Supplementary Material 6

Evidence of effectiveness - Level 1 synthesis – Additional tables

Table 1: Characteristics of excluded studies

STUDY	REASON FOR EXCLUSION
Systematic reviews judged to be at high/unclear risk of bias or to overlap with a more up-to-date or comprehensive systematic review (n=13)	
Ahmed 2012 [1]	Intervention addressed: Laxatives ROB assessment: High ROB Reason for exclusion: Not low ROB
Candy 2009 [2]	Intervention addressed: Laxatives ROB assessment: High ROB Reason for exclusion: Not low ROB
Chen 2014 [3]	Intervention addressed: Laxatives ROB assessment: Low ROB Reason for exclusion: superseded by more up to date / comprehensive review
Dziechciarz 2015 [4]	Intervention addressed: Laxatives ROB assessment: Low ROB Reason for exclusion: superseded by more up to date / comprehensive review
Han 2017 [5]	Intervention addressed: Fibre ROB assessment: Low ROB Reason for exclusion: Piccoli 2017 (see level 0) more comprehensive & up-to-date
Horn 2012 [6]	Intervention addressed: Laxatives ROB assessment: High ROB Reason for exclusion: Not low ROB
Kateralis 2016 [7]	Intervention addressed: Laxatives ROB assessment: Unclear ROB Reason for exclusion: Not low ROB
Lee-Robichaud 2010 [8]	Intervention addressed: Laxatives ROB assessment: Low ROB Reason for exclusion: superseded by more up to date / comprehensive review
Minguez 2016 [9]	Intervention addressed: Laxatives ROB assessment: High ROB Reason for exclusion: Not low ROB
Pijpers 2009 [10]	Intervention addressed: Fibre / laxatives

	ROB assessment: Low ROB Reason for exclusion: Superseded by Piccoli 2017 (see level 0) / Superseded by Gordon 2016 - More comprehensive, high quality and up to date
Price 2001 [11]	Intervention addressed: Laxatives ROB assessment: Low ROB Reason for exclusion: superseded by more up to date / comprehensive review
Tabbers 2011b [12]	Intervention addressed: Non pharmacological ROB assessment: High ROB Reason for exclusion: Not low ROB
Thomas 2013 [13]	Intervention addressed: Laxatives ROB assessment: Unclear ROB Reason for exclusion: Not low ROB
Studies judged not to meet inclusion criteria (n=50)	
Strisciuglio 2021 [14] EUCTR2015-005111-32-IT NCT02751411	Intervention is considered part of specialist / secondary care services. Study (now published) included in Level 2 synthesis. Linked to two clinical trial register entries.
Aboumarzouk 2011 [15]	Systematic review of prokinetic agent (Cisapride). Cisapride has been withdrawn. Discussion with stakeholder group led to consensus that we should not update evidence relating to this intervention
Acharyya 2018 [16]	Focus is laxatives
Akca 2015 [17]	Focus is on mechanism of action of drugs
Akhavan 2019 IRCT20190722044310N [18]	Aim: To compare Quchi point massage therapy with standard treatment in children with functional constipation Study moved to 'Complementary' synthesis.
Benninga 2005 ISRCTN99089299 [19]	Study not conducted
Benninga 2006 ISRCTN71579145 [20]	Study not conducted
Boles 2012 [21]	Focus is laxatives
Borowitz 2002 [22]	Intervention is considered part of specialist / secondary care services. Study included in Level 2 synthesis.
Brazzelli 2011 [23]	Aim: To summarise systematically evidence from all relevant randomised controlled trials on the effects of behavioural

	(including biofeedback training) and cognitive therapies with or without other treatments for the management of children defaecation disorders. Moved to synthesis on psychosocial / behavioural interventions.
Campeotto 2020 [24, 25]	Aim: To estimate the frequency of functional gastrointestinal disorders (FGIDs) in infants aged up to 12 months according to the new ROME IV criteria defining these disorders, and to describe the management of FGIDs in France. This observational study does not explore effectiveness of interventions.
Carmo 2015 [26]	Colon transit study – not relevant
Chase 2011 [27]	Aim: The primary aim of this systematic review was to establish the efficacy of non-pharmacological, non-surgical and non-behavioural treatments of functional chronic constipation in children. A secondary aim was to identify any of nonpharmacological, non-surgical and non-behavioural treatments of functional chronic constipation, used either alone or in combination with pharmacological, surgical and behavioural interventions. The studies included in this review focussed on interventions that were alternative therapies, or interventions delivered by health professionals; therefore not relevant to this question/systematic review (included under other syntheses).
Clarke 2009a [28]	Intervention is considered part of specialist / secondary care services. Study considered for Level 2 synthesis (but excluded because it was already included in a systematic review included in Level 2 synthesis).
El-Shabrawi 2018 [29]	Cohort study, exploring combined programmes. Does not report any prioritised outcomes.
Evans 2007 [30]	Aim: To evaluate the efficacy and tolerability of tegaserod for the treatment of IBS and chronic constipation in adults and adolescents aged 12 years and above. No included trials had a population of children with constipation.
Feng 2014 NCT02255747[31]	Intervention is considered part of specialist / secondary care services. Study included in Level 2 synthesis.
Festekjian 2013 NCT01823848 [32]	Randomized control trial of the three types of pediatric enemas readily used in our ED to determine the best approach. Recruitment terminated due to insufficient staff. Unable to find published results.
Foster 2019 [33]	Describes a guideline which is no longer available
Freeman 2014 [34]	Aim: To synthesize the effects of behavioral treatment of fecal incontinence with constipation in children aged 4–18 years. Moved to synthesis on psychosocial / behavioural interventions.
Guest 2006 [35]	Focus is on disimpaction not treatment of constipation
Heemskerk 2018 [65] NCT02961582	Intervention is considered part of specialist / secondary care services. Study moved to Level 3 synthesis.
Herguner 2012 [36]	Letter to the editor (not a study)
Kasiri 2019 [37]	Not a randomised study
Ladi Seyedian 2014 [38]	Aim: To combine functional pelvic floor muscle training exercises with Swiss ball exercises, with a behavioral urotherapy program, and compare treatment outcomes of this combination in the management of children with dysfunctional voiding. This study is focussed on urinary tract problems and urine voiding, and not constipation.
Mahon 2017 [39]	Aim: To estimate the cost of FGIDs and related signs and symptoms in infants to the third party payer and to parents.

	Focus is on cost and not on intervention effectiveness.
Maruit Madhale 2018 [40] CTRI/2018/08/015415	Intervention is considered part of specialist / secondary care services. Study included in Level 2 synthesis.
Masnata 2017 [41]	Cohort study, reported as abstract only, exploring combined programme. Does not report any prioritised outcomes. Mixed population of children with urinary tract symptoms.
McMaster Uni 2018 NCT03593252 [42]	Intervention is considered highly specialist. Study moved to Level 3 synthesis.
Molina 2018 [43]	Does not explore effectiveness of interventions.
Muddasani 2017 [44]	Not focussed on constipation
Nader 2016 [45]	Intervention is considered part of specialist / secondary care services. Study included in Level 2 synthesis.
Ntr4797 2014 [46]	Intervention is considered part of specialist / secondary care services. Study included in Level 2 synthesis (this is the protocol for Van Summeren 2020).
Orhan 2018 [47]	Intervention is considered part of specialist / secondary care services. Study included in Level 2 synthesis.
Ormarsson 2016 [48]	Intervention is considered part of specialist / secondary care services. Study included in Level 2 synthesis.
Ostaszkiewicz 2005B [49]	Aim: To evaluate the relationship between constipation or faecal impaction and urinary incontinence (UI) and other lower urinary tract symptoms (LUTS). Focus is on relationship between symptoms and not on intervention effectiveness.
Pare 2014 [50]	Aim: To review relevant research evidence from clinical studies investigating the efficacy and safety of commercially available pharmacological laxatives in Canada. Combines trials with adult and child populations, but does not present data for children separately.
Penuelas Calvo 2016 [51]	Single case study
Prynn 2011 [52]	Not an intervention study
Satish Joshi 2019 CTRI/2019/06/019596 [53]	Intervention is considered part of specialist / secondary care services. Study included in Level 2 synthesis.
Silverman 2013 (abstract only) [54]	Aim: To evaluate the prevalence of fecal incontinence in children with functional constipation defined by Rome III criteria and to compare the current management practices for the two conditions. This study describes current treatment practices, but does not explore effectiveness of interventions.
Sood 2017 [55]	Aim: To identify gaps and unmet medical and educational needs in paediatric functional constipation. Overview of any intervention for constipation; not specifically focussed on evidence of effectiveness. (Abstract only)
Tabbers 2010 [56]	Aim: What are the effects of treatments for children with chronic constipation? What are the effects of treatments for

	clearing the bowel in children with faecal impaction? Focus is on specialist services; therefore not relevant to this question / systematic review.
Okumura 2018 [57]	Aim: To compare the efficacy of linaclotide with other medications for chronic constipation, including functional constipation, irritable bowel syndrome with constipation, and opioid-induced constipation, by conducting a systematic literature review and network meta-analysis. No clear if trials with children were included or not. Analysis does not present separate data focussed on children. (Poster)
Torres 2015 [58]	Not an intervention study
van der Plas 1996 [59]	Intervention is considered part of specialist / secondary care services. Study included in Level 2 synthesis.
Van Schaick, 2016	Summarises two studies which are already included
Van Summeren 2020 [60]	Intervention is considered part of specialist / secondary care services. Study included in Level 2 synthesis.
Van Summeren 2019 [61]	Intervention is considered part of specialist / secondary care services. Study included in Level 2 synthesis (this is a duplicate of van Summeren 2020).
NCT04282551 [62]	Intervention is considered an everyday life intervention. Study included in Level 0 synthesis (as Belzer 2020).

Table 2: Characteristics of ongoing studies

Study	Aim	Study design	Anticipated completion date
Systematic reviews (n=1)			
Rezaie 2012 [63]	To assess the efficacy and safety of prucalopride for the treatment of chronic constipation.	Systematic review (Cochrane)	Unknown
RCTs (n=10)			
NCT04110145 (2019) [64] This trial is also linked to a EudraCT Number: 2019-002126-75	To evaluate the dose response, safety, and efficacy of linaclotide when compared with placebo in pediatric participants, 2 to 5 years of age, with Functional Constipation.	RCT	Actual Study Completion Date: April 20, 2021. Results posted on the clinical trials website: 26/4/2022. No full publication found, so unable to conduct methodological assessment (leave as ongoing).
Kasiri 2015 IRCT2013120415530N3 (2015) [65]	Comparison of two treatment regimens of powders and syrup of polyethylene glycol 40% in the treatment of chronic functional constipation in children under 15 years	RCT	Study on-going. No data is reported that is linked to this trial to date.
NCT04026113 [66]	To evaluate the safety, tolerability and efficacy of 12 weeks of linaclotide therapy in comparison with placebo in pediatric participants aged 6 to 17 years who fulfill modified Rome III Criteria for Child/Adolescent.	RCT	Estimated Study Completion Date: December 14, 2022
NCT04166058 [67]	Study of Oral Linaclotide Administered to Pediatric Participants With Functional Constipation (FC) or Irritable Bowel Syndrome With Constipation (IBS-C)	RCT	Estimated Study Completion Date: December 14, 2023
Emtyazi 2018 IRCT20180910040992N [68]	The Efficacy Of Rosa Damascena Mill On Children Constipation	RCT	Reported as completed. No publication found.
Jagadisian 2018 [69]	Trial of combination of polyethylene glycol with or without sodium picosulphate for treatment of constipation in children	RCT	Children 1-12 years who meet ROME IV criteria. Reported as completed 5/11/2019. No publication found.

Jordan-Ely 2016 ACTRN12616000561482[70]	Healthy Poos in ED - The efficacy of different sets of instructions for Polyethylene glycol and electrolytes administration for the treatment of constipation in children presenting to the emergency department	RCT	Targeting children aged 4-18 years who meet ROME III criteria Clinical trial entry reports this as currently recruiting.
NCT02961556 [71]	General clinical study of AJG555 in Pediatric patients with Chronic Constipation	Non-RCT (Single arm primary study)	Reported as completed. No results reported on the clinical trials website: date of last clinical trial update is. 24/10/2017. No publication found.
NCT03120520 [72]	An Efficacy and Safety Study of Plecanatide in Adolescents 12 to <18 Years of Age with Chronic Idiopathic Constipation	RCT	Reported as completed. Results posted on the clinical trials website: 19/9/2019. Adolescents aged between 12-< 18 years Compared Plecanatide (various doses: 0.5mg, 1.0 mg, 1.5 mg) to Placebo control. No full publication found, so unable to conduct methodological assessment (leave as ongoing).
Weissman 2015 NCT02559570 [73]	A Safety and Efficacy Study of a Range of Linaclotide Doses Administered Orally to Children Ages 6-17 Years Who Fulfill Modified Rome III Criteria for Child/Adolescent Functional Constipation (FC)	RCT	Reported as completed. Results posted on the clinical trials website: 14/05/2019. Target: 173 children aged 6-17 years; Compared range of Linaclotide doses (9 ug or 18 ug; 18 ug or 36 ug; 36 ug or 72 ug; 145 µg) with placebo control. No full publication found, so unable to conduct methodological assessment (leave as ongoing).

Table 3: Studies awaiting assessment for inclusion in Level 1 synthesis

Study (n=3)	**Reason still awaiting assessment**
Borowitz 2005 [74]	Unable to access interlibrary loan
Kasiri 2019 (IRCT20190717044239N1) [75]	Unable to confirm study design: methods state "nonrandomised" and "randomised".
TX152643 [76]	Refers to a study – unable to find.

Table 4: Risk of bias judgements for included systematic reviews, using ROBIS tool

	Domain 1: concerns regarding specification of study eligibility criteria	**Domain 2: Concerns regarding methods used to identify and/or select studies**	**Domain 3: Concerns regarding methods used to collect data and appraise studies**	**Domain 4: Concerns regarding the synthesis and findings**	**Overall risk of bias in the review**
Gordon 2016 [77]	LOW risk	LOW risk	LOW risk	LOW risk	LOW risk
Rachel 2020 [78]	UNCLEAR risk	LOW risk	UNCLEAR risk	LOW risk	LOW risk

Table 5: Risk of bias judgements for included RCTs, using Cochrane ROB1 tool

Study (n=13)	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Selective reporting (reporting bias)
Bekkali 2018 [79]	LOW risk	LOW risk	LOW risk	LOW risk	LOW risk
Benninga 2022 [80] NCT02042183	LOW risk	LOW risk	LOW risk	LOW risk	LOW risk
Benninga 2022 [80] NCT02138136	LOW risk	LOW risk	LOW risk	LOW risk	LOW risk
Cao 2018 [81]	LOW risk	LOW risk	LOW risk	LOW risk	LOW risk
Esmaeilidooki 2016 [82]	LOW risk	UNCLEAR risk	HIGH risk	HIGH risk	UNCLEAR risk
Hashemi 2015 [83]	UNCLEAR risk	UNCLEAR risk	LOW risk	LOW risk	UNCLEAR risk
Imanieh 2019 [84]	UNCLEAR risk	UNCLEAR risk	UNCLEAR risk	HIGH risk	UNCLEAR risk
Jarzebicka 2019 [85]	LOW risk	LOW risk	HIGH risk	HIGH risk	UNCLEAR risk
Lomas Mevers 2020 [86]	LOW risk	LOW risk	HIGH risk	HIGH risk	UNCLEAR risk
Modin 2018 [87]	LOW risk	LOW risk	LOW risk	LOW risk	LOW risk
Pranoto 2016 [88]	LOW risk	UNCLEAR risk	HIGH risk	UNCLEAR risk	HIGH risk
Shatnawi 2019 [89]	UNCLEAR risk	UNCLEAR risk	UNCLEAR risk	UNCLEAR risk	HIGH risk

Torabi 2017 [90]	UNCLEAR risk	UNCLEAR risk	LOW risk	LOW risk	UNCLEAR risk

Table 6: Risk of bias judgements for cohort studies, using CASP tool for cohort Studies

Study (n=6)	Did the study address a clearly focused issue?	Was the cohort recruited in an acceptable way?	Was the exposure accurately measured to minimise bias?	Was the outcome accurately measured to minimise bias?	Have the authors identified all important confounding factors?	Have they taken account of the confounding factors in the design and/or analysis?	Was the follow up of subjects complete enough?	Was the follow up of subjects long enough?	Do you believe the results?	Can the results be applied to the population of interest?	OVERALL ASSESSMENT
Axelrod 2016 [91]	No	Can't tell	Yes	Can't tell	Can't tell	No	Yes	Yes	Yes	Yes	Serious concerns
Farahmand 2015 [92]	Yes	Yes	Can't tell	Yes	Can't tell	Can't tell	Yes	Yes	Yes	Yes	Minor concerns
Hankinson 2018 [93]	Yes	Yes	Can't tell	No	Can't tell	Can't tell	No	Yes	Yes	Yes	Moderate concerns
Soares 2009 [94]	Yes	Can't tell	Can't tell	Can't tell	Can't tell	Can't tell	Yes	Yes	Yes	Yes	Moderate concerns
Jordan-Ely 2013 [95]	Can't tell	Can't tell	Can't tell	Can't tell	Can't tell	Can't tell	Can't tell	Can't tell	Can't tell	Can't tell	Serious concerns
Speridiao 2003 [96]	yes	Can't tell	Can't tell	Can't tell	Can't tell	Can't tell	No	Yes	Yes	Yes	Moderate concerns

Table 7: Outcomes reported in Included Studies

Study	Outcomes Addressed								
	Painful defecation	QOL	Frequency	Consistency	Side Effects	Faecal Incontinence	Abdominal pain	School Attendance	Other
Axelrod 2016 [91]			x			x			Successful self-initiated bowel movements in the toilet
Bekkali 2018 [79]	x		x	x	x	x	x		Calculated a total sum score based on five constipation-related symptoms, dose range determination (based on number of sachets/day), proportion of subjects with treatment success defined as (defined as a defecation frequency >3 times per week and <1 episodes of faecal incontinence per week), defecation frequency, stool consistency (hard, normal, soft, or watery), duration of treatment (i.e., number of days from inclusion to the date of last intake of study medication) and safety evaluation.
Benninga 2022 [80] (reports 2 studies)	x		x	x	x	x	x		Occurrence of spontaneous bowel movements (in or not in toilet), associated straining, treatment effectiveness, large diameter stools, retentive posturing. Safety evaluation.
Cao 2018 [81]			x	x	x		x		Flatulence.
Esmaeilidooki 2016 [82]	x		x	x	x	x			Recovery rate defined as rate of 'total exited cases from the criteria of CFC in each arm', retentive posturing, safety and compliance.
Farahmand 2015 [92]	x		x	x		x			Overall improvement in constipation'; stool withholding
Hankinson 2015 [93]	x						x		Multidisciplinary Chronic Constipation Questionnaire; Pediatric Incontinence/Constipation Score
Hashemi 2015 [83]									Limited details available (English abstract only). Report treatment success rates but no description is available.
Imanieh 2019[84]	x		x	x		x			Satisfactory outcome was defined as defecation > two times weekly, soft stool and no pain on defecation, no palpation of hard stool on abdominal examination, no faecal incontinence, not

Study	Outcomes Addressed								
	Painful defecation	QOL	Frequency	Consistency	Side Effects	Faecal Incontinence	Abdominal pain	School Attendance	Other
									palpating hard and large stool on rectal examination, and no blood in stool.
Jarzebicka 2019 [85]	x		x	x	x	x	x		Daily diary, lack of clinical improvement.
Jordan-Ely 2013 [95]			x	x		x			
Lomas Mevers 2020 [86]						x			Constipation improvement (CGI-I); fidelity measures
Modin 2018 [87]			x		x	x	x		Number of successfully treated children defined as the absence of any ROME III criteria (with or without use of medication), number of children who needed rescue medication, time on study medication, use of study medication, whether parents believed their children had received PEG or placebo as study medication. Safety evaluation.
Pranoto 2016 [88]			x						Recovery of constipation was defined as an increase in defecation to more than 3 times/ week. Recurrence of constipation defined to be defecation frequency returning to less than two times/week after a period of recovery.
Shatnawi 2019 [89]					x				Demographics, day of disimpaction, possible adverse events, parents/ child satisfaction, compliance and acceptability.
Soares 2009 [94]	x		x			x	x		Fear; colonic transit times.
Speridiao 2003 [96]	x		x			x			Difficulty evacuating; bleeding on evacuation; anthropometric data; dietary data
Torabi 2017 [90]	x		x	x		x	x		Rectal bleeding, treatment success defined as three or more painless defecations per week with a soft or normal consistency.

Table 8: Studies addressing questions relating to Level 1 of the pyramid

Main heading	**Pharmacological**		**Lifestyle**	**Combined**
Sub-heading	**Laxatives**		**Physical exercise**	**Pharmacological + Lifestyle + Information + Psychosocial**
Question addressed	***What are the effects of laxatives***	***What are the effects of laxatives plus domperidone?***	***What is the effect of physical exercise (focused on pelvic floor muscles)?***	***What is the effect of a combined pharmacological, diet and behavioural program?***
Systematic reviews (n=1)	***Gordon 2016*** [77] ***Rachel 2020*** [78]			
RCTs to be added to systematic review (n=10)	Bekkali 2018 [79] Benninga 2022 [80], Cao 2018 [81], Esmaeilidooki 2016 [82], Hashemi 2015 [83], Jarzebicka 2019 [85], Modin 2018 [87], Pranoto 2016 [88], Shatnawi 2019 [89], Torabi 2017 [90]			
RCTs (n=3)		Imanieh 2019 [84]		Lomas Mevers 2020 [86]
Other primary studies (			Farahmand 2015 [92]	Axelrod 2016 [91] Hankinson 2018 [93] Soares 2009 [94] Jordan-Ely 2013 [95]* Speridiao 2003 [96]

* - published abstract only. Red = high ROB (serious concerns), Amber = Moderate ROB (moderate concerns), Green = Low ROB (no or minor concerns), RCT=Randomized controlled trial.

Table 9: Judgement of certainty in evidence and summary of findings relating to each research question

Question	Studies	Limitations	Inconsistency	Indirectness	Imprecision	Publication bias	Judgement of certainty in evidence	Summary of findings
What are the effects of laxatives?	Gordon 2016 [77], Modin 2018 [87] Jarzebicka 2019 [85] Shatnawi 2019[89] Torabi 2017 [90] Bekkali 2018 [79] Cao 2018 [81] Pranoto 2016 [88] Hashemi 2015 [83] Benninga 2022 [80] Rachel 2020 [78]	**See narrative synthesis for comparisons**					**Low – very low**	
What are the effects of laxatives plus motilium?	<u>RCTs:</u> Imanieh 2019 [84]	Downgrade once as studies had high/unclear ROB; downgrade once as only 52	No downgrade – consistent findings (only one study)	No downgrade – single study focussed on children with cerebral palsy	Downgrade once – lack of results data presented	Downgrade once – unclear if all measured outcomes are reported.	VERY LOW	There is some limited evidence that the combination of PEG plus motilium may be more beneficial than PEG only in

		participants						children with cerebral palsy. There is no presented data on side effects, but concerns have been reported for this drug in other populations. Note: MHRA advise against use of motilium in children under 16 years, due to serious side effects.
What is the effect of physical exercise (focused on pelvic floor muscles)?	Cohort study: Farahmand 2015 [92]	Downgrade onces as only one study (44 participants-	No downgrade – consistent findings (only one study)	No downgrade	Downgrade once – lack of results data presented	No downgrade	LOW	There is low certainty that physical exercise (focussed on pelvic floor muscles) may improve overall symptoms, defecation frequency and stool consistency. Further research to investigate the effect of physical exercise is warranted.
What is the effect of a combined	Lomas Mevers 2020 [86] Axelrod 2016	Downgrade once as all studies had	No downgrade – consistent findings across	Downgrade once – Some	Downgrade once – uncertainty	Downgrade once – unclear if all	VERY LOW	There is some very limited data which suggests

pharmacological, diet and behavioural program?	[91] Hankinson 2015 [93], Soares 2009 [94], Jordan-Ely 2013 [95], Speridiao 2003 [96]	high/unclear ROB;	studies	differences in populations studies, and some information on participant inclusion is unclear	around methods of collecting data, and no prioritised outcomes from some studies	measured outcomes are reported.		that a combined pharmacological, dietary and behavioural program may have some benefits. We have very low certainty in this finding due to the quantity and quality of available studies.

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