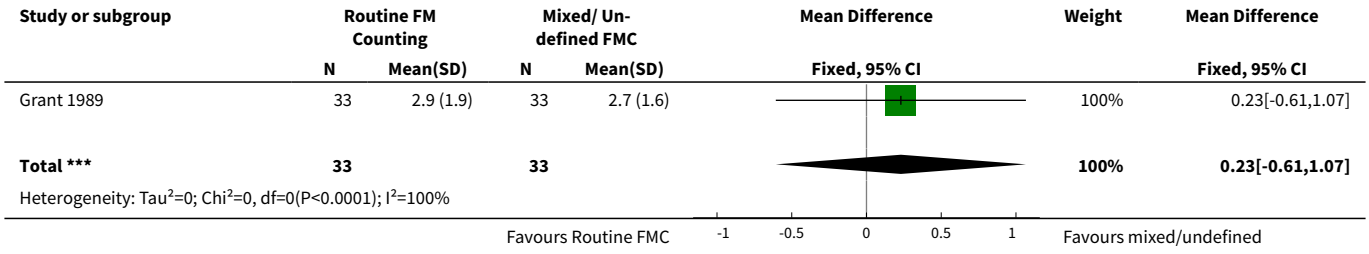
Analysis 1.7. Comparison 1 Routine fetal movement counting versus mixed or undefined fetal movement counting, Outcome 7 Other fetal testing (cardiotocogram) on presentation with DFM.

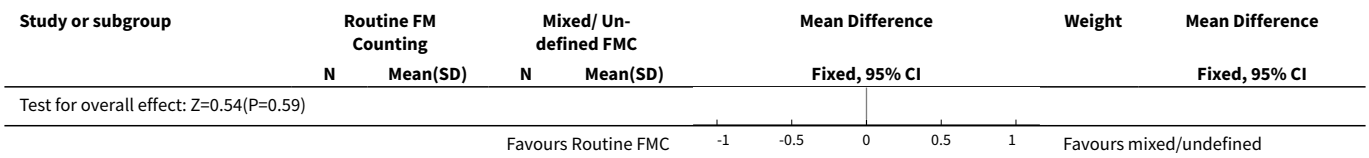


Analysis 1.8. Comparison 1 Routine fetal movement counting versus mixed or undefined fetal movement counting, Outcome 8 Other fetal testing (ultrasound) on presentation with DFM.

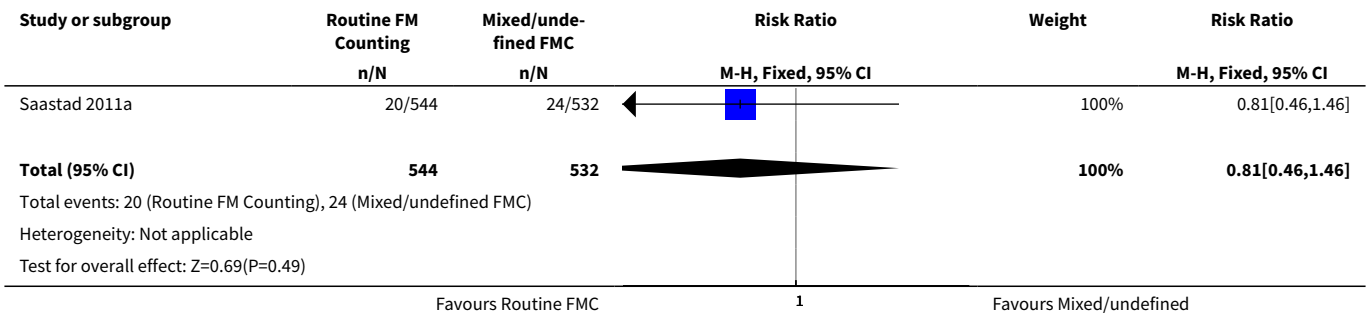


Analysis 1.9. Comparison 1 Routine fetal movement counting versus mixed or undefined fetal movement counting, Outcome 9 Stillbirth rate per cluster (mean).

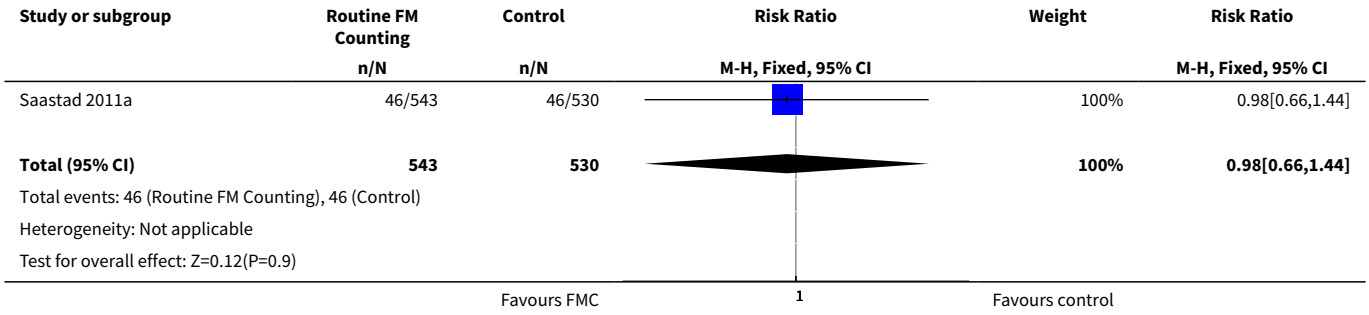




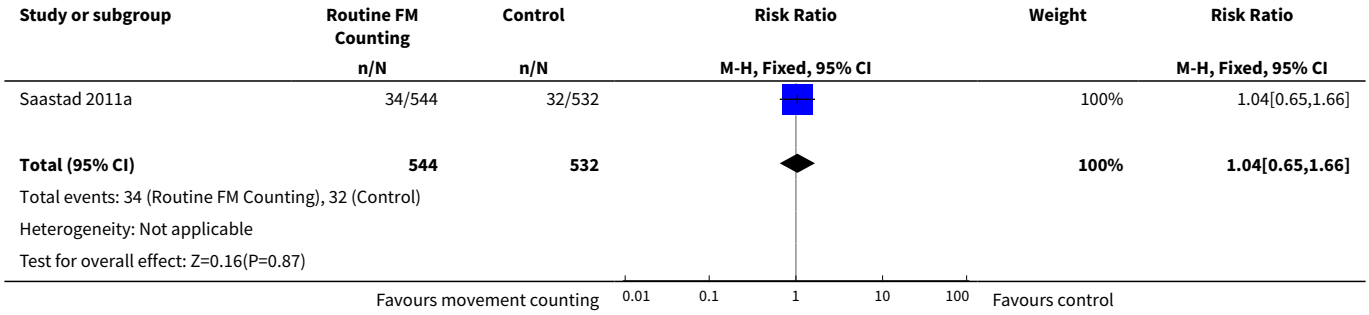
Analysis 1.10. Comparison 1 Routine fetal movement counting versus mixed or undefined fetal movement counting, Outcome 10 Premature birth.



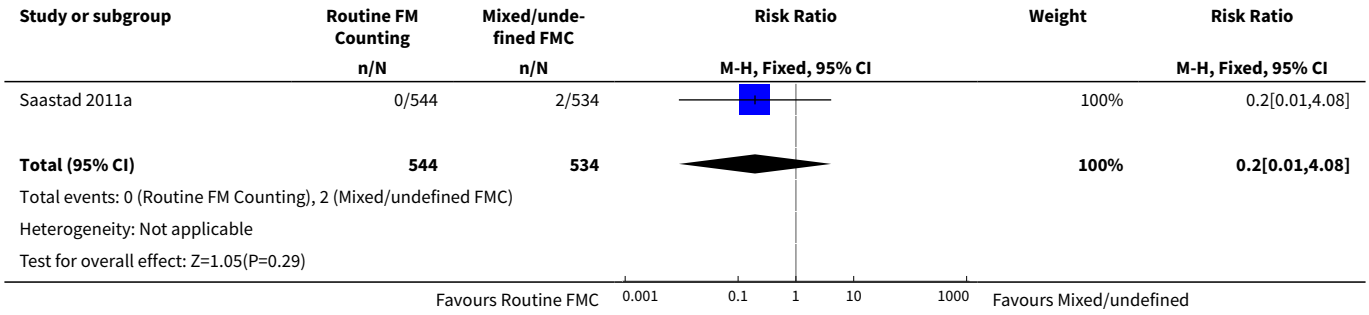
Analysis 1.11. Comparison 1 Routine fetal movement counting versus mixed or undefined fetal movement counting, Outcome 11 Low birthweight (< 2500 g or < 10th centile).



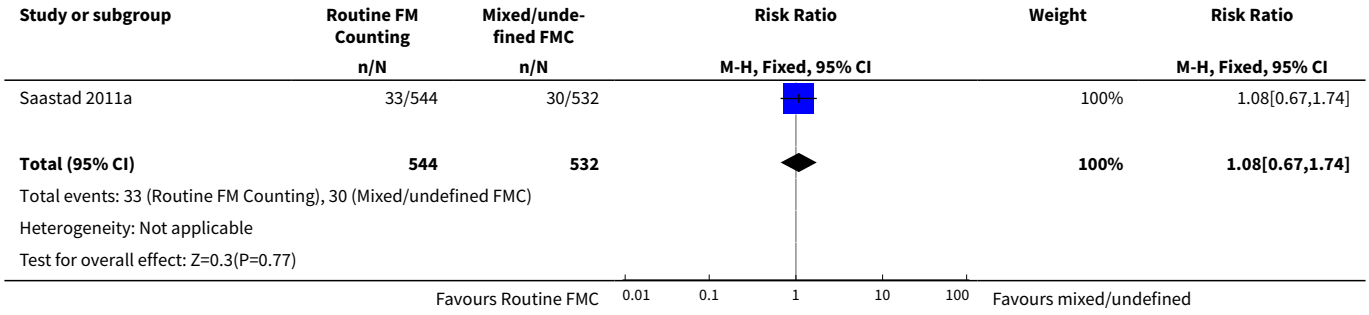
Analysis 1.12. Comparison 1 Routine fetal movement counting versus mixed or undefined fetal movement counting, Outcome 12 Assisted birth (vaginal).



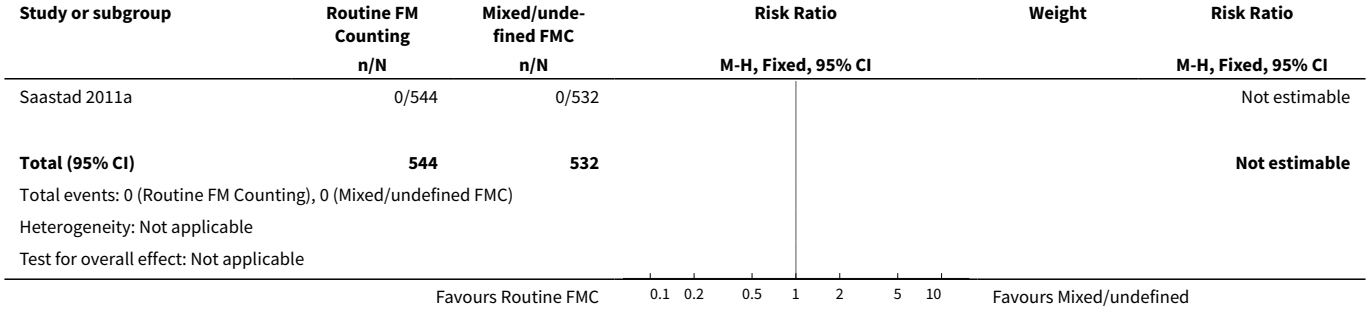
Analysis 1.13. Comparison 1 Routine fetal movement counting versus mixed or undefined fetal movement counting, Outcome 13 5 minute Apgar score < 4.



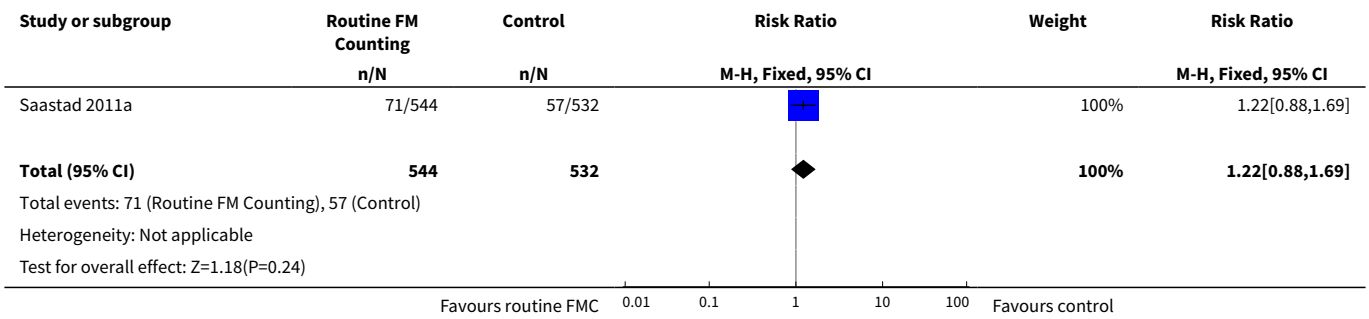
Analysis 1.14. Comparison 1 Routine fetal movement counting versus mixed or undefined fetal movement counting, Outcome 14 Neonatal ICU admission.



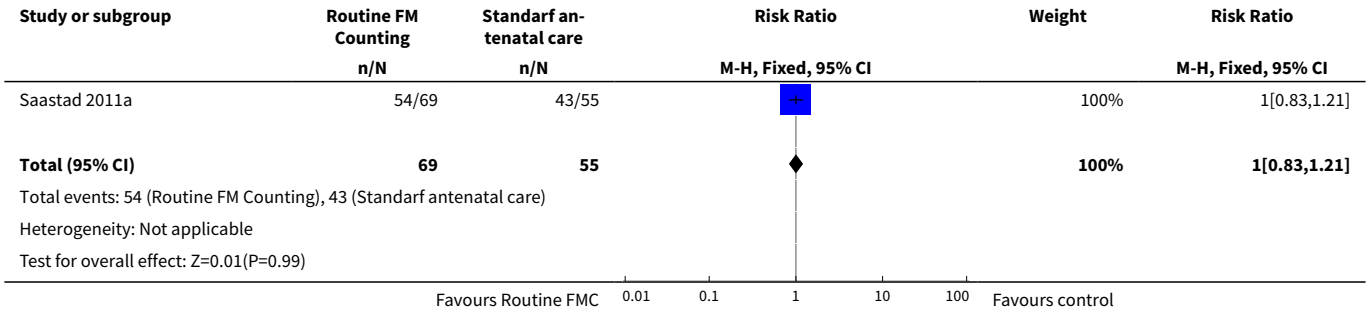
Analysis 1.15. Comparison 1 Routine fetal movement counting versus mixed or undefined fetal movement counting, Outcome 15 Perinatal death.



Analysis 1.16. Comparison 1 Routine fetal movement counting versus mixed or undefined fetal movement counting, Outcome 16 Consultation for DFM.



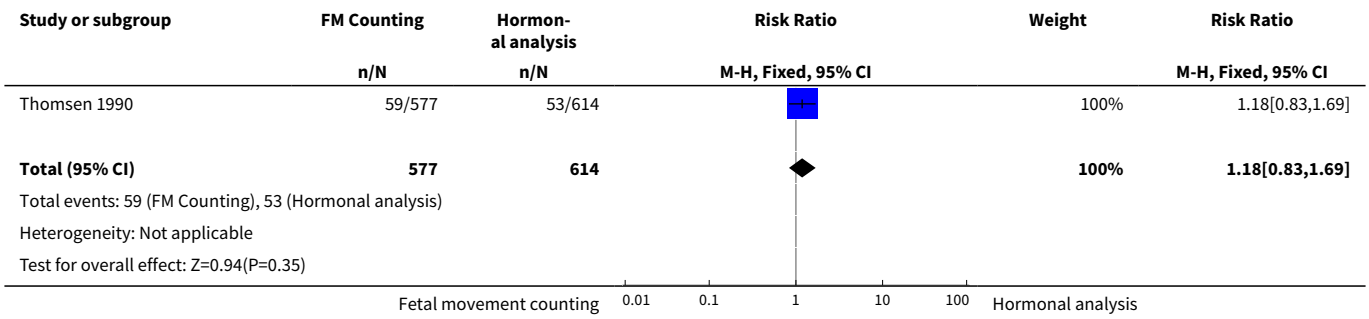
Analysis 1.17. Comparison 1 Routine fetal movement counting versus mixed or undefined fetal movement counting, Outcome 17 Use of ultrasound (for foetal growth, amniotic fluid and foetal activity).



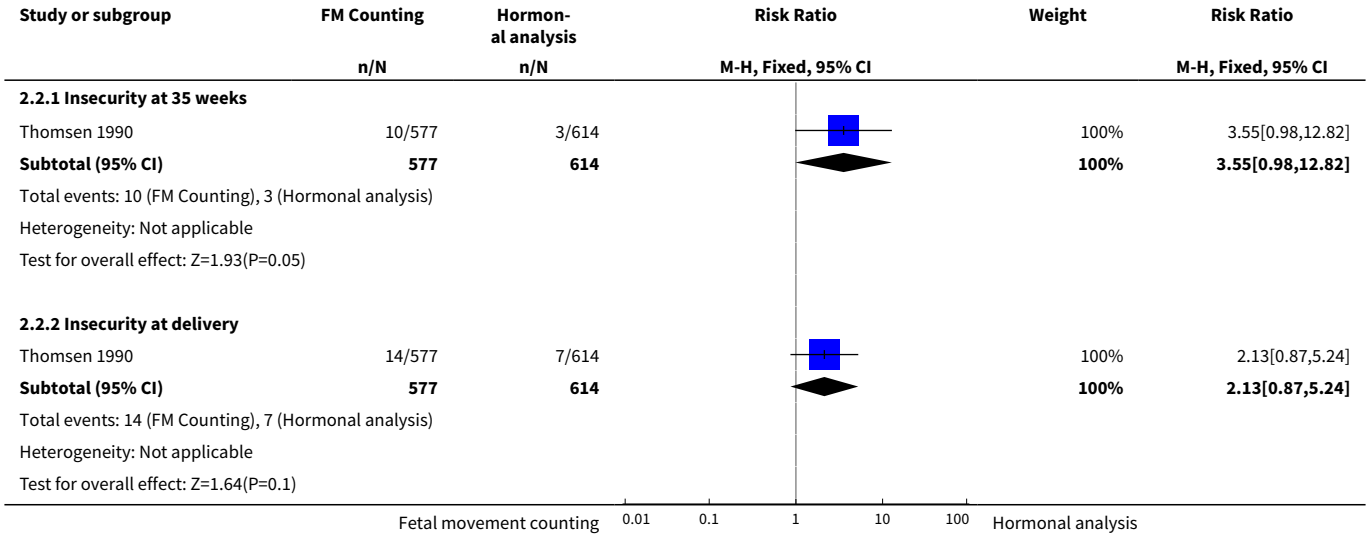
Comparison 2. Fetal movement counting versus hormonal analysis

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Caesarean section	1	1191	Risk Ratio (M-H, Fixed, 95% CI)	1.18 [0.83, 1.69]
2 Maternal anxiety/Created insecurity	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.1 Insecurity at 35 weeks	1	1191	Risk Ratio (M-H, Fixed, 95% CI)	3.55 [0.98, 12.82]
2.2 Insecurity at delivery	1	1191	Risk Ratio (M-H, Fixed, 95% CI)	2.13 [0.87, 5.24]
3 Antenatal hospital admissions	1	1191	Risk Ratio (M-H, Fixed, 95% CI)	0.87 [0.55, 1.37]
4 Stillbirths	1	1191	Risk Ratio (M-H, Fixed, 95% CI)	3.19 [0.13, 78.20]
5 Apgar score < 7 in 5 minutes	1	1112	Risk Ratio (M-H, Fixed, 95% CI)	1.72 [1.01, 2.93]
6 Assisted birth	1	1191	Risk Ratio (M-H, Fixed, 95% CI)	1.20 [0.97, 1.49]
7 Number of hospital visits (not pre-specified)	1	1191	Risk Ratio (M-H, Fixed, 95% CI)	0.26 [0.20, 0.35]

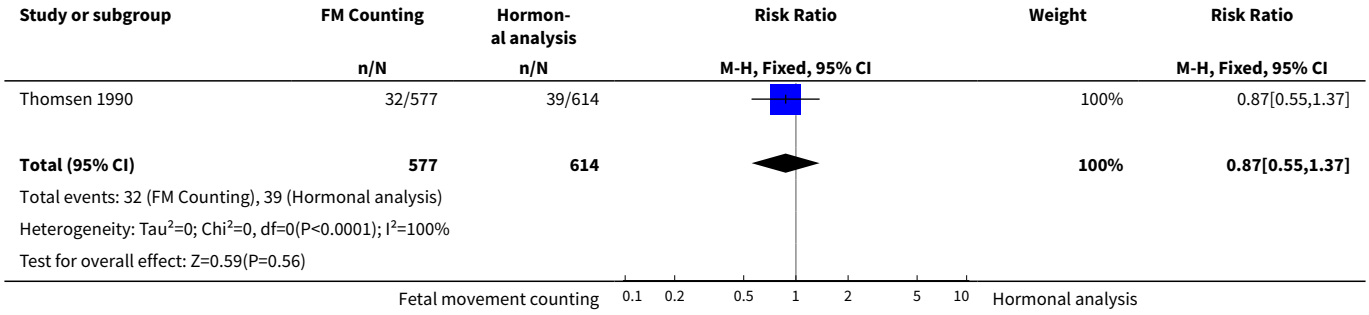
Analysis 2.1. Comparison 2 Fetal movement counting versus hormonal analysis, Outcome 1 Caesarean section.



Analysis 2.2. Comparison 2 Fetal movement counting versus hormonal analysis, Outcome 2 Maternal anxiety/Created insecurity.

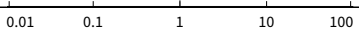


Analysis 2.3. Comparison 2 Fetal movement counting versus hormonal analysis, Outcome 3 Antenatal hospital admissions.



Analysis 2.4. Comparison 2 Fetal movement counting versus hormonal analysis, Outcome 4 Stillbirths.

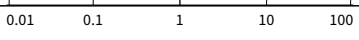
Study or subgroup	FM Counting n/N	Hormonal analysis n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Thomsen 1990	1/577	0/614		100%	3.19[0.13,78.2]
Total (95% CI)	**577**	**614**		**100%**	**3.19[0.13,78.2]**
Total events: 1 (FM Counting), 0 (Hormonal analysis)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.71(P=0.48)					



Fetal movement counting — Hormonal analysis

Analysis 2.5. Comparison 2 Fetal movement counting versus hormonal analysis, Outcome 5 Apgar score < 7 in 5 minutes.

Study or subgroup	FM Counting n/N	Hormonal analysis n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Thomsen 1990	31/501	22/611		100%	1.72[1.01,2.93]
Total (95% CI)	**501**	**611**		**100%**	**1.72[1.01,2.93]**
Total events: 31 (FM Counting), 22 (Hormonal analysis)					
Heterogeneity: Tau^2=0; Chi^2=0, df=0(P<0.0001); I^2=100%					
Test for overall effect: Z=1.99(P=0.05)					



Fetal movement counting — Hormonal analysis

Analysis 2.6. Comparison 2 Fetal movement counting versus hormonal analysis, Outcome 6 Assisted birth.

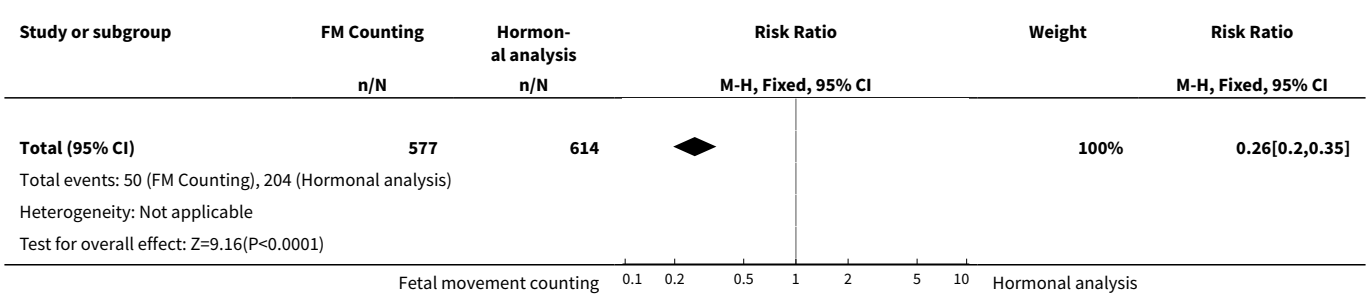
Study or subgroup	FM Counting n/N	Hormonal analysis n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Thomsen 1990	140/577	124/614		100%	1.2[0.97,1.49]
Total (95% CI)	**577**	**614**		**100%**	**1.2[0.97,1.49]**
Total events: 140 (FM Counting), 124 (Hormonal analysis)					
Heterogeneity: Tau^2=0; Chi^2=0, df=0(P<0.0001); I^2=100%					
Test for overall effect: Z=1.69(P=0.09)					

Fetal movement counting — Hormonal analysis

Analysis 2.7. Comparison 2 Fetal movement counting versus hormonal analysis, Outcome 7 Number of hospital visits (not pre-specified).

Study or subgroup	FM Counting n/N	Hormonal analysis n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Thomsen 1990	50/577	204/614		100%	0.26[0.2,0.35]

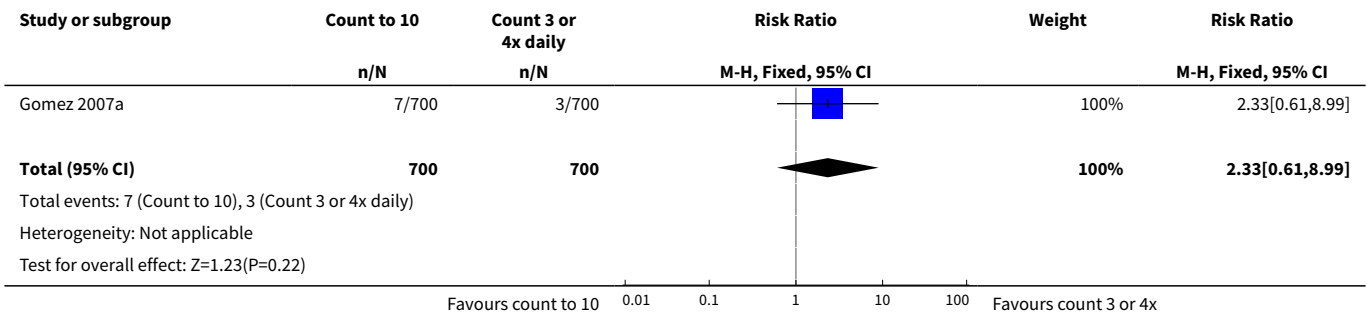
Fetal movement counting — Hormonal analysis



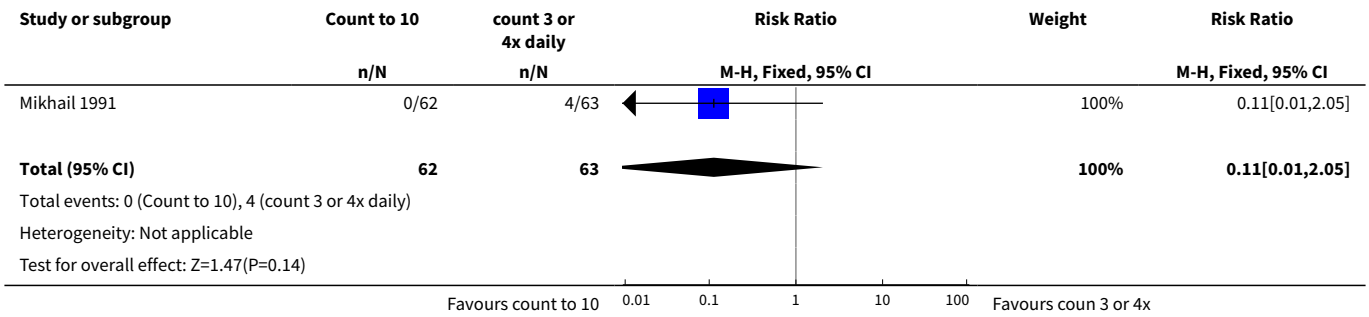
Comparison 3. 'count-to-10' method versus 'count three (Sadovsky) or four (CLAP) times daily method"

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Caesarean section due to absent FM (not pre-specified)	1	1400	Risk Ratio (M-H, Fixed, 95% CI)	2.33 [0.61, 8.99]
2 Maternal anxiety	1	125	Risk Ratio (M-H, Fixed, 95% CI)	0.11 [0.01, 2.05]
3 Maternal fetal attachment	1	125	Mean Difference (IV, Fixed, 95% CI)	0.02 [-0.12, 0.16]
4 Other tests of fetal wellbeing	1	1400	Risk Ratio (M-H, Fixed, 95% CI)	0.85 [0.74, 0.97]
5 Premature birth	1	1400	Risk Ratio (M-H, Fixed, 95% CI)	0.75 [0.55, 1.01]
6 Perinatal death	1	1400	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
7 Non-compliance (not pre-specified)	2		Risk Ratio (M-H, Random, 95% CI)	Subtotals only

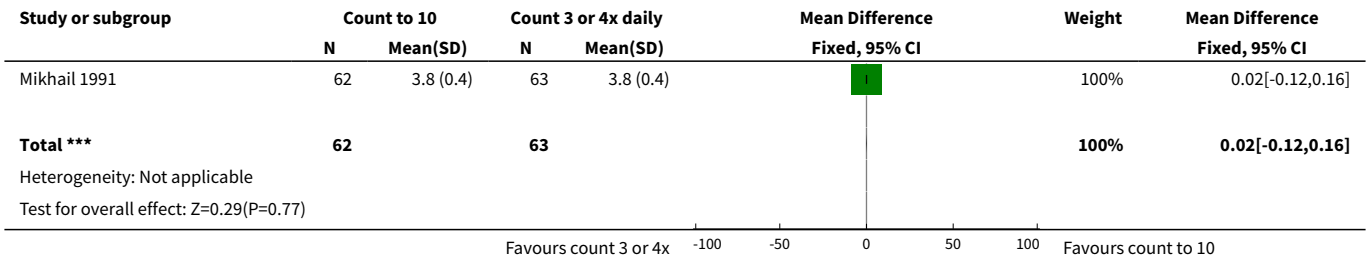
Analysis 3.1. Comparison 3 'count-to-10' method versus 'count three (Sadovsky) or four (CLAP) times daily method", Outcome 1 Caesarean section due to absent FM (not pre-specified).



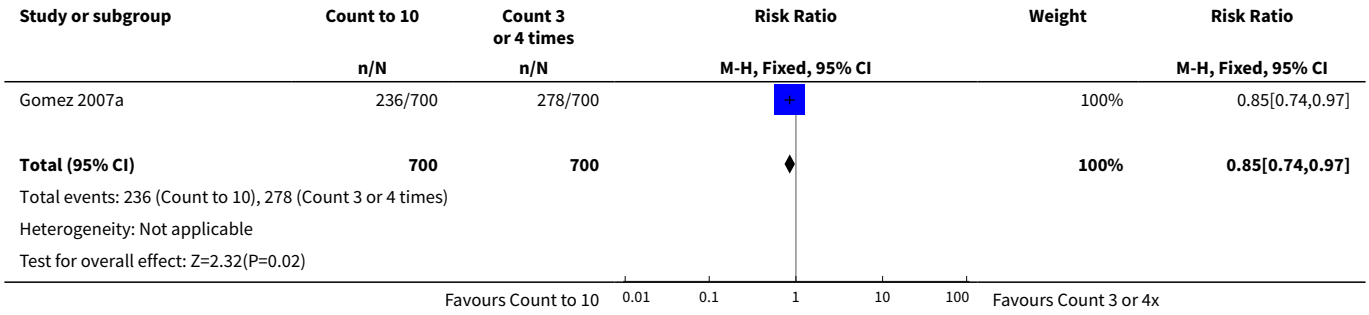
Analysis 3.2. Comparison 3 'count-to-10' method versus 'count three (Sadovsky) or four (CLAP) times daily method", Outcome 2 Maternal anxiety.



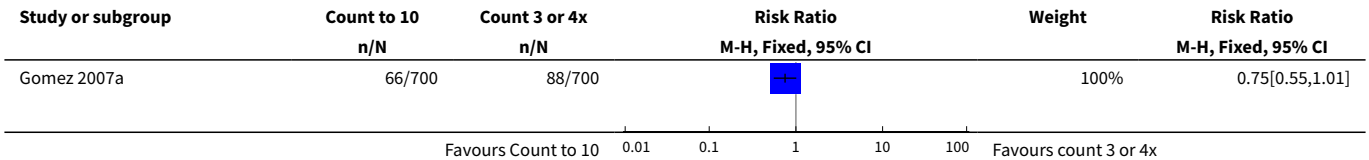
Analysis 3.3. Comparison 3 'count-to-10' method versus 'count three (Sadovsky) or four (CLAP) times daily method", Outcome 3 Maternal fetal attachment.

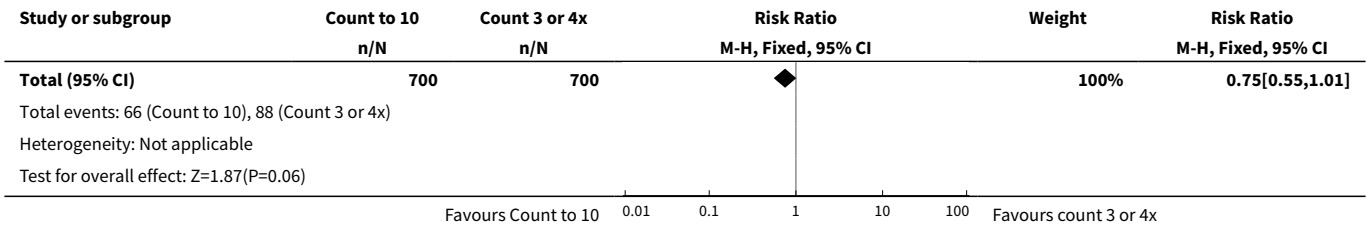


Analysis 3.4. Comparison 3 'count-to-10' method versus 'count three (Sadovsky) or four (CLAP) times daily method", Outcome 4 Other tests of fetal wellbeing.

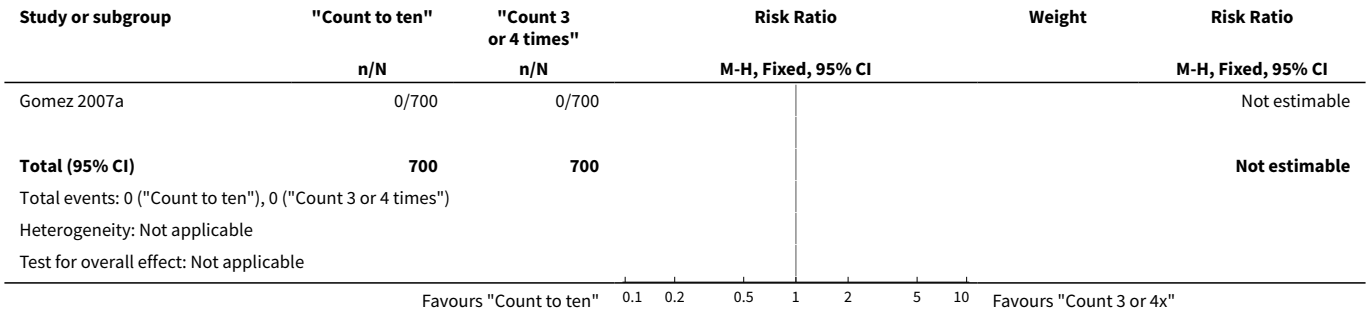


Analysis 3.5. Comparison 3 'count-to-10' method versus 'count three (Sadovsky) or four (CLAP) times daily method", Outcome 5 Premature birth.

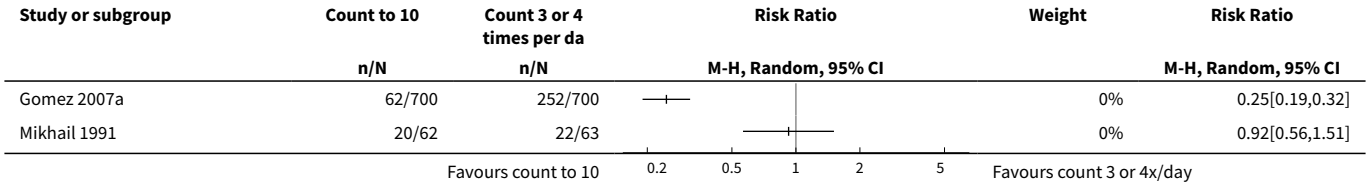




Analysis 3.6. Comparison 3 'count-to-10' method versus 'count three (Sadovsky) or four (CLAP) times daily method", Outcome 6 Perinatal death.



Analysis 3.7. Comparison 3 'count-to-10' method versus 'count three (Sadovsky) or four (CLAP) times daily method", Outcome 7 Non-compliance (not pre-specified).



ADDITIONAL TABLES

Table 1. Descriptions of formal fetal movement counting

Method	Description
Cardiff Method	A method of fetal movement counting where a woman monitors the first 10 movements and indicates when the movements were felt (Freda 1993).
Modified Cardiff Method	1. Women were to record the time taken to feel 10 fetal movements on a modified Cardiff 'count-to-10' chart. Women had to count as early in the day as was convenient for them (Grant 1989). 2. Women were counting fetal movements daily on a modified 'count-to-10' chart indicating the time required to experience 10 consecutive movements. All women were to count in the evening (Thomsen 1990).

Table 1. Descriptions of formal fetal movement counting *(Continued)*

Sadovsky Method	Women were requested to count the first 4 movements after each meal, indicate each movement with an X and stop counting (Freda 1993).
Fetal Movement Chart	Fetal movements are recorded during 30 minutes after meals and before bedtime at night. 10 or more fetal movements per day are considered normal (Gomez 2007a).
'Count-to-ten' chart	A chart that a woman uses to record the number of times and the times her baby moved (Freda 1993).
Hormone analysis	Oestriol and human placental lactogen were measured by radio-immunoassay at 33, 36, 39 and 41 weeks of gestation and from then twice a week (Thomsen 1990).

WHAT'S NEW

Date	Event	Description
31 May 2015	New citation required but conclusions have not changed	In this update, five trials are included, eight excluded, three are ongoing and one is awaiting classification. The conclusions remain the same.
31 May 2015	New search has been performed	Search updated. One new trial has been included (Saastad 2011a). One study previously excluded (Mikhail 1991) was reviewed and considered to be an additional report of the previously included study (Freda 1993). Methods updated. A 'Summary of findings' table has been incorporated. A new review author helped to prepare this update.

HISTORY

Protocol first published: Issue 3, 2004
Review first published: Issue 1, 2007

Date	Event	Description
8 June 2012	Amended	Search updated. Three reports added to Studies awaiting classification (Abasi 2010a; Saastad 2011; Saastad 2011a).
1 October 2009	Amended	Search updated. One report added to Studies awaiting classification (Gomez 2007a). Contact person's contact details updated. Minor amendments made to text.
2 September 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

LM and VS identified studies for inclusion and exclusion independently. GJH reviewed the study selection and resolved disagreements on whether the studies had to be included or excluded. LM and VS independently entered completed data extraction forms and GJH resolved disagreements. LM, VS and RS worked on the background. LM and GJH entered data and did the analysis. RS assessed the quality of the evidence using the GRADE approach. LM and GJH wrote the results and conclusion. LM, VS, RS and GJH contributed content to the discussion.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- Effective Care Research Unit, University of the Witwatersrand, University of Fort Hare, Eastern Cape Department of Health, South Africa.

External sources

- 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.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The original protocol did not specify that we would exclude quasi-randomised trials, this was added to the methods for "Types of studies" in the first published version of the review.

The outcomes "non-compliance", "number of hospital visits", "birthweight less than 10th centile", "consultation for decreased fetal movements" and "caesarean section due to absent fetal movement" which were not pre-specified in the protocol have been added to this review.

INDEX TERMS

Medical Subject Headings (MeSH)

Fetal Monitoring [*methods]; Fetal Movement [*physiology]; Pregnancy Outcome; Randomized Controlled Trials as Topic; Time Factors

MeSH check words

Female; Humans; Pregnancy