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Fetal scalp stimulation for assessing fetal well-being during labour (Review)

Murphy DJ, Devane D, Molloy E, Shahabuddin Y

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TABLE OF CONTENTS

[Intervention Review]

Fetal scalp stimulation for assessing fetal well-being during labour

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ABSTRACT

Background

Continuous fetal heart rate monitoring by cardiotocography (CTG) is used in labour for women with complicated pregnancies. Fetal heart rate abnormalities are common and may result in the decision to expedite delivery by caesarean section. Fetal scalp stimulation (FSS) is a second-line test of fetal well-being that may provide reassurance that the labour can continue.

Objectives

To evaluate methods of FSS as second-line tests of intrapartum fetal well-being in cases of non-reassuring CTG. FSS and CTG were compared to CTG alone, and to CTG with fetal blood sampling (FBS).

Search methods

We searched Cochrane Pregnancy and Childbirth's Trials Register (which includes trials from CENTRAL, MEDLINE, Embase, CINAHL, the WHO ICTRP and conference proceedings), ClinicalTrials.gov (18 October 2022), and reference lists of retrieved studies.

Selection criteria

Eligible studies were randomised controlled trials (RCTs) that compared any form of FSS to assess fetal well-being in labour. Quasi-RCTs, cluster-RCTs and studies published in abstract form were also eligible for inclusion, but none were identified.

Data collection and analysis

Two review authors independently assessed studies for inclusion and risk of bias, extracted data and checked them for accuracy. We assessed the certainty of the evidence using the GRADE approach.

Main results

Two trials, involving 377 women, met the inclusion criteria for this review. Both trials were conducted in hospital settings and included women with singleton, term (37+0 weeks or more) pregnancies, a cephalic presentation, and abnormal CTG. Follow-up was until hospital discharge after the birth. A pilot trial of 50 women in a high-income country (Ireland) compared CTG and digital fetal scalp stimulation (dFSS) with CTG and fetal blood sampling (FBS). A single-centre trial of 327 women in a lower middle-income country (India) compared CTG and manual fetal stimulation (abdominal or vaginal scalp stimulation) with CTG alone. The two included studies were at moderate or unclear risk of bias. Both trials provided clear information on allocation concealment but it was not possible to blind participants or health professionals in relation to the intervention. Although objective outcome measures were reported, outcome assessment was not blinded or blinding was unclear.

dFSS and CTG versus FBS and CTG

There were no perinatal deaths and data were not reported for neurodevelopmental disability at >/= 12 months. The risk of caesarean section (CS) may be lower with dFSS compared to FBS (risk ratio (RR) 0.38, 95% confidence interval (CI) 0.16 to 0.92; 1 pilot trial, 50 women; very low-certainty evidence) but the evidence is very uncertain. There were no cases of neonatal encephalopathy reported. The evidence was also very uncertain between dFSS and FBS for assisted vaginal birth (RR 1.44, 95% CI 0.76 to 2.75; very low-certainty evidence) and for the spontaneous vaginal birth rate (RR 2.33, 95% CI 0.68 to 8.01, very low-certainty evidence). Maternal acceptability of the procedures was not reported.

FSS and CTG versus CTG alone

Manual stimulation of the fetus was performed either abdominally (92/164) or vaginally (72/164). There were no perinatal deaths and data were not reported for neurodevelopmental disability at >/= 12 months. There may be little differences in the risk of CS on comparing manual fetal stimulation and CTG with CTG alone (RR 0.83, 95% CI 0.59 to 1.18; 1 trial, 327 women; very low-certainty evidence), but again the evidence was very uncertain. There were no cases of neonatal encephalopathy reported. There may be no differences in the risk of assisted vaginal birth (RR 1.43, 95% CI 0.78 to 2.60; very low-certainty evidence) or in the rates of spontaneous vaginal birth (RR 1.01, 95% CI 0.85 to 1.21, very low-certainty evidence), but again the evidence is very uncertain. Maternal acceptability of abdominal stimulation/FSS was not reported although 13 women withdrew consent after randomisation due to concerns about fetal well-being.

Authors' conclusions

There is very low-certainty evidence available which makes it unclear whether stimulating the fetal scalp is a safe and effective way to confirm fetal well-being in labour. Evidence was downgraded based on limitations in study design and imprecision. Further high-quality studies of adequate sample size are required to evaluate this research question. In order to be generalisable, these trials should be conducted in different settings, including broad clinical criteria at both preterm and term gestational ages, and standardising the method of stimulation. There is an ongoing study (FIRSST) that will be incorporated into this review in a subsequent update.

PLAIN LANGUAGE SUMMARY

Stimulating the baby's scalp as a test of the baby's well-being in labour

We set out to look for evidence from randomised controlled trials on the effectiveness and safety of stimulating the baby's scalp as a second-line test of well-being when there are concerns about the baby's heart rate monitoring.

What is the issue?

Women with complicated pregnancies are recommended continuous monitoring of the baby's heart rate using an electronic recorder called a CTG. Babies commonly demonstrate abnormal features on the CTG during labour. In some cases the abnormal features are of sufficient concern to warrant an emergency caesarean section. To reduce the chance of an unnecessary caesarean section additional 'second-line' tests can be offered. One such test is where the baby's scalp is stimulated vaginally in an attempt to cause an increase in the baby's heart rate. This healthy response suggests that the baby is receiving enough oxygen. An alternative approach is to take a small blood sample from the baby's scalp and test the acid-base level in the blood.

Why is this important?

If stimulation of the baby's scalp as a second-line test of well-being is demonstrated to be safe and effective, then it may be possible to reduce the chance of an unnecessary caesarean section for women in labour.

What evidence did we find?

We searched for evidence on 18 October 2022 and identified two eligible studies (involving 377 women). A pilot study of 50 women in Ireland compared digital fetal scalp stimulation (dFSS) and CTG with fetal blood sampling (FBS) and CTG. A study in India of 327 women compared manual fetal scalp stimulation (FSS) (abdominal side to side movement of the fetal head or vaginal pinching of the fetal scalp) and CTG with CTG alone. In both studies, women and hospital staff were aware that fetal scalp stimulation had been performed. This may have had an impact on the results. Both studies were conducted in hospitals and recruited women in labour at term with a single baby presenting head first. Overall, the included studies were at moderate or unclear risk of bias, and the certainty of the generated evidence was very low or unclear.

dFSS and CTG versus FBS and CTG

There were no perinatal deaths and no data reported on disability in the babies at or after 12 months. We found very low-certainty evidence that stimulation of the baby's scalp in addition to CTG may lower the risk of caesarean section compared to scalp blood sampling and CTG (1 pilot trial; 50 women). There were no babies born with evidence of brain injury during labour. There was no difference in the risk of assisted vaginal birth by vacuum or forceps, or in the rate of spontaneous vaginal birth. The acceptability of the procedures to the mother was not reported.

FSS and CTG versus CTG alone

There were no perinatal deaths and no data reported on disability in the babies at or after 12 months. We found that stimulation of the baby's scalp in addition to CTG had little or no difference in the risk of caesarean section compared to CTG alone (1 trial; 327 women). There were no babies born with evidence of brain injury during labour. There was no difference in the risk of assisted vaginal birth by vacuum or forceps, or in the rate of spontaneous vaginal birth. All of the evidence was found to be of very low certainty. The acceptability of the procedures to the mother was not reported.

What does this mean?

The evidence is unclear whether stimulating a baby's scalp in labour is a safe and effective way to confirm the baby's well-being in labour. Further high-quality studies of adequate sample size, including a broad range of settings and eligibility criteria, are required to evaluate this research question.

SUMMARY OF FINDINGS

Summary of findings 1. Summary of findings

Digital fetal scalp stimulation and CTG compared with fetal blood sampling and CTG for assessment of fetal well-being in labour

Patient or population: women with an abnormal cardiotocograph (CTG) in labour

Settings: university-affiliated maternity hospital in Ireland

Intervention: digital fetal scalp stimulation (dFSS) and CTG

Comparison: fetal blood sampling (FBS) and CTG

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Certainty of the evidence (GRADE)	Comments
	FBS and CTG	dFSS and CTG				
Perinatal death	**Study population**		_	50 women (1 RCT)	_	No events
	0 per 1000	0 per 1000				
Neurodevelopmental disability at >/ = 12 months	Not known	Not known	_	50 women (1 RCT)	_	Outcome not reported by trial authors
Caesarean section (all indications)	**Study population**		RR 0.38 (0.16 to 0.92)	50 women (1 RCT)	⊕⊖⊖⊖ very low[a,b]	Imprecise
	520 per 1000	200 per 1000 (68 to 407)				
Neonatal encephalopathy	**Study population**		_	50 women (1 RCT)	_	No events
	0 per 1000	0 per 1000 (inestimable)				
Assisted vaginal birth (all indications)	**Study population**		RR 1.44 (0.76 to 2.75)	50 women (1 RCT)	⊕⊖⊖⊖ very low[a,b]	Imprecise
	260 per 1000	520 per 1000 (313 to 722)				
Spontaneous vaginal birth	**Study population**		RR 2.33 (0.68 to 8.01)	50 women	⊕⊖⊖⊖ very low[a,b]	Imprecise

	120 per 1000	280 per 1000 (121 to 494)		(1 RCT)		
Maternal acceptability of procedure(s)	Not known	Not known	_	50 women (1 RCT)	_	Outcome not reported by trial authors

*__The risk in the intervention group__ (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **RCT:** randomised controlled trial; **RR:** risk ratio.

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

[a]Evidence certainty downgraded by 1 level due to serious limitations in study design (lack of blinding of participants and personnel, and lack of assessor blinding).
[b]Evidence certainty downgraded by 2 levels due to very serious imprecision (few or no events, very small sample size, wide confidence intervals).

Summary of findings 2. Summary of findings

Manual fetal stimulation and CTG compared with CTG only for assessment of fetal well-being in labour

Patient or population: women with an abnormal CTG in labour

Settings: university-affiliated maternity hospital in India

Intervention: manual fetal stimulation (abdominal or vaginal) and CTG

Comparison: CTG only

Outcomes	**Illustrative comparative risks* (95% CI)**		**Relative effect (95% CI)**	**Number of participants (studies)**	**Certainty of the evidence (GRADE)**	**Comments**
	Assumed risk	**Corresponding risk**				
	CTG alone	**Fetal stimulation and CTG**				
Perinatal death	**Study population**		_	327 women	_	No events

	0 per 1000	0 per 1000 (inestimable)		(1 RCT)		
Neurodevelopmental disability at >/= 12 months	**Study population**		_	327 women (1 RCT)	_	Outcome not reported by trial authors
	Not known	Not known				
Caesarean section **(all indications)**	**Study population**		RR 0.83 (0.59 to 1.18)	327 women (1 RCT)	⊕⊖⊖⊖ very low[a,b]	Imprecise
	307 per 1000	256 per 1000 (191 to 330)				
Neonatal encephalopathy	**Study population**		_	327 women (1 RCT)	_	No events
	0 per 1000	0 per 1000 (inestimable)				
Assisted vaginal birth (all indications)	**Study population**		RR 1.43 (0.78 to 2.60)	327 women (1 RCT)	⊕⊖⊖⊖ very low[a,b]	Imprecise
	98 per 1000	140 per 1000 (91 to 203)				
Spontaneous vaginal birth	**Study population**		RR 1.01 (0.85 to 1.21)	327 women (1 RCT)	⊕⊖⊖⊖ very low[a,b]	Imprecise
	595 per 1000	604 per 1000 (524 to 679)				
Maternal acceptability of procedure	**Study population**		_	327 women (1 RCT)	_	Outcome not reported by trial authors
	Not known	Not known				

[*]**The risk in the intervention group** (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RCT:** randomised controlled trial; **RR:** risk ratio.

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

[a]Evidence certainty downgraded by 1 level due to serious limitations in study design (lack of blinding of participants and personnel, and lack of assessor blinding).
[b]Evidence certainty downgraded by 2 levels due to very serious imprecision (few or no events, very small sample size, wide confidence intervals).

BACKGROUND

Caesarean section rates are increasing globally. The primary caesarean section rate among nulliparous women due to emergency procedures in labour contributes to much of the increase. A reliable test of fetal well-being in labour remains elusive.

Description of the condition

The term 'suspected fetal compromise' is used where the fetus is judged to be at greater risk of hypoxic injury, brain damage or death, and is one of the most common indicators for emergency caesarean section in labour (NICE 2017). In high-income countries, continuous electronic fetal heart rate monitoring (cEFM) recorded by cardiotocography (CTG), is used routinely in high-risk labours to identify fetuses that are thought to be at higher risk of compromise and who might benefit from additional assessment of fetal well-being or other interventions including operative birth, or both (ACOG 2009; Alfirevic 2017; NICE 2017).

CTG tracings display the fetal heart rate (FHR) pattern alongside maternal uterine activity. CTG patterns are often classified into discrete overall categories based on four criteria: baseline FHR, heart rate variability, the presence or absence of accelerations, and decelerations in the FHR. An example of such a classification system is that produced by the National Institute for Health and Care Excellence (NICE), which classifies the CTG tracing into one of three categories: normal, suspicious, and pathological (NICE 2017). Irrespective of the classification system used, abnormal FHR patterns that do not respond to basic resuscitation measures require further assessment of fetal well-being or delivery, either by caesarean section, assisted vaginal birth or expedited spontaneous vaginal birth (ACOG 2009; NICE 2017).

It is well-recognised that CTG has a high false-positive rate for fetal compromise (60% or more) and that many fetuses demonstrating abnormal features on the CTG are mounting a physiological response to the stress of labour and have sufficient reserve to continue in the labouring environment (Chauhan 2008; Ugwumadu 2014). This means that in many cases, potentially unnecessary caesarean sections are performed, with implications for the mother and baby, and for future births (Alfirevic 2017).

When an abnormal FHR pattern is detected and immediate delivery is not warranted, additional assessment of fetal well-being is required. Such assessments or second-line tests include fetal scalp stimulation (FSS) and fetal blood sampling (FBS) (ACOG 2009; Bretscher 1967; East 2015; Elimian 1997; NICE 2017; Weber 1979; Wiberg-Itzel 2008). FSS is performed during a vaginal examination by digital rubbing of the fetal scalp where the aim is to elicit an FHR acceleration on the CTG. National clinical guidelines support the use of digital FSS, but also highlight that the research evidence to support the use of FSS is limited (ACOG 2009; NICE 2017). An alternative form of stimulation is to apply an Allis forceps (a surgical instrument with sharp teeth used to grasp tissue) to the fetal scalp. This will produce a painful stimulus to the fetus and again the intention is to elicit an FHR acceleration on the CTG. FBS involves collection of a capillary sample of blood from the fetal scalp to assess pH or lactate. This requires an amnioscope (specialised speculum) to be passed into the maternal vagina and through the cervix to visualise the fetal scalp. A small laceration on the fetal scalp is made and the blood sample is collected in a heparinised capillary tube. The procedure will result in FSS, but the primary intention is to collect an FBS that allows quantitative analysis of fetal pH or lactate, reflecting oxygenation of the fetal blood (Clark 1984; Elimian 1997; Lazebnik 1992; Mahmood 2018; Spencer 1991).

FSS and FBS tests are all intrusive to varying degrees. Digital fetal scalp stimulation (dFSS) is the least invasive approach as there is no instrument required and the fetal stimulation is a surface rubbing pressure, unlike the Allis clamp/forceps that grasps the fetal scalp. dFSS takes no more than two to three minutes and a response should be apparent on the CTG in the following 10 minutes (Elimian 1997). FBS is a more technically challenging procedure that involves use of an amnioscope, direct visualisation of the fetal scalp, and collection of an analysable capillary sample. It is not technically possible in the early stages of labour. It has several other disadvantages; it is invasive and can be painful, it has a failure rate and contraindications, and it has cost implications for the equipment and disposable packs. FBS should be avoided where there is a risk of vertical transmission of infection (e.g. active maternal HIV, hepatitis B/C) or suspected fetal bleeding disorders. FBS procedures take on average 18 minutes. While it provides a quantitative result of pH/lactate, rather than relying on further CTG interpretation, failure to achieve an analysable sample occurs in up to 10% of attempted procedures (Annappa 2008; Tuffnell 2006).

Description of the intervention

dFSS is a procedure where a health professional performs a vaginal examination and applies a rubbing pressure to the fetal scalp with the examining fingers for a duration of approximately 30 to 60 seconds (ACOG 2009; Elimian 1997). FSS can also be performed more invasively by application of a surgical Allis clamp or forceps. FSS using an Allis clamp (cFSS) is a procedure whereby a clamp is applied transvaginally onto the fetal scalp, closed to the first ratchet and left in place for 15 seconds (Clark 1984).

The FHR pattern on the CTG is monitored closely for 1 to 10 minutes following FSS looking for evidence of an elicited FHR acceleration (defined as an increase in the FHR ≥ 15 bpm (beats per minute) for at least 15 seconds) or normal FHR variability (5 to 25 bpm), or both (NICE 2017). The presence of an FHR acceleration or increased variability (where previously reduced), or both, is interpreted as a positive response, comparable to a normal FBS result, and requires ongoing monitoring or a repeat in ~60 minutes (Clark 1984).

How the intervention might work

FSS is used to assess if the fetus can generate an elicited acceleration in the FHR or an increase in baseline FHR variability, or both. The presence of either or both after direct FSS reflects a physiological sympathetic response to scalp stimulation and thus normal functioning of the autonomic nervous system. A reassuring response suggests an infant who is not compromised (Clark 1984; Skupski 2002). This is different from spontaneous accelerations on the CTG which are generally considered to be a reassuring finding but are not always apparent on CTGs in labour (NICE 2017).

Why it is important to do this review

Most women who embark on labour are hoping for an uncomplicated vaginal birth. CTG is intended to enhance the safety of labour for mothers and babies; the consequences of its false-positive rate (poor specificity) means that many women have unnecessary operative procedures including vacuum, forceps, and emergency caesarean section (Alfirevic 2017). This has

consequences not only for the index birth but for future births. A woman who has a caesarean section for her first birth has on average only a 30% to 40% likelihood of a spontaneous vaginal birth in a subsequent pregnancy (RCOG 2015).

FBS is commonly used as a secondary test to differentiate fetuses that are actually compromised and who might benefit from expedited delivery from those that are coping with the physiological stress of labour. However, FBS has several disadvantages; it is invasive for the mother and fetus and can be painful, it has a procedural failure rate, contraindications (such as maternal infection, potential fetal bleeding disorder) and is not technically possible in the early stages of labour, and it has cost implications for the equipment and disposable packs (Annappa 2008; Mahendru 2011; Sherman 1994; Tuffnell 2006). FBS has also been shown to have no significant effect on the rate of caesarean sections in women monitored by cEFM (Alfirevic 2017).

In contrast, dFSS, has many potential advantages over FBS; it is less invasive, can be performed by a midwife or an obstetrician, provides a timely result, and is not dependent on equipment accuracy, cost or maintenance, and does not have as such, a failure rate (Mahendru 2011; Mahmood 2018; O'Brien 2013). If found to be safe, effective and acceptable, dFSS could be incorporated into an algorithm for managing abnormal FHR patterns as a substitute or alternative to FBS.

OBJECTIVES

To evaluate fetal scalp stimulation (FSS) as second-line tests of intrapartum fetal well-being in cases of non-reassuring cardiotocography (CTG) tracing; CTG and FSS compared with CTG only, or CTG and FSS compared with CTG and fetal blood sampling (FBS) (pH or lactate analysis, or both).

METHODS

Criteria for considering studies for this review

Types of studies

All randomised controlled trials (RCTs), published, ongoing or unpublished, that compare the use of any form of fetal scalp stimulation (FSS) to assess fetal well-being in labour. We would have included cluster-RCTs and studies published in abstract form but none were found.

Types of participants

Women in labour with abnormal cardiotocography (CTG) that requires a second-line test of fetal well-being. A second-line test of fetal well-being is any assessment undertaken to determine fetal well-being once a CTG is deemed sufficiently abnormal. Abnormal CTG was defined by local protocols (as per trial authors) which were based on RCOG (Royal College of Obstetricians and Gynaecologists) and ACOG (American College of Obstetricians and Gynecologists) guidelines (ACOG 2009; NICE 2017).

Types of interventions

Fetal scalp stimulation (FSS)

1. Digital fetal scalp stimulation (dFSS).
2. Application of Allis clamp (cFSS).

Comparisons

FSS is predominantly used as an adjunct to CTG. We would therefore compare CTG + FSS with:

- CTG (only);
- CTG + fetal blood sampling (FBS) (by pH or lactate, or both);
- CTG + other fetal stimulation methods.

Types of outcome measures

We included studies whether or not they reported the following outcome measures of interest.

Primary outcomes

1. Perinatal death.
2. Neurodevelopmental disability assessed at 12 months of age or more[a].
3. Caesarean section - all indications.

[a]Neurodevelopmental disability, defined as any one or combination of the following: non-ambulant cerebral palsy, developmental delay, auditory and visual impairment. Development should have been assessed using a previously validated tool, such as Bayley Scales of Infant Development (Psychomotor Developmental Index and Mental Developmental Index score < 80) (Bayley 1993).

Secondary outcomes

1. Fetal acidosis – cord arterial pH < 7.00.
2. Apgar score less than seven at five minutes.
3. Neonatal encephalopathy (as defined by authors).
4. Procedure-related fetal injury/complication.
5. Assisted vaginal birth – all indications.
6. Spontaneous vaginal birth.
7. Maternal acceptability of procedure (as defined by authors).

Search methods for identification of studies

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

Electronic searches

We searched Cochrane Pregnancy and Childbirth's Trials Register by contacting their Information Specialist (18 October 2022).

The Register is a database containing over 34,000 reports of controlled trials in the field of pregnancy and childbirth. It represents over 30 years of searching. For full current search methods used to populate Pregnancy and Childbirth's Trials Register including the detailed 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, please follow this link.

Briefly, Cochrane Pregnancy and Childbirth's Trials Register is maintained by their Information Specialist and contains trials identified from:

1. monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL) (which includes Cochrane's centralised

searching of the WHO International Clinical Trials Registry Platform (ICTRP));
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.

Search results are screened by two people and the full text of all relevant trial reports identified through the searching activities described above is reviewed. Based on the intervention described, each trial report is assigned a number that corresponds to a specific Pregnancy and Childbirth review topic (or topics), and is then added to the Register. The Information Specialist searches the Register for each review using this topic number rather than keywords. This results in a more specific search set that has been fully accounted for in the relevant review sections (Included studies, Excluded studies or Ongoing studies).

In addition, we searched ClinicalTrials.gov (18 October 2022) for unpublished, planned and ongoing trial reports (see Appendix 1 for search terms used).

Searching other resources

We searched the reference lists of retrieved studies.

We did not apply any language or date restrictions.

Data collection and analysis

Screening eligible studies for trustworthiness

All studies meeting our inclusion criteria were evaluated by at least two review authors against pre-defined criteria to select studies that, based on available information, are deemed to be sufficiently trustworthy to be included in the analysis. The Cochrane Pregnancy and Childbirth have developed a Trustworthiness Screening Tool (CPC-TST) which includes the following criteria.

Research governance

- Are there any retraction notices or expressions of concern listed on the Retraction Watch Database relating to this study?
- Was the study prospectively registered (for those studies published after 2010)? If not, was there a plausible reason?
- When requested, did the trial authors provide/share the protocol or ethics approval letter, or both?
- Did the trial authors engage in communication with the Cochrane Review authors within the agreed timelines?
- Did the trial authors provide individual participant data (IPD) upon request? If not, was there a plausible reason?

Baseline characteristics

- Is the study free from characteristics of the study participants that appear too similar (e.g. distribution of the mean (standard deviation (SD)) excessively narrow or excessively wide, as noted by Carlisle 2017)?

Feasibility

- Is the study free from characteristics that could be implausible? (e.g. large numbers of women with a rare condition (such as severe cholestasis in pregnancy) recruited within 12 months)?
- In cases with (close to) zero losses to follow-up, is there a plausible explanation?

Results

- Is the study free from results that could be implausible? (e.g. massive risk reduction for main outcomes with small sample size)?
- Do the numbers randomised to each group suggest that adequate randomisation methods were used (e.g. is the study free from issues such as unexpectedly even numbers of women 'randomised' including a mismatch between the numbers and the methods, if the authors say "no blocking was used" but still end up with equal numbers, or if the authors say they used "blocks of four" but the final numbers differ by six)?

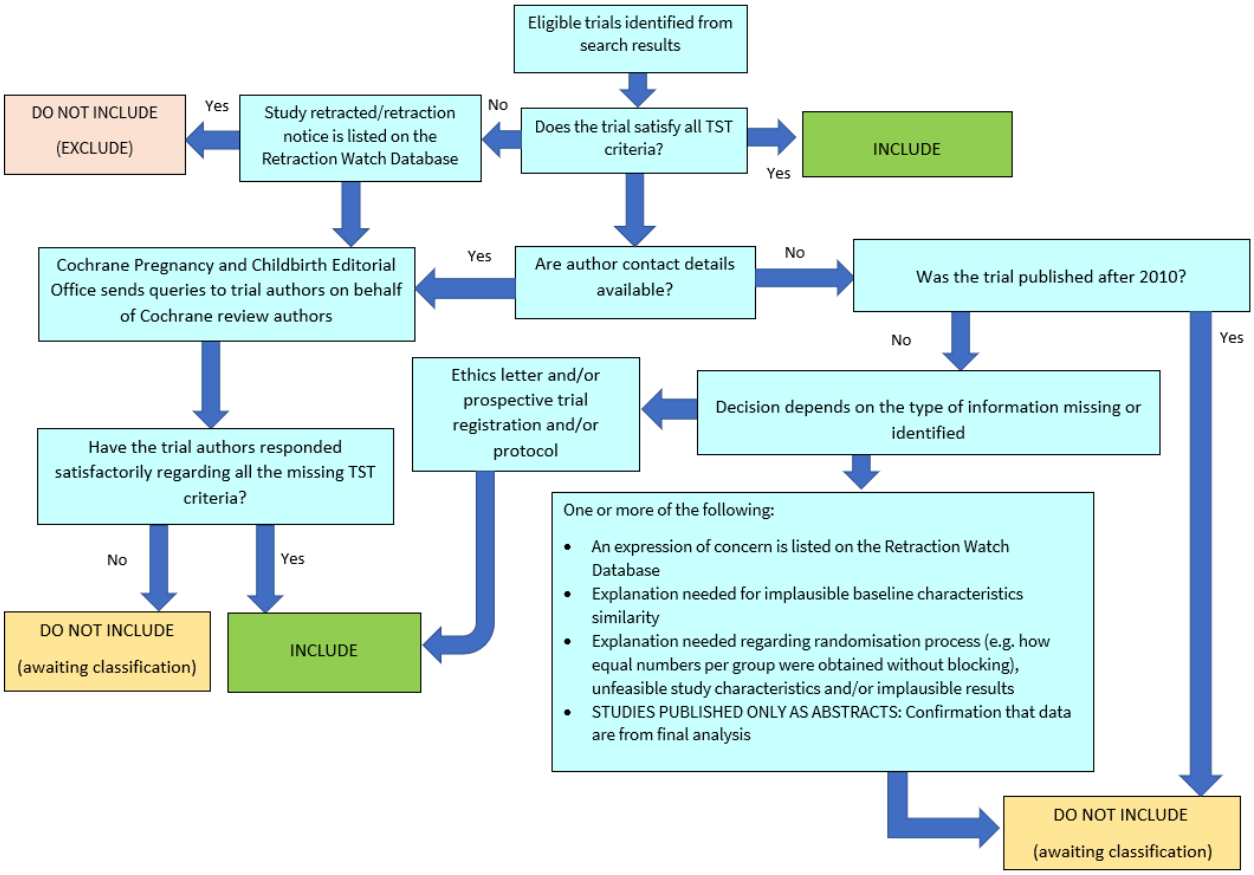
Studies assessed as being potentially 'high risk' would not be included in the review. If a study had been classified as 'high risk' we would attempt to contact the study authors to address any possible lack of information/concerns. In cases where we could not obtain contact details for the study authors, or where adequate information remained unavailable, the study would have remained in 'awaiting classification'. The reasons and communications with the author (or lack of) would have been described in detail.

Abstracts

Data from abstracts would only be included if, in addition to the trustworthiness assessment, the study authors confirmed in writing that the data to be included in the review came from the final analysis and would not change. If such information was not available/provided, the study would remain in 'awaiting classification' (as above).

See Figure 1 for details of how we applied the trustworthiness screening criteria.

Figure 1. Applying the Cochrane Pregnancy and Childbirth Trustworthiness Screening Tool.



We used the methods described below.

Selection of studies

At least two review authors (Deirdre J Murphy (DJM) and Yulia Shahabuddin (YS)) independently assessed for inclusion all the potential studies we identified as a result of the search strategy. We resolved any disagreement through discussion or, if required, we consulted a third review author (Declan Devane (DD)). DJM is the lead author of the pilot RCT and took no part in assessing that study or extracting data. The selection and assessment of that study was performed by YS and DD.

We have created a study flow diagram to map out the number of records identified, included and excluded.

Data extraction and management

We designed a form to extract data. For eligible studies, at least two review authors extracted the data using the agreed form. We also extracted information relating to trial dates, sources of trial funding, and trial authors' declarations of interest. We resolved discrepancies through discussion or, if required, we consulted a third review author. We entered data into Review Manager software (Review Manager 2020) and checked them for accuracy. When information regarding any of the above was unclear, we contacted authors of the original reports to provide further details.

Assessment of risk of bias in included studies

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

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

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

We assessed the methods as being:

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

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

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

We assessed the methods as being:

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

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

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

We assessed the methods as being:

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

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

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

We assessed methods used to blind outcome assessment as:

- low, high, or unclear risk of bias.

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

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

We assessed methods as being:

- low risk of bias (missing outcome data balanced across groups);
- high risk of bias (numbers or reasons for missing data imbalanced across groups; 'as treated' analysis done with substantial departure of intervention received from that assigned at randomisation);
- unclear risk of bias.

(5) Selective reporting (checking for reporting bias)

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

We assessed the methods as being:

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

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

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

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

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

(7) Overall risk of bias

We made explicit judgements about whether studies were at high risk of bias, according to the criteria given in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). With reference to (1) to (6) above, we assessed the likely magnitude and direction of the bias and whether we considered it was likely to impact on the findings. We planned to 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 have presented results as summary risk ratio with 95% confidence intervals.

Continuous data

For continuous data, we would use the mean difference with 95% confidence intervals if outcomes were measured in the same way between trials. We would use the standardised mean difference with 95% confidence intervals to combine trials that measured the same outcome, but used different methods.

Unit of analysis issues

Cluster-randomised trials and quasi-randomised trials

We planned to include cluster-randomised trials and individually-randomised trials; no such trials were identified for this version of the review. If we identify cluster-randomised trials for inclusion in future updates, we will adjust their sample sizes using the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Section 16.3.4 or 16.3.6) using an estimate of the intracluster correlation co-efficient (ICC) derived from the trial (if possible), from a similar trial or from a study of a similar population. 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 each type of trial 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 relevant for this review.

Other unit of analysis issues

Trials with more than one treatment arm

It is conceivable that there may be future trials with more than one treatment arm. Should any trial be identified that includes multiple tests of fetal well-being, where the tests are sufficiently similar, for example where comparison is made between two interventions of the same type (e.g. FBS for pH or lactate), we will combine dichotomous data. For outcomes reported on a continuous scale, we will combine data using the formula in Higgins 2011.

Where the interventions are not sufficiently similar, we will split the comparator arm data following the methods reported in Higgins 2011.

Dealing with missing data

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

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

Assessment of heterogeneity

In future updates with additional studies we would assess statistical heterogeneity in each meta-analysis using the Tau^2, I^2 and Chi^2 statistics. We would regard heterogeneity as substantial if I^2 was greater than 30% and either Tau^2 was greater than zero, or there was a low P value (less than 0.10) in the Chi^2 test for heterogeneity.

Assessment of reporting biases

In future updates, 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 performed statistical analysis using the Review Manager software (Review Manager 2020). For future updates with multiple studies, we planned to 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 would 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 would be treated as the average of the range of possible treatment effects and we would discuss the clinical implications of treatment effects differing between trials. If the average treatment effect was not clinically meaningful, we would not combine trials.

In future updates, 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

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

We planned to carry out the following subgroup analyses.

1. Gestational age: term (>/= 37 weeks) versus preterm (< 37 weeks).
2. Parity: nulliparous versus parous.

Gestational age and parity are important because of their influence on the likelihood of CTG abnormalities, the need for multiple second-line tests and the incidence of adverse perinatal outcomes and caesarean section.

Subgroup analysis will be restricted to the review's primary outcomes.

In future updates, we will assess subgroup differences by interaction tests available within RevMan (Review Manager 2020). We will report the results of subgroup analyses quoting the Chi^2 statistic and P value, and the interaction test I^2 value.

Sensitivity analysis

In future updates, we will conduct sensitivity analyses to explore the effect of trial quality on summary effect estimates. We will do this by excluding studies at high risk of bias for concealment of allocation or high attrition rates, or both, to assess if this makes any difference to the overall result. Where we include cluster-RCTs we will carry out sensitivity analysis to investigate the effect of the randomisation unit.

Summary of findings and assessment of the certainty of the evidence

The certainty of the evidence was assessed using the GRADE approach as outlined in the GRADE Handbook in order to assess the certainty of the body of evidence relating to the following outcomes for the main comparisons.

1. Perinatal death.

2. Neurodevelopmental disability assessed at 12 months of age or more[a].
3. Caesarean section – all indications.
4. Neonatal encephalopathy (as defined by authors).
5. Assisted vaginal birth – all indications.
6. Spontaneous vaginal birth.
7. Maternal acceptability of the procedure.

[a]Neurodevelopmental disability, defined as any one or combination of the following: non-ambulant cerebral palsy, developmental delay, auditory and visual impairment. Development should have been assessed using a previously validated tool, such as Bayley Scales of Infant Development (Psychomotor Developmental Index and Mental Developmental Index score < 80) (Bayley 1993).

We used GRADEpro GDT to import data from Review Manager 5 to create summary of findings tables (Review Manager 2020). A summary of the intervention effect and a measure of certainty 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 certainty of the body of evidence for each outcome. The evidence can be downgraded from high certainty by one level for serious (or by two levels for very serious) limitations, depending on assessments for risk of bias, indirectness of evidence, inconsistency, imprecision of effect estimates, or potential publication bias.

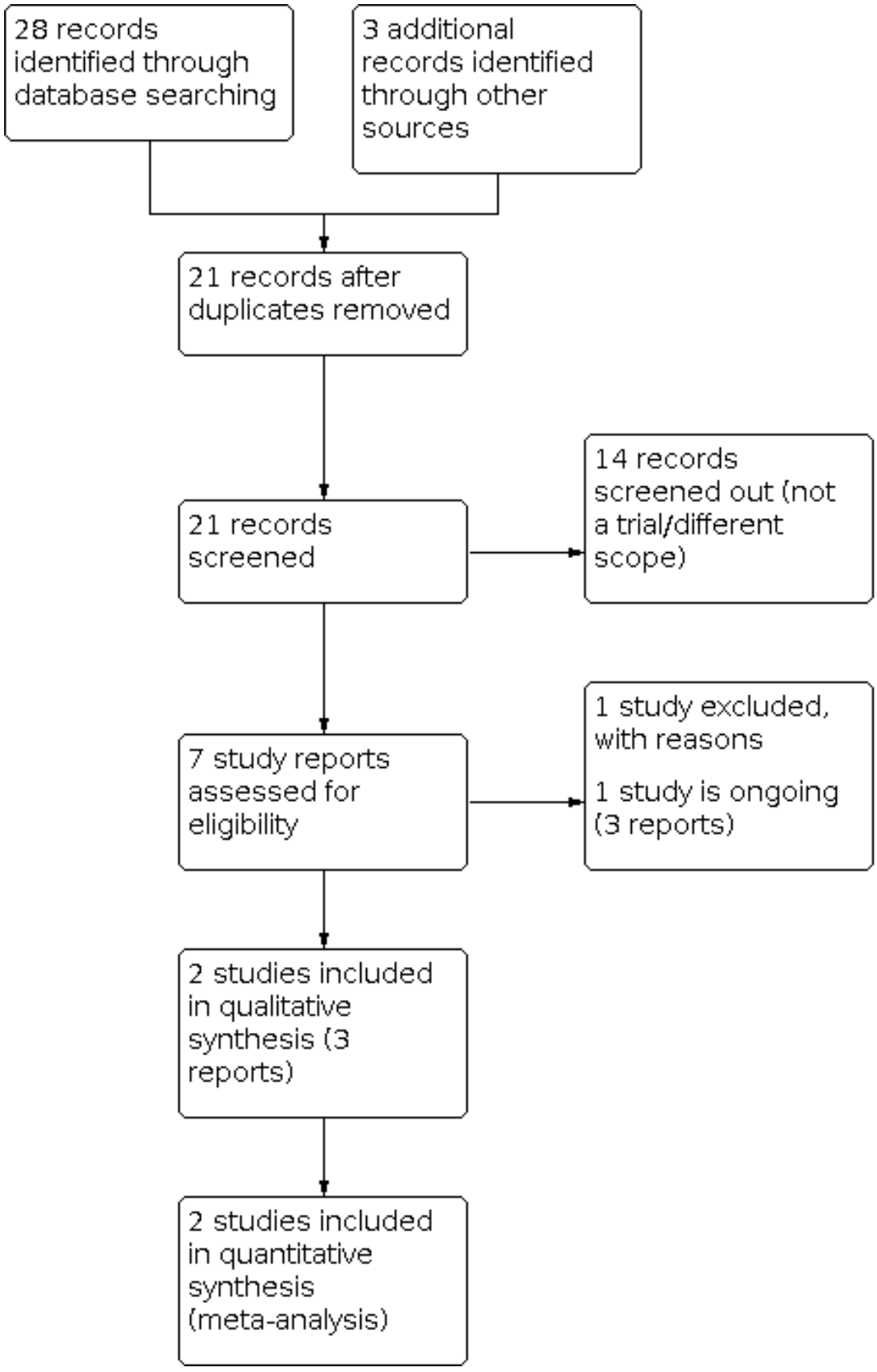
RESULTS

Description of studies

Results of the search

The search strategy initially retrieved four trial reports for consideration in this review. We added three further reports subsequently identified while assessing these four. See Figure 2.

Figure 2. Study flow diagram.



The seven reports that we assessed corresponded to a total of four studies. From these four studies, we included two in the review (three reports), excluded one and the fourth is listed as ongoing (three reports, currently suspended due to Covid-19 pandemic). The study that is listed as ongoing (ISRCTN13295826 suspended during Covid-19 pandemic, due to restart May 2022) is the definitive trial planned to follow the pilot randomised controlled trial (RCT) that has been included in this review (Hughes 2022). For more information see Characteristics of included studies; Characteristics of excluded studies; Characteristics of ongoing studies.

Screening eligible studies for trustworthiness

From the two eligible studies identified from the search we judged that neither failed to meet our criteria for trustworthiness for the following reasons.

- For the pilot trial (Hughes 2022), the author provided the protocol, ethics approval letter, trial registration details (although the pilot study was accounted for within the main trial registration, which was prospectively registered) and confirmed that the published data were final.
- For the second study (Tahmina 2022), the author provided additional unpublished data, confirmation of ethics approval and trial registration and confirmation that the data were analysed in final form.

Included studies

Design and setting

We included two studies in this review. Included studies were conducted between 2014 and 2018. Both studies were two-arm trials. The first study was a pilot RCT that compared digital fetal scalp stimulation (dFSS) and cardiotocography (CTG) with fetal blood sampling (FBS) and CTG (Hughes 2022). The second study was an RCT that compared manual fetal simulation and CTG with CTG alone (no fetal stimulation) (Tahmina 2022). The fetal stimulation was performed either digitally by pinching the fetal scalp (dFSS) or abdominally by grasping and moving the presenting part. The intervention could not be blinded in either study. Both studies were conducted in university-affiliated hospitals. One was conducted in a high-income country (Dublin, Ireland: Hughes 2022) and the other in a lower middle-income country (Pondicherry, India: Tahmina 2022). There were no studies identified that used application of an Allis forceps for fetal scalp stimulation (cFSS).

Dates, sources of funding and conflict of interest of trial authors

Dates of recruitment in the studies were reported as follows: from January to May 2018 (Hughes 2022); from March 2014 to February 2016 (Tahmina 2022). Funding sources were reported in both studies: Trinity College Dublin (Hughes 2022); and the Pondicherry Institute of Medical Sciences (Tahmina 2022).

The trial authors declared no conflicts of interest in either study (Hughes 2022; Tahmina 2022).

Participants

The two included studies recruited women with singleton pregnancies at term (>/= 37 weeks' gestation) with a cephalic presentation and a non-reassuring/abnormal fetal heart rate pattern on CTG. In one study, participation was limited to nulliparous women (Hughes 2022) and the other study included women of any parity (Tahmina 2022). In one study, women were excluded if they had limited English, were aged below 18 years or at the discretion of the obstetrician (Hughes 2022), and in the other study women were excluded if vaginal delivery was precluded, immediate caesarean delivery was required at the time of recruitment, or if intrauterine fetal demise or gross congenital abnormality was diagnosed during the antenatal or neonatal period (Tahmina 2022).

Interventions

The trial in Ireland (Hughes 2022) compared digital fetal scalp stimulation (dFSS) performed during a vaginal examination with the index and middle finger rubbing the fetal scalp over a period of 30 seconds with fetal blood sampling (FBS) for capillary pH. The CTG was observed over a five-minute interval following dFSS. If an FHR acceleration and normal variability were observed, the dFSS test was classified as normal and interpreted in the same way as a normal pH result following FBS. If there was no FHR acceleration and no episode of normal variability, the dFSS was classified as abnormal. If there was normal variability but no acceleration or uncertainty whether the criteria for a normal dFSS had been fully met, the test was classified as borderline and would need to be repeated in 30 minutes as with a borderline FBS pH result.

The trial in India (Tahmina 2022) compared manual fetal stimulation with no fetal stimulation. If the cervical dilatation was less than 3 cm, the fetal head was stimulated by holding it in the palm of one hand abdominally and gently making a side to side movement for 30 seconds. If cervical dilation was 3 cm or more, the fetal stimulation was performed by pinching the scalp vaginally for 10 seconds. If an acceleration was seen on the CTG over the following 20 minutes, then routine monitoring continued. If the non-reassuring fetal heart rate recurred, the manual stimulation could be repeated once more. If an acceleration was not observed, the decision for operative delivery or caesarean delivery should be made according to the institution protocol.

Excluded studies

We excluded one study (CTRI/2009/091/000030) because the method of fetal monitoring was by intermittent auscultation (IA) and there was no use of CTG (see Characteristics of excluded studies).

Risk of bias in included studies

See Figure 3 and Figure 4 for a summary of our risk of bias assessments.

Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

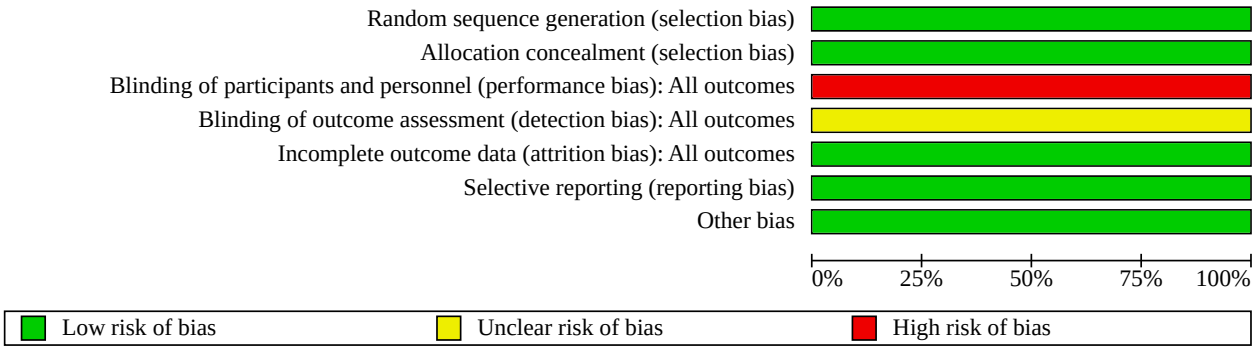
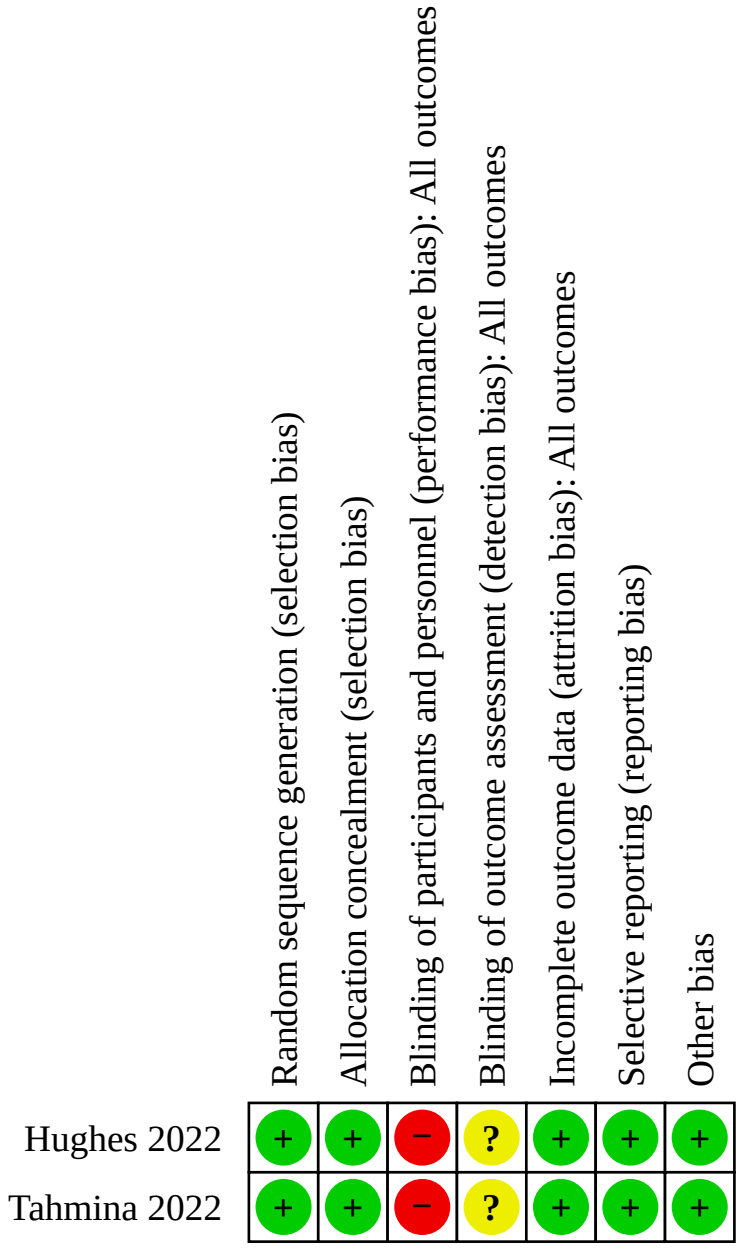


Figure 4. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.



Allocation

We judged both of the included studies (Hughes 2022; Tahmina 2022) to be at low risk of bias for random sequence generation and for the method of allocation concealment.

Blinding

Performance bias

By virtue of the type of intervention (digital fetal scalp stimulation, manual fetal stimulation), it was not possible to blind participants or personnel to the treatment allocation and both studies have been assessed to be at high risk of performance bias (Hughes 2022; Tahmina 2022).

Detection bias

Blinding of outcome assessment was not described in either study and while most outcomes (such as mode of delivery) are objective measures, we assessed the risk of detection bias to be unclear.

Incomplete outcome data

Both studies were assessed to be at low risk of attrition bias.

Selective reporting

The authors confirmed that the pilot RCT (Hughes 2022) was registered as part of the planned definitive RCT (ISRCTN13295826) and this was registered prospectively. The Indian study (Tahmina 2022) was registered at the time of conducting the study. All pre-specified outcomes were reported by both studies. We assessed both studies to be at low risk of reporting bias.

Other potential sources of bias

The lead author for the pilot RCT (Hughes 2022) is also the lead author for this review. The assessment for inclusion and data extraction for this study was completed independently by two other review authors (Declan Devane (DD) and Yulia Shahabuddin (YS)) who had no part in the conduct of the study.There were no other potential sources of bias identified for the second study (Tahmina 2022).

Effects of interventions

See: **Summary of findings 1** Summary of findings; **Summary of findings 2** Summary of findings

Fetal scalp stimulation and CTG compared to fetal blood sampling and CTG

See Summary of findings 1.

Only one study involving 50 women (Hughes 2022) was included for this comparison therefore meta-analysis was not possible.

Primary outcomes

Perinatal death

There was one pilot trial (involving 50 women) that compared digital fetal scalp stimulation and CTG with fetal blood sampling (for capillary pH) and CTG. There were no perinatal deaths but given the sample size it is unclear whether fetal scalp stimulation has any effect on perinatal death (Analysis 1.1).

Neurodevelopmental disability at >/= 12 months

The study (involving 50 women) provided no data for this outcome therefore, it is unclear whether fetal scalp stimulation compared with fetal blood sampling has any effect on neurodevelopmental disability at >/= 12 months (Analysis 1.2).

Caesarean section (all indications)

The study (involving 50 women) reported on caesarean section (all indications) as an outcome. Fetal scalp stimulation and CTG may reduce the risk of caesarean section (all indications) compared to fetal blood sampling and CTG (risk ratio (RR) 0.38, 95% confidence interval (CI) 0.16 to 0.92; very low-certainty evidence; Summary of findings 1; Analysis 1.3), although the evidence is very uncertain. Subgroup analysis based on parity was planned but was not relevant as the pilot trial included only nulliparous women. Sensitivity analysis exploring the effect of bias risk was not relevant as there was only one eligible study.

Secondary outcomes

Fetal acidosis cord arterial pH < 7.00

The study (involving 50 women) reported on fetal acidosis as an outcome, however, the cut-off used was pH < 7.10 and there was only one event reported. Therefore, it is unclear whether fetal scalp stimulation has any effect on the occurrence of cord arterial pH < 7.00.

Apgar score less than seven at five minutes

The study (involving 50 women) reported on Apgar score less than seven at five minutes as an outcome. There was only one event in the fetal scalp stimulation group (RR 3.00, 95% CI 0.13 to 70.30; very low-certainty evidence; Analysis 1.8).

Neonatal encephalopathy

The study (involving 50 women) reported on neonatal encephalopathy as an outcome. There were no events therefore, it is unclear whether fetal scalp stimulation compared with fetal blood sampling has any effect on the occurrence of neonatal encephalopathy (Analysis 1.4).

Procedure-related fetal injury/complication

Procedure-related fetal injury or complication was not reported as a specific outcome in the pilot study.

Assisted vaginal birth - all indications

The study (involving 50 women) reported on assisted vaginal birth (AVB; all indications) as an outcome. On comparing assisted vaginal births, fetal scalp stimulation and CTG may have little or no effect on AVB compared to fetal blood sampling and CTG, although the evidence is very uncertain (RR 1.44, 95% CI 0.76 to 2.75; very low-certainty evidence; Summary of findings 1; Analysis 1.5).

Spontaneous vaginal birth

The study (involving 50 women) reported on spontaneous vaginal birth as an outcome. Fetal scalp stimulation and CTG may make little or no difference to spontaneous vaginal birth compared to fetal blood sampling and CTG, although the evidence is very uncertain (RR 2.33, 95% CI.68 to 8.01; very low-certainty evidence; Summary of findings 1; Analysis 1.6).

Maternal acceptability of procedure

The study (involving 50 women) did not report on maternal acceptability of the procedures as an outcome. It is unclear whether fetal scalp stimulation compared with fetal blood sampling has any effect on maternal acceptability of the procedure.

Fetal scalp stimulation and CTG compared to CTG alone

See Summary of findings 2.

There was one study (involving 327 women) that compared fetal scalp stimulation and CTG with CTG alone (Tahmina 2022). A proportion of women (92/164; 56%) received abdominal fetal stimulation and the remainder (72/164; 44%) received fetal scalp stimulation vaginally. As there was only one study for this comparison, meta-analysis was not possible.

Primary outcomes

Perinatal death

There were no perinatal deaths and given the sample size, it is unclear whether fetal scalp stimulation and CTG compared to CTG alone has any effect on perinatal death (Analysis 2.1).

Neurodevelopmental disability at >/= 12 months

The study (involving 327 women) did not report on this outcome therefore, it is unclear whether fetal scalp stimulation (as part of manual fetal stimulation) has any effect on neurodevelopmental disability at >/= 12 months (Analysis 2.2).

Caesarean section (all indications)

The study (involving 327 women) reported on caesarean section (all indications) as an outcome. Fetal scalp stimulation (as part of manual fetal stimulation) and CTG may make little or no difference to the risk of caesarean section (all indications) compared to CTG alone, although the evidence is very uncertain (RR 0.83, 95% CI 0.59 to 1.18; very low-certainty evidence; Summary of findings 2; Analysis 2.3).

Secondary outcomes

Fetal acidosis cord arterial pH < 7.00

Fetal acidosis defined as pH < 7.00 was not reported as a specific outcome in the study.

Apgar score less than seven at five minutes

Apgar score less than seven at five minutes was not reported as a specific outcome in the study.

Neonatal encephalopathy

The study (involving 327 women) reported on neonatal encephalopathy as an outcome. There were no events therefore, it is unclear whether fetal scalp stimulation and CTG compared with CTG alone has any effect on the occurrence of neonatal encephalopathy (Analysis 2.4).

Procedure-related fetal injury/complication

Procedure-related fetal injury or complication was not reported as a specific outcome in the study.

Assisted vaginal birth - all indications

The study (involving 327 women) reported on assisted vaginal birth (AVB; all indications) as an outcome. On comparing assisted vaginal births, fetal scalp stimulation and CTG had little effect on AVB compared to CTG alone, although the evidence is very uncertain (RR 1.43, 95% CI 0.78 to 2.60; very low-certainty evidence; Summary of findings 2; Analysis 2.5).

Spontaneous vaginal birth

The study (involving 327 women) reported on spontaneous vaginal birth as an outcome. Fetal scalp stimulation and CTG may make little or no difference to spontaneous vaginal birth compared to CTG alone, although the evidence is very uncertain (RR 1.01, 95% CI 0.85 to 1.21; very low-certainty evidence; Summary of findings 2; Analysis 2.6).

Maternal acceptability of procedure

The study (involving 327 women) did not report on maternal acceptability of the procedures as an outcome although 13 women withdrew consent after randomisation due to concerns about fetal well-being. It is unclear whether fetal scalp stimulation and CTG compared with CTG alone has any effect on maternal acceptability of the procedure.

The study (involving 327 women) reported most secondary outcomes as summary statistics of mean values and standard deviations. It was not possible to analyse these data although additional data were provided by the author on mode of delivery.

DISCUSSION

Summary of main results

We identified two studies including a total of 377 women; a pilot study in Ireland of 50 women that compared digital fetal scalp stimulation and cardiotocography (CTG) with fetal blood sampling and CTG, and a study in India of 327 women that compared manual fetal stimulation (abdominal or vaginal scalp stimulation) and CTG with CTG alone.

Fetal scalp stimulation and CTG compared with fetal blood sampling and CTG may lower the risk of caesarean section among women with an abnormal CTG, but the evidence is very uncertain. The effect on important primary outcomes including perinatal death and neurodevelopmental disability at >/= 12 months is either unclear or unknown. There were no perinatal death events and neurodevelopmental disability was not reported. The effect on secondary outcomes such as neonatal encephalopathy, assisted vaginal birth, spontaneous vaginal birth, and fetal acidosis is unclear due to very low-certainty evidence. Procedure-related complications and maternal acceptability of the procedures were not reported.

Fetal scalp stimulation and CTG compared with CTG alone may have little or no effect on the risk of caesarean section, but the evidence is very uncertain. The effect on perinatal mortality is unclear as there were no events. Neurodevelopmental disability at >/= 12 months was not reported. The effect on neonatal encephalopathy, assisted vaginal birth, and spontaneous vaginal birth is unclear due to very low-certainty evidence. Procedure-related complications and maternal acceptability of fetal scalp stimulation were not reported.

Overall completeness and applicability of evidence

We identified two small studies conducted within the last decade, one from a high-income country and one from a lower middle-income country. The method of fetal scalp stimulation varied. In the Irish study, the fetal scalp was rubbed digitally with two fingers introduced through the cervix at a vaginal examination. In the Indian study, fetal stimulation was performed abdominally by side to side movement of the fetal head if the cervix was < 3 cm dilated and by pinching of the fetal scalp at vaginal examination if the cervix was at least 3 cm dilated. The findings overall were too limited to be applied to routine clinical practice. There were no studies evaluating the use of the Allis forceps as a means of fetal scalp stimulation.

Certainty of the evidence

The studies contributing to the review had both low and high-risk of bias assessments. Both studies were judged to be at a low risk of selection bias, attrition bias and other bias. Both studies were at a high risk of performance bias as neither study blinded participants or health professionals, albeit difficult to do so. Detection bias was also unclear for both studies although the outcome measures were objective. Both studies were considered to be at low risk for reporting bias.

Using the GRADE approach for appraisal of the certainty of the evidence, our confidence in the effect estimates of this review for the GRADE outcomes is very low. The evidence certainty was downgraded due to serious limitations in study design (lack of blinding of participants and personnel, and unclear assessor blinding) and due to very serious imprecision (small sample size, lack of events and wide confidence intervals, mostly including the line of no effect). See Effects of interventions and Summary of findings 1 and Summary of findings 2.

Potential biases in the review process

We minimised potential bias by the use of a comprehensive search strategy. Two review authors independently assessed eligibility and certainty of the evidence, and performed data extraction. The pilot trial (Hughes 2022) was co-authored by one of the Cochrane Review authors (Deirdre J Murphy (DJM)). Two independent review authors (Declan Devane (DD) and Yulia Shahabuddin (YS)) assessed this study for eligibility and bias, for trustworthiness, and completed the data extraction.

Agreements and disagreements with other studies or reviews

This is the first Cochrane Review addressing this topic.

AUTHORS' CONCLUSIONS

Implications for practice

There is very low-certainty evidence currently in relation to fetal scalp stimulation as an approach for assessing fetal well-being in labour. The effect and safety of fetal scalp stimulation as a means to reduce unnecessary intervention in labour is unclear. The review findings are currently insufficient to inform clinical practice.

Implications for research

Further well-designed randomised controlled trials are required to establish whether fetal scalp stimulation has a role to play in assessing fetal well-being in labour. In order to be generalisable, these trials should be conducted in different settings, including broad clinical criteria, and at both preterm and term gestational ages. Although it is difficult to blind participants and health professionals in relation to the intervention(s), outcome assessment should be blinded where possible. Standard operating procedures should be designed to ensure that the intervention(s) are conducted in a consistent manner. The use of Allis forceps is unlikely to warrant future research as it is invasive and potentially traumatic to the fetus. There is an ongoing study (FIRSST) that will be incorporated into this review in a subsequent update. Two new independent authors will be recruited for a future update of this review as several of the current review authors are involved in the ongoing trial.

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Tahmina 2022 *{published data only (unpublished sought but not used)}* **100574**

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

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

Hughes 2022

Study characteristics	
Methods	Parallel-group RCT (pilot prior to definitive RCT).
Participants	**Setting:** university-affiliated maternity hospital, Republic of Ireland.

Hughes 2022 *(Continued)*

	Dates of recruitment: from January to May 2018. **Total randomised:** 50 women in labour with an abnormal CTG requiring a second-line test of fetal well-being; 25 to dFSS and CTG and 25 to FBS and CTG. **Inclusion criteria:** women aged 18 years or older, nulliparous, at term (>/= 37+0 weeks), singleton pregnancy, cephalic presentation, capable of informed consent. **Exclusion criteria:** contraindication to FBS, limited English, and at the discretion of the obstetrician where there was urgency due to suspected fetal compromise.
Interventions	**Experimental intervention:** dFSS and CTG. dFSS was performed using the index and middle finger to rub the fetal scalp over 20 to 30 seconds. The CTG was observed over a 5-minute interval following this to detect an FHR acceleration and normal variability (5 to 25 bpm). The test is classified as normal if there is an acceleration and normal variability. The test is classified as borderline if there is normal variability but no acceleration or uncertainty whether the criteria for normal have been met. The test is classified as abnormal if there is no acceleration and no episode of normal variability. The test result should be interpreted in the same way as FBS; normal - review after 1 hour; borderline - repeat after 30 minutes (or perform FBS); abnormal either deliver (or perform FBS). **Comparison intervention:** FBS and CTG. Fetal capillary blood samples were taken and analysed for pH. The result of the first technically reliable sample was interpreted and acted upon according to the local protocol; normal (pH >/= 7.25); borderline (pH 7.21 to 7.24); abnormal (pH </= 7.20). Allocated approach taken for each subsequent second-line test in labour.
Outcomes	Mode of delivery, fetal acidosis pH artery < 7.10, Apgar score < 7 at 5 minutes, admission to neonatal unit, neonatal encephalopathy, perinatal mortality, number of second-line tests in labour, failed procedures, procedure-related fetal injury or complication.
Notes	**Funding:** Trinity College, University of Dublin, Ireland. **CoI:** the authors declared no conflicts of interest. DJ Murphy is the only member of the Cochrane Review who was involved in the pilot RCT. Completed in advance of FIRSST study which is due to commence in May 2022 (ClinicalTrials.gov NCT05306756).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation in a 1:1 ratio.
Allocation concealment (selection bias)	Low risk	Allocation was concealed using opaque sealed envelopes.
Blinding of participants and personnel (performance bias) All outcomes	High risk	It was not possible to blind the participants or the clinical staff to the intervention.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not specified whether outcome assessor was blinded but primary and secondary outcome measures are objective and unlikely to be at risk of detection bias.

Hughes 2022 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	1 consented participant was randomised in error (to FBS) but a second-line test was not required.
Selective reporting (reporting bias)	Low risk	All outcomes reported as per protocol (provided by author). Pilot trial was registered as part of the ongoing definitive trial (ISRCTN13295826 which was registered prospectively).
Other bias	Low risk	The Cochrane Review lead author is the Principal Investigator for this pilot trial and took no part in the decision on eligibility for inclusion or data extraction. Two independent review authors (Declan Devane and Yulia Shahabuddin) completed all assessments for this study.

Tahmina 2022

Study characteristics	
Methods	Parallel-group RCT.
Participants	**Setting:** Institute of Medical Sciences, Pondicherry, India. **Dates of recruitment:** start March 2014, end February 2016. **Total randomised:** 345 women in labour monitored with cardiotocography who record CTG abnormalities; 172 to fetal stimulation and CTG and 173 to CTG only. **Inclusion criteria:** women with singleton pregnancy > 37 weeks' gestation, cephalic presentation with non-reassuring FHR patterns (FHR < 110 bpm; FHR > 160 bpm; variable decelerations, late decelerations, minimal or absent beat to beat variability) who give informed consent. **Exclusion criteria:** women in whom vaginal delivery is precluded; intrauterine fetal demise or gross congenital anomaly diagnosed during antenatal or neonatal period; women with an indication for immediate caesarean delivery at the time of recruitment.
Interventions	**Experimental intervention:** manual fetal stimulation (abdominal or vaginal) and CTG. If cervical dilatation < 3 cm, the fetal head is stimulated by holding it in the palm of 1 hand abdominally and gently moving side to side for 30 seconds. If cervical dilatation is > 3 cm, fetal stimulation is performed by pinching the fetal scalp vaginally for 10 seconds. If an acceleration is seen over the next 20 minutes, then routine monitoring with 2-hourly review of the CTG. Manual stimulation can be repeated 1 more time. If acceleration is not observed, decision for instrumental delivery or caesarean delivery according to institutional protocol. **Control/comparison intervention:** CTG only. Decisions as per institutional protocol.
Outcomes	Mode of delivery, cord blood pH at birth (continuous), Apgar scores at 1 and 5 minutes (continuous), NICU admissions and duration of stay (continuous).
Notes	**Funding:** Pondicherry Institute of Medical Sciences, India. **CoI:** none reported.
Risk of bias	

Tahmina 2022 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation.
Allocation concealment (selection bias)	Low risk	Sequentially numbered, sealed, opaque envelopes.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind participants or personnel.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcomes are objective, irrespective of allocation but blinding of outcome assessment not stated; probably not blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	5 participants allocated to Group 1 (fetal stimulation and CTG) and 8 allocated to Group 2 (CTG alone) did not receive the allocated intervention due to withdrawal of consent, citing concerns for fetal well-being. 4 participants were excluded from the analysis (3 from Group 1 and 1 from Group 2) as they needed an emergency caesarean section. 1 additional participant was excluded from Group 2 as a gross congenital anomaly was detected in the immediate neonatal period. Data were analysed for the remaining 327 women.
Selective reporting (reporting bias)	Low risk	Trial registered prospectively.
Other bias	Low risk	None identified.

bpm: beats per minute; CoI: conflict of interest; CTG: cardiotocography; dFSS: digital fetal scalp stimulation; FBS: fetal blood sampling; FHR: fetal heart rate; NICU: neonatal intensive care unit; RCT: randomised controlled trial.

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

Study	Reason for exclusion
CTRI/2009/091/000030	Cardiotocography not used, intermittent auscultation only. Only observational study completed, trial not commenced. Confirmed by author who was contacted.

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

ISRCTN13295826

Study name	FIRSST Fetal scalp stimulation (FSS) versus fetal blood sampling (FBS) to assess fetal well-being in labour - a multicentre randomised controlled trial.
Methods	Parallel-group RCT.

ISRCTN13295826 *(Continued)*

Participants	Women in labour at term (>/= 37+0 weeks), nulliparous, with singleton pregnancy, cephalic presentation, with abnormal CTG requiring second-line test of fetal well-being.
Interventions	dFSS and CTG versus FBS and CTG.
Outcomes	Mode of delivery, cord pH, Apgar scores, admission to NNU.
Starting date	Suspended in 2019 - re-registered as NCT05306756 due to start May 2022.
Contact information	murphyd4@tcd.ie
Notes	Trial suspended during Covid-19 pandemic, due to restart May 2022.

CTG: cardiotocography; dFSS: digital fetal scalp stimulation; FBS: fetal blood sampling; NNU: neonatal unit; RCT: randomised controlled trial.

DATA AND ANALYSES

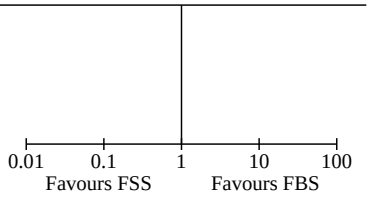
Comparison 1. CTG and FSS (all methods) versus CTG and FBS (pH only)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 Perinatal death	1	50	Risk Ratio (M-H, Random, 95% CI)	Not estimable
1.2 Neurodevelopmental disability at >/= 12 months	1	50	Risk Ratio (M-H, Random, 95% CI)	Not estimable
1.3 Caesarean section (all indications)	1	50	Risk Ratio (M-H, Random, 95% CI)	0.38 [0.16, 0.92]
1.4 Neonatal encephalopathy	1	50	Risk Ratio (M-H, Random, 95% CI)	Not estimable
1.5 Assisted vaginal birth (all indications)	1	50	Risk Ratio (M-H, Random, 95% CI)	1.44 [0.76, 2.75]
1.6 Spontaneous vaginal birth	1	50	Risk Ratio (M-H, Random, 95% CI)	2.33 [0.68, 8.01]
1.7 Maternal acceptability of procedure	1	50	Risk Ratio (M-H, Random, 95% CI)	Not estimable
1.8 Apgar < 7 at 5 minutes	1	50	Risk Ratio (M-H, Random, 95% CI)	3.00 [0.13, 70.30]
1.9 Procedure (dFSS or FBS)-related fetal injury	1	275	Odds Ratio (M-H, Random, 95% CI)	Not estimable

Analysis 1.1. Comparison 1: CTG and FSS (all methods) versus CTG and FBS (pH only), Outcome 1: Perinatal death

Study or Subgroup	FSS Events	FSS Total	FBS Events	FBS Total	Weight	Risk Ratio M-H, Random, 95% CI
Hughes 2022	0	25	0	25		Not estimable
Total (95% CI)		**25**		**25**		**Not estimable**
Total events:	0		0			

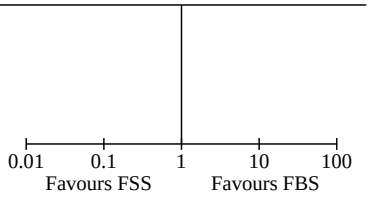
Heterogeneity: Not applicable
Test for overall effect: Not applicable
Test for subgroup differences: Not applicable



Analysis 1.2. Comparison 1: CTG and FSS (all methods) versus CTG and FBS (pH only), Outcome 2: Neurodevelopmental disability at >/= 12 months

Study or Subgroup	FSS Events	FSS Total	FBS Events	FBS Total	Weight	Risk Ratio M-H, Random, 95% CI
Hughes 2022	0	25	0	25		Not estimable
Total (95% CI)		**25**		**25**		**Not estimable**
Total events:	0		0			

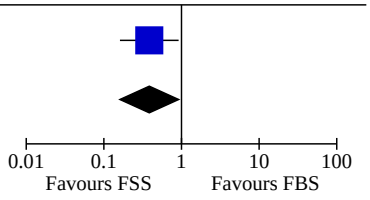
Heterogeneity: Not applicable
Test for overall effect: Not applicable
Test for subgroup differences: Not applicable



Analysis 1.3. Comparison 1: CTG and FSS (all methods) versus CTG and FBS (pH only), Outcome 3: Caesarean section (all indications)

Study or Subgroup	FSS Events	FSS Total	FBS Events	FBS Total	Weight	Risk Ratio M-H, Random, 95% CI
Hughes 2022	5	25	13	25	100.0%	0.38 [0.16 , 0.92]
Total (95% CI)		**25**		**25**	**100.0%**	**0.38 [0.16 , 0.92]**
Total events:	5		13			

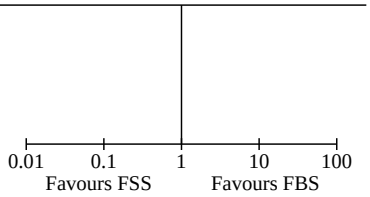
Heterogeneity: Not applicable
Test for overall effect: Z = 2.15 (P = 0.03)
Test for subgroup differences: Not applicable



Analysis 1.4. Comparison 1: CTG and FSS (all methods) versus CTG and FBS (pH only), Outcome 4: Neonatal encephalopathy

Study or Subgroup	FSS Events	FSS Total	FBS Events	FBS Total	Weight	Risk Ratio M-H, Random, 95% CI
Hughes 2022	0	25	0	25		Not estimable
Total (95% CI)		**25**		**25**		**Not estimable**
Total events:	0		0			

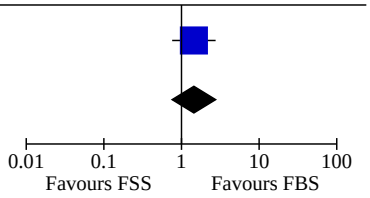
Heterogeneity: Not applicable
Test for overall effect: Not applicable
Test for subgroup differences: Not applicable



Analysis 1.5. Comparison 1: CTG and FSS (all methods) versus CTG and FBS (pH only), Outcome 5: Assisted vaginal birth (all indications)

Study or Subgroup	FSS Events	FSS Total	FBS Events	FBS Total	Weight	Risk Ratio M-H, Random, 95% CI
Hughes 2022	13	25	9	25	100.0%	1.44 [0.76 , 2.75]
Total (95% CI)		**25**		**25**	**100.0%**	**1.44 [0.76 , 2.75]**
Total events:	13		9			

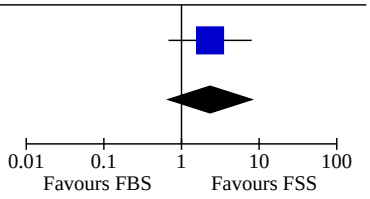
Heterogeneity: Not applicable
Test for overall effect: Z = 1.12 (P = 0.26)
Test for subgroup differences: Not applicable



Analysis 1.6. Comparison 1: CTG and FSS (all methods) versus CTG and FBS (pH only), Outcome 6: Spontaneous vaginal birth

Study or Subgroup	FSS Events	FSS Total	FBS Events	FBS Total	Weight	Risk Ratio M-H, Random, 95% CI
Hughes 2022	7	25	3	25	100.0%	2.33 [0.68 , 8.01]
Total (95% CI)		**25**		**25**	**100.0%**	**2.33 [0.68 , 8.01]**
Total events:	7		3			

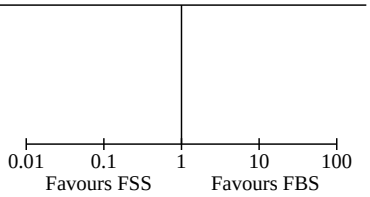
Heterogeneity: Not applicable
Test for overall effect: Z = 1.35 (P = 0.18)
Test for subgroup differences: Not applicable



Analysis 1.7. Comparison 1: CTG and FSS (all methods) versus CTG and FBS (pH only), Outcome 7: Maternal acceptability of procedure

Study or Subgroup	FSS Events	FSS Total	FBS Events	FBS Total	Weight	Risk Ratio M-H, Random, 95% CI
Hughes 2022	0	25	0	25		Not estimable
Total (95% CI)		**25**		**25**		**Not estimable**
Total events:	0		0			

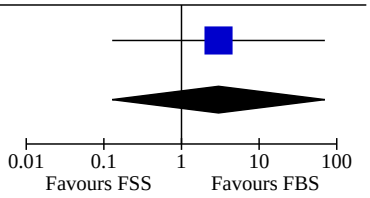
Heterogeneity: Not applicable
Test for overall effect: Not applicable
Test for subgroup differences: Not applicable



Analysis 1.8. Comparison 1: CTG and FSS (all methods) versus CTG and FBS (pH only), Outcome 8: Apgar < 7 at 5 minutes

Study or Subgroup	FSS Events	FSS Total	FBS Events	FBS Total	Weight	Risk Ratio M-H, Random, 95% CI
Hughes 2022	1	25	0	25	100.0%	3.00 [0.13 , 70.30]
Total (95% CI)		**25**		**25**	**100.0%**	**3.00 [0.13 , 70.30]**
Total events:	1		0			

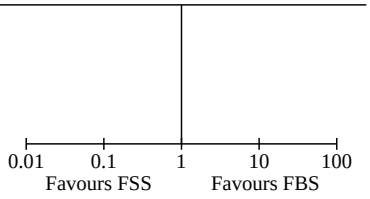
Heterogeneity: Not applicable
Test for overall effect: Z = 0.68 (P = 0.49)
Test for subgroup differences: Not applicable



Analysis 1.9. Comparison 1: CTG and FSS (all methods) versus CTG and FBS (pH only), Outcome 9: Procedure (dFSS or FBS)-related fetal injury

Study or Subgroup	FSS Events	FSS Total	FBS Events	FBS Total	Weight	Odds Ratio M-H, Random, 95% CI
Hughes 2022	0	250	0	25		Not estimable
Total (95% CI)		**250**		**25**		**Not estimable**
Total events:	0		0			

Heterogeneity: Not applicable
Test for overall effect: Not applicable
Test for subgroup differences: Not applicable



Comparison 2. CTG and FSS (all methods) versus CTG only

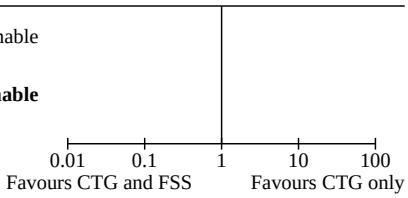
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.1 Perinatal death	1	327	Risk Ratio (M-H, Random, 95% CI)	Not estimable
2.2 Neurodevelopmental disability at >/= 12 months	1	327	Risk Ratio (M-H, Random, 95% CI)	Not estimable

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.3 Caesarean section (all indications)	1	327	Risk Ratio (M-H, Random, 95% CI)	0.83 [0.59, 1.18]
2.4 Neonatal encephalopathy	1	327	Risk Ratio (M-H, Random, 95% CI)	Not estimable
2.5 Assisted vaginal birth (all indications)	1	327	Risk Ratio (M-H, Random, 95% CI)	1.43 [0.78, 2.60]
2.6 Spontaneous vaginal birth	1	327	Risk Ratio (M-H, Random, 95% CI)	1.01 [0.85, 1.21]
2.7 Maternal acceptability of procedure	1	327	Risk Ratio (M-H, Random, 95% CI)	Not estimable
2.8 Procedure (FSS)-related fetal injury	1	327	Risk Difference (M-H, Random, 95% CI)	0.00 [-0.01, 0.01]

Analysis 2.1. Comparison 2: CTG and FSS (all methods) versus CTG only, Outcome 1: Perinatal death

Study or Subgroup	CTG and FSS Events	CTG and FSS Total	CTG only Events	CTG only Total	Weight	Risk Ratio M-H, Random, 95% CI
Tahmina 2022	0	164	0	163		Not estimable
Total (95% CI)		**164**		**163**		**Not estimable**
Total events:	0		0			

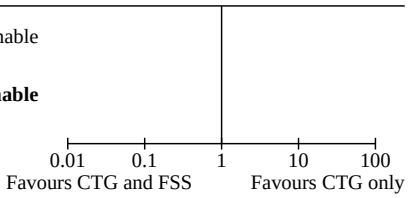
Heterogeneity: Not applicable
Test for overall effect: Not applicable
Test for subgroup differences: Not applicable



Analysis 2.2. Comparison 2: CTG and FSS (all methods) versus CTG only, Outcome 2: Neurodevelopmental disability at >/= 12 months

Study or Subgroup	CTG and FSS Events	CTG and FSS Total	CTG only Events	CTG only Total	Weight	Risk Ratio M-H, Random, 95% CI
Tahmina 2022	0	164	0	163		Not estimable
Total (95% CI)		**164**		**163**		**Not estimable**
Total events:	0		0			

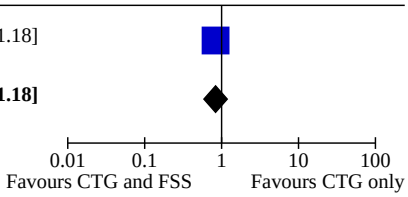
Heterogeneity: Not applicable
Test for overall effect: Not applicable
Test for subgroup differences: Not applicable



Analysis 2.3. Comparison 2: CTG and FSS (all methods) versus CTG only, Outcome 3: Caesarean section (all indications)

Study or Subgroup	CTG and FSS Events	CTG and FSS Total	CTG only Events	CTG only Total	Weight	Risk Ratio M-H, Random, 95% CI
Tahmina 2022	42	164	50	163	100.0%	0.83 [0.59 , 1.18]
Total (95% CI)		**164**		**163**	**100.0%**	**0.83 [0.59 , 1.18]**
Total events:	42		50			

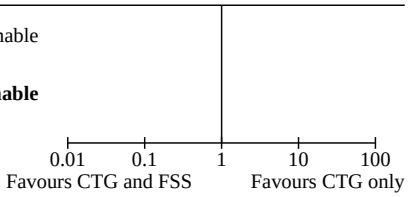
Heterogeneity: Not applicable
Test for overall effect: Z = 1.02 (P = 0.31)
Test for subgroup differences: Not applicable



Analysis 2.4. Comparison 2: CTG and FSS (all methods) versus CTG only, Outcome 4: Neonatal encephalopathy

Study or Subgroup	CTG and FSS Events	CTG and FSS Total	CTG only Events	CTG only Total	Weight	Risk Ratio M-H, Random, 95% CI
Tahmina 2022	0	164	0	163		Not estimable
Total (95% CI)		**164**		**163**		**Not estimable**
Total events:	0		0			

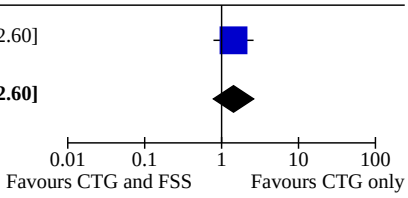
Heterogeneity: Not applicable
Test for overall effect: Not applicable
Test for subgroup differences: Not applicable



Analysis 2.5. Comparison 2: CTG and FSS (all methods) versus CTG only, Outcome 5: Assisted vaginal birth (all indications)

Study or Subgroup	CTG and FSS Events	CTG and FSS Total	CTG only Events	CTG only Total	Weight	Risk Ratio M-H, Random, 95% CI
Tahmina 2022	23	164	16	163	100.0%	1.43 [0.78 , 2.60]
Total (95% CI)		**164**		**163**	**100.0%**	**1.43 [0.78 , 2.60]**
Total events:	23		16			

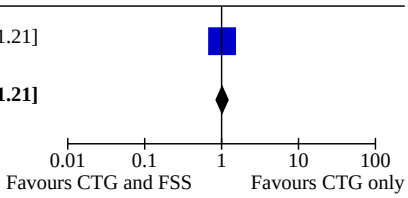
Heterogeneity: Not applicable
Test for overall effect: Z = 1.17 (P = 0.24)
Test for subgroup differences: Not applicable



Analysis 2.6. Comparison 2: CTG and FSS (all methods) versus CTG only, Outcome 6: Spontaneous vaginal birth

Study or Subgroup	CTG and FSS Events	CTG and FSS Total	CTG only Events	CTG only Total	Weight	Risk Ratio M-H, Random, 95% CI
Tahmina 2022	99	164	97	163	100.0%	1.01 [0.85 , 1.21]
Total (95% CI)		**164**		**163**	**100.0%**	**1.01 [0.85 , 1.21]**
Total events:	99		97			

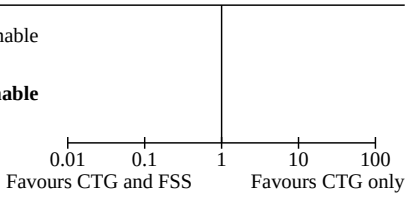
Heterogeneity: Not applicable
Test for overall effect: Z = 0.16 (P = 0.87)
Test for subgroup differences: Not applicable



Analysis 2.7. Comparison 2: CTG and FSS (all methods) versus CTG only, Outcome 7: Maternal acceptability of procedure

Study or Subgroup	CTG and FSS Events	CTG and FSS Total	CTG only Events	CTG only Total	Weight	Risk Ratio M-H, Random, 95% CI
Tahmina 2022	0	164	0	163		Not estimable
Total (95% CI)		**164**		**163**		**Not estimable**
Total events:	0		0			

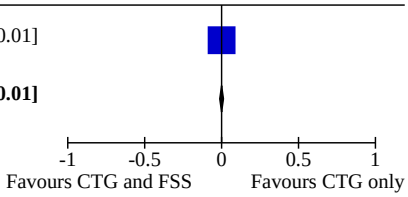
Heterogeneity: Not applicable
Test for overall effect: Not applicable
Test for subgroup differences: Not applicable



Analysis 2.8. Comparison 2: CTG and FSS (all methods) versus CTG only, Outcome 8: Procedure (FSS)-related fetal injury

Study or Subgroup	CTG and FSS Events	CTG and FSS Total	CTG only Events	CTG only Total	Weight	Risk Difference M-H, Random, 95% CI
Tahmina 2022	0	164	0	163	100.0%	0.00 [-0.01 , 0.01]
Total (95% CI)		**164**		**163**	**100.0%**	**0.00 [-0.01 , 0.01]**
Total events:	0		0			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.00 (P = 1.00)
Test for subgroup differences: Not applicable



APPENDICES

Appendix 1. ClinicalTrials.gov - search methods

ClinicalTrials.gov

Advanced search

Interventional studies | scalp | fetal

Interventional studies | fetal | blood sampling

Interventional studies | labor | scalp

Interventional studies | labour | scalp

WHAT'S NEW

Date	Event	Description
13 January 2023	Amended	Author affiliations for Professor Declan Devane have been corrected.

HISTORY

Protocol first published: Issue 12, 2020
Review first published: Issue 1, 2023

CONTRIBUTIONS OF AUTHORS

Two of the authors are obstetricians (Deirdre J Murphy (DJM) and Yulia Shahabuddin (YS)), one has a midwifery and trials methodology background (Declan Devane (DD)), and one is a neonatologist with expertise in neonatal encephalopathy (Eleanor Molloy (EM)). Three of the authors (DJM, YS, DD) participated in assessing studies for inclusion, assessed risk of bias, extracted data and carried out analyses and grade assessment. DJM is an author of one of the included studies and all review tasks relating to this study were carried out by other members of the review team (DD and YS) who were not directly involved in the study. The review text was drafted by DJM and all four review authors revised the draft and contributed to the choice and definition of outcomes, study comparisons, and methodological aspects of the review.

DJM is lead author and guarantor of the review.

DECLARATIONS OF INTEREST

Deirdre J Murphy.

1. Medico-legal expert for cases of cerebral palsy that involve interpretation of cardiotocography monitoring.
2. Chief Investigator on an ongoing study (CTN05306756. Comparing second-line tests in labour to assess fetal well-being (Fetal scalp stimulation (FSS) versus fetal blood sampling (FBS) to assess fetal well-being in labour - a multicentre randomised controlled trial). Funded by Health Research Board, Ireland.

Declan Devane.

1. Principal Investigator for a grant from the Health Research Board (HRB, Ireland) and the Health and Social Care, Research and Development (HSC R&D) Division of the Public Health Agency in Northern Ireland to establish Evidence Synthesis Ireland within which Cochrane Ireland is hosted.
2. Director of Cochrane Ireland and Director of Cochrane Ireland and paid 0.5 FTE (full-time equivalent) from grant in point 1 above.
3. Editor, Cochrane Pregnancy and Childbirth Group.
4. Collaborator on an ongoing study (CTN05306756. Comparing second-line tests in labour to assess fetal well-being (Fetal scalp stimulation (FSS) versus fetal blood sampling (FBS) to assess fetal well-being in labour - a multicentre randomised controlled trial). Funded by Health Research Board, Ireland.

Eleanor Molloy.

1. Associate Editor-in-Chief of the journal *Pediatric Research*.
2. Eleanor has received reimbursement of expenses relating to travel to the European and US paediatric research societies on behalf of the journal.
3. Eleanor holds fellowship and project awards in neonatology from the National Children's Research Centre, Ireland and Health Research Board, Ireland.

Yulia Shahabuddin: none known.

SOURCES OF SUPPORT

Internal sources

- No sources of support provided

External sources

- No sources of support provided

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Any differences between our published protocol (Murphy 2020) and the full review are listed below.

- We have added the Cochrane Pregnancy and Childbirth Trustworthiness Screening Tool.

INDEX TERMS

Medical Subject Headings (MeSH)

*Brain Diseases; Fetus; *Labor, Obstetric; Parturition; *Perinatal Death; Scalp

MeSH check words

Female; Humans; Infant, Newborn; Pregnancy