Antenatal cardiotocography for fetal assessment (Review)

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[Intervention Review]

Antenatal cardiotocography for fetal assessment

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ABSTRACT

Background

Cardiotocography (CTG) is a continuous recording of the fetal heart rate obtained via an ultrasound transducer placed on the mother's abdomen. CTG is widely used in pregnancy as a method of assessing fetal well-being, predominantly in pregnancies with increased risk of complications.

Objectives

To assess the effectiveness of antenatal CTG (both traditional and computerised assessments) in improving outcomes for mothers and babies during and after pregnancy.

Search strategy

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (April 2009).

Selection criteria

Randomised and quasi-randomised trials that compared traditional antenatal CTG with no CTG or CTG results concealed; computerised CTG with no CTG or CTG results concealed; and computerised CTG with traditional CTG.

Data collection and analysis

Two authors independently assessed eligibility, quality and extracted data.

Main results

Six studies (involving 2105 women) are included. Overall, the included studies were not of high quality, and only two had both adequate randomisation sequence generation and allocation concealment. All studies that were able to be included enrolled only women at increased risk of complications.

Comparison of traditional CTG versus no CTG showed no significant difference identified in perinatal mortality (risk ratio (RR) 2.05, 95% confidence interval (CI) 0.95 to 4.42, 2.3% versus 1.1%, four studies, N = 1627) or potentially preventable deaths (RR 2.46,

95% CI 0.96 to 6.30, four studies, N = 1627, though the meta-analysis was underpowered to assess this outcome. Similarly, there was no significant difference identified in caesarean sections (RR 1.06, 95% CI 0.88 to 1.28, 19.7% versus 18.5%, three trials, N = 1279) nor in the secondary outcomes that were assessed.

There were no eligible studies that compared computerised CTG with no CTG.

Comparison of computerised CTG versus traditional CTG showed a significant reduction in perinatal mortality with computerised CTG (RR 0.20, 95% CI 0.04 to 0.88, two studies, 0.9% versus 4.2%, 469 women, graph 3.1.1). However, there was no significant difference identified in potentially preventable deaths (RR 0.23, 95% CI 0.04 to 1.29, two studies, N = 469), though the meta-analysis was underpowered to assess this outcome. There was no significant difference identified in caesarean sections (RR 0.87, 95% CI 0.61 to 1.24, 63% versus 72%, one study, N = 59) or in secondary outcomes.

Authors' conclusions

There is no clear evidence that antenatal CTG improves perinatal outcome, but further studies focusing on the use of computerised CTG in specific populations of women with increased risk of complications are warranted.

PLAIN LANGUAGE SUMMARY

Cardiotocography (a form of electronic fetal monitoring) for assessing a baby's well-being in the womb during pregnancy

Some pregnancies can be complicated by a medical condition in the mother (e.g. diabetes or high blood pressure) or a condition that might affect the health or development of the baby. If these babies with potential difficulties could be identified, and if there were effective interventions to improve the outcomes, then an accurate test that could be used during pregnancy could be beneficial. Cardiotocography (CTG) is a continuous electronic record of the baby's heart rate obtained via an ultrasound transducer placed on the mother's abdomen. It is sometimes referred to as 'electronic fetal monitoring' (EFM). The review looked to see if using CTG during pregnancy might improve outcomes for babies by identifying those with complications. It looked for studies that included women at both increased risk, and at low risk, of complications. The review included six studies with all of the women at increased risk of complications. Four of the studies were undertaken in the 1980s and two in the late 1990s. There was no differences in outcomes identified, although when computerised interpretation of the CTG trace was used, the findings looked promising. However, CTG monitors, associated technologies and the way midwives and obstetricians care for women with different complications in pregnancy have changed over the years. This means that more studies are needed now to see if outcomes for babies at increased risk of complications can be improved with antenatal CTG, particularly computerised CTG.

BACKGROUND

This review updates the review 'Cardiotocography for antepartum fetal assessment' by N Pattison and L McCowan (Pattison 1999).

Description of the condition

Pregnancy may be complicated by conditions that need additional ways of assessment of fetal well-being. These conditions include medical problems in the mother, which may impact on the fetus, pregnancy-specific problems and diseases of the fetus in which fetal health may be affected. Medical problems in the mother that are

associated with increased risk to the fetus include essential hypertension, pre-eclampsia, renal and autoimmune disease, maternal diabetes and thyroid disease (Lloyd 2003a; LLoyd 2003b; Nelson-Piercy 2001; NICE 2008b). Other situations in pregnancy that pose an increased risk to fetal health are prolonged pregnancy, vaginal bleeding, reduced fetal movements and prolonged ruptured membranes (Gribbin 2006). Fetal conditions include intrauterine growth restriction and fetal infection, and multiple pregnancies also increase the risks to the fetuses (Fisk 2001; Gribbin 2006). These risks include possible neurodevelopmental problems in infancy including non-ambulant cerebral palsy, developmental de-

lay, auditory and visual impairment. These can be quantified using validated tools such as Bayley Scales of Infant Development (Psychomotor Developmental Index and Mental Developmental Index) (Bayley 1993).

The indication for additional fetal assessment in all of the above situations is a real, or perceived, increased risk of fetal compromise that might lead to morbidity or mortality in the fetus or newborn.

Description of the intervention

The cardiotocograph (CTG) is a continuous electronic record of the fetal heart rate obtained via an ultrasound transducer placed on the mother's abdomen (external or indirect CTG). A second transducer is placed on the mother's abdomen over the uterine fundus to record simultaneously the presence of any uterine activity. Both fetal heart rate and uterine activity are traced simultaneously onto a paper strip. Components of the fetal heart rate that can be assessed include: baseline rate, baseline variability, accelerations and decelerations. The relationship between fetal heart rate and the timing of uterine contractions is also assessed. Cardiotocography is used widely in maternity care, both in the antepartum and intrapartum periods. Although the theoretical basis for applying and interpreting the test and indications for monitoring are similar, the focus of this review is on the use of CTG during pregnancy and before labour starts. There is a separate Cochrane review on the effectiveness of continuous intrapartum cardiotocography (Alfirevic 2006).

The term 'electronic fetal monitoring' is sometimes used synonymously with CTG monitoring, but is considered to be a less precise term because (1) CTG monitoring also includes monitoring the mother's contractions and (2) other forms of fetal monitoring might also be classed as 'electronic', e.g. ECG, fetal pulse oximetry. Antenatal CTG is a commonly used form of fetal assessment in pregnancy and uses the fetal heart rate as an indicator of fetal well-being (Boyle 2004). It may be used in isolation, sometimes referred to as the 'non-stress test' or with the stimulation of uterine activity to see how the fetal heart responds, sometimes known as the 'contraction stress test' (Owen 2001).

Antenatal CTG is most commonly performed in the third trimester of pregnancy (after 28 weeks). The gestational age at which CTG commences varies in practice, and at least in part depends on the minimum age of survival in the local neonatal unit and therefore in some institutions may be used even before 26 weeks' gestation (Smith 1987).

Antenatal CTG can also be used in combination with other methods of fetal assessment such as ultrasound Doppler measurements and amniotic fluid volume measurement (Turan 2008), and as part of a formal biophysical profile (where fetal movements, fetal tone and fetal breathing, and liquor volume are assessed with or without assessment of the fetal heart rate) (Lalor 2008). Frequency of testing varies widely in practice, depending on the indication

for the CTG and gestational age, and ranges from weekly to three times a day.

Central monitoring and computerised analysis of CTG traces

Modern cardiotocography systems are often linked to a centralised monitoring station and, therefore, the CTG can be viewed away from the women and recorded and kept on the computer system (Weiss 1997). However, there is a possibility that this may contribute further to some women's feelings of an overly technical atmosphere in labour (Snydal 1988) and may contribute to an increase in the overall caesarean section rate (Weiss 1997).

Since the 1990s, computerised fetal heart rate analysis systems have been developed to allow the automated evaluation of the CTG through numerical indices with the aim of bringing objectivity and reliability to CTG interpretation (Dawes 1992). It is also thought that the computerised CTG analysis system may be able to extract more diagnostic information from the fetal heart rate signal than visual analysis alone (Valensise 2006). The computerised CTG has been investigated in a range of clinical situations including fetal growth restriction, preterm rupture of the membranes, post-term pregnancy and in pregnancies without increased risk factors (Bellver 2004; Buscicchio 2006; Guzman 1996; Kuhnert 2007; Soncini 2006).

How the intervention might work

The underlying theoretical concept for the use of CTG in pregnancy is that it is a screening test for the identification of babies with acute or chronic fetal hypoxia or at risk of developing such hypoxia. Fetal hypoxia is believed to result in specific pathophysiological adaptations in the fetus, which in turn may cause changes in the pattern of the fetal heart rate parameters mentioned below (ACOG 1994). Therefore, accepted 'normal' limits for fetal heart rate parameters are used when interpreting antenatal CTGs.

The normal fetal heart rate varies with vagal and sympathetic tone adjustments and, therefore, varies with gestational age due to maturation of the fetal nervous system. Accepted normal parameters for the term fetus are reported as follows (Gribbin 2006; RCOG 2001).

- Baseline fetal heart rate of 110 to 160 beats per minute.
- Baseline variability should be greater than five beats per minute.
- Presence of two or more accelerations of the fetal heart rate exceeding 15 beats per minute, sustained for at least 15 seconds in a 20-minute period (Devoe 1990) this pattern is termed reactive.
 - Absence of decelerations.

In addition, consideration should be given to the frequency, duration, intensity and resting tone of uterine contractions and their relationship to the fetal heart rate pattern.

When the fetus is hypoxic, baseline heart rate variability and accelerations may decrease or disappear and decelerations in the fetal heart rate may occur (Gribbin 2006).

Test characteristic

The antenatal CTG is essentially a screening test for fetal well-being. When an antenatal CTG is performed and interpreted as abnormal, this may result in a range of further actions. These could include further testing, hospital admission, induction of labour or caesarean section.

It is important that the caregiver understands the potential advantages and disadvantages of the application of the test before the test is offered to the woman, including information about the further testing that it may lead to. As with any other test that is used in pregnancy, the test should only be undertaken with the informed consent of the woman after adequate and appropriate counselling as to the implications, benefits, limitations and consequences of such investigation (RANZCOG 2006b).

Application of a test requires subsequent interpretation of the results according to what is defined or accepted as normal and abnormal. Many local guidelines for the use of CTG also include the use of classification systems to grade or score the CTG and its components, with the aim of standardising the CTG interpretation. However, both the RCOG and RANZCOG Guidelines focus on the use of intrapartum CTG and they give no guidance on its use in the antenatal period (NICE 2007; RANZCOG 2006a; RCOG 2001).

The basis for performing and interpreting the antenatal CTG is the belief that the 'normal' CTG reflects a well, uncompromised fetus and that certain abnormalities indicate an increased possibility of fetal compromise. However, it is important to consider aspects of the testing process, such as sensitivity and specificity, and the importance of recognition of abnormalities by those interpreting the test (inter- and intra-observer variability).

Initial observational studies showed a strong correlation between an abnormal CTG and poor fetal outcome (Freeman 1982a; Freeman 1982b; Phelan 1981). In high-risk pregnancies in particular, 'non-reactive' CTGs were associated with increased morbidity and mortality for the baby (Boehm 1986; Flynn 1977). This observation has led to the belief that performance of a CTG would allow early identification of fetal heart rate changes associated with hypoxia and allow subsequent early intervention with improved outcomes. However, later studies have demonstrated a lack of specificity and high false positive rates when using the CTG to detect fetal compromise (Sadovsky 1981; Trimbos 1978b). Early studies investigating the observer reliability of antenatal

CTGs recognised that correct assessment of CTGs was not always

easy (Trimbos 1978a). Intra-observer variability when a subjective

visual assessment was used was as low as 57%, although agreement did seem to increase when basic scoring systems were used (Trimbos 1978a). Subsequent studies have confirmed poor agreement of both visual interpretation and classification or scoring of antenatal CTGs (Ayres-de-Campos 1999; Bernades 1997; Devane 2005). Even when standard scoring systems are used, inter- and intra-observer variability is significant, therefore affecting the reliability and reproducibility of the test (Borgotta 1988; Lotgering 1982).

Potential adverse effects of antenatal CTGs

It is important to consider the potential adverse effects of this form of fetal assessment. These may include the consequences of false negative results, inappropriate interpretation and subsequent false reassurance of fetal well-being for the mother and the health practitioner. Also, in the case of a false positive result, the consequences are unnecessary procedures or interventions for mother or fetus or newborn and increased use of healthcare resources.

High-risk pregnancies are also associated with maternal anxiety, and it is important to consider the effect of fetal testing on the women's emotional well-being (Mancuso 2008). There is some evidence of increased anxiety for women during and after antenatal CTG monitoring (Mancuso 2008). Mancuso measured anxiety scores in women at term presenting for computerised CTG, and found that anxiety levels were significantly increased after the CTG compared to before the test. This increase in anxiety seemed more pronounced in women with pregnancies affected by obstetric complications (Mancuso 2008). However, other evidence suggests that CTG either increases or decreases maternal anxiety depending on the individual woman's characteristics (Snydal 1988).

Women's views

There have been some studies on women's views of intrapartum CTG, which indicated that the support that women received from staff and labour companions was, overall, more important to them than the type of monitoring used (Garcia 1985; Hindley 2008; Killien 1989; Munro 2004; Soncini 2006). However, there appears to be a lack of evidence on women's views on antenatal CTG monitoring.

Why it is important to do this review

At present, CTG it is not recommended in the UK as a method of routine fetal assessment in low-risk pregnancy (NICE 2008a). However, antenatal CTGs have and continue to be used widely in the assessment of fetal well-being during pregnancy in women at increased risk of complications.

Hence, it is important to systematically review the evidence on the effectiveness of antenatal CTG. This should be assessed in women

at increased risk of complications that may adversely affect the fetus. If benefits are found for these women and babies, then it would be important to assess the potential benefits of using antenatal CTG assessments in all pregnancies. Other Cochrane reviews that relate to this topic include: 'Regimens of fetal surveillance for impaired fetal growth' (Grivell 2008); 'Fetal and umbilical Doppler ultrasound in high-risk pregnancies' (Alfirevic 2009); 'Fetal and umbilical Doppler ultrasound in normal pregnancy' (Alfirevic in progress); 'Utero-placental Doppler ultrasound in pregnancy' (Alfirevic - in progress); 'Biochemical tests for placental function' (Neilson 2003); 'Fetal movement counting for assessment of fetal well-being' (Mangesi 2007); 'Fetal manipulation for facilitating tests of fetal well-being' (Tan 2001a); 'Fetal vibroacoustic stimulation for facilitating tests of fetal well-being' (Tan 2001b); 'Maternal glucose administration for facilitating tests of fetal well-being' (Tan 2001c); 'Amniotic fluid index versus single deepest vertical pocket as a screening test for predicting adverse pregnancy outcomes' (Nabhan 2008); 'Biophysical profile for fetal assessment in high risk pregnancies' (Lalor 2008).

OBJECTIVES

We assessed the effectiveness of antenatal cardiotocograph (CTG) in improving outcomes for babies and also how effective computerised CTG might be. We aimed to assess these both in women at increased risk of problems and as a routine intervention for all pregnant women.

METHODS

Criteria for considering studies for this review

Types of studies

Any randomised and quasi-randomised trials that compared antenatal cardiotocography (including computerised CTG analysis) with alternative methods of fetal assessment.

Types of participants

All pregnant women and their babies. We assessed the use of antenatal CTG both for women at increased risk of complications that impact on the fetus, and as a routine intervention for all pregnant women.

Types of interventions

CTG performed in the antenatal period to assess fetal well-being. This would include the following.

- 1. Antenatal CTG performed in the traditional manner and recorded on paper with a subsequent interpretation by a health professional. Control group with no CTG; standard care; performance of the same test whilst withholding the result from the caregiver.
- 2. Computerised antenatal CTG, i.e. some form of quantitative analysis with subsequent interpretation by a health professional. Control groups with no CTG; standard care; performance of the same test whilst withholding the result from the caregiver.
- 3. 'Computerised' CTG versus 'traditional' CTG. Comparisons with other ways of assessing fetal well-being in pregnancy, e.g. biophysical profile, Doppler ultrasound, are covered in other Cochrane reviews (*see* 'Background' section).

Types of outcome measures

Primary outcomes

- 1. Perinatal mortality
- 2. Caesarean section

Secondary outcomes

- 1. Potentially preventable perinatal mortality (perinatal mortality excluding lethal congenital anomalies)
 - 2. Apgar less that seven at five minutes
 - 3. Apgar less than four at five minutes
- 4. Cord pH less than 7.10 or low pH/low base excess as defined by trialists
 - 5. Admission to neonatal special care or intensive care unit
 - 6. Length of stay in neonatal special care or intensive care unit
- 7. Preterm birth (less than 37 completed weeks, less than 34 completed weeks, less than 28 completed weeks)
 - 8. Gestational age at birth
- 9. Neonatal seizures (seizures in the neonatal period, either apparent clinically or detected by electro-encephalographic recordings)
- 10. Hypoxic ischaemic encephalopathy, as defined by trialists
- 11. Cerebral palsy at 12 months
- 12. Neurodevelopmental disability at more than 12 months (assessed by a validated tool, e.g. Bayley Scale)
- 13. Caesarean section for non-reassuring or abnormal fetal heart rate patterns (in the absence of known fetal hypoxia, i.e. fetal blood sampling, lactate)
- 14. Induction of labour
- 15. Antenatal hospital admission
- 16. Length of antenatal hospital stay

- 17. Emotional distress/depression/anxiety
- 18. Women's satisfaction with care

Search methods for identification of studies

Electronic searches

We contacted the Trials Search Co-ordinator to search the Cochrane Pregnancy and Childbirth Group's Trials Register (April 2009).

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

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

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

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

Searching other resources

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

We did not apply any language restrictions.

Data collection and analysis

Selection of studies

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

Data extraction and management

We designed a form to extract data. For eligible studies, two review authors extracted the data using the agreed form. We resolved discrepancies through discussion or, if it had been required, we would have consulted with a third review author.

If information regarding any of the above had been unclear, we would have attempted to contact authors of the original reports to provide further details.

Assessment of risk of bias in included studies

Two review authors independently assessed the risk of bias for each study using the criteria outlined in the *Cochrane Handbook* for Systematic Reviews of Interventions (Higgins 2008). We resolved any disagreements by discussion, and had it been necessary we would have involved a third review author.

I) Sequence generation (checking for possible selection bias)

We have 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 have assessed the method as:

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

2) Allocation concealment (checking for possible selection bias)

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

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

3) Blinding (checking for possible performance bias)

We have 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 judged studies at low risk of bias if they were blinded, or if we judged that the lack of blinding could not have affected the results. We assessed blinding separately for different outcomes or classes of outcomes. We have assessed the blinding as:

- · adequate, inadequate or unclear for participants;
- adequate, inadequate or unclear for personnel;
- adequate, inadequate or unclear for outcome assessors.

In these studies, blinding was not possible for the clinician, but it would have been possible for the women where studies assessed revealing the cardiotocograph data versus concealing it. Outcome assessors could also have been blinded.

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

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

We have discussed whether missing data greater than 20% might (a) be reasonably expected (acknowledging that with long-term follow up, complete data are difficult to attain), and (b) impact on ourcomes.

5) Selective reporting bias

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

We have assessed the methods as:

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

6) Other sources of bias

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

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

yes;

- no:
- unclear.

7) Overall risk of bias

We have made explicit our judgements about whether studies are at high risk of bias, according to the criteria given in the *Handbook* (Higgins 2008). With reference to (1) to (6) above, we have assessed the likely magnitude and direction of the bias and whether we considered it was likely to impact on the findings. There were insufficient data to explore the impact of the level of bias through sensitivity analyses - see Sensitivity analysis' for what we would have done had there been sufficient data.

Measures of treatment effect

Dichotomous data

For dichotomous data, we have presented the results as risk ratio (RR) with 95% confidence intervals.

Continuous data

For continuous data, we have presented the results as mean difference (MD) with 95% confidence intervals. When pooling data across studies, we have used the mean difference if outcomes are measured in the same way in studies, and the standardised mean difference (SMD), where possible, if outcomes were measured in studies using different methods of assessment.

Unit of analysis issues

Cluster-randomised trials

We have not found any cluster-randomised trials but had we done so, we would have included them in the analyses along with individually randomised trials using the methods described in the *Handbook* (Higgins 2008).

Dealing with missing data

For included studies, we noted levels of attrition. Had it been necessary, we would have explored the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis according to the methods outlined in the *Handbook* (Higgins 2008). We would have considered there to be high levels of missing data when there were greater than 20% loss and/or an imbalance in missing data between the groups. However, this was not necessary.

For all outcomes, we carried out analyses, as far as possible, on an intention to treat basis, i.e. we have attempted to include all participants randomised to each group in the analyses. The denominator for each outcome in each trial was be the number of participants with data ('available case' analysis) (Higgins 2008).

Assessment of heterogeneity

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

We found no heterogeneity, but had we done so we would have explored it by pre-specified subgroup analysis.

Assessment of reporting biases

We found no specific reporting bias (see 'Selective reporting bias' above), but had we done so we would have attempted to contact study authors asking them to provide missing outcome data. Where this is not possible, and we thought the missing data were likely to introduce serious bias, we would have explored the impact of including such studies in the overall assessment of results by a sensitivity analysis.

If there had been 10 or more studies in a meta-analysis, we would have investigated reporting biases (such as publication bias) using funnel plots. We would have assessed funnel plot asymmetry visually, and used formal tests for funnel plot asymmetry. For continuous outcomes we would have used the test proposed by Egger 1997, and for dichotomous outcomes we would have used the tests proposed by Harbord 2006 or Peters 2006. If we had detected asymmetry by any of these tests, or a visual assessment had suggested it, we would have performed exploratory analyses to investigate it.

Data synthesis

We have carried out statistical analysis using the Review Manager software (RevMan 2008). We have used fixed-effect meta-analysis for combining data, as it was reasonable to assume that studies were estimating the same underlying treatment effect: i.e. the 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 differed between trials, or if we had detected substantial statistical heterogeneity, we would have used a random-effects analysis to produce an overall summary, if this had been considered clinically meaningful. If an average treatment effect across trials had been considered not clinically meaningful, we would not have combined the heterogeneous trials. If we had used randomeffects analyses, we would have presented the results as the average treatment effect and its 95% CI, the 95% prediction interval for the underlying treatment effect, and the estimates of T^2 and I^2 .

Subgroup analysis and investigation of heterogeneity

We had planned to carry out the following subgroup analyses assessing primary outcomes only; however, we decided to do subgroup analyses for other outcomes as we felt this would be important information to capture.

- 1. Women with increased risk of complications for the fetus versus women with low risk of complications versus those with no defined risk.
- 2. Women with singleton pregnancies versus women with multiple pregnancies.
- 3. Antenatal CTG testing begun on fetus at less than 37 completed weeks' gestation (preterm) versus antenatal CTG testing begun on fetus at 37 or more completed weeks' gestation (term and post-term).

If there had been data for women at low risk, then for fixed-effect inverse variance meta-analysis we would have assessed differences between the subgroups by interaction tests (Deeks 2001). For random-effects analyses and fixed-effect analyses using methods other than inverse variance, we would have assessed differences between subgroups by inspection of the subgroups' confidence intervals; non-overlapping confidence intervals indicated a difference in treatment effect between the subgroups.

Sensitivity analysis

We would have performed sensitivity analysis based on trial quality, separating high-quality trials from trials of lower quality. We would have defined 'high quality', for the purposes of this sensitivity analysis, as a trial having adequate allocation concealment and a 'reasonably expected loss to follow up' classified as less than 20%, given the stated importance of attrition as a quality measure (Tierney 2005). We considered that there were insufficient data for such sensitivity analyses.

RESULTS

Description of studies

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

See 'Characteristics of included studies', 'Characteristics of excluded studies' and 'Characteristics of studies awaiting classification'.

Results of the search

Our search strategy identified 15 publications involving 13 studies for potential inclusion. Of those, we included six studies with 2105 women (Bracero 1999; Brown 1982; Flynn 1982;

Kidd 1985; Lumley 1983; Steyn 1997) and excluded six studies (Hertz 1979; Moffatt 1997; Nathan 2000; Newnham 1988; Piyamongkol 2006; Reece 1992). One study is awaiting classification (van Geijn 1991).

Included studies

Four studies with 1636 women compared antenatal CTG (or CTG with results revealed) with no CTG (or CTG with results concealed) (Brown 1982; Flynn 1982; Kidd 1985; Lumley 1983). Two studies with 469 women compared antenatal CTG with computerised analysis with traditional CTG (i.e. visual analysis) (Bracero 1999; Steyn 1997).

The six included studies only recruited women considered at increased risk of pregnancy complications (Bracero 1999; Brown 1982; Flynn 1982; Kidd 1985; Lumley 1983; Steyn 1997), thus we were unable to perform our planned subgroup analysis by risk status. Two studies only included women who were at less than 37 weeks' gestation at study entry (Brown 1982; Steyn 1997). The remaining four studies (Bracero 1999; Flynn 1982; Kidd 1985; Lumley 1983) included women with fetuses at any gestation at study entry; however, insufficient information was provided to allow a less than 37 weeks and a 37 or more weeks subgroup analysis for these studies. None of the included studies provided information about singleton and multiple pregnancies.

For the comparison of 'antenatal CTG' (or CTG with results revealed) with 'no antenatal CTG' (or CTG with results concealed), three studies (Brown 1982; Kidd 1985; Lumley 1983) reported sufficient information for both our primary outcomes of perinatal

mortality and caesarean section. One study reported data on perinatal mortality; however, insufficient information was reported to include the second primary outcome of caesarean section (Flynn 1982).

For analysis of our secondary outcomes, we found information from our included studies only for the outcomes of: Apgar less than seven at five minutes; admission to special care unit or intensive care unit; gestational age at birth; neonatal seizures and induction of labour.

For the comparison of computerised CTG versus traditional CTG, two studies reported information for both our primary outcomes (Bracero 1999; Steyn 1997).

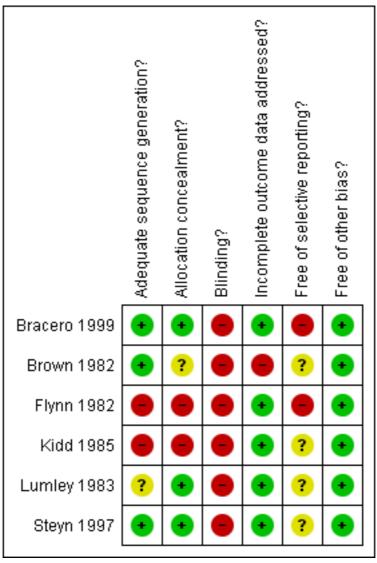
Excluded studies

We excluded six studies; see 'Characteristics of excluded studies'.

Risk of bias in included studies

We assessed included studies for methodological quality on the basis of selection bias (sequence generation and allocation concealment), performance bias (blinding), attrition bias (incomplete outcome data), and selective reporting bias (see 'Methods' above). Overall, the studies were not of high quality, which was perhaps not surprising as four were undertaken in the 1980s and one in the 1990s when our understanding of the importance of the issues of risk of bias were not so well understood as they are now (Figure 1).

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



Allocation

We assessed two included studies as having neither adequate sequence generation nor allocation concealment as they were quasirandomised trials (Flynn 1982; Kidd 1985). We assessed two studies as having both adequate sequence generation and allocation concealment (Bracero 1999; Steyn 1997) and one as having adequate sequence generation but unclear allocation concealment (Brown 1982). One study did not report on methods for se-

quence generation; however allocation concealment was adequate (Lumley 1983).

Blinding

We assessed blinding as unclear or not adequate for all included studies, as blinding of either participants, clinicians or outcome assessors was not undertaken or reported.

Incomplete outcome data

We assessed risk of attrition bias as low for four out of the six included studies. Three studies reported no loss to follow up (Flynn 1982; Kidd 1985; Steyn 1997) and one study reported a 1.6% overall loss to follow up (women either withdrew or gave birth elsewhere) (Lumley 1983). In this same study, 11% (30 women) allocated to CTG did not receive it but analysis was by intention to treat (Lumley 1983).

In the study by Brown, 48 (25%) women were excluded postrandomisation, and not assessed with CTG (Brown 1982). This would be considered to be a significant loss to follow up/postrandomisation exclusion. We were only able to re-include data on perinatal mortality because it was reported that there were no deaths or morbidity in the babies excluded after randomisation. In the study by Bracero, the study authors excluded five babies from the analyses because of congenital abnormalities (one from the computerised CTG group and four from the traditional CTG group). We re-included these babies in both the numerator and denominator for the outcome of PNM, so the comparison of the primary outcome of PNM is compared 'as randomised' (Bracero 1999). These babies are excluded from the numerator for the secondary outcome on 'Potentially preventable PNM'. For the 'Apgar scores less than seven at five minutes', we have added back the babies with congenital abnormalities in the denominators, so the comparison is 'as randomised' (Bracero 1999).

Selective reporting

As we were unable to assess the protocols for the trials, we assessed the studies included in this review as unclear or not free of selective reporting. In addition, Flynn did not report all caesarean section outcomes, only elective and after induction of labour (Flynn 1982), and Bracero did not report caesarean sections for fetal distress as intended (Bracero 1999).

Other potential sources of bias

We assessed all studies as seeming to be free of other potential sources of bias.

Effects of interventions

All the studies included in the review looked at women at increased risk of complications and none of the studies assessed women at low risk of complications. In addition, the lack of clarity regarding the quality of the studies, and the small numbers of studies included, has meant that we have not always undertaken any sensitivity analyses by quality and the findings, therefore, remain uncertain.

I) Traditional antenatal CTG versus no CTG (four studies, 1636 women)

For this comparison, all the studies compared CTG with findings revealed versus CTG with findings concealed. We have included four studies involving 1636 women for this comparison (Brown 1982; Flynn 1982; Kidd 1985; Lumley 1983). All the studies involved women at increased risk of complications. Two of the studies were not of high quality, being quasi-RCTs (Flynn 1982; Kidd 1985) and of the remaining two, one had unclear allocation concealment (Brown 1982) and the other unclear sequence generation (Lumley 1983). So, overall, the quality of the evidence in this comparison is not high.

Primary outcomes

There was no significant difference identified in the risk of perinatal mortality (risk ratio (RR) 2.05, 95% confidence interval (CI) 0.95 to 4.42, 2.3% versus 1.1%, four studies, N = 1627, graph 1.1.1). Although the 95% confidence interval does approach one in favour of no antenatal CTG, only one study was of good quality with adequate allocation concealment (Lumley 1983). Two of the four studies were quasi-RCTs (Flynn 1982; Kidd 1985) and the third had unclear allocation concealment (Brown 1982). Excluding these three studies and just using the only high-quality study still showed no significant difference identified for perinatal mortality (RR 1.53, 95% CI 0.51 to 4.61, one study, N = 530, graph 1.1.1). However, the review is clearly underpowered to assess this outcome.

We identified no significant difference in the risk of caesarean section for women (RR 1.06, 95% CI 0.88 to 1.28, 19.7% versus 18.5%, three trials, N = 1279, graph 1.2.1).

Secondary outcomes

We identified no significant difference in potentially preventable perinatal mortality (RR 2.46, 95% CI 0.96 to 6.30, four studies, N = 1627, graph 1.3.1). The result for this outcome was similar to that for overall mortality, although the confidence intervals are wider. There was also no significant difference identified in Apgar scores less than seven at five minutes (RR 0.83, 95% CI 0.37 to 1.88, one trial, N = 396, graph 1.4.1); admission to neonatal special care units or neonatal intensive care units (RR 1.08, 95% CI 0.84 to 1.39, two trials, N = 883, graph 1.7.1); gestational age at birth (mean difference (MD) 0.00, 95% CI -0.33 to 0.33, one trial, N = 353, graph 1.12.1); or of neonatal seizures (RR 0.54, 95% CI 0.05 to 5.91, one trial, N = 300, graph 1.13.1).

For all other secondary outcomes, there were no data available to include in the analysis.

Subgroup analyses

1) Women with increased risk of complications for the fetus versus women with low risk of complications versus those with no defined risk

As all women involved in the four studies included for this comparison were at increased risk of complications, so the above results are, therefore, relevant to this subgroup.

2) Women with singleton pregnancies versus women with multiple pregnancies

None of the studies reported on whether they included singleton or multiple pregnancies.

3) Antenatal CTG testing begun on fetus less than 37 completed weeks' gestation versus antenatal CTG testing begun on fetus 37 or more completed weeks' gestation

Three studies included both women recruited at less than 37 weeks and at 37 or more weeks;, however they did not provide a breakdown of these groups (Flynn 1982; Kidd 1985; Lumley 1983). Only one study clearly enrolled only women at less than 37 weeks' gestation (Brown 1982). So there were insufficient data to address this question.

2) Computerised CTG versus no CTG (no studies)

There were no studies that addressed this comparison.

3) Computerised CTG versus traditional CTG (two studies, 469 women)

For this comparison, we included two studies involving 469 women (Bracero 1999; Steyn 1997). All women in the trials were at increased risk of complications and were recruited at variable gestations. The studies were of good overall quality, with low risk of bias for sequence generation and allocation concealment, though lack of being able to blind the clinicians may affect some outcomes like caesarean section. The small size of the studies is also a limitation.

Primary outcomes

There was a significant reduction in perinatal mortality (RR 0.20, 95% CI 0.04 to 0.88, 0.9% versus 4.2%, two studies, N = 469, graph 3.1.1).

There was no difference in the risk of caesarean section (RR 0.87, 95% CI 0.61 to 1.24, 63% versus 72%, one trial, N = 59, graph 3.2.1).

Secondary outcomes

We identified no significant difference in potentially preventable perinatal mortality (RR 0.23, 95% CI 0.04 to 1.29, two studies, N = 469, graph 3.3.1). We also identified no significant difference in: Apgar scores less than seven at five minutes (RR 1.31, 95% CI 0.30 to 5.74, two studies, N = 469, graph 3.4.1); length of stay in neonatal intensive care unit (MD -0.40, 95% CI -0.99 to 0.19, one study, N = 405, graph 3.8.1) or gestational age at birth (MD -0.10, 95% CI -0.43 to 0.23, one study, N = 405, graph 3.12.1). For all other outcomes, there are no data suitable for inclusion in the analysis.

Subgroup analyses

1) Women with increased risk of complications for the fetus versus women with low risk of complications versus those with no defined risk

As all women involved in the two studies included for this comparison were at increased risk of complications, so the above results are therefore relevant to this subgroup.

2) Women with singleton pregnancies versus women with multiple pregnancies

None of the studies reported on whether they included singleton or multiple pregnancies.

3) Antenatal CTG testing begun on fetus at less than 37 completed weeks' gestation versus antenatal CTG testing begun on fetus at 37 or more completed weeks' gestation

One study began testing at less than 37 weeks (Steyn 1997) and the other included included both women recruited at less than 37 weeks and at 37 or more weeks (Bracero 1999). So there were again insufficient data to assess this question.

DISCUSSION

Antenatal cardiotocography (CTG) is a widely used method of fetal assessment and is commonly applied to a large and varied population of pregnant women and their babies. The basic technology that underlies the performance and application of the traditional CTG has changed little since its introduction more than 20 years ago. Despite concerns regarding the reliability and reproducibility of the antenatal CTG as a test of fetal assessment, it has widely infiltrated maternity care practice.

We have systematically reviewed the evidence on the effectiveness of antenatal CTG for the improvement of maternal and infant health. We have found no clear benefit for mothers or their babies in the studies included in this review.

However, the included studies have limitations with regard to implications for current practice. Firstly, four of the six studies were undertaken in the 1980s during a time when both screening of and management of risks to fetal health were possibly different to current maternity care practice. For example, many of the included studies were undertaken at a time when practice included the use of many tests that are today considered obsolete (e.g. blood tests for placental function). Ultrasound assessment of fetal anatomy and, in particular, use of Doppler studies have improved in quality and become a useful tool for diagnosis and surveillance in pregnancies at high risk of complications (Alfirevic 2009). Outcomes for premature babies have also improved greatly in terms of both survival and morbidity (Chan 2008). Some of these aspects may make the translation of results from studies performed in the 1980s difficult and less relevant to current practice. Secondly, all included studies were performed in high-income countries. The use of a basic CTG might be feasible and affordable in certain healthcare settings where other tools to assess fetal health such as ultrasound might be unaffordable. Thirdly, despite the probable lack of highquality evidence to support this, fetal assessment in current practice often involves a combination of methods and this perhaps reduces the relevance of the effectiveness of a single method of testing. Thirdly, the review is clearly underpowered for assessing perinatal mortality.

Another limitation is that the included studies only recruited women at increased risk of complications. However, since these studies have failed to show a benefit for these women and their babies, then it is perhaps even less likely that a benefit would be found in low-risk women.

One advantage of our review is a separate analysis of two small studies assessing the effects of computerised CTG. This type of CTG, with automated assessment of the heart rate parameters, may overcome some problems of standard CTG such as low reproducibility, inter- and intra-observer variation in interpretation and high false positive rates. Further evaluation is, however, needed and should include consideration of women's and clinician's views. Pregnancies with complications may increase anxiety and women often value the 'human touch' when anxious in pregnancy. The evaluation of women's views with traditional CTG should also be a focus of further studies.

AUTHORS' CONCLUSIONS

Implications for practice

We found no good evidence to support the use of traditional cardiotocography (CTG), or computerised CTG, in pregnancy for improving fetal outcomes. The data are not of high quality and lacked power to detect possible important differences in either benefit or harm. We recognise that many aspects of maternity care may have changed since the trials reviewed here were carried out, so new studies are needed to assess the effects of traditional and computerised antenatal CTG before they are used in clinical practice.

Implications for research

Research on the effectiveness of traditional CTG should focus on women with specific conditions that pose risks to fetal health. For example, the use of CTG for fetal assessment in women with a post-term pregnancy, assessment of fetal health in pregnancies with hypertension requiring 'day stay' assessment, or CTG in women with decreased fetal movements or at increased risk of stillbirth. In addition, both high-income and low-income studies are required, and the use of CTG in combination with other tests of fetal well-being should also be assessed.

The use of computerised CTG should be evaluated with some urgency as there is currently little high-quality evidence to support its use, but preliminary findings appear encouraging. Clinical trials should not only assess infant and maternal health outcomes, but women's views and satisfaction with care. The use of the minimum data set for identifying outcomes proved useful here (Devane 2007) and the outcomes listed in this review should be used in future trials. Assessing women's views will require good qualitative research methods.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Bracero 1999

Methods	RCT, randomised in blocks of 10.	
Participants	410 women refereed for antenatal monitoring because of concerns of increased risk.	
Interventions	Intervention: computerised CTG (N = 205). Control: traditional CTG (visual analysis) (N = 205).	
Outcomes	PNM; gestational age at birth; birthweight; Apgar scores; length NICU stay.	
Notes	Subgroups: increased risk/singletons or multiples/mixed gestation at trial entry. Outcomes not specified in the review protocol: PNM excluding congenital malformations; PN morbidity as defined by authors; Apgar < 7 at 1 minute; number of babies in NICU for > 2 days; length hospital stay (antenatal or for birth and postnatal not specified); number of surveillance tests antenatally.	

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	"computer-generated random table of random numbers"
Allocation concealment?	Yes	"the group assignment was placed in opaque envelopes. The indication for performing FHR monitoring was documented for each participant." Although not specific that the order the enveloped were opened could not be changed, it would seem that allocation concealment was adequate.
Blinding? All outcomes	No	Women did not know which group they were in because as the same Sonicaid was used but the computer function turned off for the control group. However, clinicians knew as they used the findings to make decision. There could be bias a number of outcomes here.
Incomplete outcome data addressed? All outcomes	Yes	5 of the babies who died were excluded because of congenital abnormalities, 1 from the computerised group and 4 from the traditional group. We have added these back so the analysis is by randomised groups and so ITT.

Bracero 1999 (Continued)

Free of selective reporting?	No	We have not assessed the trial protocol but in addition the authors were to report on CS for fetal distress and did not do so.
Free of other bias?	Yes	Groups were similar with respect to age, ethnicity, gravidity, and fetal sex. Also similar in primary indication for FH monitoring. There were no obvious other biases.

Brown 1982

Methods	RCT.
Participants	401 women considered at increased risk for complications between 32 and 36 weeks of pregnancy.
Interventions	Intervention: <u>CTG revealed</u> performed weekly from 34 weeks (30 minute duration) and more often if indicated, assessed by scoring system of Pearson and Weaver. Other care included biochemical assessment and ultrasound. (N = 201). Control: <u>CTG concealed</u> performed as above, other care as per intervention group. (N = 200).
Outcomes	Apgar scores, admission to SCBU, neonatal acid base status, mode of birth, birthweight, gestational age, abnormal FH in labour, perinatal mortality, onset of labour.
Notes	Subgroups: increased risk/singletons or multiples/< 37 weeks at trial entry. Outcomes not specified in the review protocol: this study also assessed: spontaneous vaginal births; vaginal breech births; use of forceps; Apgar score < 7 at 1 minute; low Apgar scores at 5 minutes; birthweight.

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	"computer randomised"
Allocation concealment?	Unclear	"computer randomised series of numbered envelopes"; how- ever, we are not sure if the envelopes were opaque.
Blinding? All outcomes	No	Participant: yes. Clinician: no, it was not possible to blind clinicians. Outcome assessor: unclear. We have scored this 'no' as the clinician will make many of the judgements regarding care and outcomes, particularly the primary outcome of CS could be biased by the intervention not being blinded.

Brown 1982 (Continued)

Incomplete outcome data addressed? All outcomes	No	48 (25%) women excluded post randomisation, and not assessed with CTG. We can only re-include the data on PNM because it is reported that there were no deaths or morbidity in the babies excluded after randomisation.
Free of selective reporting?	Unclear	We have not assessed the trial protocol.
Free of other bias?	Yes	There are no obvious other biases.

Flynn 1982

Methods	Quasi-RCT.	
Participants	300 women either admitted in the antenatal period for conditions that might be associated with "fetal jeopardy" or outpatients at term (preferably > 41 weeks).	
Interventions	Intervention: non-stress CTG revealed (outpatients 1 per week, inpatients twice per week) ($N = 144$). Comparison: non-stress CTG concealed (outpatients 1 per week, inpatients twice per week) ($N = 156$).	
Outcomes	Perinatal mortality, neonatal neurological signs, Apgars, antenatal visits, type of AN care, labour onset, mode of birth, patients discharged from hospital.	
Notes	Subgroups: increased risk/singletons or multiples/mixed gestation at trial entry. Outcomes not specified in the review protocol: this study also assessed: elective caesarean; spontaneous vaginal birth following induction of labour; forceps following induction of labour; caesarean following induction of labour; neonatal irritability; mean Apgar score at 1 minute (though no SD reported); mean Apgar score at 5 minutes (though no SD reported).	

Item	Authors' judgement	Description
Adequate sequence generation?	No	Quasi-RCT, even or odd hospital number.
Allocation concealment?	No	Quasi-RCT, even or odd hospital number.
Blinding? All outcomes	No	Participant: yes. Clinician: no, it was not possible to blind clinicians. Outcome assessor: unclear. We have scored this 'no' as the clinician will make many of the judgements regarding care and outcomes, particularly the primary outcome of CS could be biased by the intervention not being blinded.

Flynn 1982 (Continued)

Incomplete outcome data ad All outcomes	ddressed? Yes	No loss to follow up reported.
Free of selective reporting?	No	They do not report on all CS data, only elective and after induction. They would need to collect all CS data to be able to report what they do, do there is some selection in reporting outcomes.
Free of other bias?	Yes	There are no obvious other biases.

Kidd 1985

Methods	Quasi-RCT (by date of birth).	
Participants	396 women admitted to the antenatal ward after 26 weeks' gestation for maternal/fetal/obstetric reasons (including: hypertension, preterm labour, antepartum haemorrhage, diabetes, cardiac disease, suspected fetal growth restriction).	
Interventions	Intervention: <u>CTG revealed</u> : daily for 30 minutes (N = 198). Control: <u>CTG concealed</u> : daily for 30 minutes (N = 198).	
Outcomes	Obstetric interventions, fetal compromise, fetal outcome, mode of birth, spontaneous/induced labour, use of intrapartum CTG, fetal distress, Apgar scores.	
Notes	Subgroups: increased risk/singletons or multiples/mixed gestation at trial entry. Outcomes not specified in the review protocol: this study also assessed: operative vaginal births; use of intrapartum CTG.	

Item	Authors' judgement	Description
Adequate sequence generation?	No	Allocation by 1st numeral of date of birth.
Allocation concealment?	No	Open quasi-RCT as 'Date of birth'.
Blinding? All outcomes	No	Participant: unclear. Clinician: no, it was not possible to blind clinicians. Outcome assessor: no. We have scored this 'no' as the clinician will make many of the judgements regarding care and outcomes, particularly the primary outcome of CS could be biased by the intervention not being blinded.
Incomplete outcome data addressed? All outcomes	Yes	No loss to follow up.
Free of selective reporting?	Unclear	Outcomes do not seem to be prespecified.

Kidd 1985 (Continued)

Free of other bias?	Yes	There are no obvious other biases.					
Lumley 1983							
Methods	RCTs.						
Participants	539 women after 26 w poor placental functio	reeks, admitted to the antenatal ward for obstetric complications, n and social reasons.					
Interventions	tests per usual care in monitoring).	Intervention: antenatal non-stress CTG performed once a week for 40-60 minutes, other tests per usual care include serum tests of placental function. ($N = 271, 241$ received monitoring). Control: no antenatal CTG, other tests as per intervention group ($N = 259$).					
Outcomes		mortality, admission to SCBU, neurological signs in the neonate, of birth, birthweight, gestation, abnormal fetal heart rate in labour.					
Notes	Outcomes not specifie 7 at 2 minutes; sponta	Subgroups: increased risk/singletons or multiples/mixed gestation at trial entry. Outcomes not specified in the review protocol: this study also assessed: Apgar scours < 7 at 2 minutes; spontaneous labour; abnormal FHR; spontaneous vaginal birth; use of forceps; neurological signs; birthweight < 5th centile; birthweight < 10th centile.					
Risk of bias							
Item	Authors' judgement	Description					
Adequate sequence generation?	Unclear	No information given.					
Allocation concealment?	Yes	"numbered, sealed, opaque envelope"					
Blinding? All outcomes	No	Participant: unclear. Clinician: no, it was not possible to blind clinicians. Outcome assessor: unclear. We have scored this 'no' as the clinician will make many of the judgements regarding care and outcomes, particularly the primary outcome of CS could be biased by the intervention not being blinded.					
Incomplete outcome data addressed? All outcomes	Yes	1.6% overall loss to follow up; either withdrew or gave birth elsewhere. 11% (30 women) allocated to CTG did not receive it but analysis was by intention to treat.					
Free of selective reporting?	Unclear	Trial protocol not assessed.					
Free of other bias?	Yes	There are no obvious other biases.					

Steyn 1997

Methods	RCT.
Participants	59 women with severe preeclampsia between 28 and 34 weeks' gestation admitted to high-risk obstetric ward for expectant management.
Interventions	Intervention: computerised CTG, 4 times daily for 10-60 minutes (N = 30). Control: traditional CTG (visual analysis), 4 times daily for 10 minutes (N = 29).
Outcomes	Perinatal mortality and morbidity, mode of birth (indications for delivery, onset of labour, neonatal outcomes, NICU admission and stay).
Notes	Subgroups: increased risk/singletons or multiples/< 37 weeks at trial entry. Continuous outcomes: this study also assessed the following continuous outcomes but did not report SD so we are unable to use the data: length of stay in NICU; gestational age at birth. Outcomes not specified in the review protocol: this study also assessed: neonatal morbidity; birthweight.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	"generated by computer"
Allocation concealment?	Yes	"random numbers, enclosed in successively numbered, sealed, opaque envelopes"
Blinding? All outcomes	No	Participant: unclear. Clinician: no, it was not possible to blind clinicians. Outcome assessor: unclear. We have scored this 'no' as the clinician will make many of the judgements regarding care and outcomes, particularly the primary outcome of CS could be biased by the intervention not being blinded.
Incomplete outcome data addressed? All outcomes	Yes	No loss to follow up.
Free of selective reporting?	Unclear	We did not assess the trial protocol.
Free of other bias?	Yes	There are no obvious other biases.

AN: antenatal CS: caesarean section CTG: cardiotocograph FH: fetal heart FHR: fetal heart rate ITT: intention to treat NICU: neonatal intensive care unit

PNM: perinatal mortality

RCT: randomised controlled trial SCBU: special care baby unit SD: standard deviation

Characteristics of excluded studies [ordered by study ID]

Hertz 1979	Not an RCT.
Moffatt 1997	This study did not assess antenatal CTG but compared lateral tilt during antenatal CTG assessment with no lateral tilt during antenatal CTG assessment.
Nathan 2000	This study compared sitting upright for the CTG test with lying supine for the CTG test.
Newnham 1988	This study did not assess antenatal CTG but compared non-stress CTG with contraction stress test, with intention to see which test provided information more quickly.
Piyamongkol 2006	This study looked at manual stimulation compared with non-stress CTG.
Reece 1992	Not an RCT. Women did a non-stress test at home then came in for a repeat by a nurse. Experts then assessed the traces.

CTG: cardiotocograph

RCT: randomised controlled trial

Characteristics of studies awaiting assessment [ordered by study ID]

van Geijn 1991

Methods	Trial to assess the validity of computerized FHR monitoring using system 8000 versus conventional FHR on intrauterine growth retardation.
Participants	Women with pregnancies affected by intrauterine growth restriction (and other high-risk pregnancies?).
Interventions	Computerised CTG versus conventional CTG.
Outcomes	Pregnancy outcomes, number of instrumental deliveries, diagnosis of fetal distress and duration of pregnancies.
Notes	We only have information about the protocol of this study. We are attempting to contact the authors for their results.

CTG: cardiotocograph FHR: fetal heart rate

DATA AND ANALYSES

Comparison 1. Traditional antenatal CTG versus no antenatal CTG

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Perinatal mortality	4	1627	Risk Ratio (M-H, Fixed, 95% CI)	2.05 [0.95, 4.42]
1.1 Women at increased risk of complications	4	1627	Risk Ratio (M-H, Fixed, 95% CI)	2.05 [0.95, 4.42]
1.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.3 Women with no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2 Caesarean section	3	1279	Risk Ratio (M-H, Fixed, 95% CI)	1.06 [0.88, 1.28]
2.1 Women at increased risk of complications	3	1279	Risk Ratio (M-H, Fixed, 95% CI)	1.06 [0.88, 1.28]
2.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
3 Any potentially preventable perinatal deaths	4	1627	Risk Ratio (M-H, Fixed, 95% CI)	2.46 [0.96, 6.30]
3.1 Women at increased risk of complications	4	1627	Risk Ratio (M-H, Fixed, 95% CI)	2.46 [0.96, 6.30]
3.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
3.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
4 Apgar less than 7 at 5 minutes	1	396	Risk Ratio (M-H, Fixed, 95% CI)	0.83 [0.37, 1.88]
4.1 Women at increased risk of complications	1	396	Risk Ratio (M-H, Fixed, 95% CI)	0.83 [0.37, 1.88]
4.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
4.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
5 Apgar less than 4 at 5 minutes	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
5.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
5.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
5.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
6 Cord pH less than 7.10 or low pH as defined by trialists	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
6.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
6.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
6.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

7 Admission to neonatal special care unit or intensive care unit	2	883	Risk Ratio (M-H, Fixed, 95% CI)	1.08 [0.84, 1.39]
7.1 Women at increased risk of complications	2	883	Risk Ratio (M-H, Fixed, 95% CI)	1.08 [0.84, 1.39]
7.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
7.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
8 Length of stay in neonatal special	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
care unit or intensive care unit			,	
8.1 Women at increased risk of complications	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
8.2 Women at low risk of complications	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
8.3 Women at no defined risk	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
9 Preterm birth less than 37 weeks	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
9.1 Women at increased risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
of complications			,	
9.2 Women at low risk of	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
complications				
9.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
10 Preterm birth less than 34	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
weeks				
10.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
10.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
10.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
11 Preterm birth less than 28	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
weeks	Ü	O	rusk ratio (Wi-11, 11xcu, 7)/0 Ci)	140t estillable
11.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
11.2 Women at low risk of	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
complications				
11.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
12 Gestational age at birth	1	353	Mean Difference (IV, Fixed, 95% CI)	Not estimable
12.1 Women at increased risk	1	353	Mean Difference (IV, Fixed, 95% CI)	Not estimable
of complications				
12.2 Women at low risk of complications	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
12.3 Women at no defined	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
13 Neonatal seizures (seizures in the neonatal period, either apparent clinically or detected by electroencephalographic recordings)	1	300	Risk Ratio (M-H, Fixed, 95% CI)	0.54 [0.05, 5.91]
13.1 Women at increased risk of complications	1	300	Risk Ratio (M-H, Fixed, 95% CI)	0.54 [0.05, 5.91]

13.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
13.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
14 Hypoxic ischaemic encephalopathy as defined by trialists	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
14.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
14.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
14.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
15 Cerebral palsy at 12 months of age	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
15.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
15.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
15.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
16 Neurodevelopmental disability at 12 months of age	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
16.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
16.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
16.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
17 Caesarean section for non- reassuring or abnormal fetal heart rate patterns	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
17.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
17.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
17.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
18 Induction of labour	2	696	Risk Ratio (M-H, Fixed, 95% CI)	0.97 [0.80, 1.17]
18.1 Women at increased risk of complications	2	696	Risk Ratio (M-H, Fixed, 95% CI)	0.97 [0.80, 1.17]
18.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
18.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
19 Antenatal hospital admission	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
19.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
19.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

19.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
20 Length of antenatal hospital stay	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
20.1 Women at increased risk of complications	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
20.2 Women at low risk of complications	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
20.3 Women at no defined risk	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
21 Emotional distress/depression/ anxiety	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
21.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
21.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
21.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
22 Women's satisfaction with care	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
22.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
22.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
22.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

Comparison 3. Computerised antenatal CTG versus traditional antenatal CTG

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Perinatal mortality	2	469	Risk Ratio (M-H, Fixed, 95% CI)	0.20 [0.04, 0.88]
1.1 Women at increased risk of complications	2	469	Risk Ratio (M-H, Fixed, 95% CI)	0.20 [0.04, 0.88]
1.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.3 Women with no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2 Caesarean section	1	59	Risk Ratio (M-H, Fixed, 95% CI)	0.87 [0.61, 1.24]
2.1 Women at increased risk of complications	1	59	Risk Ratio (M-H, Fixed, 95% CI)	0.87 [0.61, 1.24]
2.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
3 Any potentially preventable perinatal death	2	469	Risk Ratio (M-H, Fixed, 95% CI)	0.23 [0.04, 1.29]
3.1 Women at increased risk of complications	2	469	Risk Ratio (M-H, Fixed, 95% CI)	0.23 [0.04, 1.29]

3.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
3.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
4 Apgar less than 7 at 5 minutes	2	469	Risk Ratio (M-H, Fixed, 95% CI)	1.31 [0.30, 5.74]
4.1 Women at increased risk	2	469	Risk Ratio (M-H, Fixed, 95% CI)	1.31 [0.30, 5.74]
of complications	_		- 2001 - 2001 (2001 - 20)	
4.2 Women at low risk of	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
complications				
4.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
5 Apgar less than 4 at 5 minutes	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
5.1 Women at increased risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
of complications				
5.2 Women at low risk of	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
complications				
5.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
6 Cord pH less than 7.10 or low	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
pH as defined by trialists				
6.1 Women at increased risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
of complications				
6.2 Women at low risk of	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
complications			,	
6.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
7 Admission to neonatal special	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
care unit or intensive care unit			,	
7.1 Women at increased risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
of complications		•	(,, , , , , , ,,	- 1.00 000000000000000000000000000000000
7.2 Women at low risk of	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
complications	Ü	Ü	radic ratio (11 11, 11 act, 75 % Ci)	1 vot estimatie
7.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
8 Length of stay in neonatal special	1	405	Mean Difference (IV, Fixed, 95% CI)	-0.40 [-0.99, 0.19]
care unit or intensive care unit	•	10)	media 2 merenee (11, 1 med, 75, 70 Gr)	0.10 [0.55, 0.15]
8.1 Women at increased risk	1	405	Mean Difference (IV, Fixed, 95% CI)	-0.40 [-0.99, 0.19]
of complications	•	10)	ivicali Dilicicine (17, 11xed, 77/0 OI)	0.10 [0.55, 0.15]
8.2 Women at low risk of	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
complications	O	O	ivicali Dilicicine (17, 11xed, 77/0 OI)	1 vot estimable
8.3 Women at no defined risk	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
9 Preterm birth less than 37 weeks	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
9.1 Women at increased risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
of complications	Ü	Ü	radic ratio (11 11, 11 act, 75 % Ci)	1 vot estimatie
9.2 Women at low risk of	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
complications	O	O	radio (W 11, 11xea, 7570 Cl)	1 vot estimable
9.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
10 Preterm birth less than 34	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
weeks	O	U	Risk Ratio (Wi-11, 11Acti, 7)/0 Ci)	1 vot estillable
10.1 Women at increased risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
of complications	O	O	radio (W 11, 11xea, 7570 Cl)	1 vot estimable
10.2 Women at low risk of	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
complications	U	U	140K 14410 (111-11, 11ACU, 7)/0 (1)	1 tot Collinable
10.3 Women at no defined	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
risk	J	U	1400 1410 (111 11, 11ACU, 7)/0 (1)	1 tot commanic
11012				

11 Preterm birth less than 28 weeks	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
11.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
11.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
11.3 Women at no defined	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
12 Gestational age at birth	1	405	Mean Difference (IV, Fixed, 95% CI)	-0.10 [-0.43, 0.23]
12.1 Women at increased risk of complications	1	405	Mean Difference (IV, Fixed, 95% CI)	-0.10 [-0.43, 0.23]
12.2 Women at low risk of complications	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
12.3 Women at no defined risk	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
13 Neonatal seizures (seizures in the neonatal period, either apparent clinically or detected by electroencephalographic recordings)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
13.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
13.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
13.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
14 Hypoxic ischaemic encephalopathy as defined by trialists	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
14.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
14.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
14.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
15 Cerebral palsy at 12 months of age	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
15.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
15.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
15.3 Women at no defined	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
16 Neurodevelopmental disability at 12 months of age	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
16.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
16.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
16.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

17 Caesarean section for non- reassuring or abnormal fetal heart rate patterns	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
17.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
17.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
17.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
18 Induction of labour	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
18.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
18.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
18.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
19 Antenatal hospital admission	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
19.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
19.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
19.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
20 Length of antenatal hospital stay	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
20.1 Women at increased risk of complications	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
20.2 Women at low risk of complications	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
20.3 Women at no defined risk	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
21 Emotional distress/depression/ anxiety	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
21.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
21.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
21.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
22 Women's satisfaction with care	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
22.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
22.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
22.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

Analysis I.I. Comparison I Traditional antenatal CTG versus no antenatal CTG, Outcome I Perinatal mortality.

Review: Antenatal cardiotocography for fetal assessment

Comparison: I Traditional antenatal CTG versus no antenatal CTG

Outcome: I Perinatal mortality

Study or subgroup	Traditional AN CTG	No AN CTG	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H,Fixed,95% CI		M-H,Fixed,95% CI
Women at increased risk of	of complications				
Flynn 1982	4/144	3/156	-	30.3 %	1.44 [0.33, 6.34]
Lumley 1983	8/271	5/259	-	53.8 %	1.53 [0.51, 4.61]
Brown 1982	3/201	1/200		10.6 %	2.99 [0.31, 28.45]
Kidd 1985	4/198	0/198	-	5.3 %	9.00 [0.49, 166.06]
Subtotal (95% CI)	814	813	•	100.0 %	2.05 [0.95, 4.42]
Total events: 19 (Traditional /	AN CTG), 9 (No AN CTG)				
Heterogeneity: Chi ² = 1.58,	$df = 3 (P = 0.66); I^2 = 0.0\%$				
Test for overall effect: $Z = 1$.	83 (P = 0.067)				
2 Women at low risk of com	plications				
Subtotal (95% CI)	0	0		0.0 %	0.0 [0.0, 0.0]
Total events: 0 (Traditional A	N CTG), 0 (No AN CTG)				
Heterogeneity: not applicable	e				
Test for overall effect: not ap	plicable				
3 Women with no defined ri	isk				
Subtotal (95% CI)	0	0		0.0 %	0.0 [0.0, 0.0]
Total events: 0 (Traditional A	N CTG), 0 (No AN CTG)				
Heterogeneity: not applicable	e				
Test for overall effect: not ap	plicable				
Total (95% CI)	814	813	•	100.0 %	2.05 [0.95, 4.42]
Total events: 19 (Traditional /	AN CTG), 9 (No AN CTG)				
Heterogeneity: Chi ² = 1.58,	$df = 3 (P = 0.66); I^2 = 0.0\%$				
Test for overall effect: $Z = 1$.	83 (P = 0.067)				

0.01 0.1 10 100 Favours CTG Favours no CTG

Analysis I.2. Comparison I Traditional antenatal CTG versus no antenatal CTG, Outcome 2 Caesarean section.

Comparison: I Traditional antenatal CTG versus no antenatal CTG

Outcome: 2 Caesarean section

Risk Ratio	Weight	Risk Ratio	No AN CTG	Traditional AN CTG	Study or subgroup
M-H,Fixed,95% C		M-H,Fixed,95% CI	n/N	n/N	
				of complications	I Women at increased risk of
1.26 [0.82, 1.95]	19.2 %	-	29/171	39/182	Brown 1982
1.08 [0.78, 1.48]	34.1 %	+	53/198	57/198	Kidd 1985
0.97 [0.73, 1.28]	46.7 %	•	71/259	72/271	Lumley 1983
1.06 [0.88, 1.28]	100.0 %	+	628	651	Subtotal (95% CI)
			(G)	I AN CTG), 153 (No AN CT	Total events: 168 (Traditional
			,	$df = 2 (P = 0.60); I^2 = 0.0\%$	Heterogeneity: Chi ² = 1.03,
				62 (P = 0.53)	Test for overall effect: $Z = 0$.
				plications	2 Women at low risk of com
0.0 [0.0, 0.0]	0.0 %		0	0	Subtotal (95% CI)
				N CTG), 0 (No AN CTG)	Total events: 0 (Traditional A
				e	Heterogeneity: not applicable
				plicable	Test for overall effect: not ap
					3 Women at no defined risk
0.0 [0.0, 0.0]	0.0 %		0	0	Subtotal (95% CI)
				N CTG), 0 (No AN CTG)	Total events: 0 (Traditional A
				e	Heterogeneity: not applicable
				plicable	Test for overall effect: not ap
1.06 [0.88, 1.28]	100.0 %	†	628	651	Total (95% CI)
			G)	I AN CTG), 153 (No AN CT	Total events: 168 (Traditional
				$df = 2 (P = 0.60); I^2 = 0.0\%$	Heterogeneity: Chi ² = 1.03,
				62 (P = 0.53)	Test for overall effect: $Z = 0$.

Favours CTG Favours no CTG

Analysis I.3. Comparison I Traditional antenatal CTG versus no antenatal CTG, Outcome 3 Any potentially preventable perinatal deaths.

Comparison: I Traditional antenatal CTG versus no antenatal CTG

Outcome: 3 Any potentially preventable perinatal deaths

Risk Ratio	Weight	Risk Ratio	No AN CTG	Traditional AN CTG	Study or subgroup
M-H,Fixed,95% C		M-H,Fixed,95% CI	n/N	n/N	
				of complications	I Women at increased risk of
4.98 [0.24, 102.98]	8.3 %	-	0/200	2/201	Brown 1982
2.17 [0.20, 23.64	15.9 %	-	1/156	2/144	Flynn 1982
7.00 [0.36, 134.64]	8.3 %	-	0/198	3/198	Kidd 1985
1.67 [0.50, 5.65]	67.6 %	-	4/259	7/271	Lumley 1983
2.46 [0.96, 6.30]	100.0 %	•	813	814	Subtotal (95% CI)
				AN CTG), 5 (No AN CTG)	Total events: 14 (Traditional
				$df = 3 (P = 0.78); I^2 = 0.0\%$	Heterogeneity: Chi ² = 1.09,
				.88 (P = 0.060)	Test for overall effect: $Z = 1$.
				nplications	2 Women at low risk of con
0.0 [0.0, 0.0]	0.0 %		0	0	Subtotal (95% CI)
				N CTG), 0 (No AN CTG)	Total events: 0 (Traditional A
				e	Heterogeneity: not applicable
				pplicable	Test for overall effect: not ap
				(3 Women at no defined risk
0.0 [0.0, 0.0]	0.0 %		0	0	Subtotal (95% CI)
				N CTG), 0 (No AN CTG)	Total events: 0 (Traditional A
				e	Heterogeneity: not applicable
				pplicable	Test for overall effect: not ap
2.46 [0.96, 6.30]	100.0 %	•	813	814	Total (95% CI)
				AN CTG), 5 (No AN CTG)	Total events: 14 (Traditional
				$df = 3 (P = 0.78); I^2 = 0.0\%$	Heterogeneity: $Chi^2 = 1.09$,
				.88 (P = 0.060)	Test for overall effect: $Z = 1$.

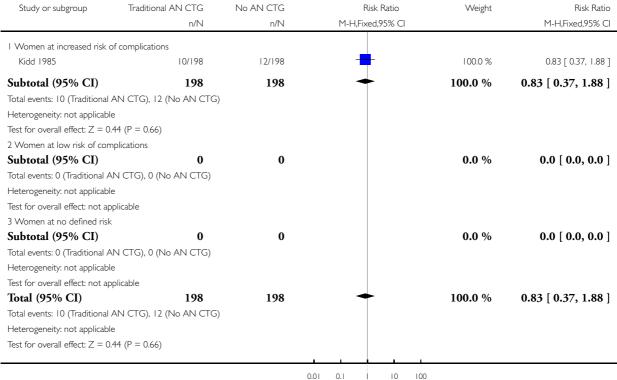
0.01 0.1 Favours CTG

10 100 Favours no CTG

Analysis I.4. Comparison I Traditional antenatal CTG versus no antenatal CTG, Outcome 4 Apgar less than 7 at 5 minutes.

Comparison: I Traditional antenatal CTG versus no antenatal CTG

Outcome: 4 Apgar less than 7 at 5 minutes



0.01 0.1 10 100

Favours CTG Favours no CTG

Analysis I.7. Comparison I Traditional antenatal CTG versus no antenatal CTG, Outcome 7 Admission to neonatal special care unit or intensive care unit.

Comparison: I Traditional antenatal CTG versus no antenatal CTG

Outcome: 7 Admission to neonatal special care unit or intensive care unit

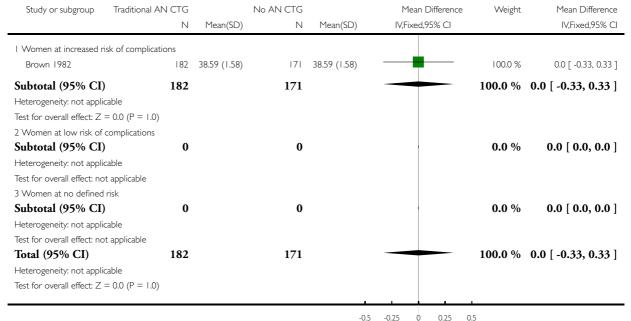
Risk Ratio M-H,Fixed,95% C	Weight	Risk Ratio M-H,Fixed,95% CI	No AN CTG n/N	Traditional AN CTG n/N	Study or subgroup
				of complications	I Women at increased risk of
1.14 [0.64, 2.01]	21.7 %	+	19/171	23/182	Brown 1982
1.07 [0.81, 1.41]	78.3 %	•	69/259	77/271	Lumley 1983
1.08 [0.84, 1.39]	100.0 %	•	430	453	Subtotal (95% CI)
			ā)	al AN CTG), 88 (No AN CTG	Total events: 100 (Traditiona
				$df = 1 (P = 0.84); I^2 = 0.0\%$	Heterogeneity: $Chi^2 = 0.04$,
				.62 (P = 0.54)	Test for overall effect: Z = 0
				nplications	2 Women at low risk of con
0.0 [0.0, 0.0]	0.0 %		0	0	Subtotal (95% CI)
				AN CTG), 0 (No AN CTG)	Total events: 0 (Traditional A
				e	Heterogeneity: not applicabl
				pplicable	Test for overall effect: not ap
				<	3 Women at no defined risk
0.0 [0.0, 0.0]	0.0 %		0	0	Subtotal (95% CI)
				AN CTG), 0 (No AN CTG)	Total events: 0 (Traditional A
				e	Heterogeneity: not applicabl
				pplicable	Test for overall effect: not ap
1.08 [0.84, 1.39]	100.0 %	†	430	453	Total (95% CI)
			5)	al AN CTG), 88 (No AN CTG	Total events: 100 (Traditiona
				$df = 1 (P = 0.84); I^2 = 0.0\%$	Heterogeneity: $Chi^2 = 0.04$,
				.62 (P = 0.54)	Test for overall effect: $Z = 0$

Favours CTG Favours no CTG

Analysis 1.12. Comparison I Traditional antenatal CTG versus no antenatal CTG, Outcome 12 Gestational age at birth.

Comparison: I Traditional antenatal CTG versus no antenatal CTG

Outcome: 12 Gestational age at birth

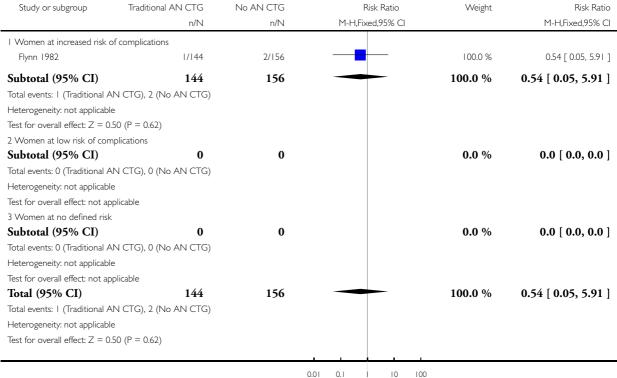


Favours no CTG Favours CTG

Analysis 1.13. Comparison I Traditional antenatal CTG versus no antenatal CTG, Outcome 13 Neonatal seizures (seizures in the neonatal period, either apparent clinically or detected by electroencephalographic recordings).

Comparison: I Traditional antenatal CTG versus no antenatal CTG

Outcome: 13 Neonatal seizures (seizures in the neonatal period, either apparent clinically or detected by electroencephalographic recordings)



0.01 0.1 1 10 100 Favours CTG Favours no CTG

Analysis 1.18. Comparison I Traditional antenatal CTG versus no antenatal CTG, Outcome 18 Induction of labour.

Review: Antenatal cardiotocography for fetal assessment

Comparison: I Traditional antenatal CTG versus no antenatal CTG

Outcome: 18 Induction of labour

Risk Ratio M-H,Fixed,95% C	Weight	Risk Ratio M-H,Fixed,95% CI	No AN CTG n/N	Traditional AN CTG n/N	Study or subgroup
				of complications	I Women at increased risk of
1.03 [0.79, 1.35]	45.3 %	•	63/156	60/144	Flynn 1982
0.92 [0.70, 1.20]	54.7 %	•	73/198	67/198	Kidd 1985
0.97 [0.80, 1.17]	100.0 %	•	354	342	Subtotal (95% CI)
			rG)	` '	Total events: 127 (Traditional Heterogeneity: $Chi^2 = 0.36$, Test for overall effect: $Z = 0$
0.0 [0.0, 0.0]	0.0 %		0	nplications 0	2 Women at low risk of con
0.0 [0.0, 0.0]	0.0 %		U	-	Subtotal (95% CI) Total events: 0 (Traditional A
				, , ,	Heterogeneity: not applicabl
					Test for overall effect: not ap
				'	3 Women at no defined risk
0.0 [0.0, 0.0]	0.0 %		0	0	Subtotal (95% CI)
				AN CTG), 0 (No AN CTG)	Total events: 0 (Traditional A
				e	Heterogeneity: not applicabl
				pplicable	Test for overall effect: not ap
0.97 [0.80, 1.17]	100.0 %	•	354	342	Total (95% CI)
			G)	ıl AN CTG), 136 (No AN CT	Total events: 127 (Traditiona
				$df = 1 (P = 0.55); I^2 = 0.0\%$	Heterogeneity: Chi ² = 0.36,
				.32 (P = 0.75)	Test for overall effect: $Z = 0$

0.01 0.1 1 10 100

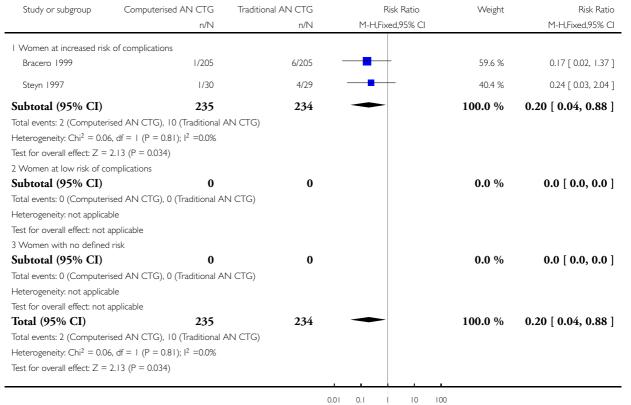
Favours CTG Favours no CTG

Analysis 3.1. Comparison 3 Computerised antenatal CTG versus traditional antenatal CTG, Outcome I Perinatal mortality.

Review: Antenatal cardiotocography for fetal assessment

Comparison: 3 Computerised antenatal CTG versus traditional antenatal CTG

Outcome: I Perinatal mortality



Favours computerised CTG

Analysis 3.2. Comparison 3 Computerised antenatal CTG versus traditional antenatal CTG, Outcome 2 Caesarean section.

Review: Antenatal cardiotocography for fetal assessment

Comparison: 3 Computerised antenatal CTG versus traditional antenatal CTG

Outcome: 2 Caesarean section

Study or subgroup	Computerised AN CTG	Traditional AN CTG	Risk	Ratio	Weight	Risk Ratio
	n/N	n/N	M-H,Fixed,	95% CI		M-H,Fixed,95% CI
I Women at increased risk	of complications					
Steyn 1997	19/30	21/29	=		100.0 %	0.87 [0.61, 1.24]
Subtotal (95% CI)	30	29	+	1	00.0 %	0.87 [0.61, 1.24]
Total events: 19 (Computer	rised AN CTG), 21 (Traditional	AN CTG)				
Heterogeneity: not applicab	le					
Test for overall effect: $Z = 0$	0.74 (P = 0.46)					
2 Women at low risk of co	mplications					
Subtotal (95% CI)	0	0			0.0 %	0.0 [0.0, 0.0]
Total events: 0 (Computeris	sed AN CTG), 0 (Traditional A	N CTG)				
Heterogeneity: not applicab	le					
Test for overall effect: not a	pplicable					
3 Women at no defined ris	k					
Subtotal (95% CI)	0	0			0.0 %	0.0 [0.0, 0.0]
Total events: 0 (Computeris	sed AN CTG), 0 (Traditional A	N CTG)				
Heterogeneity: not applicab	le					
Test for overall effect: not a	pplicable					
Total (95% CI)	30	29	+	1	00.0 %	0.87 [0.61, 1.24]
Total events: 19 (Computer	rised AN CTG), 21 (Traditional	AN CTG)				
Heterogeneity: not applicab	le					
Test for overall effect: $Z = 0$	0.74 (P = 0.46)					
			0.01 0.1 1	10 100		

0.01 0.1 1 10 100

Favours computerised CTG

Analysis 3.3. Comparison 3 Computerised antenatal CTG versus traditional antenatal CTG, Outcome 3 Any potentially preventable perinatal death.

Comparison: 3 Computerised antenatal CTG versus traditional antenatal CTG

Outcome: 3 Any potentially preventable perinatal death

Risk Ratio	Weight	Risk Ratio	Traditional AN CTG	Computerised CTG	Study or subgroup
M-H,Fixed,95% C		M-H,Fixed,95% CI	n/N	n/N	
				of complications	I Women at increased risk of
0.20 [0.01, 4.14]	38.1 %	-	2/205	0/205	Bracero 1999
0.24 [0.03, 2.04]	61.9 %	-	4/29	1/30	Steyn 1997
0.23 [0.04, 1.29]	100.0 %	-	234	235	Subtotal (95% CI)
			CTG)	ed CTG), 6 (Traditional AN	Total events: (Computerise
				$df = 1 (P = 0.92); I^2 = 0.0\%$	Heterogeneity: $Chi^2 = 0.01$,
				.67 (P = 0.095)	Test for overall effect: $Z = 1$.
				mplications	2 Women at low risk of com
0.0 [0.0, 0.0]	0.0 %		0	0	Subtotal (95% CI)
			CTG)	ed CTG), 0 (Traditional AN	Total events: 0 (Computerise
				le	Heterogeneity: not applicable
				oplicable	Test for overall effect: not ap
				<	3 Women at no defined risk
0.0 [0.0, 0.0]	0.0 %		0	0	Subtotal (95% CI)
			CTG)	ed CTG), 0 (Traditional AN	Total events: 0 (Computerise
				le	Heterogeneity: not applicable
				oplicable	Test for overall effect: not ap
0.23 [0.04, 1.29]	100.0 %	-	234	235	Total (95% CI)
			CTG)	ed CTG), 6 (Traditional AN	Total events: (Computerise
			•	$df = 1 (P = 0.92); I^2 = 0.0\%$	Heterogeneity: $Chi^2 = 0.01$,
				.67 (P = 0.095)	Test for overall effect: $Z = 1$.

0.01 0.1 10 100

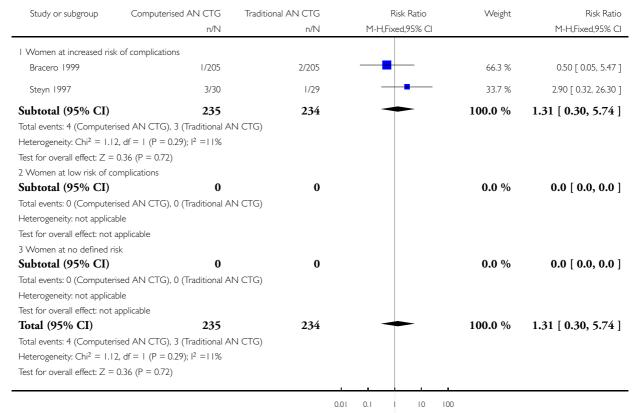
Favours computerised CTG Favours traditional CTG

Analysis 3.4. Comparison 3 Computerised antenatal CTG versus traditional antenatal CTG, Outcome 4

Apgar less than 7 at 5 minutes.

Comparison: 3 Computerised antenatal CTG versus traditional antenatal CTG

Outcome: 4 Apgar less than 7 at 5 minutes



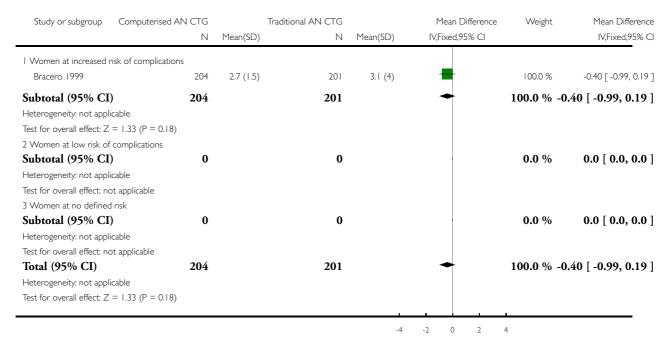
Favours computerised CTG

Analysis 3.8. Comparison 3 Computerised antenatal CTG versus traditional antenatal CTG, Outcome 8

Length of stay in neonatal special care unit or intensive care unit.

Comparison: 3 Computerised antenatal CTG versus traditional antenatal CTG

Outcome: 8 Length of stay in neonatal special care unit or intensive care unit



Favours computerised CTG

Analysis 3.12. Comparison 3 Computerised antenatal CTG versus traditional antenatal CTG, Outcome 12 Gestational age at birth.

Review: Antenatal cardiotocography for fetal assessment

Comparison: 3 Computerised antenatal CTG versus traditional antenatal CTG

Outcome: 12 Gestational age at birth

I CTG		Traditional AN CTG		Mean Difference	Weight	Mean Difference
Ν	Mean(SD)	Ν	Mean(SD)	IV,Fixed,95% CI		IV,Fixed,95% CI
204	39.8 (1.7)	201	39.9 (1.7)		100.0 %	-0.10 [-0.43, 0.23]
204		201			100.0 % -0	.10 [-0.43, 0.23]
0		0			0.0 %	0.0 [0.0, 0.0]
0		0			0.0 %	0.0 [0.0, 0.0]
204		201			100.0 % -0	.10 [-0.43, 0.23]
			ı			
			-100	-50 0 50	100	
	204 204 0	N Mean(SD) 204 39.8 (1.7) 204 0	N Mean(SD) N 204 39.8 (1.7) 201 204 201 0 0	N Mean(SD) N Mean(SD) 204 39.8 (1.7) 201 39.9 (1.7) 204 201 0 0 0	N Mean(SD) N Mean(SD) IV,Fixed,95% CI 204 39.8 (1.7) 201 39.9 (1.7) 204 201 0 0 204 201	N Mean(SD) N Mean(SD) N Mean(SD) NV,Fixed,95% CI 100.0 % 100.0 % 0 0 0 0.0 % 204 204 201 100.0 % -0 100.0 %

Favours traditional CTG

Favours computerised CTG

HISTORY

Protocol first published: Issue 3, 2009 Review first published: Issue 1, 2010

CONTRIBUTIONS OF AUTHORS

Rosalie Grivell (RG) and Gill Gyte (GG) drafted the protocol with valuable guidance from Zarko Alfirevic (ZA) and Declan Devane. All four authors discussed the scope of the review and inclusion/exclusion criteria. RG and GG undertook the data extraction and RG entered the data into RevMan (RevMan 2008) with GG checking the data entry. RG drafted the results and discussion text and all four authors discussed and agreed the interpretation of the data.

DECLARATIONS OF INTEREST

Declan Devane has acted as an expert midwifery witness in legal cases centering around aspects of fetal monitoring and has been paid for same. Declan provides and has been paid to deliver fetal monitoring education programmes, which are organised by a commercial company who provide, among other products, CTG machines. The company do not vet nor have any other input into the content of the programmes.

SOURCES OF SUPPORT

Internal sources

• The University of Liverpool, UK.

External sources

• National Institute for Health Research, UK.

NIHR NHS Cochrane Collaboration Programme Grant Scheme award for NHS-prioritised centrally-managed, pregnancy and childbirth systematic reviews: CPGS02

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We have added an additional secondary outcome, 'Potentially preventable perinatal mortality', defined as perinatal mortality excluding lethal congenital anomalies.

Although the protocol stated we would use the inverse variance meta-analysis, we have used fixed-effect Mantel-Haenszel meta-analysis for combining data because the *Handbook* suggested it was more commonly used.

We have modified the wording in the methods sections for 'Assessment of heterogeneity', 'Assessment of reporting bias' and 'Data synthesis' to update them with the new methods being used by the group, developed in conjunction with the group's statistician, Simon Gates, and Richard Riley. We have used these new methods in the review.