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Dietary interventions for the management of chronic constipation in children (Protocol)

Rajindrajith S, Gordon M, Dovey TM, Benninga MA, Sinopoulou V

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[Intervention Protocol]

Dietary interventions for the management of chronic constipation in children

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ABSTRACT

Objectives

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

To evaluate the efficacy and safety of dietary interventions for the management of chronic childhood functional constipation.

BACKGROUND

Description of the condition

Chronic constipation in children is a global public health problem. It is highly prevalent worldwide, with a pooled prevalence of 9.5% (Koppen 2018a). Chronic constipation is among the most common reasons for healthcare-seeking in children (Loening-Baucke 2007), and high healthcare expenditure (Choung 2011). Chronic constipation negatively impacts the health-related quality of life of children, affecting their physical well-being (e.g. abdominal pain), as well as their social and educational well-being (e.g. school absences; Vriesman 2019). Longitudinal studies have shown that a sizeable proportion of poorly treated children with chronic constipation progress to adulthood with the same disease entity (Bongers 2010; van Ginkel 2003). Most children with chronic constipation do not have an organic cause for their symptoms, which are considered to constitute functional constipation (Benninga 2004).

The medical literature contains many definitions of chronic constipation in children. Before the publication of the Rome criteria, several other official definitions were in use, including the Iowa criteria and the Paris Consensus for Childhood Constipation Terminology (PACCT) criteria (Benninga 2005; Loening-Baucke 1993). Researchers use the latest iteration of the Rome criteria to diagnose chronic constipation in children in epidemiological and clinical settings, including therapeutic trials. The current iteration of Rome criteria for childhood constipation (Rome IV) defines functional constipation as two or more of the following, occurring at least once per week for a minimum of one month, with insufficient criteria for diagnosing irritable bowel syndrome (Hyams 2016).

- Two or fewer defecations in the toilet per week
- At least one episode of faecal incontinence per week
- History of retentive posturing or excessive volitional stool retention
- History of painful or hard bowel movement
- Presence of a large faecal mass in the rectum
- History of large diameter stools that can obstruct the toilet

Management of chronic constipation is multifaceted. It involves toilet training, dietary modifications, pharmacological interventions, and psychological support (Gordon 2016a; Gordon 2016b). Most clinicians consider dietary interventions an effective therapeutic modality for managing chronic constipation. Different guidelines have assigned varying weights to these interventions in the management of children with the condition (NICE 2010; Tabbers 2014). The modifications assigned the greatest weight include increasing intake of fibre-containing foods (e.g. fruits and vegetables), increasing consumption of water, and eliminating cow's milk (Tabbers 2014). However, joint guidelines from the European Society for Paediatric Gastroenterology Hepatology and Nutrition (ESPGHAN) and the North American Society For Pediatric Gastroenterology, Hepatology & Nutrition (NASPGHAN) do not recommend dietary modifications in the management of childhood constipation owing to a lack of evidence (Tabbers 2014).

Description of the intervention

Both the ESPGHAN/NASPGHAN guidelines and the UK National Institute for Health and Care Excellence (NICE) guidelines include strategies for managing chronic constipation in children (NICE 2010; Tabbers 2014). Both categorise dietary treatments, including fluid and fibre, as non-pharmacological interventions.

Several studies have shown an association between a low-fibre diet and chronic childhood constipation in countries across the world (Lee 2008; Roma 1999; Tam 2012). These findings may have created the impression that a diet rich in fibre can cure the symptoms of chronic constipation. The fibre in the intestine increases bulk, which induces mass movements through high amplitude propagatory contractions, increases fluid in the intestine by retaining water, and beneficially alters the intestinal microbiome to relieve symptoms (Eswaran 2013). However, several clinical trials studying the effect of a fibre-rich diet in children with chronic constipation have found no clinically meaningful reduction in symptoms among the participants who received the intervention (Castillejo 2006; Chmielewska 2011; Kokke 2008; Loening-Baucke 2004). Similarly, trials have found no beneficial effects of increased consumption of fluid in this population (Arnaud 2003; Chung 1999; Young 1998). Despite these findings, surveys among paediatric gastroenterologists and trainees have shown that most still recommend water and fibre as a treatment modality for chronic constipation (Koppen 2018b; Yang 2015).

Cow's milk protein intolerance has long been implicated in the aetiology of chronic constipation in children. Two studies have shown that children with constipation improve with a cow's milk elimination diet (Daher 2001; Iacono 1998), while others have not found this beneficial effect (Bergmann 2014). The proctocolitis associated with cow's milk protein allergy is thought to interfere with colorectal motility, leading to symptoms of constipation (Borrelli 2009). Therefore, eliminating cow's milk from the diet may benefit a subset of children with chronic constipation.

Waingankar and colleagues assessed the value of a sugar elimination diet in children with refractory rapid transit constipation, based on findings of breath tests. The intervention led to reduced severity of constipation, reduced abdominal pain, reduced pain on defecation, and increased stool wetness; these results suggested that fructose and lactose may play a role in the generation and propagation of constipation symptoms in children (Waingankar 2018).

How the intervention might work

Current guidelines recommend that children older than two years consume a quantity of fibre equivalent to their age (in years) plus 5 g to 10 g every day to maintain good health and bowel function (Williams 1995). The underpinning mechanisms of how fibre helps with constipation are not fully understood. Soluble fibres are fermented in the distal ileum and the colon and absorb water, forming a gel-like structure that may facilitate the passage of stools (Axelrod 2018). Soluble and highly fermentable fibre types produce short-chain fatty acids that improve colonic function by providing energy to colonic mucosal cells, increasing cholinergic-mediated colonic circular smooth muscle contraction, and stimulating myenteric neurones (Eswaran 2013). In addition, lower pH and the presence of prebiotics in fibre promote the growth of lactobacilli and bifidobacteria (Kleessen 1997). Insoluble fibres

increase stool bulk and help reduce transit time through the large bowel (Eswaran 2013).

One of the commonest recommendations offered to children with chronic constipation and their families by the medical fraternity is to increase water consumption as a dietary measure (Yang 2015). This is based on the theory that water that reaches the colon can soften impacted stools and facilitate their passage (Arnaud 2003).

The ESPGHAN/NASPGHAN guideline recommends a cow's milk elimination diet for children who are refractory to standard medical management (Tabbers 2014). However, the pathological process is unclear. Cow's milk protein intolerance is known to induce proctocolitis, which could lead to alterations in anorectal functions, predisposing children to constipation (Borrelli 2009).

The underlying mechanism of a diet low in fructose and lactose is unclear.

Why it is important to do this review

Dietary advice is the most frequent mode of treatment offered to children with constipation, although guidelines and reviews question the efficacy of this approach (Axelrod 2018; NICE 2010; Tabbers 2014; Tabbers 2015). Most paediatric gastroenterologists and fellows still use dietary interventions as the first-line therapeutic option (Koppen 2018b; Yang 2015). At least 30% of children with constipation will still have the condition in adulthood despite treatment (van Ginkel 2003), and around 40% of children who see a doctor for constipation still need treatment after five years (Tabbers 2015). With this review, we aim to determine whether dietary modification is a helpful strategy in the management of chronic constipation in children.

OBJECTIVES

To evaluate the efficacy and safety of dietary interventions for the management of chronic childhood functional constipation.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs) on dietary interventions for children with constipation. Cross-over and cluster-RCTs will be eligible. We will consider studies published as full texts or abstract only, as well as unpublished data. We will record details of ongoing RCTs that may be eligible for inclusion in future updates of this review.

Quasi-randomised trials (i.e. trials with inappropriate randomisation methods) are ineligible.

Types of participants

We aim to study children aged 18 years or younger who have been diagnosed with functional constipation, with or without incontinence. We will accept the diagnostic criteria used in each study, provided they include several specific clinical features (such as bowel movement frequency, firmness, and painful bowel movements).

Subsets of eligible participants, such as participants with constipation and anorexia nervosa or autism, will be analysed separately. If a study contains a mixture of eligible and ineligible participants (e.g. children and adults), we will contact the study authors to request separate data for eligible participants. If these data are unavailable, we will exclude the study.

Types of interventions

We will include studies that evaluate any dietary intervention in children against another treatment or against placebo/no intervention.

We expect the dietary interventions will fall under the following categories.

- Any form of dietary education of children or parents/guardians with the explicit intention of improving bowel or toileting outcomes
- Any intervention that involves dietary supplements (e.g. fibre or nutrients)
- Any intervention that involves eliminating food or food groups from a child's diet with the explicit intention of improving bowel or toileting outcomes
- Any intervention that alters meal frequency or meal size to improve bowel or toileting outcomes
- Any form of fluid therapy

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

When the intervention is delivered as part of a suite or package of measures, we will only include the study if it assesses the impact of the dietary intervention specifically.

We will list all intervention and comparator groups of eligible studies in the 'Characteristics of included studies' table, even if not all groups are relevant to this review.

Types of outcome measures

Reporting of our prespecified outcomes is not an inclusion criterion for this review.

If a study uses more than one scale for a given outcome, we will extract data from all scales. When meta-analysing data, we will prioritise the scales most frequently reported among the included studies. Any scale data not used for meta-analysis will be reported narratively.

Primary outcomes

- Non-fulfilment of criteria for functional constipation (as defined in each study), measured at the end of the study (dichotomous)
- Frequency of defecation (number of stools per week), measured at the end of the study (continuous)
- Treatment success (as defined in each study, e.g. ≥ 3 bowel movements/week and < 1 faecal incontinence episode/week), measured at the end of the study (dichotomous)
- Serious adverse events (as defined in each study; dichotomous)

Secondary outcomes

- Quality of life, measured using a validated questionnaire (e.g. Pediatric Quality of Life Inventory (PedsQL)) at the end of the study
- Faecal incontinence frequency (episodes per week) at the end of the study
- Abdominal pain (severity or frequency), measured using a validated scale (e.g. visual analogue scale (VAS)) at the end of the study
- School absence (as measured by the study authors, e.g. days per week) at the end of the study
- Adverse events
- Withdrawal due to adverse events

Search methods for identification of studies

Electronic searches

The Cochrane Gut Information Specialist will search the following sources.

- AMED via OvidSP (1985 to search date)
- CENTRAL via Cochrane Library (until search date)
- CINAHL via EBSCOhost (1937 to search date)
- Embase via OvidSP (1974 to search date)
- MEDLINE via OvidSP (1946 to search date)
- U.S. National Institutes of Health Ongoing Trials Registry ClinicalTrials.gov (clinicaltrials.gov/; until search date)
- World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP; trialsearch.who.int; until search date).

We will adapt the MEDLINE search strategy to the other sources (Appendix 1). We will use Cochrane's sensitivity-maximising RCT filter for Ovid MEDLINE (Lefebvre 2019), Cochrane's RCT filter for Embase (Glanville 2019a), and the RCT filter for CINAHL (Glanville 2019b).

If we identify 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 searches.

We will search MEDLINE and Embase for the latest version of the citations, in case they have since been corrected or retracted. In addition, we will visit the original report on the publisher's website because there might be a delay between the publication of the correction or retraction and its indexing in bibliographic databases. We will also search the Retraction Watch database and blog (retractiondatabase.org; retractionwatch.com).

Searching other resources

In an attempt to identify additional trials that could be eligible for inclusion, we will inspect the reference lists of all included studies and of any relevant systematic reviews identified by the search. We will contact the authors of any registered trials that are not yet completed to enquire about their progress and expected date of completion.

Data collection and analysis

We will carry out data collection and analysis according to the methods recommended in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2023a).

Selection of studies

Two review authors will independently screen the titles and abstracts of all records identified by the literature search, eliminating those that are clearly irrelevant. We will then obtain the full-text articles of all potentially eligible records, and two review authors will independently decide which studies meet our eligibility criteria. We will resolve disagreements by discussion or by involving a third review author.

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 and 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

Two review authors will independently extract data from the included studies using templates generated from the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2023a). We will resolve any disagreements by discussion or by involving a third review author. Data of interest include the following.

- Characteristics of participants: age, sex, duration of symptoms, specific definition of chronic constipation (explicit definition, if stated; if not stated, characteristics of children that led to inclusion, e.g. length of unsuccessful therapy before enrolment, number of therapies tried without success, or a combination, as described in the study)
- Study methods, number of participants randomised to each treatment group
- Intervention: description of the intervention, session length, objectives of the intervention
- Control: placebo, other drugs, other interventions
- Concurrent medications or other interventions
- Outcomes: time of assessment, length of follow-up, definitions, scales, units, reporting methods (e.g. child, parent/guardian, physician), primary and secondary outcome data
- Number of withdrawals and reasons for withdrawal

Assessment of risk of bias in included studies

Two review authors will independently assess the risk of bias in the included studies using the Cochrane risk of bias tool RoB 1, which covers the following domains (Higgins 2011).

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

- 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 free of other problems that could put it at high risk of bias?)

We will judge risk of bias on a nominal scale (high, low, or unclear). Wherever a publication provides insufficient information regarding methodological quality (resulting in an 'unclear' judgement), we will contact the study authors for clarification. We will justify all risk of bias judgements in the appropriate section of the 'Characteristics of included studies' table.

Measures of treatment effect

For dichotomous outcomes, we will express treatment effects as risk ratios (RRs) with the corresponding 95% confidence intervals (CIs). For continuous outcomes, we will express the treatment effects as mean differences (MDs) with 95% CIs wherever studies have used the same scale and the same methods to measure the outcome. However, if different studies assess the same continuous outcome using different scales, we will estimate the treatment effect using the standardised mean difference (SMD) with 95% CI. We will present SMDs as standard deviation (SD) units and interpret them as follows.

- 0.2 represents a small effect.
- 0.5 represents a moderate effect.
- 0.8 represents a large effect.

Unit of analysis issues

The participant will be the unit of analysis. If we identify any studies with three or more eligible arms, we will analyse them by making 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. For continuous outcomes, we will use the means and SDs and divide by the total number of participants.

We will only include cross-over studies that report separate data for the first intervention phase (before cross-over). Cluster-RCTs will only be eligible if the study authors have used appropriate statistical methods to account for the clustering effect. We will test the robustness of our results though sensitivity analysis after removing cluster-RCTs (Higgins 2023b).

Dealing with missing data

We will base our analysis on the data provided in the publications or made available by the study authors. We will contact study authors to request missing data wherever necessary.

For dichotomous efficacy outcomes, we will use the number of randomised participants as denominators, and the number of participants who have the event as numerators. We will assume that any participants with missing or unclear outcome data are treatment failures. For continuous data, we will use the mean and SD values and the participant numbers used to calculate the mean as reported by the study authors, or our best estimation if this information is not reported. If a measure of variance other than SD is reported, we will attempt to convert it to SD.

For safety outcomes, we will assume that participants with missing or unclear withdrawal data have dropped out/been withdrawn due to adverse events. The denominators for this outcome will be as reported by the study authors. For serious and total adverse events, we will use the number of events per participant, as reported by the study authors.

We will estimate missing SDs using relevant statistical tools and calculators available in RevMan if studies report standard errors (RevMan 2024). Studies that do not report measures of variance will be judged at high risk of reporting bias.

Assessment of heterogeneity

To evaluate statistical heterogeneity among trials, we will visually assess forest plots and use the Chi^2 test, considering a P value below 0.1 to be statistically significant. We will also calculate the I^2 statistic to quantify statistical heterogeneity, interpreting the results as follows (Higgins 2003; Higgins 2023a).

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

We will assess clinical and methodological heterogeneity through subgroup and sensitivity analyses (Subgroup analysis and investigation of heterogeneity; Sensitivity analysis).

Assessment of reporting biases

If we include more than 10 trials in a single meta-analysis, we will create a funnel plot and explore publication bias (funnel plot asymmetry) through visual assessment and Egger's test (Egger 1997). Critical values will be set at $P < 0.1$ for 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 9 of the *Cochrane Handbook for Systematic Reviews of Interventions* (McKenzie 2023). These may consist of and will be limited to: summarising effect estimates, combining P values, and vote counting based on the direction of effect.

Where two or more studies of similar interventions in similar populations have reported the same outcome, we will meta-analyse the outcome data using the random-effects model in RevMan (RevMan 2024). 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, following the SWiM reporting strategy (Campbell 2020).

Subgroup analysis and investigation of heterogeneity

If sufficient data are available, we will perform the following subgroup analyses.

- By specific dietary preparation/regimen (e.g. dietary fibre, elimination diet, or other intervention reported by the study authors)
- By length of therapy/follow-up (i.e. 12 weeks, six months, 12 months)

- By definition of chronic constipation (i.e. Rome criteria (IV, III, II, I) or other)
- Be definition of treatment success

We will compare subgroups using the formal test for subgroup differences in RevMan (RevMan 2024).

Sensitivity analysis

To assess whether the findings of the review are robust to the decisions made during the review process, we plan to perform the following sensitivity analyses.

- We intend to perform an analysis that only includes studies at low risk of bias for all items. We will then perform the analysis again excluding only studies at high risk of bias.
- We will repeat the analyses using the fixed-effect model to explore heterogeneity.
- We will investigate the effect of child-reported, parent/guardian-reported, or physician-reported outcomes on the results to explore heterogeneity.

Summary of findings and assessment of the certainty of the evidence

We will create summary of findings tables to show the results for our primary outcomes (non-fulfilment of criteria for functional constipation, frequency of defecation, treatment success, and serious adverse events), measured at the end of the studies. Each pairwise comparison will have its own summary of findings table, provided we can meta-analyse data from at least 50 participants for at least one primary outcome. We will not pool the results of different comparators (e.g. placebo, other treatment, no intervention).

We will export data to GRADEpro software (GRADEpro GDT), and two review authors will independently assess the certainty of the evidence, resolving any disagreements by discussion or by involving the rest of the review author team.

Based on the five GRADE considerations (risk of bias, inconsistency, imprecision, indirectness, and publication bias), we will rate the certainty of the evidence for each outcome as high, moderate, low, or very low, and interpret the ratings as follows.

- 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.

We will justify all decisions to downgrade the certainty of the evidence using footnotes. We will make comments to aid the reader's understanding of the review where necessary.

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Editorial and peer-reviewer contributions

Cochrane Central 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): Grigorios Leontiadis, McMaster University, Canada
- Managing Editor (selected peer reviewers, collated peer-reviewer comments, provided editorial guidance to authors, edited the article): Sam Hinsley, Cochrane Central Editorial Service
- Editorial Assistant (conducted editorial policy checks and supported editorial team): Lisa Wydrzynski, Cochrane Central Editorial Service
- Copy Editor (copy editing and production): Julia Turner, Cochrane Central Production Service
- Peer-reviewers (provided comments and recommended an editorial decision): Susan Gibb, RCH Melbourne, Australia (clinical/content review); Daniel Mallon, Division of Pediatric Gastroenterology, Hepatology and Nutrition, Cincinnati Children's Hospital Medical Center, University of Cincinnati College of Medicine, USA (clinical/content review); Erick Manuel Toro Monjaraz, Instituto Nacional de Pediatria (clinical/content review), Mexico, Alysia De Nino (consumer review); Nuala Livingstone, Cochrane Evidence Production and Methods Directorate (methods review); Jane Dennis, Cochrane Injuries (search review); Robin Featherstone, Cochrane Central Editorial Service (search review)

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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 Hospitals, Pediatric/ 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 or NICU or PICU).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 Dietary Supplements/ OR exp Diet/ OR Nutrition Therapy/ OR exp Diet Therapy/ OR Dietetics/ OR Nutritionists/ OR Portion Size/ OR Fasting/ OR exp Feeding Behavior/ OR exp Food/ OR Breast Feeding/ OR exp Meals/ OR exp Fluid Therapy/ OR Rehydration Solutions/ OR Drinking/ OR Drinking Water/ OR Carbonated Water/ OR Diet Therapy.fs. OR (Diet* OR Pre?biotic* OR Pro?biotic* OR Synbiotic* OR Regimen OR Nutri* OR N?utraceutical* OR Food* OR Hebal OR Oligosaccharide* OR Oligofructose* OR Fructooligosaccharide* OR Monosaccharide* or FODMAP* OR Gluten* OR Polyol* OR Omega* OR Sugar* OR Carbo* OR Fruit* OR Vegetable* OR Sodium OR Fatty Acid* OR Dairy OR Fiber OR Fibre OR Protein* OR Vegetarian* OR Vegan* OR Macro* OR Keto* OR Paleo* OR Dissacharide* OR Lactose OR Sucrose OR Fructose OR Bran* OR Sorbitol OR Xylitol OR Psyllium OR Metamucil OR Plantaglucide* OR Ispaghula OR Isogel OR Reguval OR Plantago Seed OR Ispaghule Gum OR Portion Size* OR Serving Size* OR Meal OR Meals OR Mealtime* OR Dinner* OR Supper OR Suppers OR Breakfast* OR Lunch* OR Snack* OR Fasting OR Feeding* OR Breast?fed* OR Breast?feed* OR Bottle?feed* OR Bottle?fed* OR Wet Nursing OR Carnivor* OR Herbivor* OR Hydrat* or Subcutaneous Fluid Administrat* or Hypodermoclys* or Fluid Therap* or Rehydrat* or Drinking* or Water Consumption or Water Intake or Drinking Water or Potable Water or Bottled Water or Carbonated Water).tw,kw.

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

5 and/1-4

CONTRIBUTIONS OF AUTHORS

SR led the writing of the protocol and conceived the idea for the review.
MG contributed to the concept and design of the protocol, provided support, and edited the protocol.

TD contributed to the writing, provided support, and reviewed the protocol.
MB contributed to the concept and design of the protocol and provided support.
VS contributed to the concept and design of the protocol, provided support, and edited the protocol.

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VS: none

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