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High feedback versus low feedback of prenatal ultrasound for reducing maternal anxiety and improving maternal health behaviour in pregnancy (Review)

Nabhan AF, Aflaifel N

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[Intervention Review]

High feedback versus low feedback of prenatal ultrasound for reducing maternal anxiety and improving maternal health behaviour in pregnancy

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ABSTRACT

Background

Prenatal ultrasound is one of many techniques used in screening and diagnosis. It gives parents instant access to the images of the fetus. Receiving information promotes knowledge and understanding, but it may also increase maternal anxiety.

Objectives

To compare high feedback versus low feedback during prenatal ultrasound for reducing maternal anxiety and improving maternal health behaviour.

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (12 May 2015), the Central Register of Controlled Trials (*The Cochrane Library* 2015, Issue 5), MEDLINE (January 1966 to 12 May 2015), and the ISRCTN Registry (12 May 2015). We handsearched citation lists of relevant publications. We did not apply any language or date restrictions.

Selection criteria

Randomised controlled trials (RCTs) of high feedback (women can see the monitor screen and receive detailed visual and verbal explanations) versus low feedback (women can not see the monitor screen and women are given only a summary statement of the scan) during prenatal ultrasound. The primary outcome measure was maternal state anxiety.

Data collection and analysis

Two review authors independently assessed trials for inclusion and risk of bias, extracted data and checked for accuracy. We have expressed results as risk ratio (RR) or mean differences (MD), together with their 95% confidence intervals (CI).

Main results

We included four studies (365 women). Three RCTs (346 participants) reported the effect of high versus low feedback during ultrasound on state anxiety scores (mean difference (MD) 0.92, 95% confidence interval (CI) -0.58 to 2.43; participants = 346; three studies, *low quality evidence*). Two trials (148 participants) reported women's views of the level of feedback. They do not show that women in the high feedback groups are more likely to choose very positive adjectives to describe their feelings after the scan (risk ratio (RR) 3.30; 95% CI 0.73 to 14.85).

Women who had a high feedback during ultrasound were more likely to stop smoking during pregnancy (RR 2.93, 95% CI 1.25 to 6.86; participants = 129; one study; *low quality evidence*) and to avoid alcohol during pregnancy (RR 2.96, 95% CI 1.15 to 7.60; participants = 129; one study; *low quality evidence*). Downgrading of evidence was based on the unclear risk of bias of included studies, wide CI crossing the line of no effect or presence of heterogeneity.

Authors' conclusions

There is insufficient evidence to support either high or low feedback during a prenatal ultrasound to reduce maternal anxiety and promote health behaviour.

PLAIN LANGUAGE SUMMARY

Effect of high feedback versus low feedback of prenatal ultrasound on maternal anxiety and health behaviour in pregnancy

Ultrasound is a routine part of prenatal care offered to pregnant women in most countries with developed health services. It is used during prenatal care to help achieve a healthy mother and child. Pregnant women want reassurance and to check that all is normal by verifying fetal life and growth and to exclude fetal abnormalities. The parents are given immediate access to the images of the fetus, which may promote maternal attachment and positive attitudes toward health during the pregnancy. The obstetricians can identify high-risk conditions including multiple pregnancy, abnormalities of amniotic fluid volume and the placenta, fetal anomalies and growth restriction. During high-feedback ultrasound scans, women can see the screen and they receive detailed explanations of the images. In low-feedback ultrasound scans, only the operator can see the screen and the women are told the results at the end of the scan. High feedback might reduce pregnancy anxiety but it can impact both ways, not only adding excessive stress on the pregnant women and their partners but also on the physicians, especially when there is the possibility of an abnormal finding. We carried out this systematic review to compare high feedback versus low feedback during prenatal ultrasound for reducing maternal anxiety and improving maternal health behaviour and other pregnancy outcomes.

We included four studies involving 365 women. High or low feedback of prenatal ultrasound to reduce women's state of anxiety is not supported by evidence from the three randomised controlled trials, involving 346 pregnant women, that looked at this outcome (*low-quality evidence*). Two trials with a total of 148 women reported on the women's views on the level of feedback. The women in the high feedback groups were not clearly more likely to choose very positive adjectives to describe their feelings after the scan. One trial with 129 participants reported that women who had high feedback during ultrasound were more likely to stop smoking and avoid alcohol during pregnancy. The trials were reported on between 1985 and 1996.

Summary of findings for the main comparison. High feedback compared with low feedback of routine prenatal ultrasound for reducing maternal anxiety and improving maternal health behaviour in pregnancy

High feedback compared with low feedback of routine prenatal ultrasound for reducing maternal anxiety and improving maternal health behaviour in pregnancy

Patient or population: Pregnant women undergoing routine ultrasound during pregnancy
Settings: Israel, UK and USA
Intervention: High feedback
Comparison: Low feedback of routine prenatal ultrasound

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Low feedback of routine prenatal ultrasound	High feedback				
Maternal anxiety - throughout pregnancy	The mean maternal anxiety throughout pregnancy in the low-feedback group was 22.07	The mean maternal anxiety throughout pregnancy in the intervention group was 0.92 higher (0.58 lower to 2.43 higher)	**SMD** 0.10 (- 0.11 to 0.31)	346 (3 RCTs)	⊕⊕⊝⊝ LOW [1,2]	
Maternal anxiety - In the second trimester	The mean maternal anxiety in the second trimester in the low-feedback group was 31.5	The mean maternal anxiety in the second trimester in the intervention group was 2.00 higher (3.40 lower to 7.40 higher)	**SMD** 0.23 (- 0.40 to 0.85)	40 (1 RCT)	⊕⊕⊝⊝ LOW [1,2]	
Cessation of alcohol	Study population		**RR** 2.96 (1.15 to 7.60)	129 (1 RCT)	⊕⊕⊝⊝ LOW [1,3]	
	81 per 1000	239 per 1000 (93 to 613)				
	Moderate					
	81 per 1000	239 per 1000 (93 to 613)				
Cessation of smoking	Study population		**RR** 2.93 (1.25 to 6.86)	129 (1 RCT)	⊕⊕⊝⊝ LOW [1,3]	
	97 per 1000	284 per 1000 (121 to 664)				

	Moderate				
	97 per 1000	284 per 1000 (121 to 664)			
Women's views of level of feedback	Study population		**RR** 3.30 (0.73 to 14.85)	148 (2 RCTs)	⊕⊖⊖⊖ VERY LOW [1,2,4]
	157 per 1000	519 per 1000 (115 to 1000)			
	Moderate				
	307 per 1000	1000 per 1000 (224 to 1000)			

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

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1]Most of pooled effect provided by studies with unclear risk of bias
[2]Wide CI crossing the line of no effect
[3]One study of small sample size and few events.
[4]Presence of substantial heterogeneity (I^2 = 88%)

BACKGROUND

Routine prenatal care and ultrasonography

Ultrasound may be used as a tool to diagnose complications that may arise during pregnancy (including multiple pregnancy, fetal growth restriction, placenta praevia). It may also be offered as part of routine obstetric care in many countries with developed healthcare services (Bricker 2000; Garcia 2002; Jahn 2002; Lalor 2006; Sen 2003).

Routine prenatal ultrasonography has become an integral part of the psychological experience of having a baby (Harris 2004). Women may seek prenatal ultrasonography for reassurance and to make informed decisions later in pregnancy. Other reasons why pregnant women request a prenatal ultrasound in the absence of clinical indications include their desire to know the sex of the fetus, to exclude fetal anomalies, to verify fetal life and to assess fetal growth. Those reasons vary according to the parity; duration of gestation; prior obstetric history (e.g. prior miscarriage or fetal loss); and personal factors. Lower income was more significantly related to wanting to see the baby and wanting an ultrasound picture, whereas higher income was more significantly related to checking that all was normal and for reassurance. Women in their first pregnancy were more likely to want themselves and the father to see the baby. Women who had given birth previously were more likely to want reassurance, as were women with a previous miscarriage or induced abortion. Women who would agree to an abortion in case of fetal trisomies were more likely to want to know about abnormalities. Women in the second trimester were more likely to want to check for abnormalities and appropriate fetal growth than those in the first trimester (Gudex 2006).

Description of the intervention

The prenatal real time ultrasound is one of a range of techniques used in screening and diagnosis, but it differs from most others because it gives parents instant access to the images of the fetus (Garcia 2002). In addition to instant access to a fetal image, the care giver provides information (feedback) to the pregnant woman. In current practice there are two types of feedback depending on the amount of information given to the pregnant woman. During high-feedback ultrasound scans, women can see the screen and receive detailed explanations, while in low-feedback ultrasound scans, only the operator can see the screen and the women are told the results at the end of the scan (Bricker 2000; Field 1985; Reading 1982a; Reading 1985; Zlotogorski 1996). Feedback includes how the physicians provide information about the examination procedure itself, as well as how they inform the pregnant woman about her pregnancy and whether or not a complication is detected (Gotzmann 2001).

How the intervention might work

The amount of information given to the pregnant woman may have an impact on the level of state anxiety of a pregnant woman, maternal-fetal attachment and health attitudes during pregnancy e.g. cessation of smoking and alcohol consumption (Crandon 1979; Janus 1980; Lobel 2008; Sjöström 2002; Teixeira 1999). The impact of the amount of feedback might be influenced by clinical, for example duration of gestation and parity, and demographic factors that might independently influence anxiety and health attitudes in pregnant women.

State anxiety is a transitory emotional state and refers to a palpable reaction or process taking place at a given time and level of intensity. State anxiety, unlike trait anxiety, is affected by situational circumstances e.g. undergoing a diagnostic test as an ultrasound scan. It must be noted that the individual differences in reactions (called trait anxiety) (Endler 2001) may have a more profound impact on state anxiety than the timing or nature of the feedback itself (Zlotogorski 1995).

The tools used to assess anxiety include Spielberger State-Trait Anxiety Inventory (STAI) (Spielberger 1983) and Beck Anxiety Investory (Beck 1988). The STAI differentiates between temporary or emotional state anxiety versus longstanding personality trait anxiety in adults. The STAI contains four-point Likert items. The instrument is divided into two sections, each having 20 questions. The first sub scale measures state anxiety, the second measures trait anxiety. The range of scores is 20 to 80, the higher score indicating greater anxiety. Approximately 10 minutes are required for adults to complete the STAI.

High feedback during a prenatal ultrasound might reduce pregnancy anxiety, particularly for the primigravida women (Field 1985). High feedback might also increase maternal-fetal attachment and promote positive attitudes toward health during pregnancy (Boukydis 2006; Reading 1982b). But it can impact both ways, not only adding excessive stress on the pregnant women and their partners, but also on the physicians, especially when there are fetal anomalies (Gotzmann 2001). Needless to say, the amount of information given to the pregnant woman in case of detecting an ultrasonographic soft marker is very important in light of the relatively high false-positive rates of ultrasonographic soft markers. In a recent study including 215 women, it was found that women with a possible soft ultrasound findings who were referred for further tests had significantly higher state anxiety than women who were referred because of their advanced age (Hoskovec 2008). Therefore, it seems very important to know what to say and how to say it and It should be acknowledged that a number of factors contribute to successful detection of anomalies, including the type of anomaly, gestational age at scanning, the skill of the sonographer and the ultrasound machine used (Bricker 2000).

Whereas, low feedback with a less detailed approach may be preferable for a routine screening program for low-risk pregnancy, as extensive provision of information about possible abnormal finding can cause unnecessary anxiety until further scans or tests resolve the issue (Lalor 2006). The clinical situation of 'absence of reassuring findings' during a scan might make some obstetricians provide a low level of feedback to avoid unnecessary anxiety. A recent study has shown that, contrary to their expectation of reassurance, most antenatal care attendees are warned about possible abnormalities, which often lead to further investigations and cause considerable anxiety. Two-thirds (67.2%) of antenatal care attendees reported suspicious or abnormal findings, almost half of which (45.1%) resulted from routine ultrasound scans. More than half (53.2%) of those with suspicious findings had higher state anxiety scores. The suspected problem often did not materialise: 13 of 16 suspected malformations and 34 of 42 suspected growth-retarded babies were in the normal range (Petersen 2008).

Obstetricians should be careful not to give a false reassurance while providing a detailed high feedback. This false reassurance may be due to women's lack of knowledge about what ultrasound can and cannot test for. One more issue is whether informing the

parents of the fetal sex is part of the “high feedback”. The effect this information has on the parents may colour the rest of the results. The effect would also be influenced by whether the sex is the desired sex for this baby.

Why it is important to do this review

A systematic review is needed to identify whether to provide high feedback or low feedback during prenatal ultrasound examinations; and whether high or low feedback improves maternal positive health attitudes during pregnancy and reduces maternal state anxiety.

OBJECTIVES

To compare high feedback versus low feedback during prenatal ultrasound for reducing maternal anxiety and improving maternal health behaviour and pregnancy outcomes.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs). We did not include quasi-RCTs.

Types of participants

Pregnant women undergoing routine ultrasound during pregnancy.

Types of interventions

High feedback versus low feedback during ultrasound during routine antenatal care.

Types of outcome measures

Primary outcomes

1. Maternal anxiety measured by State Trait Anxiety Inventory as defined by the investigators of each included study.

Secondary outcomes

1. Cessation of alcohol
2. Cessation of smoking
3. Women's views of level of feedback

Search methods for identification of studies

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

Electronic searches

We searched the Cochrane Pregnancy and Childbirth Group’s Trials Register by contacting the Trials Search Co-ordinator (12 May 2015).

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

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

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

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

In addition, we searched CENTRAL (*The Cochrane Library,* 2015 Issue 5), MEDLINE (January 1966 to 12 May 2015) and the ISRCTN Registry (12 May 2015) using the search strategies detailed in Appendix 1.

Searching other resources

We handsearched citation lists of relevant publications.

We did not apply any language or date restrictions.

Data collection and analysis

For methods used in the previous version of this review, *see* Nabhan 2010.

For this update, the following methods were used for assessing the one trial (Stotts 2009), previously in Studies awaiting classification. This trial was excluded.

In future updates, the methods outlined in Appendix 2 will be used for assessing any new trial reports identified from an updated search.

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

Selection of studies

Two review authors independently assessed for inclusion the one study from Studies awaiting classification. We planned to resolve any disagreement through discussion or, if required, we would have consulted a third assessor.

Data extraction and management

There were no eligible studies identified to carry out any further data extraction. We entered data into Review Manager software (RevMan 2014) and checked for accuracy.

Assessment of the quality of the evidence

For this update, no new reports were identified for assessment but we assessed the quality of evidence of the existing studies using the GRADE approach (Schunemann 2009) in order to assess the quality of the body of evidence relating to the following outcomes for the comparison 'high feedback versus low feedback of routine prenatal ultrasound':

1. Maternal anxiety (throughout pregnancy or during the second trimester)
2. Cessation of alcohol
3. Cessation of smoking
4. Women's views of level of feedback

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

In future updates, if new reports are identified, we will use the methods described in Appendix 2.

RESULTS

Description of studies

We have provided descriptions of studies in the Characteristics of included studies and Characteristics of excluded studies tables.

Results of the search

We identified eight potentially eligible studies (13 reports), (Boukydis 2006; Cox 1987; Field 1985; Reading 1985; Reading 1982a; Salkovskis 2001; Stotts 2009; Zlotogorski 1996). In this update (2015), we excluded one trial report which had previously been in Studies awaiting classification.

Included studies

We included four studies (365 participants) (Field 1985; Reading 1985; Reading 1982a; Zlotogorski 1996). All included studies compared low feedback and high feedback during ultrasound scan in pregnancy.

Excluded studies

We excluded four studies: Boukydis 2006 and Salkovskis 2001 did not compare high feedback and low feedback during ultrasound scan. Cox 1987 was a quasi-RCT. Stotts 2009 was excluded as it did not compare high and low feedback during a routine ultrasound scan.

Risk of bias in included studies

We have provided detailed descriptions of the risk of bias in the included studies in the Risk of bias' tables.

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

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

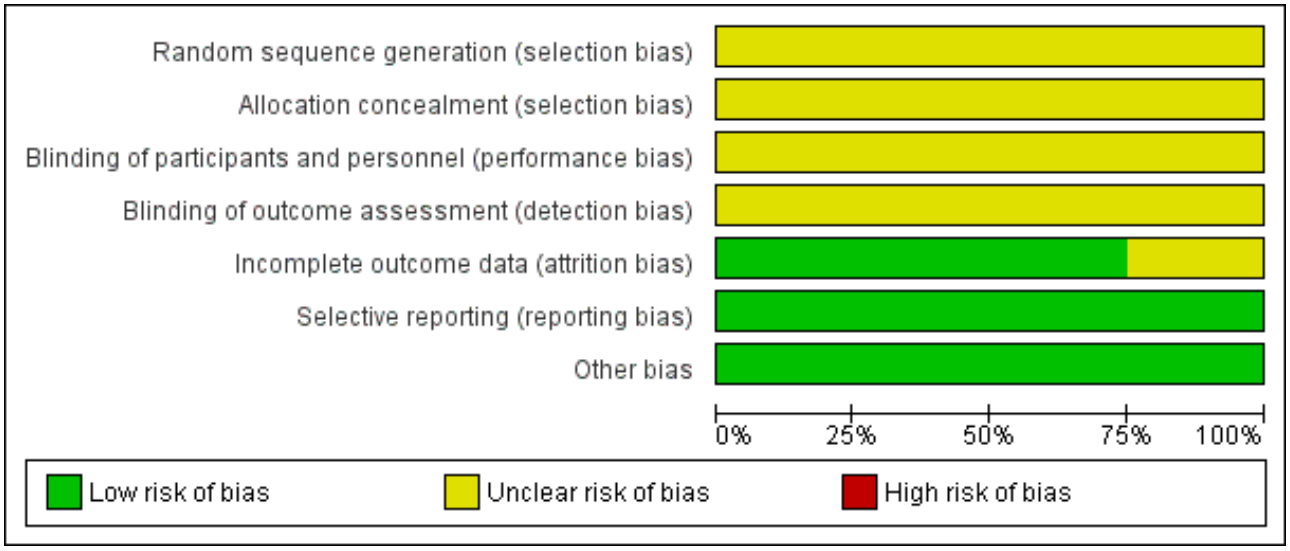
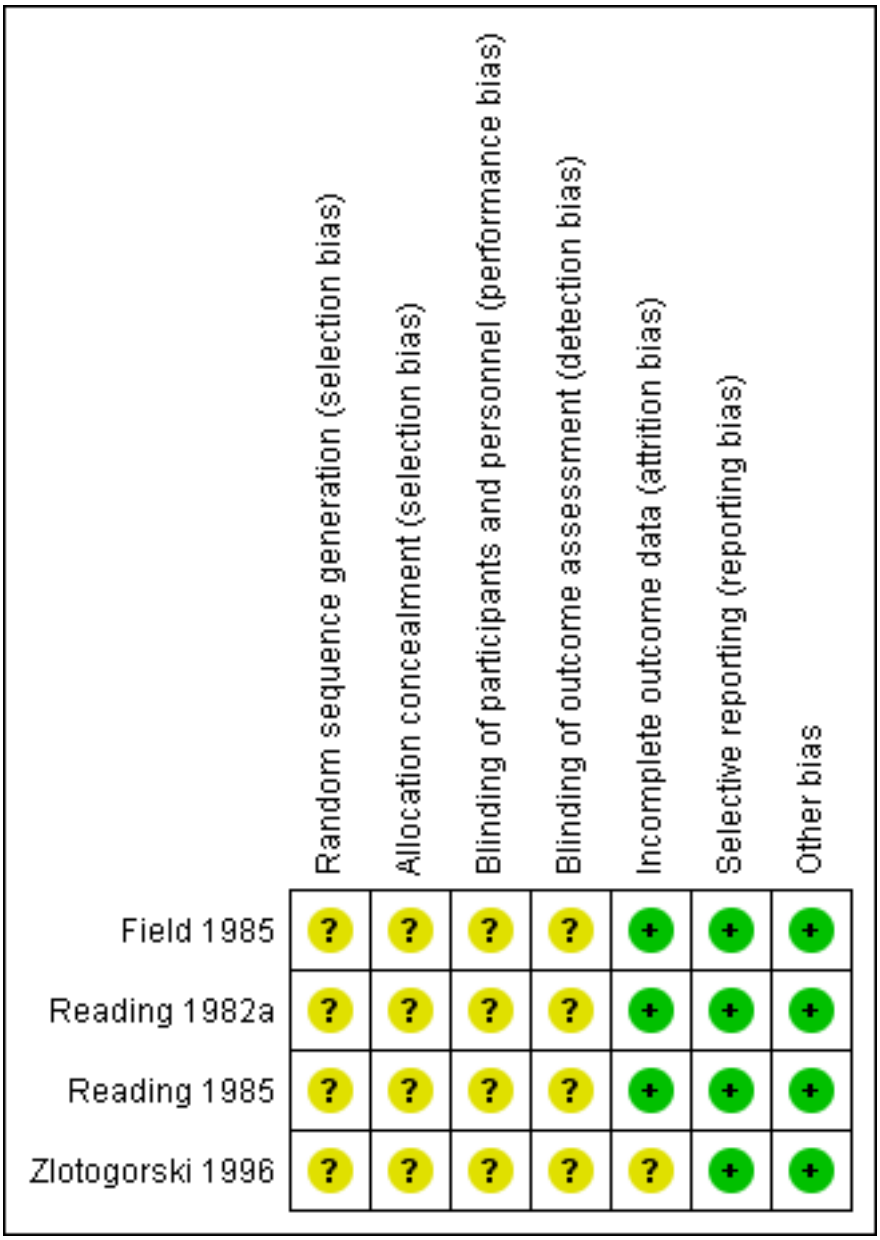


Figure 2. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.



Allocation

In the four included studies (Field 1985; Reading 1985; Reading 1982a; Zlotogorski 1996), there was neither a description of the method of sequence generation nor the method used for allocation concealment.

Blinding

None of the four included trials included any description of blinding for any of the outcomes and whether the outcome assessors were blind to the group allocation.

Incomplete outcome data

In the Zlotogorski 1996 study, 211 women were the participants recruited (three participants with findings of congenital fetal malformations or other pathological findings were excluded, 10 participants dropped out at different stages of the study and 15 participants failed to complete the questionnaires). One participant was never accounted for in the trial. Therefore, only 182 women were available for analysis. For the state anxiety scores, data from 177 participants were recorded. The trial did not account for the missing five participants. For the rest of included studies, no incomplete outcome data were noted as all pre-specified outcomes were reported for both groups.

Selective reporting

There is no evidence that there was selective reporting of outcomes.

Other potential sources of bias

There is no evidence that there were other potential sources of bias.

Effects of interventions

See: **Summary of findings for the main comparison** High feedback compared with low feedback of routine prenatal ultrasound for reducing maternal anxiety and improving maternal health behaviour in pregnancy

Primary outcome

Maternal anxiety

All included trials used the same tool, the State Trait Anxiety Inventory, which is a valid tool for use in pregnant adults to assess the effect of intervention on maternal anxiety. Three trials including 346 women (Field 1985; Reading 1982a; Zlotogorski 1996), provided data that allowed quantitative analysis with a mean difference (MD) 0.92, 95% confidence interval (CI) -0.58 to 2.43 (Analysis 1.1). We carried out the subgroup analysis: high feedback versus low feedback in second trimester pregnancy ultrasound. Only one trial (Field 1985), including 40 women, reported data on the effect of level of feedback during second trimester routine ultrasound scan on maternal anxiety and showed no difference between high and low feedback (MD 2.00, 95% CI -3.40 to 7.40; participants = 40; one study) (Analysis 1.1).

Secondary outcomes

Health behaviour

Cessation of alcohol

One trial (Reading 1982a; 129 participants) reported the effect of the level of feedback on alcohol consumption during pregnancy. Women who had a high feedback during ultrasound were more likely to avoid alcohol during pregnancy (risk ratio (RR) 2.96, 95% CI 1.15 to 7.60) *see* Analysis 1.2.

Cessation of smoking

One trial (Reading 1982a; 129 participants) reported the effect of the level of feedback on smoking during pregnancy. Women who had a high feedback during ultrasound were more likely to stop smoking during pregnancy (RR 2.93, 95% confidence interval (CI) 1.25 to 6.86), *see* Analysis 1.3.

Women's views of level of feedback

Two trials (Reading 1982a; Reading 1985; 148 participants) reported women's views of the level of feedback. Women in the high-feedback groups were not more likely to choose very positive adjectives to describe their feelings after the scan (RR (random-effects) 3.30, 95% CI 0.73 to 14.85; *see* Analysis 1.4). It has to be noted that there was substantial heterogeneity among studies (I^2 = 88%) that could not be explained and therefore we used a random-effects meta-analysis.

DISCUSSION

We conducted this systematic review to compare high feedback versus low feedback during prenatal ultrasound for reducing maternal state anxiety and improving maternal health behaviour. Receiving information promotes knowledge and understanding, but it may also increase state anxiety (Yee 2007).

Summary of main results

Four RCTs (365 women) reported the impact of level of feedback during ultrasound examination on maternal (pregnancy) state anxiety and prenatal health attitudes. There is insufficient evidence regarding what amount of feedback works better to reduce state anxiety. There was no difference between high and low feedback regarding women's views of the level of feedback. Only one small trial reported the impact of feedback level on the health attitudes of women, namely smoking cessation and alcohol consumption. Women who had high-level feedback during ultrasound were more likely to stop smoking and avoid alcohol during pregnancy.

Overall completeness and applicability of evidence

The four included trials are not sufficient to address an important issue in our daily practice. Currently, there are no practice guidelines or consensus on the amount of information given to pregnant women and their families and who should do that, particularly in low-risk pregnancy.

Quality of the evidence

The results from this systematic review do not allow a robust conclusion regarding the impact of the level of feedback on maternal state anxiety. The evidence was of low/very low quality for all prespecified outcomes (Summary of findings for the main comparison). In all the included RCTs, it is unclear how randomisation (both sequence generation and allocation concealment) was implemented. The sample size in all four included trials was not sufficient to address the outcomes sought. This very small number of participants in all included studies is a limitation to information.

Potential biases in the review process

The possibility of introducing bias was present at every stage of the reviewing process. We attempted to minimise bias in a number of ways; two review authors assessed eligibility for inclusion, carried out data extraction and assessed risk of bias. Each worked independently. However, the process of assessing risk of bias, for example, is not an exact science and includes many personal judgements. Further, the process of reviewing research studies is known to be affected by prior beliefs and attitudes. It is difficult to control for this type of bias in the reviewing process.The robustness of the methodology along with the peer review process will help to prevent any important effect on the results or recommendations of the review.

Agreements and disagreements with other studies or reviews

One prior report has systematically reviewed trials regarding the level of feedback during an ultrasound scan as part of a large work on women's views of pregnancy ultrasound (Bricker 2000; Garcia 2002). This earlier review claimed that women in the high-feedback groups are more likely to choose very positive adjectives to describe their feelings after the scan. We could not find evidence from the included RCTs to show an impact of the amount of information provided on maternal state anxiety and women's views of the scan.

On the other hand, we have shown that women in the high-feedback group were more likely to act positively towards cessation

of smoking and alcohol consumption during pregnancy. Others have not found that high feedback has an influence on smoking and other aspects of health behaviour (Bricker 2000; Garcia 2002).

AUTHORS' CONCLUSIONS

Implications for practice

There is insufficient evidence to support either high or low feedback during an ultrasound scan in pregnancy to have a favourable influence on maternal anxiety or health behaviour during pregnancy.

Implications for research

The question of the amount of information delivered to women and their families needs to be properly addressed in large, well-designed and conducted randomised controlled trials. It might not be possible to conduct such studies in the majority of developed countries where there is the expectation that women are provided with high feedback during their ultrasound examinations.

Further trials are required:

1. to examine clinical and demographic factors that might independently influence anxiety in a low-risk population;
2. to examine the effect of level of feedback on positive health attitude during pregnancy.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

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

Field 1985

Methods	Women were randomly assigned to either a feedback or no feedback group.

Field 1985 *(Continued)*

Participants	40 pregnant women who were referred for ultrasound assessment of gestational age. They did not differ in background characteristics including age, education, socioeconomic status or ethnicity. Half of the sample was primiparous.
Interventions	Women assigned to the feedback group could see the monitor and were given a running description of the fetal anatomy, measurements and movements. In the no feedback group, women could not see the monitor and they were given only a summary statement of the scan.
Outcomes	Maternal anxiety using the Spielberger STAI, fetal movement, maternal sleep behaviour, neonatal behaviour, neonatal activity level and birthweight.
Notes	USA.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The study does not include any description of sequence generation.
Allocation concealment (selection bias)	Unclear risk	The study does not include any description of allocation concealment.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not described in the paper.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	The study does not indicate if outcome assessors were blind to allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No attrition and exclusion reported.
Selective reporting (reporting bias)	Low risk	Pre-specified outcomes reported for both groups.
Other bias	Low risk	None noted.

Reading 1982a

Methods	Women were randomly assigned at their first clinical visit (10-14 weeks) to either a high-feedback (number = 67) or low-feedback (number = 62) group. Women were asked to complete the STAI before and after the scan. They were also asked to rate their attitude toward receiving a scan and to describe the emotional state at the time by selecting the most appropriate word from the Subjective Stress Scale.
Participants	A consecutive series of primiparous Caucasian women fulfilling the selection criteria of obstetrically "low risk" and attending King's College hospital antenatal booking clinics, were studied. Mothers with a history of previous miscarriages or having undergone extended (more than 2 months) infertility treatment were excluded, along with those identified by accredited criteria as being at risk of congenital malformation.

Reading 1982a *(Continued)*

Interventions	Women assigned to the high-feedback group could see the monitor and were given standardised visual and verbal feedback as to fetal size, shape and movement. In the low-feedback group, women could not see the monitor and were not given specific visual or verbal feedback. They only received a global evaluation of the form "all is well". The examination was of comparable duration and the operator interacted in a similarly reassuring pattern as with high feedback women.
Outcomes	STAI score Maternal rating of feelings towards being pregnant and towards the fetus Attitude toward receiving a scan and the emotional state at the time Cessation of alcohol Cessation of smoking
Notes	UK

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The study does not include any description of sequence generation.
Allocation concealment (selection bias)	Unclear risk	The study does not include any description of allocation concealment.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not described in the paper.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	The study does not indicate if outcome assessors were blind to allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data for all women randomised.
Selective reporting (reporting bias)	Low risk	Pre-specified outcomes reported for both groups.
Other bias	Low risk	None noted.

Reading 1985

Methods	The women were assigned at random to one of four conditions: (1) high-feedback ultrasonography (number = 11), (2) low-feedback ultrasonography (number = 8), fetal monitoring (number = 11), and video control (number = 7). All women were informed that they would be taking part in a study of attitudes towards ultrasonography. None of the women approached refused to participate, and all signed informed consent forms. Before and after the procedure the women completed the state scale of the STAI. Immediately following the procedure the women were asked to select the word best describing their emotional state then from the Subjective Stress Scale, which consists of a series of adjectives describing such states.

Reading 1985 *(Continued)*

Participants	A consecutive series of women attending the USC/LAC Women's hospital prenatal clinic for ultrasonography was studied.
Interventions	Women assigned to high-feedback group (number = 11) could see the monitor during their real time examination and a nurse pointed out the features visualised. In the low-feedback group (number = 8), women could not see the monitor and so received only global feedback, in the form of "all appears to be well".
Outcomes	1. STAI scores 2. Emotional state following the procedure
Notes	UK

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The study does not include any description of sequence generation.
Allocation concealment (selection bias)	Unclear risk	The study does not include any description of allocation concealment.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not described in the paper.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	The study does not indicate if outcome assessors were blind to allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data for all women randomised.
Selective reporting (reporting bias)	Low risk	Pre-specified outcomes reported for both groups.
Other bias	Low risk	None noted.

Zlotogorski 1996

Methods	Participants were randomly assigned to one of two feedback conditions, high feedback and low feedback during an ultrasound examination. All participants completed the STAI before and after the ultrasound examination.
Participants	The participants for the study were 211 pregnant women (4 to 41 weeks' gestation) who underwent an ultrasound examination. Three participants with findings of congenital fetal malformations or other pathological findings were excluded. In addition, 10 participants who dropped out at different stages of the study and 15 participants who failed to complete the questionnaires were also excluded. The final sample of 182 women was reported in the results.
Interventions	Women assigned to high-feedback group were shown the monitor screen and were given a standardised visual and verbal feedback of fetal heart, head and limbs. Finally printed pictures of what was seen

Zlotogorski 1996 *(Continued)*

	on the monitor were handed to the participants by the staff. In the low-feedback group, women were not able to see the monitor and the doctor limited himself to providing standardised verbal feedback: "head ... normal, heart ... normal, limbs ... normal, everything ... normal". Printed pictures were not handed to the participants.
Outcomes	Maternal STAI scores.
Notes	Israel

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The study does not include any description of sequence generation.
Allocation concealment (selection bias)	Unclear risk	The study does not include any description of allocation concealment.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not described in the paper.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	The study does not indicate if outcome assessors were blind to allocation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	211 women were the participants recruited (3 participants with findings of congenital fetal malformations or other pathological findings were excluded, 10 participants dropped out at different stages of the study and 15 participants failed to complete the questionnaires). One participant was never accounted for in the trial. Therefore, only 182 women were reported in the results. For the state anxiety scores, data from 177 participants were recorded. The trial did not account for the missing 5 participants.
Selective reporting (reporting bias)	Low risk	Pre-specified outcomes reported for both groups.
Other bias	Low risk	None noted.

STAI: State Trait Anxiety Inventory

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

Study	Reason for exclusion
Boukydis 2006	This RCT did not compare high and low feedback during an ultrasound scan.
Cox 1987	Women were consecutively assigned to either low feedback or high feedback during ultrasound scan.
Salkovskis 2001	This RCT did not compare high and low feedback during a routine ultrasound scan.
Stotts 2009	This RCT did not compare high and low feedback during a routine ultrasound scan.

RCT: randomised controlled trial

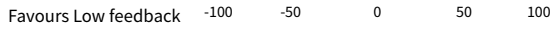
DATA AND ANALYSES

Comparison 1. High feedback versus low feedback of routine prenatal ultrasound

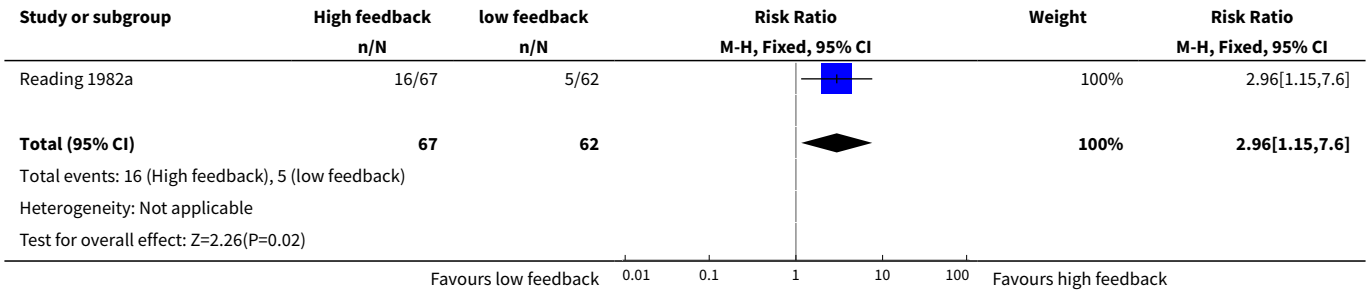
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Maternal anxiety	3		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.1 Throughout pregnancy	3	346	Mean Difference (IV, Fixed, 95% CI)	0.92 [-0.58, 2.43]
1.2 In the second trimester	1	40	Mean Difference (IV, Fixed, 95% CI)	2.0 [-3.40, 7.40]
2 Cessation of alcohol	1	129	Risk Ratio (M-H, Fixed, 95% CI)	2.96 [1.15, 7.60]
3 Cessation of smoking	1	129	Risk Ratio (M-H, Fixed, 95% CI)	2.93 [1.25, 6.86]
4 Women's views of level of feedback	2	148	Risk Ratio (M-H, Random, 95% CI)	3.30 [0.73, 14.85]

Analysis 1.1. Comparison 1 High feedback versus low feedback of routine prenatal ultrasound, Outcome 1 Maternal anxiety.

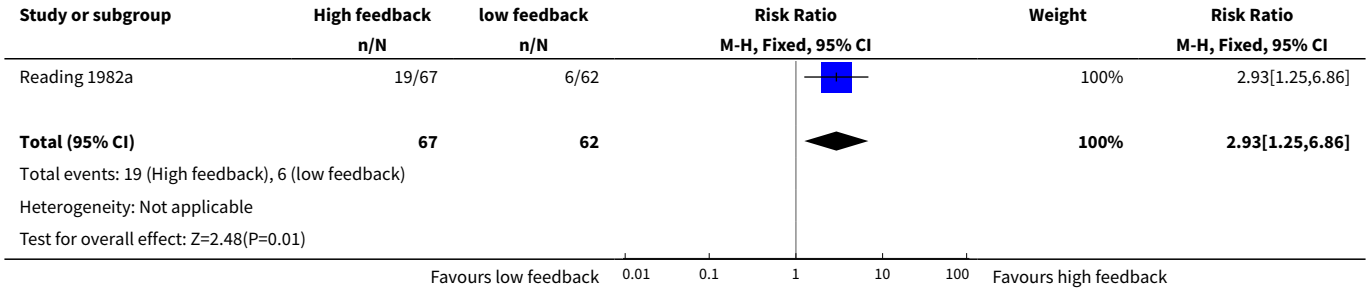
Study or subgroup	High feedback N	High feedback Mean(SD)	low feedback N	low feedback Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
1.1.1 Throughout pregnancy							
Field 1985	20	34.3 (8.2)	20	35 (7.3)		9.75%	-0.7[-5.51,4.11]
Reading 1982a	67	29.5 (9.9)	62	30.2 (7.1)		25.82%	-0.7[-3.66,2.26]
Zlotogorski 1996	92	2.8 (9)	85	1 (1.9)		64.42%	1.82[-0.05,3.69]
Subtotal ***	**179**		**167**			**100%**	**0.92[-0.58,2.43]**
Heterogeneity: Tau^2=0; Chi^2=2.48, df=2(P=0.29); I^2=19.24%							
Test for overall effect: Z=1.2(P=0.23)							
1.1.2 In the second trimester							
Field 1985	20	33.5 (8.4)	20	31.5 (9)		100%	2[-3.4,7.4]
Subtotal ***	**20**		**20**			**100%**	**2[-3.4,7.4]**
Heterogeneity: Not applicable							
Test for overall effect: Z=0.73(P=0.47)							
Test for subgroup differences: Chi^2=0.14, df=1 (P=0.71), I^2=0%							



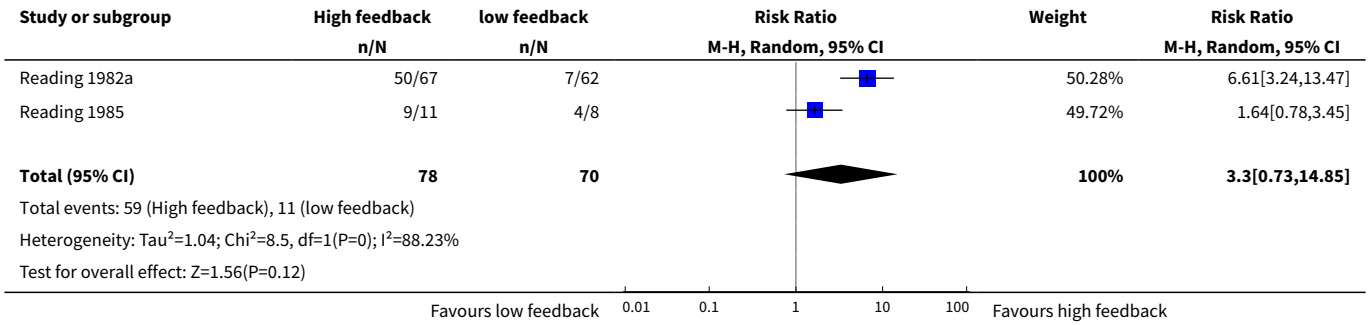
Analysis 1.2. Comparison 1 High feedback versus low feedback of routine prenatal ultrasound, Outcome 2 Cessation of alcohol.



Analysis 1.3. Comparison 1 High feedback versus low feedback of routine prenatal ultrasound, Outcome 3 Cessation of smoking.



Analysis 1.4. Comparison 1 High feedback versus low feedback of routine prenatal ultrasound, Outcome 4 Women's views of level of feedback.



APPENDICES

Appendix 1. Search strategies for CENTRAL, MEDLINE and mRCT

CENTRAL

#1 MeSH descriptor Ultrasonography, Prenatal explode all trees
#2 ultraso*
#3 pregnan* or antenatal* or prenatal* or antepart*

#4 (#2 AND #3)
#5 (#1 OR #4)
#6 feedback or anxiety or attitude* or psychol*
#7 MeSH descriptor Maternal Behavior explode all trees
#8 MeSH descriptor Mothers explode all trees with qualifier: PX
#9 (#6 OR #7 OR #8)
#10 (#5 AND #9)

MEDLINE

1 exp Ultrasonography, Prenatal/
2 exp Ultrasonography/
3 (pregnan$ or prenatal$ or antenatal$ or antepart$)
4 2 and 3
5 1 or 4
6 feedback.tw. or exp Feedback/ or exp Feedback, Psychological/
7 exp Mothers/px [Psychology]
8 exp Attitude/
9 6 or 7 or 8
10 9 and 5

ISRCTN Registry

ultraso% AND pregnan%

Appendix 2. Methods to be used in future updates

For methods used in the previous version of this review, *see* Nabhan 2010.

For future updates, we will use the following methods for assessing any new trials identified.

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

Selection of studies

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

Data extraction and management

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

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

Assessment of risk of bias in included studies

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

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

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

We will assess the method as:

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

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

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

We will assess the methods as:

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

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

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

We will assess the methods as:

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

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

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

We will assess methods used to blind outcome assessment as:

- low, high or unclear risk of bias.

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

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

We will assess methods as:

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

(5) Selective reporting (checking for reporting bias)

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

We will assess the methods as:

1. low risk of bias (where it is clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review have been reported);
2. 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);
3. unclear risk of bias.

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

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

(7) Overall risk of bias

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

Measures of treatment effect

Dichotomous data

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

Continuous data

We will use the mean difference if outcomes were measured in the same way between trials. We will use the standardised mean difference to combine trials that measured the same outcome, but used different methods.

Unit of analysis issues

Cluster-randomized trials

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

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

Cross-over trials

It is unlikely that cross-over designs will be a valid study design for Pregnancy and Childbirth reviews and so, if identified, we will exclude them.

Dealing with missing data

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

For all outcomes, we will carry out analyses, as far as possible, on an intention-to-treat basis, that is, we will attempt to include all participants randomised to each group in the analyses. The denominator for each outcome in each trial will be the number randomised minus any participants whose outcomes are known to be missing.

Assessment of heterogeneity

We will assess statistical heterogeneity in each meta-analysis using the Tau^2, I^2 and Chi^2 statistics. We will regard heterogeneity as substantial if an I^2 is greater than 30% and either a Tau^2 is greater than zero, or there was a low P value (less than 0.10) in the Chi^2 test for heterogeneity. If we identify substantial heterogeneity (above 30%), we plan to explore it by pre-specified subgroup analysis.

Assessment of reporting biases

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

Data synthesis

We will carry out statistical analysis using the Review Manager software (RevMan 2014). We will use fixed-effect meta-analysis for combining data where it is reasonable to assume that studies are estimating the same underlying treatment effect: i.e. where trials are examining the same intervention, and the trials' populations and methods are judged to be sufficiently similar.

If there is clinical heterogeneity sufficient to expect that the underlying treatment effects differ between trials, or if substantial statistical heterogeneity is detected, we will use random-effects meta-analysis to produce an overall summary, if an average treatment effect across trials is considered clinically meaningful. The random-effects summary will be treated as the average range of possible treatment effects and we will discuss the clinical implications of treatment effects differing between trials. If the average treatment effect is not clinically meaningful, we will not combine trials. If we use random-effects analyses, we will present the results as the average treatment effect with 95% confidence intervals, and the estimates of Tau^2 and I^2.

Subgroup analysis and investigation of heterogeneity

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

We will carry out the following subgroup analysis.

1. High risk pregnancy versus low risk pregnancy

Subgroup analysis will be restricted to the primary outcomes.

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

Sensitivity analysis

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

WHAT'S NEW

Date	Event	Description
12 May 2015	New search has been performed	Search updated. No new trials identified. One trial report previously in Studies awaiting classification was excluded (Stotts 2009). A 'Summary of findings' table has been incorporated.
12 May 2015	New citation required but conclusions have not changed	Review updated.

CONTRIBUTIONS OF AUTHORS

For the first published version of the review, AF Nabhan proposed the topic and developed the first draft of the protocol. AF Nabhan edited all the revised drafts of the protocol. AF Nabhan conducted analysis and interpretation of data; drafting the review and revising it critically for important intellectual content; and final approval of the version to be published.

For the 2015 update, Nasreen Aflaifel created of the 'Summary of findings' table. AF Nabhan finalised the review for publication.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

- Department of Obstetrics and Gynecology, Ain Shams University, Egypt.
- UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP), Department of Reproductive Health and Research, World Health Organization, Switzerland.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Methods updated to current standard methods for the Cochrane Pregnancy and Childbirth. GRADE methods added and a 'Summary of findings' table incorporated.

INDEX TERMS

Medical Subject Headings (MeSH)

*Feedback, Psychological; *Health Behavior; Alcohol Drinking [prevention & control]; Anxiety [*prevention & control]; Communication; Maternal Behavior [*psychology]; Randomized Controlled Trials as Topic; Smoking Prevention; Ultrasonography, Prenatal [*psychology]

MeSH check words

Female; Humans; Pregnancy