Supplementary Material 4

Evidence of effectiveness – service delivery synthesis – Additional tables

Table 1: Characteristics of Excluded Studies

Study (n=24)	Aim	Reason for exclusion
Banoub 2019 [1]	To audit practice relating to management of feeding and swallowing problems, including constipation	Focus is on children with additional needs. Abstract only. Does not report any prioritized outcomes.
Burgers 2012 [2]	To investigate the approach to childhood constipation by primary care physicians in three Western countries.	The aim of the study was to describe the approaches, rather than explore the effectiveness.
Call 2017 [3]	To evaluate a combined behavioural and medical regimen to treat encopresis in three participants with developmental disabilities.	The "behavioural and medical" regimen is not a "model of care", but rather an intense toilet training intervention.
Garman 2012 [4]	To define encopresis and discuss its etiology, diagnosis and treatment, and describe the role of the school nurse.	Systematic review; judged to be at high risk of bias.
Gulati 2017 [5]	A unique paediatric gastroenterology-primary care childhood constipation collaborative for development of a constipation tool kit to enhance detection and standardize management of constipation in children in the ambulatory pediatric department of an inner-city hospital	Study is a survey of delivered interventions; no focus on effectiveness
Kilpatrick 2020 [6]	To explore success rates of a bowel management program.	Investigated a "bowel management week". Does not report any prioritized outcomes.
Malamisura 2018 [7]	To determine incidence of children presenting at emergency department with functional constipation and describe presentation.	Abstract only. Does not report any prioritized outcomes.
Mosca 2013 [8]	To summarise typical causes for functional encopresis and support development of an individualized healthcare plan.	Systematic review; judged to be at high risk of bias.
Moser 2014 [9]	To stimulate the development of integrated behavioural health services that reflect biopsychosocial models of health using a paediatric gastroenterology (GI) service as a model	Describes a paediatric psychology service which is part of the multidisciplinary care of children with gastrointestinal problems, including some with CFC. Numbers of children with CFC unclear. No prioritized outcomes reported.
Peck 2017 [10]	To create an expert care team consisting of a paediatric nurse practitioner, a paediatric psychologist and gastroenterologist to provide consistent medical management, emotional support and behavioural therapy to promote adherence.	Abstract only. Does not report any prioritized outcomes.

Perez 2014 [11]	Aim not stated. Paper describes causes of continence problems in children, and role of the community practitioner.	Narrative review / Judged to be at high risk of bias.
Poo Passport 2016 [12]	To identify a standardised assessment tool that can be used to diagnose and treat children with idiopathic constipation, without the need for referral to secondary care	Intervention development study. Does not report any prioritized outcomes.
Protheroe 2004 [13]	To assess the effect of the introduction of a primary care-based intervention for children with constipation compared to conventional hospital based management.	This is a protocol for a RCT. Anticipated completion date is stated as 2004. We have been unable to find a published completed RCT. Editorial notes to trials database in 2016 confirm that no publication has been found.
Puoti 2019 [14]	To explore a multidisciplinary approach to chronic refractory constipation, within a 'Lower Gastrointestinal Dysmobility Clinic'. To identify psychosocial factors and the need for further interventions	Abstract only. Does not report any prioritized outcomes.
Prynn 2011 [15]	In this article: causes of idiopathic constipation, diagnosing the condition, different therapies to manage idiopathic constipation, the importance of follow-up.	This article does not report a primary study, and cannot be considered a literature review as no references are provided.
Raghu 2019 [16]	To collect baseline data on the management of constipation at our hospital, use data to develop a clinical pathway for constipation management, and assess the pathway's effect on utilization of hospital services, readmission rate, and length of stay	Non comparative study of practice in ED. Abstract only. Does not report any prioritized outcomes.
Rogers 2012 [17]	To discuss new model of care for pediatric continence problems.	Intervention development study. Does not report any prioritized outcomes.
Russell 2015 [18]	To assess the effectiveness of a structured bowel management program in children with a diagnosis of idiopathic constipation	Studied an intensive week of tailored bowel management programme for children with CFC. No prioritized outcomes reported.
Sanders 2014 [19]	To explore the experiences and views of professionals' and parents' using trans-anal irrigation with children.	This is a qualitative study, and not focussed on effectiveness.
Sandweiss 2018 [20]	To develop a standardized approach, emphasizing clinical history, physical examination, less reliance on AR and home management.	Non comparative study. Does not report any prioritized outcomes.
Shabde 2016 [21]	To share the Cumbrian experience of the development of a child centred constipation pathway, based on NICE guidance which has	Intervention development study. Abstract only. Does not report any prioritized outcomes.

	been used to empower and support families and professionals to ensure best outcomes for children in a community setting.	
Trinkley 2015 [22]	To identify patterns in pharmacologic and non-pharmacologic treatment of constipation and associations between treatment and other variables across age groups	This retrospective study reports treatment prescription for people (including children) with constipation. Treatment outcomes are not reported, so there is no focus on effectiveness.
Webster 2018 [23]	The goal of this quality improvement project is to decrease referrals from the primary care network to pediatric gastroenterology for functional constipation.	Survey. Abstract only. Does not report any prioritized outcomes.
Wolfe 2019 [24]	Investigation of a health partnership aimed at reducing numbers of children attending accident and emergency.	Focus on reduction at ED for a number of conditions including constipation. Abstract only. Does not report any prioritized outcomes.

Study (n=4)	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)

Table 2: Characteristics of ongoing Studies

Study (n=4)	**Aim**	**Study design**	**Anticipated completion date**
Bennett 2015 [25] NCT02354820	To explore the effectiveness of Computer Automation of Constipation Management in Primary Care	RCT	2017 No publication identified
Feng 2013 [26] PROSPERO 2013 CRD42013003765	To conduct a systematic review of RCTs to explore whether specialist nursing interventions improve the care and management of patients with chronic constipation	Systematic review	2013. No publication identified.
Gordon 2014 [27]	To evaluate PEBBLES: A family-centred, community-based continence service improving bladder and bowel health in children with disabilities in Western Australia	Non comparative study	Not stated
Huang 2018 [28] PROSPERO 2018 CRD42018106589	To explore effectiveness of nurse-led interventions with or without other treatments for the management of functional constipation in children and adolescents	Systematic review of RCTs	2018 No publication identified

Table 3: Risk of bias judgements for included RCTs, using Cochrane ROB1 tool

Burnett 2004 [29]	LOW risk	LOW risk	HIGH risk	HIGH risk	UNCLEAR risk
Faramarzian 2018 [30]	HIGH risk	HIGH risk	HIGH risk	HIGH risk	HIGH risk
Karagiozoglou-Lampoudi 2012 [31]	UNCLEAR risk	UNCLEAR risk	UNCLEAR risk	HIGH risk	UNCLEAR risk
Modin 2016 [32]	LOW risk	LOW risk	HIGH risk	HIGH risk	LOW risk

Table 4: 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
Costigan 2019 [33]	Can't tell	Yes	No	Can't tell	No	No	Can't tell	Can't tell	Can't tell	No	Serious concerns
Gabr 2020 [34]	Yes	Yes	No	Yes	Can't tell	Can't tell	Can't tell	Yes	Yes	Yes	Minor concerns
Gonring 2019 [35]	Yes	Yes	Yes	Yes	Can't tell	Can't tell	No	Yes	Yes	Yes	Minor concerns
Mallon 2015 [36]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No or very minor concerns
Norbedo 2017 [37]	Yes	Yes	Can't tell	Can't tell	Can't tell	Can't tell	Yes	Yes	Can't tell	No	Moderate concerns
Short 2018 [38]	Yes	Yes	Yes	Can't tell	Yes	Yes	Yes	Yes	Yes	No	Moderate concerns

Table 5: Risk of bias judgements of studies with other designs, using WEIRD tool

Study (n=6)	Is there a clearly stated aim, objective or purpose for the source material?	Is there a clear description of the source of the information reported (transparency)?	Is there a clear description of the programme or intervention or policy or reform on which the source material focuses?	Is there a clear description of the context/s to which the information described in the source material relates?	Is the information accurate (source materials other than empirical studies)?	Is the information accurate (empirical studies only)?	Is the evidence representative?	Are any limitations of the information and / or methods discussed in the source material?	Is evidence provided to support any findings or conclusions made?	Are relevant rights and ethics considerations described?	Are any interests declared and any potential conflicts of interest noted?	Overall Assessment
Non-comparative studies												
Athanasakos, 2020 [39]	Yes	Yes	Yes	Yes		Yes	Yes	Unclear	Yes	Yes	Yes	No or very minor concerns
Bellesheim 2018 [40]	Yes	Yes	Yes	Yes		Unclear	Yes	Yes	Yes	No	Yes	No or very minor concerns
Ismail 2011 [41]	Yes	Yes	Yes	Yes		Unclear	Unclear	Yes	Yes	Yes	Unclear	Minor concerns
Poenaru 1997 [42]	Yes	Unclear	Unclear	Unclear		Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Serious concerns
Tappin 2013 [43]	Yes	Yes	Yes	Yes		Yes	Yes	Unclear	Yes	No	Yes	No or very minor concerns

Table 6: Outcomes reported in Included Studies

Study (n=15)	Outcomes Addressed								
	Painful defecation	QOL	Frequency	Consistency	Side Effects	Faecal Incontinence	Abdominal pain	School Attendance	Other
Athanasakos, 2020 [39]		x				x			Patient improvement scores in terms of severity of their condition (physical and emoti
Bellesheim 2018 [40]	x*		x*				x*		Constipation improvement rate. Duration to improvement.
Burnett 2004 [29]			x*	x*		x*			Time to "cure"
Costigan 2019 [33]						x			Use of washout systems
Faramarzian 2018 [30]	x		x						"scores on constipation" (from bowel diaries – Improvement.
Gabr 2020 [34]		x				x			
Gonring 2019 [35]				x		x			Number completing treatment programme. Investigations performed and intervention delivered.
Ismail 2011 [41]	x		x	x		x			Using toilet willingly, difficulty sleeping, general health, parent understanding, Parent satisfaction, laxative dose
Karagiozoglou -Lampoudi 2012 [31]									Diet composition, weight-for-age
Mallon 2015 [36]						x	x		Rate of referral. Impact on disease severity, and pre-referral management of children r to GI subspecialists for constipation.
Modin 2016 [32]						x			Primary: number of successfully treated children after 3, 6, and 12 months defined a presence of <2 Rome III criteria with or without the use of laxatives. Rectal impaction

Study (n=15)	Outcomes Addressed								
	Painful defecation	QOL	Frequency	Consistency	Side Effects	Faecal Incontinence	Abdominal pain	School Attendance	Other
									and 12 months Extra contacts. Use of laxatives
Norbedo 2017 [37]							x		Interventions delivered; readmission.
Poenaru 1997 [42]			x	x		x	x		Rectal pain, rectal bleeding
Short 2018 [38]					x				Number of ERP interventions received, length of stay (LOS),complications, and readm
Tappin 2013 [43]	x		x			x			Parent satisfaction with the service. Still taking medication at follow-up. Overall bette prior to first clinic visit. Withholding behaviour during the last week. Stool that blocke toilet in the last week.

X* = outcomes measured but results not provided.

Table 7: Studies addressing questions relating to service delivery

Level on Pyramid	Across all levels	Level 1	Level 2		Level 3
Question	**What is the effect of nurse led models of care as compared to alternative models of care?**	**What is the effect of a constipation care pathway / algorithm used in primary care / community settings?**	**What are the effects of, specialist (level 2) services and models of care?**	**What is the effect of different follow-up regimes following appointments with specialists?**	**What are the effects of highly specialist (level 3) services and models of care?**
RCT	Burnett 2004 [29] Faramarzian 2018 [30]		Karagiozoglou-Lampoudi 2012 [31]	Modin 2016 [32]	
Cohort study (retrospective)		Mallon 2015 [36] Norbedo 2017 [37]	Costigan 2019 [33] Gabr 2020 [34] Gonring 2019 [35]		Short 2018 [38]
Non-comparative study	Ismail 2011 [41] Tappin 2013 [43]	Bellesheim 2018 [40]	Athanasakos 2020 [39] Poenaru 1997 [42]		

* - 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 8: Judgement of certainty in evidence and summary of findings relating to each research question

Question	Relevant studies	Limitations	Inconsistency	Indirectness	Imprecision	Publication bias	Judgement of certainty in evidence	**Summary of findings**
What is the effect of nurse led models of care as compared to alternative models of care?	Burnett 2004 [29] Faramarzian 2018 [30] Ismail 2011 [41] Tappin 2013 [43]	Downgrade once – concerns about ROB of RCT evidence	Downgrade once – some inconsistencies in reported findings	Downgrade once – some variations in intervention and population between studies	Lack of results data	Downgrade once – not all measured outcomes are reported	VERY LOW	Nurse-led clinics are feasible and could result in equivalent (or possibly better) outcomes than traditional physician -led clinics.
What is the effect of a constipation care pathway/algorithm used in primary care/community settings?	Mallon 2015 [36] Bellesheim 2018 [40] Norbedo 2017 [37]	Downgrade once – limitations in study designs	No downgrade – consistent findings reported.	Downgrade once – variations in population and interventions.	Lack of results data.	Downgrade once – not all measured outcomes are reported	VERY LOW	There is very limited evidence that an algorithm, or care pathway, used in primary care settings to guide the management and referral of children with constipation (including children with ASD) may be beneficial. There is insufficient evidence on which to reach

								conclusions relating to care pathways within emergency departments.
What are the effects of specialist (level 2) services and models of care?	Karagiozoglou-Lampoudi 2012 [31] Costigan 2019 [33] Gabr 2020 [34] Gonring 2019 [35] Athanasakos 2020 [39] Poenaru 1997 [42]	Downgrade once – RCT is high ROB; other studies are observational	No downgrade – all studies report benefit of specialist services	Downgrade once – variations in population and interventions	Downgrade once - Lack of results data	No downgrade	VERY LOW	Consistent findings from studies with some limitations provides very low quality evidence that specialist services may have a beneficial impact on outcomes of children with chronic constipation, but further research is required.
What is the effect of different follow-up regimes following appointments with specialists?	Modin 2016 [32]	Downgrade once – RCT is judged to be high ROB for blinding	No downgrade	No downgrade	Downgrade once – only one study (n=235)	No downgrade	LOW	Access to web-based information may benefit recovery from constipation.
What are the effects of highly specialist (level 3) services and models of care?	Short 2018 [38].	Downgrade once – moderate concerns	No downgrade	Downgrade once – most patients did not have constipation	Downgrade once – only one study	No downgrade	VERY LOW	A recovery protocol may benefit outcomes following colorectal surgery. This evidence does not relate specifically to the

								population of children with functional constipation.

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