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## Interventions for treating postpartum constipation (Review)

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Interventions for treating postpartum constipation (Review)

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[Intervention Review]

# Interventions for treating postpartum constipation

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## ABSTRACT

### Background

Constipation is a functional bowel disorder that can reduce quality of life in the puerperium period. The diagnosis of postpartum constipation is both subjective and objective. It is characterised by symptoms such as pain or discomfort, straining, hard lumpy stools and a sense of incomplete bowel evacuation. Haemorrhoids, pain at the episiotomy site, effects of pregnancy hormones and hematinics used in pregnancy can increase the risk of postpartum constipation. Although a high fibre diet and increased fluid intake is encouraged to assist defecation in the puerperium, pain-relieving drugs and laxatives are common drugs of choice to alleviate constipation. However, the effectiveness and safety of laxatives on the nursing mother need to be ascertained.

### Objectives

To evaluate the effectiveness of interventions for treating postpartum constipation.

### Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (28 March 2014), the [metaRegister](#) of Controlled Trials, the US National Institutes of Health Ongoing Trials Register ([ClinicalTrials.gov](#)), the Australian New Zealand Clinical Trials Registry ([ANZCTR](#)), the World Health Organization International Clinical Trials Registry platform ([ICTRP](#)), the ProQuest database, Stellenbosch University database and Google Scholar (28 March 2014). We also searched the reference lists of potentially relevant studies identified by the search, reviewed articles for relevant trials and contacted experts to identify any additional published or unpublished trials (10 April 2014).

### Selection criteria

All randomised controlled trials comparing any intervention for the treatment of postpartum constipation to another intervention, placebo or no intervention.

Interventions could include laxatives, surgery, as well as educational and behavioural interventions.

### Data collection and analysis

Two review authors independently screened the results of the search to select potentially relevant studies using pre-designed eligibility inclusion criteria. Discrepancies were resolved through discussion. We did not identify any studies for inclusion.

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## Main results

We did not identify any studies that met our inclusion criteria. We excluded nine studies.

## Authors' conclusions

We could not make explicit conclusions on interventions for treating postpartum constipation because we found no studies for inclusion in this review. Rigorous and well-conducted large randomised controlled trials aimed at treating postpartum women diagnosed with constipation would be beneficial. These trials should also address the criteria for administering the intervention (time and stage of a diagnosis of postpartum constipation), and the safety and effectiveness of such interventions.

## PLAIN LANGUAGE SUMMARY

### Interventions for treating postpartum constipation

Women may experience constipation during the postpartum period. Constipation is defined as a functional bowel disorder that is characterised by pain and discomfort, straining, hard lumpy stools and a sense of incomplete bowel evacuation. Haemorrhoids, pain at the episiotomy site, effects of pregnancy hormones and iron supplementation can increase the risk of postpartum constipation; as can damage to the anal sphincter or pelvic floor muscles during childbirth. It is a source of concern to the new mother who is recovering from the stress of delivery. The discomfort does not only affect the mother's health, but also impacts on the new baby's well-being, since it needs most of the mother's attention at this time.

A high fibre diet and increased fluid intake can prevent constipation in the puerperium period. Pain-relieving drugs and laxatives are common drugs in relieving constipation. Laxatives are grouped according to their function, as bulk-forming laxatives (such as bran, psyllium and methycellulose) that increase the weight and water content of the stool to facilitate bowel movement; osmotic laxatives (such as lactulose and polyethylene glycol (PEG)) that add water to the colon to improve bowel movement; and stimulant laxatives (such as bisacodyl, castor oil and senna), which act by irritating the intestinal wall. Stool softeners lubricate stools to improve their passage.

This review aimed to evaluate the effectiveness and safety of the available interventions to treat postpartum constipation. We did not find any randomised controlled trials where women diagnosed with postpartum constipation were treated with different interventions. We are thus unable to make any conclusions. There is a need for large trials to evaluate the effectiveness and safety of interventions (such as laxatives, surgery, as well as educational and behavioural interventions) during the postpartum period.

## BACKGROUND

### Description of the condition

Postpartum constipation is a common condition affecting postpartum mothers (Cheng 2008). Traditionally, the postpartum period starts from childbirth and includes the following six weeks during which the mother's body returns to the pre-pregnant state (Liu 2009). Evidence from studies however, suggests that a great number of women experience constipation up to three to six months postpartum and in some individuals it may even persist to 12 months following delivery (van Brummen 2006). Constipation can be defined as difficult bowel evacuation characterised by strain-

ing, lumpy or hard and dry stools, sensation of incomplete evacuation, anorectal obstruction, or the use of manual manoeuvres (Higgins 2004). According to the Rome III criteria (Drossman 2006), chronic functional constipation in adults is defined as having two or more of the following symptoms for at least three months: straining in at least 25% of defecations, lumpy or hard stools in at least 25% of defecations, sensation of incomplete evacuation in at least 25% of defecations, sensation of anorectal obstruction or blockade in at least 25% of defecations, the use of manual manoeuvres (e.g. digital evacuation, support of the pelvic floor) to facilitate at least 25% of defecations, fewer than three defecations per week; loose stools are rarely present without the use of laxative (Lee-Robichaud 2011). Since the pelvic floor muscles play an important role in defecation, injury to the levator ani

muscle during childbirth may lead to constipation in the postpartum period (Shafik 2002). Other studies found that forceps delivery, prolonged second stage of labour and higher child birth-weight could result in anal sphincter injury resulting in postpartum constipation (Sultan 1993). Haemorrhoids are also a common anorectal medical condition in pregnancy and the postpartum period causing painful defecation and swelling at the anus resulting in constipation. Some other specific postpartum factors such as breastfeeding and obstetric events seem to affect bowel function during the postpartum period (Bradley 2007).

The prevalence of postpartum constipation was estimated to be 24% at three months postpartum by Bradley 2007. The same study found that constipation (as classified by the Rome II criteria Drossman 2000), affects up to 25% of women throughout pregnancy and at three months postpartum. Another study (Ponce 2008) reports a prevalence of constipation in the puerperium as 41.8% by self-report and 24.7% as classified by the Rome II criteria (Drossman 2000). Defecation symptoms in early pregnancy (12 weeks' gestation) in women with a lower body mass index (BMI) was also found to be associated with constipation at 12 months after childbirth (van Brummen 2006).

Constipation is a functional bowel disorder and can significantly reduce the quality of life in adults (Daisy 2002). Postpartum constipation is identified mostly by symptoms such as pain or discomfort and bowel habits and stool characteristics, which makes the diagnosis both subjective and objective. Therefore, the use of time transit (Bristol Stool Form Scale) and Rome criteria is necessary for clinical diagnosis, evidence-based management and research (Longstreth 2006). The causes of constipation can be classified as lifestyle-related, disease-related, or drug-induced (Candy 2011).

### **Description of the intervention and how the intervention might work**

Appropriate interventions for the treatment of constipation depend on the cause (Candy 2011). Although interventions specifically tailored for postpartum constipation treatment are few, some of the interventions targeting constipation in general can also be used to treat postpartum constipation. Lifestyle modifications that include adequate fibre (such as fruits, vegetables, for example cucumber, and soup) (Liu 2009) and water and fluids (Candy 2011) in the diet can help to relieve the symptoms and prevent recurrences of constipation. Soluble fibre (which helps soften the stools) and insoluble fibre (which adds bulk to the stools) both promote regular bowel movements (Balch 2010). Laxatives can be used to treat constipation and are grouped in the following categories according to their function: bulk-forming laxatives, osmotic laxatives, stimulant laxatives, faecal softeners and lubricants (Candy 2011). Bulk-forming laxatives (such as bran, psyllium, and methylcellulose) work by increasing the weight and water content of the stools and thereby facilitate the peristaltic movement of stools (Balch 2010). Osmotic laxatives (such as lactulose and

polyethylene glycol (PEG)) add water into the colon, which then improves bowel movement (NIH 2007). A recent Cochrane review reported the treatment effect of two osmotic laxatives (lactulose versus PEG) for chronic constipation and concluded that PEG is superior to lactulose in improving the form and frequency of the stool, relieving abdominal pain, and in decreasing the need for additional products (Lee-Robichaud 2011). Stimulant laxatives (such as bisacodyl, castor oil, and senna) ease the bowel movement by irritating the intestinal wall (Balch 2010). Stool softeners work by lubricating stools, thereby improving the passage of stools through the intestines (NIH 2007). Surgical interventions can also be used to treat constipation, for example, surgical repair of anorectal problems such as rectal prolapse (NIH 2007). Studies have also reported on the efficacy of acupuncture and Chinese herbal medicine as an intervention in treating postpartum constipation (Cheng 2009). A randomised controlled trial (Eogan 2007) found that administration of a stool-bulking agent in addition to a laxative is not more effective in preventing constipation during the postpartum period for women who have sustained anal sphincter injury at vaginal delivery.

### **Why it is important to do this review**

The postpartum period is an important stage in a mother's life, and for her newborn baby. Considering the morbidity effects of constipation, cost and negative impact on quality of life (Peppas 2008), an evaluation of the effectiveness and safety of available interventions for the treatment of postpartum constipation is necessary. Although a number of systematic reviews on constipation have been published (for example, Gordon 2011; Higgins 2004; Jewell 2001; Lee-Robichaud 2011; Mugie 2011; Peppas 2008), currently there is no systematic review published on interventions for the treatment of postpartum constipation specifically. Although there are some interventions for the treatment of general constipation, not all of them are suitable for use in the postpartum period. Furthermore, cultural beliefs about the postpartum period may result in some lifestyles with certain prescribed diets and lack of exercise, both of which may promote postpartum constipation (Liu 2009). A systematic review is therefore necessary to summarise and evaluate the effectiveness and safety of various interventions for the treatment of postpartum constipation.

## **OBJECTIVES**

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

## **METHODS**

## Criteria for considering studies for this review

### Types of studies

All randomised controlled trials (including those using a cluster-randomised design) comparing any intervention for the treatment of postpartum constipation versus another intervention or placebo or no treatment were eligible for inclusion. Studies presented only as abstracts were eligible for inclusion. Studies using a cross-over design were not eligible for inclusion because the physiological condition of women during the first month postpartum might not be the same as six months after childbirth.

### Types of participants

Postpartum women (from day one to six months postpartum) diagnosed with postpartum constipation (using pre-specified criteria (Rome and Bristol Stool Form Scale) and self-report). We also planned to include postpartum women with co-morbidities, e.g. sphincter injuries.

The six months criterion was used 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 treatment of postpartum constipation including laxatives, surgery, as well as educational and behavioural interventions.

#### Control

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

### Types of outcome measures

#### Primary outcomes

1. Pain or straining on defecation.
2. Participant-reported relief of constipation symptoms.
3. Stool frequency.

#### Secondary outcomes

1. Stool consistency (e.g. Bristol Stool Scale): The Bristol Stool Form Scale is a formal research tool used to evaluate the effectiveness of treatments for gastrointestinal tract disease as well as in clinical communication. It assists the patients to report on stool consistency. It is used to categorise stool into seven types according to stool consistency (Lewis 1997).
2. Use of additional products (e.g. alternative laxative agents, enemas).
3. Relief of abdominal pain.
4. Change in quality of life.
5. Adverse effects caused by the intervention, including:
  - nausea or vomiting;
  - pain;
  - flatus;
  - diarrhoea;
  - faecal incontinence.

### Search methods for identification of studies

#### Electronic searches

We contacted the Trials Search Co-ordinator to search the Cochrane Pregnancy and Childbirth Group's Trials Register (28 March 2014).

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

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

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

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

In addition, we searched the following (28 March 2014) to identify relevant trials:

- The [metaRegister](#) of Controlled Trials.
- The US National Institutes of Health Ongoing Trials Register ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)).

- The Australian New Zealand Clinical Trials Registry ([ANZCTR](#)).
- The World Health Organization International Clinical Trials Registry platform ([ICTRP](#)).

We also searched the ProQuest database, Stellenbosch University database and Google scholar (28 March 2014). See [Appendix 1](#) for search terms used.

## Searching other resources

### Reference lists and correspondence

We searched the reference lists of potentially relevant studies identified by the search and reviewed articles for relevant trials. We also contacted experts in the field of constipation and obstetrics to identify any additional published or unpublished trials. We did not apply any date or language restrictions.

## Data collection and analysis

The methods of data collection and analysis are based on the standard methods text of the Cochrane Pregnancy and Childbirth Group.

### Selection of studies

Two review authors, Eunice Turawa (ET) and Alfred Musekiwa (AM), independently screened the results of the search to select potentially relevant studies. Applying eligibility criteria using a pre-designed eligibility form based on the inclusion criteria, we excluded duplicates and studies that were not relevant to the review. We retrieved the full-text articles of potentially relevant studies.

Each of the articles was scrutinised to ensure that multiple publications of the same trial were included only once. Where eligibility was unclear, we sought clarification from the trial authors and reassessed the corresponding articles. We resolved any disagreement through discussion and consultation with the third review author (Anke Rohwer (AR)). We excluded studies that did not meet the inclusion criteria and stated the reasons in the [Characteristics of excluded studies](#) table.

## Data extraction and management

We did not identify any studies that met our inclusion criteria and thus were unable to perform data extraction and analysis. We have outlined the methods to be used in future updates of this review in [Appendix 2](#) and [Appendix 3](#).

# RESULTS

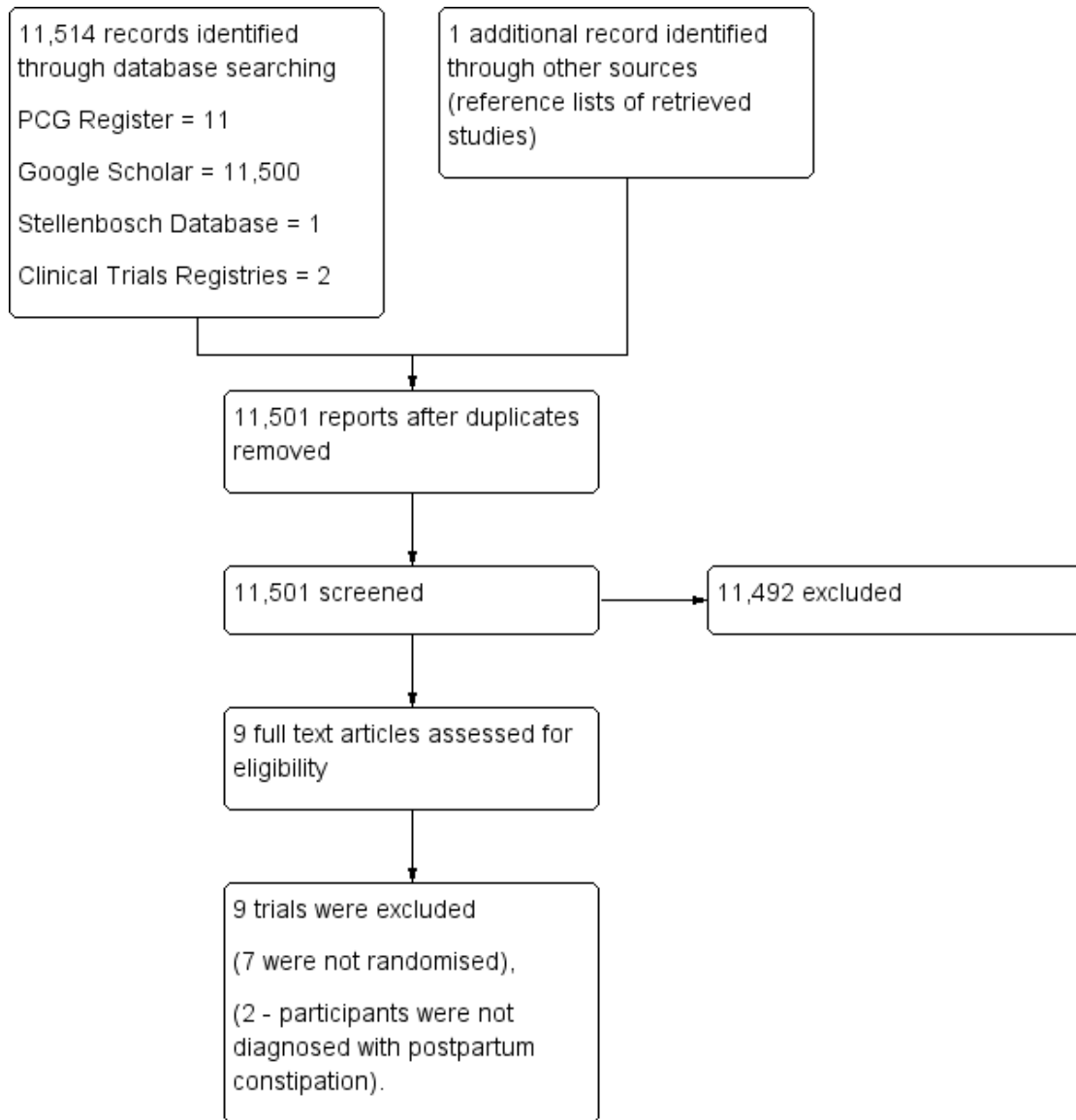
## Description of studies

[Characteristics of excluded studies](#).

### Results of the search

We summarised the search results in detail in [Figure 1](#). The Cochrane Pregnancy and Childbirth Group's Trials Register retrieved 11 trial reports; Stellenbosch University database, one report; Google Scholar, 11,500 reports, Clinical Trials Registries, two reports; screening study references yielded one extra trial making a total of 11,515 trial reports. After deduplication, we screened 11,501 reports resulting in nine potentially relevant reports.

**Figure 1. Study flow diagram**





Scrutinising the full texts of the remaining nine trials (two non-English studies inclusive) resulted in none of the trials meeting our eligibility criteria. Nine trials (Du 2008; Duncan 1957; Diamond 1968; Goplerud 1967; Mundow 1975; Nardulli 1995; Raatikainen 1974; Shelton 1980; Zuspan 1960) were excluded for the reasons displayed in the [Characteristics of excluded studies](#).

### Included studies

We could not include any trials because none of the trials met the pre-specified inclusion criteria.

### Excluded studies

We excluded nine trials (Du 2008; Duncan 1957; Diamond 1968; Goplerud 1967; Mundow 1975; Nardulli 1995; Raatikainen 1974; Shelton 1980; Zuspan 1960). The most common reason for exclusion was that study design was not randomised trial (Du 2008; Duncan 1957; Goplerud 1967; Mundow 1975; Nardulli 1995; Raatikainen 1974; Zuspan 1960). For Diamond 1968 and Shelton 1980, the participants were not clinically diagnosed with postpartum constipation. See the [Characteristics of excluded studies](#).

### Risk of bias in included studies

There are no included studies.

### Effects of interventions

There are no included studies in this review.

## DISCUSSION

### Summary of main results

There are no included studies in this review.

The objective of this review was to assess the effectiveness and safety of different forms of interventions for treating postpartum constipation. A comprehensive electronic search without language restrictions of potential trials was conducted and nine trial reports identified. However, we did not find any trials of postpartum women clinically diagnosed with constipation and subsequently treated for constipation. We therefore excluded all nine studies.

### Potential biases in the review process

We sought published and unpublished trials irrespective of languages. Translators were involved to assist in studies published in foreign languages. At least two review authors independently assessed trials for inclusion in the review.

## AUTHORS' CONCLUSIONS

### Implications for practice

The available trials did not meet this review's pre-specified inclusion criteria. Therefore, we cannot make any conclusions on the effectiveness and safety of interventions for the treatment of postpartum constipation.

### Implications for research

We did not identify any studies evaluating treatment of postpartum constipation on the following outcomes: pain or straining on defecation; participant-reported relief of constipation symptoms, stool frequency (using Bristol scale); use of additional products (e.g. alternative laxative agents, enemas); change in quality of life and adverse effects caused by the intervention such as, nausea or vomiting, pain and flatus. Rigorous and well-conducted large randomised controlled trials of high quality would be beneficial to address the criteria to assess the need for laxatives, time and stage when diagnosis of postpartum constipation can be made, assessment of effectiveness and safety of interventions for prevention and treatment of postpartum constipation. Trials exploring educational and behavioural interventions in treating postpartum constipation would also be beneficial.

## ACKNOWLEDGEMENTS

We acknowledge Charles Okwundu for giving content advice on the protocol. For translation of non-English language studies, we acknowledge Tizzy Mann for translating Du 2008 and Pedro Ruiz for translating Nardulli 1995.

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As part of the pre-publication editorial process, this review has been commented on by three peers (an editor and two referees who are external to the editorial team), a member of the Pregnancy and Childbirth Group's international panel of consumers and the Group's Statistical Adviser.

## REFERENCES

### References to studies excluded from this review

#### Diamond 1968 *{published data only}*

Diamond RA, Gall SA, Spellacy WN. Bisoxatin acetate as a postpartum oral laxative: a random double blind controlled experiment in 106 subjects. *Lancet* 1968;**88**:16–7.

#### Du 2008 *{published data only}*

Du GZ, Ma X, Wang C, Li S. Clinical observation of moxibustion at “tongbian Point” treatment for postpartum constipation. *Journal of Hebei Medical College for Continuing Education* 2008;**25**(5):53–5.

#### Duncan 1957 *{published data only}*

Duncan AS. Standardized senna as a laxative in the puerperium. A clinical assessment. *British Medical Journal* 1957;**4**:39–41.

#### Goplerud 1967 *{published data only}*

Goplerud DR. Postpartum evaluation of two rectal suppositories for bowel evacuation. *Southern Medical Journal* 1967;**60**(2):198.

#### Mundow 1975 *{published data only}*

Mundow L. Danthron/poloxalkol and placebo in puerperal constipation. *British Journal of Clinical Practice* 1975;**29**: 95–6.

#### Nardulli 1995 *{published data only}*

Nardulli G, Limongi F, Sue G, Zapata L, Bompert I. Use of polyethylene glycol in the treatment of puerperal constipation. *G.E.N.: Gastroenterología, Endocrinología i Nutrición* 1995;**49**(3):224–6.

#### Raatikainen 1974 *{published data only}*

Raatikainen R, Silvennoinen R. Constipation after delivery: double-blind comparative study of 2 laxative preparations. *Kätilölehti* 1974; Vol. 79, issue 11:421–2.

#### Shelton 1980 *{published data only}*

Shelton MG. Standardised senna in the management of constipation in the puerperium - a clinical trial. *South African Medical Journal* 1980;**57**:78–80.

#### Zuspan 1960 *{published data only}*

Zuspan FP. A double-blind laxative study on postpartum patients. *American Journal of Obstetrics and Gynecology* 1960;**80**:548–50.

### Additional references

#### Balch 2010

Balch PA. *Prescription for Nutritional Healing: a Practical A-to-Z Reference to Drug-free Remedies using Vitamins,*

*Minerals, Herbs & Food Supplements.* 5th Edition. New York: Avery, 2010.

#### Bradley 2007

Bradley CS, Kennedy CM, Turcea AM, Rao SS, Nygaard IE. Constipation in pregnancy: prevalence, symptoms, and risk factors. *Obstetrics and Gynecology* 2007;**110**(6):1351–7.

#### Candy 2011

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#### Cheng 2008

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#### Cheng 2009

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#### Daisy 2002

Daisy AA, Carlos AE, Hildegarde C. Evaluation of constipation. *American Family Physician* 2002;**65**(11): 2283–90.

#### Drossman 2000

Drossman DA, Corazziari E, Talley NJ, Grant Thompson W, Whitehead WE, editors. *Rome II: the Functional Gastrointestinal Disorders. Diagnosis, Pathophysiology and Treatment: a Multinational Consensus.* 2nd Edition. McLean: Degnon Associates, 2000.

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Gordon M, Naidoo K, Akobeng AK, Thomas AG. Osmotic and stimulant laxatives for the management of childhood

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van Brummen HJ, Bruinse HW, van de Pol G, Heintz AP, van der Vaart CH. Defecatory symptoms during and after the first pregnancy: prevalences and associated factors. *International Urogynecology Journal and Pelvic Floor Dysfunction* 2006;**17**(3):224–30.
- \* Indicates the major publication for the study

## CHARACTERISTICS OF STUDIES

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

Study	Reason for exclusion
Diamond 1968	Participants not diagnosed with postpartum constipation.
Du 2008	Not a randomised controlled trial.
Duncan 1957	Not a randomised controlled trial.
Goplerud 1967	Not randomised controlled trial.
Mundow 1975	Not randomised controlled trial
Nardulli 1995	Not randomised controlled trial.
Raatikainen 1974	Not a randomised controlled trial.
Shelton 1980	Participants not diagnosed with postpartum constipation.
Zuspan 1960	Not randomised controlled trial.

## DATA AND ANALYSES

This review has no analyses.

## APPENDICES

### Appendix 1. Search terms

We searched the [metaRegister](#) of Controlled Trials, the US National Institutes of Health Ongoing Trials Register ([ClinicalTrials.gov](#)), the Australian New Zealand Clinical Trials Registry ([ANZCTR](#)), the World Health Organization International Clinical Trials Registry platform ([ICTRP](#)), (using the terms 'constipation' AND ('postpartum OR postnatal')

**Search method used in Stellenbosch University database:**

(postnatal OR "post delivery" OR postpartum) AND (constipation OR constipat\* OR hard stool\*OR "impacted stool"OR "lumpy stool"OR "rock-like stool") AND (interventions OR treatment OR treat\* OR management OR therapy)

**Search method used in Google scholar search:**

(postpartum OR postnatal OR "post delivery" OR "after birth") AND (constipation OR "hard stool" OR "lumpy stool") AND (management OR relief OR treatment)

### Appendix 2. Data Extraction Form

Review title: Interventions for treating postpartum constipation

Review ID:	Study ID:	Reference ID:
Person extracting data and date:	Date of date extraction:	Year of study publication:
Title:		
Author:	Publication type: Full text / Abstract / Book chapter/ report / others	progress
	Country:	
	Checked by:	

### Study design

---

Type of study design (cluster-RCT; block randomisation; stratified randomisation; multi-arm; factorial etc):

Unit of randomisation:

---

### Participants and setting

---

Describe setting:

Inclusion criteria:

Exclusion criteria:

---

**PARTICIPANTS:** Postpartum women diagnosed with constipation

---

### Intervention

---

Were comparison groups treated with pre-specified  
Intervention in one group and control intervention in the other group?

---

Experimental intervention:

Type of intervention: Laxatives/Acupunctures/Educational intervention/Chinese herbs

---

### Comparison

---

Type of control : Active/Placebo/Active + placebo/No therapy

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---

**OUTCOMES ASSESSED:**

Definition of outcome assessed:

---

(Continued)

Primary outcomes:	
Secondary outcomes	
Outcome not specified:	
<b>REASONS FOR EXCLUSION OF STUDY FROM REVIEW ACCORDING TO PROTOCOL</b>	
<b>Method</b>	No RCT / Other
Participant related	Not postpartum women
Outcomes	
Others:	Duplication, etc
<b>TRIAL CHARACTERISTICS</b>	
Sample size :	Study design:
No. randomised:	No. excluded:
	Funding:
Recruitment method :	
Length of follow-up = from ---- to ----	Conflict of interest statement:
No. of drop-outs = Reasons for drop-out NR	Loss to follow-up symmetric in both arms?

**Study methods**

**Risk of bias**

Domain	Judgement	Quote /Comments	
<b>Adequate random sequence generation:</b> Was the allocation sequence adequately generated?	Low High Unclear		
<b>Allocation concealment</b> Was allocation concealment adequate?	Low High Unclear		
<b>Performance Bias</b>			
<b>Blinding of participants/ Providers</b> Was knowledge of the allocated intervention adequately prevented during the study?	Low High Unclear		
<b>Detection Bias</b>			
<b>Blinding of outcome assessors</b> Was knowledge of the allocated interventions adequately prevented during measurement?	Low High Unclear		
<b>Attrition Bias</b>	Low High Unclear		
<b>Complete outcome data addressed</b> Were incomplete outcome data adequately addressed?	Low High Unclear		
<b>Reporting bias</b>			
<b>Free of selective reporting</b> Are reports of the study free of suggestion of selective outcome reporting?	Low High Unclear		



(Continued)

<b>Other Bias</b>				
<b>Free of other bias</b> Was the study apparently free of other problems that could put it at a high risk of bias?	Low	High	Unclear	

<b>Number of participants entering trial</b>	
15% or fewer excluded	
More than 15% excluded	
Analysed as 'intention-to-treat'	
Unclear	

**ADDITIONAL INFORMATIONS**

**Were withdrawals described? Low High Unclear**

**Discuss if appropriate.....**

**Outcomes for main analysis**

Outcome Measures (Dichotomous)	Total number of participants in study =			
	Intervention group Total no. in study =		Control group Total no. in study =	
	events	total	events	total
Primary:				
1				
2				
Secondary:				
3				
4				
5				

Outcome Measures (Continuous)	Total number of participants in study =			
	Intervention group Total no. in study =		Control group Total no. in study =	
	total	mean SD	total	mean SD
Primary:				
1				
2				
Secondary:				
3				
4		I		I

(Continued)

5		I		I
---	--	---	--	---

**Outcomes for subgroup analyses**

	Outcome Measures (Dichotomous)	Total number of participants in study =			
		Intervention group Total no. in study =		Control group Total no. in study =	
		events	total	events	total
	Primary:				
1					
2					
	Secondary:				
3					
4					
5					

	Outcome Measures (Continuous)	Unit of measurement	Total number of participants in study =					
			Intervention group Total no. in study =			Control group Total no. in study =		
			total	mean	SD	total	mean	SD
	Primary:							
1								
2								

(Continued)

	Secondary:					
3						
4				I		
5				I		I

### General conclusions

Very brief summary of study authors main findings/conclusions:

Notes

### Exclusion after data extraction

Reasons for exclusion: (study design? participants? interventions/ outcomes? attrition? bias?)

Dates:

Date entered into RevMan and by whom?

Date checked and by whom?

Date copy sent to editorial base and by whom?

## Appendix 3. Data collection and analysis (for future updates of this review)

### Data collection and analysis

#### Selection of studies

Two review authors, Eunice Turawa (ET) and Alfred Musekiwa (AM), will independently screen the results of the search to select potentially relevant studies and apply eligibility criteria using a pre-designed eligibility form based on the inclusion criteria. Corresponding full-text articles will be retrieved and used in applying the eligibility criteria. Each of the articles will be scrutinised to ensure that multiple publications of the same trial will be included only once. If eligibility is unclear, we will seek clarification from the trial authors and re-assess the corresponding articles. We will resolve any disagreement through discussion. We will exclude studies that do not meet the inclusion criteria and state the reasons in the 'Characteristics of excluded studies' table.

#### Data extraction and management

Using a specially designed pre-piloted data extraction form, two review authors (ET and AM) will independently extract information on methods, participants, interventions and outcomes from each included study. The following information will be extracted:

- author, year of publication, country of origin, journal citation, and language;
- study methods (trial design, duration, risk of bias, setting, study inclusion criteria);
- participants (number, age, source, inclusion and exclusion criteria, duration of symptoms, previous treatments, underlying conditions, drop-outs/withdrawals);
- interventions (type, dose, duration, route of delivery, control used, run-in phase, treatment phase, follow-up);
- outcome data for each of the primary and secondary outcomes above.

For each dichotomous outcome, we will extract the number of participants experiencing the event and the number of participants in each treatment group. For each continuous outcome, we will extract the arithmetic means, standard deviations (or information to estimate the standard deviations), and the number of participants, in each treatment group. For continuous data, if geometric means and their standard deviations on the log scale have been reported, we will extract them. Medians and ranges will also be extracted if these are reported in place of means and standard deviations. We will enter data into Review Manager software ([RevMan 2014](#)) and check for accuracy. When information regarding any of the above is unclear, we will attempt to contact the authors of the original reports to provide further details. We will resolve discrepancies through discussion.

### Assessment of risk of bias in included studies

#### Individually-randomised trials

Two review authors (ET and AM) will independently assess risk of bias for each included study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2011](#)). The criteria is given in [Appendix 1](#). The domains that will be assessed are adequate sequence generation, allocation concealment, blinding, incomplete outcome data, selective reporting and other potential sources of bias. Each included study will be judged as 'yes' (low risk of bias), 'no' (high risk of bias), or 'unclear' (uncertain risk of bias) according to each of the six domains. The results will be summarised using the 'Risk of bias' summary and the 'Risk of bias' graph in addition to the 'Risk of bias' tables. Where clarity is required or in case of missing data, we will contact the trial authors for clarification. We will resolve any disagreement by discussion.

#### Cluster-randomised trials

For cluster-randomised trials, we will assess recruitment bias, baseline imbalance, loss of clusters, incorrect analysis, and incomparability with individually-randomised trials. ([Higgins 2011](#)).

## Measures of treatment effect

### Dichotomous data

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

### Continuous data

For continuous data, we will use the mean difference if outcomes are measured in the same way between trials. We will use the standardised mean difference to combine trials that measure the same outcome, but use different methods. In either case, corresponding 95% confidence intervals will also be presented.

## Unit of analysis issues

### Cluster-randomised trials

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

### Individually-randomised trials

Attention to the unit of analysis at the level of randomisation (individual) will be noted using the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

### Multi-arm trials

When 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 precautions will be taken to avoid the inclusion of data from the same patient more than once in the same analysis.

## Dealing with missing data

No imputation measures for missing data will be applied. Where data from the trial reports are insufficient, unclear or missing, we will contact the trial authors by email for additional information or clarification. For included studies, we will note levels of attrition. We will explore the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis. For all outcomes, we will carry out analyses, as far as possible, on an intention-to-treat basis, i.e. we will attempt to include all participants randomised to each group in the analyses, and all participants will be analysed in the group to which they were allocated, regardless of whether or not they received the allocated intervention. The denominator for each outcome in each trial will be the number randomised minus any participants whose outcomes are known to be missing.

## Assessment of heterogeneity

We will assess statistical heterogeneity in each meta-analysis using the  $T^2$ ,  $I^2$  and  $\text{Chi}^2$  statistics. We will regard heterogeneity as substantial if the  $I^2$  is greater than 30% and either the  $T^2$  is greater than zero, or there is a low P value ( $< 0.10$ ) in the  $\text{Chi}^2$  test for heterogeneity.

### Assessment of reporting biases

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

### Data synthesis

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

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

### Subgroup analysis and investigation of heterogeneity

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

We plan to carry out subgroup analyses (only on primary outcomes) with respect to:

- type of laxatives (bulk-forming laxatives versus other types of laxatives);
- study design (individually- versus cluster-randomised trials).

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

### Sensitivity analysis

Sensitivity analysis will be performed (only on primary outcomes) provided there are sufficient trials. We plan to conduct sensitivity analysis with respect to:

- robustness of the methods used regarding allocation concealment;
- losses to follow-up;
- randomisation (randomised versus quasi-randomised);
- imputed values of intra-cluster correlations (ICC).

We will report where the analysis alters the overall treatment effect.

## CONTRIBUTIONS OF AUTHORS

Eunice Turawa (ET) conceived the topic and developed the protocol with the assistance of Alfred Musekiwa (AM). AM wrote the data collection and analysis section and also assisted with the writing of the background. Anke Rohwer (AR) critically engaged with the protocol. ET and AM assessed trials for inclusion and exclusion based on pre-specified criteria and AR gave input when discrepancies were encountered. AR wrote various sections of the review and edited all of the version of the review. ET is the guarantor for the review. All authors approved the final version of the review.

## DECLARATIONS OF INTEREST

Eunice Turawa: none known.

Anke Rohwer: none known

Alfred Musekiwa: none known.

## SOURCES OF SUPPORT

### Internal sources

- Faculty of Health Sciences, Stellenbosch University, Cape Town, South Africa.
- Wits Reproductive Health & HIV INstitute (WRHI), Johannesburg, South Africa.

### External sources

• Effective Health Care Research Consortium, UKaid from the UK Government Department for International Development, UK. AR is supported in part by the Effective Health Care Research Consortium, which is funded by UKaid from the UK Government Department for International Development

## DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Our methods text has been updated in accordance with the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011) and the standard methods text of the Cochrane Pregnancy and Childbirth Group.

We also modified the [Types of participants](#) section to include postpartum women with co-morbidities (e.g. sphincter injuries) and extended the scope of postpartum period for this review to six months post delivery because evidence shows that postpartum constipation can extend further than six weeks after delivery (van Brummen 2006).

We extended the scope of our own additional searches by also searching the following databases: ProQuest database, Stellenbosch University database and Google scholar for potential trials. Reference lists of potential studies and reviewed articles were searched for relevant trials and we contacted experts in the field of constipation and obstetrics for additional published or unpublished trials. Two authors independently screened the search output and studies that were not relevant were excluded.

## INDEX TERMS

### Medical Subject Headings (MeSH)

\*Postpartum Period; Constipation [\*therapy]



## **MeSH check words**

Adult; Female; Humans