Lifestyle Interventions for Managing Functional Constipation in Children:
A Systematic Review

Master Thesis

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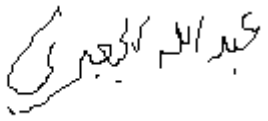
Declaration

I certify that this thesis submitted for the degree of master in health sciences at University of Twente and has resulted of my own research. No part of it has been submitted to any other university or institution.

Signature

Date: March 2021



Ethical Consideration

Ethical approval was not required in this thesis as it is a literature review and there was no direct contact with patients nor with practical care provided to them.

Acknowledgment

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Abstract

Introduction: Constipation is considered a symptom of dry, hard, or infrequent stooling or bowel movement. Functional constipation (FC) is the case that is not due to an underlying cause of a medical condition nor medication side effect. An average of 95% of constipated children has no evident anatomic, biochemical, or physiologic abnormalities. ROME III criteria are the standard criteria used for the definition and diagnosis of functional constipation in children. Laxatives and fecal disimpaction are the recommended treatment options, but 40% of children are not recovered after using these treatments. Thus, investigation about lifestyle interventions is required when other medical treatments are not effective.

To investigate the evident effectiveness of specific lifestyle interventions that help in treating functional constipation.

Methods: An extensive literature search in Pubmed, Embase and Cochrane was performed regarding functional constipation among children aged 0-18 years and associated lifestyle interventions. Treatment success was defined according to the absence of any of ROME III criteria for constipation. Defecation frequency was the primary outcome, while defecation pain was the secondary outcome. Included studies were randomized controlled trials, randomized clinical trials or pre-post designs. Quality assessment for the included studies was consistent with PRISMA and assessed according to the Cochrane risk of bias tool.

Results: A total of 135 studies were found during the search. Eleven studies found eligible and were included in this review. These included studies were classified into three categories: Dietary intervention, physical intervention, and behavioral intervention. Findings showed no evidence for the effectiveness of behavioral and dietary therapies, except a study that showed the effectiveness of cacao fibrous husk on colonic transit time, and another showed the effectiveness of goat probiotic mix. However, all five studies about physical therapy showed significant effectiveness.

Conclusion: Although few studies showed the effectiveness of dietary intervention, physical intervention found the most promising therapy in managing functional constipation in children. However, more studies in the field are still needed.

Keywords: Functional constipation, ROME III, Lifestyle interventions, behavioral therapy, conventional therapy, dietary fiber, laxatives, standard medical care, physical/physiotherapy, Probiotics, toilet training, biofeedback therapy, bowel transit time.

Abbreviations

FC: Functional constipation
SMC: Standard Medical Care
Mesh: Medical Subject Headings
Tiab: Title and Abstract
RCT: Randomized Controlled Trials
PPT: Pelvic Physiotherapy
PFPT: Pelvic Floor Physical Therapy
PEG: Polythelene Glycol
BT: Behavioral Therapy
CT: Conventional Therapy
IMT: Intensive Medical Therapy
ETT: Enhanced Toilet Training
BF: Biofeedback

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Introduction

Background

Constipation refers to stooling or bowel movements that are infrequent, dry, or hard to pass.[1] Constipation is considered a symptom, not a disease.[2] It is mainly associated with infrequent bowel movements. However, there is a wide variation in stool frequency and consistency in normal healthy children.[3] The pattern of bowel movements in children is different from that found in adults. The average of bowel movements in infants is 3-4 movements per day and toddlers 2 to 3 bowel movements per day.[4,5] Due to this complexity in defining and classifying the normalcy and insanitary of bowel movements in children, the ROME III Criteria[6] were developed for an accurate and standardized definition of constipation in children of various age groups.

Constipations that are not due to an underlying cause of a medical condition or medication side effects are considered functional constipations.[1]

ROME III Criteria (2006) provided two distinct definitions for functional constipation: one for children below 4 years old and the other for children from 4-18 years old.

ROME III Criteria (2006) defined functional constipation in children of ages below 4 years as the occurrence of two or more of the following characteristics lasting for four weeks with no evidence of organic pathology:

- Less than 2 defecations /week.
- History of excessive stool retention.
- History of hard stool or painful bowel movement.
- Presence of large fecal mass in the rectum.
- History of thick diameter stools.[6]

Additionally, the criteria defined functional constipation in children of age 4-18 years as the occurrence of two or more of the following characteristics lasting for eight weeks with no evidence of organic pathology:

- Two or fewer defecations/week.
- One or more episodes of fecal incontinence/week.
- History of retentive posturing or excessive volitional stool retention.
- History of painful and hard bowel movement.
- Presence of large fecal mass in rectum.
- History of large diameter stools that may obstruct toilet.[6]

Constipation is a common gastrointestinal health problem. An average of 12% of the population worldwide complain of having constipation.[7] In the Netherlands, constipation occurs in population with an average prevalence of 24.5%.[8] In children, prevalence ranges between 0.7% to 29.6%, depending on the criteria used.[9]

Only a small number of childhood constipation is due to organic causes. However, the most common cause of it is functional and has been called idiopathic constipation and characterized by fecal retention and fecal withholding. [10]

Problem Statement

The treatment of constipation depends mainly on its underlying cause and its duration of occurrence.[11] However, functional constipation, which is the common type of constipation, has no underlying cause. There is no specific therapeutic solution for it, as no abnormalities found. Laxatives and fecal disimpaction are the recommended treatment course. A study showed that an average of 50% of the children referred to a pediatric gastroenterologist will recover and can go on without laxatives after 6 to 12 months, 10% will be well while taking laxatives, and 40% will still be symptomatic despite the use of laxatives.[12]

This situation is worrying, especially to parents because, although constipation is not directly associated with mortality, it is emotionally stressful to children and care-givers.[13] Many children with chronic constipation exhibit withholding behavior that leads to poor health-related quality of life, poor school performance, and one-third of children with chronic constipation continue to have problems beyond puberty.[14] Hence, it is essential to search for other alternative or effective approaches to manage functional constipation.

A form of an alternative approach with great potential for managing pediatric constipation is lifestyle intervention. Lifestyle intervention is defined as any intervention that includes diet, exercise, movement, social adjustment, sleep, counselling, and stress management. Many population-based studies mentioned that modifications of lifestyle behaviors with dietary and physical components prevent the burden of several chronic diseases.[15] Despite these reported benefits of lifestyle modifications, the coordinated use of lifestyle intervention in treating functional constipation in children is underreported.

Objective

This literature review study aims to investigate lifestyle interventions as potential solutions to functional constipation in children.

Research Question

What lifestyle interventions have been found effective in the treatment and management of functional constipation in children aged 0 to 18 years.

Methods

Review Protocol

This systematic review has been conducted consistent with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA)[16].

Data Sources and Search Methodology

The systematic literature search was conducted in October 2020. The studies were identified through a web-based search carried out in the PubMed, Embase and Cochrane Central Register of Controlled Trials (CENTRAL) databases.
The search strategy adopted, utilized MeSH terms and keywords such as, "lifestyle intervention", "behavioral intervention", "behavioral therapy", "dietary intervention", "physical therapy", "sleep", "child", "children", "constipation" have been used. (Appendix 1)
Search strategy that has been used in the PubMed is as the following.
"Healthy Lifestyle"[Mesh] OR "Healthy Lifestyle/therapy"[Mesh] OR "Behavior Therapy"[Mesh] OR "Diet Therapy"[Mesh] OR Sleep/therapy [Mesh] OR "lifestyle intervention*"[tiab] OR "behavioral intervention*"[tiab] OR "behavioral therap*"[tiab] OR "dietary intervention*"[tiab] OR "physical therap*"[tiab] OR sleep[tiab] AND Child [Mesh] OR Children[tiab] OR child[tiab] AND Constipation [Mesh] OR Constipation*[tiab]

Study Screening and Selection

All identified studies have been downloaded to Cochrane Covidence., duplicates were removed, and the remaining studies have been screened against predetermined eligibility criteria. Studies were discarded if their title or abstracts failed to meet any of the eligibility criteria. Furthermore, the full-text articles have been assessed before a final selection of studies to be included in the review.

Eligibility Criteria

The eligibility criteria for this review are as the following:
Inclusion Criteria to be included, studies must:

- Be randomized controlled trials, randomized clinical trials or pre-post study designs.
- Be published in English language and full manuscript form.

- Report participants aged 0 – 18 years with a diagnosis of functional constipation, with or without incontinence. The diagnosis should be consistent with Rome III criteria. Studies about constipated children due to pathological etiology have been excluded.
- Involve studies in which the lifestyle interventions are described by the authors as behavioral, cognitive, diet modification or physical exercises.

Exclusion Criteria studies were excluded, if:

- They are not randomized controlled trials, not randomized clinical trials and not pre-post studies.
- They were not published in the English language or if they were available as short abstracts only.
- Study participants aged above 18 years and/or suffering from pathologic origins of constipation.
- If the study involved medical or pharmacological intervention only.

Data Extraction and Management

A data extraction form, which adheres to the PRISMA guidelines, was developed for extracting study characteristics. The following information were extracted for each study:

- Number of Participants.
- Age of Participants.
- Diagnostic Criteria.
- Time to Outcome.
- Type of Intervention.
- Intervention Characteristics.
- Primary Outcome.
- Secondary Outcome.
- Quality of Evidence

The methodological quality of selected studies has been assessed following the Cochrane risk of bias tool[17]. The following criteria have been assessed:

- Random sequence generation.
- Allocation concealment.
- Blinding of participants.
- Blinding of outcome assessment.
- Incomplete outcome data.
- Other sources of bias.

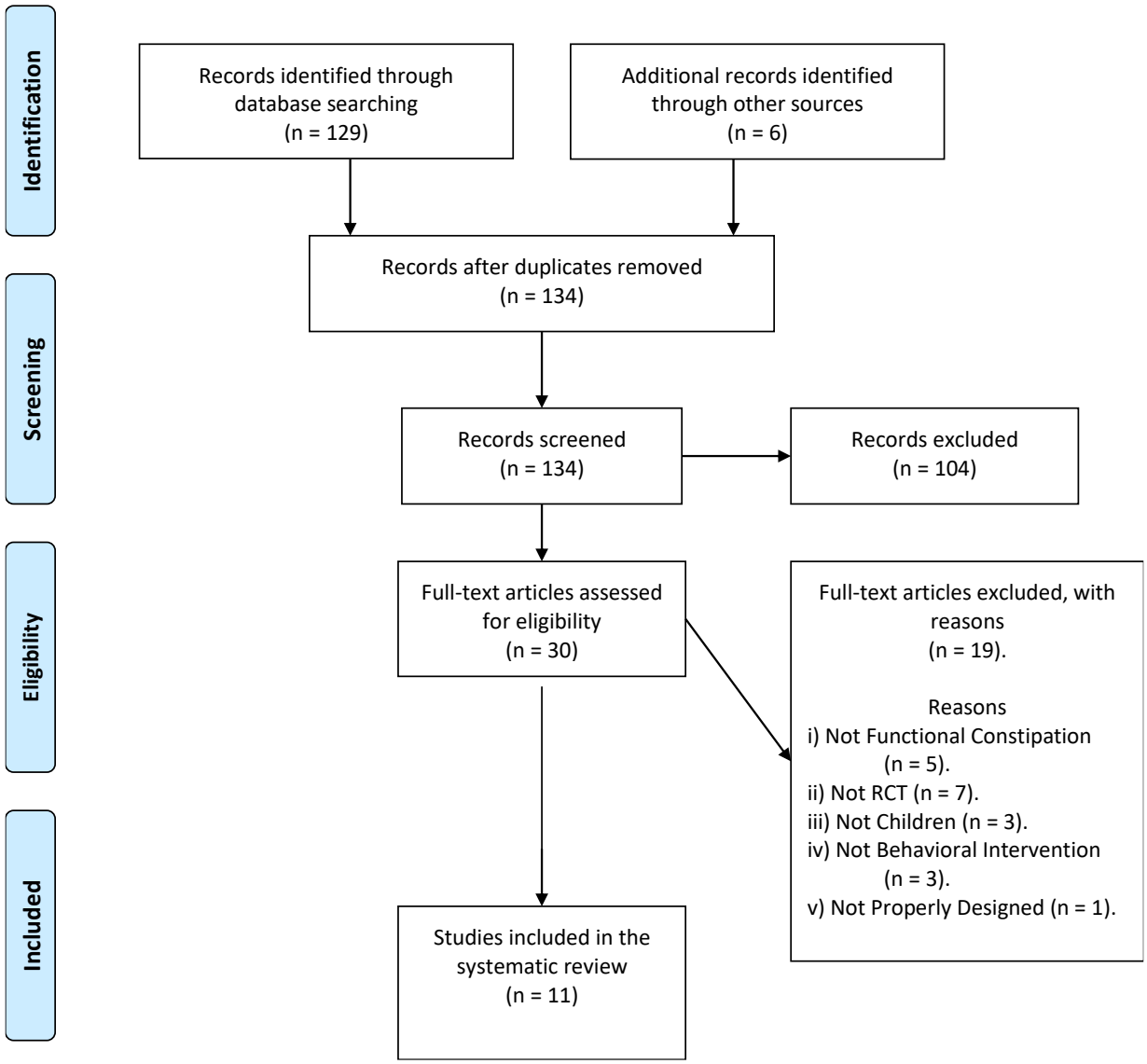
The overall risk of bias has been judged as the following "low risk", "unclear risk" or "high risk".

Results

Study Selection

A total of 129 studies have been retrieved from the database searches. One duplicate has been removed, and 104 have been excluded after analyzing their titles and abstracts. Other 6 studies were identified and added after reviewing the references of relevant selected studies. After assessing the full texts of the remaining 24 studies, nineteen studies did not meet the inclusion criteria. In the end, as shown in the flow chart, 11 studies were considered appropriate (Fig. 1).

Fig. 1: Study Selection



Description of Included Studies

Four of the included studies have been conducted in the Netherlands, two in Brazil and two in USA, while the others have been conducted in Spain, Iran and Italy.

Across the 11 studies, there were a total of 870 participants, aged 3 to 18 years who underwent chronic constipation. The time to the outcome of the interventions ranged from 4 weeks to 12 months.

The interventions compared the use of dietary interventions, physical therapy interventions and behavioral therapy to standard medical care. Five studies evaluated the use of dietary interventions. Other five studies examined the effect of physical therapy interventions, while one study examined the effect of behavioral therapy.

Most of the studies used stool evacuation frequency and stool consistency as primary outcomes. Only the study by Castillejo et al. 2006 used intestinal transit time to measure the primary outcome. Secondary outcomes include defecation pain, retentive behavior, and therapeutic success.

The detailed characteristics of the included 11 studies in this systematic review are presented in the following table (Table 1).

Table 1: Characteristics of Included Studies

Study	n	Age(Years	Diagnostic	Time to Outcome	Intervention	Intervention Characteritics	Primary Outcome	Results
Castillejo 2006	56	(3-10)	ROME lll	4 weeks	dietry fiber vs placebo	cocoa shell rich in dietry fiber with milk vs. glucose with milk	intestinal transit time and evacuation frequency	a greater decrease in intestinal transit time found in dietry fiber group(45.4 hrs vs. 8.7 hrs), also incresed bowel movements and evacuations in dietry fiber group (2.40 vs. 1.73 evactations per week).
Kokke 2008	97	(1-13)	ROME lll	8 weeks	Fibre vs. Laxative	Fibre with yoghurt fluid mixture (1-3 bottles daily) vs. Lactulose with yoghurt fluid mixture (1-3 bottles daily).	Defecation frequency and Faecal incontinence	There was no significant difference between groups in defecation frequency: 7 times per week with fibre vs. 6 times per week with lactulose (P = 0.481) T no significant difference in the number of children with one or more faecal incontinence per week. 4% with fibre vs. 3% with lactulose (P = 0.084).
Russo 2017	55	(4-12)	ROME lll	8 weeks	Probiotic & PEG vs. (PEG) only	Probiotic Mix and PEG 400 (1 sachet/day) vs. PEG 400 (1 sachet/day)	Defecation frequency, Stool consistency and Faecal incontinence	In the second week, treatment success was higher with PEG (72%) vs. Probiotic Mix (59%) (P = 0.02). After four weeks, there was no difference in treatment success between the two groups
Tabbers 2011	148	(3-16)	ROME lll	5 weeks	Probiotic vs. Placebo	Probiotic (Bifidobacterium lactis DN-173010 2×/day, 4.25 × 109 CFU/fermented milk) vs. Low lactose non-fermented diary	Defecation frequency and Faecal incontinence	Treatment success was higher in the probiotic group (38%) compared to the placebo group (24%), but it was not statistically significant difference (p = 0.06).
Guerra 2011	59	(5-15)	ROME lll	5 weeks	Probiotic vs. Placebo	Probiotic (Bifidobacterium longum 109 CFU/ml of goat yoghurt) vs. Goat yoghurt only.	Defecation frequency, Stool consistency and Abdominal/defecation pain.	The probiotic group showed significant improvement from the baseline symptoms. There were significant differences for defecation frequency (p = 0.012), defecation pain (p = 0.046) and abdominal pain (p = 0.015).
Silva 2013	72	(4-18)	ROME lll	6 weeks	physiotherapy vs. medication	training of abdominal muscles, breath exercises, abdominal massage and toilet training vs. medical care with laxatives	defecation frequency and retentive fecal incontinence	frequency of bowel movement was higher in physiotherapy group than in medication group (5.1 days/week vs. 3.9 days/week). Also frequency of fecal incontinence was not so different between both groups(3.6 vs. 3 days/week).
Van Engelenburg and Van Lonkhuyzen 2017	53	(5-16)	ROME lll	6 months	Pelvic physiotherapy (PPT) vs. Standard medical care (SMC)	Exercises involving proper straining to defecate, posture adjustment and sensitivity	Absence of functional constipation as defined by meeting 1 or more of the 6 ROME III criteria	92.3% of the children undergoing PPT vs. 63% children receiving only SMC were treated successfully. (P = 0.011).
Zar-kessler 2019	69	(5-18)	ROME lll	3 months	Pelvic floor physical therapy vs. Medical treatment	Training to engage the transversus abdominus and pelvic floor muscles (3-8 sessions) vs. Medical therapy	Decreased straining, Decreased faecal incontinence and Reduction in number of post-treatment hospitalizations	76% of the PFPT group vs. 25% of the non-PFPT group responded to treatment. (P < 0.01). Only 4% of the PFPT group vs. 25% of the non-PFPT group proceeded to hospitalization. (P = 0.014).
Farahmand 2015	40	(4-18)	ROME lll	8 weeks	Pelvic Floor Exercise vs. Standard Medical care	Walking in a semi-sitting (squatting) position for 5 minutes	Defecation frequency, Stool consistency, Stool diameter and Abdominal/defecation pain	95% improvement in defecation frequency. 100% improvement in stool consistency. 97.5% improvement in stool thickness diameter
Borowitz 2002	87	(6-15)	ROME lll	12 months	(IMT)vs.IMT + ETT vs.IMT + ETT + BF.	Laxatives vs. Laxatives + Toilet Training vs. Laxatives + Toilet Training + BF	Frequency of bowel movements and Frequency of faecal soiling.	improvement rates for IMT, ETT and BF were 45, 78, and 54, respectively (P < 0.05).
Van Dijk 2020	134	(4-18)	ROME lll	22 weeks	Behavioural therapy (BT) vs. Conventional treatment (CT)	Teaching behavioural procedure and therapy vs. conventional treatment procedure	Defecation frequency and Faecal incontinency	Defecation frequency 7.2 per week in the CT group vs. 5.4 in the BT group (P = 0.021). Faecal incontinence 2.1 and 5.0 per week respectively for CT and BT treatment groups

Results of Individual Studies

The following are the results of the included studies, presented according to the type of intervention utilized:

Physical/Physiotherapy Intervention

The study by Silva et al. 2013 compared the efficacy of physiotherapy or using medical treatment alone. The patients were randomly assigned into two groups: physiotherapy group and medication only group. Members of the physiotherapy group were given laxatives and then subjected to exercises, such as training of abdominal muscles and diaphragmatic breathing exercises administered by a trained physiotherapist for 12-40 minutes twice a week. Patients in the medication group were given laxatives only. The study revealed a higher frequency of bowel movements in participants of physiotherapy group [5.1 ± 2.1) days/week] than in participants of the medication only group [3.9 ± 2.0) days/week] (p= 0.01). In contrast, the frequency of fecal incontinence had no difference between the groups [3.6 ± 1.9 days/week vs 3.0 ± 2.1 days/week] (p= 0.31).

Van Engelenburg van Lonkhuyzen et al. 2017 compared the effectiveness of adding pelvic physiotherapy (PPT) to the standard medical care (SMC). Participants had been randomly assigned to a group that took PPT in addition to their SMC while the other group took SMC only. Specific physiotherapeutic interventions were administered to the first group, while SMC included education, toilet training and laxatives. The primary outcome measure was the absence of functional constipation according to the 6 ROME III criteria, as: frequency of bowel movements, fecal incontinence, hard stools, and large amounts of stools that obstruct the toilet, postponing defecation, and abdominal pain. Meeting at least 1 of the six criteria was considered a treatment success. The study reported that adding PPT to SMC was more effective than SMC alone on most outcome measures. After 6 months of the intervention, two of the ROME III criteria showed a significant difference between groups; for hard stool and painful bowel movement, all 15 children in the added PPT intervention group and 10 of the 17 children in the SMC group improved (p = 0.008). Concerning the criterion of a large amount of stool that obstruct the toilet, all 15 children in the added PPT intervention group and 8 of the 12 children in the SMC group improved (p = 0.042). Treatment was effective for 92.3% of the children receiving additional PPT and 63.0% of the children receiving SMC alone (p = 0.011).

Zar-Kessler et al. 2019 compared the clinical outcome of patients who underwent pelvic floor physical therapy (PFPT) to control patients who received only medical treatment with laxatives and stool softeners. The patients have been classified into two categories: a treatment group and no treatment group. Those in the treatment group received physical therapy while those in the no treatment group received medical treatment only. Response to treatments was determined according to the following primary outcomes; decrease in straining, decreased fecal

incontinence and reduced number of patients who proceeded to hospitalization for stool cleanouts or surgical interventions. The study showed PFPT to be effective in the treatment of functional constipation in children. Thirty-seven (76%) of the patients who received PFPT responded to treatment and had improvement in constipation symptoms, compared to 5 (25%) of the patients on conservative treatment ($p < 0.01$). Additionally, patients who received pelvic physical therapy had fewer hospitalizations for cleanouts (4 vs 25%, $p = 0.01$) and colonic surgery than those who were treated with medical treatment (0 vs 10%, $p = 0.03$).

Farahmand et al. 2015 evaluated the effectiveness of a physical exercise program for the pelvic floor in constipated children compared to standard medical treatment. Standard medical treatment included both laxatives and toilet training. Children diagnosed with functional constipation who did not respond to medical therapy performed pelvic floor muscle exercise sessions at home twice a day for eight weeks. The exercise consisted of walking in a semi-sitting (squatting) position for 5 minutes under parents' supervision. To motivate the patients and to increase treatment adherence, constipated children have been encouraged to carry a toy of their choice playfully during the exercise. The primary outcome measure for treatment success was the change in defecation frequency at the final week of intervention compared to the baseline. Secondary outcomes were overall improvement of constipation, stool withholding, painful defecation and stool consistency. There were significant improvements in stool frequency, stool diameter and thickness. Stool frequency less than three times per week was present in 2 patients (5%) after participation in the exercise program, compared to 39 patients (97.5%) in the baseline evaluation ($p < 0.01$). Twenty-one patients (52.5%) reported hard or very hard stool in the baseline evaluation, but stool consistency was soft in all the patients after eight weeks of exercise program ($p < 0.001$). Twenty patients (50%) had a large stool diameter before treatment, and it was present in only one patient (2.5%) after the treatment ($p < 0.05$). An overall improvement of the symptoms was present in 36 patients (90%). This study showed that pelvic physical exercise is an effective treatment for pediatric functional constipation.

Borowitz et al. 2002 compared the effectiveness of three additive treatment protocols in children experiencing chronic encopresis attributed to functional constipation. The study hypothesized that children who received the most therapy would receive the best clinical response. Participants were assigned randomly to three treatment groups; intensive medical therapy (IMT group), intensive medical therapy combined with enhanced toilet training (ETT group) and intensive medical treatment with improved activity and biofeedback therapy (BF group). The IMT intervention involved sufficient laxative therapy in producing at least one soft stool each day without associated pain. The laxatives prescribed were Milk of Magnesia or Senna (Senokot). Laxative dosages were adjusted regularly to produce one to three soft bowel movements daily. In addition to laxative therapy, the participants of ETT group were provided

a specialized therapy involved demonstrations for legs and feet relaxation, holding a deep breath while sitting up straight, and pushing down with breath-holding and pull in from the lower abdomen to propel out a stool. The children then replicated this while sitting on a portable toilet. The BF group used the same instructions that the IMT and ETT groups did and simultaneously received electromyographic biofeedback training, which involved using a classic Egg Drop game. The game helps the child to learn to tighten and relax the external anal sphincter to control a "basket" that moved horizontally across the bottom of the screen, depending on muscle contraction, to catch the "falling egg."

Treatment success was assessed based on the number of bowel movements passed in the toilet per day, the frequency of self-initiated toileting per day and frequency of fecal soiling every day too. At the end of 12 months, there found no statistically significant differences among groups concerning cure rates. However, over time, the three treatments resulted in significant increases in daily bowel movements passed in the toilet and self-initiated toileting and resulted in decreased average everyday soiling at 3, 6, and 12 months ($p < 0.05$). The improvement rates for IMT, ETT and BF, were 45, 78, and 54, respectively ($p < 0.05$). Thus, the study concluded that the intervention involved enhanced toilet training (ETT) is somewhat more effective than either intensive medical therapy or anal sphincter biofeedback therapy.

Dietary Intervention

Castillejo et al. 2006 reported a difference between the treatment and control groups in terms of improved transit time. The treatment group was given a sachet of cocoa husk supplement; a dietary fiber supplement in powdered form, containing 4g of cocoa husk and 1g of beta fructosan. The control group participants were given a placebo in a powdered form containing glucose, cocoa flavoring, and excipients. The intestinal transit time and the number of bowel movements were the main primary outcome measurements. Amore significant decrease in colon transit time in children who received the cocoa husk supplement than children who received the placebo (treatment group decreased by 45.4 ± 38.4 hours, control group decreased by 8.7 ± 28.9 hours. $p = 0.015$). There was an increase in the number of bowel movements in children who received cocoa husk supplements than in those of the placebo group. However, no significant differences regarding bowel movements between groups could be found (2.40 ± 3.16 vs 1.73 ± 1.73 bowel movements per week. $p = 0.780$). There also was a reduction in the percentage of patients who reported hard stool in the cocoa husk group 41.7% than the placebo group 75.0% ($p = 0.017$). A significantly higher number of children (or their parents) reported a subjective improvement in stool consistency. No significant adverse effects have been reported during the study.

Kokke et al. 2008 compared the effect of dietary fiber to laxatives in the treatment of functional constipation. Participants were randomly placed into a fiber group or a laxative group. The

participants of the fiber group have been given 10g of fiber in 125ml yoghurt drink while the laxative group have been given 10g of lactulose in 125ml yoghurt drink. The fiber mixture yoghurt contained 3.0g transgalactic-oligosaccharides, 3.0g inulin, 1.6g soy fiber, and 0.33g resistant starch per 100ml. Defecation frequency and fecal incontinence were the primary outcomes that were measured. After eight weeks, the study found no significant difference between groups in defecation frequency per week (7 times per week with fiber vs six times per week with laxative, $p = 0.481$). There was also no significant difference in the number of children with one or more fecal incontinence episodes per week (4% with fiber vs 3% with lactulose, $p = 0.084$).

Russo et al. (2017) compared adding probiotic mix to polyethene glycol (PEG) VS. using (PEG) alone. The probiotic mixture included 10^9 CFU/ml each of *Bifidobacteria brene* M-16, *infantis* M-63 and *longum* BB536. Participants placed in the probiotic group have been given one sachet/day of the probiotic mix and PEG 400, while those in the only PEG group have been given one sachet/day of PEG 400. Primary outcomes measured included: frequency of bowel movements, stool consistency, fecal incontinence, and abdominal pain. Treatment success was considered as three or more bowel movements per week and no episodes of abdominal pain, fecal incontinence, or rectal bleeding. The study results showed that, in the second week of the study, treatment success was higher with PEG (72%) compared to the probiotic mixture group (59%). After four weeks, there was no difference in treatment success between PEG group (88%) and the probiotic group (81.8%). Moreover, there was no difference between bowel movement frequency, stool consistency, fecal incontinence, abdominal pain, and rectal bleeding after eight weeks.

Tabbers et al. 2011 examined the difference in clinical outcomes between two groups: treatment and placebo groups. The treatment group people were given a probiotic (10^9 Bifidobacterium lactis DN-173010) in fermented milk twice a day, while the placebo group people received a low lactose non-fermented dairy twice a day. The primary outcome measure was the frequency of bowel movements. Treatment success determination was based on three or more bowel movements/week and one or no fecal incontinence episodes in two weeks. After five weeks, treatment success was higher in the probiotic group (38%) compared to the placebo group (24%), but this difference was not significant ($p = 0.06$).

Guerra et al. 2011 evaluated the treatment of functional constipation with probiotic goat yoghurt. Participants have been randomized into two groups of 59 constipated young students: The treatment group consisted of 30 students received daily goat yoghurt supplemented with 10^9 CFU/ml Bifidobacterium longum (probiotic). The placebo group which consisted of 29 students have been given only goat yoghurt daily. Defecation frequency, stool consistency and abdominal and defecation pain have been assessed. The group treated with probiotic showed significant improvement than placebo group. There were significant differences observed

between the two groups regarding defecation frequency ($p = 0.012$), defecation pain ($p = 0.046$) and abdominal pain ($p = 0.015$).

Behavioral Intervention

Van Dijk et al. 2020 evaluated the clinical effectiveness of adding behavioral therapy (BT) to conventional therapy or using conventional therapy alone. The BT protocol involved behavioral play therapy and procedures with the child in the presence of parents. On the other hand, CT included laxative treatment (polyethylene glycol) and bowel movement education, in addition to explaining symptoms and instructing children not to withhold stool when they feel urge to defecate. Participants have been randomly assigned to BT or CT treatment group. Treatment success was defined as defecation frequency of 3 or more times per week and fecal incontinence of 1 or fewer times per 2 weeks. The study reported that behavioral therapy with laxatives had no added value over conventional treatment in treating childhood constipation. Defecation frequency was higher in the CT group, 7.2 per week compared to the 5.4 in the BT group. ($p = 0.021$). Fecal incontinence decreased to 2.1 and 5.0 per week, respectively, for CT and BT treatment groups. Although success rates were higher in CT (62.3%) than in BT (52.5%), no statistically significant difference between the treatments was found ($p = 0.249$).

Risk of Bias

Eight studies were assessed and judged to have a low risk of bias in all categories except for blinding the participants and personnel. Three studies were assessed and judged to have a high or unclear risk of bias in random sequence generation, allocation concealment, blinding of participants and personnel and blinding of outcome assessment.

The following table number 2 and the table number 3 in the appendix provide a detailed description of the risk of bias for the included studies in this review.

Table 2: Risk for bias

Trial	Design	Random sequence generation	Allocation concealment	Blinding of participants& personnel	Blinding of outcome assessment
Castillejo et al. 2006	Randomized controlled trial	+	+	+	+
Kokke et al. 2008	Randomized controlled trial	+	+	+	+
Russo et al. 2017	Randomized controlled trial	+	?	?	?
Tabbers et al. 2011	Randomized controlled trial	+	+	+	+
Guerra et al. 2011	Randomized controlled trial	+		?	?
Silva et al. 2013	Randomized clinical trial	+	?	?	+
van Engelenburg-van Lonkhuyzen et al. 2017	Randomized controlled trial	+	+	?	+
Zar-Kessler et al. 2019	Retrospective clinical trial	?	?	?	?
Farahmand et al. 2015	Pre-post study design	?	?	?	?
Borowitz et al. 2002	Randomized clinical trial	+	+	+	+
van Dijk et al. 2008	Randomized controlled trial	+	+	?	+

\+ *Low risk bias*

? *High risk or unclear bias*

Discussion

This systematic review aimed to explore effective approaches other than the standard medical care for treating functional constipation in children. Overall, alternative/lifestyle interventions such as behavioral therapy, physical therapy and dietary therapy were identified and reported to manage childhood functional constipation. Out of the eleven included studies in this review, we found seven studies reported a statistically significant effect of the intervention used. Two studies that used dietary interventions (Castillejo *et. al.* 2006 and Guerra *et.al.*2011) found effective. Additionally, all the five studies that used physical therapy interventions reported significantly effective outcomes (Silva *et. al.* 2013, van Engelenburg-van Lonkhuyzen *et. al.* 2012, Zar-kessler *et. al.* 2019, Farahmand *et. al.* 2015 and Borowitz *et. al.* 2002).

There is more children's adherence to cacao husk, that's maybe due to its delicious flavoring taste, while less adherence to probiotics because children do not like its taste and because it causes gas accumulation and abdominal cramps.

Although, the study of Castillejo et al. showed significant improvement in colonic transit time, it showed no significant improvement in defecation frequency (p=0.780). Additionally, cacao husk contains caffeine and theobromine**.**[18] These two substances are known as stimulants; therefore, this supplement is not recommended for children.

In recent systematic reviews, the available studies could not demonstrate significant effects of probiotic concerning treatment success in functional constipated children. [19] Furthermore, another systematic review found no significant improvement after fiber intake by constipated children. [20]

Hence, physical therapy had the best potential to serve as effective intervention to treat functional constipation in children. Reports of the five studies in this systematic review suggested that interventions involving physical therapy resulted in significant improvements. The added advantage of physical therapy is that physical exercises in this intervention are combined with cognitive and behavioral elements, such as education and toilet training.[21] However, before physical therapy can be recommended as an effective treatment in childhood constipation, more extensive studies need to be conducted.[22]

In sum, the results presented from the studies included in this systematic review should be interpreted with caution, as these studies were not of high methodological quality. Also, the studies did not have a long-term follow-up and monitoring, which are necessary for functional constipation as a long-lasting problem.

Implications of the Study

This systematic review highlighted the effectiveness of lifestyle interventions in treating pediatric constipation and a practical contribution of the study because it provides information on evidence for/against unconventional and non-pharmacological interventions. Thus, this study answers the question raised by Khan (2018) who asked if there was any evidence to support the different non-pharmacologic modalities for treating constipation in children.[23]

Although there is a clinical practice guideline for pediatric constipation management using standard medical care,[24] there is no such guideline for alternative treatment methods. This systematic literature review provides information on such alternative treatment methods that could be reviewed and used to formulate a guideline for non-pharmacological interventions in clinical practice.

Another implication for this study is the necessity for future research. The study highlights the lack of quality regarding the studies about alternative/lifestyle interventions in treating constipation in children. It also points out that the limited number of studies in this area makes the available evidence insufficient in supporting any of the examined lifestyle interventions. Hence, this study indicates the need for more, large-sampled RCTs to manage pediatric constipation with lifestyle interventions.

Limitations

One limitation of this systematic review is the low number of randomized controlled trials evaluating various forms of lifestyle interventions to treat pediatric functional constipation. Qualified studies are scarce; for this reason, articles with low methodological quality and high/unclear risk of bias were still included in the study.

The shortage of quality studies also accounted for using a broad and loosely efficient search strategy to identify any research remotely associated with this systematic review.

Another limitation of this study is the heterogeneity in the outcome measures used in the included studies. We found variation in primary outcomes measured in this review for treatment success as defined by the investigators in each included study. Hence, these definitions varied widely across the included studies. It is challenging to eliminate heterogeneity from the review. The systematic review combines several different studies where different sample sizes, different population characteristics and different sittings are used. However, we could minimize heterogeneity by using the same standard primary outcome measure for treatment success. Each study should report the common primary outcome measure as three or more defecations per week to be considered as standard criterion for treatment success.

Conclusion

This systematic review discussed various lifestyle interventions for treating functional constipation in children using dietary intervention, behavioral intervention, or physical therapy intervention.

Although both dietary and physical therapies found effective, the physical treatment showed the most promising intervention. Functional constipation is a known prevalent problem in the pediatric age group. However, this area of research does have a shortage of studies. Hence, more randomized controlled trials are needed regarding lifestyle interventions and alternative treatments. Furthermore, large, and well-designed studies are necessary to provide more insight into the efficacy of physical therapy in managing childhood constipation.

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Appendix

Appendix 1: Search Strategy

#1	"Healthy Lifestyle"[Mesh] OR "Healthy Lifestyle/therapy"[Mesh] OR "Behavior Therapy"[Mesh] OR "Diet Therapy"[Mesh] OR "Sleep/therapy"[Mesh] OR “lifestyle intervention” [tiab] OR “behavioral intervention*” [tiab] OR “behavioral therap*” [tiab] OR “dietary intervention*” [tiab] OR “physical therap*”[tiab] OR sleep[tiab]
#2	"Child"[Mesh] OR Children[tiab] OR child[tiab]
#3	"Constipation"[Mesh] OR Constipation*[tiab]
#4	#1 AND #2 AND #3

Table 3: Summary for risk of bias

Study	Bias	Extract from the Methodology of the Study	Judgement of Risk
Castillejo et al. 2006	Random Sequence Generation	• A randomization list was designed by the manufacturers of the supplement and the placebo (Madaus SA) using a computer random-number generator in 20 blocks of 4 patients each. • The details of the randomization codes were kept in sealed envelopes away from the investigators. • Eligible patients were randomly assigned to treatment 1 or 2 in a ratio of 1:1.	**LOW**
	Allocation Concealment.	• The details of the randomization codes were kept in sealed envelopes away from the investigators. • A randomization list was designed by the manufacturers of the supplement and the placebo (Madaus SA) using a computer random-number generator in 20 blocks of 4 patients each. • Treatment was blinded to both patients and investigator until the study was completed and analysed.	**LOW**
	Blinding of Participants and Personnel.	• Treatment was blinded to both patients and investigator until the study was completed and analysed. • Adherence to the standardized toilet training procedures (evaluated by a visual analogic scale from 0 to 10) in both groups was rated at the same level by the study investigators (5 of 10) during the study intervention. • Three days before the start of the intervention and 3 days before the end of the intervention, patients' feces were collected to evaluate their weight and level of hydration.	**LOW**
	Blinding of Outcome Assessment.	• Treatment was blinded to both patients and investigator until the study was completed and analysed. • Adherence to the intervention was evaluated by the same investigator using a visual analogic scale (in the case of standardized toilet training procedures) and counting the empty sachets that were returned to the investigator.	**LOW**
Kokke et al. 2008	Random Sequence Generation	• Randomization was performed by use of sequential numbers allocated to the patients at study entry and coordinated by the logistics manager of Numico Research using a block design. • 65 chidren were randomized to treatment with fibre mixture and 70 to treatment with lactulose.	**LOW**
	Allocation Concealment.	• The study had a randomized double-blind parallel group design.	**LOW**

	Blinding of Participants and Personnel.	• The treatment products could not be distinguished from each other with respect to colour, taste, or consistency.	**LOW**
	Blinding of Outcome Assessment.	• The study had a randomized double-blind parallel-group design. • During the treatment period, patients were seen at the outpatient clinic 3 and 8 weeks after inclusion.	**LOW**
Russo et al. 2017	Random Sequence Generation	• All the enrolled children were then randomly assigned into two groups according to an automatically generated randomization list. • According to the randomization list, 28 children (13 boys) were randomly assigned to receive PEG and 27 children (13 boys) to receive an oral combination of PEG plus the probiotic mixture (PEG + PM).	**LOW**
	Allocation Concealment.	• The investigators, the children, and their parents were aware of the study group assignment.	**HIGH/UNCLEAR**
	Blinding of Participants and Personnel.	• We did not perform a blinded study because both investigators and patients were aware of the assigned medication.	**HIGH/UNCLEAR**
	Blinding of Outcome Assessment.	• We did not perform a blinded study because both investigators and patients were aware of the assigned medication.	**HIGH/UNCLEAR**
Tabbers et al. 2011	Random Sequence Generation	• Random numbers were generated by a computer program with an allocation ratio of 1:1 and with well-balanced blocks. • In this prospective randomized, double-blind, controlled trial, 159 constipated children were randomly allocated to receive either a fermented dairy product that contains *B. lactis* DN-173 010 or a control product twice a day for 3 weeks.	**LOW**
	Allocation Concealment	• The randomization lists were kept confidential by the person responsible for the preparation of the study products and their labelling.	**LOW**
	Blinding of Participants and Personnel	• The 2 study products were identical in weight, colour, smell, taste, and packaging. • After revealing the results of the blinded analyses to the study group, the randomization code was broken on October 26, 2009. • After agreement, analyses were done with blinding of the given products preserved.	**LOW**

	Blinding of Outcome Assessment.	• All doctors, research staff, and patients with their caregivers involved remained unaware of the product administered to the patient. • Independent clinical research associates visited the recruiting sites to monitor all patients' data. • The randomization lists were kept confidential by the person responsible for the preparation of the study products and their labelling	**LOW**
Guerra et al. 2011	Random Sequence Generation	• The allocation sequence and randomization list were computer-generated using the Epi Info Program.	**LOW**
	Allocation Concealment	• All doctors and children involved were unaware of the treatment administered	**LOW**
	Blinding of Participants and Personnel	• The two products, goat yogurt with or without *B. longum* were identical in weight, colour, smell, taste, and package.	**UNCLEAR**
	Blinding of Outcome Assessments	• Defecation frequency, stool consistency and abdominal or defecation pain were assessed.	**UNCLEAR**
Silva et al. 2013	Random Sequence Generation	• A table of random numbers was created by a person not involved in the study. • The information remained the exclusive knowledge of one research assistant, who used these numbers to allocate patients by order of study entry immediately after receiving informed consent and was made known to the researchers only after the statistical analysis. • This was used to determine the random distribution sequence of the patients.	**LOW**
	Allocation Concealment	• In the first case training began with two series of eight contractions and relaxations until the third week and was then increased to two series of 12 contractions and relaxations for 6 weeks.	**HIGH/UNCLEAR**
	Blinding of Participants and Personnel	• All patients were prescribed a laxative (magnesium hydroxide) at a dosage according to individual need (minimum of 2 ml/kg) and received guidance regarding fibre dietary intake, water, and toilet training, under the same conditions as the patients in the intervention group. • Patients in the medication group were only given laxatives.	**HIGH/UNCLEAR**
	Blinding of Outcome Assessments	• Medication group (control) Patients in the control group were monitored on a weekly basis by a paediatric gastroenterologist who was unaware of the group to which the patient had been randomized since the patients were undergoing clinical follow-up only. • The information remained the exclusive knowledge of one research assistant, who used these numbers to allocate patients by order of study entry	**LOW**

		immediately after receiving informed consent and was made known to the researchers only after the statistical analysis. • These data were checked and submitted to the research assistant weekly.	
Van Engelenburg - Van Lonkhuyzen et al. 2017.	Random Sequence Generation.	• To reduce the likelihood of foreknowledge of the intervention assignment, restricted randomization was performed (e.g., 1:1) using a central computer in combination with concealed randomization. • Group allocation was concealed using a central computer system. • Of the remaining 80 children, 27 (24.3%) were excluded before randomization, and 53 children were assigned randomly to the PPT (n = 26) or SMC (n = 27) group.	**LOW**
	Allocation Concealment.	• Group allocation was concealed using a central computer system. • At baseline, the children in both treatment groups were comparable in terms of clinical characteristics.	**LOW**
	Blinding of Participants and Personnel.	• To normalize toilet behaviour, the children were told not to withhold stools when they felt the urge to defecate, and they were instructed to sit on the toilet in a relaxed manner for at least 5 minutes after the 3 main meals. • The practitioners and patients were not blinded to the treatment interventions, although the outcome assessor was blinded	**UNCLEAR**
	Blinding of Outcome Assessment.	• At the follow-up evaluation, the GPE, NRS, and SDQ were completed before the last visit to the physiotherapist. • Secondary outcomes were global perceived effect (range, 1-9; success was defined as a score 8), numeric rating scales assessing quality of life (parent and child; scale, 1-10), and the strengths and difficulties questionnaire (SDQ). • Secondary Parent-Reported Outcomes were measured.	**LOW**
Zar-Kessler et al. 2019	Random Sequence Generation.	• There were a similar number of patients in each group on osmotic and stimulant medications at the time of initiation of PFPT (Table 1). • The treatment group consisted of 49 patients, and the nontreatment group had 20 patients. • We received approval from the Institutional Review Board prior to data collection.	**HIGH/UNCLEAR**
	Allocation Concealment.	• It should be noted that in our study, all patients (control and study group) were evaluated the same way, and abnormalities of defecation that were encountered were consistent between groups, with <50% of all patients meeting criteria for dyssynergias defecation. • The patients were classified into 2 categories: treatment and nontreatment group.	**HIGH/UNCLEAR**

	Blinding of Participants and Personnel.	• Within the physical therapy reports, presenting symptoms, physical exam, and response to treatment were also obtained. • Those in the nontreatment group were treated with medical treatment only.	**UNCLEAR**
	Blinding of Outcome Assessment.	• An indicator on the probe was used to align the probe appropriately throughout the entire study. • The physical therapy intervention consisted of an intake session where the patient was evaluated for motor control, strength, and endurance of the primary muscle groups involved with defecation: as respiratory diaphragm, transversus abdominus, and the pelvic floor musculature.	**HIGH/UNCLEAR**
Farahmand et al. 2015	Random Sequence Generation	• Children with chronic constipation aged 4 to 18 years referred to Children's Medical Center (affiliated hospital of Tehran university of medical sciences) from January 2012 to January 2013 were eligible for enrolment if they had a diagnosis of FC and had previously tried and failed adequate treatment for constipation.	**HIGH/UNCLEAR**
	Allocation Concealment.	• After obtaining verbal assent from children and written informed consent from parents or legal guardians, we instructed the patients to perform sessions of pelvic muscle exercise at home twice a day for 8 weeks.	**HIGH/UNCLEAR**
	Blinding of Participants and Personnel.	• After 8 weeks, patients were re-evaluated for the symptoms of constipation by a blinded physician in a follow up visit.	**HIGH/UNCLEAR**
	Blinding of Outcome Assessment.	• After 8 weeks, patients were re-evaluated for the symptoms of constipation by a blinded physician in a follow up visit	**HIGH/UNCLEAR**
Borowitz et al. 2002	Random Sequence Generation	• Using a random number generator, blocks of six consecutive children were randomly assigned to one of three treatment groups: IMT, ETT, or BF.	**LOW**
	Allocation Concealment	• All data were collected and allocated using the Automated Patient Symptom Monitor System.	**LOW**
	Blinding of Participants and Personnel.	• One of two paediatric gastroenterologists and two psychologists directed treatment. A computerized voice-mail system telephones the families each day. With each telephone call, the computer asked parents to identify themselves by entering their social security number and then asked the same eight pre-recorded questions.	**LOW**
	Blinding of Outcome Assessment.	• With all three treatment protocols, children were observed 10 and 14 days after the initial assessment. At that visit, the clinician assessed the efficacy of the prescribed disimpaction procedure and laxative regimen, and made appropriate changes based on clinical judgment.	**LOW**

Van Dijk et al. 2020	Random Sequence Generation.	• A computer-based system was used to generate a sequence of random group assignment for consecutive patients. • After baseline measurement and if written informed consent was given, a research assistant performed a telephone call to a randomization centre and revealed the allocation to parents immediately. • Random assignment was stratified by age (4 -8 years or 8 years) and gender.	**LOW**
	Allocation Concealment	• After baseline measurement and if written informed consent was given, a research assistant performed a telephone call to a randomization centre and revealed the allocation to parents immediately.	**LOW**
	Blinding of Participants and Personnel.	• The visit frequency and duration of treatment of the CT were made equivalent to that of the BT group to strengthen the comparison of treatments, which, however, could also jeopardize generalizing the findings to general practice. • The study had a 2-parallel group, randomized, controlled design.	**UNCLEAR**
	Blinding of Outcome Assessment.	• Outcomes were evaluated at the end of treatment and at 6-months follow-up. • CT was conducted by paediatric gastroenterologists and consisted of visits lasting 20 to 30 minutes, during which laxative treatment (polyethylene glycol 3350 and, if necessary, Klyx enemas or bisacodyl suppositories) and the bowel diary were discussed.	**LOW**

PubMed

"Healthy Lifestyle"[Mesh] OR "Healthy Lifestyle/therapy"[Mesh] OR "Behavior Therapy"[Mesh] OR "Diet Therapy"[Mesh] OR Sleep/therapy [Mesh] OR "lifestyle intervention*"[tiab] OR "behavioural intervention*"[tiab] OR "behavioural therap*"[tiab] OR "dietary intervention*"[tiab] OR "physical therap*"[tiab] OR sleep[tiab] AND Child [Mesh] OR Children[tiab] OR child[tiab] AND Constipation [Mesh] OR Constipation*[tiab]

Embase

'Healthy Lifestyle'/exp OR 'Healthy Lifestyle/therapy'/exp OR 'Behavior Therapy'/exp OR 'Diet Therapy'/exp OR 'Sleep/therapy'/exp OR "lifestyle intervention*"ti,ab OR "behavioural intervention*":ti,ab OR "behavioural therap*":ti,ab OR "dietary intervention*":ti,ab OR "physical therap*":ti,ab OR sleep:ti,ab AND 'Child'/exp OR Children:ti,ab OR child:ti,ab AND 'Constipation'/exp OR Constipation*:ti,ab

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