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Interventions for fear of childbirth (tocophobia) (Protocol)

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TABLE OF CONTENTS

HEADER 1
ABSTRACT 1
BACKGROUND 1
OBJECTIVES 5
METHODS 5
ACKNOWLEDGEMENTS 10
REFERENCES 11
APPENDICES 14
CONTRIBUTIONS OF AUTHORS 15
DECLARATIONS OF INTEREST 15
SOURCES OF SUPPORT 16

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[Intervention Protocol]

Interventions for fear of childbirth (tocophobia)

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

The primary objective of this review is to investigate the effectiveness of non-pharmacological interventions on reducing fear of childbirth (FOC) compared with standard maternity care in pregnant women with FOC.

BACKGROUND

Description of the condition

Introduction

It is common for pregnant women to experience anxiety, worry or fear with varying severity in relation to childbirth, particularly in first-time mothers (Zar 2001; Melender 2002; Salomonsson 2010; Nilsson 2018). Women are three times more likely to be diagnosed with an anxiety disorder than depression in the postnatal period (Fairbrother 2007) yet, research on anxiety in the perinatal period has lacked attention to date, in comparison with the focus on perinatal depression (Hofberg 2003; Howard 2014). There is a growing body of literature which recognises the importance of identifying fear of childbirth (FOC) and pregnancy-related anxieties in maintaining women's perinatal mental health (Hofberg 2003; Weaver 2013; Toohill 2014; Stoll 2018) and there is cumulative evidence that FOC predisposes women to postnatal depression (Alipour 2012; Räisänen 2014) and post-traumatic stress disorder (PTSD) (Ayers 2016). In addition, the significance of recognising psychological and psychosocial risk factors for postnatal depression in the antenatal period has been determined by various epidemiological studies and Cochrane Reviews (Alipour 2012; Dennis 2013; Räisänen 2014; Ayers 2016; Dennis 2017; Stoll 2018).

For some women, FOC is so severe that it affects their daily lives, and spoils their experience of pregnancy (Salomonsson 2010). Feelings of isolation, guilt and shame, due to perceived stigma have

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been reported by women with FOC, since pregnancy is generally seen as a time of happiness, and women may feel unable to talk about their fears with their partners or midwives (Eriksson 2006; Nilsson 2009; Lyberg 2010). In extreme cases, women use scrupulous methods of contraception to avoid pregnancy, experience psycho-sexual difficulty, may choose to terminate a healthy pregnancy, conceal or be in denial about pregnancy (Gutteridge 2013). In the latter case, women refuse scans and demonstrate avoidance behaviours by mentally blocking out feelings of being pregnant such as fetal movement (Gutteridge 2013). Moreover, physical and psychological effects such as sleeplessness, nightmares, stomach aches, depression and anxiety leading to panic attacks haven been reported (Zar 2001; Laursen 2008; Hall 2009; Räisänen 2014). Women who are in denial about pregnancy may avoid birth preparation classes (Salomonsson 2010), and as a result experience low self-efficacy in the ability to give birth (Lowe 2000). Furthermore, it is well-established that women with FOC are more likely to have a caesarean birth (both emergency and due to maternal request), and physiological effects related to fear such as prolonged labour (Saisto 2001; Karlström 2009; Adams 2012; Haines 2012; Weaver 2013; Räisänen 2014; Ryding 2015; O'Donovan 2018).

Women may have different attitudes or cultural beliefs towards childbirth which can influence how they experience the birth process (Haines 2012; Gutteridge 2013). These attitudes are determined by the culture of birth for example, risk-averse medical models tend to influence the woman's decisions in relation to interventions during childbirth and whether the woman takes an active role or is passive during childbirth (Haines 2012). Generally, a cultural shift in women's attitudes towards birth has been noted, corresponding with the increased use of medical interventions, such as induction of labour and epidural use, leading to women losing confidence in their ability to give birth and to cope with labour pain (Green 2003; Haines 2012). There has also been a shift in women's expectations of birth.

While, in theory, maternity care aims to place women at the centre of decision-making about her care, it is evident that mostly, in clinical practice the terms 'woman-centred care' and 'informed choice' are simply rhetoric (Haines 2012). There has been a growing trend of neglectful, disrespectful or abusive behaviour in some contexts and settings, which has lacked attention by healthcare professions, but which has affected women (Bohren 2014;Freedman 2014). Examples of the mistreatment of women globally include physical abuse, such as slapping or pinching, sexual abuse, verbal abuse, stigma, neglect during the birth, poor or ineffective communication, loss of autonomy and inadequately-resourced health systems which fail to provide women with privacy and dignity during birth (Bohren 2014). It must also be acknowledged that the attitudes of healthcare professionals such as midwives and obstetricians play a significant role in the perception of risk and the consequent fear perceived by women. In one study, 31% of female obstetricians in London indicated a birth preference for caesarean sections (CS) for their own births (Al Mufti 1997), which suggests that there may be a personal bias or an influence when presenting information to women (Dahlen 2010). Aiming to provide pregnant women with a trusting relationship could help reduce fear (Dahlen 2010; Lyberg 2010; Hildingsson 2018).

Social norms and emotional experiences of women, such as lack of control or perception of safety could influence women's decision to request a CS, according to a qualitative systematic review (O'Donovan 2018). In some cultures, CS is now perceived as 'normal' and even 'fashionable', however this shift in cultural belief is deep-rooted and ultimately underpinned by fear (O'Donovan 2018). Qualitative evidence suggests that FOC may be transmitted from generation to generation through vicarious experiences of family members who had difficult labours or negative births, leading to the perception of CS as a 'safer' option (Hull 2011; O'Donovan 2018).

Various studies have investigated the causes and consequences of FOC. Typical sources of fear include (but are not limited to); fear of the unknown, fear of pain, fear of perineal trauma, feeling lack of involvement in decision-making during birth, being left alone in labour, fear for the infant's health or own health or death (Salomonsson 2010; Fenwick 2015; O'Donovan 2018). FOC is strongly associated with intimate partner violence, sexual abuse, rape and unintended pregnancy (Miller 2010; Gutteridge 2013). A large epidemiological study reported that women with FOC were more likely to have had anaemia, miscarriages, a previous early termination of pregnancy, assisted reproductive procedures, or chorionic villus sampling (Räisänen 2014). A large Australian study (n = 510,006) which looked at all singleton births in New South Wales in 2000 to 2008 found that women who experienced severe perineal trauma during their first birth are less likely to have a subsequent baby (Priddis 2013).

Defining FOC

FOC exists on a spectrum from low fear to high and phobic fear but it is difficult to assess when fear of childbirth becomes 'tocophobia'. Typically, a phobia is characterised by avoidance behaviours. From a psychiatric perspective, a structured clinical interview (SCID-5) may be performed to assess women, however there is a dearth of perinatal psychiatrists and this is not common practice in maternity care (Brockington 2017; Nath 2018). When a psychiatric assessment is performed, women with FOC will usually receive a diagnosis of Generalised Anxiety Disorder, thus FOC comes under the umbrella of anxiety disorders (Stoll 2018; Striebich 2018). In Scandinavia, FOC has been categorised in the International Classification of Diseases, 10th revision (ICD-10) code (World Health Organization 2018) when women were referred for treatment for FOC, but has not specifically been included in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5; Americian Psychiatric Association 2013). FOC is usually not a pathological fear, but a situational fear which is personal to the individual.The most common defini-

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tion of tocophobia is a Wijma Delivery Expectancy Questionnaire version A (W-DEQ A) score greater than or equal to 85 (Wijma 1998; O'Connell 2017); further details of the tool will be outlined below.

Tools for measuring FOC

FOC can be assessed using a range of self-reported questionnaires or diagnostic interviews (Wijma 1998; Lowe 2000; Rouhe 2011; O'Connell 2017; Stoll 2018; Striebich 2018). The most common tool used to assess severity of FOC is the W-DEQ A in the antenatal period, with the W-DEQ B used to assess childbirth fear in the postnatal period (Wijma 1998). It was developed originally in Sweden by Klaas Wijma, and psychometric analysis has shown it to be valid and reliable for women of all parity (Wijma 1998). The questionnaire consists of 33 questions on a Likert scale (zero to six) with the aim of evaluating women's cognitive appraisal of the upcoming birth in the antenatal period and of evaluating the experiences after birth in the postnatal period (Wijma 1998). The original author (Wijma 1998) recommended using cut-offs of greater than or equal to 85 to define severe FOC (tocophobia) and greater than or equal to 66 to represent high fear, but various other cut-offs have been used in research studies (W-DEQ A $\geq$ 71, W-DEQ A $\geq$ 86, W-DEQ A $\geq$ 100) (Wijma 1998; O'Connell 2017; Nilsson 2018).

Epidemiology of FOC

FOC exists on a spectrum from minor worries and anxieties, to moderate FOC which does not impact women's every day life, to severe FOC (tocophobia), which has a considerable impact on women's lives and affects their psychological well-being (Areskog 1981; O'Connell 2017; Larsson 2017; Nilsson 2018). Tocophobia has been examined through a psychiatric perspective to date, rather than by obstetricians or midwives and there is a significant association between previous sexual abuse and rape (Gutteridge 2013).Various definitions are used for 'tocophobia' (O'Connell 2017), which is a key challenge when estimating prevalence, assessing women for FOC, designing interventions, and evaluating outcomes. Prevalence reports of severe FOC, range from 3.7% to 43% and a meta-analysis estimated a global pooled prevalence of 14% (95% confidence interval 0.12 to 0.16), using a random-effects model (O'Connell 2017). Furthermore, approximately 20% of women experience high fear (Toohill 2014; O'Connell 2017). The majority of prevalence studies have reported that high FOC is more common in nulliparous women, but some studies have found the opposite (O'Connell 2017). In parous women, previous mode of birth (instrumental or emergency CS) is associated with FOC (Rouhe 2011; Toohill 2014), and FOC in one pregnancy is the strongest risk factor for FOC in a subsequent pregnancy (Storksen 2012). Other confounding factors, such as FOC in 'foreign-born women', who reported feeling isolated since they lacked the network of family and friends to support them and may have specific sensitive cultural requirements in maternity care (Ternström 2015; Ternström 2016), also need to be taken into consideration. Thus identifying women with FOC and interventions for FOC need to be inclusive of vulnerable groups such as migrant women, who may be at even higher risk of postnatal depression (Ternström 2015). Given the prevalence of FOC, this is a key concern for midwives and obstetricians because of its multifactorial impact on the mother as well as her partner and infant.

Management of FOC

The majority of research in this field has been conducted, where care pathways are well-established, but there are parts of the Western world where FOC is not currently recognised or provided for in maternity care (O'Connell 2017). Even in countries where FOC is recognised, approaches to care vary widely and are not based on empirical evidence (Bewley 2002; Richens 2015). In Sweden, women with FOC are referred for counselling with midwives in the Aurora Clinics, which were introduced by midwives with an interest in childbirth fear as a service for women, by using a personalised approach (Larsson 2016; Larsson 2017). This involves an inter-disciplinary team of midwives, obstetricians, social workers and psychologists as appropriate for each individual woman (Larsson 2016). This approach was not preceded by a randomised control trial, and a retrospective evaluation reported that it did not reduce CS rates, but women were satisfied with the care and half the women experienced a reduction in FOC (Ryding 2003; Larsson 2017).

There is a lack of information about current services available to women with FOC. A National survey in Sweden in 2016 revealed that while it is usual for obstetric clinics in Sweden to provide treatment for women with childbirth fear, disparities in the treatment offered to women exist in the 43 obstetric clinics in Sweden that responded to the survey (of a possible 45). Moreover, the survey findings report a variation in the education of midwives and time allocated to counselling women (Larsson 2016). Thus, the researchers called for standardisation of care and potential for a national healthcare program for FOC (Larsson 2016). The results of the availability of services were in contrast to the findings of a UK National survey on availability of services for women with FOC (in which 128 out of 202 maternity units responded) (Richens 2015). Specialist services for women with FOC were available in just over half of the UK maternity units surveyed (Richens 2015). It was reported that 52 maternity units did not offer any specialist support for women with FOC (Richens 2015). Similar to Sweden, the standards of available services varied, and a number of different healthcare professionals were named as leading the care (Richens 2015). Thus, a summary of the best available empirical evidence is needed to inform the best practice to support women with high or severe FOC.

A Cochrane Review of mind-body interventions during pregnancy

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for preventing or treating women's anxiety (Marc 2011) investigated interventions such as autogenic training, biofeedback, hypnotherapy, imagery, meditation, prayer, auto-suggestion, tai-chi and yoga in comparison with standard care found eight trials with 556 participants in total, thus no meta-analysis was possible. The review concluded that mind-body interventions such as autogenic training may reduce anxiety in pregnancy, and the use of imagery during labour and in the postnatal period may have benefits for women in labour and the postnatal period (Marc 2011). Moreover, there were no harmful effects from any mind-body interventions (Marc 2011). However, the evidence was limited since there were a small number of studies and methodological limitations (such as lack of blinding and lack of detail in relation to the randomisation) in the studies included (Marc 2011). There has been no Cochrane Review on interventions for FOC to date. There has been much debate about FOC, and an upsurge in research in the field, but little evidence as to which interventions are effective, and variation in outcomes measured (Weaver 2013; Moghaddam Hosseini 2017; Stoll 2018). To date, a lot of the research focus has been on reducing CS at maternal request, rather than on reducing fear and evaluating the overall outcome for the woman (physical, psychological and emotional). Therefore this is an emerging area of concern for women, obstetricians and midwives.

The aim of this review is to investigate the evidence in relation to antenatal interventions for FOC.

Description of the intervention

Since the reasons for FOC are multifactorial and different for each individual, interventions should ideally address the complex nature of the fear, taking into consideration the social, physical, psychological and emotional factors in women's lives. There is a need to investigate: a) severity of FOC, and the effect on women's day to day life, b) aetiology, cause or nature of the fear (i.e. lack of self-efficacy in the ability to birth, previous sexual abuse, previous negative birth experience, low social support, fear of the unknown), c) concurrent symptoms (i.e. antenatal depression, any other complications of pregnancy), d) parity/risk factors, e) social factors (i.e. social networks available, partner support, access to the treatment), f) values and world views in relation to the available treatment (i.e. culture, religion, beliefs, expectations of the treatment). Therefore, a range of different antenatal interventions will be considered in this review including (but not limited to) pharmacological interventions; such as epidural administration, and non-pharmacological interventions such as; group and individual Cognitive Behavioural Therapy (CBT) in person and via the internet, group psycho-education by midwives, counselling for FOC by midwives, childbirth preparation classes, yoga, relaxation and mindfulness techniques.

How the intervention might work

Given that the potential risk factors for FOC are low social support, single marital status, low maternal age, and co-morbid depression or anxiety (Rouhe 2011; Räisänen 2014; Stoll 2018), the importance of psychosocial factors is evident for women with FOC. Therefore, interventions usually target these psychosocial factors using a combination of various approaches and promote not only a reduction in fear but a positive birth experience, which would prepare the mother for a positive transition to motherhood (Airo Toivanen 2018). It has been proposed that providing a sense of security and safety is particularly important for women with FOC throughout the antenatal period (Airo Toivanen 2018). Other approaches have focused on understanding the birth process and awareness of the body in general in order to prepare the mother emotionally for childbirth (Airo Toivanen 2018).

There is more and more focus on applying a salutogenic model of health to birth (meaning an approach that focuses on overall maternal health and well-being rather than pathology) (Antonovsky 1987; Greer 2014). Under this theory, the main aim should be for mothers to make a smooth transition to parenthood with their physical, psychological and emotional health intact, and have a birth experience which they evaluate as positive. While various interventions exist, how treatment works is still unclear. However, women have seen benefits from non-pharmacological approaches, such as psychological interventions (CBT or psycho-education) which focus on psychological factors, and informational interventions which focus on delivering education and preparing women for the birth and transition to motherhood (Toohill 2014; Nieminen 2015). CBT has demonstrated an improvement in symptoms of FOC in this population as well as decreased CS on request (Saisto 2001; Larsson 2018). CBT is well-recognised as an effective treatment for a range of psychological disorders (Andersson 2014; Ghazaie 2016), but the causal mechanism of the treatment is largely unknown. A recent study investigating CBT for major depressive disorder and PTSD suggested that the CBT mechanism may work by enhancing the cognitive control region connectivity (the amygdala and fronto-parietal region of the brain) (Shou 2017). The researchers (Shou 2017) suggest that having strengthened these connections through CBT, may lead to improved control of affective processes in situations. Findings of this study are an important development in understanding the mechanism of CBT, but may not be generalisable due to the limitations of the study (small sample size (n = 65) and a slight variation in the therapy used in the study). Therapeutic interventions may be appropriate for assisting women to understand the source of the fear and equip them with tools to manage it (e.g. conversation, music or art therapy).

There is limited evidence in relation to the use of pharmacological interventions in women with FOC. Pain catastrophising is a concept which denotes "an exaggerated negative mental set brought to bear during painful experiences" (Sullivan 2001). It has been suggested that women with FOC are prone to catastrophise pain

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in labour and birth, leading to more intense perceived pain, therefore they may be more likely to utilise epidural analgesia during labour (Rondung 2016). In addition, previous research reported that women with FOC had reduced tolerance of labour pain during and after pregnancy (Saisto 2001 A). In a study by Adams and colleagues, women with FOC were significantly more likely to request an epidural than women without FOC (Adams 2012). More recently, a study by Logtenberg and colleagues, also found that women with FOC were more likely to request pharmacological pain relief but it was not statistically significant (Logtenberg 2018).

Some interventions have included partners, while others have focused solely on the mother. Given that the prevalence of FOC in partners was similar to the prevalence in pregnant women, 13% in a Swedish study (n = 329) (Eriksson 2005), it could be conceived that partners should be included in interventions. A small study of 100 women in Sweden in 1997 reported that 22% of partners demanded a CS (Sjogren 1997). This study also reported that partners of women who previously experienced a complicated birth were significantly more likely to be fearful (Sjogren 1997). A qualitative study of 20 Swedish men with severe FOC highlighted the need for strategies to identify and support fathers as well as mothers (Eriksson 2007). Following on from this, findings from a qualitative study of Swedish midwives' perceptions of FOC suggest that partners with FOC may give poor support to labouring women and the researchers recommend that midwives should also ask partners about FOC (Salomonsson 2010). Thus, interventions which welcome both partners should be considered in comparison with those that focus solely on the woman.

In this review, interventions for FOC will be evaluated in terms of effectiveness in reducing fear for any women identified as requiring support/an intervention for FOC during pregnancy.

Why it is important to do this review

Traditionally, research in the area of perinatal mental health focuses on depression, but anxiety is prevalent in both the general, and pregnant population (Howard 2014), therefore more evidence is required to address this knowledge gap. Moreover, it is increasingly apparent that FOC may be a predictor for maternal psychological health and well-being in the perinatal period. There is consistent evidence that FOC is strongly associated with impaired psychological well-being during pregnancy, e.g. women are more likely to have antenatal depression (Rouhe 2011) and it may be a predictor for their postnatal mental health (Howard 2014). Women with FOC may ruminate or worry, and sometimes what starts out as a little worry or anxiety in early pregnancy, can become magnified and escalate to high or severe FOC as birth becomes more imminent. Severe FOC has been linked to physical complaints, such as sleep disturbances like insomnia and nightmares, to stomach and headaches, which may result in increased attendances at the General Practitioner/midwife or hospital. Moreover, FOC can negatively impact partner relationships (Salomonsson 2010), which is important as low levels of social support and partner dissatisfaction are significantly associated with FOC (Salomonsson 2010; Toohill 2014; Gao 2015). There is evidence that information provided to women in the clinical setting may have a positive or negative influence on FOC (Salomonsson 2010). It has also been suggested that FOC may be passed on through generations from mother to daughter, where a mother may have had a traumatic experience and transmit FOC to her daughter through her vicarious experience (Hofberg 2003), therefore treatment of FOC may have transgenerational effects. Therefore, supporting mothers in the perinatal period may have long-term benefits for their own health and that of their infant.

OBJECTIVES

The primary objective of this review is to investigate the effectiveness of non-pharmacological interventions on reducing fear of childbirth (FOC) compared with standard maternity care in pregnant women with FOC.

METHODS

Criteria for considering studies for this review

Types of studies

All published, unpublished, and ongoing randomised controlled trials (RCTs) and cluster-randomised controlled trials of non-pharmacological interventions or in which the primary or secondary aim is to treat fear of childbirth (FOC).

We will exclude quasi-randomised trials (e.g. those randomised by even versus odd medical record numbers) and cross-over trials from the analysis. When studies are published in abstract form we will list the study as 'awaiting classification' and contact the study author to attempt to retrieve raw data or the full publication of the study as soon as it is available.

Types of participants

Women with high or severe FOC in pregnancy as defined in each individual trial.

Diagnosis

We will include women who are identified as having FOC according to each individual study with varying levels of severity from high to severe. This will include women with high or severe levels

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of fear using the threshold cut-off on each self-report assessment tool as designated by each individual trial protocol (i.e. Wijma Delivery Expectancy Questionnaire version A (W-DEQ A) Wijma 1998), or women who have received a diagnosis of tocophobia according to a clinical assessment using a structured clinical interview by a psychologist or psychiatrist.

Setting

We will include women from all settings in this review, e.g. primary care setting, outpatients, home and hospital, who participated in the various clinical trials.

Co-morbidities

We will include women with a co-morbid medical condition if the main focus of the study is FOC, rather than the co-morbid condition (such as depression).

Exclusion criteria

None.

Types of interventions

We will consider any non-pharmacological antenatal intervention affecting levels of FOC in women. Non-pharmacological approaches consist of psychosocial and psychological interventions (e.g. behavioural and educational strategies), physical exercise interventions (e.g. mind-body interventions like mindfulness, relaxation, yoga and Pilates) and therapeutic interventions (e.g. music and art therapy). Psychosocial interventions include diverse supportive interactions, examples of psychological interventions include CBT and psychotherapy. Psychosocial and psychological interventions may be delivered in group or individual sessions, face-to-face, or by telephone, or via the Internet. The intervention may be delivered by a trained professional (e.g. psychiatrist, psychologist, social worker, midwives or obstetricians) or by a trained lay person or a trained therapist (art or music therapist), and may, or may not, include the partner in the intervention. Any type, frequency and duration of intervention will be considered in both clinical and non-clinical settings. Two review authors (MOC and SON) will determine the type of interventions as either psychosocial, psychological, or therapeutic intervention where a lack of consensus arises, a third person (PL-W) will be consulted to reach an agreement as necessary since sometimes they are used in combination.

Comparison interventions

We will include comparisons between intervention groups versus standard or usual maternity care (as defined by the trialists) for the duration of the clinical trial. Standard or usual care will include healthcare as appropriate during the clinical trial. We will include comparisons between psychosocial versus psychological interventions.

Types of outcome measures

A number of outcomes will be examined relevant for the mother, infant and family in this review.
We will use time points of measurements as reported in the trials and assess the outcome measures at the end of treatment.

Primary outcomes

Fear of childbirth as measured by a validated tool such as the Wijma Delivery Expectancy Questionnaire version A (W-DEQ A) (Wijma 1998) or the Visual Analogue Scale (VAS) known as the Fear of Birth Scale (FOBS) (Rouhe 2011).

Secondary outcomes

1. Caesarean section.
2. Anxiety (as measured on generally accepted scales [e.g. State Trait Anxiety Index (STAI) (Brunton 2015), Generalised Anxiety Disorder Scale (GAD-2) (Nath 2018), Beck Anxiety Inventory (BAI) (Beck 1993), the anxiety subscale of the Hospital Anxiety and Depression Scale (HADS-A) (Zigmond 1983), Pregnancy Specific Anxiety Scale (PSAS) (Roesch 2004), Pregnancy Related Anxiety Questionnaire (PRAQ, PRAQ-R and PRAQ-S) (Brunton 2015)].
3. Depression (as measured on generally accepted scales, e.g. EPDS (Cox 1987).
4. Birth preferences (as reported by the woman using any self-report scale).
5. Epidural analgesia during labour.

Search methods for identification of studies

No date or language restrictions will be applied when searching and selecting the studies for inclusion in the review. The search will be conducted by the Cochrane Pregnancy and Childbirth Information Specialist using key relevant search terms for this review.

Electronic searches

We will search Cochrane Pregnancy and Childbirth's Trials Register by contacting their Information Specialist
The Register is a database containing over 25,000 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

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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);
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 will be been fully accounted for in the relevant review sections (Included, Excluded, Awaiting Classification or Ongoing).

In addition, we will search ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform (ICTRP) for unpublished, planned and ongoing trial reports (see:Appendix 1 for search terms we plan to use).

Searching other resources

We will handsearch the reference list of all relevant studies identified. Where only abstracts of studies are available, we will contact authors for further details. We will not apply any language or date restrictions.

Data collection and analysis

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

Selection of studies

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

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

Data extraction and management

We will use a standardised data extraction form for eligible studies, where two review authors (MOC, SON) will extract the data independently. This standardised data extraction form will include type of study, study setting, characteristics of participants, interventions, main outcome measures, trial dates, duration of study, results of main outcome measures, sources of trial funding and the trial authors' declarations of interest. We will resolve discrepancies through discussion or, if required, we will consult a third person (AK). We will enter data into Review Manager software (RevMan 2014) and check for accuracy.

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

Assessment of risk of bias in included studies

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

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

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

We will assess the method as:

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

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

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

We will assess the methods as:

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

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

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

We will assess the methods as:

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

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

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

We will assess methods used to blind outcome assessment as:

- low, high or unclear risk of bias.

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

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

We will assess methods as:

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

(5) Selective reporting (checking for reporting bias)

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

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

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

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

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

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

(7) Overall risk of bias

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

Assessment of the quality of the evidence using the GRADE approach

The quality of the evidence will be assessed using the GRADE approach as outlined in the GRADE handbook in order to assess the quality of the body of evidence relating to the following outcomes for all comparisons.

1. Fear of childbirth (FOC) as measured by a validated tool such as the Wijma Delivery Expectancy Questionnaire version A (W-DEQ A) (Wijma 1998) or the Visual Analogue Scale (VAS) known as the Fear of Birth Scale (FOBS) (Rouhe 2011).
2. Caesarean section.
3. Anxiety (as measured on generally accepted scales (e.g. State Trait Anxiety Index (STAI) (Brunton 2015), Generalised Anxiety Disorder Scale (GAD-2) (Nath 2018), Beck Anxiety Inventory (BAI) (Beck 1993), the anxiety subscale of the Hospital Anxiety and Depression Scale (HADS-A) (Zigmond 1983), Pregnancy Specific Anxiety Scale (PSAS) (Roesch 2004), Pregnancy Related Anxiety Questionnaire (PRAQ, PRAQ-R and PRAQ-S) (Brunton 2015)).

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4. Depression (as measured on generally accepted scales, e.g. EPDS (Cox 1987).

5. Birth preference (as reported by the woman using any self-report scale).

6. Epidural analgesia during labour.

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

Measures of treatment effect

Dichotomous data

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

Continuous data

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

Unit of analysis issues

Cluster-randomised trials

We will include cluster-randomised trials in the analyses along with individually-randomised trials. We will adjust their standard errors 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 subgroup analysis to investigate the effects of the randomisation unit.

Cross-over trials

We will not include cross-over trials.

Multi-armed trials

We will include multi-armed trials in the analysis. In cases of several treatment arms, if a randomised controlled trial (RCT) included more than two arms, each arm will be compared to the control group as a separate study. We will combine the arms if some arms in the multi-arm study could be classified into the same intervention or control group. If more than one group meets the criteria for 'standard care' then we will combine this as the 'control arm'.

Dealing with missing data

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

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

Assessment of heterogeneity

We will assess statistical heterogeneity in each meta-analysis firstly by visual inspection of a forest plot, and then by 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 the Tau^2 is greater than zero, or there is a low P value (less than 0.10) in the Chi^2 test for heterogeneity.

Assessment of reporting biases

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

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Data synthesis

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

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

Subgroup analysis and investigation of heterogeneity

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

We plan to carry out the following subgroup analyses.

1. Mode of Intervention: individual versus group
2. Presence of co-morbidity: depression (yes versus no)
3. Timing of the intervention during pregnancy: first versus second versus third trimester

Subgroup analysis will be restricted to the review's primary outcome (fear of childbirth).

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 will perform sensitivity analysis by quality of included studies as necessary. If there are sufficient included studies in the analysis (more than 10), the impact of study quality will be investigated by sensitivity analysis. We will temporarily exclude studies at high risk of bias (allocation concealment, blinding of outcome assessors) from the analyses. We will also carry out sensitivity analysis to investigate statistical heterogeneity where necessary using a fixed-effect or random-effects model for analysis. It may be necessary to carry out further analysis if it is deemed appropriate during the process of the review as per Section 9.7 of the *Cochrane Handbook for Systematic Reviews of Interventions*, "many issues suitable for sensitivity analysis are only identified during the review process when the individual peculiarities of the studies under investigation are identified" (Higgins 2011). In this case, we will provide a rationale for this additional analysis in our review and stipulate clearly that this is a "non-specified analyses". If we include cluster-RCTs and we use intracluster correlation co-efficients (ICCs) from other sources, we will report this and conduct sensitivity analysis to examine the effect of variation in ICC.

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* *Indicates the major publication for the study*

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APPENDICES

Appendix 1. Search terms used for ClinicalTrials.gov and the WHO ICTRP

We plan to run each line separately
Draft search terms for the WHO International Clinical Trials Registry Platform (ICTRP)
fear AND childbirth
tocophobia
tokophobia
parturiphobia
lockiophobia
fear AND labour
fear AND pregnancy
fear AND birth
pregnancy AND anxiety
childbirth AND anxiety
birth AND anxiety
Draft search terms for ClinicalTrials.gov
Advanced search
Interventional Studies | Tocophobia
Interventional Studies | Tokophobia
Interventional Studies | Fear of Childbirth
childbirth | Interventional Studies | Anxiety ('childbirth' also searches for delivery and birth)
pregnancy | Interventional Studies | Anxiety
childbirth | Interventional Studies | Fear
pregnancy | Interventional Studies | Fear

CONTRIBUTIONS OF AUTHORS

All seven authors were involved in the authorship of this protocol. Maeve O'Connell co-ordinated and drafted the protocol, and is the guarantor of the review. Louise Kenny, Rebecca Smyth, Eugene Dempsey and Patricia Leahy-Warren assisted in conceiving the review and gave their clinical perspective. Sinéad O'Neill and Ali Khashan provided statistical advice in addition to general advice on the development of the protocol.

DECLARATIONS OF INTEREST

Maeve A O'Connell: Maeve is the recipient of a full Cochrane Training Fellowship supported by the Health Research Board, Ireland (Grant No: CTF-2016-1858).

Sinéad M O'Neill: received a Cochrane Training Fellowship supported by the Health Research Board, Ireland to prepare a different Cochrane review (Different insulin types and regimens for pregnant women with pre-existing diabetes) that was published in 2017.

Eugene Dempsey: none known.

Ali S Khashan: none known.

Patricia Leahy-Warren: none known.

Rebecca MD Smyth: none known.

Louise C Kenny: is Director of INFANT and has numerous grant applications under review at any given time. She has been paid by Alere to given invited symposia on a proprietary screening test for preeclampsia. She is the editor of Ten Teachers and has received royalties from the publishers. She is also a limited shareholder in Metabolomic Diagnostics, an SME who have licensed technology that she has developed pertaining to the screening of preeclampsia.

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