

Antenatal maternal education for improving postnatal perineal healing for women who have birthed in a hospital setting.

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Cochrane Database of Systematic Reviews

Antenatal maternal education for improving postnatal perineal healing for women who have birthed in a hospital setting (Review)



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[Intervention Review]

Antenatal maternal education for improving postnatal perineal healing for women who have birthed in a hospital setting

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ABSTRACT

Background

The female perineum becomes suffused and stretched during pregnancy, and further strain during vaginal childbirth contributes to approximately 85% of women experiencing some degree of trauma to the perineal region. Multiple factors play a role in the type and severity of trauma experienced, including parity, delivery method, and local practices. There is ongoing debate about best midwifery practice to reduce perineal trauma. Once perineal trauma has occurred, treatment also varies greatly, depending on its degree and severity, local practice and customs, and personal preference. In order to optimise wound-healing outcomes, it is important that wounds are assessed and managed in an appropriate and timely manner. A perineal wound may cause significant physical and/or psychological impact in the short or long term, however little evidence is available on this subject.

Antenatal education serves to prepare women and their partners for pregnancy, delivery and the postpartum period. The delivery of this education varies widely in type, content, and nature. This review examined antenatal education which is specifically tailored towards perineal care and wound healing in the postnatal period via formal channels. Appropriate patient education positively impacts on wound-healing rates and compliance with wound care. Risk factors that contribute to the breakdown of wounds and poor healing rates may be addressed antenatally in order to optimise postnatal wound healing. It is important to assess whether or not antenatal wound-care education positively affects perineal healing, in order to empower women to incorporate best practice, evidence-based treatment with this important aspect of self-care in the immediate postnatal period.

Objectives

To evaluate the effects of antenatal education on perineal wound healing in postnatal women who have birthed in a hospital setting, and who have experienced a break in the skin of the perineum as a result of a tear or episiotomy, or both.

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (30 September 2017), Clinical Trials.gov (8th September 2017), the WHO International Clinical Trials Registry Platform (ICTRP) (8th September 2017) and reference lists of retrieved studies.

Selection criteria

We considered randomised controlled trials (RCTs) which referred to all formal methods of antenatal education and addressed care of a potential perineal wound as a result of a tear or episiotomy, which was experienced by pregnant women who planned to give birth within a hospital setting.

Trials using a cluster-RCT and a quasi-randomised design would have been eligible for inclusion in this review but none were identified. Cross-over trials were not eligible for inclusion in this review. Studies published in abstract form would have been eligible for inclusion in this review, but none were identified.

We planned to consider all formal methods of antenatal education which addressed care of a perineal wound. We also planned to consider all contact points where there was an opportunity for formal education, including midwifery appointments, antenatal education classes, obstetrician appointments, general practitioner appointments and physiotherapist appointments.

Data collection and analysis

Two review authors independently assessed titles and abstracts of the studies identified by the search strategy for their eligibility.

Main results

No studies met the inclusion criteria for this review. We excluded one study and one other study is ongoing.

Authors' conclusions

We set out to evaluate the RCT evidence pertaining to the impact of antenatal education on perineal wound healing in postnatal women who have birthed in a hospital setting, and who experienced a break in the skin of the perineum as a result of a tear or episiotomy, or both. However, no studies met the inclusion criteria. There is a lack of evidence concerning whether or not antenatal education relating to perineal wound healing in this cohort of women will change the outcome for these women in relation to wound healing, infection rate, re-attendance or re-admission to hospital, pain, health-related quality of life, maternal bonding, and negative emotional experiences. Further study is warranted in this area given the significant physical, psychological and economic impact of perineal wounds, and the large proportion of childbearing women who have experienced a postnatal wound. The benefits of any future research in this field would be maximised by incorporating women in a range of socio-economic groups, and with a range of healthcare options. This research could take both a qualitative and a quantitative approach and examine the outcomes identified in this review in order to assess fully the potential benefits of a tailored antenatal package, and to make recommendations for future practice. There is currently no evidence to inform practice in this regard.

PLAIN LANGUAGE SUMMARY

The impact of antenatal education on wound-healing rates for women who have given birth in a hospital

What is the issue?

In hospitals, a large majority of women who give birth vaginally suffer from an injury to their perineum, the area of skin and muscle between the anus and the vagina. This injury may be bruising or tearing, or occur as a result of a deliberate cut to assist with childbirth. As women are often discharged from hospital very shortly after childbirth, they may be left to care for this wound themselves, without healthcare supervision. The type and extent of the injury varies, as does the treatment for these wounds. They might have stitches, need cold packs and analgesics or anti-inflammatories for pain relief; or salt baths, wound packing, and antibiotics to help with healing. Many women are not warned of the likelihood or prepared for a perineal wound. They do not know how to manage and care for the wound. This may result in complications such as increased pain and discomfort, distress, risk of infection, and difficulty with urination and having sexual intercourse. This review aimed to examine whether providing education to women before childbirth, about the expectation and management of a perineal wound, made a difference to wound healing after childbirth.

Why is this important?

Perineal wounds that do not heal well impact poorly on women's health, on the relationship between the mother and her baby, and on family relationships. Healthcare professionals are in the unique position of being able to provide up-to-date and accurate advice, and can play a key role in educating women in this important aspect of their personal care. Appropriate formal education provided before childbirth might lessen the shock and distress associated with a perineal wound, and empower the mother to manage the treatment of

the wound, thereby reducing the risk of complications. This review aimed to examine whether providing education to women before childbirth, either as part of antenatal education or during visits to their healthcare provider, made a difference to wound healing after childbirth.

What evidence did we find?

We searched for evidence in September 2017 but did not find any randomised controlled studies relating to our area of interest. We excluded one study and one other study is not yet complete.

What does this mean?

We cannot say whether or not antenatal education has an effect on perineal wound healing after childbirth among women who have birthed in a hospital setting. We do not know from randomised controlled trials what the benefits and harms of this education might be. More research is this area is needed to determine the impact of education delivered before childbirth on perineal wound healing in women who have birthed in a hospital setting. Trials may also examine the outcome on related issues including infection rate, re-attendance or re-admission to hospital, pain, health-related quality of life, maternal bonding, and negative emotional experiences relating to a perineal wound. A large proportion of childbearing women experience a perineal wound in childbirth, and these wounds are known to have a significant physical, psychological and economic impact. Future research could examine the potential benefits of a tailor-made education package to be delivered to this cohort of women, as there is currently no evidence to support this.

BACKGROUND

The female perineum is the area of tissue stretching from the anus to the fourchette of the vulva (Henderson 2006). In pregnancy, this area becomes suffused due to pressure exerted from the growing uterus and the increased blood flow to the region (Henderson 2006). During childbirth, the perineum is stretched, and may experience trauma through bruising, grazing, tearing, or arising as a result of a deliberate incision (episiotomy). Perineal wounds are commonly experienced during vaginal childbirth. It is claimed that 85% of women experience perineal trauma, with at least one third of women experiencing a spontaneous tear (Kettle 2011).

Perineal tears usually extend through the weakest part of the stretched perineum (Henderson 2006). The type and extent of perineal trauma experienced varies due to a number of factors, including delivery method and speed of childbirth, parity, fetal size and position (Beckmann 2013), geographical location of the birth, and cultural and local practices. One UK study found that there was a higher incidence of perineal trauma during delivery within a hospital setting compared to delivery within a community care setting (Smith 2013). Studies have also shown that continuous support in labour lessens the rate for assisted vaginal births, which subsequently lowers the rate of perineal trauma (Kettle 2011). There is some argument that women feel more comfortable and supported when labouring in a non-medical setting, and that this accounts, in part, for the lower rate of perineal trauma outside the hospital environment (Smith 2013).

Description of the condition

Perineal trauma can be defined as being anterior or posterior. Anterior perineal trauma includes any injury to the labia, clitoris, anterior vagina or vulva, while posterior perineal trauma includes any injury to the posterior vaginal wall, perineal muscles, and anal sphincters (Henderson 2006). Posterior perineal trauma is classed on a gradient system which includes bruising, first-degree lacerations, second-degree lacerations, third-degree lacerations, and fourth-degree lacerations (Henderson 2006). Rates of perineal trauma are particularly high in women during a first vaginal birth (Albers 1999), with multiparous women (having birthed more than one child) being approximately three times more likely to have an intact perineum (31.2%) when compared to nulliparous women (9.6%) (Smith 2013). Perineal trauma is a big feature in vaginal childbirth with only 20.5% of women (nulliparous and multiparous combined) who birthed a baby vaginally in the New South Wales area of Australia in 2014 having an intact perineum postnatally (Centre for Epidemiology and Evidence 2014).

A first-degree laceration is one or more superficial lacerations involving the skin and subcutaneous tissue and/or vaginal mucosa. A second-degree laceration may involve the superficial perineal muscles, the perineal body, and/or the deep perineal muscles (Henderson 2006). A second-degree laceration can be further subcategorised into either an episiotomy (deliberate cut) or a natural tear. A third-degree laceration is an extension of a second-degree laceration through the perineal muscles into the anal sphincters. This may be subdivided into 3a (up to 50% of external anal sphincter torn), 3b (more than 50% of external anal sphincter torn),

and 3c (external anal sphincter completely torn and internal anal sphincter also torn) (Fernando 2013). A fourth-degree laceration involves the anorectal epithelium (Fernando 2013). In first world countries, second-, third-, and fourth-degree tears are commonly closed using stitches.

Interventions applied in some areas of the world to attempt to reduce perineal trauma include warm compresses and perineal massage (Aasheim 2011), and a hands-on approach during delivery of the head (McCandlish 1998). Women who had not birthed a baby vaginally before who performed digital perineal massage during the final four weeks of pregnancy experienced a reduction in perineal trauma requiring suturing (Beckmann 2013), however, the authors note that other factors may also be involved in the reduction of perineal trauma and the evidence for this practice is not strong enough to recommend it universally. There is ongoing debate about best practice for midwives with regard to perineal care and the prevention of perineal trauma. The UK 'HOOP' trial in 1998 showed that women who gave birth using the 'hands on' method of delivery reported significantly lower levels of pain 10 days post delivery at 31.1% when compared to the 'hands poised' group who showed pain levels at 34.1% 10 days post delivery (McCandlish 1998). Those in the 'hands poised' group had a significantly lower rate of episiotomy, but a significantly higher rate of manual removal of placenta (McCandlish 1998; Aasheim 2011).

Perineal trauma rates and types also vary depending on geographical location and local practice. In one hospital setting in Ireland, 18.05% of women who birthed a baby vaginally in 2014 had an episiotomy or extended episiotomy, 79.6% of which occurred in nulliparous women (The Rotunda Hospital 2014). In the same 12-month period, 7.84% of women birthing a baby vaginally had a first-degree tear, 21.08% had a second-degree tear, 1.83% had a third-degree tear, 0.06% had a fourth-degree tear, and 8.24% had grazes or lacerations which were deemed not to require suturing. Indeed, of the 8665 nulliparous and multiparous women who birthed a baby vaginally in the hospital in 2014, 57.1% had a postnatal perineal wound (The Rotunda Hospital 2014).

In 2012 in the New South Wales area of Australia, of the 67,565 women who had given birth vaginally, 18.4% of women had an episiotomy or extended episiotomy; 29.1% of women experienced a first-degree tear or graze, 27% experienced a second-degree tear, and 2% experienced a third- or fourth-degree tear (Centre for Epidemiology and Evidence 2012). A 2005 US study found an overall rate of perineal trauma of 85% including episiotomies, perineal lacerations, and all degrees of perineal tears (Albers 2005). A cross-sectional study in rural India carried out between 2004 and 2005 examined episiotomy rates in 442 vaginal births (Sathiyasekaran 2007). Significant differences were found in the rates between private birth places (80.6%) and public birth places (64.7%), and between doctor-led deliveries (77.4%), nurse-led deliveries (53.1%) and trained birth attendant deliveries (5%). Essentially, the study concluded that the episiotomy rate increased

with a corresponding increase in the standard of living. The rate decreased with parity (the number of times a woman has given birth to a fetus with a gestational age of 24 weeks or more), with a rate of 83.4% in primigravidas (pregnant for the first time), down to 30.8% in women experiencing a third or subsequent vaginal birth (Sathiyasekaran 2007). This study also showed an increase in postnatal complications among women with episiotomies, the most common reported being perineal pain and wound infections, with 14.5% of women with episiotomies experiencing complications compared to 4.8% in women who did not have episiotomies (Sathiyasekaran 2007).

Episiotomy rate can also change within a geographical area in response to changing practice and customs. For example, in England the rate of episiotomy fell from 51% in 1975 to 15% between 2010 and 2011 (Health & Social Care Information Centre 2011). There is some evidence to suggest that women of Asian ethnicity are at a higher risk of developing perineal complications from vaginal childbirth (Williams 2007). This has been reinforced by a subsequent Norwegian study examining obstetric outcomes among immigrants and found that even in a low-risk maternity unit, women of African and South Western Asian descent suffered higher rates of complications, thus suggesting more targeted antenatal and perinatal care and education (Bakken 2015). There has also been some conflicting evidence in the literature as to the type of episiotomy best performed with measured angles often significantly smaller than expected. There is a 50% relative risk reduction in third-degree tears for every six degrees away from the perineal midline, and therefore it is advocated to create as large an angle as possible in a medio-lateral incision (Eogan 2006).

Treatment for perineal trauma includes, but is not limited to, one or a combination of the following - primary treatment such as sutures (stitches) in the immediate postnatal period, cold pack application, and analgesics and anti-inflammatories for pain relief; and secondary treatment such as salt baths, wound packing to allow wounds to heal by secondary intention, pelvic floor exercises, and antibiotics (Dudley 2013). The choice of treatment used depends on the nature and severity of the trauma, and again, is often influenced by local practice and customs, and on the training and experiences of the person who is recommending the treatment. It is important that wounds are assessed and managed appropriately in order to optimise wound-healing outcomes. Furthermore, there are well-documented modifiable factors that contribute to the breakdown of wounds and poor healing rates, including obesity, malnutrition and poor hygiene (Kamrava 2013). These risk factors are of significance in postnatal women and can potentially be positively influenced with education delivered to the pregnant woman before childbirth. When perineal wound healing is delayed, the associated economic costs can be considerable, including increased GP visits and hospital admissions, and increased use of antibiotics and analgesics (Kamrava 2013).

There is also a significant physical and psychological impact on those affected by these perineal wounds. Short-term problems include haemorrhage, the need for suturing, and pain (Albers 2005), as well as incontinence, and sexual morbidity (Williams 2007). These morbidities are further increased with a delay in wound healing and subsequent delay in the return of normal perineal function. Longer-term problems may include continued perineal pain, which 22% of women in one study group experienced at eight weeks postnatal (Albers 2005). Between 7% and 9% of women reported perineal pain at three months postpartum (McCandlish 1998), and up to 40% of women in another study group reported dyspareunia (difficult or painful sexual intercourse) at three months postpartum (Mahony 2008). Weakened pelvic floor muscles contribute to longer-term effects on bowel, urinary and sexual function (Albers 2005). Perineal trauma can lead to faecal incontinence, dyspareunia and urinary problems (Kettle 2011).

Description of the intervention

The antenatal period is defined as the period of time in which a woman is pregnant - typically 37 to 42 weeks in duration. The woman may seek antenatal care throughout this period, which in developed countries may include visits with a healthcare professional, including a doctor or midwife, in order to monitor the pregnancy itself, and to receive antenatal education (Svensson 2008). Women's education is the process whereby health professionals impact knowledge to a woman with the aim of improving their health behaviours or health condition (Koongstvedt 2001).

Antenatal education was traditionally delivered in a group setting, focusing on labour and childbirth, with the primary aim to prepare women to safely birth a baby (Svensson 2008). Over time, this concept has shifted gradually to include more health promotion and the development of life skills in order to enable people to adopt better health practices (Svensson 2008), the enhancement of the birth experiences for mother and partner, while also improving antenatal and postnatal maternal and fetal well-being (Brixval 2014), and the reduction in perinatal mortality and morbidity (Gagnon 2007). One such morbidity sustained in childbirth is a perineal wound. Midwives and antenatal education providers have a key role to play in maternal education to prepare the mother for childbirth and also for perineal care after childbirth.

The education provided during the antenatal period ranges widely in type of delivery and content (Gagnon 2007), and may include some or all of the following, among others: structured antenatal classes in a group or individual setting, written educational information, formal or informal advice and information from websites, publications or social media, and social contact with family or friends. As it comes from a wide variety of sources, the content varies hugely in its reliability and robustness (Gagnon 2007). There is little evidence available on the effect of this education shift on clinical outcomes (Brixval 2014).

Appropriate education is of importance with regard to wound care, as this has the potential to minimise factors that delay wound healing, and to enhance health promotion opportunities. Indeed, ev-

idence suggests that appropriate patient education positively impacts on wound-healing rates and compliance with wound care (Shanley 2015). However, there tends to be a large variation in the practices used for perineal care, some of which may not be beneficial to promoting optimum wound healing (Grundy 1997). As women are often discharged from maternity hospitals within a few days of delivery, they are largely tending to their perineal care themselves, and varying degrees of problems are experienced, including dehiscence, infection, pain, interference with maternal bonding, and depression (Priddis 2014). In worse-case scenarios, some women will need to be readmitted to hospital for further treatment or repair. The secondary effects arising from these difficulties in perineal repair may last for several months or even years (McCandlish 1998).

The intervention to be examined in this review is antenatal education which is specifically tailored towards perineal care and wound healing in the postnatal period. For the purpose of this review, the delivery of this information via formal antenatal education classes will be included as well as that delivered during contacts with a qualified healthcare professional (including doctors and midwives). Information given informally via web sites, social media, social contact and informal publications will be excluded.

How the intervention might work

The intervention will theoretically be aimed at explaining to women what a perineal injury involves, and that they may sustain such an injury during childbirth. Perineal trauma sustained during childbirth can have a significant detrimental effect on maternal physical and psychological well-being postnatally (Stolberg 2012). Studies have shown that psychological distress can cause a substantial delay in wound healing, both through physiological processes and as stressed individuals are more likely to display unhealthy habits, including erratic sleep patterns and poor nutrition (Guo 2010). It is also established that postnatally, women focus their lives on their baby rather than themselves (Coutinho 2014), which will also affect their lifestyle, sleep patterns and nutrition, and so it is imperative that information and advice delivered be concise and easy to follow.

There is currently a lack of evidence in the literature demonstrating that having prior knowledge of the possibility of a postnatal perineal wound may decrease the negative emotional impact of such a wound for the woman on her quality of life, however studies have shown that increased education related to wound care in general can significantly increase compliance with the suggested intervention (Van Hecke 2011). It is hoped that by introducing this intervention and by explaining the importance and implications of effective self-care, women may adhere more strictly to best-practice guidelines with regard to perineal wound care.

The intervention will also provide instructions on how to care for the perineum in order to maximise recovery and minimise the negative physical, psychological, social and economic effects of the injury itself, including pain, infection, hospital readmission, GP re-attendance, antibiotic usage, fatigue, dyspareunia, delayed maternal/child bonding, and embarrassment.

There is conclusive research carried out on the prevention of perineal injury in a primigravida through perineal massage among other methods (Beckmann 2013; Seehusen 2014). The intervention of interest to this review will not include information given antenatally about potentially lessening or preventing a perineal wound, rather this review will purely focus on information given in the antenatal period relating to caring for a perineal wound after the event. Health promotion strategies have been shown to be effective in the management of chronic disease (Dennis 2008), however little is known about their effect on perineal care post childbirth.

Why it is important to do this review

Perineal trauma is a factor in a large number of vaginal births worldwide, which, if not cared for correctly, can contribute to prolonged negative experiences in the postnatal period (McCandlish 1998; Williams 2007; Mahony 2008). Short-term problems can include haemorrhage, the need for suturing and associated complications, and pain (Albers 2005). Longer-term problems may include dyspareunia, pain, depression, and interference with maternal bonding (Priddis 2014).

Evidence from research in the area of chronic venous ulceration management suggests that appropriate patient education positively impacts on wound-healing rates and compliance with wound care, with some recent seminal papers demonstrating the importance of patient education and self-management in both primary and secondary prevention of this disease, with an impact on recurrences, quality of life and hospitalisation (Kapp 2015; Shanley 2015). It is important to assess if the same may be true for antenatal wound-care education and perineal healing, in order to empower the women to incorporate best practice, evidence-based treatment with this important aspect of self-care in the immediate postnatal period. Healthcare professionals delivering antenatal care to women can play a key role in teaching the women about perineal care after childbirth.

Varying degrees of problems are experienced with regard to perineal wounds, which may result in women needing to be readmitted to hospital for further treatment or repair. The secondary effects of these difficulties may last for several months or even years, however, very little is known on this subject. The impact of antenatal maternal education on postnatal perineal healing rates in women who birthed within a hospital setting has not yet been evaluated in a systematic way, and it is important to evaluate this in order to inform policy and practice. This, therefore, was the leading motivation behind this review.

OBJECTIVES

To evaluate the effects of antenatal education on perineal wound healing in postnatal women who have birthed in a hospital setting, and who have experienced a break in the skin of the perineum as a result of a tear or episiotomy or both.

METHODS

Criteria for considering studies for this review

Types of studies

We planned to include randomised controlled trials (RCTs) including those using a cluster-randomised design and quasi-randomised design. Studies published in abstract form would have been eligible for inclusion in this review. Cross-over studies were not eligible for inclusion. We did not plan to make any exclusions on the basis of language.

Types of participants

We planned to include studies of pregnant women who intended to give birth within a hospital setting, and who experienced a break in the skin as a result of a tear or episiotomy, or both.

Types of interventions

For the purposes of this review, we planned to consider all formal methods of antenatal education which addressed care of a perineal wound. We also planned to consider all contact points where there was an opportunity for formal education, including midwifery appointments, antenatal education classes, obstetrician appointments, general practitioner appointments and physiotherapist appointments. Studies investigating the following comparisons were eligible.

- 1. Antenatal education for care of a perineal wound compared with no antenatal education for care of a perineal wound
- 2. Comparisons between different health professionals delivering the antenatal education for care of a perineal wound
- 3. Comparisons between different geographical locations for delivering the antenatal education for care of a perineal wound We planned to exclude informal social contacts and social media methods of education including Internet searches from the review.

Types of outcome measures

Primary outcomes

1. An objective measure of wound healing, such as time to complete healing; absolute or percentage change in injured area over time

Secondary outcomes

- 1. Infection rate
- 2. Re-attendance or re-admission into the healthcare service
- 3. Pain at up to three months postnatal (using validated scales where reported, for example McGill Pain scale)
- 4. Health-related quality of life (using validated scales, where reported)
 - 5. Maternal bonding (assessed using reports from women)
 - 6. Negative emotional impact of a postnatal perineal wound

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 Cochrane Pregnancy and Childbirth's Trials Register by contacting their Information Specialist (30 September 2017). The Register is a database containing over 23,000 reports of controlled trials in the field of pregnancy and childbirth. For full search methods used to populate Pregnancy and Childbirth's Trials Register including the detailed search strategies for CENTRAL, MEDLINE, Embase and CINAHL; the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service, please follow this link to the editorial information about the Cochrane Pregnancy and Childbirth in the Cochrane Library and select the 'Specialized Register' section from the options on the left side of the screen.

Briefly, the 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 has been fully accounted for in the relevant review sections (Excluded studies; Ongoing studies).

In addition, we searched Clinical Trials.gov (8th September 2017) and the WHO International Clinical Trials Registry Platform (ICTRP) (8th September 2017) for unpublished, planned and ongoing trial reports. The search methods we used are detailed in Appendix 1.

Searching other resources

We searched the reference lists of all the retrieved studies. We aimed to contact experts in the field to identify further trial information not found in the original search. We planned to write to authors of relevant publications to identify any completed or ongoing trials. We did not apply any language or date restrictions.

Data collection and analysis

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

Selection of studies

Both review authors independently assessed titles and, where available, abstracts of the studies identified by the search strategy against the eligibility criteria for inclusion in the review. We planned to obtain full-text versions of potentially relevant studies and the two review authors would have independently screened these against the inclusion criteria. We planned to include studies meeting the inclusion criteria, presented as just an abstract in the absence of a full study report, providing there was enough information within the abstract to extract the information of interest for this review. Any differences in opinion were to be resolved by discussion and, where necessary, reference to the Cochrane Pregnancy and Childbirth Group editorial base.

We created a Prisma study flow diagram (Liberati 2009) to outline the number of records identified, screened, included and excluded. Futher methods of data collection and analysis to be used in future updates of this review, are provided in Appendix 2.

RESULTS

Description of studies

Results of the search

See: Figure 1.

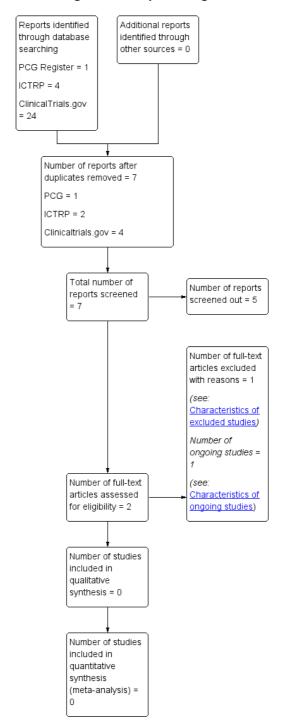


Figure I. Study flow diagram.

The search of ClinicalTrials.gov retrieved 24 results, of which four were left after exact duplicate removal. The search of the WHO International Clinical Trials Registry Platform (ICTRP) retrieved four results, of which two remained after exact duplicate removal. The search of the Cochrane Pregnancy and Childbirth Group's Trials Register retrieved one trial report. Both review authors independently examined the abstracts of all seven papers to assess for potential relevance. Following this, five papers were screened out. Once the full-texts of the remaining two studies had been obtained and examined, one was excluded (Noronha 2004) and one trial is ongoing (Hatamleh 2016).

Included studies

No studies met the criteria for inclusion in this review.

Excluded studies

We excluded one study (Noronha 2004) after reading the full text. This study did not meet the inclusion criteria for our review as it was not a randomised controlled trial. See Characteristics of excluded studies.

Ongoing studies

We have listed Hatamleh 2016 as an ongoing study, but the study has not yet begun recruiting for participants - see Characteristics of ongoing studies.

Risk of bias in included studies

No studies met the inclusion criteria.

Effects of interventions

No studies met the inclusion criteria.

DISCUSSION

Perineal wounds are common in childbirth, and can, if not correctly managed, have a profound and prolonged negative effect on a woman's quality of life postnatally, and subsequently on that of the larger family unit. Some of the detrimental physical and psychological effects of a postnatal perineal wound include haemorrhage, pain, incontinence, and dyspareunia (Albers 2005; Williams 2007; Mahony 2008). The treatment for a perineal wound varies significantly depending on numerous factors including geographical location, hygiene facilities, local customs and practices, and tradition (McCandlish 1998; Aasheim 2011; Dudley 2013). It is important that wounds are assessed and managed appropriately in order to optimise wound-healing outcomes. The existence of a perineal wound can cause shock and distress

to many women, and the wound is often poorly managed by the woman herself, potentially due to lack of accurate and understandable information. Providers of antenatal education have a key role to play in preparing the mother for perineal care after childbirth. It is hoped that in educating a woman antenatally, and her partner or support person where appropriate, the negative impact of a perineal wound may be significantly lessened, and thus the associating co-morbidities may be reduced or eliminated.

No study met the inclusion criteria for this review, and therefore it remains unclear whether or not antenatal education regarding care and management of perineal wounds makes any difference to perineal healing rates postnatally.

Summary of main results

No studies met the inclusion criteria.

Overall completeness and applicability of evidence

No studies met the inclusion criteria.

Quality of the evidence

No studies met the inclusion criteria.

Potential biases in the review process

We followed clearly described procedures including a careful literature search in order to prevent potential bias in the review process. Transparent and reproducible methods were used throughout. However, trials that were published in journals that were outside our search strategy may have been missed.

Agreements and disagreements with other studies or reviews

There is evidence available in systematic reviews for medical professionals relating to antenatal prevention of perineal trauma (Beckmann 2013) and intranatal techniques for reducing perineal trauma (Aasheim 2011). There is also evidence relating to best-practice for healthcare professionals with regard to perineal care in the immediate postnatal period, including information regarding the use and management of sutures (Elharmeel 2011), appropriate pain relief (Chou 2009; East 2012; Wuytack 2016) and antibiotic usage (Buppasiri 2014). There are, however, no systematic reviews that explore the impact that antenatal education has on postnatal perineal wound healing. Due to the lack of information in this field, we are unable to conclude whether or not the introduction of this information in the antenatal period has any effect postnatally.

AUTHORS' CONCLUSIONS

Implications for practice

There is, as yet, no data from randomised controlled trials (RCTs) to evaluate the effects of antenatal education on perineal wound healing in postnatal women who have birthed in a hospital setting, and who have experienced a break in the skin of the perineum as a result of a tear or episiotomy, or both.

women to make positive choices based on best-practice guidelines and may contribute to an overall better quality of life.

The benefits of future research in this area would be maximised by conducting large enough trials to incorporate women in a range of socio-economic groups, and with a range of healthcare options. The research could examine both qualitative and quantitative outcomes of a tailor-made antenatal care education package relating to perineal wounds.

Implications for research

Perineal wounds are common in childbirth and can cause prolonged negative physical and psychological side-effects. The effective and timely management of wounds can contribute to a positive healing experience, and a reduction in co-morbidities. There may also be a reduction in associated healthcare costs resulting from physical, social and emotional needs. We did not identify any trials exploring the impact that antenatal education has on postnatal perineal wound healing. Further research is therefore justified in this area due to the large proportion of childbearing women who have experienced a postnatal wound, and its associated negative impact. Appropriate antenatal education empowers

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REFERENCES

References to studies excluded from this review

Noronha 2004 {published data only}

Noronha JA. Effectiveness of teaching on episiotomy and perineal care among primipara women of selected hospitals in Karnataka. *Journal of Nursing India* 2004;**95**(5):105–6.

References to ongoing studies

Hatamleh 2016 {published data only}

ACTRN12616001255471. Evaluation of the effect of childbirth preparation educational programme on self-efficacy, anxiety, and birth outcomes among first time Jordanian mothers. anzetr.org.au/Trial/Registration/TrialReview.aspx?id=371095 (first received 15 July 2016).

Additional references

Aasheim 2011

Aasheim V, Nilsen ABV, Lukasse M, Reinar LM. Perineal techniques during the second stage of labour for reducing perineal trauma. *Cochrane Database of Systematic Reviews* 2011, Issue 12. [DOI: 10.1002/14651858.CD006672.pub2

Albers 1999

Albers L, Garcia J, Renfrew M, McCandlish R, Elbourne D. Distribution of genital tract trauma in childbirth and related postnatal pain. *Birth* 1999;**26**(1):11–7.

Albers 2005

Albers LL, Sedler KD, Bedrick EJ. Midwifery care measures in the second stage of labor and reduction of genital tract trauma at birth: a randomized trial. *Journal of Midwifery & Women's Health* 2005;**50**(5):365–72.

Altman 1996

Altman DG, Bland JM. Detecting skewness from summary information. *BMJ* 1996;**313**:1200.

Bakken 2015

Bakken KS, Skjeldal OH, Stray-Pederson B. Higher risk for adverse obstetric outcomes among immigrants of African and Asian descent: A comparison study at a low-risk maternity hospital in Norway. *Birth* 2015;**42**(2):132–40.

Beckmann 2013

Beckmann MM, Stock OM. Antenatal perineal massage for reducing perineal trauma. *Cochrane Database of Systematic Reviews* 2013, Issue 4. [DOI: 10.1002/14651858.CD005123.pub3

Brixval 2014

Brixval CS, Axelsen SF, Anderson SK, Due P, Koushede V. The effect of antenatal education in small classes on obstetric and psycho-social outcomes: a systematic review and meta-analysis protocol. *Systematic Reviews* 2014;**3**:12. [DOI: 10.1186/2046-4053-3-12

Buppasiri 2014

Buppasiri P, Lumbiganon P, Thinkhamrop J, Thinkhamrop B. Antibiotic prophylaxis for third- and fourth-degree

perineal tear during vaginal birth. *Cochrane Database* of Systematic Reviews 2014, Issue 10. [DOI: 10.1002/14651858.CD005125.pub4

Centre for Epidemiology and Evidence 2012

Centre for Epidemiology and Evidence. *New South Wales Mothers and Babies 2012*. Sydney: NSW Ministry of Health. 2014

Centre for Epidemiology and Evidence 2014

Centre for Epidemiology and Evidence. *New South Wales Mothers and Babies 2014*. Sydney: NSW Ministry of Health, 2016.

Chou 2009

Chou D, Abalos E, Gyte GML, Gülmezoglu AM. Drugs for perineal pain in the early postpartum period: generic review. *Cochrane Database of Systematic Reviews* 2009, Issue 3. [DOI: 10.1002/14651858.CD007734.pub2

Coutinho 2014

Coutinho EC, Silva CB, Chaves CM, Nelas PA, Parreira VB, Amaral MO, et al. Pregnancy and childbirth: What changes in the lifestyle of women who become mothers [El embarazo y el parto: Qué cambios en el estilo de vida de las mujeres que son madres?]. Revista da Escola de Enfermagen da USP 2014;48(2):17–24.

Deeks 2011

Deeks JJ, Higgins JPT, Altman DG, on behalf of the Cochrane Statistical Methods Group and the Cochrane Bias Methods Group (Editors). Chapter 9: Analysing data and undertaking meta-analysis. In: Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

Dennis 2008

Dennis SM, Zwar N, Griffiths R, Roland M, Hasan I, Powell Davies G, et al. Chronic disease management in primary care: from evidence to policy. *Medical Journal of Australia* 2008;**21**(188 Supp 8):S53–S56.

Dudley 2013

Dudley LM, Kettle C, Ismail KMK. Secondary suturing compared to non-suturing for broken down perineal wounds following childbirth. *Cochrane Database of Systematic Reviews* 2013, Issue 9. [DOI: 10.1002/14651858.CD008977.pub2

East 2012

East CE, Begg L, Henshall NE, Marchant PR, Wallace K. Local cooling for relieving pain from perineal trauma sustained during childbirth. *Cochrane Database of Systematic Reviews* 2012, Issue 5. [DOI: 10.1002/14651858.CD006304.pub3

Elharmeel 2011

Elharmeel S, Chaudhary Y, Tan S, Scheermeyer E, Hanafy A, L van Driel, M. Surgical repair of spontaneous perineal tears that occur during childbirth versus no intervention. *Cochrane Database of Systematic Reviews* 2011, Issue 8. [DOI: 10.1002/14651858.CD008534.pub2

Eogan 2006

Eogan M, Daly L, O'Connell PR, O'Herlihy C. Does the angle of episiotomy affect the instance of anal sphincter injury?. *British Journal of Obstetrics and Gynaecology* 2006; 113(2):190–4.

Fernando 2013

Fernando RJ, Sultan AH, Kettle C, Thakar R. Methods of repair for obstetric anal sphincter injury. *Cochrane Database of Systematic Reviews* 2013, Issue 12. [DOI: 10.1002/14651858.CD002866.pub3

Gagnon 2007

Gagnon AJ, Sandall J. Individual or group antenatal education for childbirth or parenthood, or both. *Cochrane Database of Systematic Reviews* 2007, Issue 3. [DOI: 10.1002/14651858.CD002869.pub2

Grundy 1997

Grundy L, Williams C. The role of the midwife in perineal wound care following childbirth. *British Journal of Nursing* 1997;**6**(10):584–8.

Guo 2010

Guo S, DiPietro LA. Factors affecting wound healing. *Journal of Dental Research* 2010;**89**(3):219–29.

Health & Social Care Information Centre 2011

Health & Social Care Information Centre. NHS Maternity Statistics - England, 2010-2011. www.hscic.gov.uk/catalogue/PUB03071/nhs-mate-eng-2010-2011-rep.pdf 2011; Vol. (accessed 9th August 2015).

Henderson 2006

Henderson C, MacDonald S. *Mayes Midwfiery: A Textbook for Midwives*. 13th Edition. Edinburgh: Baillière Tindall, 2006.

Higgins 2003

Higgins JPT, Thompson SG, Deeks JJ, Altman DG. Measuring inconsistencies in meta-analysis. *BMJ* 2003;**327** (7414):557-60.

Higgins 2011a

Higgins JPT, Green S, editors. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

Higgins 2011b

Higgins JPT, Altman DG, on behalf of the Cochrane Statistical Methods Group and the Cochrane Bias Methods Group. Chapter 8: Assessing risk of bias in included studies. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org 2011.

Higgins 2011c

Higgins JPT, Deeks JJ and Altman DG on behalf of the Cochrane Statistical Methods Group (Editors). Chapter 16: Special topics in statistics. In: Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011].

The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

Kamrava 2013

Kamrava A, Mahmoud NN. Prevention and management of nonhealing perineal wounds. *Clinics in Colon and Rectal Surgery* 2013;**26**(2):106–11.

Kapp 2015

Kapp S, Miller C. The experience of self-management following venous leg ulcer healing. *Journal of Clinical Nursing* 2015;**24**(9-10):1300–9.

Kettle 2011

Kettle C, Tohill S. Perineal care. *BMJ Clinical Evidence* 2011;4:1401.

Koongstvedt 2001

Koongstvedt P. *The Managed Health Care Handbook*. 4th Edition. Aspen: Maryland, 2001.

Liberati 2009

Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gøtzsche PC, Ioannidis JPA, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: explanation and elaboration. *BMJ* 2009;339:b2700.

Mahony 2008

Mahony R, O'Herlihy C, Foley ME. Correlation of perineal outcome at first and second vaginal deliveries. *Irish Medical Journal* 2008;**101**(10):302–4.

McCandlish 1998

McCandlish R, Bowler U, van Asten H, Berridge G, Winter C, Sames L, et al. A randomised controlled trial of care of the perineum during second stage of normal labour. *BJOG: an international journal of obstetrics and gynaecology* 1998; **105**(12):1262–72.

Priddis 2014

Priddis H, Schmied V, Dahlen H. Women's experiences following severe perineal trauma: a qualitative study. *BMC Women's Health* 2014;**14**(1):32.

RevMan 2014 [Computer program]

The Nordic Cochrane Centre, The Cochrane Collaboration. Review Manager (RevMan). Version 5.3. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014.

Sathiyasekaran 2007

Sathiyasekaran BWC, Palani G, Harihara Iyer R, Edward S, Devi Dharmappal C, Rani A, et al. Population based study of episiotomy. *Sri Ramachandra Journal of Medicine* 2007;**1** (2):9–14.

Seehusen 2014

Seehusen D, Raleigh M. Antenatal perineal massage to prevent birth trauma. *American Family Physician* 2014;**89** (5):335–6.

Shanley 2015

Shanley E, Moore ZEH. Patient education for preventing venous leg ulceration. *Cochrane Database of Systematic Reviews* 2015, Issue 5. [DOI: 10.1002/14651858.CD011696

Smith 2013

Smith L, Price N, Simonite V, Burns E. Incidence of and risk factors for perineal trauma: a prospective observational study. *BMC Pregnancy and Childbirth* 2013;**13**:59. [DOI: 10.1186/1471-2393-13-59

Stolberg 2012

Stolberg J. Enhancing Postnatal Perineal Care: Part 2. *Practising Midwife* 2012;**15**(7):34–6.

Svensson 2008

Svensson J, Barclay L, Cooke M. Effective antenatal education: strategies recommended by expectant and new parents. *Journal of Perinatal Education* 2008;17(4):33–42.

The Rotunda Hospital 2014

The Rotunda Hospital. The Rotunda Hospital Clinical Report 2014. www.rotunda.ie/Portals/0/Annual%20 Clinical%20Report%202012.pdf 2015; Vol. (accessed 26th March 2016).

Van Hecke 2011

Van Hecke A, Grypdonck M, Beele H, Vanderwee K, Defloor T. Adherence to leg ulcer lifestyle advice: qualitative and quantitative outcomes associated with a nurse-led intervention. *Journal of Clinical Nursing* 2011;**20**(3-4): 429–43.

Williams 2007

Williams A, Herron-Marx S, Knibb R. The prevalence of enduring postnatal perineal morbidity and its relationship to type of birth and birth risk factors. *Journal of Clinical Nursing* 2007;**16**(3):549–61.

Wuytack 2016

Wuytack F, Smith V, Cleary BJ. Oral non-steroidal anti-inflammatory drugs (single dose) for perineal pain in the early postpartum period. *Cochrane Database of Systematic Reviews* 2016, Issue 7. [DOI: 10.1002/14651858.CD011352.pub2

References to other published versions of this review

O'Kelly 2016

O'Kelly SM, Moore ZEH. Antenatal maternal education for improving postnatal perineal healing for women who have birthed in a hospital setting. *Cochrane Database of Systematic Reviews* 2016, Issue 6. [DOI: 10.1002/14651858.CD012258

^{*} Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of excluded studies [ordered by year of study]

Study	Reason for exclusion
Noronha 2004	Not a randomised controlled trial.

Characteristics of ongoing studies [ordered by study ID]

Hatamleh 2016

Trial name or title	Evaluation of the effect of childbirth preparation educational program on self-efficacy, anxiety, and birth outcomes among first time Jordanian mothers
Methods	Randomised controlled trial (parallel)
Participants	"Inclusion criteria: The target population is all Jordanian primigravida pregnant women and the accessible population is the women who attend the antenatal clinics at king Hussein medical center. To overcome the effect of extraneous variables on the study outcomes, the inclusion criteria will include participants who are healthy primiparous, aged 18-45 years, pregnant for at least 32 weeks and have low risk singleton pregnancy. Only woman who planned to deliver at king Hussien Medical Center, and who possess a smart phone will be recruited Exclusion criteria: high risk pregnancy."
Interventions	Intervention: Orientation round for the maternity ward, lasting 10 minutes, followed by four individualised educational sessions, delivered by a registered nurse or midwife, at antenatal clinic, once a week, and each lasting 30 minutes. The content will be based on recommendations within the Standards of Care for Health Centers, published by USAID and the Jordanian ministry of health. The sessions will use a range of techniques such as verbal information, discussion of issues or questions raised by the women and practical demonstration of breathing exercises. The contents include: anatomy and physiology of the reproductive system; signs of labour; labour and delivery process; labour relaxation techniques; postpartum care; breastfeeding; and how to pack a hospital bag. After each session the women will receive a pamphlet containing detailed information about what was being explained and the content of each session will be shared with the women through their smart phone applications (whatsapp). Adherence will be monitored by checking attendance at education sessions Control: Usual antenatal care and there will be no attempt to control information from other sources but if they ask about any obstetric procedure, then usual information or care will be provided
Outcomes	Primary: Self-efficacy (Childbirth Self-Efficacy Inventory (CBSEI)); Anxiety (The State Trait Anxiety Inventory) Secondary: Infants: Apgar score at 1st minute, Apgar score at 5 minutes, infant mortality, birth weight, birth trauma, assisted newborn ventilation, Maternal: Post-partum haemorrhage, use of analgesia during labour, perineal trauma, episiotomy, need for electronic fetal heart rate monitor, gestational age, delivery method, type of cesarean section, indication for caesarean section, labour onset, length of 1st stage of labour, length of hospital stay, onset of breast feeding, postnatal medications

Hatamleh 2016 (Continued)

Starting date	Recruitment status as at 11 October 2017 = 'not yet recruiting'
Contact information	Dr Reem Hatamleh - Ar Ramtha, Irbid PO Box (22110) street (amman-alramtha street) Jordan university of science and technology, Jordan Email: rahatamleh@just.edu.jo
Notes	Target sample size: 128 women Funder: asma' abuabed

DATA AND ANALYSES

This review has no analyses.

APPENDICES

Appendix I. Planned search terms for ICTRP and ClinicalTrials.gov

We ran each line individually and manually de-duplicated. antenatal AND education AND perineum antenatal AND education AND perineal prenatal AND education AND perineum prenatal AND education AND perineal antenatal AND advice AND perineum antenatal AND advice AND perineal prenatal AND advice AND perineal prenatal AND advice AND perineal antenatal AND advice AND perineal antenatal AND teach AND perineum antenatal AND teach AND perineal prenatal AND teach AND perineal prenatal AND teach AND perineum prenatal AND teach AND perineum

Appendix 2. Data collection and analysis methods to be used in future updates

Data extraction and management

Two review authors will independently extract data from eligible studies using a data extraction sheet, see Appendix 3. Any differences in opinion will be resolved by discussion and, where necessary, with reference to the Cochrane Pregnancy and Childbirth Group editorial base. If information within studies is unclear, or if there are data missing from reports, we will attempt to contact study authors to obtain the missing information.

Assessment of risk of bias in included studies

Two review authors will independently assess the included studies using Cochrane's tool for assessing risk of bias (Higgins 2011b). This tool addresses six specific domains: namely, sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting and other issues (e.g. extreme baseline imbalance). We will assess blinding and completeness of outcome data for each outcome separately.

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 2011a). We will resolve any disagreement by discussion or by involving a third assessor.

(I) 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 randomization; consecutively-numbered, sealed, opaque envelopes);
- high risk of bias (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear risk of bias.

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

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

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

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

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

We will assess methods used to blind outcome assessment as:

• low, high or unclear risk of bias.

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

We will describe for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We will state whether attrition and exclusions were reported and the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information is reported, or can be supplied by the trial authors, we will re-include missing data in the analyses that 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 have been reported incompletely and so cannot be used; study failed 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 *Cochrane Handbook* for Systematic Reviews of Interventions (Higgins 2011a). 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.

Assessing the quality of the body of evidence using the GRADE approach

We will assess the quality of the evidence 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. We have selected the following outcomes for use in GRADE, for the main comparisons.

- 1. An objective measure of wound healing, such as time to complete healing; absolute or percentage change in injured area over time
- 2. Infection rate
- 3. Re-attendance or re-admission into the healthcare service
- 4. Pain at up to three months postnatal (using validated scales where reported, for example McGill Pain scale)
- 5. Health-related quality of life (using validated scales, where reported)
- 6. Maternal bonding (assessed using reports from women)
- 7. Negative emotional impact of a postnatal perineal wound

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. Similarly, the evidence can also be upgraded.

Measures of treatment effect

For dichotomous outcomes, we will calculate risk ratio (RR) plus 95% confidence intervals (CIs). For continuous outcomes, we will calculate mean difference (MD) plus 95% CIs. We will analyse time-to-event data (e.g. time to perineal breakdown) as survival data using hazard ratios (HR), using the appropriate analytical method (as per the *Cochrane Handbook for Systematic Reviews of Interventions* version 5) (Higgins 2011a). We will not analyse time-to-event data incorrectly presented as continuous data, but present the data in a narrative format in the review. Skewed data are difficult to enter into a meta-analysis unless 'normalised' by log transformation, however, if scale data have finite upper and lower limits we will apply an easy rule of thumb in order to test for skewedness. If the standard deviation, when doubled, is greater than the mean, it is unlikely that the mean is the centre of the distribution and will not be entered into the meta-analysis (Altman 1996). Where continuous data have less obvious finite boundaries the situation is more problematic and may be a matter of judgement. If we find relevant data that are skewed we will present the data in 'Other data' tables. In addition, some of our secondary outcomes may be measured using ordinal scales. For simplicity, we will assume that these are continuous and analyse data with the standardised mean difference (SMD). It is also possible that different tools may be used to measure the same outcome (for example, quality of life and pain). We will collect data only from those studies where scales have been validated and are self-reported or completed by an independent rater or relative (not the therapist or investigator). We will use the SMD as the summary statistic in any meta-analysis of such data (Deeks 2011).

Unit of analysis issues

Cluster-randomised controlled trials

For cluster-randomised controlled trials, we will undertake the analysis at the level of the individual while accounting for the clustering in the data, using the intra cluster correlation coefficient (ICC). We will use the effective sample size of a single intervention group in a cluster-randomised trial, which is its original sample size divided by a quantity called the 'design effect'. The design effect is 1 + (M - 1) ICC. Where M is the average cluster size and ICC is the intra cluster correlation coefficient. For dichotomous outcomes, both the number of participants and the number of events in each intervention group will be divided by the design effect. For continuous outcomes, only the number of participants in each intervention group will be divided by the design effect (means and standard deviations will not be adjusted) (Higgins 2011c). 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.

Multiple-armed trials

If identified, we will include multi-armed trials and attempt to overcome potential unit of analysis errors by combining groups to create a single pair-wise comparison, or select one pair of interventions and exclude the others. All intervention groups of a multi-intervention study will be mentioned in the table of 'Characteristics of included studies', either in the 'Interventions' cell or the 'Notes' cell. However, we will provide detailed descriptions of only the intervention groups relevant to the review, and only these groups will be used in analyses. We will check that the data are presented for each of the groups to which participants were randomised (Higgins 2011c).

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 explore clinical heterogeneity by examining potentially influential factors, e.g. care setting or woman's characteristics. We will assess statistical heterogeneity in each meta-analysis using the T^2 , I^2 and Chi^2 statistics. We will regard heterogeneity as substantial if an I^2 is greater than 30% and either a T^2 is greater than zero, or there is a low P value (< 0.10) in the Chi^2 test for heterogeneity (Higgins 2003). Where heterogeneity is absent or low, we will use a fixed-effect model; if there is evidence of heterogeneity (an I^2 more than 25%), we will use a random-effects model. If heterogeneity is very high (an I^2 over 75%), we will not pool the data (Higgins 2003).

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 (Higgins 2011b).

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 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% CIs, and the estimates of T^2 and I^2 .

Subgroup analysis and investigation of heterogeneity

We plan to carry out the following subgroup analyses.

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 (Deeks 2011). 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% CIs, and the estimates of I² (Deeks 2011).

- 1. Mode of delivery of the intervention (information leaflet, versus multimedia)
- 2. Socio-economic status of the population (high and medium versus low)
- 3. Nulliparous versus multiparous
- 4. Degree of perineal trauma (first- and second-degree trauma versus third- and fourth-degree trauma)
- 5. Co-morbidities (women who are not diabetic versus women who are diabetic) versus no co-morbidities

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

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

Sensitivity analysis

We will perform a sensitivity analysis by excluding studies of the lowest quality. In this sensitivity analysis, we will only include studies that are assessed as having a low risk of bias in all key domains, namely adequate generation of the randomisation sequence, adequate allocation concealment and blinding of outcome assessor, for the estimates of treatment effect. If cluster-randomised trials are included, sensitivity analysis will also be used to investigate the effect of variation in the ICC and to investigate the effect of the unit of randomisation. We will restrict sensitivity analyses to the primary outcomes.

Appendix 3. Data extraction

We plan to extract the following information:

- 1. author, title, source;
- 2. date of study, study's geographical location;
- 3. care setting;
- 4. inclusion/exclusion criteria;
- 5. woman's characteristics;
- 6. study design detail;
- 7. method of randomisation;
- 8. sample size calculation and sample size;
- 9. intervention details, concurrent interventions;
- 10. length of hospital stay;
- 11. length of follow-up;
- 12. outcome measures:
- 13. results;
- 14. intention-to-treat analysis
- 15. risk of bias
- 16. conclusions, as reported by the study authors;
- 17. sources of trial funding;
- 18. trial authors' declarations of interest.

CONTRIBUTIONS OF AUTHORS

Sonia O'Kelly is the contact person and guarantor of the review.

Both review authors conceived the review question, developed the review, and co-ordinated review development, wrote, edited and advised on the review.

Zena Moore approved the final version of the review prior to submission.

DECLARATIONS OF INTEREST

Sonia O'Kelly: none known.

Zena Moore has received an honorarium for speaking at a professional meeting for Vancive.

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Internal sources

• School of Nursing & Midwifery, Royal College of Surgeons in Ireland, Ireland.

External sources

• No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

There are some differences between our published protocol (O'Kelly 2016) and the full Cochrane review, these are detailed below.

We have edited the section on dealing with missing data within the data collection element of the methods section in order to align this section with the Pregnancy and Childbirth Group's standard methods text. We have also added 'sources of trial funding' and 'trial authors' declarations of interest' to our data extraction template.

INDEX TERMS

Medical Subject Headings (MeSH)

*Postnatal Care; *Wound Healing; Mothers [*education]; Perineum [*injuries]; Prenatal Care [*methods]

MeSH check words

Female; Humans; Pregnancy