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[Intervention Protocol]

Osmotic and stimulant laxatives for the management of childhood constipation

Morris Gordon^{1a}, Shiyao Liu¹, Vasiliki Sinopoulou¹, Anna de Geus^{2,3,4}, Yuhong Yuan^{5,6}, MA Benninga^{2,3,4}, Merit M Tabbers^{2,3,4}

¹School of Medicine and Dentistry, University of Lancashire, Preston, UK. ²Department of Paediatric Gastroenterology, Emma Children's Hospital, Amsterdam UMC, Amsterdam, Netherlands. ³Amsterdam Gastroenterology and Metabolism Research Institute, Amsterdam, Netherlands. ⁴Amsterdam Reproduction and Development Research Institute, Amsterdam, Netherlands. ⁵Division of Gastroenterology and Hepatology, Toronto Western Hospital, University Health Network, Toronto, Canada. ⁶Department of Medicine, McMaster University, Hamilton, Canada

^aORCID iD: <https://orcid.org/0000-0002-1216-5158>

Contact: Morris Gordon, morris@betterprescribing.com.

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ABSTRACT

Objectives

This is a protocol for a Cochrane review (intervention). The objectives are as follows:

To assess the efficacy and safety of osmotic and stimulant laxatives for the treatment of functional constipation in children.

BACKGROUND

Description of the condition

Functional constipation (FC) is a common condition in children worldwide, characterised by a range of symptoms including infrequent or painful bowel movements, stool withholding, and faecal incontinence [1, 2]. The global pooled prevalence of FC in children is estimated at 9.5%, with higher rates reported in the Americas and Europe compared with Asia, and no significant differences observed by sex or age [3]. Functional constipation has also been associated with dietary habits (including low fruit and vegetable intake and high fast-food consumption), lower levels of physical activity, and potentially, early feeding practices [3, 4, 5, 6]. The condition not only affects the child's quality of life but also places a considerable burden on healthcare services, due to the need for ongoing management and treatment [7, 8, 9].

The term functional constipation is used when no underlying organic cause (e.g. anatomical, neurological, or metabolic disorders) can be identified for the symptoms, after appropriate medical evaluation. Criteria have varied over time but are primarily based on a collection of symptoms. To standardise the diagnostic approach for functional gastroenterological disorders in children, a consensus group first published the paediatric Rome II criteria in 1999 [10]. These were subsequently updated through the Rome III process in 2006 [11, 12], and most recently revised to the Rome IV criteria in 2016 [13, 14, 15].

To diagnose functional constipation using the Rome IV criteria for infants and children up to four years of age:

The child must exhibit at least two of the following criteria for at least one month, or two or fewer defecations per week:

- History of excessive stool retention;
- History of painful or hard bowel movements;
- History of large-diameter stools;
- Presence of a large faecal mass in the rectum.

In toilet-trained children, these criteria may be added:

- At least one episode per week of incontinence;
- History of large-diameter stools that may obstruct the toilet.

To diagnose functional constipation using the Rome IV criteria for children older than four years with insufficient criteria for a diagnosis of irritable bowel syndrome:

The child must exhibit two or more of the following criteria at least once a week, for at least one month:

- Two or fewer defecations in the toilet;
- At least one episode of faecal incontinence;
- 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;
- History of large-diameter stools that may obstruct the toilet.

The goals of treatment are to establish and maintain regular bowel movements. Non-pharmacological management is the first step in the treatment of functional constipation, which includes

education and lifestyle modification [16]. Pharmacological treatment in children with functional constipation involves disimpaction, followed by maintenance therapy to ensure long-term symptom control [17]. Surgery may be considered when maximal conventional therapy fails and symptoms severely impair the child's quality of life [18, 19]. Effective management extends beyond diagnosis and prescription, hinging on the establishment of a strong therapeutic alliance with both the child and their family. This partnership requires a foundation of parental education, guidance, and support. Clinicians must provide clear, non-accusatory information to demystify the condition, explain the rationale for treatment, and set realistic expectations, acknowledging that progress is often irregular, with periods of improvement and deterioration [16, 19].

Description of the intervention and how it might work

Laxative therapies are the mainstay of medical therapy for childhood functional constipation, supported by a consensus across major international clinical guidelines. They are considered a safe and essential intervention for both faecal disimpaction and maintenance. Osmotic laxatives, such as lactulose, milk of magnesia, and polyethylene glycol (PEG), are usually supplied as solutions or powders to be dissolved in water, and therefore, are relatively easy to administer to young children.

Stimulant laxatives, such as senna and bisacodyl, come in a variety of forms, including tablets, liquids, and suppositories. Stimulant laxatives are commonly used as second-line therapy.

To achieve sustained success, these pharmacological interventions must be integrated with adjuvant behavioural, educational, and dietary strategies.

Osmotic laxatives are poorly absorbed in the gut and act as hyperosmolar agents, drawing water into the intestinal lumen. These increase stool water content and bulk, softening stools and making them easier to pass, while indirectly stimulating colonic peristalsis.

Stimulant laxatives act directly on the intestinal mucosa and the enteric nervous system to enhance peristaltic activity and reduce water and electrolyte absorption, which accelerates stool transit through the colon.

Why it is important to do this review

Childhood functional constipation is one of the most common gastrointestinal problems worldwide and often leads to significant discomfort, school absence, and family stress. Previous efforts have been made to produce guidance on this topic [1, 20], most recently by the European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) and the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) [21]. Although both osmotic and stimulant laxatives are widely used and recommended in international guidelines, practice varies, and the supporting evidence for their relative benefits, safety, and optimal use in children remains limited, and sometimes inconsistent. A systematic review that brings together all available randomised evidence will help clarify the comparative effectiveness of these treatments and inform evidence-based recommendations for clinicians and families [22].

Evidence on laxatives for paediatric constipation has been examined in several Cochrane reviews. Lee-Robichaud and colleagues compared polyethylene glycol (PEG) with lactulose in mixed adult and paediatric populations [23], while an earlier review of stimulant laxatives in children found insufficient evidence to draw firm conclusions [22]. Comprehensive Cochrane syntheses were subsequently conducted by Gordon and colleagues, with the most recent update published in 2016 [24]. The present review updates Gordon 2016 using Cochrane methods, collating and appraising randomised trials of osmotic and stimulant agents in children to provide an up-to-date assessment of efficacy and safety.

In addition to updating the evidence base, this review will incorporate recent methodological developments for systematic reviews. We will follow current guidance for risk of bias assessment, data synthesis, and the application of the GRADE approach. Building on experience from the previous review, we refined the planned subgroup and sensitivity analyses to enhance their clinical relevance and interpretability [21, 25]. We defined clinically relevant thresholds using a structured thresholding method, following the operating procedures developed for the recent clinical guidelines. These thresholds were established as part of the guideline development process, and are reported in our previous work [26]. We will apply the predefined thresholds in this review to inform judgments of imprecision, ensuring that effect estimates are interpreted in clinically meaningful terms.

OBJECTIVES

To assess the efficacy and safety of osmotic and stimulant laxatives for the treatment of functional constipation in children.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCT) that compare interventions for the management of functional constipation (FC).

Cross-over RCTs will only be eligible if the results are presented separately for each stage of the trial.

We will exclude trials of refractory or intractable constipation. These populations are considered distinct from functional constipation and are typically managed with different interventions. We will exclude quasi-randomised trials.

Types of participants

We will include participants from the newborn period up to 18 years of age with a diagnosis of functional constipation with or without faecal incontinence, as defined by the study authors. The diagnosis may be self-reported by participants or caregivers, made by a physician, or established according to consensus criteria, such as the Rome IV criteria.

We will exclude studies in which participants have an underlying organic or structural cause of constipation (e.g. thyroid disease, Hirschsprung's disease, or previous bowel surgery at study entry).

If a study includes both adults and children, we will only include the paediatric data, provided that the results for children are reported separately or can be obtained from the study authors. We will

exclude studies that do not allow the extraction of paediatric-specific data.

Types of interventions

We will include studies comparing osmotic or stimulant laxatives with another intervention or placebo. We will consider all preparations and dosing regimens. Other interventions may include, but are not limited to, alternative pharmacological treatments, dietary interventions, or behavioural interventions.

We will include studies evaluating combination therapies in which the effect of the laxative can be distinguished from that of the co-interventions.

We will extract details of the interventions, including dose, frequency, and duration, and consider them when assessing clinical heterogeneity. We will also include studies using multiple osmotic or stimulant laxative combinations, or combinations of both.

Outcome measures

The core research team defined the outcome set to include treatment success, defaecation frequency, withdrawals due to adverse events, stool consistency, quality of life, faecal incontinence, abdominal pain, and serious and total adverse events.

Although additional outcomes, such as school attendance, tolerability, and painful defaecation, are recognised as clinically important, they will not be prioritised or included in this review. This is because they are expected to be infrequently reported and inconsistently measured across studies, as identified in the team's recent guideline development and systematic review work, which limits their suitability for meaningful synthesis [21].

When multiple time points are reported, we will consider the latest time point. If time points differ substantially across studies, we will consider this a potential source of heterogeneity and explore it accordingly. Where multiple measurement methods are available for the same outcome, we will prioritise validated and commonly used measures. If more than one eligible measure is available, we will select the measure most frequently reported across studies.

Critical outcomes

- 1. Treatment success at the end of the study**, as defined by the study authors (e.g. resolution of symptoms or achievement of predefined clinical criteria), reported as dichotomous or continuous variables. We will not restrict treatment success to a single definition; instead, we will consider all reported definitions across included studies. We recognise that variation in definitions of treatment success may introduce clinical and methodological heterogeneity, which we will explore as a potential source of heterogeneity;
- 2. Defecation frequency**, defined as the number of bowel movements over a given time period, as reported in the included studies, reported as continuous variables. Where possible, we will standardise data to a common time unit; and
- 3. Withdrawals due to adverse events**, defined as the number of participants who discontinued treatment because of adverse events, as reported in the included studies, reported as dichotomous variables.

Important outcomes

1. **Faecal incontinence**, defined as the involuntary passage of stool, as reported in the included studies. This may be measured as the frequency of incontinence episodes over a specified time period or as the interval between episodes. We will analyse outcomes as either dichotomous or continuous variables, depending on how they are reported;
2. **Stool consistency**, measured using validated scales or as reported in the included studies. We will analyse outcomes as either dichotomous or continuous variables;
3. **Total adverse events**, defined as the number of participants experiencing any adverse event, as reported in the included studies. We will analyse outcomes as dichotomous variables; and
4. **Serious adverse events**, defined as the number of participants experiencing any serious adverse event, as reported in the included studies. We will analyse outcomes as dichotomous variables.

Search methods for identification of studies

An experienced information specialist will conduct comprehensive, systematic literature searches. As this review updates Gordon 2016 [24], whose searches were conducted up to 10 March 2016, we will restrict the updated searches to studies published from 2016 onwards. This approach provides overlap with the previous review, while identifying newly published evidence.

Electronic searches

We will perform a computer-assisted search of the following electronic databases from 2016 to the date of the final search:

- Cochrane Central Register of Controlled Trials (CENTRAL; current issue) in the Cochrane Library;
- MEDLINE via Ovid (2016 to present);
- Embase via Ovid (2016 to present);
- PubMed (excluding MEDLINE; 2016 to present).

See appendix for details of the planned MEDLINE search strategies ([Supplementary material 1](#)).

For the searches above, we will employ the Cochrane Highly Sensitive Search Strategies to identify clinical trials in MEDLINE, Embase, and PubMed [27].

Searching other resources

We will screen the reference lists of all included studies and relevant reviews that are identified in the searches, to identify additional eligible trials.

We will also search the following trial registries for ongoing or unpublished completed studies: the US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (www.clinicaltrials.gov), and the World Health Organisation International Clinical Trials Registry Platform (WHO ICTRP; <https://www.who.int/tools/clinical-trials-registry-platform>).

We will check for post-publication amendments, including retractions, expressions of concern, errata, and corrigenda, related to included or eligible studies by searching relevant sources, such

as Retraction Watch Database, and by reviewing notices linked to the original publications.

Data collection and analysis

We will report the review in line with PRISMA guidelines [28].

Selection of studies

At least two review authors will independently screen titles and abstracts of retrieved records for potential eligibility. We will upload the retrieved records to Covidence, a web-based collaborative software platform that facilitates the screening and data extraction process [29]. Before screening begins, we will conduct a calibration exercise by screening and jointly discussing a subset of records to ensure consistent application of the inclusion criteria. Two review authors will then independently assess the full texts of potentially relevant studies against the predefined inclusion criteria. We will systematically record reasons for excluding ineligible studies at the full-text assessment stage. We will resolve any disagreements through discussion, and if necessary, by consultation with a third review author.

We will document the study selection process in sufficient detail to enable the construction of a PRISMA flow diagram and a characteristics of excluded studies table [28, 30].

Data extraction and management

We will develop and pilot a data extraction form. At least two review authors will independently extract data and enter them into Covidence to ensure accuracy. We will resolve any disagreements through discussion, and if necessary, by consultation with a third review author. We will transfer the final dataset to Review Manager (RevMan) for analysis [31].

Extracted information will include:

1. Characteristics of participants: age, sex, disease definition, duration of symptoms;
2. Study methods, total number of participants originally assigned to each treatment group;
3. Intervention: preparations, dose, administration regime;
4. Control: placebo, other drugs;
5. Concurrent medications;
6. Outcomes: outcome definition, unit of measurement, time of collection, and length of follow-up;
7. Withdrawals and reasons for withdrawals;
8. Dietary and behavioural advice.

Risk of bias assessment in included studies

Two review authors will independently assess the risk of bias in the included studies using Cochrane's RoB 2 [32], as described in Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* [33]. We will resolve any disagreements through discussion, and if necessary, by consultation with a third review author. We will contact study authors when information required for the assessment is unclear or unavailable.

We will assess the following domains:

1. bias arising from the randomisation process;
2. bias due to deviations from intended interventions;

3. bias due to missing outcome data;
4. bias in measurement of the outcome; and
5. bias in selection of the reported result.

To implement RoB 2, we will use the RoB 2 Excel tool (available at www.riskofbias.info/welcome/rob-2-0-tool/current-version-of-rob-2). Reviewers will classify bias as low risk, some concerns, or high risk for each domain using the signalling questions and criteria in RoB 2. We will use the overall judgments generated by RoB 2, while reviewing and amending these decisions where necessary.

Measures of treatment effect

When it is possible to include studies in a meta-analysis, we will use mean differences (MDs) with 95% confidence intervals (CIs) for continuous outcomes measured on the same scale, or standard mean differences (SMD) with 95% CI for outcomes measured on similar but different scales. For dichotomous (binary) outcomes, we will calculate risk ratios (RRs) with 95% CIs. When studies cannot be combined in a meta-analysis or displayed in a forest plot, we will summarise the measures of treatment effect narratively using the effect estimates reported in the original publications, in accordance with the SWiM (Synthesis Without Meta-analysis) guidelines [34].

Unit of analysis issues

The individual participant will be the unit of analysis. For studies that include more than two intervention groups, we will make multiple pairwise comparisons between all relevant arms. To prevent double-counting of participants, we will divide both the number of events and the total number of participants evenly for dichotomous outcomes; for continuous outcomes, we will divide only the total number of participants and leave the means and standard deviations unchanged. If we include cross-over trials, we will use only data reported for the pre-cross-over period.

Dealing with missing data

We will perform intention-to-treat (ITT) analyses using Cochrane recommendations for handling missing data. If required, we will contact study authors to obtain clarification or additional information on missing or incomplete outcome data. Studies that failed to report measures of variance will be judged at high risk of selective reporting.

Reporting bias assessment

To assess potential publication bias, we will construct funnel plots for outcomes with at least 10 studies. We will use these plots to visually examine the relationship between study size and effect estimates, with asymmetry potentially suggesting small-study effects, including publication bias. We will interpret any observed asymmetry with caution [35].

Synthesis methods

We will not combine different types of laxatives within the same analysis; each type of laxative will be analysed separately. When the included studies are sufficiently similar in clinical and methodological characteristics, we will pool their data in a meta-analysis using RevMan, following the *Cochrane Handbook for Systematic Reviews of Interventions* [35]. We will use a random-effects model, since we expect there will be clinical diversity. We will use the Restricted Maximum Likelihood (REML) estimator to estimate between-trial variance. We will use the Hartung-Knapp-

Sidik-Jonkman method to calculate a confidence interval for the meta-analysis effect estimate when there are at least three studies, and the estimate of heterogeneity is greater than zero. We will use the Wald-type method to pool data from two studies, or where the estimate of heterogeneity is equal to zero [36].

Investigation of heterogeneity and subgroup analysis

For studies evaluating comparable interventions and outcomes, we will assess statistical heterogeneity using both visual inspection and quantitative measures. We will examine forest plots to assess the overlap of confidence intervals. We will quantify statistical heterogeneity using the I^2 statistic (to estimate the proportion of variability due to heterogeneity), the χ^2 test (to assess evidence of heterogeneity), and τ^2 (to estimate between-study variance) [36]. We will conduct all analyses using RevMan.

We will interpret heterogeneity using guidance from the *Cochrane Handbook for Systematic Reviews of Interventions* [36]. As a general guide, we will consider an I^2 value greater than 50%, a χ^2 P value less than 0.10, or a τ^2 value greater than zero indicative of substantial heterogeneity. However, for decisions regarding data synthesis, we will also take into account the direction and magnitude of effects, the number of included studies, and the clinical relevance of the comparisons.

When unexplained I^2 is over 50%, with no clear clinical or methodological explanation, the research team has agreed on the following approach: we will contact study authors up to three times to request further details and primary data, where possible. If we do not receive a response, we will contact the corresponding journal editors for the information. In the absence of any response, we will exclude the study in a sensitivity analysis.

We will carry out these subgroup analyses to further study the effects of a number of variables on the outcomes:

1. Whether participants received pre-treatment: participants who received pre-treatment versus those who did not;
2. The effect of length of therapy: short duration (≤ 4 weeks) versus longer duration (> 4 weeks);
3. The effect of length of follow-up: short follow-up (< 4 weeks) versus longer follow-up (≥ 4 weeks); and
4. Dosage: standard versus high dose, defined according to available prescribing guidance and informed by previous systematic reviews [25]. For example, for macrogol, we will consider doses ≥ 0.8 g/kg/day as high doses; for lactulose, we will consider doses ≥ 1 g/kg/day as high doses.

We will assess differences between subgroups using the test for subgroup differences in RevMan.

Equity-related assessment

We considered potential equity-related factors that might influence treatment effects [37], and identified gender and socioeconomic status as relevant characteristics [38, 39]. Gender differences, including variations in body weight, metabolism, and hormonal changes during puberty, may influence treatment response and gastrointestinal motility [40]. Socioeconomic status may affect treatment tolerability, adherence, and access to care. However, based on the team's recent guideline work, insufficient evidence was identified to support inclusion of these data.

Children with neurodevelopmental or neurodisability conditions (e.g. Down syndrome, cerebral palsy) are commonly excluded from eligible studies. Consequently, there is limited evidence available for these populations.

Nevertheless, we will extract and report available data on participant characteristics, such as age and sex, to describe the representation of different population groups across included studies.

Sensitivity analysis

1. Random-effects versus fixed-effect models
2. Risk of bias: excluding studies judged to have a high risk of bias in any domain
3. The impact of decisions made during the review process, including the exclusion of studies due to missing data and the handling of potential outliers. Where appropriate, we will perform leave-one-out analyses to assess the influence of individual studies on the overall effect estimates.

Certainty of the evidence assessment

We will present a summary of findings table in the main manuscript for each key comparison identified in the review. These comparisons have been informed by recent published systematic reviews [25], and clinical guidelines [21], and are expected to include polyethylene glycol versus placebo, polyethylene glycol versus lactulose, polyethylene glycol versus magnesium hydroxide, linaclotide versus placebo, probiotic versus placebo, magnesium oxide versus placebo, prucalopride versus placebo. We will prepare additional summary of findings tables for other relevant comparisons identified during the review. However, we will present comparisons supported by only a single study or by evidence judged to be of very low certainty in the supplementary materials.

The tables will report the critical outcomes of treatment success, defaecation frequency, and withdrawals due to adverse events, as well as the important outcomes of faecal incontinence, stool consistency, total adverse events, and serious adverse events.

We will apply the GRADE approach to assess the overall certainty of evidence for each outcome included in the summary of findings tables [41, 42]. Two review authors will independently assess the certainty of the evidence for each outcome. We will resolve any disagreements through discussion, and if necessary, by consultation with a third review author.

Evidence from randomised trials will initially be considered high quality, and may be downgraded based on the five GRADE considerations: risk of bias, indirectness, inconsistency (unexplained heterogeneity), imprecision (sparse data), and publication bias.

GRADE Working Group grades of evidence:

- High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
- Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
- Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.

- Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

Consumer involvement

Consumers were not involved in this protocol and will not be involved in the review due to limited resources. However, the review authors used core outcome sets for the review outcomes, which were developed with consumer involvement.

SUPPLEMENTARY MATERIALS

Supplementary materials are available with the online version of this article: [10.1002/14651858.CD016371](https://doi.org/10.1002/14651858.CD016371).

Supplementary material 1 Search strategies

ADDITIONAL INFORMATION

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Editorial and peer-reviewer contributions

Cochrane supported the authors in the development of this Protocol.

The following people conducted the editorial process for this article:

- Sign-off Editor (final editorial decision): Anju Sinha
- Managing Editor (selected peer reviewers, provided editorial guidance to authors, edited the article): Alan Thomas, Central Editorial Service;
- Editorial Assistant (conducted editorial policy checks, collated peer-reviewer comments and supported the editorial team): Joshua Guinoo, Central Editorial Service;
- Copy Editor (copy editing and production): Victoria Pennick, Cochrane Central Production Service
- Peer-reviewers (provided comments and recommended an editorial decision): Gina J. Sanchez Canon, Cochrane supporter (patient and public review); Katharina da Silva Lopes, Cochrane Evidence Production and Methods Directorate (methods review); Jo Platt, Central Editorial information Specialist (search review).

Contributions of authors

Conceptualisation: MG

Writing – original draft: MG, SL, VS, AG, MMT, MAB

Writing – review and editing: MG, SL, VS, AG, YY, MMT, MAB

Declarations of interest

MG is a Cochrane Editor. He was not involved in the editorial process for this review.

MAB is a consultant for Coloplast, Wellspect, Danone, Sensus, Cosun, FrieslandCampina, Allergan, Abbott, and Mallinckrodt. He is an author on one of the studies likely to be included in the review [43], and will not participate in eligibility decisions, data extraction, risk of bias judgements, or GRADE assessment for that study.

Shiyao Liu, Vasiliki Sinopoulou, Anna de Geus, Yuhong Yuan and Merit M Tabberbs have no commercial or non-commercial conflicts of interest.

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Internal sources

- None, Other

No sources of internal support received.

External sources

- None, Other

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Registration and protocol

Cochrane approved the proposal for this review on 24 September 2025.

Data, code and other materials

Data sharing is not applicable to this article as it is a protocol, so no datasets were generated or analysed.

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