

Constipation in children




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ABSTRACT

INTRODUCTION: Prevalence of childhood constipation has been estimated at 0.7% to 29.6% in the general population worldwide; most children have no obvious aetiological factors. One third of children with chronic constipation continue to have problems beyond puberty. Half of children with chronic faecal impaction and faecal incontinence have experienced an episode of painful defecation, and many children with chronic constipation exhibit withholding behaviour. **METHODS AND OUTCOMES:** We conducted a systematic review and aimed to answer the following clinical questions: What are the effects of treatments for children with chronic constipation? What are the effects of treatments for clearing the bowel in children with faecal impaction? We searched: Medline, Embase, The Cochrane Library, and other important databases up to August 2009 (Clinical Evidence reviews are updated periodically; please check our website for the most up-to-date version of this review). We included harms alerts from relevant organisations such as the US Food and Drug Administration (FDA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA). **RESULTS:** We found 14 systematic reviews and RCTs that met our inclusion criteria. We performed a GRADE evaluation of the quality of evidence for interventions. **CONCLUSIONS:** In this systematic review, we present information relating to the effectiveness and safety of the following interventions: anal dilatation, behavioural treatments (biofeedback, diaries, or toilet training), bulk-forming laxatives, enemas, faecal softeners, fibre, macrogols, oral fluids, osmotic laxatives, prebiotics, probiotics, stimulant laxatives, and surgical disimpaction.

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INTERVENTIONS	
TREATMENTS FOR CHRONIC CONSTIPATION	
 Unknown effectiveness	
Fibre	3
Osmotic laxatives	4
Behavioural treatments (biofeedback, diaries, or toilet training)	7
Bulk-forming laxatives	8
Faecal softeners	9
Anal dilatation	11
Prebiotics New	12
Probiotics New	12
 Unlikely to be beneficial	
Stimulant laxatives (senna seems less effective than lactulose at increasing passage of normal stools and than liquid paraffin at increasing bowel movement)	10
Oral fluids	11
TREATMENTS FOR CLEARING FAECAL IMPACTION	
 Unknown effectiveness	
Enemas	13
Macrogols (by oral or nasogastric tube)	13
Surgical disimpaction	14

Key points

- Diagnostic criteria for functional constipation in children vary, but involve infrequent, possibly painful, passing of large, hard stools with or without faecal incontinence.
 - Prevalence of chronic constipation has been estimated at 1% to 5% of children in the UK and USA, most of whom have no obvious aetiological factors.
 - One third of children with chronic constipation continue to have problems beyond puberty.
 - Half of children with chronic faecal impaction and faecal incontinence have experienced an episode of painful defecation, and many children with chronic constipation exhibit withholding behaviour.
 - Disimpaction may be needed if spontaneous expulsion of the faecal mass is unlikely, or if it is causing discomfort or affecting normal feeding.
- Low fibre intake is associated with constipation, and limited evidence shows that extra **fibre** reduces constipation compared with placebo. Increased fibre intake is not as effective as lactulose.
 - Increasing **oral fluid** intake has not been shown to be beneficial.
- We found limited evidence suggesting that the stimulant laxative **senna** is less effective than **mineral oil** (liquid paraffin) or lactulose, and is more likely to cause colic, diarrhoea, or abdominal distension. We found limited evidence suggesting that lactulose is less effective than mineral oil (liquid paraffin).
 - We found evidence that macrogol (an osmotic laxative) is more effective than placebo and lactulose. We found limited evidence suggesting that macrogol may be no more effective than milk of magnesia.
 - Osmotic laxatives** can cause abdominal pain and flatulence.

We found no evidence on the use of **bulk-forming laxatives** such as methylcellulose, ispaghula husk, or sterculia, or on the use of **prebiotics**.

We found limited evidence that **probiotics** may be as effective as osmotic laxatives at improving symptoms of constipation.

- **Behavioural treatments**, such as biofeedback, diaries, toilet training or anorectal manometry, or **anal dilatation**, have shown no benefit, but the evidence is limited.
- We found no evidence assessing the effectiveness of **macrogols**, **enemas**, or **surgical disimpaction** in the treatment of faecal impaction.

DEFINITION Initially **Rome II criteria** (1999) defined functional childhood constipation as at least 2 weeks of: scybalous, pebble-like, hard stools for most of the stools; or firm stools two or fewer times a week and no evidence of structural endocrine or metabolic disease.^[1] These criteria were not necessarily comprehensive and were found to be restrictive by some researchers.^[2] In 2004, the **PACCT group** (Paris Consensus on Childhood Constipation Terminology) defined childhood constipation as the occurrence of two or more of the following six criteria in the previous 8 weeks: frequency of movements fewer than 3 a week; more than one episode of faecal incontinence a week; large stools in the rectum or palpable on abdominal examination; passing of stools so large that they may obstruct the toilet; retentive posturing and withholding behaviour; and painful defecation.^[3] These criteria were integrated into Rome III criteria (2006).^[4]^[5] Functional constipation is now defined as the occurrence of two or more of the following six criteria in the previous 2 months in a child with a developmental age of at least 4 years, who has insufficient criteria for the diagnosis of irritable bowel syndrome (including no evidence of an inflammatory, anatomical, metabolic, or neoplastic process): two or fewer defecations in the toilet a week; at least one episode of faecal incontinence a week; history of retentive posturing or excessive volitional stool retention; history of painful or hard bowel movements; presence of a large faecal mass in the rectum; and a history of large diameter stools that may obstruct the toilet. Infants up to 4 years of age have to fulfil two or more criteria for at least 1 month. Many other terms are used in performed studies. Soiling is defined as the involuntary passage of small amounts of stools, resulting in staining of the underwear. The quantity of faecal loss is the main difference between encopresis and soiling. In practice, parents are often unable to accurately estimate the amount of faeces lost in the underwear and thus cannot differentiate between encopresis and soiling. Therefore, according to Rome III, the more neutral term of faecal incontinence was adopted rather than the terms encopresis and soiling. Furthermore, paediatric faecal incontinence is divided into either organic faecal incontinence (e.g., resulting from anorectal malformations or neurological damage) or functional faecal incontinence. Functional faecal incontinence can be subdivided into constipation-associated faecal incontinence and non-retentive faecal incontinence. For this review, we focused on constipation-associated faecal incontinence.^[6] In selecting studies for this review, we did not use a singular definition owing to no clear agreement over the definitions (see methods). We used the original wording of the authors.

INCIDENCE/ PREVALENCE One systematic review showed a worldwide prevalence of childhood constipation in the general population ranging from 0.7% to 29.6%. Similar prevalence rates were reported for boys and girls.^[7]

AETIOLOGY/ RISK FACTORS Aetiological factors are not found in most children. Hirschsprung's disease, cystic fibrosis, anorectal abnormalities, and metabolic conditions such as hypothyroidism are rare organic causes of childhood constipation. An episode of painful defecation was noted in more than 50% of people who were suffering from faecal soiling or chronic faecal impaction.^[8] **Risk factors:** One study found higher incidence of constipation among children with birth weight under 750 g associated with neurodevelopment impairment.^[9] Low fibre intake may be associated with childhood constipation.^[10] Constipation and faecal incontinence are more prevalent in obese children.^[11] We found no evidence for a difference between bottle-fed and breastfed babies, although it is generally accepted that bottle-fed babies are more at risk of relative water deficiency and breastfed babies frequently have delays of many days between passing normal stools.

PROGNOSIS Childhood constipation continues beyond puberty in up to one third of the children followed up.^[12] Children aged 2 to 4 years seem to have a higher recurrence rate and a need for prolonged medication and support than younger infants.^[13] One follow-up study has noted increased risk of persistent constipation in children who developed constipation early in infancy and who have a family history of constipation.^[14] Another follow-up study assessing the clinical course of severe functional constipation in early childhood found that after initial success of treatment, a relapse occurred in 15% of the children within 3 years. Symptom duration of 3 months or less before referral was significantly correlated with better outcome.^[15] **Faecal impaction:** Disimpaction is necessary if the amount and character of faeces in the colon is of such magnitude that spontaneous expulsion is

unlikely, or if it is causing discomfort and affecting normal feeding. Some children with a large rectosigmoid faecaloma may have difficulty passing urine.

AIMS OF INTERVENTION The management of constipation is essentially multifactorial and, along with medical treatment, should address the social and psychological issues that may be associated with it.^[16] Families and particularly children vary considerably in their tolerance of symptoms and treatments. This necessitates a very personal selection and intensity of treatments, making controlled studies very difficult to perform. Medical treatment is aimed at disimpaction of the impacted faeces and restoration of regular bowel habits, which consist of passage of soft, normal stools without discomfort at least once every 3 days and in appropriate places.

OUTCOMES **Treatment success:** includes pain; faecal incontinence; defecation three times or more a week; soiling fewer than twice a week/frequency of soiling; no laxatives for at least 4 weeks; gut transit time as measured by timing the passage of radio-opaque pellets; difficulty with defecation; worsening constipation. **Quality of life.** Outcomes for harms of stimulant laxatives: cancer, tolerance, dependence. We have not considered faecal texture or hardness as an outcome.

METHODS *Clinical Evidence* search and appraisal August 2009. The search was limited to infants and children under 16 years of age. Trials were selected for inclusion if they focused on the management of constipation or encopresis with a history of constipation in either the primary health or specialist setting. We included children with idiopathic constipation, but excluded children with a known underlying cause for their constipation (e.g., Hirschsprung's disease [congenital megacolon], operated anorectal malformations, or patients with other pelvic causes). The following databases were used to identify studies for this review: Medline 1966 to August 2009, Embase 1980 to August 2009, and The Cochrane Database of Systematic Reviews and Cochrane Central Register of Controlled Clinical Trials, Issue 4, 2009. Additional searches were carried out using these websites: NHS Centre for Reviews and Dissemination (CRD) — for Database of Abstracts of Reviews of Effects (DARE) and Health Technology Assessment (HTA), Turning Research into Practice (TRIP), and NICE. Abstracts of the studies retrieved from the initial search were assessed by an information specialist. Selected studies were then sent to the contributors for additional assessment, using predetermined criteria to identify relevant studies. Study design criteria for inclusion in this review were: published systematic reviews and RCTs in any language, and containing more than 20 individuals. There was no minimum length of follow-up required for inclusion, and no maximum loss to follow-up. We did not exclude studies described as "blinded", "open", "open label", or not blinded. We also searched for cohort studies on specific harms of named interventions. In addition, we use a regular surveillance protocol to capture harms alerts from organisations such as the US Food and Drug Administration (FDA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA), which are added to the review as required. To aid readability of the numerical data in our reviews, we round many percentages to the nearest whole number. Readers should be aware of this when relating percentages to summary statistics such as relative risks (RRs) and odds ratios (ORs). The categorisation of the quality of the evidence (high, moderate, low, or very low) reflects the quality of evidence available for our chosen outcomes in our defined populations of interest. These categorisations are not necessarily a reflection of the overall methodological quality of any individual study, because the *Clinical Evidence* population and outcome of choice may represent only a small subset of the total outcomes reported, and population included, in any individual trial. For further details of how we perform the GRADE evaluation and the scoring system we use, please see our website (www.clinicalevidence.com). We have performed a GRADE evaluation of the quality of evidence for interventions included in this review (see table, p 17).

QUESTION What are the effects of treatments for children with chronic constipation?

OPTION FIBRE

Treatment success

Compared with placebo Fibre may be more effective at improving bowel movements and abdominal pain at 4 weeks in children with constipation (*very low-quality evidence*).

Compared with lactulose Fibre and lactulose may be equally effective at reducing faecal incontinence episodes, abdominal pain, or flatulence at 3 or 8 weeks in children with constipation (*low-quality evidence*).

For GRADE evaluation of interventions for constipation in children, see table, p 17.

Benefits: We found one systematic review (search date 2007; 28 trials [21 RCTs, 1 comparative clinical trial and 6 crossover studies]; 1912 children aged 0–18 years with functional constipation and with or without faecal incontinence) comparing laxatives or dietary measures versus placebo, no treatment,

or alternative treatments.^[17] We also found one subsequent RCT comparing fibre versus lactulose.^[18]

Fibre versus placebo:

The review identified two RCTs comparing fibre versus placebo. The first small crossover RCT identified by the review (31 children aged 4.5–11.7 years with constipation for 6 months or longer; 18/31 [58%] had *encopresis*; children were initially disimpacted with phosphate enemas if required before treatment) compared fibre (glucomannan 100 mg/kg up to 5 g/day, with 50 mL of fluid per 500 mg of fibre) versus placebo for 4 weeks.^[19] The initial daily fibre intake was low in 22/31 [71%] children included in the study. Pre-crossover, the RCT found that the proportion of children who had fewer than three bowel movements a week and abdominal pain was significantly smaller with fibre compared with placebo (fewer than 3 bowel movements weekly: 19% with fibre v 52% with placebo; P less than 0.05; abdominal pain: 10% with fibre v 42% with placebo; P less than 0.05; absolute numbers not reported for either outcome). It also found that the proportion of children who were rated by their physician as having been treated successfully and rated as improved by their parents was significantly larger after treatment with fibre compared with placebo (physician rated: 45% with fibre v 13% with placebo; P less than 0.05; parent rated: 68% with fibre v 13% with placebo; P less than 0.05; absolute numbers not reported for either comparison). Physician-rated treatment success was defined as more than three bowel movements a week and one or no episodes of *encopresis* over 3 weeks with no abdominal pain.

The second RCT included in the review (56 children aged 3–10 years with chronic idiopathic constipation according to Rome II criteria) compared fibre (cocoa husk supplement, 1 sachet weighted 5.2 g; 3–6 years of age: 2 sachets daily; 7–10 years: 4 sachets daily; dissolved in 200 mL milk) versus placebo for 4 weeks.^[20] Difference in the mean basal dietary fibre intake was not significant and was near to the recommended amount in both groups (12.3 g daily with fibre v 13.4 g daily with placebo; P value not reported). The RCT found no significant difference at 4 weeks between fibre and placebo in the change of total colon transit time or in subjective improvement in pain (total colon transit time: from 61.4 to 43.6 hours with fibre v from 71.5 to 61.5 with placebo; change difference –12.8, 95% CI –29.7 to +4; subjective improvement in pain: 16/24 [4%] with fibre v 11/24 [3%] with placebo; P = 0.109).^[20] A subgroup analysis of 12 children with a total basal intestinal transit time greater than the 50th percentile found that the change in total intestinal transit time was significantly longer with fibre compared with placebo (45.4–38.4 hours with fibre v 8.7–28.9 hours with placebo; change difference –38.1 hours, 95% CI –67.9 to –8.4; P less than 0.015).^[20]

Fibre versus lactulose:

The subsequent RCT (97 children aged 1–13 years with at least 2 of 4 criteria for constipation: fewer than 3 bowel movements weekly; 2 or more fecal incontinence episodes weekly; periodic passage of stool at least once every 7–30 days; or a palpable abdominal or rectal mass) compared fibre (10 g in 125 mL yoghurt drink) versus lactulose (10 g in 125 mL yoghurt drink) for 8 weeks followed by 4 weeks of weaning.^[18] Polyethylene glycol (PEG; macrogol 3350) was added if no clinical improvement was observed after 3 weeks in either group. The RCT found no significant difference in the number of children with one or more faecal incontinence episodes a week (9/42 [4%] with fibre v 5/55 [3%] with lactulose; P = 0.084) or in the mean scores (scale: 0 = not at all, 1 = sometimes, 2 = often, and 3 = continuous) of people with abdominal pain or flatulence at weeks 3 and 8 of follow-up (abdominal pain; week 3: 1.58 with fibre v 1.43 with lactulose; P = 0.33; week 8: 1.49 with fibre v 1.39 with lactulose; P = 0.50; flatulence; week 3: 1.9 with fibre v 2.0 with lactulose; P = 0.70; week 8: 2.0 with fibre v 1.9 with lactulose; P = 0.94). The RCT also found no significant difference between groups for necessity of step-up medication (P = 0.99, absolute numbers not reported).^[18]

Harms: The systematic review^[17] and subsequent RCT^[18] reported no adverse effects were associated with fibre.

Comment: None.

Clinical guide:

Low fibre intake is associated with constipation and therefore every child with or without constipation needs a normal daily fibre intake. The role of extra fibre on constipation requires further evaluation.

OPTION OSMOTIC LAXATIVES

Treatment success

Macrogol compared with placebo Macrogol 0.2, 0.4, or 0.8 g/kg daily may be more effective at increasing bowel movements to three or more times a week, and may be more effective at improving pain on defecation in children with constipation at 2 weeks (*low-quality evidence*).

Lactulose compared with mineral oil (liquid paraffin) Lactulose may be less effective at increasing the number of bowel movements at 4 to 8 weeks in children with constipation (very low-quality evidence).

Lactulose compared with senna Lactulose may be more effective at increasing the number of normal stools passed (very low-quality evidence).

Lactulose compared with fibre Lactulose and fibre may be equally effective at reducing faecal incontinence episodes, abdominal pain, or flatulence at 3 or 8 weeks in children with constipation (low-quality evidence).

Macrogol compared with lactulose PEG 3350 may be more effective at increasing defecation rates to three or more times a week, decreasing encopresis rates to once in 2 weeks or fewer at 8 weeks, and reducing gut transit time at 2 weeks in children with constipation (very low-quality evidence).

Macrogol compared with milk of magnesia PEG 3350 may be as effective as milk of magnesia at improving rates of bowel movement, faecal incontinence episodes, or abdominal pain (with or without laxative therapy, 1 month or more) at 1, 3, 6, or 12 months in children with constipation (very low-quality evidence).

Osmotic laxatives compared with probiotics Osmotic laxatives seem as effective as probiotics at increasing rates of treatment success at 4 weeks, and at reducing episodes of faecal incontinence at 4 weeks in children with functional constipation, but less effective at decreasing rates of abdominal pain (moderate-quality evidence).

For GRADE evaluation of interventions for constipation in children, see table, p 17 .

Benefits:

We found one systematic review (search date 2007; 28 trials [21 RCTs, 1 comparative clinical trial, and 6 crossover studies]; 1912 children aged 0–18 years with functional constipation, with or without faecal incontinence) comparing laxatives or dietary measures versus placebo, no treatment, or alternative treatments.^[17] We also found one subsequent RCT comparing macrogol versus placebo.^[21]

Macrogol versus placebo:

The review identified one crossover RCT (51 children aged 2–11 years with chronic constipation [lasting 3 months or more; defined as 2 or fewer complete bowel movements weekly and 1 of the following: pain on defecation on 25% of days; 25% or more of bowel movements with straining; 25% or more of bowel movements with hard/lumpy stools]) comparing polyethylene glycol 3350 plus electrolytes (PEG+E) versus placebo during a 2-week treatment period separated by a 2-week placebo washout.^[22] The dosage was dependent on the child's age. Children aged 2 to 6 years were given either placebo or PEG+E sachets as follows: days 1 and 2 = 1 sachet; days 3 and 4 = 2 sachets taken together; days 5 and 6 = 3 sachets (2 morning, 1 evening); days 7 and 8 = 4 sachets (2 morning, 2 evening). Children aged 7 to 11 years were given either placebo or PEG+E sachets as follows: days 1–4 = 2 sachets taken together; days 5 and 6 = 5 sachets (2 morning, 3 evening); days 7 and 8 = 6 sachets (3 morning, 3 evening). The RCT found that, compared with placebo, PEG+E significantly improved the mean score for pain on defecation (scale: 0 = none, 1 = mild, 2 = moderate, 3 = severe) and number of complete defecations a week (mean score for pain on defecation: 0.49 with PEG+E v 0.77 with placebo; P = 0.04; number of complete defecations a week; ITT: 3.12 with PEG+E v 1.45 with placebo; P less than 0.001). However, the RCT found no significant difference in the number of mean faecal incontinence episodes between groups (4.70 with PEG+E v 4.85 with placebo; P = 0.68).^[22]

The subsequent RCT (103 children aged 4–16 years with chronic constipation [lasting 3 months or more; defined as 3 or fewer spontaneous bowel movements weekly and 1 or more symptoms of: straining; hard stools; sensation of incomplete evacuation; large bowel movements; or painful defecation]) compared three doses of PEG 3350 (0.2, 0.4, or 0.8 g/kg daily) versus placebo for 14 days.^[21] The RCT found that all doses of PEG 3350 significantly increased the rate of bowel movements compared with placebo after 14 days' treatment (3 or more: 77% with PEG 0.2 g/kg daily v 74% with PEG 0.4 g/kg daily v 73% with PEG 0.8 g/kg daily v 42% with placebo; P = 0.04 for each group compared with placebo; absolute numbers not reported). The RCT also found that PEG 0.8 g/kg significantly increased the proportion of children with three or more bowel movements a week compared with placebo during the 2-week treatment period (62% with PEG 0.8 g/kg v 29% with placebo; P less than 0.027; absolute numbers not reported).

The RCT found no significant difference in the proportion of children responding to treatment without faecal incontinence between any dose of PEG compared with placebo at 14 days (31% with PEG 0.2 g/kg v 26% with PEG 0.4 g/kg v 31% with PEG 0.8 g/kg v 8% with placebo; P = 0.2 for among group comparison; absolute numbers not reported).

Lactulose versus mineral oil:

See benefits of faecal softeners, p 9 .

Lactulose versus senna:

See benefits of stimulant laxatives, p 10 .

Lactulose versus fibre:

See benefits of fibre, p 3 .

Macrogol versus lactulose:

One RCT included in the review (100 children aged 6 months–15 years with chronic constipation [defined as having at least 2 of the following symptoms for the last 3 months: 3 bowel movements or fewer weekly; encopresis once weekly or more; large amounts of stool every 7–30 days; and a palpable abdominal or rectal mass) compared (after faecal disimpaction) PEG 3350 (2.95 g/sachet: children under 6 years, 1 sachet daily; children over 6 years, 2 sachets daily) versus lactulose (6 g/sachet; children over 6 years, 2 sachets daily) for 8 weeks.^[23] The RCT found that PEG 3350 significantly improved successful treatment (defecation frequency 3 a week or more and encopresis 1 or less every 2 weeks) compared with lactulose (56% with PEG 3350 v 29% with lactulose; P = 0.02; absolute numbers not reported) at 8 weeks. The first RCT included in the review also reported that children in the PEG 3350 group had significantly less abdominal pain, straining, and pain at defecation compared with children in the lactulose group (P less than 0.05 for all comparisons; absolute numbers not reported).^[23]

The second crossover RCT included in the review (37 children aged 2–16 years with constipation [definition not stated]) compared PEG 3350 (10 g/m² daily) versus lactulose (1.3 g/kg divided twice daily up to 20 g) for 2 weeks.^[24] The RCT found that PEG 3350 significantly decreased the mean total colonic transit time compared with lactulose (47.6 hours with PEG v 55.3 hours with lactulose; P = 0.038). The RCT also found that the ease of stool passage was similar for both groups (no further data reported).^[24]

Macrogol versus milk of magnesia:

One unblinded RCT identified by the review (79 children aged 4–16 years with functional constipation with faecal incontinence [at least 8 weeks of 2 or more of the following criteria: fewer than 3 bowel movements weekly; more than 1 episode of faecal incontinence weekly; large stools in the rectum or palpable during abdominal examination; passing of large stools and retentive posturing]) compared PEG 3350 (0.7 g/kg daily, in a solution of 2 g/30 mL) versus milk of magnesia (2 mL/kg daily) for 12 months.^[25] The RCT found no significant difference in rates of improvement (3 or more bowel movements weekly, 2 episodes of faecal incontinence monthly or fewer, and no abdominal pain, with or without laxative therapy) or rates of recovery (3 or more bowel movements weekly, 2 episodes of faecal incontinence monthly or fewer, and no abdominal pain, with no laxative treatment for 1 month or longer) between PEG 3350 and milk of magnesia at 1, 3, 6, or 12 months (data presented graphically; reported as not significant for months 1, 3, and 6; improvement at 12 months: 62% with PEG v 43% with milk of magnesia; recovery at 12 months: 33% with PEG v 23% with milk of magnesia; data presented graphically; reported as not significant). This RCT had a high withdrawal rate of seven children in the PEG group and 20 children in the milk of magnesia group at 12 months' follow-up.^[25]

Osmotic laxatives versus probiotics:

See benefits of probiotics, p 12 .

Harms:**Macrogol versus placebo:**

The RCT included in the review reported similar rates of adverse effects (31/49 [63%] with PEG+E v 28/49 [57%] with placebo; significance assessment not performed). Most were GI symptoms, particularly abdominal pain.^[22]

The subsequent RCT reported similar percentages of adverse effects among groups (9/24 [35%] with PEG 0.2 g/kg v 16/27 [59%] with PEG 0.4 g/kg v 17/26 [65%] with PEG 0.8 g/kg v 14/24 [58%] with placebo; significance assessment not performed).^[21] The RCT reported that GI-related events were more frequent in the PEG 3350 group compared with placebo (no further data reported), and that as the dose of PEG 3350 was increased, there was a higher incidence of flatulence, abdominal pain, nausea, and diarrhoea (no further data reported).^[21]

Lactulose versus mineral oil:

See harms of faecal softeners, p 9 .

Lactulose versus senna:

See harms of stimulant laxatives, p 10 .

Lactulose versus fibre:

See harms of fibre, p 3 .

Macrogol versus lactulose:

The first ^[23] and second ^[24] RCTs included in the review gave no information on adverse effects of treatment.

Another RCT included in the review (96 children with constipation aged 6 months to 3 years) compared PEG 4000 (4–8 g) versus lactulose (3.33–6.66 g) for 3 months. ^[26] The RCT found no significant difference in the percentage of children with at least one blood value (total protein; albumin; iron; electrolytes; and vitamins B₉, A, and D [25OHD3]) out of normal range at day 84 compared with baseline (0/46 [87%] with PEG 4000 v 35/39 [90%] with lactulose; P = 0.7). The RCT also reported five episodes of diarrhoea in two children in both treatment groups, and anorexia in one child in the lactulose group. No significant difference was found between PEG 4000 and the lactulose group with respect of digestive tolerance except for the median (interquartile range) duration of either new onset or worsened flatulence and of either new onset or worsened vomiting episodes (duration of either new onset or worsened flatulence: 3 days with PEG 4000 v 5 days with lactulose; P = 0.005; either new onset or worsened vomiting episodes: 1 day with PEG 4000 v 2 days with lactulose; P less than 0.05). Anal irritation was reported in 2/40 [5%] of children in the lactulose group. ^[26]

Macrogol versus milk of magnesia:

The RCT included in the review reported that one child withdrew due to an allergic reaction to PEG. ^[25]

Osmotic laxatives versus probiotics:

See harms of probiotics, p 12 .

Comment:**Clinical guide:**

Although good-quality evidence is lacking, macrogol seems to be a more effective laxative compared with lactulose and placebo. The role of milk of magnesia requires further evaluation.

OPTION**BEHAVIOURAL TREATMENTS****Treatment success**

Biofeedback plus conventional treatment compared with conventional treatment alone (laxatives, dietary advice, or toilet training) We don't know whether biofeedback plus conventional treatment or anorectal manometry plus conventional treatment are more effective at increasing treatment success rates at 6 to 104 weeks in children with constipation or encopresis with or without constipation (*very low-quality evidence*).

Behavioural treatment compared with conventional treatment Behavioural treatment may be no more effective at improving success rates at 22 weeks to 6 months in children with constipation and taking laxatives (*low-quality evidence*).

Behavioural interventions alone compared with senna plus behavioural interventions We don't know whether behavioural interventions alone are more effective at 3 to 6 months at relieving faecal soiling in children with or without constipation (*very low-quality evidence*).

For GRADE evaluation of interventions for constipation in children, see table, p 17 .

Benefits:**Behavioural treatment versus no treatment/sham treatment:**

We found one systematic review (search date 2006), which found no RCTs. ^[27]

Biofeedback plus conventional treatment versus conventional treatment alone:

We found one systematic review (search date 2006; 18 RCTs, 1186 children; 17 of the 18 RCTs investigating children with functional faecal incontinence) comparing behavioural and/or cognitive interventions with or without other treatments for the management of faecal incontinence in children. ^[27] The review found no significant difference in the number of children cured or improved with biofeedback (where the muscle tone of the external anal sphincter is displayed on a screen or a sound modulation) plus conventional treatment (laxatives, dietary advice, and toilet training) at 12 or 18 months compared with conventional treatment alone (12 months; 9 RCTs; 510 children: 133/260 [51%] with biofeedback v 121/250 [48%] with conventional treatment; OR 1.11, 95% CI 0.78 to 1.58; P = 0.55; 18 months; 2 RCTs; 251 children: 67/128 [52%] with biofeedback v 56/123 [45%] with conventional treatment; OR 1.31, 95% CI 0.80 to 2.15; P = 0.29). Children with functional non-retentive faecal incontinence, or functional or organic constipation were included in this analysis. However, a sensitivity analysis excluding two studies (which enrolled either children with non-retentive fecal incontinence or with fecal incontinence due to congenital causes) found no significant difference between biofeedback plus conventional treatment and conventional treatment alone in the number of children not cured or improved by treatment at 12- and 18-month follow-up (12 months; 7 RCTs; 432 children: 112/218 [51%] with biofeedback v 103/214 [48%] with conventional

treatment; OR 1.13, 95% CI 0.77 to 1.66; P = 0.52; 18 months; 1 RCT; 184 children: 48/92 [52%] with biofeedback v 40/92 [43%] with conventional treatment; OR 1.42, 95% CI 0.79 to 2.53; P = 0.24). However, the review highlighted that methodological flaws, such as lack of consistent baseline data and outcome measures, non-randomised trials, heterogeneity of study populations, and small samples, precluded meaningful conclusions.^[27]

We found one additional RCT (212 children with 2 of the following: fewer than 3 stools weekly; 2 or more episodes of soiling or encopresis weekly; passing of large amounts of faeces every 7–30 days; palpable abdominal or rectal faecal mass) comparing anorectal manometry (2 sessions) plus conventional treatment versus conventional treatment alone (dietary advice, diary, toilet training, oral laxatives [lactulose]) for 6 weeks.^[28] The RCT found no significant difference between the groups in treatment success (defined as: 3 or more defecation episodes weekly, 1 or fewer encopresis episodes within 2 weeks, no laxative use) at 6 or 104 weeks' follow-up (6 weeks: 4/111 [4%] with conventional treatment v 6/91 [7%] with conventional treatment plus anorectal manometry; RR 0.55, 95% CI 0.16 to 1.89; 104 weeks: 36/83 [43%] with conventional treatment v 23/65 [35%] with conventional treatment plus anorectal manometry; RR 1.23, 95% CI 0.81 to 1.85).

Behavioural treatment versus conventional treatment:

We found one RCT (134 children aged 4–18 years with at least 2 of the 4 criteria: defecation frequency fewer than 3 times weekly; faecal incontinence twice weekly; passage of large amounts of stool at least once every 7–30 days or a palpable abdominal or rectal faecal mass) comparing behavioural therapy (learning process to reduce phobic reactions related to defecation consists of 5 sequential steps: know, dare, can, will, and do) versus conventional treatment (education, diary, toilet training with rewarding system) over 22 weeks (12 visits).^[29] Both used similar laxative therapy. The RCT found no significant difference in success rates (3 or more bowel movements weekly and faecal incontinence frequency of 1 or fewer over 2 weeks irrespective of laxative use) for behavioural treatment at 22 weeks or at 6 months compared with conventional treatment (22 weeks: 52% with behavioural therapy v 62% with conventional treatment; P = 0.24; 6 months: 42% with behavioural therapy v 57% with conventional treatment; P = 0.09).^[29]

Behaviour modifications alone versus behaviour modifications plus stimulant laxatives:

See [benefits of stimulant laxatives](#), p 10 .

Harms:

Behavioural treatment versus no treatment/sham treatment:

We found no RCTs.

Behavioural treatment plus conventional treatment versus conventional treatment alone:

The systematic review^[27] and additional RCT^[28] gave no information on adverse effects.

Behavioural treatment versus conventional treatment:

The RCT gave no information on adverse effects.^[29]

Behaviour modifications alone versus behaviour modifications plus stimulant laxatives:

See [harms of stimulant laxatives](#), p 10 .

Comment:

Anorectal manometry is a diagnostic tool, but because it provides a visualisation of anorectal function it has been used as a part of biofeedback treatment. As research into the patterns of dysmotility is ongoing, anorectal manometry does not offer a specific diagnosis of constipation.

Clinical guide:

Biofeedback treatment in children with abnormal defecation patterns requires further evaluation. The outcome of the intervention is also likely to be mediated by the skill of the therapist. Comparing different psychological interventions head-to-head is the way forward. Biofeedback is not generally available in the UK because of the lack of evidence of benefit in childhood.

OPTION

BULK-FORMING LAXATIVES

We found no direct information from RCTs about bulk-forming laxatives (methylcellulose, ispaghula husk, or sterculia) in the treatment of children with constipation.

For GRADE evaluation of interventions for constipation in children, see table, p 17 .

Benefits: We found one systematic review (search date 2006), which identified no RCTs.^[17]

Harms: We found no RCTs.

Comment: None.

OPTION	FAECAL SOFTENERS
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Treatment success

Mineral oil (liquid paraffin) compared with biofeedback plus conventional treatment Mineral oil (liquid paraffin) may be as effective as biofeedback plus conventional treatment (toilet training, use of mineral oil as laxative) at improving cure rates in children with faecal incontinence or constipation at 12 months ([low-quality evidence](#)).

Mineral oil (liquid paraffin) compared with lactulose Mineral oil (liquid paraffin) may be more effective at increasing the number of bowel movements at 4 to 8 weeks in children with constipation ([very low-quality evidence](#)).

Mineral oil (liquid paraffin) compared with senna Liquid paraffin may be more effective at increasing bowel movements and reducing daily soiling in children with chronic constipation ([low-quality evidence](#)).

Note

We found no direct information from RCTs about whether faecal softeners (mineral oils [liquid paraffin], arachis oil) are better than no active treatment in children with constipation.

For GRADE evaluation of interventions for constipation in children, see table, p 17 .

Benefits:**Faecal softeners versus placebo:**

We found one systematic review (search date 2006), which found no RCTs. ^[17]

Mineral oil (liquid paraffin) versus biofeedback plus conventional treatment:

We found one systematic review (search date 2006; 18 RCTs, 1186 children; 17 of the 18 RCTs investigating children with functional faecal incontinence) comparing behavioural, cognitive, or behavioural plus cognitive interventions with or without other treatments for the management of faecal incontinence in children. ^[27] The review included one RCT (50 children with faecal incontinence or constipation) comparing conventional treatment (toilet training, use of mineral oil as laxative) versus biofeedback plus conventional treatment. ^[30] The RCT included in the review found no significant difference between groups for the proportion of children not cured or improved (10/26 [38%] with conventional treatment v 13/24 [54%] with biofeedback plus conventional treatment; OR 1.86, 95% CI 0.61 to 5.83) at 12 months. ^[30]

Mineral oil (liquid paraffin) versus lactulose:

We found one systematic review (search date 2007; 28 trials [21 RCTs; 1 comparative clinical trial and 6 crossover studies]; 1912 children aged 0–18 years with functional constipation and with or without faecal incontinence) comparing laxatives or dietary measures versus placebo, no treatment, or alternative treatments. ^[17] The review identified one RCT (40 children aged 2–12 years with chronic constipation with at least 2 of the following in the last 3 months: hard stools, painful defecation, rectal bleeding, encopresis and fewer than 3 bowel movements weekly) comparing mineral oil versus lactulose both 1 mL/kg twice daily orally for 8 weeks. ^[31] The RCT found mineral oil significantly improved the number of bowel movements a week compared with lactulose during the last 4 weeks (16.1 with liquid paraffin v 12.3 with lactulose; P less than 0.05).

We found one subsequent RCT (247 children aged 2–12 years with chronic constipation with at least 2 of the following in the last 3 months: fewer than 3 bowel movements weekly; more than 1 weekly episode of faecal soiling, large amounts of stool every 7–30 days; and palpable or rectal faecal mass) comparing liquid paraffin versus lactulose 1–2 mL/kg orally once daily for 8 weeks after faecal disimpaction. ^[32] It found that liquid paraffin significantly increased success rate (defined as 3 or more spontaneous bowel movements weekly with encopresis episodes once every 2 weeks or fewer; 85% with liquid paraffin v 29% with lactulose; P less than 0.001, no absolute numbers reported) compared with lactulose. ^[32] However, the randomisation of the RCT and the number of children who needed additional stimulant laxatives was not clear. ^[32]

Mineral oil (liquid paraffin) versus senna:

See [benefits of stimulant laxatives, p 10](#) .

Harms:**Faecal softeners versus placebo:**

We found no RCTs.

Mineral oil (liquid paraffin) versus biofeedback plus conventional treatment:

The review gave no information on adverse effects. ^[27] ^[30]

Mineral oil (liquid paraffin) versus lactulose:

The RCT included in the review reported abdominal distention and cramping in three children in the lactulose group and watery stool in two children in the mineral oil group. ^[31] The subsequent RCT did not provide clear data about adverse effects. ^[32]

Mineral oil (liquid paraffin) versus senna:

See harms of stimulant laxatives, p 10 .

Comment: None.

OPTION	STIMULANT LAXATIVES
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Treatment success

Senna compared with lactulose Senna may be less effective at increasing the number of normal stools passed ([very low-quality evidence](#)).

Senna compared with mineral oil (liquid paraffin) Senna may be less effective at increasing bowel movements and at reducing daily soiling in children with chronic constipation ([low-quality evidence](#)).

Senna plus behavioural interventions compared with behavioural interventions alone We don't know whether senna plus behavioural interventions is more effective at 3 to 6 months at relieving faecal soiling in children with encopresis with or without constipation ([very low-quality evidence](#)).

Note

We found no direct information from RCTs about whether stimulant laxatives (bisacodyl, dantron, senna, docusate, sodium picosulfate, or glycerol) are better than no active treatment in children with constipation.

For GRADE evaluation of interventions for constipation in children, see table, p 17 .

Benefits:

We found two systematic reviews. ^[33] ^[17] The first systematic review (search date not reported) identified no RCTs. ^[33] The second review (search date 2007, 28 trials [21 RCTs; 1 comparative clinical trial and 6 crossover studies]; 1912 children aged 0–18 years with functional constipation with or without faecal incontinence) comparing laxatives or dietary measures versus placebo, no treatment, or alternative treatments. ^[17]

Stimulant laxatives versus placebo:

We found two systematic reviews, which identified no RCTs. ^[33] ^[17]

Senna versus lactulose:

The second review ^[17] identified one RCT comparing senna versus lactulose. ^[34] The crossover RCT included in the review (21 children aged under 15 years with constipation treated at home for 3 months or longer) compared senna syrup (10–20 mL/day for 7 days) versus lactulose (10–15 mL/day for 7 days) with a 1-week washout period between. The RCT found that on each day of the week significantly fewer children in the senna group passed normal stools compared with the lactulose group (P less than 0.01; absolute numbers for statistical analysis not reported). The RCT did not report pre-crossover results. ^[34]

Senna versus mineral oil (liquid paraffin):

The second review ^[17] identified one RCT. ^[35] The RCT included in the review (37 children with chronic constipation aged 3–12 years) compared senna (dose not reported) versus mineral oil (1.5–5.0 cm³/kg daily) after an initial catharsis with oral bisacodyl or with an enema, if necessary, for all children. ^[35] It found that, compared with the mineral oil group, the proportion of children reporting a daily bowel movement was significantly smaller for the senna group (9/18 [50%] with senna v 16/19 [89%] with mineral oil; P less than 0.05) and the proportion reporting daily soiling was significantly larger (8/18 [44%] with senna v 1/19 [6%] with mineral oil; P less than 0.05). Mean follow-up was 10.5 months for the senna group and 10.1 months for the mineral oil group.

Senna plus behavioural interventions versus behavioural interventions alone:

The second review ^[17] identified one RCT. ^[36] The RCT included in the review (44 children; mean age 7.9 years with [encopresis](#); 89% [absolute number not reported] with a history of constipation) compared three interventions: senna tablets, placebo tablets, and no tablets; and all children were given behavioural treatment (use of toilet and freedom from soiling). ^[36] It found no significant difference among groups in the proportion of children with relief from faecal soiling at 3 and 6 months' follow-up (3 months: 5/14 [35%] with behavioural treatment plus senna v 2/11 [18%] with behavioural treatment plus placebo v 9/15 [60%] with behavioural treatment alone; 6 months: 5/14 [35%] with behavioural treatment plus senna v 5/10 [50%] with behavioural treatment plus placebo v 7/13 [54%] with behavioural treatment alone; P greater than 0.05 for comparison of 3 groups for each follow-up time).

Harms:**Stimulant laxatives versus placebo:**

We found no RCTs.

Senna versus lactulose:

The RCT included in the review found that senna was associated with significantly more adverse effects compared with lactulose (colic, diarrhoea, or distension: 31 with senna v 1 with lactulose; P less than 0.001).^[34] The adverse effects were measured as the total number of days in which they were reported for each child (i.e., to a maximum of 21 children x 7 days). There were also six adverse effect days reported in the washout week.

Senna versus mineral oil (liquid paraffin):

The RCT gave no information on adverse effects.^[35]

Senna plus behavioural interventions versus behavioural interventions alone:

The RCT gave no information on adverse effects.^[36]

Comment:**Clinical guide:**

There seems to be no role for senna in the treatment of constipation.

OPTION**ANAL DILATATION****Treatment success**

Compared with no dilatation Anal dilatation may be no more effective at decreasing symptom severity scores at 12 months in children with constipation, irrespective of having anorectal manometry, evacuation of faeces, intensified treatment, and toilet training ([very low-quality evidence](#)).

For GRADE evaluation of interventions for constipation in children, [see table, p 17](#).

Benefits:

We found one RCT (68 neurologically normal children who failed to respond to medical treatment for constipation; mean age 7.9 years) comparing anal dilatation versus no dilatation.^[37] All children had anorectal manometry under ketamine anaesthesia followed by evacuation of faeces. Also, all children had intensified medical treatment and toilet training during their hospital stay. The RCT did not report on individual outcomes (e.g., increased defecation or reduced faecal incontinence) but used a scoring system developed by the authors of the study to assess overall symptom severity; the system combined scores for difficulty and pain on passing stool, delay in defecation, soiling problem, intensity of laxative treatment and general health (parent rated: 0 = worst, 65 = best). The RCT found no significant difference between groups at 12 months in change in symptom severity scores (decrease in symptom severity score: -18 with dilatation v -10 with no dilatation; P less than 0.92).

Harms:

The RCT gave no information on adverse effects.^[37]

Comment:

None.

Clinical guide:

To date, there is no evidence for the use of anal dilatation in children with constipation. It is an invasive treatment and should therefore not be used.

OPTION**ORAL FLUIDS****Treatment success**

Compared with normal fluid intake Increasing oral fluid intake, or supplementing with hyperosmolar fluids, may be no more effective at 3 weeks at increasing stool frequency, or at reducing difficulties in passing stools in children with constipation ([very low-quality evidence](#)).

For GRADE evaluation of interventions for constipation in children, [see table, p 17](#).

Benefits:

We found one RCT (108 children; mean age 7.5 years; mean number of stools 2.73 weekly, with moderate to severe constipation; difficulty in passing stool scale: 0 = no problem, 1 = some problem, and 2 = severe problem) comparing three groups: 50% water intake increase; hyperosmolar (greater than 600 mOsm/L) supplemental fluid; and normal fluid intake.^[38] The RCT found similar stool frequency at 3 weeks and difficulty in passing stools for the three groups (stool frequency at 3 weeks: 3.70 with water increase v 3.44 with hyperosmolar fluid v 3.40 with normal fluid; difficulty in passing stools: 0.87 with water increase v 0.62 with hyperosmolar fluid v 1.06 with normal fluid; significance not assessed).

Harms:

The RCT gave no information on adverse effects.^[38]

Comment:

None.

OPTION	PREBIOTICS	New
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We found no direct information from RCTs about **prebiotics** in the treatment of children with constipation.

For GRADE evaluation of interventions for constipation in children, see table, p 17 .

Benefits: We found no systematic review or RCTs.

Harms: We found no RCTs.

Comment: None.

OPTION	PROBIOTICS	New
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Treatment success

Probiotics plus osmotic laxatives compared with placebo plus osmotic laxatives Probiotics plus osmotic laxatives seem no more effective at increasing rates of treatment success at 12 to 24 weeks, or at reducing the number of episodes of faecal soiling or frequency of straining at 12 weeks, or the number of children using laxatives at 24 weeks in children with functional constipation (**moderate-quality evidence**).

Probiotics compared with osmotic laxatives Probiotics seem as effective as osmotic laxatives at increasing rates of treatment success at 4 weeks, and at reducing episodes of faecal incontinence at 4 weeks in children with functional constipation, but more effective at decreasing rates of abdominal pain (**moderate-quality evidence**).

Note:

We found no direct information from RCTs about whether probiotics are better than no active treatment in children with constipation.

For GRADE evaluation of interventions for constipation in children, see table, p 17 .

Benefits: We found one systematic review (search date 2007; 28 trials [21 RCTs; 1 comparative clinical trial and 6 crossover studies]; 1912 children aged 0–18 years with functional constipation and with or without faecal incontinence) comparing laxatives or dietary measures versus placebo, no treatment, or alternative treatments. ^[17]

Probiotics versus placebo:

The review identified one RCT comparing **probiotics** versus placebo. ^[39] The RCT (45 children aged under 10 years with functional constipation for more than 2 months) compared the osmotic laxative magnesium oxide 50 mg/kg daily (18 children), 8×10^9 colony-forming units of the probiotic *Lactobacillus rhamnosus* (18 children), and placebo (9 children). The RCT does not meet *Clinical Evidence* reporting criteria for comparisons versus placebo (number of children in the placebo group falls below inclusion criteria of 10 in each arm) and is not discussed further in this section; please see probiotics versus osmotic laxatives below for data on this comparison. ^[39]

Probiotics plus osmotic laxatives versus placebo plus osmotic laxatives:

The review identified one RCT comparing probiotics plus osmotic laxatives versus placebo plus osmotic laxatives. The RCT (84 children with functional constipation [fewer than 3 stools weekly for more than 12 weeks] aged 2–16 years) compared 10^9 colony-forming units of *Lactobacillus rhamnosus* GG (LGG) plus 1 mL/kg daily of 70% lactulose versus placebo plus 1 mL/kg daily of 70% lactulose, twice daily orally for 12 weeks. ^[40] It found no significant difference in treatment success (defined as more than 3 spontaneous stools weekly with no faecal soiling) at 12 and 24 weeks between probiotics (LGG) and placebo (12 weeks: 31/43 [72%] with probiotics v 28/41 [68%] with placebo; P = 0.9; 24 weeks: 27/43 [64%] with probiotics v 27/41 [65%] with placebo; P = 1.0). It also found no significant difference between probiotics and placebo in episodes of faecal soiling a week at 12 weeks, frequency of straining a week at 12 weeks, and the number of children using laxatives at 24 weeks (mean episodes of faecal soiling at 12 weeks: 0.8 with probiotics v 0.3 with placebo; P = 0.9; mean frequency of straining a week at 12 weeks: 1.3 with probiotics v 1.6 with placebo; P = 0.6; use of laxatives at 24 weeks: 19/43 [44%] with probiotics v 18/41 [43%] with placebo; P less than 0.9).

Probiotics versus osmotic laxatives:

The review identified one RCT comparing probiotics versus osmotic laxatives. ^[39] The RCT (45 children aged under 10 years with functional constipation for more than 2 months and at least 1 of the following symptoms: anal fissures with bleeding; faecal soiling; or passage of large and hard stool) compared the osmotic laxative magnesium oxide 50 mg/kg daily (18 children), 8×10^8 colony-forming units of the probiotic *Lactobacillus casei rhamnosus* (18 children), and placebo (9 children), all twice daily for 4 weeks, in a three-arm trial. We report the comparison of probiotics (*Lactobacillus*

casei rhamnosus) versus osmotic laxatives (magnesium oxide) here. All outcomes were assessed at 4 weeks. The RCT found that probiotics significantly reduced abdominal pain compared with osmotic laxatives (1.9 episodes with probiotics v 4.8 episodes with osmotic laxatives; $P = 0.04$). However, it found no significant difference in treatment success (defined as 3 or more spontaneous defecations a week with no episodes of faecal soiling by the fourth week) between probiotics and osmotic laxatives (78% with probiotics v 72% with osmotic laxatives; $P = 0.71$; absolute results not reported). The RCT also found similar rates of faecal soiling for probiotics and osmotic laxatives (2.1 episodes with probiotics v 2.7 episodes with osmotic laxatives; statistical significance between groups not assessed).^[39]

- Harms:** **Probiotics plus osmotic laxatives versus placebo plus osmotic laxatives:**
The RCT found no significant difference between LGG plus lactulose and placebo plus lactulose in the number of adverse events, which included abdominal pain, vomiting, and headache (4/43 [9%] with LGG v 6/41 [15%] with placebo).^[40]
- Probiotics versus osmotic laxatives:**
The RCT reported no adverse effects associated with probiotics, but reported one case of mild diarrhoea in a child receiving osmotic laxatives.^[39]
- Comment:** The two RCTs compared two different probiotic agents.^[39] ^[40] *Lactobacillus rhamnosus* GG was not an effective adjunct to lactulose in treating constipation,^[40] and *Lactobacillus casei rhamnosus* was no more effective than the osmotic laxative magnesium oxide in most of the outcomes assessed.^[39] There are many different probiotic microorganisms with different effects, but, to date, there is no evidence to recommend the use of probiotics. Use of probiotics requires further evaluation by RCTs.

QUESTION What are the effects of treatments for clearing the bowel in children with faecal impaction?

OPTION ENEMAS

We found no direct information from RCTs about enemas in the treatment of children with faecal impaction.

Note

Phosphate enema administration may be associated with adverse effects in people with intestinal or renal system abnormalities.

For GRADE evaluation of interventions for constipation in children, see table, p 17 .

- Benefits:** We found one systematic review (search date 2006), which identified no RCTs.^[17]
- Harms:** We found no RCTs.
- Comment:** We found one review of case studies (search date 1995; 21 case studies of adverse effects of hypertonic sodium phosphate enema).^[41] It reported adverse effects such as pyrexia, lethargy, hypocalcaemia, and hyperphosphataemia (no further data reported). Also, there were electrolyte imbalances leading to irritability, tetany, and in one case cardiac arrest (no further data reported). However, nearly two-thirds of the children reporting adverse effects had pre-existing intestinal or renal system abnormalities; in this review, we only consider constipation in children without an organic cause.

Clinical guide:

The review found a paucity of data surrounding enema administration in children and recommended that it should not be used in children under 2 years of age or in children under 5 years of age with intestinal abnormalities, renal abnormalities, or both.^[41] Placebo-controlled trials for forms of disimpaction would be unethical and any rectal administration would not be a true placebo by its stimulatory effect on the rectal function.

OPTION MACROGOLS

We found no direct information from RCTs about macrogols in the treatment of children with faecal impaction.

For GRADE evaluation of interventions for constipation in children, see table, p 17 .

- Benefits:** We found no systematic review or RCTs.
- Harms:** We found no RCTs.

Comment: Placebo-controlled trials for forms of disimpaction would be unethical, and any rectal administration would not be a true placebo by its stimulatory effect on the rectal function.

Clinical guide:

Many children are afraid of any rectal procedure, so any alternative to enemas or suppositories is likely to be preferable. However, it requires an individual decision as to whether the use of a nasogastric tube is more or less acceptable to a particular child than an enema when the child is unable to take a sufficiently high volume of macrogol orally.

OPTION SURGICAL DISIMPACTATION

We found no direct information from RCTs about surgical disimpaction in the treatment of children with faecal impaction.

For GRADE evaluation of interventions for constipation in children, see table, p 17 .

Benefits: We found no systematic review or RCTs.

Harms: We found no RCTs.

Comment: None.

Clinical guide:

There is no information about surgical disimpaction in the treatment of children with faecal impaction. The procedure is invasive and should therefore be used in very limited cases.

GLOSSARY

Prebiotics Non-digestible food ingredients that beneficially affect the host by selectively stimulating the growth, activity, or both of one or a limited number of bacteria in the colon, and thus improve host health.

Probiotics Live micro-organisms which, when administered in adequate amounts, confer a health benefit on the host.

Encopresis Faeces that is involuntary passed.

Scybalous A dry, hard mass of faeces.

Faecaloma A large amount of faeces that forms a tumour-like mass.

Low-quality evidence Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Moderate-quality evidence Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Very low-quality evidence Any estimate of effect is very uncertain.

SUBSTANTIVE CHANGES

Prebiotics New option for which we found no evidence.

Probiotics: New option for which we found one systematic review comparing laxatives or dietary measures versus placebo, no treatment, or alternative treatments.^[17] The review found no significant difference in treatment success at 12 and 24 weeks between probiotics and placebo. It also found no significant difference between probiotics plus osmotic laxative and placebo plus osmotic laxative in episodes of faecal soiling, frequency of straining a week at 12 weeks, or the number of children using laxatives at 24 weeks. The review identified one RCT comparing probiotics versus osmotic laxatives, which found probiotics reduced abdominal pain compared with osmotic laxatives, but reported no difference between groups for treatment success.^[17] Categorized as Unknown effectiveness, as there remains insufficient evidence to assess the effects of probiotics.

Behavioural treatments: One systematic review assessing the effects of biofeedback plus conventional treatment versus conventional treatment alone updated.^[27] The review found no difference in the number of children cured or improved with biofeedback plus conventional treatment at 12 or 18 months compared with conventional treatment alone. One RCT added assessing the effects of behavioural treatment versus conventional treatment.^[29] The RCT found no significant difference in success rates for behavioural treatment at 22 weeks or at 6 months compared with conventional treatment.^[29] Categorisation unchanged (Unknown effectiveness) as there remains insufficient good-quality evidence to assess the effects of behavioural treatments.

Bulk-forming laxatives: One systematic review added, which found no RCTs.^[17] Categorisation unchanged (Unknown effectiveness).

Enemas: One systematic review added, which did not include any RCTs.^[17] Categorisation unchanged (Unknown effectiveness).

Faecal softeners: Two systematic reviews added^{[27] [17]} which included two RCTs.^{[30] [31]} One subsequent RCT also added.^[32] The RCT included in the second review compared conventional treatment versus biofeedback plus conventional treatment, and found no difference between groups for the proportion of children not cured or improved at 12 months.^[30] The RCT included in the first review and the subsequent RCT compared liquid paraffin versus lactulose.^{[31] [32]} Both RCTs found that liquid paraffin improved the number of bowel movements a week compared with lactulose; however, the subsequent RCT had methodological flaws.^{[31] [32]} Categorisation unchanged (Unknown effectiveness) as there remains insufficient good-quality evidence to assess faecal softeners.

Fibre: One systematic review added^[17] comparing fibre versus placebo identified two RCTs. The first crossover RCT was previously included in this review; the second RCT found no difference in the change of total colon transit time, or subjective improvement in pain with fibre compared with placebo at 4 weeks. One RCT added comparing fibre versus lactulose.^[20] It found no difference in the number of children with one or more faecal incontinence episodes a week, or in the mean scores of people with abdominal pain or flatulence at week 3 and 8 of follow-up.^[20] Categorisation changed from Likely to be beneficial to Unknown effectiveness based on the new evidence showing no differences between groups for any outcome.

Osmotic laxatives: One systematic review^[17] and one subsequent RCT^[21] added comparing macrogol versus placebo, lactulose, PEG 3350, and milk of magnesia. One RCT^[22] included in the review^[17] and the subsequent RCT^[21] found that macrogol improved pain on defecation and number of defecations a week compared with placebo, but found no difference between groups for episodes of faecal incontinence. One RCT^[23] included in the review^[17] compared PEG 3350 versus lactulose for 8 weeks. The RCT found that PEG 3350 improved successful treatment compared with lactulose.^[23] A second RCT^[24] included in the review^[17] compared PEG 3350 versus lactulose, it found that PEG 3350 decreased total time to colonic transit compared with lactulose at 2 weeks. One unblinded RCT^[25] identified by the review^[17] compared polyethylene glycol 3350 versus milk of magnesia for 12 months. The RCT found no difference in rates of improvement or rates of recovery between PEG 3350 compared with milk of magnesia at 1, 3, 6, or 12 months.^[25] Categorisation unchanged (Unknown effectiveness) as there remains insufficient good-quality evidence to assess osmotic laxatives.

Stimulant laxatives: One systematic review added.^[17] However, the review did not include any additional RCTs, therefore no data was added. Categorisation unchanged (Unlikely to be beneficial).

Anal dilation: Evidence re-evaluated. Categorisation changed from Likely to be beneficial to Unknown effectiveness as the authors of the included RCT used a scale they had developed for assessment rather than an externally validated scale.

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TABLE GRADE evaluation of interventions for constipation in children

Important outcomes			Treatment success					GRADE	Comment	
	Number of studies (participants)	Outcome	Comparison	Type of evidence	Quality	Consistency	Directness			Effect size
What are the effects of treatments for children with chronic constipation?										
	2 (87) ^[19] ^[20]	Treatment success	Fibre v placebo	4	-2	-1	-1	0	Very low	Quality points deducted for sparse data and for incomplete reporting of results. Consistency point deducted for no agreement between studies. Directness point deducted for inclusion of children requiring disimpaction before treatment
	1 (97) ^[18]	Treatment success	Fibre v lactulose	4	-2	0	0	0	Low	Quality points deducted for sparse data and for incomplete reporting of results
	2 (154) ^[21] ^[22]	Treatment success	Macrogol v placebo	4	-2	0	0	0	Low	Quality points deducted for sparse data and incomplete reporting of results
	2 (137) ^[24] ^[23]	Treatment success	Macrogol v lactulose	4	-2	0	-1	0	Very low	Quality points deducted for sparse data and incomplete reporting of results. Directness point deducted for inclusion of children requiring disimpaction before treatment
	1 (79) ^[25]	Treatment success	Macrogol v milk of magnesia	4	-3	0	0	0	Very low	Quality points deducted for sparse data, unblinded, and high withdrawal rate
	10 (722) ^[27] ^[28]	Treatment success	Biofeedback plus conventional treatment v conventional treatment alone	4	-2	0	-1	0	Very low	Quality points deducted for lack of consistent baseline and outcome measures and for randomisation flaws. Directness point deducted for heterogeneous population (inclusion of children with encopresis without constipation)
	1 (134) ^[29]	Treatment success	Behavioural treatment v conventional treatment	4	-2	0	0	0	Low	Quality points deducted for sparse data and incomplete reporting of results
	1 (50) ^[30]	Treatment success	Mineral oil v biofeedback plus conventional treatment	4	-2	0	0	0	Low	Quality points deducted for sparse data and no ITT analysis
	2 (287) ^[31] ^[32]	Treatment success	Mineral oil v lactulose	4	-2	0	-1	0	Very low	Quality points deducted for unclear blinding and incomplete reporting of results. Directness point deducted for inclusion of children requiring disimpaction before treatment
	1 (21) ^[34]	Treatment success	Senna v lactulose	4	-3	0	0	0	Very low	Quality points deducted for sparse data, incomplete reporting of results, and for non-reporting of pre-crossover results
	1 (37) ^[35]	Treatment success	Senna v mineral oil	4	-1	0	-1	0	Low	Quality point deducted for sparse data. Directness point deducted for catharsis with another laxative (oral bisacodyl) or an enema before treatment
	1 (40) ^[36]	Treatment success	Senna plus behavioural interventions v behavioural interventions alone	4	-1	0	-2	0	Very low	Quality point deducted for sparse data. Directness points deducted for no statistical analysis of between group comparison and for heterogeneous population (inclusion of children with encopresis without constipation)

Important outcomes			Treatment success							Comment
Number of studies (participants)	Outcome	Comparison	Type of evidence	Quality	Consistency	Directness	Effect size	GRADE		
1 (60) ^[37]	Treatment success	Anal dilatation v no dilatation	4	-2	0	-1	0	Very low	Quality points deducted for sparse data and for use of non-standardised scoring system. Directness point deducted for inclusion of co-interventions	
1 (108) ^[38]	Treatment success	Oral fluids v normal fluid intake	4	-3	0	0	0	Very low	Quality points deducted for sparse data, incomplete reporting of results, and for not carrying out a statistical assessment	
1 (84) ^[42]	Treatment success	Probiotics plus osmotic laxatives v placebo plus osmotic laxatives	4	-1	0	0	0	Moderate	Quality point deducted for sparse data	
1 (45) ^[39]	Treatment success	Probiotics v osmotic laxatives	4	-1	0	0	0	Moderate	Quality point deducted for sparse data	

What are the effects of treatments for clearing the bowel in children with faecal impaction?
 We found no RCTs.
 Type of evidence: 4 = RCT; 2 = Observational.
 Consistency: similarity of results across studies
 Directness: generalisability of population or outcomes
 Effect size: based on RR or OR