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TABLE OF CONTENTS

[Intervention Protocol]

Psychological and educational interventions for childhood constipation

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ABSTRACT

Objectives

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

To evaluate the efficacy of psychological and educational intervention programmes used for functional constipation in children.

BACKGROUND

Description of the condition

Paediatric constipation accounts for a significant proportion of primary, secondary and tertiary consultations (de Campos 2022; Liem 2009), with functional constipation being the most common presentation (Philichi 2018). Functional constipation refers to any presentation whereby the faeces are retained and is not caused by any diagnosable physical disorder of the gastrointestinal system (Khan 2018). To diagnose constipation in children over four years old, using the Rome IV criteria (Kellow 2016), at least two of these symptoms must be present at least once per week for one month, with insufficient criteria for the diagnosis of irritable bowel syndrome (Hyams 2016):

- Two or fewer defecations in the toilet per week;
- History of painful or hard bowel movements;
- History of retentive posturing (standing or sitting with legs straight or stiff), or excessive conscious stool retention (withholding from passing stool);
- History of large diameter stools that can obstruct the toilet;
- Presence of a large faecal mass in the rectum;
- One or more episodes of faecal incontinence per week.

These criteria were amended for infants and toddlers in Rome IV, excluding reference to incontinence or large diameter stools until the child is toilet trained (Zeevenhooven 2017).

Upper prevalence estimates indicate that around 30% of children meet loose criteria for functional constipation (NICE 2013), and between 3% to 10% meet the accepted clinical criteria outlined by the Rome IV (LeLeiko 2020); suggesting that this condition has a heavy burden for global paediatric health services. The wide range of reported incidence offers insight into the severity of functional constipation. Population studies tend to report high incidence that is steadily increasing across most geographical regions (Rajindrajith 2016), while clinical studies tend to offer lower rates (Pawasarat 2021). Although there is an increasing acceptance amongst healthcare professionals towards the Rome IV criteria (Zeevenhooven 2017), and its previous iterations, specific clinical features such as abdominal pain alongside fewer passing of stools for that individual can lead to over-the-counter medication use or presentation at primary healthcare setting (Liyanarachchi 2021).

Children that meet the strict clinical criteria and are unresponsive to conventional treatments for three or more months should be referred to specialist services for intractable constipation investigations (Tabbers 2014). Although a variety of tests are advised for children at the most severe end of functional constipation, such as anorectal and colonic manometry, one area that has received less attention has been the impact of psychological and educational interventions into childhood constipation.

Description of the intervention

Psychological programmes is an umbrella term that encompasses a variety of techniques and approaches to intervening with functional constipation in children. It has long been held that medical therapies should be delivered alongside behavioural interventions (Brazzelli 2011; van Tilburg 2018). Psycho-educational programmes are also necessary as children may try to tense rather than relax their anus during toileting (Loening-Baucke 1987), and parents may believe that their children are intentionally engaging in inappropriate behaviours (Young 1995). Therefore, a comprehensive psycho-education programme can promote understanding and empathy within the family affected by the functional constipation.

In clinical practice, psychological interventions are often delivered simultaneously through a set number of short sessions across several weeks or months. In-between sessions, children and their families are encouraged to implement what they have learnt during the session. Subsequent sessions review the effectiveness of the previous interventions and offer to tackle emerging or additional problems. Psychological interventions for functional constipation predominately include, but are not limited to, behavioural and cognitive-behavioural techniques. Behavioural techniques include a variety of operant conditioning processes that aid the child in using the toilet. Biofeedback training, Rao 2015, consists of placing electromyography probes on the anus to record muscles changes during simulated defecation training (Narayanan 2019). In biofeedback training, children practice toileting without excessive straining during five to 10 one-hour sessions. To simulate the process, children practice passing water-filled rectal balloons or through sensory retraining (Rao 2015). The goal of the intervention is to help the child control their anal sphincter and abdominal muscles efficiently to pass a stool, as well as normalise the sensory experience of defecating. Additional behavioural techniques, such as positive reinforcement and posture training, may also aid in altering the toileting experience (Stantucci 2021).

Cognitive Behavioural Therapy (CBT) seeks to engage with the cognitions, emotions and behaviours that generally interfere with optimal outcomes or make the symptoms worse (van Tilburg 2016). CBT therapy is often delivered over 10 to 12 sessions, with each session building on the last to alter maladaptive thoughts around a particular behaviour, in this case functional constipation (van Tilburg 2021). Children can often develop anxiety around toileting after a number of aversive experiences. CBT in this context seeks to alter their thoughts around toileting and thus alleviate the anxiety. In addition, teaching the child techniques to manage stress and aid relaxation can also aid in a successful treatment outcome (Hussong 2021).

How the intervention might work

There are three distinct transition periods in a child's early life that can result in functional constipation. Each of these three stages can psychologically condition the child to retain their stools. The first potential adverse event can occur during weaning (Morais 1999). The transition between a fluid-based breast milk diet to a more solid diet alters the composition of the child's stool from a loose watery to a harder pebble-like consistency. This change in stool consistency creates a new sensation for the child to experience when defecating. If painful, through irritating or stretching the anus or surrounding tissue, it may condition the child to engage in behaviours to avoid or escape defecating. The second transition period is during continence training (Howarth 2016). During this period a child is learning to hold onto stools and use toilet facilities. If the child makes a mistake and withholds opening their bowels too long then they can develop functional constipation. The final critical period that can increase the likelihood of developing functional constipation is starting school (Auth 2012). Changes to routine and additional social

pressures can lead to children avoiding defecating at school. Each of these transition periods can result in a cycle towards larger and harder stools further reinforcing the faecal retention and functional constipation. Primary interventions for functional constipation are often delivered by general practitioners and predominantly result in advocating for helpful behaviours or the use of laxatives, or both (Bradshaw 2021). Children who develop a chronic profile or are unresponsive to initial consultations may be referred for specialist assessment and treatment. It is these children that are typically offered psychological interventions. Therefore, despite the three distinct periods, it is not until the problem is longstanding or unresponsive to standard primary treatments, or both, that the psychologist will be involved. As such, psychological interventions are rarely offered to very young children of preschool age.

Psychological interventions help the child in relearning appropriate toileting behaviour, how their current behaviour is counter-productive to what they wish to avoid, and dispel myths surrounding toileting (Danda 2014). Effectively, they tackle the underlying causes - the mislearning, avoidance and anxiety associated with their experience of defecating rather than use of laxatives in an attempt to aid relearning through overriding the child's current tendencies to hold in stools and decrease the frequency of hard stools that cause the pain. Techniques such as biofeedback to relax the anus while practising defecation habits through simulation (Narayanan 2019), behavioural change techniques (e.g. positive reinforcement, token economies, natural reinforcement tracking of bowel movement patterns, toileting plans and assessments, relapse prevention [Danda 2014; LeLeiko 2020]) and cognitive behaviour interventions (e.g. anxiety interventions, tackling inappropriate thoughts and beliefs concerning toileting, denial of symptoms or sensations warning of the urgency to defecate; Firestone Baum 2013) are all important in altering the long-term behaviours of children and lowing the relapse rates of functional constipation. All of these interventions together are believed to work through eliminating faecal retentive behaviours and reducing anxiety associated with toileting.

Why it is important to do this review

With a large clinical burden on paediatric gastroenterologists and the accompanying allied health professionals with an interest in gastroenterology, there is a need to understand the effect of all potential treatments for functional constipation. There are a number of significant problems with leaving childhood functional constipation untreated. Functional constipation has a significant impact on quality of life (Vriesman 2019). Furthermore, should the condition become intractable then more invasive approaches may be necessary (e.g. trans-anal irrigation, antegrade enemas and neuromodulation), which may not resolve the problem in the long-term (Chan 2016).

The most common form of medical intervention, laxative therapy, can have complications. Compliance with laxative therapy is not total, with between 5% to 10% of children not completing their course of treatment after four weeks (Paré 2014; Urganci 2005), and with many users reporting embarrassing side effects such as abdominal discomfort and flatulence (McClung 2004). Furthermore, the therapy does not treat the condition, with resurgence often occurring, leading to dependence on this medication (Nurko 1996). In the absence of any biological malaise to treat in the context of functional constipation, any lifestyle or behavioural approaches that can be adopted are likely to have a longer-lasting impact on the quality of life and reported symptoms of these children. Therefore, understanding the relative impact and efficacy of psychological and educational interventions is of importance to medical and allied health professionals, as well as their patients and families. Although, psychological interventions do not tackle issues with compliance, it does attempt to engage with the underlying causes of functional constipation and alleviate them to improve the outcomes for the child.

OBJECTIVES

To evaluate the efficacy of psychological and educational intervention programmes used for functional constipation in children.

METHODS

Criteria for considering studies for this review

Types of studies

We will include all published, unpublished and ongoing randomised controlled trials (RCTs) on psychological and educational interventions, for children with constipation. Cross-over and cluster-RCTs and studies published as full text, abstract only, and unpublished data will be eligible for inclusion.

Types of participants

We will include any trial that includes children between the ages of 0 and 18 years with a diagnosis of functional constipation, as defined by the trial authors. If we are unable to retrieve the relevant data from the published trial, we will contact the trial authors to provide the information for inclusion in the review.

We will include subsets of eligible participants, such as participants with constipation and anorexia nervosa or autism. We will analyse these separately.

Types of interventions

We will include studies that compare educational interventions, psychological focused or led interventions (or any combination of these) in children against another treatment, or placebo or no intervention. The interventions included will be those that use training techniques under the auspices of psychology. These include interventions that employ CBT, biofeedback techniques or any educational intervention that specifically targets behaviour changes that impact bowel movements through manipulating or engaging with variables that fall within the remit of a psychologist (e.g. mood, cognitions, perceptions, psychopathology, behaviours, habits, learning, behaviour change, acceptance of conditions, family systems). It is expected that most comparator variables or interventions will be services as normal; typically consultations with medical professionals. Other controlled or comparator variables may include waiting lists, another intervention, specially designed interventions that do not target functional constipation or educational programmes. We will consider any comparator intervention, including no intervention.

We expect that the psychological intervention will include but will not necessarily be limited to the following:

- Any form of (psycho)educational teaching of children or parents regarding the bowel or toileting behaviour with the intention to improve frequency of bowel movements or pain outcomes in children diagnosed with functional constipation. The content of the education sessions will focus on the outcomes of functional constipation for the children through promoting treatment adherence, acceptance and commitment to the intervention programme, highlighting the importance of various psychological factors on recovery (e.g. coping mechanisms, mood, and environment) from functional constipation.
- Any intervention that involves biofeedback techniques with the intention to improve the frequency of bowel movements or pain in those children diagnosed with functional constipation. Biofeedback techniques all focus on either improving coordination or the abdominal, rectal, puborectalis and sphincter muscles or improving awareness that a stool is ready to evacuate. Only those biofeedback techniques that explicitly focus on one of these targets will be included in the review.
- Any CBT intervention for functional constipation that includes, but is not limited to, relaxation, stress management, anxiety or maladaptive thoughts around toileting with the objective to improve the frequency of bowel movements or pain. CBT interventions can vary by the number of sessions and the targets within each session for all types of interventions. Within this Cochrane Review, we will consider included studies that purport to use CBT interventions as the primary intervention method as a single form of intervention. Should the analysis reveal heterogeneity within the outcomes, we will conduct further exploratory analyses focusing on content of the intervention and number of sessions offered to the family.
- Hypnotherapy through any means.

Education will include any type of formal or informal educational intervention, lasting for any time, that has content focussed directly on knowledge about constipation or skills needed for direct management of constipation or its symptoms for children or their families. We will include interventions that use education to deliver a different set of skills, such as psychological techniques. However, as the given content and goal is to achieve the psychological approaches through an educating approach, we will classify these as psychological interventions.

Delivery methods may include face-to-face or remote sessions or workshops, guided study via the use of printed or online materials, the use of mobile applications or any other method that delivers the intervention to patients and their families.

We will contact the study authors if relevant information specific to the psychological intervention is not published to ensure that we are comparing the impact of the target intervention. If we are unable to distinguish between the two, we will note the confounding factor in any narrative description of tabulation of the results.

We will list all intervention and comparator groups in the 'Characteristics of included studies' table. We intend to compare the outcomes of psycho-educational programmes, biofeedback techniques and CBT interventions with each other and controls.

Types of outcome measures

The Rome Committee recommends that successful treatment is the primary endpoint of all trials (Koppen 2018). However, what these endpoints are have not been clarified until recently. Saps 2021 has identified that endpoints of a successful outcome should measure reduction in symptoms, spontaneous bowel movements, reduction in functional faecal incontinence and improvement of the most bothersome symptom. The latter criteria are difficult to determine and so will require interpretation. Equally, the fact that these endpoints were only recently resolved, and arguably are not fully resolved, the primary and secondary outcomes of this Cochrane Review will need to reflect the historic position, while presenting and organising the results in the context of the current guidance. We will consider both dichotomous and continuous outcomes for this review.

All data points within each study will be extracted and tabulated.

Neither the primary nor secondary outcomes will determine the eligibility of the studies' inclusion in the review.

We will analyse different measurements of the same outcome separately.

When more than the end of study time point are reported per any given outcome, we will report and tabulate all. We will prioritise the end of study time points for meta-analysis. We will meta-analyse all other time points if more than two studies have reported outcome data appropriately for the same time point, for any given outcome.

Primary outcomes

The primary outcomes of this review will be as follows:

- Treatment success, measured at the end of the study period (as defined by the primary study) (dichotomous).
- The frequency of defecation (number of stools per week), measured at the end of the study period (continuous).
- No change in the outcomes for functional constipation as defined by the primary authors as measured at the end of the study period (dichotomous).
- Serious adverse events (as defined by the primary study) (dichotomous).

Secondary outcomes

- Quality of life, measured at the end of the study period (as measured by e.g. Pediatric Quality of Life Scale [PedsQL]).
- Faecal incontinence frequency, measured at the end of the study period (number of stools or faecal matter released outside the toilet per week).
- Abdominal pain, measured at the end of the study period (as reported by the participant through pain diaries or visual analogue or Likert scales or an abdominal pain scale).
- School absence, measured at the end of the study period (as measured by number of days missing school).

Search methods for identification of studies

We will adopt the following methods for identifying studies to include in this review.

Electronic searches

The Cochrane Gut Information Specialist will search the following sources:

- CENTRAL via Cochrane Library (until search date).

- CINAHL via EBSCOhost (1937 to search date).
- ClinicalTrials.gov (until search date).
- Embase via Ovid SP (1974 to search date).
- ERIC via ProQuest (1966 to search date).
- MEDLINE via Ovid SP (1946 to search date).
- APA PsycINFO viaOvid SP (1806 to search date).
- World Health Organization International Clinical Trials Registry Platform (WHO ICTRP) (until search date).

We will adapt the MEDLINE search strategy (Appendix 1) for the other sources. We will use Cochrane's sensitivity-maximising RCT filter for Ovid MEDLINE (Lefebvre 2019), Cochrane's RCT filter for Embase (Glanville 2019a), and RCT filter for CINAHL (Glanville 2019b). We will also use the search string for interventions from two published Cochrane Reviews (Gordon 2021; Timmer 2011).

For studies published in a non-English language, we plan to have them professionally translated in full. We will collate references and remove any duplicates. We will not impose any date, language, publication status or document type restrictions on the literature searches.

Searching other resources

We will inspect the references of all identified studies for additional RCTs that may potentially be eligible for inclusion.

In addition, we will contact trial authors of registered and not yet completed trials concerning their progress and expected completion date.

Data collection and analysis

Regarding any data that is required to be collected and analysed, we will follow the guidance of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2021).

Selection of studies

Two review authors (TD, VS) will independently screen the titles and abstracts identified from the literature search. We will discard studies that do not meet the inclusion criteria. We will obtain the full report of studies that appear to meet our inclusion criteria or for which there is insufficient information to make a final decision. Two review authors (TD, VS) will independently assess the reports to establish whether the studies meet the inclusion criteria. We will resolve disagreements by discussion, and will consult a third review author (MG) if resolution is not possible.

We will enter studies rejected at this or subsequent stages in the 'Characteristics of excluded studies' tables and will record the main reason for exclusion. We will record the selection process in sufficient detail to complete a PRISMA flow diagram (Page 2021).

Where studies have multiple publications, we will identify and exclude duplicates. We will collate the reports of the same study so that each study, rather than each report, is the unit of interest for the review. Such studies will have a single identifier with multiple references.

Data extraction and management

We will perform data extraction using forms following the auspices of the *Cochrane Handbook for Systematic Reviews* (Higgins 2021).

Relevant information will be recorded within the forms and will be generated for each eligible study. Two review authors (TD, VS) will independently perform data extraction using a piloted data extraction form. Any inconsistencies will be arbitrated through comparisons between extracted outcomes and either consensus or arbitration by a third author (MG) where appropriate. The forms will include the following information:

1. Characteristics of children: age, sex, duration of symptoms; specific definition of functional constipation (explicit definition if stated; if not stated, characteristics of children that led to inclusion as functional constipation. This may include length of unsuccessful therapy prior to enrolment, the number of therapies tried without success, or a combination, as described by the primary study).
2. Study methods, total number of participants originally assigned to each treatment group.
3. Intervention and comparator:
   a. Education - this includes description of the learning outcomes planned for the intervention by the teacher or designer, methods of education used, target audience and any resources required.
   b. For psychological interventions, the technique used, its underpinning alignment, specific method of delivery, number of sessions, resources and any underpinning psychological frameworks that informed this.
4. Control: placebo, other drugs, other interventions.
5. Concurrent medications or other interventions.
6. Outcomes: time of assessment, length of follow-up, primary and secondary outcomes.
7. Outcomes from education: educational outcomes, if described, reported and classified as either satisfaction/reaction, attitudes or knowledge and skills.
8. Withdrawals and reasons for withdrawals.

For papers that are written in a foreign language, we will use translation software. If this is inadequate, we will approach a translator to answer questions on the paper to aid extracting the relevant information for inclusion. We will include the translated information from the paper in the review.

Assessment of risk of bias in included studies

Two review authors (TD, VS) will independently assess the quality of the included trials employing the Cochrane Risk of bias 1 tool (Higgins 2011). Should any discrepancies or disagreements be reported, then these will be resolved through discussion between the review authors based on the extracted data. If consensus is not reached, a third review author (MG) will arbitrate between the two positions and a majority rule will be presented.

We will assess the quality of the included studies as follows:

- Sequence generation (i.e. was the allocation sequence generation adequately randomised?)
- Allocation sequence concealment (i.e. was allocation adequately concealed?)
- Blinding of participants and personnel (i.e. was knowledge of the allocated intervention adequately hidden from the participants and personnel during the study?)

- Blinding of outcome assessment (i.e. was the allocation of the participants to the intervention condition adequately hidden from the outcome assessors?)
- Incomplete outcome data (i.e. were incomplete outcome data adequately addressed?)
- Selective outcome reporting (i.e. are reports of the study free of suggestion of selective outcome reporting?)
- Other potential sources of bias (i.e. was the study apparently free of other problems that could put it at high risk of bias?)

We will judge risk of bias on a nominal scale, with 'high risk' meaning that there was a risk of bias, 'low risk' meaning that there was not a risk of bias, and 'unclear risk' indicating that the review authors could not determine a clear decision of bias within the report's description. For any unclear outcome, we will contact the study authors to seek further clarity and information as prescribed in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We will assess risk of bias using the Cochrane Risk of bias 1 tool. Due to the nature of the interventions proposed to be covered in this review, it may not be possible to adequately blind the personnel from which participants receive the intervention or not. In order to overcome this potential bias, we will assess subjective and objective outcomes separately in this review. It should be possible to adequately blind the outcome assessors regarding which group had the intervention through the inclusion of a separate statistical advisor. However, this is not common practice within the literature. In situations where the analyser was not blinded to the study, we will assess subjective and objective outcomes separately.

Measures of treatment effect

For dichotomous outcomes, we will express treatment effect as risk ratios (RR) with corresponding 95% confidence intervals (CIs). For continuous outcomes, we will express the treatment effect as mean difference (MD) with 95% CI if studies used the same scales and methods. However, if studies assessed the same continuous outcome using different methods, we will estimate the treatment effect using the standardised mean difference (SMD) with 95% CIs. We will present SMDs as standard deviation (SD) units and interpret them as follows: 0.2 represents a small effect, 0.5 a moderate effect and 0.8 a large effect.

Unit of analysis issues

The participant will be the unit of analysis. We will assess studies containing three or more groups through multiple pairwise comparisons between all possible pairs of groups. For dichotomous outcomes, we will divide the number of events by the total number of participants. We will measure participant outcomes using means and SDs.

We will only include cross-over studies if data are reported separately before cross-over occurred, and we will use only pre-crossover data. Cluster RCTs will be analysed regardless of whether study authors took clustering into effect for their analysis, and we will perform our own analysis to account for the clustering effect. We will accommodate repeated observations on individual participants by obtaining the original dataset, if possible, or we will combine pre-test observations to create an average and then include immediately-after data along with any follow-up as close to six months post-trial as possible (Higgins 2021).

Dealing with missing data

We will contact the authors of included studies to request any missing data. We will attempt to estimate missing SDs using relevant statistical tools and calculators available in RevMan Web 2023 if studies report standard errors. We will judge studies that fail to report measures of variance as at high risk of selective reporting bias.

Assessment of heterogeneity

Heterogeneity amongst trials will be assessed by calculating the Chi^2 test for heterogeneity (critical value will be set at $P < 0.05$) and I^2 statistic to quantify the effect of heterogeneity (Higgins 2003). We will use forest plots to highlight any studies that suggest heterogeneity too. Both random-effect and fixed-effect models will be used to explore heterogeneity. Thresholds for heterogeneity are as follows (Higgins 2021):

- 0% to 40%: might not be important.
- 30% to 60%: may represent moderate heterogeneity.
- 50% to 90%; may represent substantial heterogeneity.
- 75% to 100%: considerable heterogeneity.

Assessment of reporting biases

We will create a funnel plot to explore possible publication bias if more than 10 trials are identified alongside an Egger's test to determine reporting bias (Egger 1997). Critical values will be set at $P < 0.05$ for the Egger's test.

Data synthesis

To summarise the study characteristics, we will conduct a synthesis of all the included studies following the edicts outlined in Chapter 12 of the *Cochrane Handbook for Systematic Reviews of Interventions* (McKenzie 2022). These may include and will be limited to: summarising effect estimates, combining P values, and vote counting based on direction of effect.

We then will carry out a meta-analysis if there are two or more studies that assessed similar populations, interventions and outcomes. This will place particular focus on the form of psychological intervention considering the categories stated under 'Types of interventions'. We will only perform analysis of outcomes for the same intervention types (i.e. psychological or educational). For educational interventions, we will carry out analysis of all pedagogical techniques. We will perform analysis if there is a significant similarity in educational material and goals of the intervention.

We will synthesise data using the random-effects model in RevMan Web 2023. We will combine effect estimates of studies that report data similarly in the meta-analysis. We will pool RRs for dichotomous outcomes and MDs or SMDs for continuous outcomes with 95% CIs. Where we are unable to carry out a meta-analysis (e.g. due to lack of uniformity in data reporting), we will present a narrative summary of the included studies. In a situation where a narrative report is merited, we will undertake this process using the SWiM reporting strategy as an extension to PRISMA (Campbell 2020).

For psychological interventions, we aim to assess psycho-education versus biofeedback, psycho-education versus CBT,

psycho-education versus control, biofeedback versus CBT, biofeedback versus control, and CBT versus control. We expect variation in protocols within the literature to be low enough to allow psycho-education, biofeedback and CBT to be considered as a single intervention. Heterogeneity, if it exists, is likely to be linked to number of sessions rather than content or objectives. In such situations, we will assess the impact of session duration prior to inclusion and will fully describe the differences between studies. CBT may require separating due to interventions that are more behavioural in nature, especially if the target participants are very young children. If that is required, we will assess behavioural interventions against CBT to see if there are differences in ages. If there are differences, we will treat these as separate interventions.

Subgroup analysis and investigation of heterogeneity

We will undertake subgroup analyses of potential effect modifiers if there are four studies or more, using the formal test for subgroup differences in RevMan Web 2023 to assess subgroup difference. If sufficient data are available, we will perform subgroup analyses for our primary outcomes:

- By intervention subtype (i.e. the same psycho-education or psychological programme, or the same educational programme).
- By length of follow-up (i.e. 12 weeks, 6 months, 12 months)
- By definition used for functional constipation.
- By the age of children (under 4 years and 4 to 18 years)

We will decide the specifics of the intervention subtypes, follow-up lengths, and constipation definitions categorisation once we have completed data extraction, as they are dependent on the details provided by the study authors. We have decided on the age categorisation based on the developmental differences for children of these age groups.

These subgrouping parameters have been decided based on our expectation that they are the most likely to affect effect sizes.

Sensitivity analysis

We will perform sensitivity analyses on the primary outcomes to assess whether the findings of the review are robust to the decisions made during the review process, for analyses with more than four studies.

- We will perform a sensitivity analysis for random-effect versus fixed-effects statistical analysis model, to investigate whether the choice of model impacts the results and to explore potential heterogeneity.
- We will perform a sensitivity analysis for risk of bias, to investigate whether the risk of bias impacts the results and to explore potential heterogeneity. In particular, we intend to perform an analysis that only includes studies at low risk of bias for all risk of bias items in the first instance. Then we will conduct a further analysis that removes studies with items at high risk of bias.

Summary of findings and assessment of the certainty of the evidence

We will present the primary outcome results for the educational interventions, each psychological intervention category (psycho-education, biofeedback and CBT psychological interventions compared to placebo, no treatment or any therapy in summary of findings tables. We will prioritise the comparisons between psycho-education versus biofeedback, psycho-education versus CBT, and biofeedback versus CBT, as these will be of most interest to decision-makers interested in functional constipation in children. Each comparison and primary outcome will be exported to GRADE profiler software (developed by the GRADE Working Group) for quality assessment (GRADEpro GDT). Based on risk of bias, inconsistency, imprecision, indirectness and publication bias, we will rate the certainty of the evidence for each outcome as either high, moderate, low or very low. These ratings have been defined as follows.

- High: further research is very unlikely to change our confidence in the estimate of effect.
- Moderate: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
- Low: 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.
- Very low: any estimate of effect is very uncertain.

We will justify all decisions to downgrade the certainty of the evidence using footnotes, and we will make comments to aid the reader's understanding of the summary of findings tables where necessary.

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APPENDICES

Appendix 1. MEDLINE search strategy

1 exp Adolescent/ or exp Child/ or exp Infant/ or exp Minors/ or exp Pediatrics/ or exp Puberty/ or exp Schools/ or Schools, Nursery/ or exp Young Adult/ or exp Students/ or (Baby or Babies or Child* or P?ediatric* or P?adiatric* or Infan* or Neo?nat* or Post?Nat* or New?born* or Kid or Kids or Adolescen* or Pre?school* or Toddler* or Post?matur* or Pre?matur* or Pre?term* or Preemie or Perinat* or Boy* or Girl* or Teen* or Minors or Prepubescen* or Postpubescen* or Prepuberty or Pubescen* or Puber* or Elementary School* or High?School* or Kinder* or Jugend* or Nurser* or Primary School* or Secondary School* or Middle School* or Youth* or Young* or Student* or Juvenil* or School?Age* or Under?age* or (Under* adj Age*) or Schoolchild* or Under 16 or Under 18 or Pupils).tw,kw.

2 exp Constipation/ or Fecal Impaction/ or (Constipat* or Fecalith or Dyschezia or Coprostasis or Colonic Inertia or ((F?ecal or F?eces or Stool?) adj3 (Impact* or Retention or Retain* or Evacuat*)) or ((Bowel or Intestinal) adj3 (Delayed or Retention or Retain* or Evacuat* or Function* or Habit* or Movement* or Symptom* or Motility)) or Obstipat* or Colon Transit or Def?ecat*).tw,kw.

3 exp Psychology, Social/ OR exp Adaptation, Psychological/ OR exp Education/ OR exp Mind-Body Therapies/ OR exp Patient Education Handout/ OR exp Patient Medication Knowledge/ OR exp Psychotherapy/ OR exp Spiritual Therapies/ OR Patient Education/ OR Self Care/ OR Social Support/ or ((patient* or consumer*) adj3 (educat* or literacy or training or workshop* or handout or session* or printed or print or online or internet or booklet* or poster* or written material* or paper-based or pamphlet* or brochure* or leaflet* or circular* or flyer* or program* or teaching or knowledge or information)).tw. or ((information or education*) adj3 (workshop* or handout or session* or printed or print or online or internet or booklet* or poster* or written material* or paper-based or pamphlet* or brochure* or leaflet* or circular* or flyer* or program* or knowledge)).tw. or ((print or printed or education*) adj2 intervention*).tw. or (health education or health information or health literacy).tw. or (Acceptance adj2 Commitment).tw. or adler*.tw. or (art therap* or attack therap* or attachment therap*).tw. or Autogen* training.tw. or (behavio* adj (treat* or therap* or modif*)).tw. or verhaltenstherap*.tw. or (Biodynami* or Bioenergeti* or Biofeedback or Bionomi*).tw. or (Body adj Mind or Breathwork).tw. or (characteranalyti* or character-analyti*).tw. or (Client-centered or client-centred).tw. or (counselling or counseling).tw. or (cognitive adj1 behavio*).tw. or CBT.tw. or (coherence therap* or contemplative or conversational).tw. or (cope* or coping).tw. or (core energetic* or core process*).tw. or dance.tw. or tanz*.tw. or daseins*.tw. or (Developmental Needs Meeting Strateg* or DNMS).tw. or (Dialectical or DBT).tw. or (Dreamwork or Drama or Dyadic or DDP).tw. or (Emotional Freedom Techni* or EFT).tw. or (encounter group* or eye movement*).tw. or (EMDR or (Desensiti* adj2 (Reprocessing or re-processing))).tw. or (Experient* Dynamic or Existential therap*).tw. or (Exposure adj2 response prevent*).tw. or expressive therap*.tw. or (Family Constellation* or Family System* or Family therap* or Feminist therap* or functional analytic or Focusing or Freudian).tw. or feldenkr*.tw. or (familien* or freud*).tw. or (goal setting or Gestalt* or Group Analy* or group-based or (group adj (therap* or treatment* or intervention))).tw. or (gruppenpsychotherap* or gruppentherap* or gruppenanaly* or gestalt*).tw. or (Hakomi or Holistic or Holotropic or Humanistic or Human givens).tw. or (Hypnos* or Hypnot* or hypno-therap*).tw. or (Integral* Strateg* or (Intensive adj2 dynami*) or Interaction Therap* or Interperson* therap* or IPT).tw. or interaktionstherap*.tw. or (interpersonal or inter-personal).tw. or (interpersonell* or inter-personell*).tw. or (Jungian or Logotherap*).tw. or (Meditati* or Milieu Therap* or milieutherap* or Mindfulness* or MBSR or (Method adj2 Levels) or Morita Therap* or Multimodal* Therap* or multi-modal* therap* or Multitheoreti* or Multi-theoreti* or Music therap*).tw. or musiktherap*.tw. or (Narrative Therap* or Needs Meeting* or Neuro-linguistic program* or NLP).tw. or (Object*

Relation* or Orgonom*).tw. or (objektrelation* or orgonom*).tw. or (parent-child interact* or PCIT).tw. or eltern-kind interakt*.tw. or patient education.tw. or (person-centered or person-centred).tw. or personenzentriert*.tw. or (Personal construct or PCP or Play therap* or Primal therap* or Process Oriented or Provocative Therap* or Psychedelic or Psychoanaly* or psycho-analyti* or Psychodrama or psycho-drama or Psychodynamic or psycho-dynamic or (psycho* adj3 (care* or treat* or therap* or intervent* or support*))).tw. or psychotherap*.mp. or Pulsing.tw. or (Radix therap* or Rational Emoti* or REBT or Rational Living Therap* or RLT or Rebirthing or re-birthing or Reiki or Relationship counsel* or Relational-Cultural or relaxation or (relax* adj3 (techni* or train* or treatment* or therap*)) or Reprogram* or re-program* or Reality therap* or Rogerian or Rubenfeld Synergy or Reichian or Rolfing).tw. or (self-manag* or selfmanag*).tw. or (selbstmanagement* or selbst-management*).tw. or (SHEN or social support* or Social Therap* or social care or Solution focused or Somatic Psychology or Sophia analys* or supportive-expressive or Systematic Treatment Selection* or STS or Systemic Constellation* or Systemic Therap*).tw. or soziale unterst*.tw. or (supporti* adj3 (therap* or care or treat* or intervent*)).tw. or (Thought Field Therap* or Transactional* or trans-actional* or Transperson* or trans-person* or twelve-step program* or Vegetotherap* or vegeto-therap*).tw.

4 ((Randomized Controlled Trial or Controlled Clinical Trial).pt. or (Randomi?ed or Placebo or Randomly or Trial or Groups).ab. or Drug Therapy.fs.) not (exp Animals/ not Humans.sh.)

4 and/1-4

CONTRIBUTIONS OF AUTHORS

TD led the writing of the protocol and conceived the idea for the topic.

VS provided support and reviewed the protocol.

MG made an intellectual contribution, provided support, and reviewed the protocol.

All protocol authors read and approved the final protocol version prior to publication.

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