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Turawa EB, Musekiwa A, Rohwer AC

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[Intervention Review]

Interventions for preventing postpartum constipation

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ABSTRACT

Background

Postpartum constipation, with symptoms, such as pain or discomfort, straining, and hard stool, is a common condition affecting mothers. Haemorrhoids, pain at the episiotomy site, effects of pregnancy hormones, and haematinics used in pregnancy can increase the risk of postpartum constipation. Eating a high-fibre diet and increasing fluid intake are usually encouraged. Although laxatives are commonly used in relieving constipation, the effectiveness and safety of available interventions for preventing postpartum constipation should be ascertained. This is an update of a review first published in 2015.

Objectives

To evaluate the effectiveness and safety of interventions for preventing postpartum constipation.

Search methods

We searched Cochrane Pregnancy and Childbirth's Trials Register, and two trials registers ClinicalTrials.gov, the WHO International Clinical Trials Registry Platform (ICTRP) (7 October 2019), and screened reference lists of retrieved trials.

Selection criteria

We considered all randomised controlled trials (RCTs) comparing any intervention for preventing postpartum constipation versus another intervention, placebo, or no intervention in postpartum women. Interventions could include pharmacological (e.g. laxatives) and non-pharmacological interventions (e.g. acupuncture, educational and behavioural interventions). Quasi-randomised trials and cluster-RCTs were eligible for inclusion; none were identified. Trials using a cross-over design were not eligible.

Data collection and analysis

Two review authors independently screened the results of the search to select potentially relevant trials, extracted data, assessed risk of bias, and the certainty of the evidence, using the GRADE approach. We did not pool results in a meta-analysis, but reported them per study.

Main results

We included five trials (1208 postpartum mothers); three RCTs and two quasi-RCTs. Four trials compared a laxative with placebo; one compared a laxative plus a bulking agent versus the same laxative alone, in women who underwent surgical repair of third degree perineal tears. Trials were poorly reported, and four of the five trials were published over 40 years ago. We judged the risk of bias to be unclear for most domains. Overall, we found a high risk of selection and attrition bias.

Laxative versus placebo

We included four trials in this comparison. Two of the trials examined the effects of laxatives that are no longer used; one has been found to have carcinogenic properties (Danthron), and the other is not recommended for lactating women (Bisoxatin acetate); therefore, we did not include their results in our main findings.

None of the trials included in this comparison assessed our primary outcomes: pain or straining on defecation, incidence of postpartum constipation, or quality of life; or many of our secondary outcomes.

A laxative (senna) may increase the number of women having their first bowel movement within 24 hours after delivery (risk ratio (RR) 2.90, 95% confidence interval (CI) 2.24 to 3.75; 1 trial, 471 women; low-certainty evidence); may have little or no effect on the number of women having their first bowel movement on day one after delivery (RR 0.94, 95% CI 0.72 to 1.22; 1 trial, 471 women; very low-certainty evidence); may reduce the number of women having their first bowel movement on day two (RR 0.23, 95% CI 0.11 to 0.45; 1 trial, 471 women; low-certainty evidence); and day three (RR 0.05, 95% CI 0.00 to 0.89; 1 trial, 471 women; low-certainty evidence); and may have little or no effect on the number of women having their first bowel movement on day four after delivery (RR 0.22, 95% CI 0.03 to 1.87; 1 trial, 471 women; very low-certainty evidence), but some of the evidence is very uncertain.

Adverse effects were poorly reported. Low-certainty evidence suggests that the laxative (senna) may increase the number of women experiencing abdominal cramps (RR 4.23, 95% CI 1.75 to 10.19; 1 trial, 471 women). Very low-certainty evidence suggests that laxatives taken by the mother may have little or no effect on loose stools in the baby (RR 0.62, 95% CI 0.16 to 2.41; 1 trial, 281 babies); or diarrhoea (RR 2.46, 95% CI 0.23 to 26.82; 1 trial, 281 babies).

Laxative plus bulking agent versus laxative only

Very low-certainty evidence from one trial (147 women) suggests no evidence of a difference between these two groups of women who underwent surgical repair of third degree perineal tears; only median and range data were reported. The trial also reported no evidence of a difference in the incidence of postpartum constipation (data not reported), but did not report on quality of life. Time to first bowel movement was reported as a median (range); very low-certainty evidence suggests little or no difference between the two groups. A laxative plus bulking agent may increase the number of women having any episode of faecal incontinence during the first 10 days postpartum (RR 1.81, 95% CI 1.01 to 3.23; 1 trial, 147 women; very low-certainty evidence). The trial did not report on adverse effects of the intervention on babies, or many of our secondary outcomes.

Authors' conclusions

There is insufficient evidence to make general conclusions about the effectiveness and safety of laxatives for preventing postpartum constipation. The evidence in this review was assessed as low to very low-certainty evidence, with downgrading decisions based on limitations in study design, indirectness and imprecision.

We did not identify any trials assessing educational or behavioural interventions. We identified four trials that examined laxatives versus placebo, and one that examined laxatives versus laxatives plus stool bulking agents.

Further, rigorous trials are needed to assess the effectiveness and safety of laxatives during the postpartum period for preventing constipation. Trials should assess educational and behavioural interventions, and positions that enhance defecation. They should report on the primary outcomes from this review: pain or straining on defecation, incidence of postpartum constipation, quality of life, time to first bowel movement after delivery, and adverse effects caused by the intervention, such as: nausea or vomiting, pain, and flatus.

PLAIN LANGUAGE SUMMARY

Interventions for preventing constipation after giving birth

What is the issue?

Constipation during the postpartum period is a bowel disorder, characterised by symptoms, such as pain or discomfort, straining, hard lumpy stool, and a sense of incomplete bowel evacuation. Administration of enemas before labour, the ability of women to eat during active labour, and irregular and altered eating habits during the first few days after delivery can each have an influence on bowel movements in the days after giving birth. This is an update of a review first published in 2015.

Why is this important?

Pain and discomfort during defecation can be a source of concern to the new mother, who is recuperating from the stress of delivery, particularly if she has had perineal tears repaired, or has developed haemorrhoids. Postpartum constipation can be stressful because of undue pressure on the rectal wall, leading to restlessness and painful defecation, which may affect the quality of life of the mother and the newborn.

What evidence did we find?

We searched for trials to 7 October 2019. We found no new trials that met our inclusion criteria, thus, we included the initial five trials (involving a total of 1208 women) in this update. Overall, the trials were poorly reported, and four out of five trials were published more than 40 years ago. Four trials compared a laxative with a placebo.

Two trials assessed the effects of laxatives that we now find might be harmful for breastfeeding mothers. One drug, Danthron, has been shown to cause cancer in animals, and the other, Bisoxatin acetate, is no longer recommended when breastfeeding. Therefore, we did not include the results of these trials in our main findings.

The trials did not look at pain or straining on defecation, incidence of constipation, or quality of life, but did assess the time to first bowel movement. In one study assessing the effects of senna, compared to the placebo group, more women in the laxative group had a bowel movement on the day of delivery, and fewer women had their first bowel movement on days 2 and 3, while the results were inconclusive between groups on days 1 and 4 after delivery. More women had abdominal cramps compared to the women in the placebo group, and babies whose mothers received the laxative were no more likely to experience loose stool or diarrhoea. The evidence for all these outcomes is largely uncertain, as we have very serious concerns about risk of bias, and the results are all based on one small study that was conducted at a single institution in South Africa.

One trial compared a laxative plus a stool-bulking agent (Ispaghula husk) to a laxative only for women who underwent surgery to repair a third degree tear of the perineum (involving the internal or external anal sphincter muscles) that occurred during vaginal delivery. The trial reported on pain or straining on defecation, but did not find a clear difference in the pain score between groups. The trial reported that women who were given laxative plus a stool-bulking agent were more likely to experience fecal incontinence in the immediate postpartum period. However, the evidence is very uncertain. The trial did not report on any adverse effects on the baby.

What does this mean?

There is not enough evidence from randomised controlled trials on the effectiveness and safety of laxatives during the early postpartum period to make general conclusions about their use to prevent constipation.

We did not identify any trials assessing educational or behavioural interventions, such as a high-fibre diet and exercise. We need large, high-quality trials on this topic, specifically on non-medical interventions to prevent postpartum constipation, such as advice on diet and physical activity.

Summary of findings 1. Laxative compared to placebo for preventing postpartum constipation

Laxative compared to placebo for preventing postpartum constipation

Patient or population: women in the postpartum period
Setting: hospital setting in South Africa and the USA
Intervention: laxative
Comparison: placebo

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with placebo	Risk with laxative				
Pain or straining on defecation	-	-	-	-	-	not reported
Incidence of postpartum constipation	-	-	-	-	-	not reported
Quality of life	-	-	-	-	-	not reported
Time to first bowel movement (BM) *(№ women with 1st BM less than 24 hours after delivery)*	Study population		RR 2.90 (2.24 to 3.75)	471 (1 RCT)	⊕⊕⊖⊖ LOW[a]	
	219 per 1000	634 per 1000 (490 to 820)				
Time to first BM *(№ women with 1st BM on day 1 after delivery)*	Study population		RR 0.94 (0.72 to 1.22)	471 (1 RCT)	⊕⊖⊖⊖ VERY LOW[a,b,c]	Two other studies measured this outcome but they were not pooled in a meta-analysis. These studies investigated Danthron (a laxative that is no longer marketed due to carcinogenic properties), and bisoxatin acetate (a laxative that is not recommended for use when breastfeeding).
	328 per 1000	308 per 1000 (236 to 400)				
Time to first BM *(№ women with 1st BM on day 2 after delivery)*	Study population		RR 0.23 (0.11 to 0.45)	471 (1 RCT)	⊕⊕⊖⊖ LOW[a]	Two other studies measured this outcome but they were not pooled in a meta-analysis. These studies investigated Danthron (a laxative that is no longer marketed due to carcinogenic properties), and bisoxatin acetate
	178 per 1000	41 per 1000 (20 to 80)				

						(a laxative that is not recommended for use when breastfeeding).
Time to first BM *(№ women with 1st BM on day 3 after delivery)*	Study population 40 per 1000	2 per 1000 (0 to 36)	RR 0.05 (0.00 to 0.89)	471 (1 RCT)	⊕⊕⊖⊖ LOW[a]	One other study measured this outcome but it was not included in a meta-analysis because it investigated Danthron (a laxative that is no longer marketed due to carcinogenic properties).
Time to first BM *(№ women with 1st BM on day 4 after delivery)*	Study population 20 per 1000	4 per 1000 (1 to 38)	RR 0.22 (0.03 to 1.87)	471 (1 RCT)	⊕⊖⊖⊖ VERY LOW[a,b,c]	One other study measured this outcome but it was not included in a meta-analysis because it investigated Danthron (a laxative that is no longer marketed due to carcinogenic properties).
Adverse effects on women: abdominal cramps	Study population 24 per 1000	103 per 1000 (43 to 248)	RR 4.23 (1.75 to 10.19)	471 (1 RCT)	⊕⊕⊖⊖ LOW[a]	
Adverse effects on babies: loose stools	Study population 39 per 1000	24 per 1000 (6 to 93)	RR 0.62 (0.16 to 2.41)	281 (1 RCT)	⊕⊖⊖⊖ VERY LOW[a,b,c]	
Adverse effects on babies: diarrhoea	Study population 6 per 1000	16 per 1000 (1 to 173)	RR 2.46 (0.23 to 26.82)	281 (1 RCT)	⊕⊖⊖⊖ VERY LOW[a,b,c]	

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

CI: Confidence interval; **RR:** Risk ratio;

GRADE Working Group grades of evidence
High certainty. We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty. We are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty. Our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect
Very low certainty. We have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect

[a]Downgraded by 2 levels due to very serious study limitations (high risk of attrition bias, selection bias (quasi-randomised studies) or concern due to industry sponsorship and statistical analysis

[b]Downgraded by 1 level due to imprecision: wide confidence intervals that are consistent with possible benefit and possible harm

[c]Downgraded by 2 levels due to imprecision: few participants, few events and wide confidence intervals that are consistent with possible benefit and possible harm.

Note: We did not include in the analysis studies that assessed the effects of Danthron and Bisoxatin acetate, as the former has been shown to be carcinogenic in animals (National Toxicology Program 2016) and is no longer marketed, and the latter is no longer recommend in breastfeeding women (Omega Pharma 2016)

Summary of findings 2. Laxative plus bulking agent compared to laxative alone for preventing postpartum constipation

Laxative plus bulking agent compared to laxative alone for preventing postpartum constipation

Patient or population: postpartum women who underwent surgical repair of third degree perineal tears
Setting: hospital setting in high-income countries
Intervention: laxative plus bulking agent
Comparison: laxative alone

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with laxative alone	Risk with laxative plus bulking agent				
Pain or straining on defecation *(Likert-scale from 1 to 5; 1 = no pain; 5 = worst pain)*			No difference between groups (P = 0.11)	147 (1 study)	⊕⊖⊖⊖ VERY LOW[a,b,c]	reported in paper
Incidence of postpartum constipation	-	-	-	-	-	not reported
Quality of life	-	-	-	-	-	not reported
Time to first bowel movement			No difference between groups (P = 0.34)	147 (1 study)	⊕⊖⊖⊖ VERY LOW[a,b,c]	reported in paper
Adverse effects on women: faecal incontinence during first 10 postpartum days	Study population		RR 1.81 (1.01 to 3.23)	147 (1 study)	⊕⊖⊖⊖ VERY LOW[a,b,c]	
	182 per 1000	329 per 1000 (184 to 587)				
Adverse effects on babies	-	-	-	-	-	not reported

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

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[a]Downgraded by 1 level due to study limitations: high risk of attrition bias and unclear risk of selection, performance, and detection bias
[b]Downgraded by 1 level due to imprecision: small sample size, wide confidence intervals that are consistent with possible benefit and possible harm
[c]Downgraded by 1 level due to indirectness: participants are women undergoing surgical repair of third degree perineal tears, results based on a single study from a single institution in Ireland

BACKGROUND

The postpartum period, also referred to as postnatal or puerperium, is the critical transitional period following the expulsion of the placenta, and extends to the next six weeks following childbirth, during which the mother's body, the pregnancy hormone levels, and the size of the uterus return to their non-pregnant state (Liu 2009; WHO 2010). The physiological changes during this period can be similar, but, the effects and the experience of these changes, the duration and severity, together with how it is experienced, vary greatly from person to person, and may lead to serious adverse consequences, including physiological and psychological ill-health, low self-esteem, and poor quality of life for the mother (de Groot 2018; Zainur 2006). It is therefore important that adequate attention, appropriate advice and sufficient services and care be made available to the new mothers during this period in order to prevent postpartum health problems, identify complications at an early stage and provide adequate assistance (WHO 1998).

The postpartum period can be divided into three phases: the acute postpartum phase, the subacute postpartum phase, and the delayed postpartum phase. The acute phase is the immediate six to 12 hours after delivery and expulsion of the placenta, the subacute postpartum phase extends from two to six weeks after delivery, and the delayed postpartum phase commences after the subacute postpartum period and lasts up to six months (Romano 2010). It is the time when abdominal and pelvic muscles and the connective tissues and ligaments returns to the pre-pregnancy state. However, recovery from birth injuries and complications, such as pelvic prolapse and dyspareunia (painful intercourse), are usually very slow during this period, and in some cases, total recovery may not be achieved. It was estimated that about 87% to 94% of women suffer from at least one health complication in the acute postpartum phase, while 31% complained of health problems during the delayed postpartum phase (Borders 2006).

Description of the condition

Constipation is a bowel disorder, characterised by infrequent (fewer than three bowel movements a week in adults), hard, dry, or lumpy stools that are difficult or painful to pass, or a feeling of incomplete evacuation, anorectal obstruction, or need for manual manoeuvres (Higgins 2004). The diagnosis of constipation is both subjective and objective. According to the Rome IV diagnostic criteria, a diagnosis of functional constipation should include two of the following criteria, which must be met over the last three months, with symptom onset at least six months prior to diagnosis: straining during at least 25% of defecations, lumpy or hard stools for at least 25% of defecations, sensation of incomplete evacuation for at least 25% of defecations, sensation of anorectal obstruction or blockage for at least 25% of defecations, manual manoeuvres to facilitate at least 25% of defecations (e.g. digital evacuation, support of the pelvic floor), fewer than three spontaneous bowel movement per week; loose stools are rarely present without the use of laxatives, and there are insufficient criteria for irritable bowel syndrome (Drossman 2016; Appendix 1).

The Bristol Stool Form Scale (BSFS) is a formal research tool used to assess stool consistency and intestinal transit rate. It is an ordinal scale used to rate and categorise stool into seven classifications, according to stool consistency (Appendix 2). It is also useful in evaluating the effectiveness of an intervention for gastrointestinal tract disease and clinical assessment. It helps people to report on stool consistency adequately, thus proving a guide in the diagnosis and treatment of gastrointestinal disorders (Lewis 1997). The BSFS tool classifies stool into seven categories ranging from hard lumps like nuts stool (type 1) to watery without solid pieces, entirely liquid (type 7). Types 1 and 2 are indicative of constipation, Types 3 and 4 are considered normal stool consistency that is easy to defecate, while Types 6 and 7 are considered abnormal consistency (Lewis 1997).

Functional constipation is common across the general population, and is a source of concern during pregnancy and the postpartum period. Worldwide, the prevalence of constipation in all ages lies between 4.1% and 25.6%, in studies using self-reported measures of constipation, and between 2.6% and 26.9% in those using the Rome criteria (Schmidt 2014). The prevalence of self-reported constipation among Turkiish women during the postpartum period was estimated to be between 15.5% and 61.6% (Gozum 2005); with a higher prevalence (41.1%) among multiparous women (Aksu 2017). Kabakian-Khasholian 2014 reported that about 45.8% of women experienced constipation following delivery and about 42.4% experienced back pain, which could contribute to constipation in the postpartum period (Kabakian-Khasholian 2014). Recovery from birth trauma may extend up to six to 12 months or more in postpartum women (MacArthur 1991). About 25.5% of women may experience persistent genito-pelvic postpartum pain at three to 12 months after delivery (Cappell 2017). Similarly, an earlier study reported that about 94% of Australian women complained of discomfort and pain from haemorrhoids (24.6%) and perineal pain (21%) at six to seven months after childbirth, supporting the extension of the postpartum period, and health issues related to childbirth (Brown 1998).

The causes of postpartum constipation are multifactorial. Interruption in dietary intake during labour, and dehydration caused from prolonged hours of labour without sufficient fluid intake may contribute to postpartum constipation. Also, the effect of elevated progesterone levels during pregnancy, which may still be in circulation during the first few weeks of postpartum, is thought to be associated with postpartum constipation, due to its effect on the smooth muscles. Similarly, the effect of analgesics and opiates used in labour could lead to postpartum constipation. Pain from a raw perineum, repaired episiotomy or perineal tear, or pain from a caesarean section could make the new mother hesitate to defecate when the urge arises. Other risk factors for postpartum constipation include pain from haemorrhoids, damage to levator ani muscles (pelvic floor muscle) and pelvic floor disorders, and adverse effects of maternity drugs, such as magnesium sulphate, used as a tocolytic to prevent preterm labour, or treat pre-eclampsia. Maternal diet during the postpartum period, in terms of inadequate consumption of fruits, vegetables, whole grain cereals, and fibre also contributes to postpartum constipation. In Africa and some Asian countries, the postpartum period is often marked with cultural practices and diet restrictions that play a remarkable role in the onset of constipation during this critical and sensitive period. In the Chinese culture, for example, the new mother must follow a special diet, behaviour, and lifestyle that discourages consumption of cold food, including a low fruit and vegetable intake, alongside limited movement, behind closed doors and windows (Lin 2009).

Postpartum constipation not only causes discomfort to the new mother, but it may also impact on her physical and social health

status, and may hinder timely response to the needs of the newborn (Cheng 2006). Postpartum constipation is associated with reduced quality of life, and significant health risks that negatively affect the duties of the new mother with respect to her baby, family, and social roles, as well as her body image.

Description of the intervention

Interventions to prevent constipation include pharmacological and non-pharmacological interventions such as dietary and lifestyle modification. Lifestyle interventions refer to diet and physical exercise, and are advocated during pregnancy and the postpartum period. A diet high in fibre and adequate fluid intake may be all that is required to prevent postpartum constipation (Zainur 2006).

In terms of pharmacological interventions, laxatives are the drugs of choice in relieving symptoms of constipation, and can be taken orally in either liquid, tablet, powder, or granule form. Laxatives are grouped into categories according to their mode of action: bulk forming laxatives, osmotic laxatives, stimulant laxatives, faecal softeners, and lubricants (Candy 2011). Bulk forming laxatives include bran and methylcellulose; osmotic laxatives include magnesium hydroxide, sorbitol, lactulose, and polyethylene glycol; stimulant laxatives include bisacodyl and senna; and stool softeners include docusate sodium (Andrews 2011; Balch 2010; NIH-NIDDK 2018).

Alternative interventions for constipation also exist. Studies have reported on the efficacy of acupuncture and Chinese herbal medicine as interventions for the prevention of postpartum constipation (Jia 2009; Lin 2009).

How the intervention might work

A good understanding of the causes of constipation can help to prevent and avert problems that are associated with constipation. Constipation occurs when the stool stays in the colon longer than expected, and the colon absorbs too much water from the stool, thus making the stool hard and dry, and therefore, difficult to pass (NIH-NIDDK 2018). Interventions for preventing constipation in the postpartum are not different from the typical clinical interventions for constipation, however, the safety of these interventions during the postpartum period is unclear. Bulk forming laxatives increase the weight and water content, and facilitate peristaltic movement of stools (Balch 2010). However, inadequate water intake with the use of bulk forming laxative could increase bloating (Balch 2010). Osmotic laxatives, help retain water in the colon, thereby softening the stool and increasing the volume of the stools (NIH-NIDDK 2018). Stimulant laxatives directly stimulate the afferent nerves and irritate the intestinal wall, thereby easing the bowel movement (Andrews 2011). A stool softener softens the stool and enhances easy defecation. Enemas provide a mechanical stimulation on the walls of the rectum, thereby creating a sense of urgency to defecate.

Acupuncture and Chinese herbs reportedly work by correcting the underlying malfunctions through strengthening the intestinal tract and thereby improving peristalsis. The Yun-chang capsule, a Chinese herb capsule, was found to be effective and safe for the treatment of patients with functional constipation (Jia 2009), while a systematic review reported an overall significant benefit of traditional Chinese medicine in relieving constipation (Lin 2009).

Dietary and lifestyle interventions play an important role in preventing postpartum constipation. High-fibre foods, such as fruits and vegetables, can help to relieve symptoms and prevent constipation during the postpartum period (Liu 2009). Fibre is indigestible, adds bulk to the stool, and stimulates bowel movements; it also improves digestion, and prevents constipation by softening the stools (Balch 2010). Adequate fluid intake will help soften the stool and ease the bowel movement, thus preventing constipation during the postpartum period. Gradual resumption of aerobic and muscle conditioning activities that are medically safe should be encouraged at the appropriate time for postpartum women. Moderate, appropriate physical exercise during the postpartum period will increase muscle tone, and improve the movement of the food through the colon (Davies 2003). Aerobic exercise, such as brisk walking, increases the heart and the respiratory rates, thereby stimulating the natural contractions of the intestinal muscles, and improves peristaltic movement, thereby aiding the bowel movement. This will not only improve the quality of life, but also improve blood circulation, reduce the risk of developing heart disease, obesity, and other lifestyle diseases (Mottola 2002).It is also important to heed the urge to defecate and allow sufficient time in the bathroom without distraction, maintaining the correct posture in a relaxed atmosphere, to provide enough time to evacuate the rectum completely.

Why it is important to do this review

The postpartum period is a crucial time for the new mother, newborn baby, and the entire family. A number of health problems may occur during this period that may result in physical discomfort and poor quality of life for the mother and the baby. According to Peppas 2008, constipation has a significant, negative impact on the quality of life, in terms of morbidity and cost of treatment. A number of systematic reviews on interventions for constipation have been published (Gordon 2012; Higgins 2004; Lee-Robichaud 2010; Mugie 2011; Peppas 2008). We also completed a Cochrane Review on interventions for treating postpartum constipation (Turawa 2014). We did not find any trials eligible for inclusion, but some of the excluded trials assessed interventions for the prevention of constipation. The first version of this review included five trials (Turawa 2015b). We updated the review to inform World Health Organization guidelines.

OBJECTIVES

To evaluate the effectiveness and safety of interventions for preventing postpartum constipation.

METHODS

Criteria for considering studies for this review

Types of studies

We included all randomised controlled trials (RCTs) comparing any intervention for the prevention of postpartum constipation with another intervention, placebo, or no intervention. We included quasi-randomised controlled trials. Cluster-randomised trials were eligible for inclusion, but we did not identify any. Cross-over trials were not eligible for inclusion because the physiological condition of women during the first month postpartum might not be the same as at six months after childbirth. Studies in abstract form that reported on interventions for preventing constipation in postpartum were eligible for inclusion.

Types of participants

We included all postpartum women (up to six months post-delivery) without symptoms of postpartum constipation using prespecified criteria (Rome and Bristol Stool Form Scale) and self-report. We included postpartum women with comorbidities, such as sphincter injuries. We used the six months criterion because constipation is a problem that may last longer than six weeks following delivery, which is the usual postpartum period.

Types of interventions

Intervention

Any intervention for the prevention of postpartum constipation, both pharmacological (e.g. laxatives) and non-pharmacological interventions (e.g. acupuncture, educational and behavioural interventions).

Control

Any other intervention for the prevention of postpartum constipation, placebo, or no intervention.

We considered the following comparisons.

1. One intervention versus no intervention
2. One intervention versus placebo
3. Two different interventions compared
4. One intervention versus a combination of interventions
5. Combination of interventions versus no intervention
6. Combination of interventions versus placebo
7. Different combinations of interventions

Types of outcome measures

Primary outcomes

1. Pain or straining on defecation
2. Incidence of postpartum constipation, as per self-report and other diagnostic criteria
3. Quality of life, as measured in included studies (using e.g. maternal postpartum quality of life (MAPP-QOL) questionnaire)
4. Time to first bowel movement (days; outcome not prespecified at the protocol stage - see Differences between protocol and review)

Secondary outcomes

1. Stool consistency using Bristol Stool Form Scale (Appendix 2)
2. Use of alternative products, laxative agents, enemas
3. Relief of abdominal pain or discomfort
4. Stool frequency
5. Adverse effects in women caused by the intervention, including:
   a. pain
   b. nausea and vomiting
   c. diarrhoea, flatus, and faecal incontinence
6. Because some of these drugs can be excreted through the breast milk, we assessed any adverse effects of the intervention on the baby, e.g. diarrhoea, flatus

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

For this update, we searched Cochrane Pregnancy and Childbirth's Trials Register by contacting their Information Specialist (7 October 2019).

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

In addition, we searched ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform (ICTRP) for unpublished, planned, and ongoing trial reports (7 October 2019) using the search methods detailed in Appendix 3.

Searching other resources

We checked the reference list of retrieved studies for additional studies, and contacted authors and experts in the field.

We did not apply any language or date restrictions.

Data collection and analysis

For methods used in the previous version of this review, *see* Turawa 2015b.

For this update, we planned to use the following methods to assess the reports that were identified as a result of the updated search.

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

Selection of studies

Two review authors (Eunice Turawa (ET) and Alfred Musekiwa (AM)) independently assessed for inclusion all the potential studies we identified from the searches. We resolved any disagreement through discussion, or if required, we consulted the third review author (Anke Rohwer (AR)).

We developed a PRISMA study flow chart to display the number of records identified, included, and excluded from the review (Liberati 2009).

Data extraction and management

We designed a form to extract data. For eligible studies, two review authors extracted the data using the agreed form. We resolved discrepancies through discussion, or if required, we consulted the third review author. Data were entered into Review Manager 5 software and checked for accuracy (Review Manager 2014).

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

Assessment of risk of bias in included studies

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

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

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

We assessed the 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)

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

We assessed the methods as:

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

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

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

We assessed 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)

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

We assessed methods used to blind outcome assessment as:

- low, high, or unclear risk of bias.

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

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

We assessed 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)

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

We assessed the methods as:

- low risk of bias (where it was clear that all of the study's prespecified outcomes and all expected outcomes of interest to the review were reported);
- high risk of bias (where not all the study's prespecified outcomes were reported; one or more reported primary outcomes were not prespecified; outcomes of interest were reported

incompletely, and so could not 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)

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

(7) Overall risk of bias

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

Certainty of evidence

For this update, we assessed the certainty of the evidence using the GRADE approach, as outlined in the GRADE Handbook, in order to assess the certainty of the body of evidence relating to the following outcomes for the main comparisons (GRADE Handbook). We did not include studies that assessed the effects of Danthron and Bisoxatin acetate, as the former has been shown to be carcinogenic in animals and is no longer marketed (National Toxicology Program 2016), and the latter is no longer recommended in breastfeeding women (Omega Pharma 2016).

1. Pain or straining on defecation
2. Incidence of postpartum constipation, as per self-report and other diagnostic criteria
3. Quality of life, as measured in included studies (using e.g. maternal postpartum quality of life (MAPP-QOL) questionnaire)
4. Time to first bowel movement
5. Adverse effects of the intervention on the women
6. Adverse effect of the intervention on the babies

We used GRADEpro GDT to import data from Review Manager 5, in order to create a 'Summary of findings' table (GRADEpro GDT; Review Manager 2014). We produced a summary of the intervention effect and a measure of certainty for each of the above outcomes 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 presented results as summary risk ratio with 95% confidence intervals.

Continuous data

We had planned to calculate the mean difference if outcomes were measured in the same scale between trials, or standardised mean difference if trials measured the same outcome using different scales. However, the included trials reported continuous outcomes using medians and ranges, with corresponding P values, for comparing treatment groups, and we reported them similarly.

Time-to-event data

For the outcome time to first bowel movement, we had planned to calculate hazard ratios, however the data presented were only the number of women experiencing the event after less than 24 hours, one day, two days, three days, and four days; therefore, we calculated risk ratios at each of the time points. The separate time points were not prespecified, but were decided post hoc, according to how data were reported by the trials.

Unit of analysis issues

There were no unit of analysis issues, as we only included individually-randomised trials.

Cluster-randomised trials

We did not identify any cluster-randomised trials for this version of the review. However, in future updates of this review, if we identify any cluster-randomised trials, we will include them in the analyses along with individually-randomised trials. We will adjust their sample sizes using the methods described in the *Handbook for Systematic Reviews of Interventions* Section 16.3.4, using an estimate of the intra-cluster correlation co-efficient (ICC) derived from the trial (if possible), from a similar trial, or from a study of a similar population (Higgins 2011). 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.

Other unit of analysis issues

In future studies, if a multi-arm study contributes multiple comparisons to a particular meta-analysis, we will either combine treatment groups, or split the 'shared' group as appropriate, and take precautions to avoid the inclusion of data from the same participant more than once in the same analysis.

Dealing with missing data

For included studies, we noted levels of attrition. In future updates, if more eligible studies are included, we will explore the impact of including studies with high levels of missing data (an imbalance across each study arm of 10% or more) in the overall assessment of treatment effect by using sensitivity analysis.

For all outcomes, we carried out analyses, as far as possible, on an intention-to-treat basis, i.e. we attempted to include all participants randomised to each group in the analyses. The denominator for each outcome in each trial was the number

randomised minus any participants whose outcomes were known to be missing.

Assessment of heterogeneity

If we had carried out meta-analysis, we had planned to assess statistical heterogeneity in each meta-analysis using the Tau^2, I^2 and Chi^2 statistics. We would have regarded heterogeneity as substantial if I^2 was greater than 30%, and either Tau^2 was greater than zero, or there was a low P value (less than 0.10) in the Chi^2 test for heterogeneity. If we identified substantial heterogeneity (above 30%), we had planned to explore it by prespecified subgroup analysis.

Assessment of reporting biases

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

Data synthesis

We carried out statistical analysis using Review Manager 5 software (Review Manager 2014). We did not perform meta-analysis in this update of the review. However, if meta-analysis had been possible, we had planned to use the following methods. We would have used the fixed-effect model for combining data if it was reasonable to assume that studies were estimating the same underlying treatment effect, i.e. where trials were examining the same intervention, and the trials' populations and methods were judged sufficiently similar. Had there been clinical heterogeneity sufficient to expect that the underlying treatment effects differed between trials, or if we had detected substantial statistical heterogeneity, we would have used the random-effects model to produce an overall summary, if an average treatment effect across trials was considered clinically meaningful. We would have treated the random-effects summary as the average range of possible treatment effects, and we would have discussed the clinical implications of treatment effects differing between trials. We would have presented the results of meta-analysis as the average treatment effect with 95% confidence intervals, and the estimates of Tau^2 and I^2.

For the outcome 'time to first bowel movement', we had planned to pool hazard ratios in a meta-analysis using the generic inverse-variance method, however the primary studies only reported the numbers at each time point, which we summarized using risk ratios separately per study.

Subgroup analysis and investigation of heterogeneity

We were not able to conduct subgroup analysis in this review, since we did not perform any meta-analyses. If future updates allow meta-analysis, we will use subgroup analyses to investigate heterogeneity. We will carry out the following subgroup analyses.

1. Type of laxatives (osmotic laxatives versus stimulant laxatives; bulk forming laxatives versus stimulant laxatives)
2. Study design (individually-randomised versus cluster-randomised trials)
3. Mode of delivery (caesarean section versus spontaneous vaginal delivery)

We will limit these subgroup analyses to the primary outcomes of the review.

We will assess subgroup differences by interaction tests available within Review Manager 5 (Higgins 2011). 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 were not able to conduct sensitivity analysis in this review, since we did not perform any meta-analyses. For future updates of the review, we will perform sensitivity analysis with respect to:

1. robustness of the methods used regarding allocation concealment;
2. rates of attrition;
3. imputed values of intra-cluster correlations (ICC).

RESULTS

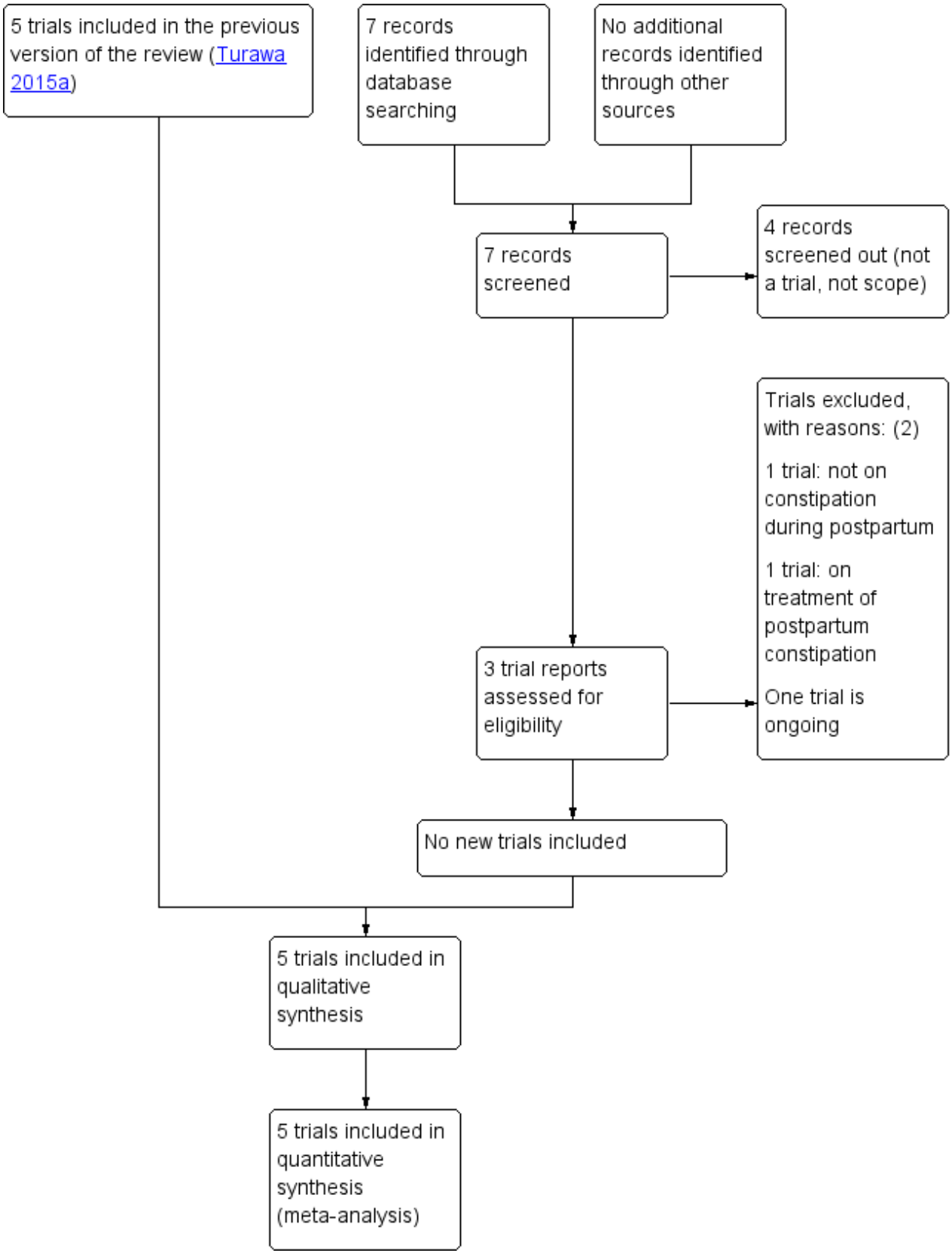
Description of studies

See Characteristics of included studies and Characteristics of excluded studies.

Results of the search

See Figure 1.

Figure 1. Study flow diagram



We included five trials in the previous version of this review (Turawa 2015b).

For this update, we retrieved three additional trial reports (ChiCTR1900023067; Sakai 2015; IRCT20190427043386N1). Of these, we excluded two studies, bringing the total number of excluded studies for this review to four (ChiCTR1900023067; Liu 2009; Mahony 2004; Sakai 2015; see Characteristics of excluded studies).

One trial is still ongoing, thus we included it under ongoing studies (IRCT20190427043386N1; see Characteristics of ongoing studies). We did not include any new studies in this update.

Included studies

Details of the included studies are provided in the 'Characteristics of included studies' table.

We included five trials, with a total of 1208 participants. Of the five trials, three were randomised controlled trials (Diamond 1968; Eogan 2007; Shelton 1980), and two were quasi-randomised controlled trials (Mundow 1975; Zuspan 1960). Four of the trials were from high-income countries, while the fifth trial was from a middle-income country (Shelton 1980). All trials were conducted in a tertiary institution, and the unit of randomisation for all trials was the individual. Trials were published in English; four of the trials compared a pharmaceutical intervention (laxative) with a placebo, while the fifth trial compared a laxative plus bulking agent with the same laxative, in the prevention of postpartum constipation. None of the trials assessed non-pharmacological interventions.

Design

Of the five included trials, three were randomised controlled trials (Diamond 1968; Eogan 2007; Shelton 1980), and two (Mundow 1975; Zuspan 1960) are quasi-randomised trials. The unit of randomisation for all trials was the individual.

Setting

Four of the included trials were conducted in high-income countries (Diamond 1968; Eogan 2007; Mundow 1975; Zuspan 1960). Diamond 1968 and Zuspan 1960 in the United Statas of America; and Eogan 2007 and Mundow 1975 in Ireland. The fifth trial was conducted in South Africa, which is a middle-income country (Shelton 1980). All trials were conducted in a tertiary healthcare institution.

Participants

All included participants were postpartum women without symptoms of constipation at enrolment. Diamond 1968 included 106 postpartum women (55 primiparous and 51 multiparous), with normal vaginal delivery, between the ages of 15 and 41 years. Eogan 2007 included 147 postpartum women undergoing primary repair of an anal sphincter tear sustained during normal vaginal delivery. Mundow 1975 included 200 postpartum women (primiparous and multiparous women); they did not specify the type of delivery. Shelton 1980 included 511 postpartum women who had either a spontaneous vaginal delivery or an assisted vaginal delivery; they excluded those who delivered by caesarean section, or those who sustained a third degree tear during vaginal delivery. Zuspan 1960 included 244 postpartum women; but did not report on the type of delivery.

Interventions and comparisons

Four of the trials compared a pharmaceutical intervention (laxative) to a placebo (Diamond 1968; Mundow 1975; Shelton 1980; Zuspan 1960). The laxatives used in the intervention groups included Dioctyl-sodium succinate plus active senna (Zuspan 1960), active senna (Shelton 1980), Bisoxatin acetate (Diamond 1968), and Danthron/Poloxaikol (Dorbanex) Mundow 1975. The fifth trial compared a laxative plus a bulking-agent (oral lactulose plus one sachet of Ispaghula husk) to the laxative alone (oral lactulose (Eogan 2007)).

It has come to our attention that two of these drugs are no longer indicated in postpartum women. Bisoxatin acetate is no longer recommended for breastfeeding women (Diamond 1968; Omega Pharma 2016); Danthron is no longer on the market in the USA and other countries, as it is 'reasonably anticipated to be a human carcinogen', based on animal studies (Mundow 1975; National Toxicology Program 2016). Therefore, we will present the data of these two studies separately, and not include them in the meta-analysis.

Outcomes

The only primary outcome reported in the included studies was time to first bowel movement. Diamond 1968 reported the number of women with loose or watery stools and frequency of stool; Eogan 2007 reported on pain or discomfort with bowel movement; Shelton 1980 and Mundow 1975 reported on the number of women having abdominal cramps; while Eogan 2007 reported faecal incontinence as an adverse effect of the intervention. Shelton 1980 also reported on adverse effects of the intervention on the baby. However, none of the included trials reported on pain or straining on defecation, or changes in quality of life.

Dates of the study

Mundow 1975 was conducted between 5 May 1974 and 11 June 1974; Eogan 2007 was carried out between May 2003 and April 2004; and Diamond 1968 was conducted between 11 April 1966 and 13 July 1966. Shelton 1980 and Zuspan 1960 did not provide the date of their trials.

Funding sources

The drugs used in three of the trials were supplied by pharmaceutical companies (Diamond 1968; Shelton 1980; Zuspan 1960). Diamond 1968 reported that the trial was supported by Wyeth laboratories, Philadelphia, Pennsylvania, in the USA. Shelton 1980 reported that the drug used for the trial was supplied by Reckitt & Colman Co., and that they also provided statistical analysis. The drug used for Zuspan 1960 was from Purdue Fredrick Co. Eogan 2007 was supported by the Irish Health research board. There was no information on the funding source for Mundow 1975.

Declarations of interest

None of the included trials disclosed conflicts of interest.

Excluded studies

We excluded four trials (ChiCTR1900023067; Liu 2009; Mahony 2004; Sakai 2015). We excluded them because they did not evaluate interventions to prevent postpartum constipation. See the Characteristics of excluded studies.

Ongoing studies

One trial is an ongoing trial (IRCT20190427043386N1). See Characteristics of ongoing studies.

Risk of bias in included studies

We presented judgements regarding the risk of bias in each of the included trials in the 'Characteristics of included studies' table. Summary tables of risk of bias in all included trials are also displayed in Figure 2 and Figure 3.

Figure 2. 'Risk of bias' graph: review authors' judgements about each 'Risk of bias' item presented as percentages across all included studies

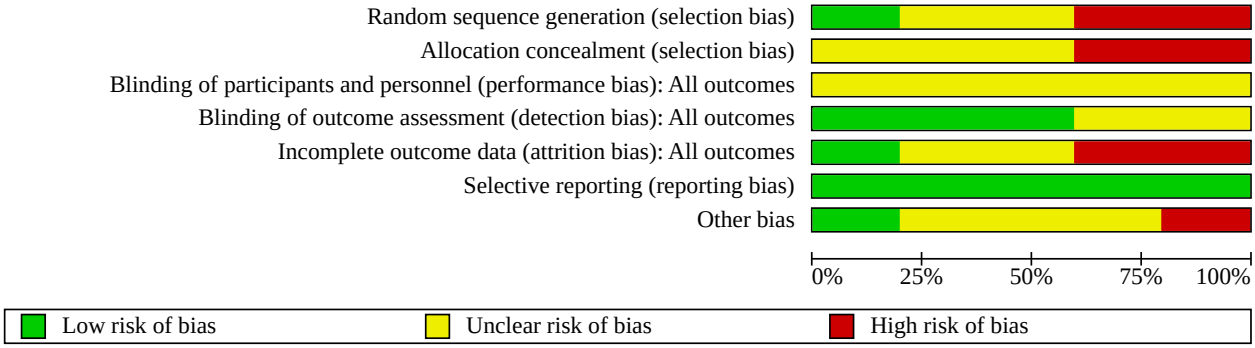
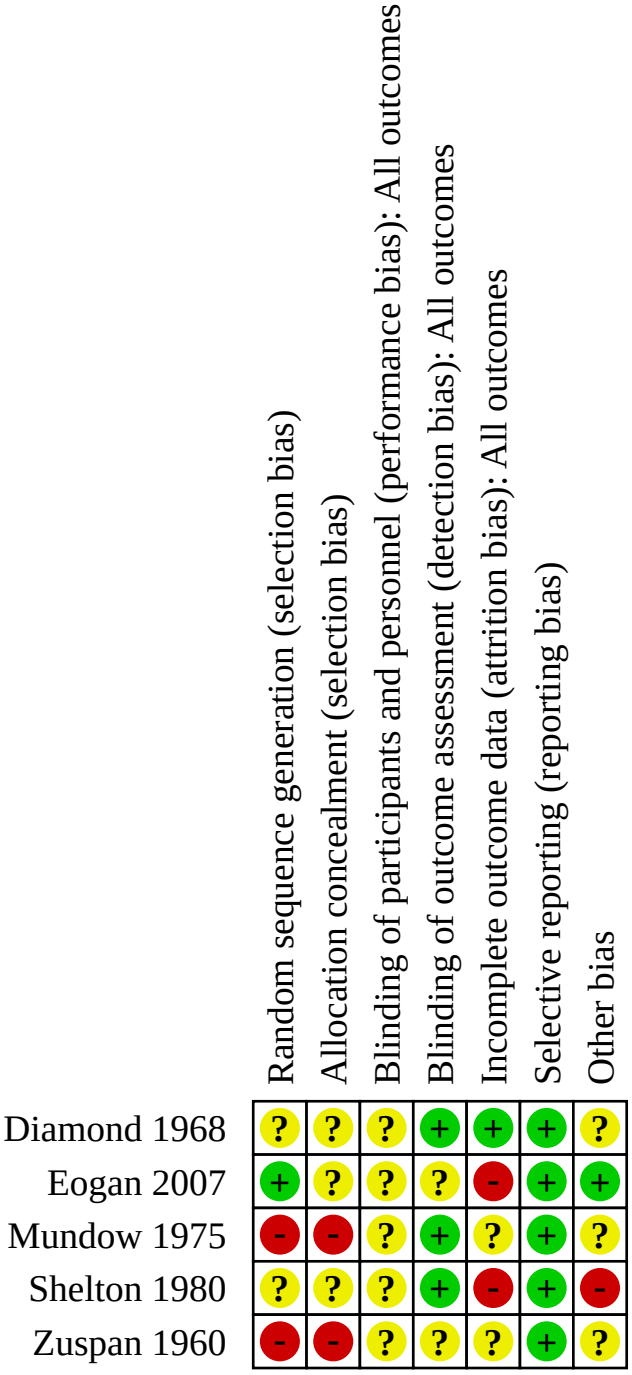


Figure 3. 'Risk of bias' summary: review authors' judgements about each 'Risk of bias' item for each included study



Allocation

Allocation refers to both the generation of the random allocation sequence and concealment of assignment to prevent selection bias.

Generation of allocation sequence

Eogan 2007 used computer-generated numbers in ratio of 1:1 to generate the allocation sequence, and thus we judged it at low risk of selection bias. Two trials provided insufficient information to enable us to judge whether there was a low or high risk of selection bias, therefore, we judged them as unclear risk of selection bias (Diamond 1968; Shelton 1980). The remaining two trials were quasi-randomised trials, which did not indicate the method used to generate allocation sequence; therefore, we considered both trials at high risk of selection bias (Mundow 1975; Zuspan 1960).

Allocation concealment

We judged three trials as unclear risk of bias, since none of them provided sufficient information to enable us to judge whether the trials were of either low or high risk of selection bias (Diamond 1968; Eogan 2007; Shelton 1980). Diamond 1968 used sealed and identical envelopes, but the authors did not report whether they were opaque and sequentially numbered. Eogan 2007 used sealed opaque envelopes, where all the tablets (active and placebo) used were identical in number and appearance, but did not explicitly state whether the envelopes were sequentially numbered. We emailed the corresponding author of Eogan 2007 requesting further information on the method of allocation concealment, but did not receive a response. For Shelton 1980, the tablets (active and placebo) were identical in all respects, and women only received drugs from a numbered bottle, allocated to them. We judged the risk of bias to be high for the two quasi-randomised trials (Mundow 1975; Zuspan 1960). Contact details of corresponding authors were not provided for the other trials.

Blinding

We assessed all included trials as unclear risk of performance bias because it was unclear whether or not the participants and personnel were adequately blinded to the assignment. There was a lack of sufficient and explicit information on the methods used for blinding.

Diamond 1968 reported that participants and investigators were not aware of the content of the identical drugs and envelopes, but did not provide information on identical colour, shape, and size of drug to enable explicit judgement. Eogan 2007 did not supply any information on blinding of participants, personnel, and the investigators; we judged it as unclear risk of bias for both performance and detection bias. Shelton 1980 reported that the trial was double-blind, but did not explicitly explain what steps were followed to ensure adequate blinding of the participants and personnel; we judged it as unclear of performance bias. Zuspan 1960 stated that the trial was double-blind, but failed to report on whether capsules were identical in appearance, shape, and size, and provided no information on blinding of participants and investigators; we judged it as unclear of performance and detection bias. Mundow 1975 reported that the active and placebo tablets were indistinguishable to participants and observers, the code was only sent to the investigator at the end of the study, but did not provide information on whether the people administering the intervention were also prevented from identifying the interventions; we judged it as low risk of detection bias, but unclear risk of performance bias. Diamond 1968 reported that "the knowledge of the random code number and type of drug was not revealed till the completion of the study"; we judged it at low risk of detection bias. Shelton 1980 stated that "statistical analyst had no knowledge of which participants received active treatment or placebo", and that the code was only broken at the final stage of analysis; we judged it at low risk of detection bias.

Incomplete outcome data

Diamond 1968 reported adequately on all participants in the trial, and included them in the final analysis; we considered it at low risk of attrition bias. We assessed two trials at high risk of attrition bias; Eogan 2007 reported that all participants attended the first follow-up at 10 days postpartum, but 26/147 participants did not turn up for assessment at three months following delivery, despite repeated reminders. Of these, 24 gave a personal reason, and two could not be traced and were therefore excluded from the final analysis. The attrition rate was more than 15% in both groups; we considered it at high risk of attrition bias. Forty of the participants in Shelton 1980 were excluded from the analysis because the result showed a small difference, and the number was small (according to trial authors); we judged it at high risk of attrition bias. We judged two trials as unclear risk of attrition bias. Mundow 1975did not give an explicit report of the number of participants in each trial group and there was no flow diagram to illustrate the flow of participants. Zuspan 1960 also did not provide adequate information on the flow of participants in the trial.

Selective reporting

We judged all five included trials to be at low risk of selective outcome reporting. There were no protocols available, but all the outcomes prespecified in the methods section were adequately reported.

Other potential sources of bias

Diamond 1968 and Zuspan 1960 were supported by drug companies. There was no declaration of interest and the trial authors did not specify whether the companies influenced the results or not. Consequently we judged them as unclear risk of other bias. We judged Mundow 1975 as unclear risk of bias, because the trial report did not contain information on conflicts of interest, funding sources, how the sample size was determined, or whether they obtained ethical approval.

We judged Shelton 1980 at high risk of other bias. The authors reported that the drugs used in the trial and statistical evaluation were provided by a drug company, but provided no information on declaration of interest, to ascertain whether the company might have influenced the trial results or not. There was also no information relating to ethical approval.

Eogan 2007 appeared to be at low risk of other bias.

Effects of interventions

See: **Summary of findings 1** Laxative compared to placebo for preventing postpartum constipation; **Summary of findings 2** Laxative plus bulking agent compared to laxative alone for preventing postpartum constipation

The five included trials examined two different comparisons (Diamond 1968; Eogan 2007; Mundow 1975; Shelton 1980; Zuspan 1960).

Comparison 1 – Laxative versus placebo

Four included trials examined the effectiveness and safety of a laxative versus a placebo control (Diamond 1968; Mundow 1975; Shelton 1980; Zuspan 1960; Summary of findings 1). We present the data for this comparison narratively, as the laxative used in one study is no longer recommended for breastfeeding women (Bisoxatin acetate; Diamond 1968), and another has been shown to be carcinogenic in animals, and is no longer allowed to be marketed (Danthron; Mundow 1975).

Primary outcomes

Pain or straining on defecation

None of the trials evaluating this comparison reported on pain or straining during defecation.

Incidence of postpartum constipation, as per self-report and other diagnostic criteria

None of the trials evaluating this comparison reported on the incidence of postpartum constipation.

Quality of life, as measured in included studies (using, e.g. maternal postpartum quality of life (MAPP-QOL) questionnaire)

None of the trials evaluating this comparison reported on quality of life.

Time to first bowel movement (days)

Four trials reported on this outcome (Diamond 1968; Mundow 1975; Shelton 1980; Zuspan 1960). Three trials reported on the number of women having their first bowel movement on the day of delivery, day one, day two, day three, and day four. Zuspan 1960 reported the mean days to first bowel movement.

Number of women having their first bowel movement in less than 24 hours

Compared to placebo, a laxative (senna) may increase the number of women having their first bowel movement in less than 24 hours (142/224 (63%) versus 54/247 (21.9%); risk ratio (RR) 2.90, 95% confidence interval (CI) 2.24 to 3.75, 1 trial, 471 women; low-certainty evidence; Analysis 1.1; Shelton 1980).

Number of women having their first bowel movement on day one

Three trials reported the number of women having their first bowel movement on day one; we are giving results separately for each study, since each trial used a different laxative.

Compared to placebo, a laxative (senna) may result in little to no difference in the number of women having their first bowel movement on day one but the evidence is very uncertain (69/224 (31%) versus 81/247 (33%); RR 0.94, 95% CI 0.72 to 1.22; 1 trial, 471 women; very low-certainty evidence; Analysis 1.2; Shelton 1980).

The laxatives used in these two trials are no longer used. In one trial, more women in the laxative group had their first bowel movement on day one, compared with placebo (23/54 (43%) versus 11/52 (21%); RR 2.01, 95% CI 1.09 to 3.70; 1 trial, 106 women; Analysis 1.2; Diamond 1968). In the second trial, fewer women in the laxative group had their first bowel movement on day one, compared with placebo (7/100 (7%) versus 9/100 (9%); RR 0.78, 95% CI 0.30 to 2.01; 1 trial, 200 women; Analysis 1.2; Mundow 1975).

Number of women having their first bowel movement on day two

Three trials reported the number of women having their first bowel movement on day two; we are providing the results separately for each study, since each trial used a different laxative.

Compared to placebo, a laxative (senna) may reduce the number of women having first bowel movement on day two (9/224 (4%) versus 44/247 (18%); RR 0.23, 95% CI 0.11 to 0.45; 1 trial, 471 women; low-certainty evidence; Analysis 1.3; Shelton 1980).

The laxatives used in these trials are no longer used. In one study, more women in the laxative group had their first bowel movement on day two, compared with placebo (26/54 (48%) versus 9/52 (17%); RR 2.78, 95% CI 1.44 to 5.36, 1 trial, 106 women; Analysis 1.3; Diamond 1968). In the second study, more women in the laxative group also had their first bowel movement on day two, compared with placebo (49/100 (49%) versus 12/100 (12%); RR 4.08, 95% CI 2.32 to 7.20; 1 trial, 200 women; Analysis 1.3; Mundow 1975).

Number of women having their first bowel movement on day three

Two trials measured this outcome. We are providing the results separately for each study, since each trial used a different laxative.

Compared to placebo, a laxative (senna) may reduce the number of women having first bowel movement on day three (0/224 (0%) versus 10/247 (4%); RR 0.05, 95% CI 0.00 to 0.89; 1 trial, 471 women; low-certainty evidence; Analysis 1.4; Shelton 1980).

The laxative used in Mundow 1975 is no longer used. Fewer women had their first bowel movement on day three with the laxative, compared with placebo (30/100 (30%) versus 33/100 (33%); RR 0.91, 95% CI 0.60 to 1.37; 1 trial, 200 women; Analysis 1.4).

Number of women having their first bowel movement on day four

Two trials measured this outcome. We are providing the results separately for each study, since each trial used a different laxative.

It is uncertain if laxative (senna), compared with placebo, has any effect on the number of women having their first bowel movement on day four (1/224 (0.4%) versus 5/247 (2%); RR 0.22, 95% CI 0.03 to 1.87; 1 trial, 471 women; very low-certainty evidence; Analysis 1.5; Shelton 1980).

The laxative used in Mundow 1975 is no longer used. Fewer women in the laxative group had their first bowel movement on day four, compared to placebo (14/100 (14%) versus 38/100 (38%); RR 0.37, 95% CI 0.21 to 0.64; 1 trial, 200 women; Analysis 1.5).

Number of days to first bowel movement

Zuspan 1960 reported that the mean number of days before the first bowel movement was 2.48 days for the laxative group versus 2.55 days for the placebo group. However, since they did not report standard deviations or P values, we were unable to analyse these data further.

Secondary outcomes

Stool consistency using the Bristol Stool Form Scale (BSFS)

None of the trials evaluating this comparison reported on stool consistency using the BSFS.

The laxative used in Diamond 1968 is no longer used. Compared to placebo, the laxative may increase the number of women having loose or watery stools (28/54 (51.9%) versus 1/52 (1.9%); RR 26.96, 95% CI 3.81 to 191.03; 1 trial, 106 women; Analysis 1.6). The CI is wide because there was only one event in the placebo group.

Use of alternative products, laxative agents, enemas

Compared to the placebo, a laxative (dioctyl-sodium succinate + senna) may result in little to no difference in the number of postpartum enemas given (20/123 (16.3%) versus 31/121 (25.6%); RR 0.63, 95% CI 0.38 to 1.05; 1 trial, 244 women; Analysis 1.7; Zuspan 1960).

The laxative used in Mundow 1975 is no longer used. Compared to placebo, a laxative may reduce the number of women receiving suppositories or enemas (7/100 (7%) versus 24/100 (24%); RR 0.29, 95% CI 0.13 to 0.65; 1 trial, 200 participants; Analysis 1.8).

Relief of abdominal pain or discomfort

None of the trials evaluating this comparison reported on relief of abdominal pain or discomfort.

Stool frequency

The laxatives used in these two trials are no longer used.

Compared to placebo, a laxative may increase the number of women having more than two bowel movements per day (13/54 (24.1%) versus 0/52 (0%); RR 26.02, 95% CI 1.59 to 426.73; 1 trial, 106 women; Analysis 1.9; Diamond 1968). The CI is wide because there were no events in the placebo group.

Mundow 1975 (200 women) reported the number of days (from zero to five days) that women recorded bowel movements (Analysis 1.10). Compared to placebo, a laxative may reduce the number of women having no bowel movement for five days (0/100 (0%) versus 9/100 (9%); RR 0.05, 95% CI 0.00 to 0.89); may result in little to no difference in the number of women having bowel movements on days one, three, and five; may reduce the number of women having bowel movements on day two (25/100 (25%) versus 42/100 (42%); RR 0.60, 95% CI 0.39 to 0.90); and may increase the number of women having bowel movements on day four (27/100 (27%) versus 10/100(10%); RR 2.70, 95% CI 1.38 to 5.28).

Adverse effects caused by the intervention

Two trials reported on the number of women having abdominal cramps.

Compared to placebo, a laxative (senna) may increase the number of women having abdominal cramps (23/224 (10.3%) versus 6/247 (2.4%); RR 4.23, 95% CI 1.75 to 10.19; 1 trial, 471 women; low-certainty evidence; Analysis 1.11; Shelton 1980).

Fewer women in the laxative group had abdominal cramps compared with the placebo group (1/100 versus 4/100; RR 0.25, 95% CI 0.03 to 2.20; 1 trial, 200 women; Analysis 1.11; Mundow 1975). The laxative used in this trial is no longer used.

Adverse effects of the intervention on the baby

Shelton 1980 reported on adverse effects of the intervention on the baby.

Compared to placebo, a laxative (senna) for mothers may have little or no effect on loose stools in their babies (RR 0.62, 95% CI 0.16 to 2.41; 1 trial, 281 babies; very low-certainty evidence), or diarrhoea (RR 2.46, 95% CI 0.23 to 26.82; 1 trial, 281 babies; very low-certainty evidence; Analysis 1.12).

Comparison 2 – Laxative plus a bulking agent versus laxative alone

One trial compared a laxative plus a bulking agent (lactulose plus a sachet of Ispaghula husk) versus laxative (lactulose) alone in women who had sustained sphincter injuries during vaginal delivery, and had subsequently undergone surgical repair of the tear (Eogan 2007; Summary of findings 2).

Primary outcomes

Pain or straining on defecation

Eogan 2007 reported on the level of pain or discomfort with the first postpartum bowel movement using a Likert scale (1 = no pain to 5 = excruciating pain) during the first 10 days postpartum. The median (range) pain score for both study groups was one (1 to 5), with no clear differences between the two groups (P = 0.11; very low-certainty evidence) as reported by trial authors. We were unable to further analyse these data, since they were only reported as medians (range).

Incidence of postpartum constipation, as per self-report and other diagnostic criteria

Eogan 2007 reported there was no difference in incidence of postpartum constipation (data not reported).

Quality of life, as measured in included studies (using, e.g. maternal postpartum quality of life (MAPP-QOL) questionnaire)

The trial evaluating this comparison did not report on change in quality of life.

Time to first bowel movement (days)

Eogan 2007 reported that the first postpartum bowel motion occurred at a median of three days (range one to six) for the group who took the laxative plus bulking agent and a median of three days (range one to five) for the group who took laxative alone; the trial authors reported little to no difference between the two treatment groups (P = 0.34; very low-certainty evidence).

Secondary outcomes

Stool consistency using Bristol Stool Form Scale

The trial evaluating this comparison did not report on stool consistency.

Use of alternative products, laxative agents, enemas

The trial evaluating this comparison did not report on use of alternative products, laxative agents, or enemas.

Relief of abdominal pain or discomfort

The trial evaluating this comparison did not report on relief of abdominal pain or discomfort.

Stool frequency

The trial evaluating this comparison did not report on stool frequency.

Adverse effects caused by the intervention

Eogan 2007 reported incontinence using a bowel function questionnaire with a score from 0 to 20 (0 = incomplete continence to 20 = complete incontinence). Scores were assigned according to participant's symptoms, including faecal urgency or incontinence, and flatus incontinence, on day three, day 10, and after three months postpartum. The incontinence score on day three was significantly higher in the laxative plus bulking agent group (median 1; range 0 to 10) compared to the laxative alone group (median 0; range 0 to 12; P = 0.02), as reported by trial authors. There was little to no difference in the incontinence scores between the two groups at three months postpartum (laxative plus bulking agent median 0 (range 0 to 6) versus laxative median 0 (range 0 to 10); P = 0.57; as reported by trial authors). No further analysis was possible since results were only reported as medians (range).

The trial also reported the number of participants having any episode of faecal incontinence during the first 10 postpartum days. Compared to laxative alone, laxative plus bulking agent may increase the number of women having any episode of faecal incontinence during the first 10 postpartum days, but the evidence is very uncertain (RR 1.81, 95%CI 1.01 to 3.23; 1 trial, 147 women; very low-certainty evidence; Analysis 2.1).

Adverse effects of the intervention on the baby

The trial included in this comparison did not report on adverse effects of the intervention on the baby.

DISCUSSION

Summary of main results

The objective of this review was to update a previous review, assessing the effectiveness and safety of different interventions for preventing postpartum constipation (Turawa 2015b). We did not identify new trials that met our inclusion criteria. We reviewed and updated the previously included five trials (involving a total of 1208 postpartum women) according to MECIR guidelines and assessed the certainty of evidence using GRADE.

We did not include the results of two trials in our main findings, as one assessed the effects of Danthron, a drug shown to have carcinogenic properties in animals (Mundow 1975), while the other trial assessed the effects of Bisoxatin Acetate, which is not recommended for use when breastfeeding (Diamond 1968). As these trials meet eligibility criteria, we included them and reported on the results in a narrative way.

For comparison 1 (laxative versus placebo), none of the included trials reported on pain or straining on defecation, incidence of postpartum constipation, or changes in quality of life.

We included results from one trial, assessing the effects of senna tablets compared to placebo in Summary of findings 1 (Shelton 1980). Results suggest that laxatives compared to placebo may increase the number of women having their first bowel movement in less than 24 hours after delivery, and may reduce the number of women having their first bowel movement on days 2 and 3 after delivery, but the evidence is low certainty. Laxatives may have little or no effect on the number of women having their first bowel movement on day 1 or day 4 after delivery, but the evidence is very uncertain. In terms of adverse effects, laxatives may increase the number of women experiencing abdominal cramps, and may increase the number of babies having loose stools or diarrhoea compared to placebo, but the evidence is very uncertain for most of these outcomes.

One trial, assessing the effects of dioctyl-sodium succinate and senna compared to placebo, reported the mean number of days before the first bowel movement was 2.48 days for the laxative versus 2.55 days for the placebo groups. However, since there were no standard deviations and P values reported we were unable to analyse these data further (Zuspan 1960).

For comparison 2 (laxative plus bulking agent versus laxative alone), we included one trial, comparing oral lactulose plus a bulking agent (Ispaghula husk) versus the same laxative in postpartum women who underwent surgical repair of a third-degree perineal tear (Eogan 2007). The trial authors reported no difference between groups in pain or straining on defecation. However, they only reported the medians and ranges for both groups, and we were unable to analyse the data further. Trial authors reported no difference in the incidence of self-reported postpartum constipation (data not available) and no difference in time to first bowel movement (median and ranges reported). In terms of adverse effects, results of the trial suggest that compared to laxative alone, laxative plus bulking agent may increase the number of women having faecal incontinence during the first 10 postpartum days, but the evidence is very uncertain. The trial did not report on any adverse effects on the baby.

Overall completeness and applicability of evidence

The five trials were conducted in three different countries (USA, Ireland, and South Africa), all in tertiary hospitals. All trials except Eogan 2007, were published more than 40 years ago.

All included trials assessed pharmaceutical interventions to prevent postpartum constipation. Of these, one trial assessed the effects of Danthron (Mundow 1975), a laxative that has shown to have carcinogenic effects in animals, and is no longer marketed in most countries (Barth 1984; National Toxicology Program 2016; Sunitha 2016; Xing 2001). Another trial assessed the effects of Bisoxatin acetate (Diamond 1968), a drug currently marketed under the trade name Wylaxine, which is not recommended for use during lactation (Omega Pharma 2016). Although we included these studies in the review, we presented the results separately from our main findings, as these drugs can be harmful when used in postpartum women.

The use of dioctyl-sodium succinate, a laxative assessed in combination with senna in the trial by Zuspan 1960, has been widely debated, with calls to remove it from hospitals' formularies, as it has been shown to be ineffective (CADTH 2014; Fakheri 2019; MacMillan 2016; Ramkumar 2005). Others have also expressed some concerns about using dioctyl-sodium succinate when breastfeeding.

The only drug currently listed on the WHO's list of essential medicines for breastfeeding women is senna, and its use is recommended only when dietary measures have failed (WHO 2002).

The trial we included in the 'Summary of findings' table assessed the effects of senna tablets on preventing postpartum constipation (Shelton 1980).

Eogan 2007 evaluated two different interventions amongst women who had undergone surgical repair of a third degree perineal tear. This is a very specific group of trial participants, and therefore, the results cannot be extrapolated to the general postpartum woman. The pain experienced with the first bowel movement was most likely attributable to pain from the perineal tear and surgery, and not necessarily to constipation. Fear of pain can also play a role in this group of women, which might lead to constipation.

None of the trials assessed other interventions, such as dietary advice and modification, promotion of healthy physical activities, or the correct positioning for defecation, which also have an important place in promoting bowel movements during the postpartum period. Consideration should also be given to other factors that might influence postpartum bowel movements, such as the administration of enemas before labour, the ability of women to eat during active labour, irregular and altered eating habits during the first few days after delivery, and fear of pain from a repaired perineal tear or episiotomy, especially third degree tears, which could involve the anal sphincter. None of these factors were reported in the included trials. Included trials only assessed bowel movements during the first five days after delivery. Constipation can become a problem at a later stage, even up to six months postpartum (Van Brummen 2006). Factors, such as limited physical exercise, irregular and altered dietary pattern, insufficient intake of fluids, and emotional concerns of being a new mother, may have a negative influence on bowel movements during this period (NIH-NIDDK 2018).

Only a few adverse effects were reported in the included trials, therefore, there is insufficient evidence to make general conclusions on safety and effectiveness of these interventions.

Quality of the evidence

All the five trials included in this review lacked methodological rigour, and four of the five trials were published prior to 1980.

We did not include studies that assessed drugs that are harmful or contra-indicated for breastfeeding women in the 'Summary of findings' table, as this would not be useful for decision-makers. For the comparison 'Laxative versus placebo', we only included one study in Summary of findings 1 (Shelton 1980). We downgraded the certainty of evidence by two levels due to very serious study limitations (high risk of attrition bias, high risk of other bias due to industry sponsorship and statistical analysis, and unclear risk of selection bias). We downgraded the certainty of evidence by another level due to imprecision, as findings were based on a single study with few participants, with results that had wide confidence intervals that crossed the line of no effect. The study excluded women who had delivered via caesarean section, or who had third degree tears, a population in which laxatives would be indicated, due to pain and fear when straining. Therefore, the certainty of evidence was low or very low for all outcomes, and we have very little confidence in the effect estimate.

For the comparison 'Laxative plus bulking agent compared to laxative alone', we included one study in Summary of findings 2 (Eogan 2007). We downgraded the certainty of evidence by one level due to study limitations (high risk of attrition bias, unclear risk of selection, performance, and detection bias). We downgraded by another level due to imprecision, as the results were based on a single study, with a small sample size, and results that had wide confidence intervals, crossing the line of no effect. We downgraded by one level due to indirectness, as results were from a single study, conducted in Ireland, and participants only included women undergoing surgical repair of third degree perineal tears. Therefore, the certainty of evidence was very low for all outcomes, and we have very little confidence in the effect estimate.

Potential biases in the review process

We attempted to minimise potential bias in this review in a number of ways. The Cochrane Pregnancy and Childbirth group Information Specialist conducted a comprehensive trial search to include published and unpublished trials in all languages. At least two review authors independently scrutinised and selected trials for inclusion in the review using eligibility criteria, assessed risk of bias, and extracted data. We were unable to examine reporting biases using funnel plots, as we had fewer than 10 included trials in a meta-analysis. We had planned to analyse the primary outcome 'number of days to first bowel movement' using time-to-event analysis methods, but we were unable to do this, due to insufficient individual patient data. The separate analyses per day did not take account of the fact that the denominator was decreasing as the number of days after delivery increased, due to the fact that once a woman experienced the event, they could not experience the event again. As four of the included trials were published more than 40 years ago; we were unable to contact authors to obtain missing data or information.

Agreements and disagreements with other studies or reviews

There is no other systematic review on interventions for preventing postpartum constipation. Our review on interventions to treat postpartum constipation did not identify any trials to include (Turawa 2014). The Cochrane Review on interventions to treat constipation during pregnancy included four trials, all published more than 30 years ago (Rungsiprakarn 2015) Included trials also did not report on pain on defecation and quality of life. Authors concluded that there was 'insufficient evidence to comprehensively assess the effectiveness and safety of interventions'.

Dietary fibre, in the form of wheat and brans, offers relief for constipation in non-pregnant mothers, and raises no serious concerns about side effects to mother and baby. Other measures, such as behavioural and educational interventions, increased exercise, and positioning during bowel movement, were not discussed in the included trials. Symptomatic rectal haemorrhoids also play a significant role in postpartum constipation, and dietary fibre seems to offer effective treatment in relieving haemorrhoids, which may contribute to constipation (Alonso-Coello 2005).

AUTHORS' CONCLUSIONS

Implications for practice

Overall, there is insufficient evidence to make general conclusions about the effectiveness and safety of laxatives for preventing postpartum constipation. Laxatives compared to placebo may lead to more women having a bowel movement during the first 24 hours after delivery, and fewer women having the first bowel

movement on day two and three after delivery, but the evidence is very uncertain. Adverse events were poorly reported. We are very uncertain whether laxatives plus bulking agent compared to laxatives alone have an effect on pain or straining on defecation, and time to first bowel movement. Laxatives plus bulking agent may increase the incidence of faecal incontinence during the first 10 days postpartum, but the evidence is very uncertain.

We found no evidence for pain or straining on defecation, incidence of postpartum constipation, or quality of life from studies comparing laxatives to placebo; we did not identify any trials assessing educational or behavioural interventions.

Trials did not follow participants through the entire postpartum period, so we did not find any evidence on the effectiveness and safety regarding the use of laxatives during the entire postpartum period, up to six months.

Implications for research

There are few trials on interventions for preventing postpartum constipation, which report on the following important outcomes: pain or straining on defecation, incidence of postpartum constipation, quality of life, time to first bowel movement after delivery, or adverse effects caused by the intervention, such as: nausea or vomiting, pain, or flatus. No trials evaluating non-pharmacological interventions, such as acupuncture, educational or behavioural interventions, or positioning during bowel movements are currently available. As some drugs are not recommended for use when breastfeeding, future trials should focus on assessing educational and behavioural interventions, aimed at promoting a healthy diet and physical activity in preventing postpartum constipation.

Large, rigorous, randomised controlled trials are needed to address the safety and effectiveness of laxatives for preventing constipation during the entire postpartum period.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

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

Diamond 1968

Study characteristics	
Methods	Study design: randomised controlled trial. Trial duration: 12 weeks (11 April 1966 to 13 July 1966) Trial location: University of Minnesota Hospitals, Minneapolis, USA
Participants	Number of participants: 106 postpartum women aged 15 to 41 years Intervention group: 54 women (29 primiparous and 25 multiparous) Control group: 52 women (26 primiparous and 26 multiparous)
Interventions	Intervention: Bisoxatin acetate (3 tablets); 1 tablet was given orally 1st day postpartum and if no bowel action occur that 1st day, the dose was increased to 2 tablets on the 2nd day. If no bowel activity occur by the 3rd day, another form of laxative was used. Control: lactose placebo (3 tablets)
Outcomes	**Primary outcomes** 1. Number of participants having their first bowel movement by day 1, day 2, and day 3 2. Number of stools per day 3. Side effects: diarrhoea, loose or watery stool
Notes	Ethics approval: not stated Correspondence with authors: no email address available. We would have requested details regarding risk of bias, for instance whether random number tables or a computer were used in random sequence generation. Dates of study: study was conduct between 11 April 1966 and 13 July 1966 Funding sources: study was supported by the Wyeth Laboratories, Philadelphia, Pennsylvania, USA Declarations of interest: no comment provided

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote "Each patient was assigned a number according to a random code". It was unclear how the random sequence was generated.
Allocation concealment (selection bias)	Unclear risk	Quote "Identical envelopes and drugs were used". It was unclear whether adequate precautions were taken to conceal the assignment from the participants and investigators.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Quote "The patients and investigators were not aware of the content of the identical drugs and envelopes".

Diamond 1968 *(Continued)*

		Insufficient information on identical colour, shape, and size of drug to enable explicit judgement.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote "The knowledge of the random code number and type of drug was not revealed till the completion of the study".
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data. All women enrolled were included in the final analysis.
Selective reporting (reporting bias)	Low risk	No published protocol available, but all outcomes that were prespecified in the methods session were addressed.
Other bias	Unclear risk	The study was supported by Wyeth Laboratories, but the trial authors did not specify whether the drug company influenced the results.

Eogan 2007

Study characteristics	
Methods	Study design: randomised controlled trial Trial duration: 12 months (May 2003 to April 2004) Trial location: National Maternity Hospital, Holles St Dublin, Ireland
Participants	Participants: 147 postpartum women with sphincter injury at vaginal delivery, undergoing primary repair of a recognised anal sphincter tear Intervention group: 70 postpartum women Control group: 77 postpartum women Exclusion criteria: history of colorectal disease, inflammatory bowel disease, diabetes mellitus, or colorectal malignancy
Interventions	Intervention: oral lactulose 10 mL thrice daily for the first 3 postpartum days, followed by sufficient lactulose to maintain a soft stool for 10 days, plus 1 sachet of Ispaghula husk for 10 days Control: oral lactulose 10 mL thrice daily for the first 3 postpartum days, followed by sufficient lactulose to maintain a soft stool for 10 days All women were given routine antibiotics (co-amoxyclavulanic acid); erythromycin and metronidazole were used in those with penicillin allergy All participants were provided with a diary card to keep record of their bowel habits and movements for 10 days Opiate was avoided in both groups
Outcomes	**Primary outcomes** 1. Discomfort with 1st postpartum bowel motion (using pain scale from 1 = no pain to 5 = excruciating pain) 2. Incidence of postnatal constipation and incontinence **Secondary outcomes**

Eogan 2007 *(Continued)*

	1. Time until first bowel motion 2. Duration of postnatal stay 3. Symptomatic and functional outcomes 3 months postpartum All participants were provided with a diary card to keep record of their bowel habits and movements for 10 days; opiate was avoided in both groups
Notes	Funding: the study was supported by the Irish Health research board Correspondence: email was sent to the author (colm.oherlihy@ucd.ie) requesting further information on method used to ensure adequate concealment of the assignment and blinding processes, but there was no response. Dates of study: the study was conducted between May 2003 and April 2004 Funding sources: the study was supported by the Irish Health research board Declarations of interest: not disclosed

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation was carried out using computer-generated allocations.
Allocation concealment (selection bias)	Unclear risk	''Sealed opaque envelopes were used to concealed allocation identity''. It was not specified whether the envelopes were sequentially numbered to prevent selection bias.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	There was no explicit information on blinding of the participants, personnel, and investigators to the assignment.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to judge whether the assessors were blinded to the assignment or not
Incomplete outcome data (attrition bias) All outcomes	High risk	All participants attended the first 10 day follow-up; 26 did not attend postpartum review at 3 months despite 2 repeated appointment-reminders being sent, 24 of whom gave a personal reason and 2 could not be traced Attrition rate in intervention group (LG) = 16% Attrition rate in control group (FG) = 20%
Selective reporting (reporting bias)	Low risk	All outcomes that were prespecified in the methods were addressed.
Other bias	Low risk	The study appeared to be free of other sources of bias.

Mundow 1975

Study characteristics

Mundow 1975 *(Continued)*

Methods	Study design: quasi-randomised trial Trial duration: 6 weeks (5 May 1974 to 11 June 1974) Trial location: St James' Hospital Dublin. Ireland
Participants	200 normal postpartum women Intervention group: 100 primiparous and multiparous women Control group: 100 primiparous and multiparous women
Interventions	Intervention: Danthron/Poloxalkol (Dorbanex). Each patient was given 2 yellow capsules at 18:00 hour every evening, starting from the 3rd day of delivery, for the next 3 days (6 capsules). The capsules were taken from numbered bottles. Control: placebo - author did not give name of placebo; it was stated that an identical code was used for both the placebo and experimental intervention
Outcomes	**Outcomes** 1. Number of days to first bowel movement 2. Visible haemorrhoids 3. Abdominal pain **Secondary outcomes** 4. Diarrhoea 5. Nausea 6. Urine discolouration
Notes	There was no information on number of participants in each arm of intervention. Ethical approval not stated, and declaration of interest not provided. The funding organisation was not reported. Dates of study: study was conducted between 5 May 1974 to 11 June 1974 Funding sources: no information on how the study was funded Declarations of interest: not disclosed

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote ''Consecutive patients were enrolled into study" Randomisation component not explicitly stated, quasi-randomised trial
Allocation concealment (selection bias)	High risk	Quasi-randomised trial
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Quote "The placebo and the active capsules were indistinguishable to the participant". No information on the personnel, or method used in blinding both participant and the personnel

Mundow 1975 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote "The code which identified the active from the placebo was held at Riker Laboratories at Loughborough, and was sent to the investigator only at the end of the study, the active and placebo were indistinguishable".
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	The number of participants in each group was not stated explicitly and there was no flow diagram to illustrate this.
Selective reporting (reporting bias)	Low risk	Study protocol was not available, but all outcomes specified in the method section were addressed.
Other bias	Unclear risk	There was no information on conflicts of interest, how sample size was determined; no comment was made on ethical approval. The funding organisation was not reported.

Shelton 1980

Study characteristics	
Methods	Study design: randomised controlled trial Trial setting: multi-centre Trial location: Department of Obstetrics and Gynaecology, University of Cape Town, Groote Schuur Hospital, and Peninsula Maternity Hospitals, Cape Town, South Africa
Participants	Participants: 511 normal postpartum women with vaginal delivery White postpartum women: 267 (from GrooteSchuur Hospital) Coloured postpartum women: 204 (Peninsula Maternity Hospital) Black postpartum women: 40 Exclusion criteria: women delivered by caesarean section or complicated by 3rd degree perineal tear
Interventions	Intervention: active senna tablets - 2 tablets were given in the morning and 2 tablets in the evening immediately after delivery, and 2 tablets twice daily until bowel action occurred or end of regimen (16 tablets used up) Control: placebo (powdered corn flakes and dried grass)
Outcomes	**Primary outcomes** 1. Initial spontaneous bowel movement within the first 24 hours of delivery 2. Initial spontaneous bowel movement within 48 hours of delivery 3. First bowel movement on the third day of delivery 4. Time of dosage 5. Time and nature of bowel action **Infant side effects** 1. Loose stools or diarrhoea 2. Number, colour, and nature of stools for duration of trial

Shelton 1980 *(Continued)*

	3. Proportion of babies with normal stools 4. Mode of feeding **Secondary outcomes** 1. Enema during labour and state of perineum following delivery 2. Maternal side effects: e.g. abdominal colic pains 3. Mode of delivery
Notes	Sponsor: the drugs were supplied by Reckitt & Colman, and statistical evaluation provided by them Ethics approval: not stated Decaration of interest: not disclosed Dates of study: date of the study was not provided by the authors Funding sources: drugs used in the trial and the analysis was done by Reckitt & Colman Company Declarations of interest: not disclosed

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote ''Trial preparation was administered according to a strict double - blind random selection procedure". Author did not provide sufficient information on how randomisation was done.
Allocation concealment (selection bias)	Unclear risk	Quote ''tablets (active and placebo) were identical in all respects and patient only received drugs from a numbered bottle allocated to her''. The authors did not provide sufficient information to enable a clear judgement.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Quote "Treatment assignment was masked from all study personnel and participants for the duration of the study". Information on methods used to mask the colour, shape, and size was not supplied.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote "Statistical analyst had no knowledge of which patients received active treatment or placebo". The code was only broken at the final stage of analysis.
Incomplete outcome data (attrition bias) All outcomes	High risk	The results of 40 participants were not included because the results showed minimal differences.
Selective reporting (reporting bias)	Low risk	All the prespecified outcomes in the method section were addressed adequately.
Other bias	High risk	Sponsor: the drugs used were supplied by Reckitt & Colman and statistical evaluation provided by them Ethics approval: not stated

Shelton 1980 *(Continued)*

	Declaration of interest: not disclosed

Zuspan 1960

Study characteristics	
Methods	Study design: quasi-randomised trial Trial setting: Department of Obstetrics and Gynaecology, University Hospital Cleveland, Ohio. USA Trial location: USA
Participants	244 postpartum women
Interventions	Intervention: Dioctyl-sodium succinate (50 mg) + senna (225 mg); 1 capsule twice daily. The 1st capsule was given as soon postpartum as practical. No other laxative drugs given except enema saponis at patients' request. Control: capsulated inert ingredients (placebo), 1 capsule twice daily. 1st dose given as soon postpartum as practical. No other laxative administered except enema saponis at patients' request.
Outcomes	1. Number of days before 1st spontaneous bowel movement 2. Number of capsule (laxative) taken before 1st spontaneous bowel movement 3. Number of postpartum enemas given
Notes	Purdue Fredrick Co. supplied the laxative (Senokap) used for the trial Dates of study: no information supplied Funding sources: the laxative used for the trial was supplied by Purdue Fredrick Co. Declarations of interest: not declared

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk	There was no information on random allocation sequence generation method (quasi-RCT).
Allocation concealment (selection bias)	High risk	Quasi-randomised trial
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Quote "All patients received double blinded capsule as soon postpartum as practical and they were intentionally not told whether the capsule was a laxative or not". No report on method used to blind both the participants and personnel
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information was given on how knowledge of allocated interventions was prevented during measurement of outcomes.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information was provided on the flow of participants.

Zuspan 1960 *(Continued)*

Selective reporting (reporting bias)	Low risk	No published protocol available, but the prespecified outcomes were addressed adequately. Prespecified outcomes 1. Number of days before 1st spontaneous bowel movement 2. Number of capsules (laxative) taken before 1st spontaneous bowel movement 3. Number of postpartum enemas given
Other bias	Unclear risk	Ethics approval not stated Purdue Fredrick Co. supplied the laxative (Senokap) used for the trial Conflict of interest was not addressed; we are not sure if there was a conflict of interest

RCT: randomised controlled trial

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

Study	Reason for exclusion
ChiCTR1900023067	Trial did not study interventions for preventing postpartum constipation.
Liu 2009	Trial did not study interventions to prevent postpartum constipation.
Mahony 2004	Trial did not study interventions to prevent postpartum constipation.
Sakai 2015	Included participants already had symptoms of constipation.

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

IRCT20190427043386N1

Study name	The effect of Kegel exercises for prevention and treatment of constipation and flatulence in antenatal and postnatal
Methods	Randomised controlled trial
Participants	Pregnant mothers, healthy. Minimum age 18 years old
Interventions	Experimental group: Kegel exercises on daily basis, 3 times a day, for 15 to 20 minutes, for 8 consecutive weeks, in addition to routine care Control group: conventional standard methods for improving constipation, such as increased fluid and fibre intake (celluloid material, such as wheat and whole wheat, wheat bran, vegetables, and fruits)
Outcomes	Constipation score; bloating score
Starting date	Expected recruitment date: 21 May 2019
Contact information	Saideh Mehrabadi (saidehmehrabadi@yahoo.com)

IRCT20190427043386N1 *(Continued)*

Notes	Email sent to the author, enquiring about the trial

DATA AND ANALYSES

Comparison 1. Laxative versus placebo

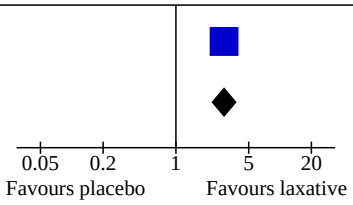
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 Number of women with first bowel movement within 24 hours after delivery	1	471	Risk Ratio (M-H, Fixed, 95% CI)	2.90 [2.24, 3.75]
1.2 Number of women with first bowel movement on day 1 after delivery	3		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
1.3 Number of women with first bowel movement on day 2 after delivery	3		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
1.4 Number of women with first bowel movement on day 3 after delivery	2		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
1.5 Number of women with first bowel movement on day 4 after delivery	2		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.6 Stool consistency - loose or watery stools	1	106	Risk Ratio (M-H, Fixed, 95% CI)	26.96 [3.81, 191.03]
1.7 Number of postpartum enemas given	1	244	Risk Ratio (M-H, Fixed, 95% CI)	0.63 [0.38, 1.05]
1.8 Number of women receiving suppositories or enemas	1	200	Risk Ratio (M-H, Fixed, 95% CI)	0.29 [0.13, 0.65]
1.9 Number of women having 2 or more bowel movements per day	1	106	Risk Ratio (M-H, Fixed, 95% CI)	26.02 [1.59, 426.73]
1.10 Number of days on which a bowel movement occurred	1		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
1.10.1 Zero days	1	200	Risk Ratio (M-H, Random, 95% CI)	0.05 [0.00, 0.89]
1.10.2 One day	1	200	Risk Ratio (M-H, Random, 95% CI)	1.12 [0.45, 2.80]
1.10.3 Two days	1	200	Risk Ratio (M-H, Random, 95% CI)	0.60 [0.39, 0.90]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.10.4 Three days	1	200	Risk Ratio (M-H, Random, 95% CI)	1.35 [0.88, 2.06]
1.10.5 Four days	1	200	Risk Ratio (M-H, Random, 95% CI)	2.70 [1.38, 5.28]
1.10.6 Five days	1	200	Risk Ratio (M-H, Random, 95% CI)	0.80 [0.22, 2.89]
1.11 Adverse effects: women with abdominal cramps	2		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
1.12 Adverse effects on the baby	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.12.1 Loose stools	1	281	Risk Ratio (M-H, Fixed, 95% CI)	0.62 [0.16, 2.41]
1.12.2 Diarrhoea	1	281	Risk Ratio (M-H, Fixed, 95% CI)	2.46 [0.23, 26.82]

Analysis 1.1. Comparison 1: Laxative versus placebo, Outcome 1: Number of women with first bowel movement within 24 hours after delivery

Study or Subgroup	Laxative Events	Laxative Total	Placebo Events	Placebo Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Shelton 1980 (1)	142	224	54	247	100.0%	2.90 [2.24 , 3.75]
Total (95% CI)		**224**		**247**	**100.0%**	**2.90 [2.24 , 3.75]**
Total events:	142		54			

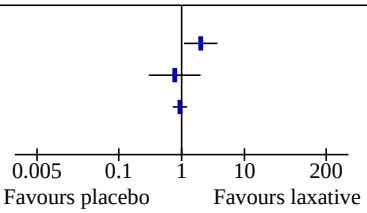
Heterogeneity: Not applicable
Test for overall effect: Z = 8.15 (P < 0.00001)
Test for subgroup differences: Not applicable



Footnotes
(1) Laxative used: active senna

Analysis 1.2. Comparison 1: Laxative versus placebo, Outcome 2: Number of women with first bowel movement on day 1 after delivery

Study or Subgroup	Laxative Events	Laxative Total	Placebo Events	Placebo Total	Risk Ratio M-H, Random, 95% CI
Diamond 1968 (1)	23	54	11	52	2.01 [1.09 , 3.70]
Mundow 1975 (2)	7	100	9	100	0.78 [0.30 , 2.01]
Shelton 1980 (3)	69	224	81	247	0.94 [0.72 , 1.22]



Footnotes

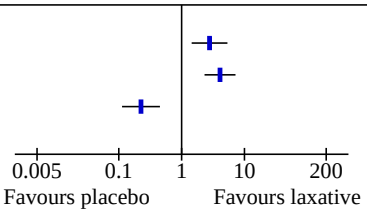
(1) Laxative used: Bisoxatin acetate (no longer recommended for breastfeeding women)

(2) Laxative used: Dorbanex (Danthron; found to be carcinogenic in animals and no longer marketed)

(3) Laxative used: active senna.

Analysis 1.3. Comparison 1: Laxative versus placebo, Outcome 3: Number of women with first bowel movement on day 2 after delivery

Study or Subgroup	Laxative Events	Laxative Total	Placebo Events	Placebo Total	Risk Ratio M-H, Random, 95% CI
Diamond 1968 (1)	26	54	9	52	2.78 [1.44 , 5.36]
Mundow 1975 (2)	49	100	12	100	4.08 [2.32 , 7.20]
Shelton 1980 (3)	9	224	44	247	0.23 [0.11 , 0.45]



Footnotes

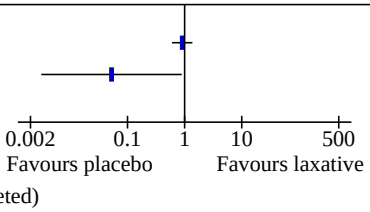
(1) Laxative used: Bisoxatin acetate (no longer recommended for breastfeeding women)

(2) Laxative used: Dorbanex (Danthron; found to be carcinogenic in animals and no longer marketed)

(3) Laxative used: active senna.

Analysis 1.4. Comparison 1: Laxative versus placebo, Outcome 4: Number of women with first bowel movement on day 3 after delivery

Study or Subgroup	Laxative Events	Laxative Total	Placebo Events	Placebo Total	Risk Ratio M-H, Random, 95% CI
Mundow 1975 (1)	30	100	33	100	0.91 [0.60 , 1.37]
Shelton 1980 (2)	0	224	10	247	0.05 [0.00 , 0.89]



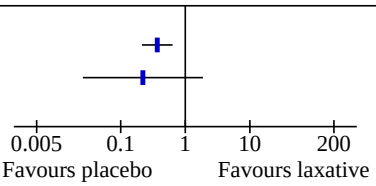
Footnotes

(1) Laxative used: Dorbanex (Danthron; found to be carcinogenic in animals and no longer marketed)

(2) Laxative used: active senna

Analysis 1.5. Comparison 1: Laxative versus placebo, Outcome 5: Number of women with first bowel movement on day 4 after delivery

Study or Subgroup	Laxative Events	Laxative Total	Placebo Events	Placebo Total	Risk Ratio M-H, Fixed, 95% CI
Mundow 1975 (1)	14	100	38	100	0.37 [0.21 , 0.64]
Shelton 1980 (2)	1	224	5	247	0.22 [0.03 , 1.87]



Footnotes

(1) Laxative used: Dorbanex (Danthron; found to be carcinogenic in animals and no longer marketed)

(2) Laxative used: active senna

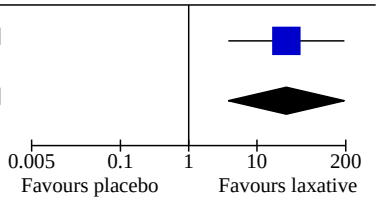
Analysis 1.6. Comparison 1: Laxative versus placebo, Outcome 6: Stool consistency - loose or watery stools

Study or Subgroup	Laxative Events	Laxative Total	Placebo Events	Placebo Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Diamond 1968 (1)	28	54	1	52	100.0%	26.96 [3.81 , 191.03]
Total (95% CI)		**54**		**52**	**100.0%**	**26.96 [3.81 , 191.03]**
Total events:	28		1			

Heterogeneity: Not applicable

Test for overall effect: Z = 3.30 (P = 0.0010)

Test for subgroup differences: Not applicable



Footnotes

(1) Laxative used: Bisoxatin acetate (no longer recommended for breastfeeding women)

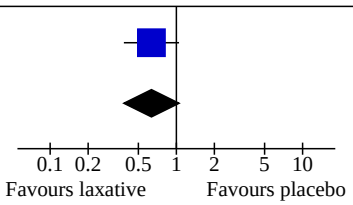
Analysis 1.7. Comparison 1: Laxative versus placebo, Outcome 7: Number of postpartum enemas given

Study or Subgroup	Laxative Events	Laxative Total	Placebo Events	Placebo Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Zuspan 1960	20	123	31	121	100.0%	0.63 [0.38 , 1.05]
Total (95% CI)		**123**		**121**	**100.0%**	**0.63 [0.38 , 1.05]**
Total events:	20		31			

Heterogeneity: Not applicable

Test for overall effect: Z = 1.77 (P = 0.08)

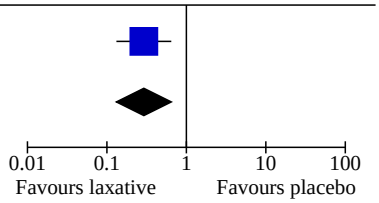
Test for subgroup differences: Not applicable



Analysis 1.8. Comparison 1: Laxative versus placebo, Outcome 8: Number of women receiving suppositories or enemas

Study or Subgroup	Laxative Events	Laxative Total	Placebo Events	Placebo Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Mundow 1975 (1)	7	100	24	100	100.0%	0.29 [0.13 , 0.65]
Total (95% CI)		**100**		**100**	**100.0%**	**0.29 [0.13 , 0.65]**
Total events:	7		24			

Heterogeneity: Not applicable
Test for overall effect: Z = 3.04 (P = 0.002)
Test for subgroup differences: Not applicable

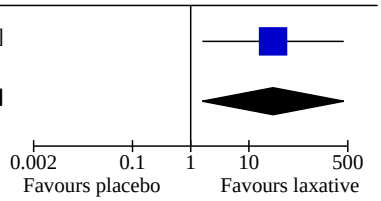


Footnotes
(1) Laxative used: Dorbanex (Danthron; found to be carcinogenic in animals and no longer marketed)

Analysis 1.9. Comparison 1: Laxative versus placebo, Outcome 9: Number of women having 2 or more bowel movements per day

Study or Subgroup	Laxative Events	Laxative Total	Placebo Events	Placebo Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Diamond 1968 (1)	13	54	0	52	100.0%	26.02 [1.59 , 426.73]
Total (95% CI)		**54**		**52**	**100.0%**	**26.02 [1.59 , 426.73]**
Total events:	13		0			

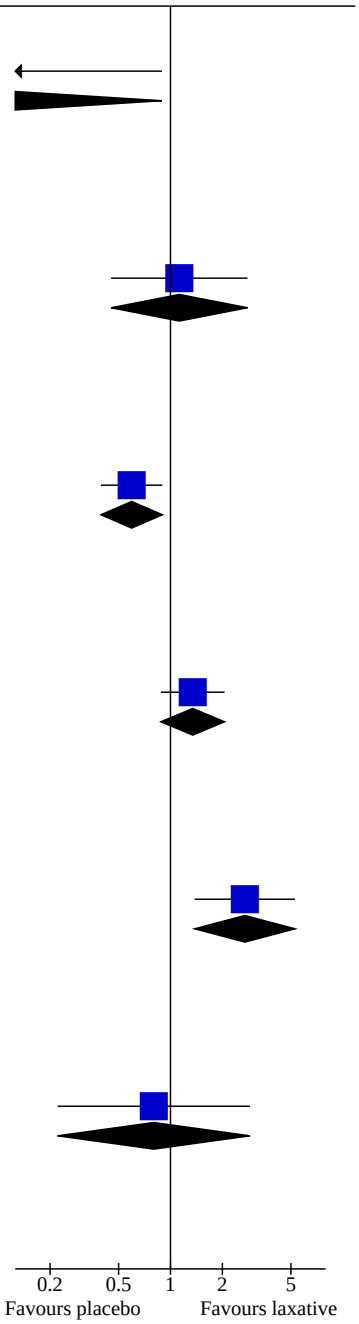
Heterogeneity: Not applicable
Test for overall effect: Z = 2.28 (P = 0.02)
Test for subgroup differences: Not applicable



Footnotes
(1) Laxative used: Bisoxatin acetate (no longer recommended for breastfeeding women)

Analysis 1.10. Comparison 1: Laxative versus placebo, Outcome 10: Number of days on which a bowel movement occurred

Study or Subgroup	Laxative Events	Laxative Total	Placebo Events	Placebo Total	Weight	Risk Ratio M-H, Random, 95% CI
1.10.1 Zero days						
Mundow 1975 (1)	0	100	9	100	100.0%	0.05 [0.00 , 0.89]
Subtotal (95% CI)		**100**		**100**	**100.0%**	**0.05 [0.00 , 0.89]**
Total events:	0		9			
Heterogeneity: Not applicable						
Test for overall effect: Z = 2.04 (P = 0.04)						
1.10.2 One day						
Mundow 1975 (1)	9	100	8	100	100.0%	1.13 [0.45 , 2.80]
Subtotal (95% CI)		**100**		**100**	**100.0%**	**1.13 [0.45 , 2.80]**
Total events:	9		8			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.25 (P = 0.80)						
1.10.3 Two days						
Mundow 1975 (1)	25	100	42	100	100.0%	0.60 [0.39 , 0.90]
Subtotal (95% CI)		**100**		**100**	**100.0%**	**0.60 [0.39 , 0.90]**
Total events:	25		42			
Heterogeneity: Not applicable						
Test for overall effect: Z = 2.48 (P = 0.01)						
1.10.4 Three days						
Mundow 1975 (1)	35	100	26	100	100.0%	1.35 [0.88 , 2.06]
Subtotal (95% CI)		**100**		**100**	**100.0%**	**1.35 [0.88 , 2.06]**
Total events:	35		26			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.37 (P = 0.17)						
1.10.5 Four days						
Mundow 1975 (1)	27	100	10	100	100.0%	2.70 [1.38 , 5.28]
Subtotal (95% CI)		**100**		**100**	**100.0%**	**2.70 [1.38 , 5.28]**
Total events:	27		10			
Heterogeneity: Not applicable						
Test for overall effect: Z = 2.90 (P = 0.004)						
1.10.6 Five days						
Mundow 1975 (1)	4	100	5	100	100.0%	0.80 [0.22 , 2.89]
Subtotal (95% CI)		**100**		**100**	**100.0%**	**0.80 [0.22 , 2.89]**
Total events:	4		5			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.34 (P = 0.73)						
Test for subgroup differences: Chi^2 = 20.75, df = 5 (P = 0.0009), I^2 = 75.9%						

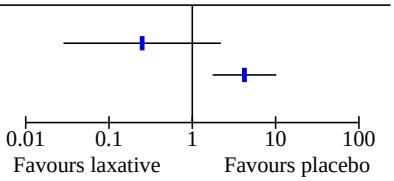


Footnotes

(1) Laxative used: Dorbanex (Danthron; found to be carcinogenic in animals and no longer marketed)

Analysis 1.11. Comparison 1: Laxative versus placebo, Outcome 11: Adverse effects: women with abdominal cramps

Study or Subgroup	Laxative Events	Laxative Total	Placebo Events	Placebo Total	Risk Ratio M-H, Random, 95% CI
Mundow 1975 (1)	1	100	4	100	0.25 [0.03 , 2.20]
Shelton 1980 (2)	23	224	6	247	4.23 [1.75 , 10.19]



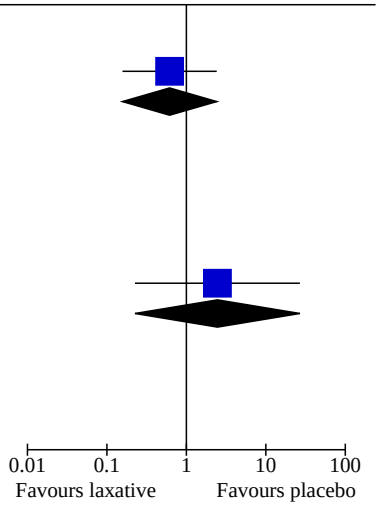
Footnotes

(1) Laxative used: Dorbanex (Danthron; found to be carcinogenic in animals and no longer marketed)

(2) Laxative used: active senna

Analysis 1.12. Comparison 1: Laxative versus placebo, Outcome 12: Adverse effects on the baby

Study or Subgroup	Laxative Events	Laxative Total	Placebo Events	Placebo Total	Weight	Risk Ratio M-H, Fixed, 95% CI
1.12.1 Loose stools						
Shelton 1980 (1)	3	126	6	155	100.0%	0.62 [0.16 , 2.41]
Subtotal (95% CI)		**126**		**155**	**100.0%**	**0.62 [0.16 , 2.41]**
Total events:	3		6			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.70 (P = 0.49)						
1.12.2 Diarrhoea						
Shelton 1980 (2)	2	126	1	155	100.0%	2.46 [0.23 , 26.82]
Subtotal (95% CI)		**126**		**155**	**100.0%**	**2.46 [0.23 , 26.82]**
Total events:	2		1			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.74 (P = 0.46)						
Test for subgroup differences: Chi² = 0.97, df = 1 (P = 0.32), I² = 0%						



Footnotes

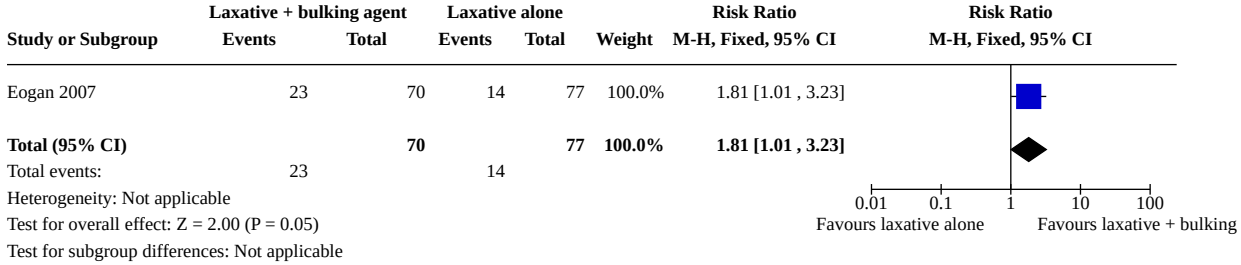
(1) Laxative used: active senna

(2) Laxative used: Active Senna

Comparison 2. Laxative plus bulking agent versus laxative alone

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.1 Faecal incontinence during first 10 postpartum days	1	147	Risk Ratio (M-H, Fixed, 95% CI)	1.81 [1.01, 3.23]

Analysis 2.1. Comparison 2: Laxative plus bulking agent versus laxative alone, Outcome 1: Faecal incontinence during first 10 postpartum days



APPENDICES

Appendix 1. Rome IV diagnostic criteria for functional constipation

Criteria	Must include 2 or more of the following:
1a	Straining during more than one-fourth (25%) of defecations
1b	Lumpy or hard stools (Bristol Stool Form Scale, 1 to 2) more than defecations
1c	Sensation of incomplete evacuation more than one-fourth (25%) of defecations
1d	Sensation of anorectal obstruction or blockage more than one-fourth (25%) of defecations
1e	Manual maneuvers to facilitate more than one fourth (25%) of defecations (e.g. digital evacuation, support of the pelvic floor)
1f	Fewer than 3 spontaneous bowel movements per week
2.	Loose stools are rarely present without the use of laxatives
3.	Insufficient criteria for irritable bowel syndrome
Note: criteria must be met for the last three months, with symptom onset at least six months prior to diagnosis	

Appendix 2. Bristol Stool Form Scale

Type	Description of stools
1	Separate hard lumps, like nuts (difficult to pass)
2	Sausage-shaped, but lumpy
3	Like a sausage, but with cracks on its surface
4	Like a sausage or snake, smooth and soft

(Continued)

5	Soft blobs with clear-cut edges (passed easily)
6	Fluffy pieces with ragged edges, a mushy stool
7	Watery, no solid pieces, entirely liquid

Appendix 3. Search strategy for ICTRP and ClinicalTrials.gov

ICTRP

(searched using all synonyms)

postpartum AND constipation

ClinicalTrials.gov

Advanced search

postpartum | Interventional Studies | Constipation

WHAT'S NEW

Date	Event	Description
7 October 2019	New search has been performed	Search was updated, but none of the identified trials met the inclusion criteria. We updated the various sections of the review using MECIR standards. We added time to first bowel movement to the primary outcomes. We used GRADEpro GDT to assess the quality of evidence by evaluating risk of bias, inconsistency, imprecision, indirectness, and publication bias. We added a 'Summary of findings' table indicating the level and reasons for downgrading. We removed data for two studies from the data and analysis tables for the comparison of laxative versus placebo. One study assessed the effects of Danthron (a laxative that is no longer marketed due to carcinogenic properties (Mundow 1975)), and the other study investigated the effects of Bisoxatin acetate (a laxative that is not recommended for using during breastfeeding (Diamond 1968)). Whilst the data have been removed from the data and analysis tables, we provide a narrative report of the results of those studies in the main results of the review.
7 October 2019	New citation required but conclusions have not changed	Search updated. No new trials included in this update. Conclusions remain unchanged.

HISTORY

Protocol first published: Issue 3, 2015
Review first published: Issue 9, 2015

CONTRIBUTIONS OF AUTHORS

A Rohwer (AR), E Turawa (ET), and A Musekiwa (AM) conceptualised the question. ET and AM drafted the review. AR provided overall guidance, critically engaged with the draft and provided comments. All authors have seen and approved the final version of the review. ET is guarantor of this review.

DECLARATIONS OF INTEREST

Eunice B Turawa: is partly supported by the Research, Evidence and Development Initiative (READ-It) project (project number 300342-104). READ-It is funded by aid from the UK government; however, the views expressed do not necessarily reflect the UK government's official policies.

Alfred Musekiwa: is partly supported by the Research, Evidence and Development Initiative (READ-It) project (project number 300342-104). READ-It is funded by aid from the UK government; however, the views expressed do not necessarily reflect the UK government's official policies.

Anke C Rohwer: is partly supported by the Research, Evidence and Development Initiative (READ-It) project (project number 300342-104). READ-It is funded by aid from the UK government; however, the views expressed do not necessarily reflect the UK government's official policies. This DFID grant aimed at ensuring the best possible systematic reviews, particularly Cochrane Reviews, are completed on topics relevant to the poor, particularly women, in low- and middle-income countries. DFID does not participate in the selection of topics, in the conduct of the review, or in the interpretation of findings.

SOURCES OF SUPPORT

Internal sources

- Centre for Evidence-based Health Care, Division of Epidemiology and Biostatistics, Faculty of Medicine and Health Sciences, Stellenbosch University, South Africa

External sources

- National Institute for Health Research (NIHR) Cochrane Review Incentive Scheme award, UK

  Award number 14/175/47
- Research, Evidence and Development Initiative (READ-It) project, UK

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We added the primary outcome 'time to first bowel movement', we assessed the certainty of evidence with GRADE, and added a 'Summary of findings" table. This was not one of the prespecified outcomes in our protocol (Turawa 2015a).

INDEX TERMS

Medical Subject Headings (MeSH)

Constipation [*prevention & control]; Defecation; Dietary Fiber [adverse effects] [*therapeutic use]; Laxatives [adverse effects] [*therapeutic use]; Perineum [injuries]; Postpartum Period; Puerperal Disorders [*prevention & control]; Randomized Controlled Trials as Topic; Time Factors

MeSH check words

Adult; Female; Humans