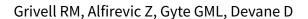


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Antenatal cardiotocography for fetal assessment (Review)



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TABLE OF CONTENTS

ABSTRACT
PLAIN LANGUAGE SUMMARY
SUMMARY OF FINDINGS
BACKGROUND
OBJECTIVES
METHODS
RESULTS
Figure 1
DISCUSSION
AUTHORS' CONCLUSIONS
ACKNOWLEDGEMENTS
REFERENCES
CHARACTERISTICS OF STUDIES
DATA AND ANALYSES
Analysis 1.1. Comparison 1 Traditional antenatal CTG versus no antenatal CTG, Outcome 1 Perinatal mortality
Analysis 1.2. Comparison 1 Traditional antenatal CTG versus no antenatal CTG, Outcome 2 Caesarean section.
Analysis 1.3. Comparison 1 Traditional antenatal CTG versus no antenatal CTG, Outcome 3 Any potentially preventable perinatal
deaths.
Analysis 1.4. Comparison 1 Traditional antenatal CTG versus no antenatal CTG, Outcome 4 Apgar less than 7 at 5 minutes
Analysis 1.7. Comparison 1 Traditional antenatal CTG versus no antenatal CTG, Outcome 7 Admission to neonatal special care
unit or intensive care unit.
Analysis 1.12. Comparison 1 Traditional antenatal CTG versus no antenatal CTG, Outcome 12 Gestational age at birth
Analysis 1.13. Comparison 1 Traditional antenatal CTG versus no antenatal CTG, Outcome 13 Neonatal seizures (seizures in the neonatal period, either apparent clinically or detected by electroencephalographic recordings).
Analysis 1.18. Comparison 1 Traditional antenatal CTG versus no antenatal CTG, Outcome 18 Induction of labour
Analysis 3.1. Comparison 3 Computerised antenatal CTG versus traditional antenatal CTG, Outcome 1 Perinatal mortality
Analysis 3.2. Comparison 3 Computerised antenatal CTG versus traditional antenatal CTG, Outcome 2 Caesarean section
Analysis 3.3. Comparison 3 Computerised antenatal CTG versus traditional antenatal CTG, Outcome 3 Any potentially preventable perinatal death.
Analysis 3.4. Comparison 3 Computerised antenatal CTG versus traditional antenatal CTG, Outcome 4 Apgar less than 7 at 5 minutes.
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.
Analysis 3.12. Comparison 3 Computerised antenatal CTG versus traditional antenatal CTG, Outcome 12 Gestational age at birth.
APPENDICES
WHAT'S NEW
HISTORY
CONTRIBUTIONS OF AUTHORS
DECLARATIONS OF INTEREST
SOURCES OF SUPPORT
DIFFERENCES BETWEEN PROTOCOL AND REVIEW
INDEX TERMS



[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 methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (26 June 2015) and reference lists of retrieved studies.

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

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, low quality evidence) 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, low quality evidence). There was also no significant difference identified for secondary outcomes related to Apgar scores less than seven at five minutes



(RR 0.83, 95% CI 0.37 to 1.88, one trial, N = 396, *very low quality evidence*); or 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, *low quality evidence*), nor in the other 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, *moderate quality evidence*). 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, *low quality evidence*), Apgar scores less than seven at five minutes (RR 1.31, 95% CI 0.30 to 5.74, two studies, N = 469, *very low quality evidence*) 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. The included studies were not of high quality. There were no differences in outcomes identified (low/very low quality evidence), 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.



Summary of findings for the main comparison. Traditional antenatal CTG compared with no antenatal CTG (women at increased risk of complication) for fetal assessment

Traditional antenatal CTG compared with no antenatal CTG (women at increased risk of complication) for fetal assessment

Patient or population: Pregnant women with/without complications

Settings: Different countries

Intervention: Traditional antenatal CTG

Comparison: No antenatal CTG (women at increased risk of complication)

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of partici- pants	Quality of the evidence	Comments
	Assumed risk	Corresponding risk	(3370 CI)	(studies)	(GRADE)	
	No antenatal CTG (Women at increased risk of complication)	Traditional antenatal CTG				
Perinatal mortality	Study population		RR 2.05 - (0.95 to 4.42)	1627 (4 RCTs)	⊕⊕⊝⊝ LOW 1,2	
	11 per 1000	23 per 1000 (11 to 49)	(0.00 to 11.12)	(11.0.0)	LOW /	
	Moderate					
	12 per 1000	25 per 1000 (11 to 53)				
Caesarean section	Study population		RR 1.06 - (0.88 to 1.28)	1279 (3 RCTs)	⊕⊕⊝⊝ LOW ^{1,2}	_
	244 per 1000	258 per 1000 (214 to 312)	(0.00 to 1.20)	(3 11013)	LOW ->-	
	Moderate					
	268 per 1000	284 per 1000 (236 to 343)				
Apgar less than 7 at 5 minutes	Study population		RR 0.83 - (0.37 to 1.88)	396 (1 RCT)	⊕⊝⊝⊝ VERY LOW 2,3	
	61 per 1000	50 per 1000	(5.57 to 1.65)	(= 1.01)	VEINT LOVY -,9	

		(22 to 114)			
Admission to neonatal special care unit or intensive care unit	71 1		RR 1.08 - (0.84 to 1.39)	883 (2 RCTs)	⊕⊕⊙⊝ LOW ^{1,2}
care and or intensive care and	205 per 1000	221 per 1000 (172 to 284)	(0.0) to 1.00)	(211013)	LOW
	Moderate				
	189 per 1000	204 per 1000 (159 to 262)			
Neurodevelopmental disability at 12 months of age	None of these outcomes v	vere reported by any of the included	studies under this	comparison.	
Caesarean section for non-reas- suring or abnormal fetal heart rate patterns					
Women's satisfaction with care					

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

CI: Confidence interval; RR: risk ratio

GRADE Working Group grades of evidence

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

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

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

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

Summary of findings 2. Computerised antenatal CTG compared with traditional antenatal CTG (women at increased risk of complications) for fetal assessment

Computerised antenatal CTG compared with traditional antenatal CTG (women at increased risk of complications) for fetal assessment

Patient or population: Pregnant women with/without complications

Settings: USA and South Africa

Intervention: Computerised antenatal CTG

¹Most of pooled effect provided by studies with unclear risk of bias.

²Wide CI crossing the line of no effect.

³Evidence provided by one study with high risk of bias.

Comparison: Traditional antenatal CTG (women at increased risk of complications)

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of partici- pants	Quality of the evidence	Comments
	Assumed risk	Corresponding risk	(3370 CI)	(studies)	(GRADE)	
	Traditional antena- tal CTG (Women at in- creased risk of compli- cations)	Computerised antenatal CTG				
Perinatal mortality	Study population		RR 0.20 - (0.04 to 0.88)	469 (2 RCTs)	⊕⊕⊕⊝ MODERATE ¹	
	43 per 1000	9 per 1000 (2 to 38)	(0.01 to 0.00)	(2 RCTS)	MODERATE 1	
	Moderate					
	84 per 1000	17 per 1000 (3 to 74)				
Caesarean section	Study population		RR 0.87 - (0.61 to 1.24)	59 (1 RCT)	⊕⊕⊝⊝ LOW 1,2	
	724 per 1000	630 per 1000 (442 to 898)	(0.01 to 1.2 i)	(I NOI)	LOW -3-	
Apgar less than 7 at 5 minutes	Study population		RR 1.31 - (0.30 to 5.74)	469 (2 RCTs)	⊕⊝⊝⊝ VERY LOW 1,3	
	13 per 1000	17 per 1000 (4 to 74)	- (0.30 to 5.74)	(2 RC15)	VERY LOW 1,3	
	Moderate					
	22 per 1000	29 per 1000 (7 to 127)				
Admission to neonatal special care unit or intensive care unit	None of these outcomes v	vere reported by any of the inc	luded studies unde	r this comparison.		
Neurodevelopmental disability at 12 months of age						

Caesarean section for non-reassuring or abnormal fetal heart rate patterns

Women's satisfaction with care

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

GRADE Working Group grades of evidence

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

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

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

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

¹Included studies were of unclear risk of bias.

²Wide CI crossing the line of no effect.

³Small studies with few events and wide CI crossing the line of no effect.



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; multiple pregnancies also increase the risks to the fetuses (Fisk 2001; Gribbin 2006). These risks include possible neurodevelopmental problems in infancy including nonambulant cerebral palsy, developmental delay, 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 2013).

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).

- 1. Baseline fetal heart rate of 110 to 160 beats per minute.
- 2. Baseline variability should be greater than five beats per minute.
- 3. 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.
- 4. 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 been 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 2012a); 'Fetal and umbilical Doppler ultrasound in high-risk pregnancies' (Alfirevic 2013a); 'Fetal and umbilical Doppler ultrasound in normal pregnancy' (Alfirevic 2015); 'Utero-placental Doppler ultrasound in pregnancy' (Alfirevic 2010c); 'Biochemical tests for placental function' (Neilson 2012); 'Fetal movement counting for assessment of fetal well-being' (Mangesi 2007); 'Fetal manipulation for facilitating tests of fetal well-being' (Tan 2013); 'Fetal vibroacoustic stimulation for facilitating tests of fetal well-being' (Tan 2013a); 'Maternal glucose administration for facilitating tests of fetal wellbeing' (Tan 2012); '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.
- 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
- 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
- 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

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

Electronic searches

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting the Trials Search Co-ordinator (26 June 2015).

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

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

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

Trials identified through the searching activities described above are each assigned to a review topic (or topics). The Trials Search Coordinator searches 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 or date restrictions.

Data collection and analysis

For methods used in the previous version of this review, see Grivell 2012b.

Assessment of the quality of the evidence

For this update the quality of the evidence was assessed using the GRADE approach (Schunemann 2009) in order to assess the quality of the body of evidence relating to the following outcomes for the two comparisons "traditional antenatal CTG versus no antenatal CTG and computerised antenatal CTG versus traditional antenatal CTG":

- 1. Perinatal mortality
- 2. Caesarean section
- 3. Apgar less than seven at five minutes
- 4. Admission to neonatal special care or intensive care unit
- 5. Neurodevelopmental disability at more than 12 months (assessed by a validated tool, e.g. Bayley Scale)
- 6. Caesarean section for non-reassuring or abnormal fetal heart rate patterns (in the absence of known fetal hypoxia, i.e. fetal blood sampling, lactate)
- 7. Women's satisfaction with care

We used GRADE profiler (GRADEpro 2014) to import data from Review Manager 5.3 (RevMan 2014) in order to create 'Summary of findings' tables. A summary of the intervention effect and a measure of quality for each of the above outcomes was produced using the GRADE approach. The GRADE approach uses five considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of the body of evidence for each outcome. The evidence can be downgraded from 'high quality' by one level for serious (or by two levels for very serious) limitations, depending on assessments for risk of bias, indirectness of evidence, serious inconsistency, imprecision of effect estimates or potential publication bias.

In future updates, if new reports are identified, we will use the methods described in Appendix 1.

RESULTS

Description of studies

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

Results of the search

Our search strategy identified 16 publications involving 14 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 eight studies (Cousins 2012; Hertz 1979; Moffatt 1997; Nathan 2000; Newnham 1988; Piyamongkol 2006; Reece 1992, 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 (PNM) and caesarean section. One study reported data on PNM; 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

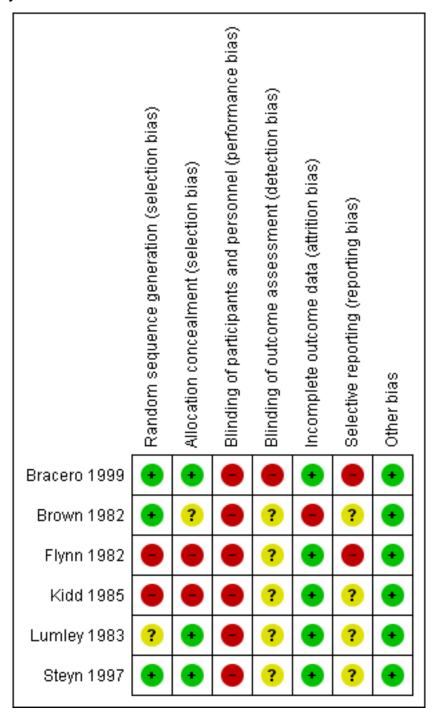
We excluded eight studies; see Characteristics of excluded studies.

Risk of bias in included studies

See Figure 1 for a summary of the 'Risk of bias' assessment.



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



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 two 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).

Allocation

We assessed two included studies as having neither adequate sequence generation nor allocation concealment as they were quasi-randomised 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 the methods for sequence generation; however allocation concealment was adequate (Lumley 1983).

Blinding

We assessed blinding as not adequate for all included studies for performance bias, as blinding of either participants or clinicians was not undertaken or reported. Outcome assessment was not reported in the majority of studies.

Incomplete outcome data

We assessed risk of attrition bias as low for five 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 post-randomisation, and not assessed with CTG (Brown 1982). This would be considered to be a significant loss to follow-up/post-randomisation exclusion. We were only able to re-include data on PNM 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 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 1999 did not report caesarean sections for fetal distress as intended.

Other potential sources of bias

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

Effects of interventions

See: Summary of findings for the main comparison Traditional antenatal CTG compared with no antenatal CTG (women at increased risk of complication) for fetal assessment; Summary of findings 2 Computerised antenatal CTG compared with traditional antenatal CTG (women at increased risk of complications) for fetal assessment

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, meant that we were not always able to undertake sensitivity analyses by quality and the findings, therefore, remain uncertain.

1) 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 (PNM) (risk ratio (RR) 2.05, 95% confidence interval (CI) 0.95 to 4.42, 2.3% versus 1.1%, four studies, N = 1627, Analysis 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 PNM (RR 1.53, 95% CI 0.51 to 4.61, one study, N = 530). 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, Analysis 1.2).

Secondary outcomes

We identified no significant difference in potentially preventable PNM (RR 2.46, 95% CI 0.96 to 6.30, four studies, N = 1627, Analysis 1.3). 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, Analysis 1.4); 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, Analysis 1.7); gestational age at birth (mean difference (MD) 0.00, 95% CI -0.33 to 0.33, one trial, N = 353, Analysis 1.12); or of neonatal seizures (RR 0.54, 95% CI 0.05 to 5.91, one trial, N = 300, Analysis 1.13).

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 such as caesarean section. The small size of the studies is also a limitation.

Primary outcomes

There was a significant reduction in PNM (RR 0.20, 95% CI 0.04 to 0.88, 0.9% versus 4.2%, two studies, N = 469, Analysis 3.1).

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, Analysis 3.2).

Secondary outcomes

We identified no significant difference in potentially preventable PNM (RR 0.23, 95% CI 0.04 to 1.29, two studies, N = 469, Analysis 3.3). 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, Analysis 3.4); length of stay in neonatal intensive care unit (MD -0.40, 95% CI -0.99 to 0.19, one study, N = 405, Analysis 3.8), or gestational age at birth (MD -0.10, 95% CI -0.43 to 0.23, one study, N = 405, Analysis 1.12).

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 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

Summary of main results

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.

Overall completeness and applicability of evidence

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 2010a). 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 high-quality 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. Fourthly, 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.

Quality of the evidence

The trials were not of high quality, which was perhaps not surprising as four were undertaken in the 1980s and two 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. Gradepro software was used to assess the quality of evidence for the outcomes listed above under two comparisons 'traditional antenatal CTG versus no antenatal CTG and computerised antenatal CTG versus traditional antenatal CTG'. For the first comparison the quality of evidence was low for the outcome of perinatal mortality and caesarean section and very low for Apgar score below seven at five minutes. Other assigned outcomes were not reported by any of the included studies under this comparison. For the comparison of 'computerised antenatal CTG versus traditional antenatal CTG', the evidence was assessed as being moderate quality for the outcome of perinatal mortality, low for caesarean section and very low quality for Apgar score below seven at five minutes. Data were not available for the other three outcomes. Downgrading of evidence was based on including studies with unclear/high risk of bias and presence of imprecise results presented as wide confidence intervals crossing the line of no effect.

Potential biases in the review process

Our search strategy was supported by the Pregnancy and Childbirth Review Group. However we are aware that there is always the possibility of introducing bias to the review process. We have tried to minimise bias in a number of ways, including assigning two review authors to assess the appropriateness of inclusion or exclusion of studies, to carry out data extraction and to assess the risk of bias, and as such we have attempted to minimise biases in the review process.

Agreements and disagreements with other studies or reviews

Since the publication of the 2009 version of this review, there have been very few systematic reviews or meta-analyses by other authors or groups. Many narrative reviews on the topic of fetal well-being assessment have found no up-to-date information and conclusions have been based largely on this systematic review. A review by O'Neill and Thorp in 2012 (O'Neill 2012) reports, "there is no benefit from nonstress test (antenatal CTG) evaluation in isolation". This points to the issue that in current clinical practice, assessment of fetal health frequently involves a number of methods in combination. A number of other recent reviews also consider a range of assessment methods, and rarely comment upon the significance of CTG alone.

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. In order to be relevant to current practice, future trials and reviews may need to assess not only antenatal CTG in isolation, but also combinations of different fetal assessment tests.

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, studies in both high-income and low-income countries 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 referred for antenatal monitoring because of concerns of increased risk.	
Interventions	Intervention: <u>computerised CTG</u> (N = 205).	
	Control: <u>traditional CTG</u> (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.	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"computer-generated random table of random numbers"
Allocation concealment (selection bias)	Low risk	"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 envelopes were opened could not be changed, it would seem that allocation concealment was adequate.
Blinding of participants and personnel (perfor- mance bias) All outcomes	High risk	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 for a number of outcomes here.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Clinicians were aware of group assignment. Blinding of outcomes assessors not described. Lack of blinding could have introduced bias for a number of outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	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.
Selective reporting (reporting bias)	High risk	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.
Other bias	Low risk	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.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"computer randomised"
Allocation concealment (selection bias)	Unclear risk	"computer randomised series of numbered envelopes"; however, we are not sure if the envelopes were opaque.
Blinding of participants and personnel (perfor- mance bias) All outcomes	High risk	Participant: yes. Clinician: no, it was not possible to blind clinicians. 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.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcomes assessors not described.
Incomplete outcome data (attrition bias) All outcomes	High risk	48 (25%) women excluded post randomisation, and not assessed with CTG. We could only re-include the data on PNM because it was reported that there were no deaths or morbidity in the babies excluded after randomisation.
Selective reporting (reporting bias)	Unclear risk	We have not assessed the trial protocol.
Other bias	Low risk	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).



Flynn 1982 (Continued)			
Interventions	Intervention: non-stres	ss CTG revealed (outpatients 1 per week, inpatients twice per week) (N = 144).	
	Comparison: non-stres	ss 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 i	risk/singletons or multiples/mixed gestation at trial entry.	
	Outcomes not specified in the review protocol: this study also assessed: elective CS; spontaneous nal birth following induction of labour; forceps following induction of labour; CS following induct labour; neonatal irritability; mean Apgar score at 1 minute (though no SD reported); mean Apgar s at 5 minutes (though no SD reported).		
Risk of bias			
Bias	Authors' judgement	Support for judgement	
Random sequence generation (selection bias)	High risk	Quasi-RCT, even or odd hospital number.	
Allocation concealment (selection bias)	High risk	Quasi-RCT, even or odd hospital number.	
Blinding of participants	High risk	Participant: yes.	
and personnel (perfor- mance bias) All outcomes		Clinician: no, it was not possible to blind clinicians. "In the revealed group the CTG traces obtained were showed to the clinician. whereas those traces from patients in the concealed group were not available to medical or midwifery staff."	
		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.	
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcomes assessors not described.	
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up reported.	
Selective reporting (reporting bias)	High risk	The authors 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, there is some selection in reporting outcomes.	
Other bias	Low risk	There are no obvious other biases.	
(idd 1985			
Methods	Quasi-RCT (by date of b	pirth).	
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).		



Kidd 1985 (Continued)			
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.		

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Allocation by 1st numeral of date of birth.
Allocation concealment (selection bias)	High risk	Open quasi-RCT as 'Date of birth'.
Blinding of participants and personnel (perfor- mance bias) All outcomes	High risk	Participant: unclear. Clinician: no, it was not possible to blind clinicians. 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.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcomes assessors not described. Authors mention that "Information was made available to the clinicians and this did not apparently affect the outcome".
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up.
Selective reporting (reporting bias)	Unclear risk	Outcomes do not seem to be prespecified.
Other bias	Low risk	There are no obvious other biases.

Lumley 1983

Methods	RCTs.
Participants	539 women after 26 weeks, admitted to the antenatal ward for obstetric complications, poor placental function and social reasons.
Interventions	Intervention: <u>antenatal non-stress CTG</u> 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: <u>no antenatal CTG</u> , other tests as per intervention group (N = 259).



Lumley 1983 (Continued)	
Outcomes	Apgar scores, perinatal mortality, admission to SCBU, neurological signs in the neonate, onset of labour, mode of birth, birthweight, gestation, abnormal fetal heart rate in labour.
Notes	Subgroups: increased risk/singletons or multiples/mixed gestation at trial entry.
	<u>Outcomes not specified in the review protocol</u> : 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

Bias	Authors' judgement	Support for judgement		
Random sequence generation (selection bias)	Unclear risk	No information given.		
Allocation concealment (selection bias)	Low risk	"numbered, sealed, opaque envelope"		
Blinding of participants and personnel (perfor- mance bias) All outcomes	High risk	Participant: unclear. Clinician: no, it was not possible to blind clinicians. 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.		
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcomes assessors not described.		
Incomplete outcome data (attrition bias) All outcomes	Low risk	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 ITT.		
Selective reporting (reporting bias)	Unclear risk	Trial protocol not assessed.		
Other bias	Low risk	There are no obvious other biases.		

Steyn 1997

Methods	RCT.
Participants	59 women with severe pre-eclampsia 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: <u>traditional CTG</u> (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.



Steyn 1997 (Continued)

<u>Continuous outcomes</u>: 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.

<u>Outcomes not specified in the review protocol</u>: this study also assessed: neonatal morbidity; birthweight.

Risk of bias

Bias	Authors' judgement	Support for judgement		
Random sequence generation (selection bias)	Low risk	"generated by computer"		
Allocation concealment (selection bias)	Low risk	"random numbers, enclosed in successively numbered, sealed, opaque e velopes"		
Blinding of participants	High risk	Participant: unclear.		
and personnel (perfor- mance bias)		Clinician: no, it was not possible to blind clinicians.		
All outcomes		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.		
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcomes assessors not described.		
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up.		
Selective reporting (reporting bias)	Unclear risk	We did not assess the trial protocol.		
Other bias	Low risk	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

PN: perinatal

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

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Cousins 2012	Does not meet inclusion criteria as it compared different assessment criteria when performing antenatal CTG.



Study	Reason for exclusion
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.
van Geijn 1991	Trial to assess the validity of computerised fetal heart rate monitoring using system 8000 versus conventional FHR on intrauterine growth retardation. Personal communication 1991. Unable to obtain authors reply.

CTG: cardiotocograph FHR: fetal heart rate

RCT: randomised controlled trial

DATA AND ANALYSES

Comparison 1. Traditional antenatal CTG versus no antenatal CTG

Outcome or subgroup title	No. of studies	No. of partici- pants	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 complica- tions	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.3 Women with no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
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 complica- tions	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
3 Any potentially preventable perinatal deaths	4	1627	Risk Ratio (M-H, Fixed, 95% CI)	2.46 [0.96, 6.30]



Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
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)	0.0 [0.0, 0.0]
3.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
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)	0.0 [0.0, 0.0]
4.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
5 Apgar less than 4 at 5 minutes	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
5.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
5.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
5.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
6 Cord pH less than 7.10 or low pH as defined by trialists	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
6.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
6.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
6.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
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)	0.0 [0.0, 0.0]
7.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
8 Length of stay in neonatal special care unit or intensive care unit	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
8.1 Women at increased risk of complications	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]



Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
8.2 Women at low risk of complications	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
8.3 Women at no defined risk	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
9 Preterm birth less than 37 weeks	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
9.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
9.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
9.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
10 Preterm birth less than 34 weeks	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
10.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
10.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
10.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
11 Preterm birth less than 28 weeks	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
11.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
11.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
11.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
12 Gestational age at birth	1	353	Mean Difference (IV, Fixed, 95% CI)	0.0 [-0.33, 0.33]
12.1 Women at increased risk of complications	1	353	Mean Difference (IV, Fixed, 95% CI)	0.0 [-0.33, 0.33]
12.2 Women at low risk of complications	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
12.3 Women at no defined risk	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
13 Neonatal seizures (seizures in the neonatal period, either apparent clinically or detected by electroen- cephalographic 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]



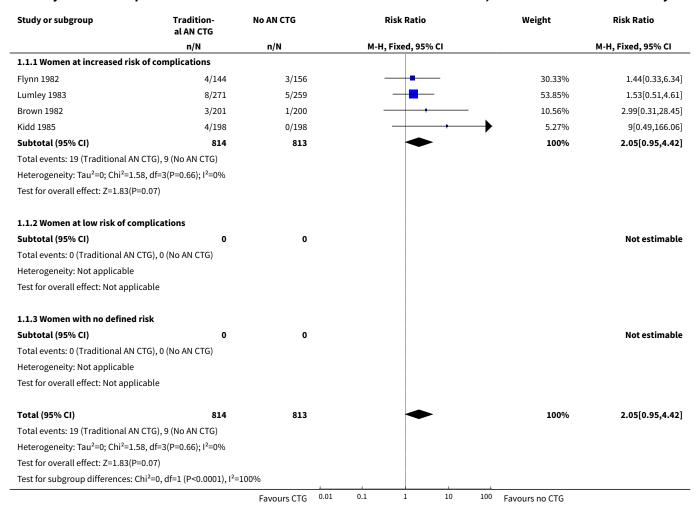
Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
13.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
13.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
14 Hypoxic ischaemic encephalopa- thy as defined by trialists	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
14.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
14.2 Women at low risk of complica- tions	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
14.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
15 Cerebral palsy at 12 months of age	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
15.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
15.2 Women at low risk of complica- tions	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
15.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
16 Neurodevelopmental disability at 12 months of age	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
16.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
16.2 Women at low risk of complica- tions	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
16.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
17 Caesarean section for non-reassur- ing or abnormal fetal heart rate pat- terns	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
17.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
17.2 Women at low risk of complica- tions	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
17.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
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]



Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
18.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
18.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
19 Antenatal hospital admission	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
19.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
19.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
19.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
20 Length of antenatal hospital stay	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
20.1 Women at increased risk of complications	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
20.2 Women at low risk of complications	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
20.3 Women at no defined risk	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
21 Emotional distress/depression/anxiety	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
21.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
21.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
21.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
22 Women's satisfaction with care	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
22.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
22.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
22.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]



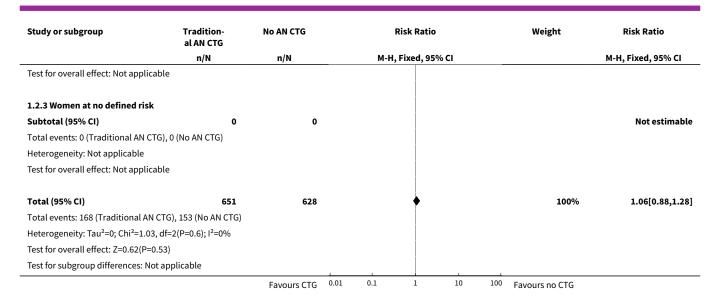
Analysis 1.1. Comparison 1 Traditional antenatal CTG versus no antenatal CTG, Outcome 1 Perinatal mortality.



Analysis 1.2. Comparison 1 Traditional antenatal CTG versus no antenatal CTG, Outcome 2 Caesarean section.

Study or subgroup	Tradition- al AN CTG	No AN CTG		Risk Ratio			Weight	Risk Ratio	
	n/N	n/N		M-H, Fixed, 95% CI				M-H, Fixed, 95% CI	
1.2.1 Women at increased ris	k of complications								
Brown 1982	39/182	29/171			+-		19.23%	1.26[0.82,1.95]	
Kidd 1985	57/198	53/198			+		34.08%	1.08[0.78,1.48]	
Lumley 1983	72/271	71/259			+		46.69%	0.97[0.73,1.28]	
Subtotal (95% CI)	651	628			*		100%	1.06[0.88,1.28]	
Total events: 168 (Traditional A	AN CTG), 153 (No AN CTG)								
Heterogeneity: Tau ² =0; Chi ² =1.	.03, df=2(P=0.6); I ² =0%								
Test for overall effect: Z=0.62(F	P=0.53)								
1.2.2 Women at low risk of co	omplications								
Subtotal (95% CI)	0	0						Not estimable	
Total events: 0 (Traditional AN	CTG), 0 (No AN CTG)								
Heterogeneity: Not applicable						1 1			
		Favours CTG	0.01	0.1	1 1	100	Favours no CTG		



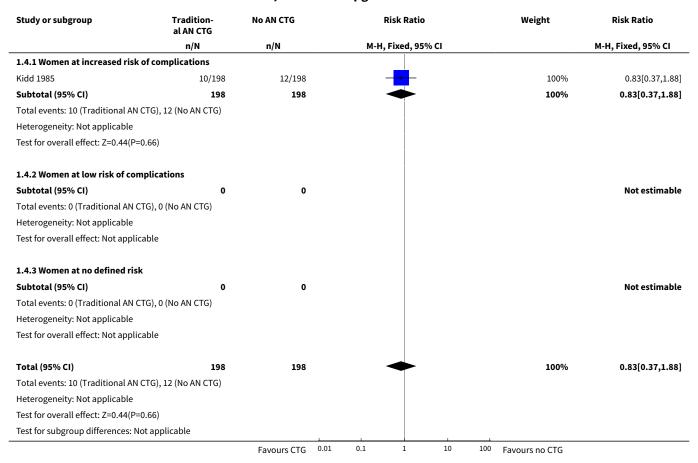


Analysis 1.3. Comparison 1 Traditional antenatal CTG versus no antenatal CTG, Outcome 3 Any potentially preventable perinatal deaths.

Study or subgroup	Tradition- al AN CTG	No AN CTG	Risk Ratio	Weight	Risk Ratio	
	n/N	n/N	M-H, Fixed, 95% CI		M-H, Fixed, 95% CI	
1.3.1 Women at increased risk of com	plications					
Brown 1982	2/201	0/200	-	8.28%	4.98[0.24,102.98]	
Flynn 1982	2/144	1/156	+	15.86%	2.17[0.2,23.64]	
Kidd 1985	3/198	0/198	-	8.26%	7[0.36,134.64]	
Lumley 1983	7/271	4/259	 	67.59%	1.67[0.5,5.65]	
Subtotal (95% CI)	814	813	•	100%	2.46[0.96,6.3]	
Total events: 14 (Traditional AN CTG), 5	(No AN CTG)					
Heterogeneity: Tau ² =0; Chi ² =1.09, df=3	(P=0.78); I ² =0%					
Test for overall effect: Z=1.88(P=0.06)						
1.3.2 Women at low risk of complicat	ions					
Subtotal (95% CI)	0	0			Not estimable	
Total events: 0 (Traditional AN CTG), 0 ((No AN CTG)					
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
1.3.3 Women at no defined risk						
Subtotal (95% CI)	0	0			Not estimable	
Total events: 0 (Traditional AN CTG), 0 ((No AN CTG)					
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
Total (95% CI)	814	813	-	100%	2.46[0.96,6.3]	
Total events: 14 (Traditional AN CTG), 5	(No AN CTG)					
Heterogeneity: Tau ² =0; Chi ² =1.09, df=3	(P=0.78); I ² =0%					
Test for overall effect: Z=1.88(P=0.06)						
Test for subgroup differences: Not appl	licable					
		Favours CTG 0.01	0.1 1 10	100 Favours no CTG		



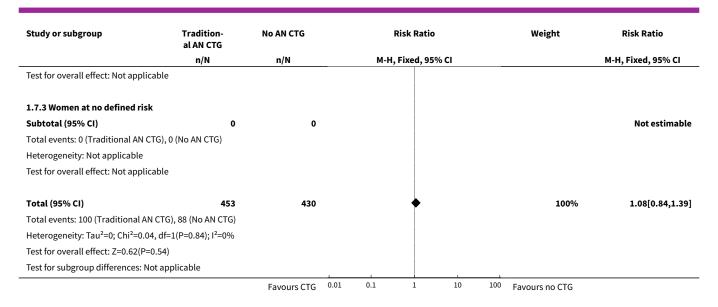
Analysis 1.4. Comparison 1 Traditional antenatal CTG versus no antenatal CTG, Outcome 4 Apgar less than 7 at 5 minutes.



Analysis 1.7. Comparison 1 Traditional antenatal CTG versus no antenatal CTG, Outcome 7 Admission to neonatal special care unit or intensive care unit.

Study or subgroup	Tradition- al AN CTG	No AN CTG	No AN CTG Risk Ra		Risk Ratio	ntio Weight			Risk Ratio
	n/N	n/N		M-H	I, Fixed, 95% (:1			M-H, Fixed, 95% CI
1.7.1 Women at increased risk	of complications								
Brown 1982	23/182	19/171			-			21.73%	1.14[0.64,2.01]
Lumley 1983	77/271	69/259			<u> </u>			78.27%	1.07[0.81,1.41]
Subtotal (95% CI)	453	430			•			100%	1.08[0.84,1.39]
Total events: 100 (Traditional AN	I CTG), 88 (No AN CTG)								
Heterogeneity: Tau ² =0; Chi ² =0.04	4, df=1(P=0.84); I ² =0%								
Test for overall effect: Z=0.62(P=0	0.54)								
1.7.2 Women at low risk of com	plications								
Subtotal (95% CI)	0	0							Not estimable
Total events: 0 (Traditional AN C	TG), 0 (No AN CTG)								
Heterogeneity: Not applicable						,			
		Favours CTG	0.01	0.1	1	10	100	Favours no CTG	



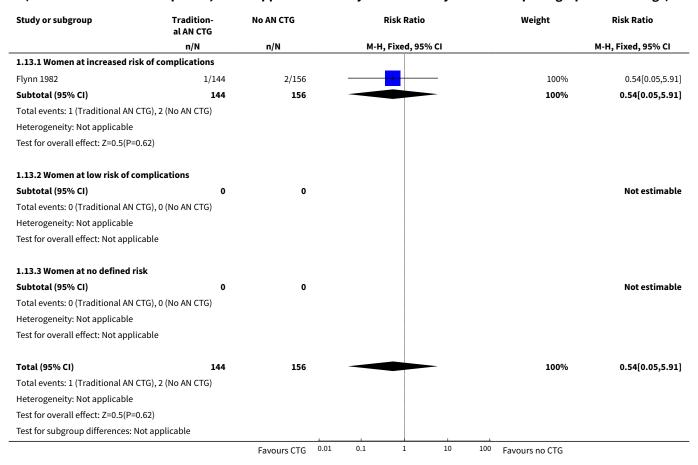


Analysis 1.12. Comparison 1 Traditional antenatal CTG versus no antenatal CTG, Outcome 12 Gestational age at birth.

Study or subgroup	Traditi	onal AN CTG	No	AN CTG	Mean Difference	Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI		Fixed, 95% CI
1.12.1 Women at increased risk o	f complica	ations					
Brown 1982	182	38.6 (1.6)	171	38.6 (1.6)		100%	0[-0.33,0.33]
Subtotal ***	182		171			100%	0[-0.33,0.33]
Heterogeneity: Not applicable							
Test for overall effect: Not applicab	le						
1.12.2 Women at low risk of com	olications						
Subtotal ***	0		0				Not estimable
Heterogeneity: Not applicable							
Test for overall effect: Not applicab	le						
1.12.3 Women at no defined risk							
Subtotal ***	0		0				Not estimable
Heterogeneity: Not applicable							
Test for overall effect: Not applicab	le						
Total ***	182		171			100%	0[-0.33,0.33]
Heterogeneity: Not applicable							
Test for overall effect: Not applicab	le						
Test for subgroup differences: Not	applicable						
			Fa	avours no CTG	-0.5 -0.25 0 0.25 0.5	Favours CTG	i



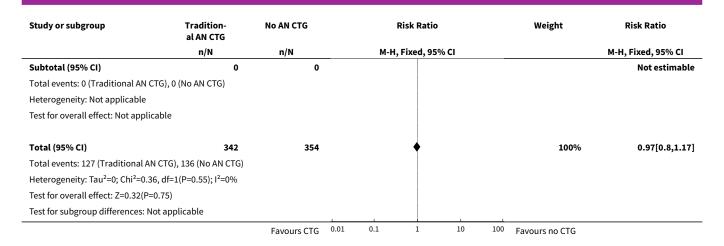
Analysis 1.13. Comparison 1 Traditional antenatal CTG versus no antenatal CTG, Outcome 13 Neonatal seizures (seizures in the neonatal period, either apparent clinically or detected by electroencephalographic recordings).



Analysis 1.18. Comparison 1 Traditional antenatal CTG versus no antenatal CTG, Outcome 18 Induction of labour.

Study or subgroup	Tradition- al AN CTG	No AN CTG		Risk Ratio			Weight	Risk Ratio
	n/N	n/N		M-H, Fixe	ed, 95% CI			M-H, Fixed, 95% CI
1.18.1 Women at increased risk o	f complications							
Flynn 1982	60/144	63/156		+	=		45.31%	1.03[0.79,1.35]
Kidd 1985	67/198	73/198		•	•		54.69%	0.92[0.7,1.2]
Subtotal (95% CI)	342	354		•			100%	0.97[0.8,1.17]
Total events: 127 (Traditional AN C	TG), 136 (No AN CTG)							
Heterogeneity: Tau ² =0; Chi ² =0.36, o	df=1(P=0.55); I ² =0%							
Test for overall effect: Z=0.32(P=0.7	75)							
1.18.2 Women at low risk of com	plications							
Subtotal (95% CI)	0	0						Not estimable
Total events: 0 (Traditional AN CTG	i), 0 (No AN CTG)							
Heterogeneity: Not applicable								
Test for overall effect: Not applicab	le							
1.18.3 Women at no defined risk			1	1		1		
		Favours CTG	0.01	0.1	1 10	100	Favours no CTG	





Comparison 3. Computerised antenatal CTG versus traditional antenatal CTG

Outcome or subgroup title	No. of studies	No. of partici- pants	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)	0.0 [0.0, 0.0]
1.3 Women with no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
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)	0.0 [0.0, 0.0]
2.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
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)	0.0 [0.0, 0.0]
3.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
4 Apgar less than 7 at 5 minutes	2	469	Risk Ratio (M-H, Fixed, 95% CI)	1.31 [0.30, 5.74]



Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
4.1 Women at increased risk of complications	2	469	Risk Ratio (M-H, Fixed, 95% CI)	1.31 [0.30, 5.74]
4.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
4.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
5 Apgar less than 4 at 5 minutes	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
5.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
5.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
5.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
6 Cord pH less than 7.10 or low pH as defined by trialists	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
6.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
6.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
6.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
7 Admission to neonatal special care unit or intensive care unit	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
7.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
7.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
7.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
8 Length of stay in neonatal special care unit or intensive care unit	1	405	Mean Difference (IV, Fixed, 95% CI)	-0.40 [-0.99, 0.19]
8.1 Women at increased risk of complications	1	405	Mean Difference (IV, Fixed, 95% CI)	-0.40 [-0.99, 0.19]
8.2 Women at low risk of complications	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
8.3 Women at no defined risk	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
9 Preterm birth less than 37 weeks	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]



Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
9.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
9.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
9.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
10 Preterm birth less than 34 weeks	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
10.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
10.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
10.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
11 Preterm birth less than 28 weeks	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
11.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
11.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
11.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
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)	0.0 [0.0, 0.0]
12.3 Women at no defined risk	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
13 Neonatal seizures (seizures in the neonatal period, either apparent clinically or detected by electroen- cephalographic recordings)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
13.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
13.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
13.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
14 Hypoxic ischaemic encephalopathy as defined by trialists	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]



Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
14.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
14.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
14.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
15 Cerebral palsy at 12 months of age	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
15.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
15.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
15.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
16 Neurodevelopmental disability at 12 months of age	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
16.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
16.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
16.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
17 Caesarean section for non-reassuring or abnormal fetal heart rate patterns	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
17.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
17.2 Women at low risk of complica-	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
17.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
18 Induction of labour	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
18.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
18.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
18.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
19 Antenatal hospital admission	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
19.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

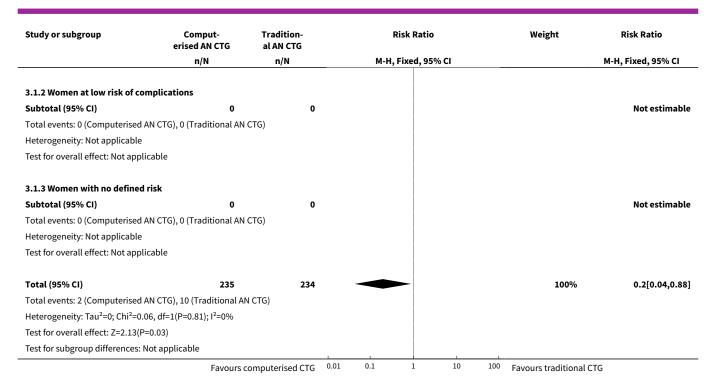


Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
19.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
19.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
20 Length of antenatal hospital stay	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
20.1 Women at increased risk of complications	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
20.2 Women at low risk of complications	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
20.3 Women at no defined risk	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
21 Emotional distress/depres- sion/anxiety	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
21.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
21.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
21.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
22 Women's satisfaction with care	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
22.1 Women at increased risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
22.2 Women at low risk of complications	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
22.3 Women at no defined risk	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

Analysis 3.1. Comparison 3 Computerised antenatal CTG versus traditional antenatal CTG, Outcome 1 Perinatal mortality.

Study or subgroup	Comput- erised AN CTG	Tradition- al AN CTG		Risk Rat	tio		Weight	Risk Ratio
	n/N	n/N		M-H, Fixed,	95% CI			M-H, Fixed, 95% CI
3.1.1 Women at increased r	isk of complications							
Bracero 1999	1/205	6/205		-			59.6%	0.17[0.02,1.37]
Steyn 1997	1/30	4/29		-	-		40.4%	0.24[0.03,2.04]
Subtotal (95% CI)	235	234	-				100%	0.2[0.04,0.88]
Total events: 2 (Computerise	al events: 2 (Computerised AN CTG), 10 (Traditional AN CTG)							
Heterogeneity: Tau ² =0; Chi ² =	0.06, df=1(P=0.81); I ² =0%							
Test for overall effect: Z=2.13	(P=0.03)							
	Favours co	omputerised CTG	0.01 0	.1 1	10	100	Favours traditional CTG	i





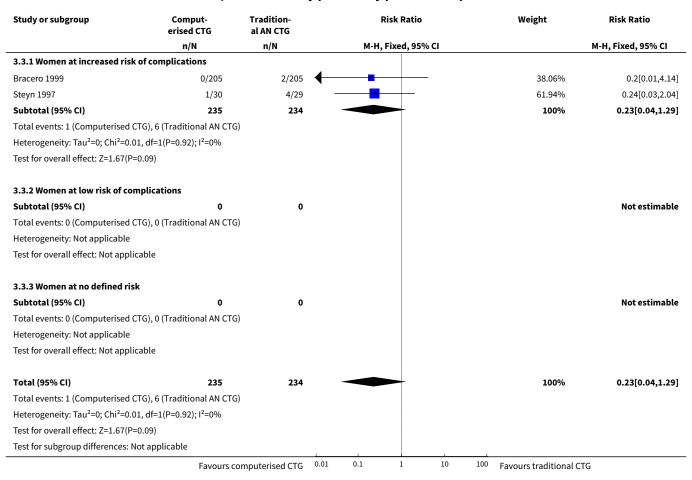
Analysis 3.2. Comparison 3 Computerised antenatal CTG versus traditional antenatal CTG, Outcome 2 Caesarean section.

Study or subgroup	Comput- erised AN CTG	Tradition- al AN CTG	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H, Fixed, 95% CI		M-H, Fixed, 95% CI
3.2.1 Women at increased risk of o	complications				
Steyn 1997	19/30	21/29		100%	0.87[0.61,1.24]
Subtotal (95% CI)	30	29	*	100%	0.87[0.61,1.24]
Total events: 19 (Computerised AN	CTG), 21 (Traditional A	N CTG)			
Heterogeneity: Tau ² =0; Chi ² =0, df=0	(P<0.0001); I ² =100%				
Test for overall effect: Z=0.74(P=0.46	5)				
3.2.2 Women at low risk of compli	cations				
Subtotal (95% CI)	0	0			Not estimable
Total events: 0 (Computerised AN C	TG), 0 (Traditional AN	CTG)			
Heterogeneity: Not applicable					
Test for overall effect: Not applicabl	e				
3.2.3 Women at no defined risk					
Subtotal (95% CI)	0	0			Not estimable
Total events: 0 (Computerised AN C	TG), 0 (Traditional AN	CTG)			
Heterogeneity: Not applicable					
Test for overall effect: Not applicabl	е				
Total (95% CI)	30	29	•	100%	0.87[0.61,1.24]
Total events: 19 (Computerised AN	CTG), 21 (Traditional A	N CTG)			
Heterogeneity: Tau ² =0; Chi ² =0, df=0	(P<0.0001); I ² =100%				
Test for overall effect: Z=0.74(P=0.46	6)				
	Favours c	omputerised CTG 0.01	0.1 1 10 1	Favours traditional C	ГG



Study or subgroup	Comput- erised AN CTG	Tradition- al AN CTG		1	Risk Ratio	•		Weight	Risk Ratio
	n/N	n/N		М-Н,	Fixed, 95	% CI			M-H, Fixed, 95% CI
Test for subgroup differences	: Not applicable								
	Favours	computerised CTG	0.01	0.1	1	10	100	Favours traditional C	TG

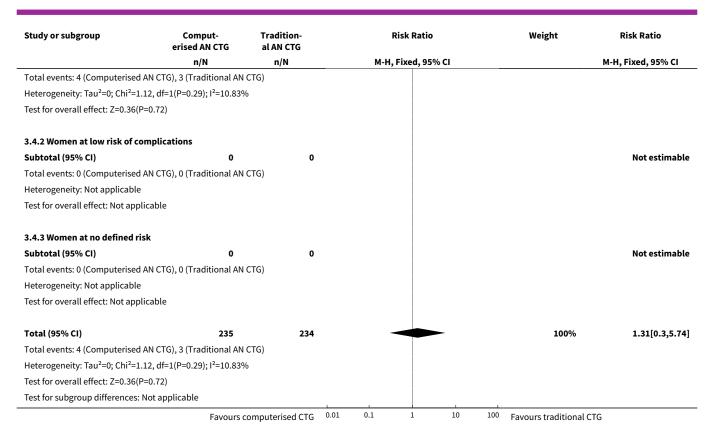
Analysis 3.3. Comparison 3 Computerised antenatal CTG versus traditional antenatal CTG, Outcome 3 Any potentially preventable perinatal death.



Analysis 3.4. Comparison 3 Computerised antenatal CTG versus traditional antenatal CTG, Outcome 4 Apgar less than 7 at 5 minutes.

Study or subgroup	Comput- erised AN CTG	Tradition- al AN CTG		Risk Ratio			Weight	Risk Ratio	
	n/N	n/N		М-Н	, Fixed, 95	% CI			M-H, Fixed, 95% CI
3.4.1 Women at increased r	risk of complications								
Bracero 1999	1/205	2/205			-			66.29%	0.5[0.05,5.47]
Steyn 1997	3/30	1/29			-			33.71%	2.9[0.32,26.3]
Subtotal (95% CI)	235	234			—	-		100%	1.31[0.3,5.74]
	Favours c	omputerised CTG	0.01	0.1	1	10	100	Favours traditional CTG	i





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.

Study or subgroup		omput- ed AN CTG	Traditi	onal AN CTG	Mean Difference	Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI		Fixed, 95% CI
3.8.1 Women at increased risk of o	omplica	tions					
Bracero 1999	204	2.7 (1.5)	201	3.1 (4)	-	100%	-0.4[-0.99,0.19]
Subtotal ***	204		201		•	100%	-0.4[-0.99,0.19]
Heterogeneity: Not applicable							
Test for overall effect: Z=1.33(P=0.18	3)						
3.8.2 Women at low risk of compli	cations						
Subtotal ***	0		0				Not estimable
Heterogeneity: Not applicable							
Test for overall effect: Not applicabl	e						
3.8.3 Women at no defined risk							
Subtotal ***	0		0				Not estimable
Heterogeneity: Not applicable							
Test for overall effect: Not applicabl	e						
Total ***	204		201		•	100%	-0.4[-0.99,0.19]
Heterogeneity: Not applicable							
Test for overall effect: Z=1.33(P=0.18	3)						
Test for subgroup differences: Not a	pplicable						
		Fav	ours com	outerised CTG	-4 -2 0 2	4 Favours tra	ditional CTG



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

Study or subgroup		omput- ed AN CTG	Traditi	onal AN CTG	Mean Difference	Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI		Fixed, 95% CI
3.12.1 Women at increased risk o	f complic	ations					
Bracero 1999	204	39.8 (1.7)	201	39.9 (1.7)	i i	100%	-0.1[-0.43,0.23]
Subtotal ***	204		201			100%	-0.1[-0.43,0.23]
Heterogeneity: Not applicable							
Test for overall effect: Z=0.59(P=0.5	55)						
3.12.2 Women at low risk of comp	olications						
Subtotal ***	0		0				Not estimable
Heterogeneity: Not applicable							
Test for overall effect: Not applicab	le						
3.12.3 Women at no defined risk							
Subtotal ***	0		0				Not estimable
Heterogeneity: Not applicable							
Test for overall effect: Not applicab	le						
Total ***	204		201			100%	-0.1[-0.43,0.23]
Heterogeneity: Not applicable							
Test for overall effect: Z=0.59(P=0.5	5)						
Test for subgroup differences: Not a	applicable	!					
			Favours tr	aditional CTG -100	-50 0 50	100 Favours con	nputerised CTG

APPENDICES

Appendix 1. Methods to be used in future updates

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

Selection of studies

Two review authors will independently assess for inclusion all the potential studies we identify as a result of the search strategy. We will resolve any disagreement through discussion or, if required, we will consult a third review author.

We will create a Study flow diagram to map out the number of records identified, included and excluded.

Data extraction and management

We will design a form to extract data. For eligible studies, two review authors will extract the data using the agreed form. We will resolve discrepancies through discussion or, if required, we will consult a third person. We will enter data into Review Manager software (RevMan 2014) and check for accuracy.

When information regarding any of the above is unclear, we will attempt to contact authors of the original reports to provide further details.

Assessment of risk of bias in included studies

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



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

We will describe 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 will assess the method as:

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

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

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

We will assess the methods as:

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

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

We will describe for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We will consider that studies are at low risk of bias if they were blinded, or if we judge that the lack of blinding would be unlikely to affect results. We will assess blinding separately for different outcomes or classes of outcomes.

We will assess the methods as:

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

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

We will describe for each included study the methods used, if any, to blind outcome assessors from knowledge of which intervention a participant received. We will assess blinding separately for different outcomes or classes of outcomes.

We will assess methods used to blind outcome assessment as:

· low, high or unclear risk of bias.

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

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

We will assess methods as:

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

(5) Selective reporting (checking for reporting bias)

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

We will assess the methods as:

• low risk of bias (where it is clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review have been reported);



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

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

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

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

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

(7) Overall risk of bias

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

Measures of treatment effect

Dichotomous data

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

Continuous data

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

Unit of analysis issues

Cluster-randomised trials

We will include cluster-randomised trials in the analyses along with individually-randomised trials. We will adjust either sample sizes or standard errors using the methods described in the *Handbook* [Section 16.3.4 or 16.3.6] using an estimate of the intracluster correlation coefficient (ICC) derived from the trial (if possible), from a similar trial or from a study of a similar population. If we use ICCs from other sources, we will report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. If we identify both cluster-randomised trials and individually-randomised trials, we plan to synthesise the relevant information. We will consider it reasonable to combine the results from both if there is little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomisation unit is considered to be unlikely.

We will also acknowledge heterogeneity in the randomisation unit and perform a sensitivity analysis to investigate the effects of the randomisation unit.

Cross-over trials

Cross-over trials will not be included.

Dealing with missing data

For included studies, we will note levels of attrition. We will explore the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis.

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

Assessment of heterogeneity

We will assess statistical heterogeneity in each meta-analysis using the Tau^2 , I^2 and Chi^2 statistics. We will regard heterogeneity as substantial if an I^2 is greater than 30% and either a Tau^2 is greater than zero, or there is a low P value (less than 0.10) in the Chi^2 test for heterogeneity.



Assessment of reporting biases

If there are 10 or more studies in the meta-analysis, we will investigate reporting biases (such as publication bias) using funnel plots. We will assess funnel plot asymmetry visually. If asymmetry is suggested by a visual assessment, we will perform exploratory analyses to investigate it.

Data synthesis

We will carry out statistical analysis using the Review Manager software (RevMan 2014. We will use fixed-effect meta-analysis for combining data where it is reasonable to assume that studies are estimating the same underlying treatment effect: i.e. where trials are examining the same intervention, and the trials' populations and methods are judged sufficiently similar. If there is clinical heterogeneity sufficient to expect that the underlying treatment effects differ between trials, or if substantial statistical heterogeneity is detected, we will use random-effects meta-analysis to produce an overall summary, if an average treatment effect across trials is considered clinically meaningful. The random-effects summary will be treated as the average of the range of possible treatment effects and we will discuss the clinical implications of treatment effects differing between trials. If the average treatment effect is not clinically meaningful, we will not combine trials.

If we use random-effects analyses, the results will be presented as the average treatment effect with 95% confidence intervals, and the estimates of Tau^2 and I^2 .

Subgroup analysis and investigation of heterogeneity

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

The following outcomes will be used in subgroup analysis.

- 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 versus antenatal CTG testing begun on fetus at 37 or more completed weeks' gestation

The subgroup analysis will be conducted for all outcomes within the main analysis.

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

Selection of studies

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

WHAT'S NEW

Date	Event	Description
9 May 2019	Amended	Edited Declarations of interest

HISTORY

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

Date	Event	Description
15 January 2015	New citation required but conclusions have not changed	No new trials included.



Date	Event	Description
15 January 2015	New search has been performed	Search updated. 'Summary of findings' tables have been incorporated.
17 September 2012	New citation required but conclusions have not changed	Review updated.
17 September 2012	New search has been performed	Search updated in July 2012. One further citation added to Excluded studies (Cousins 2012).

CONTRIBUTIONS OF AUTHORS

Rosalie Grivell (RG) updated the review for this 2015 update. All review authors commented on the final draft.

DECLARATIONS OF INTEREST

Declan Devane: none known.

Gill Gyte received royalties from John Wiley & Sons in respect of 'A Cochrane Pocketbook – Pregnancy and Childbirth' Hofmeyr GJ et al. 2008. This Cochrane Pocketbook is a Cochrane/Wiley publication.

Zarko Alfirevic: none known.

Rosalie Grivell: none known.

SOURCES OF SUPPORT

Internal sources

• The University of Liverpool, UK.

External sources

· National Institute for Health Research, UK.

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

• UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP), Department of Reproductive Health and Research (RHR), World Health Organization, Switzerland.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

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 *Cochrane Handbook for Systematic Reviews of Interventions* suggested it was more commonly used.

Methods updated to current standard methods text for Cochrane Pregnancy and Childbirth. 'Summary of findings' tables have been incorporated.

INDEX TERMS

Medical Subject Headings (MeSH)

Cardiotocography [*methods]; Diagnosis, Computer-Assisted [methods]; Perinatal Mortality; Randomized Controlled Trials as Topic

MeSH check words

Female; Humans; Infant, Newborn; Pregnancy