CHRONIC IDIOPATHIC CONSTIPATION IN CHILDREN GUIDELINE

Appendix J - EVIDENCE TABLES

Key Components of the History Taking and the Physical Examination in Children with chronic constipation

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
Borowitz et al.	Study type:	220 children	220 children	Test	Degree of difficulty with toilet	Additional information from study
Precipitants of	Case-control			History of events	training (mean \pm SD)	Constipation defined as passage of < 3
constipation		Inclusion	-Patients	occurring in the 3	(0=none, 4=extreme)	bowel movements each week for at
during early	Evidence	criteria:	n=125	months prior to		least 2 consecutive weeks
childhood.	level:	Aged 2y 0m to	mean age	onset of	Patients: 2.1±1.3	
2003. Journal of	111	6y 11m, at least	(months): 44±13	constipation:	Controls: 1.4±1.1	22 non-patient siblings matched as
the American		average	49% male		p<0.001	controls, an additional 73 non-sibling
Board of Family	Study aim:	intelligence		-large/painful		controls recruited from advertisements
Practice 16[3],	То		-Controls	bowel movement	Degree of difficulty passing	
213-218United	determine	 patients: First 	n=95	-toilet training	some bowel movements (%	Likert scale: 0 to 4. 0 being not at all
States.	the	time	mean age	-started day care	<u>children)</u>	difficult and 4 being extremely difficult
Borowitz, 2003	precipitants	presentation to	(months):	-travelling		
	to	physician with	46±18	-liquid to solid	None: patients 3, controls 49	Questionnaire for parents to fill out
	constipation	constipation	54% male	foods	Mild: patients 86, controls 49	describing children's bowel habits.
	in early			-breast to bottle	Moderate: patients 80,	- indication of how difficult toilet training
	childhood	- controls: no		-family move	controls 10	had been for bowel movements using
		history of	Country:	-vomiting	Extreme: patients 76, controls	Likert scale
		constipation	USA	/denydration	5	- parents to indicate if any of 18
		E	O a Win an	-new medication	- 0.001 (a stients as seven and	different events occurred in the 3
		EXCIUSION	Setting:	-parental	p<0.001 (patients as compared	months preceding the onset of
		<u>Criteria:</u>	26 primary care	separation	to controls in each category)	constipation, and which of these they
		Underlying	nacinities (15	-birth of a sibling	Degree of pain passing some	
		neulcal	fomily modicino	high fovor	beyond may amonte (% abildren)	consupation
		medication that	centres)	-nightievel	bower movements (% children)	Both arouns comparable regarding age
		could account	0011103/	-surgery	None: patients 5, controls 56	and sov
		for constination		rest -trauma in	Mild: patients 82 controls 40	

Bibliographic	Study type	Number of	Population Characteristics	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
mormation	level	prevalence	onaracteristics	standard		
		protaionoo		bathroom -sexual	Moderate: patients 69, controls	Reviewer comments
				abuse	8	Potential recall bias
				-family death	Severe: patients 67, controls 6	
				5		Source of funding:
				Reference	p<0.001 (patients as compared	NIH grant RO1HD 28160
				Standard	to controls in each category)	
				None		
					Children expressing worry	
					about passing bowel	
					movements (% children)	
					Patiants: 75	
					Controls: 8	
					p<.001	
					-Family history of constipation	
					and initial age of toilet training	
					no significantly different	
					between the 2 groups	
					-Subgroup analysis: children	
					arouped according to whether	
					they became constipated	
					before or after their second	
					birthday. The events parents	
					reported having occurred in the	
					3 months before the onset of	
					constipation were similar in the	
					two groups, with the exception	
					of toilet training having	
					occurred more often before	
					constipation in the older	
					children (40% vs. 20%), and	
					from broast to bottle and from	
					liquid to solid diste baying	
					occurred more often before	

Bibliographic Information	Study type & Evidence level	Number of patients & prevalence	Population Characteristics	Type of test and Reference standard	Sensitivity, Specificity, PPV and NPV	Reviewer comment
					constipation in the younger children (30% vs. 0). Large or painful bowel movements were seen by far the most frequent precipitating event for both age groups. Toilet training was seen as more of a precipitant for older onset children (20% vs. 10%), whereas transition from breast to bottle and from liquid to solid foods was seen to be more of a problem for younger-onset children (25% vs. 0)	

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
Ereedman et al	Study type:	238 patients	238 natients	Tosts	-Positive findings on history	Additional information from study
The crying	Retrospectiv	200 patients	200 patients	Abdominal	and/or physical examination	Patients presenting with chief complaint
infant:	e case	Inclusion	Males 124 (52%)	radiograph	alone suggested the final	of crying identified retrospectively by
Diagnostic	series	criteria:	Median age 2.3	ladiograph	diagnosis in 66.4% (158 of	searching electronic database using a
testing and		- less than 12	months (range 1.0	Abdominal	238) of the crying children	chief complaint family word root search
frequency of	Evidence	months age	to 5.4)	ultrasound	, , , , , , , , , , , , , , , , , , , ,	for: "cry", "irritable", "fuss", "scream" and
serious	level:	- afebrile			-11 cases of constipation were	"colic". Afebrile defined as < 38°C
underlying	111	 presenting to 	Country:	Reference	diagnosed, all diagnosed by	
disease. 2009.		ED during 9	Canada	Standard	category 1 data source –	37,549 ED visits during 9 month
Pediatrics	Study aim:	month eligibility		History taking and	positive history and physical	eligibility period, of which 238 children
123[3], 841-	То	period with chief	Setting:	physical	examination only	met inclusion criteria
848United	determine	complaint of	Tertiary care	examination		
States.	the	crying	referral hospital		Constipation defined as history	Patients and their final diagnoses
Freedman,	proportion of				of difficult, infrequent, hard	grouped into 1 - 4 categories according
2009	children	Exclusion			stools, palpation of small	to the sources of data that contributed
	evaluated in	criteria:			pellets on abdominal	the diagnosis
	an	Not stated			examination	Data source categories:
	emergency					1) Diagnosis was based on the history
	department				Abdominal radiograph –	(HX) and/or physical examination (PE)
	because of				performed 14 times with 0	alone
	crying who				positive indings	2) Diagnosis was based on positive test
	nave a				Abdominal ultropound	
	senous				Abdominal ultrasound –	2) Diagnasia was based on tests
	undenying				periorned to lines with	3) Diagnosis was based on tests
	aetiology				(12.5%) contributing only to the	from the Hy and/or PE that suggested a
					diagnosis of intussuscention	
					and acute cholocyctitic but not	(A) Noither Hy, DE per investigations
					constinution	were diagnostic
					consupation	
					-History and examination were	Required sample size calculated to
					found to be the most important	vield stable estimates (+5%) of the
					aspect in the evaluation of the	primary outcome measure (proportion
					crying infant. Investigations	of infants who had potentially serious
					only helpful in 3% of sample in	underlying aetiology). Estimated that
					this study	10% sample would have underlying
						serious aetiologies. Minimum sample of
						138 subjects required. Anticipated

Bibliographic Information	Study type & Evidence level	Number of patients & prevalence	Population Characteristics	Type of test and Reference standard	Sensitivity, Specificity, PPV and NPV	Reviewer comment
	level	prevalence		standard		follow-up telephone call response rate of only 75%. Final size after adjustment:: 245 <u>Reviewer comments</u> No data on follow up care of accuracy of constipation cases Minimum sample size required not achieved <u>Source of funding:</u>
						Not stated

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information		patients &	Characteristics	standard		
Lewis et al	Study type:	315 children	315 children:	Tests:	Clinical features in children	Additional information from study
Diagnosing	Retrospectiv			Rectal biopsy	with Hirschsprung's disease	Questionnaires, telephone interviews
Hirschsprung's	e cohort	Inclusion	-265 children who		and idiopathic constipation (IC.	and patients visits used to compile long-
disease:		criteria:	hade undergone		n=40)	term data. In reporting features listed in
increasing the	Evidence	-Cohort 1:	rectal biopsy			the questionnaire only patients with
odds of a	level:	Children			-Onset of constipation <1 year	definite information were included: the
positive rectal	III	presenting with	-50 children,		old	number of patients in each analysis
biopsy result.		constipation to	concurrent selected		Delayed passage of meconium	varies to exclude those with missing
2003. Journal of	Study aim:	diagnose	cohort (cohort 2)		(%)	data
Pediatric	To test the	Hirschsprung's			HD: 65	
Surgery 38[3],	hypothesis	disease (HD)	Country:		IC: 13	Delayed passage of meconium defined
412-416	that key		USA		P< 0.05	as failure to pass meconium in the first
Lewis et al.,	features in	-Cohort 2:				48h of life. These data were available in
2003	the history,	idiopathic			Abdominal distension (%)	59% of cases
	physical	constipation			HD: 80	
	examination				IC: 42	Abdominal distension determined from
	and	Exclusion			P< 0.05	parental response to questionnaire or
	radiographic	<u>criteria:</u>				data noted during patients visits
	evaluation	Patients			Vomiting (%)	Enterne elitic defined en dierrheese
	would allow	undergoing re-				Enterocolitis defined as diarmoea
		constinution			R = 0.05	
	roctal	offer pull			F< 0.03	Poviower comments:
	hionsies	through			Eaecal impaction requiring	Data on clinical features not available
	biopsies	procedure for			manual evacuation (%)	for all children
					HD: 6	
					IC: 30	Unclear what kind of rectal biopsy was
					P< 0.05	performed and how the diagnosis of HD
						was made
					Enterocolitis (%)	
					HD: 13	Source of funding:
					IC: 15	Not stated
					NS	
					-Onset of constipation >1 year	
					old	
					Delayed passage of meconium	
					(%)	

Bibliographic Information	Study type & Evidence level	Number of patients & prevalence	Population Characteristics	Type of test and Reference standard	Sensitivity, Specificity, PPV and NPV	Reviewer comment
					HD: 81 IC: 1 P< 0.05	
					Abdominal distension (%) HD: 53 IC: 7 P< 0.05	
					Vomiting (%) HD: 23 IC: 0 P< 0.05	
					Faecal impaction requiring manual evacuation (%) HD: 46 IC: 30 NS	
					Enterocolitis (%) HD: 13 IC: 14 NS	
					Age at onset of symptoms -Hirschsprung's (HD) (n=46) Mean: 8 months (range 1 day to 9 years) 1rst week of life: 60 % 1rst month of life: 70% 1rst year of life: 87% after 1 year of life: 13%	
					-Idiopathic constipation (IC) (n=40) Mean: 15 months (range 7 days to 16 years)	

Bibliographic Information	Study type & Evidence	Number of patients &	Population Characteristics	Type of test and Reference standard	Sensitivity, Specificity, PPV and NPV	Reviewer comment
					1rst week of life: 15% 1rst month of life: 55% 1rst year of life: 68% after 1 year of life: 32% At least 34% of HD patients had the classic triad (delayed passage of meconium + vomiting + abdominal distension). At least 1 feature of the triad noted in 98% of patients with HD. Only 60% of patients with IC had a history of delayed passage of meconium, vomiting or abdominal distension. 100 % HD patients vs. 64% IC patients had 1 or more of the following: delayed passage of meconium, vomiting, abdominal distension and a transition zone on contrast enema. 36% of IC patients had none of these features.	

Diagnostic Value of the Digital Rectal Examination (DRE) Children with Chronic Idiopathic Constipation

Bibliographic Information	Study type & Evidence	Number of patients &	Population Characteristics	Type of test and Reference	Sensitivity, Specificity, PPV and NPV	Reviewer comment
	level	prevalence		standard		
Beckmann et al.	Study type:	251 children	Group 1:	Test:	Clinical variables (as a model)	Abdominal radiograph was either a
Accuracy of	Prospective		141 children with	Clinical variables	Sensitivity: 77% (+)	single flatplate or a flatplate with upright
clinical	case series	Inclusion	radiologically		Specificity: 35% (-)	view, ordered by the ED attending
variables in the		criteria:	proven	-History of	PPV 60%	physician based on customary
identification of	Evidence	Children aged	constipation	gastrointestinal	NPV: 55%	practices. The ED physicians ordering
radiographically	level:	2-12 years old		problems		the radiographs were blinded to study
proven	111	who presented	Age: 7.9 +-3.1	-Duration of	Only the following clinical	objectives
constipation in		to the	years	abdominal pain	variables were significantly	
children. 2001.		Emergency	63 (25%) male	-Stool habits	different between the two	32% of the enrolled subjects did not
Wisconsin	Study aim:	Department		-Straining on	groups:	undergo rectal exam
Medical Journal	to determine	(ED) of		defecation		
100[1], 33-	whether	Children's	Group 2:	-Faecal consistency	History of normal/hard stool	A clinical diagnose previous to
36United	clinical	Hospital of	110 children with	(normal/hard stools)	consistency:	radiology was made and reported.
States.	variables	Wisconsin with	no radiographic	-Medication		However it was not clear how many of
	accurately	abdominal pain	evidence of	-Physical exam:	Group 1:	the clinical variables needed to be
	identify	and underwent	constipation	rebound, rigidity,	74% (100/135)	present to diagnose constipation.
	children with	radiographic		guarding,		Furthermore, the physical exam was
	radiologically	evaluation.	Age: 7.4 +-3.0	tympanic/distended	Group 2:	completed by one of several paediatric
	proven		years	-Physical exam-	61% (61/99) p: 0.016	ED physicians and no assessment of
	constipation	Exclusion	57 (23%) male	tenderness: diffuse,		inter-rater reliability was performed.
		criteria:		each of four	Absence of rebound	
		previous	Country:	quadrants, flank,	tenderness	Official radiologic diagnosis was
		abdominal	USA	epigastric,		provided by a single board certified
		surgery, known		periumbilical	Group 1:	paediatric radiologist blinded to the
		abdominal		-Physical exam:	98% (138/141)	study. This was compared with the ED
		pathology,		bowel sounds, rectal		physician interpretation of the
		menarche or		exam	Group 2:	radiograph and the patients were
		sickle cell			90% (99/110) p: 0.007	divided into the two groups, but it is not
		disease		Clinical examination		clear on the basis of what this decision
				(including rectal	Presence of left lower quadrant	was made.
		Setting: hospital		exam) performed by	tenderness:	A data sheet with demographic-clinical

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
	level	prevalence		standard		
		Emergency		the ED physician		data was required before an abdominal
		Department			Group 1:	radiograph was ordered, but in 159
				Reference test:	20% (19/96)	patients no data-sheet was submitted
				Abdominal		for various reasons. These patients
				radiograph	Group 2:	were excluded from the study and the
					9% (6/69) p: 0.0499	lack of data makes impossible to tell
				Radiological		whether they differed from the group of
				diagnose of	Stool present in rectal vault as	included patients
				constipation (based	per rectal exam:	
				on faecal loading		Source of funding:
				score originated and	Group 1:	Not reported
				validated by Barr et	69% (70/102)	
				al and later revised		
				by Blethyn et al)	Group 2:	
				-Normal, grade 0:	43% (29/68) p: 0.008	
				faeces in rectum		
				and cecum only		
				-Grade 1, mild		
				constipation: faeces		
				in rectum, cecum		
				and discontinuous		
				Crode 2 moderate		
				constinution: faeces		
				in rectum cecum		
				with continuous		
				faeces affecting all		
				segments but		
				allowing for gas		
				-Grade 3 severe		
				constination.		
				continuous faeces		
				with dilated colon		
				and rectal impaction		

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
	level	prevalence		standard		
Rockney et al.	Study type:	60 encopretic	Age: 4-11 years	<u>Test:</u>	Values for rectal examination:	78 encopretic children originally
The plain	Retrospectiv	children	old	Rectal examination		enrolled but only 60 children for whom
abdominal	e case		_		a) When the diagnosis of	Rx could be retrieved were included in
roentgenogram	series	Inclusion/	<u>Group 1</u>	Reference test:	retention by abdominal RX,	analysis. There were no significant
in the		exclusion	47 encopretic	Plain abdominal	systematic reading was agreed	differences between encopretic children
management of	<u>Evidence</u>	<u>criteria</u>	children with	roentgenogram	by at least two radiologists:	whose abdominal Rx were reviewed for
encopresis.	<u>level</u> :	Encopresis as	faecal retention			the study and those who did not have a
1995. Archives	111	defined by the	by	Three radiologists,	(%)	Rx or whose Rx could not be retrieved.
of Pediatrics		DSM Revised	roentgenogram	two paediatric and	Sensitivity: 88.6	There were no significant differences in
and Adolescent	Study aim:	Third Edition:	criteria on	one general, at	Specificity: 41.6	patients' characteristics at the two sites.
Medicine	to determine	"repeated	presentation	three separate	Positive predictive value: 84.8	Not all data were available for every
149[6], 623-627	whether	involuntary (or,		institutions, blind to	Negative predictive value: 50	subject
	faecal	much more	Male sex: 74.5%	the identity of the		
	retention in	rarely,		subjects evaluated	b) When the diagnosis of	Children with retention (as per Rx) were
	encopretic	intentional)	<u>Group 2</u>	the plain abdominal	retention by abdominal RX,	significantly more likely to have stool in
	children can	passage of	13 encopretic	Rx twice: a	systematic reading was agreed	the rectum on presentation (p 0.015)
	be assessed	faeces into	children without	"subjective" reading	by the three radiologists:	and were significantly less likely to have
	objectively	places not	faecal retention	assessed faecal		parents report a difficult toilet training (p
	using the	appropriate for	by	content as markedly	(%)	0.018). There were no other significant
	plain	that purpose	roentgenogram	excessive,	Sensitivity: 91.7	differences between the two groups
	abdominal	(e.g., clothing or	criteria on	moderately	Specificity: 71.4	regarding the rest of the variables
	roentgenogr	floor)the	presentation	excessive or normal	Positive predictive value: 94.3	measured.
	am and	event must		and a "systematic"	Negative predictive value: 62.5	
	whether	occur at least	Male sex: 61.5 %	reading where a		Each patient's medical record was
	roentgenogr	once a month		stool retention rating	Not all data were available for	reviewed separately by one of the
	aphic	for at least 6	Country:	record was	every subject	authors and a research assistant. When
	evidence of	months, the	USA	completed and a		discrepancies existed charts were
	faecal	chronological		score assigned (0-		reviewed again conjointly and
	retention is	and mental age		25) reflecting the		discrepancies resolved for both
	associated	of the child		severity of faecal		reviewers' satisfaction.
	with clinical	must be at least		retention (score of		
	findings on	4 years, and		10 or greater		The reliability of the radiologists'
	presentation	physical		indicates faecal		assessments was tested by two
	in encopretic	disorders that		retention, scale		different procedures.
	children	can cause		validated by Barr et		
		faecal		al.) Final results		Overall agreement among the three
		incontinence,		were taken from the		radiologists was 77.8% for the
		such as		systematic reading		subjective assessment, k=0.53 (z=7.04,

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
	level	prevalence		standard		
		aganglionic		only. At least two		p<0.0001). Agreement using the
		megacolon,		radiologists had to		systematic assessment was 87.4%,
		must be ruled		agree in order to		k=0.65 (z=7.2, p<0.0001). There were
		out"		classify		no differences in interrater reliabilities
		Children		roentgenograms		between pairs of radiologists.
		younger than 4		either as in the		
		years old and		retention or		The study from which the systematic
		children who		nonretention		scoring system was derived has not
		had a soiling		category		been replicated, and the cut-off point of
		frequency of		Presence of stool in		10, might not be valid for all populations
		less than once		rectal examination		
		a month or who		was recorded in the		Source of funding:
		had recently		patient records as		Primary Care Faculty Development
		stopped soiling		"none", "small",		Fellowship Programme at Michigan
		were excluded		"moderate" or		State University, East Lansing.
				"large" amount.		
		<u>Setting:</u> two		Patients with		
		paediatric		moderate or large		
		incontinence		amounts of stool on		
		clinics, one		rectal examination		
		located in the		were classified as		
		ambulatory care		having stool in the		
		facility of a		rectum for		
		tertiary care		subsequent		
		hospital and the		analysis.		
		other at a				
		community		The specific		
		hospital		professional		
				qualification of the		
				person who		
				performed the rectal		
				examination was not		
				reported		

Bibliographic Information	Study type & Evidence	Number of patients	Population Characteristics	Type of test (s)	Follow-up & Outcome Measures	Reviewer comment
	level				Effect Size	
Bonamico et al.	Study type:	1202 patients	1202 patients	Tests:	Signs/symptoms (%):	Additional information from study
Prevalence and	Prospective			-Coeliac disease:		Levels of IgA AGA were measured by
clinical picture	cohort	Inclusion	609 males		-Group 1 (n=55):	enzymelinked immunosorbent assay by
of celiac		criteria:		Revised		the Alfa-gliatest (Eurospital, Trieste,
disease in	Evidence	Down's	1110 children	European	Growth failure 52.7	Italy). Levels of EMA IgA were
Italian down	level:	syndrome	age range: 15	Society of	Diarrhoea 41.8	evaluated by an indirect
syndrome	2+		months to 18 years	Paediatric	Vomiting 20	immunofluorescence method
patients: A		Exclusion		Gastroenterology,	Anorexia 18.2	(Eurospital, Trieste, Italy). Sections
multicenter	Study aim:	criteria:	92 adults	Hepatology and	Constipation 29.1	from the distal portion of monkey
study. 2001.	To estimate	IgA deficiency	age range 18 to 46	Nutrition	Distended abdomen 23.6	oesophagus were used as a substrate,
Journal of	the		years	(ESPGHAN)		and fluorescein-labeled goat antihuman
Pediatric	prevalence	Setting:		criteria Patients	-Group 2 (n=55):	IgA antibody was used as the second
Gastroenterolog	of coeliac	Community	Country:	selected for		antibody. The patients' serum was
y and Nutrition	disease (CD)		Italy	intestinal	Growth failure 10.9	diluted 1:5 in phosphate buffer at pH
33[2], 139-	in patients			biopsy on the	Diarrhoea 1.8	7.2. The presence of a brilliant green
143United	with Down			basis of EMA	Vomiting 1.8	network pattern under a fluorescence
States.	syndrome		-Group 1: 55 CD	positivity, AGA	Anorexia 1.8	microscope was taken as a positive
	and to define		patients diagnosed	IgA positivity,	Constipation 14.5	result. Intestinal biopsies performed by
	the clinical		by ESPGHAN	or both in children	Distended abdomen 14.5	Watson capsule or by paediatric or
	characteristi		Criteria (36 males,	< 2 years of age		adult endoscopes
	cs of CD		aged 4 to 46 years)		-Group 3 (n=57):	
	among			(AGA: antigliadin		Patients selected for intestinal biopsy
	Down		-Group 2: 55 IgA	antibodies; EMA:	Growth failure 7	on the basis of both EMA positivity and
	Syndrome		AGA-positive EMA	antiendomysium	<i>P</i> < 0.001	AGA IgA positivity in children < 2 years
	patients		negative DS	antibodies; IgA:	Diarrhoea 6.9	of age, because in this age group, EMA
			patients (33 males,	immunoglobulin	<i>P</i> < 0.001	positivity may have a false-negative
			aged 3 to 40 years)	A)	Vomiting 1.7	result
					<i>P</i> < 0.001	
			-Group 3: 57 IgA	-Down syndrome:	Anorexia 3.4	A detailed questionnaire was completed
			AGA-negative	confirmed by	<i>P</i> < 0.01	to obtain information about familial
			EMA-negative DS	cariotype in all	Constipation	gastroenterologic history with special
			patients (34 males,	cases	8.8 <i>P</i> < 0.05	attention to feeding habits (breast milk

Prevalence of Coeliac Disease and Hypothyroidism in children with Chronic Idiopathic Constipation

Bibliographic	Study type & Evidence	Number of	Population Characteristics	Type of test (s)	Follow-up & Outcome	Reviewer comment
internation	level	patients	onaracteristics		Effect Size	
			aged 4 to 38 years)		Distended abdomen 15.5 NS P values are the results of	or formula, age of introduction of gluten- containing foods); gastrointestinal function, particularly the features of CD, such as chronic diarrhoea, vomiting,
					comparing group 1 vs. group 2 and group 3	failure to thrive, and anorexia; presence of autoimmune or neoplastic conditions
						All patients were receiving a gluten- containing diet. Weight and height were evaluated using Down syndrome percentile charts (DSPC)
						The clinical features of 55 CD patients diagnosed by ESPGHAN Criteria (group 1) were compared with those observed in 55 IgA AGA-positive EMA negative DS patients (group 2) and in 57 IgA AGA-negative EMA-negative DS patients (group 3). Group 2 and group 3 patients were selected randomly from among the screened patients to be age and gender matched to group 1.
						18 symptomatic patients belonging to group 2 underwent intestinal biopsy and showed normal small bowel mucosa
						Parents of 8 EMA positive children and 2 EMA-positive adults did not give permission for intestinal biopsy to be performed and were not included among the 55 CD patients
						Reviewer comments: It is unclear whether some patients had EMA and others had AGA IgA measured alternatively, or whether all patients had both EMA and AGA IgA

Bibliographic Information	Study type & Evidence level	Number of patients	Population Characteristics	Type of test (s)	Follow-up & Outcome Measures Effect Size	Reviewer comment
						measured at the same. This considered it is also unclear why only IgA AGA- positive EMA-negative patients and IgA AGA-negative EMA-negative patients were chosen as control groups and there is no mention of the EMA-positive IgA AGA-negative group <u>Source of funding:</u> Not stated

Bibliographic	Study type	Number of	Population	Type of test (s)	Follow-up & Outcome	Reviewer comment
Information	& Evidence	patients	Characteristics		Measures	
	level				Effect Size	
Bingley et al.	Study type:	5470 children	5470 children	Tests:	Any constipation reported at	Additional information from study
Undiagnosed	Prospective		age: 7.5 years	-Coeliac disease:	age 6.75 years (No, %):	Children with tTG antibodies < 97.5 th
coeliac disease	cohort	Inclusion	gender not reported		-tTG antibody negative	centile were defined as antibody
at age seven:		criteria:		Two stage	controls (n=4285	negative
Population	Evidence	Children aged	Country:	screening:	questionnaires):	
based	level:	7.5 years	UK			Details of gastrointestinal symptoms
prospective	2+	participating		1. Sensitive initial	435 (10)	and special diets collected by routine
birth cohort		In the Avon		radioimmunoassa		questionnaire at age 6.75 years
study. 2004.	Study aim:	Longitudinal		y for antibodies to	-IgA-EMA positive (n=42	
British Medical	to establish	Study of		tissue	questionnaires):	Total tTG antibody negative controls
Journal	the	Parents and		transglutaminase		(n=5333 children). Total IgA-EMA
328[7435], 322-	prevalence	Children		(endomysial	6 (14)	positive children (n=54) (1.0%; 95%
323United	of	(ALPASC), a		antigen) (tTG	odds ratio (95% CI):	confidence interval 0.8 to 1.4)
Kingdom.	undiagnosed	population		antibodies)	1.48 (0.62 to 3.52)	
	coeliac	based birth				4324 children (79%) returned
	disease in	cohort study		If positive to	Other symptoms reported at	questionnaires
	the general	established in		previous, serum	age 6.75 years (No, %):	
	population at	1990		IgA	-tTG antibody negative	An additional 137 children were tTG
	age seven			antiendomysial	controls (n=4285	antibody positive, but Ig-EMA negative
	and to look	Exclusion		antibodies (IgA-	questionnaires):	
	for any	<u>criteria:</u>		EMA) by indirect		IgA-EMA were more common in girls
	associated	Not stated		inmunofluorescen	any diarrhoea: 1450 (34)	(OR 2.12; 1.20 to 3.75). IgA-EMA
	clinical			се	any vomiting: 1933 (45)	positive children were shorter and
	features	Setting:			any stomach pains: 2557 (60)	weighted less than those who tested
		Community		-Constipation:	≥3 GI symptoms: 931 (22)	negative fro tTG antibody (p<0.0001 for all comparisons)
				Clinical variables	-IgA-EMA positive (n=42	
					questionnaires):	Since ALPASC is an observational
						study based on analysis of anonymous
					any diarrhoea: 21 (50)	samples, confirmatory biopsy was not
					odds ratio (95% CI):	possible
					1.96 (1.06 to 3.59)	
						Reviewer comments:
					any vomiting: 23 (55)	Unclear how the symptom
					odds ratio (95% CI):	"constipation" was defined in the first
					1.47 (0.80 to 2.71)	place
					any stomach pains: 28 (66)	No data regarding clinical symptoms at

Bibliographic Information	Study type & Evidence level	Number of patients	Population Characteristics	Type of test (s)	Follow-up & Outcome Measures Effect Size	Reviewer comment
					odds ratio (95% CI): 1.35 (0.71 to 2.57) ≥3 GI symptoms: 17 (40) odds ratio (95% CI): 2.45 (1.33 to 4.5)	6.75 years for 21% of the total sample <u>Sources of funding:</u> Coeliac UK, Medical Research Council, Wellcome Trust, UK government departments, and various charitable organisations and commercial companies, ALSPAC is part of the WHO initiated European Longitudinal Study on Pregnancy and Childhood

Bibliographic	Study type	Number of	Population	Type of test (s)	Follow-up & Outcome	Reviewer comment
Information	& Evidence	patients	Characteristics		Measures	
	level				Effect Size	
Cataldo et al.	Study type:	1917 children	Total: 1917 children	Test:	Clinical pattern and presenting	Additional information from study
Epidemiological	Retrospectiv		with CD	-coeliac disease:	symptoms at diagnosis (n=36)	Classical forms not clearly defined, but
and clinical	e case	Inclusion		diagnosis based		included the following symptoms:
features in	series	criteria:	36 immigrant	on the revised	-Classical forms (25/36)	chronic diarrhoea, weight loss,
immigrant		Italian and	children with CD	criteria of the	(69.4%):	abdominal distension and vomit
children with	<u>Evidence</u>	immigrant	15 males	European Society		
coeliac disease:	level:	children	age range 6	of Paediatric	No child with constipation	Atypical forms included: iron-deficiency
An Italian	3	consecutively	months to 15 years	Gastroenterology	reported	anaemia, short stature, delayed
multicentre		diagnosed as	(mean 7.3)	and Nutrition		puberty, recurrent oral aphtae
study. 2004.	Study aim:	having CD		(ESPGAN):	-Atypical forms (9/36) (25%):	
Digestive and	To evaluate	between	1881 Italian			Silent forms included: serological
Liver Disease	the	January 1999 to	children	1. Finding of a flat	Abdominal pain with	screening of first degree relative, loss of
36[11], 722-	prevalence	December 2001	891 males	small intestinal	constipation :	Kerckring folds at endoscopy
729United	of immigrant		age range 6	mucosa with the	2/9	
States.	children with	Exclusion	months to 16 years	features of		Clinical patterns in Italian children were
	coeliac	criteria:	(mean 7.9)	hyperplastic	-Silent forms (2/36) (5.5%):	similar to those of immigrant children
	disease (CD)	Not stated		villous atrophy on		
	in Italy, the		Country:	histological	No child with constipation	Reviewer comments:
	clinical	Setting:	Italy	examination of a	reported	Unclear how the symptom
	findings in	Hospital		biopsy specimen,		"constipation" was defined in the first
	these	(multicentre)		while the patient		place
	patients and			is eating		
	the possible			adequate		Presenting symptoms at diagnosis were
	relationship			amounts of gluten		not reported for Italian children
	between					
	immigration,			2. Clear cut		Source of funding:
	dietary			clinical remission		Study supported by grants of Ministero
	habits and			on a strict gluten		dell'Universita e della Ricerca
	CD in			free diet with		Scientifica e Tecnologica (MURST)
	childhood			relief of all		60% di F.C.
				symptoms of the		
				disease. This		
				response should		
				be reasonably		
				rapid occurring		
				within a matter of		
				weeks rather than		
				many months		

Bibliographic Information	Study type & Evidence level	Number of patients	Population Characteristics	Type of test (s)	Follow-up & Outcome Measures Effect Size	Reviewer comment
				3. The finding of circulating antibodies (IgA gliadin, antireticulin, and antiendomysiun) at time of diagnosis and their disappearance when the patient is taking a gluten free diet add weight to the diagnosis		

Bibliographic	Study type	Number of	Population	Type of test (s)	Follow-up & Outcome	Reviewer comment
Information	& Evidence	patients	Characteristics		Measures	
	level				Effect Size	
Egan-Mitchell et	Study type:	112 children	112 children	Tests:	Incidence of constipation:	Additional information from study
al. Constipation	Retrospectiv			-Coeliac disease		Growth retardation assessed on the
in childhood	e case	Inclusion	12 children with		12 children constipated at	graphs of Tanner and Whitehouse
coeliac disease.	series	<u>criteria:</u>	constipation: 6	1. Clinical	some stage before diagnoses:	(1959) and subsequently confirmed by
1972. Archives	L	Coeliac disease	males, age range 6	variables:		catch-up growth following treatment
of Disease in	Evidence		to 102 months	undernutrition	-9 of those children presented	with gluten-free diet
Childhood	<u>level</u> :	Exclusion		and retarded	with constipation and faecal	
47[252], 238-	3	criteria:	Country:	growth.	impaction, of these 5 had	Mucosal damage according to authors'
240		Not stated	Ireland		intermittent diarrhoea and	classification (normal mucosa grade 0;
	Study aim:			2. Jejunal biopsy:	constipation but 4 never had	mild non-specific change grade 1;
	To assess	Setting:		Grade 2/3 or	diarrhoea. Of these 4, 3	grade 2 and 3 correspond to moderate
	the	Regional and		grade 3 jejunal	children presented at around 1	and severe villous atrophy)
	incidence of	university		mucosal damage	year of age with anorexia,	
	constipation	hospitals			failure to thrive and faecal	Reviewer comments:
	in coeliac			-Constipation:	impaction	Unclear whether authors' classification
	disease					system for jejunal mucosa damage has
				Clinical variables:	-the 3 children who did not	been validated
				passage of stools	have faecal impaction when	
				of harder	investigated had histories of	Source of funding:
				consistency than	constipation alternating with	The main author was receiving a grant
				normal, or the	mild diarrhoea and all had	from the Medical Research Council of
				clinical	been given laxatives frequently	Ireland
				observation of	for their constipation	
				impaction of		
				abnormal		
				amounts of hard		
				(usually pale)		
				faeces in colon		
				and rectum		

Diagnostic Value of the Anorectal Manometry in Children with Chronic Idiopathic Constipation

Bibliographic	Study type	Number of	Population	Type of test (s)	Follow-up & Outcome	Reviewer comments
Information	& Evidence	patients	Characteristics		Measures	
	level				Effect Size	
Jarvi et al.	Study type:	81 patients	81 patients	Tests:	Rectoanal inhibitory reflex	Additional information from study
Anorectal	Retrospectiv		49 male	-Anorectal	(RAIR) and histology results	Records of all patients who met the
manometry with	e case	Inclusion		manometry:		inclusion criteria were reviewed
reference to	series	criteria:	median age at time		-RAIR present (N=40)	
operative rectal		Patients under	of ARM and biopsy:	Performed using		In each case ARM was performed
biopsy for the	Evidence	1 year of age	2 months (range	a 4-cm long rectal	HD: no children	under ketamine anaesthesia by a
diagnosis/exclu	level:	who presented	0.1 to 11 months)	balloon inflated	Normal histology: 39 children	consultant paediatric surgeon, and
sion of	111	with delayed		incrementally with	Hypoganglionosis: 1 child	operative rectal biopsy was taken
Hirschprung's		passage of	Country:	5 to 50 mL of air		simultaneously
disease in	Study aim:	meconium,	Finland		-RAIR absent (N=41)	
children under 1	To report on	abdominal		-Operative rectal		RAIR defined as greater than 25% drop
year of age.	the value of	distension and		biopsy:	HD: 33 children	in the anal sphincter pressure for at
2009.	anorectal	vomiting or			Normal histology: 8 children	least 5 seconds
International	manometry	constipation		Taken 3 cm		
Journal of	(ARM) with	who underwent		above the dentate	Diagnostic variables for ARM	Patients who had HD were significantly
Colorectal	reference to	ARM		in the posterior	and operative rectal biopsy in	younger at the time of investigation than
Disease 24[4],	operative			midline,	<u>HD (%):</u>	those who did not
451-	rectal biopsy	Exclusion		consisting of a		
454Germany.	in the	criteria:		generous,	-Biopsy:	In the case of patients diagnosed with
	diagnosis/ex	Other		longitudinal		HD histology from bowel resected at
	clusion of	congenital		specimen	Sensitivity: 100	pull-through operation was consistent
	Hirschsprun	gastrointestinal		extending to the	Specificity: 100	with pre-operative diagnosis in all cases
	g's disease	malformations		submucosa	Positive predictive value: 100	
	in children	such as			Negative predictive value: 100	Operative rectal biopsy was adequate
	under 1 year	anorectal				and diagnostic in all cases. There was
	of age and	anomaly, funnel			-ARM:	one case of rectal bleeding following
	on the	anus or				biopsy which required suturing in
	prognostic	gastroschisis			Sensitivity: 100	theatre
	significance				Specificity: 83	
	of a normal				Positive predictive value: 80	Reviewer comments:

Bibliographic Information	Study type & Evidence	Number of patients	Population Characteristics	Type of test (s)	Follow-up & Outcome Measures	Reviewer comments
	level	Panono			Effect Size	
	RAIR in				Negative predictive value: 100	Unclear how the reviewing process was
	these					conducted
	patients					I Inclear how the bionsy specimens
						were processed and analysed
						Source of funding:
						Not stated

Bibliographic	Study type	Number of	Population	Type of test (s)	Follow-up & Outcome	Reviewer comments
Information	& Evidence	patients	Characteristics		Measures	
	level				Effect Size	
Lee et al.	Study type:	105 children	105 children	Tests:	Rectoanal inhibitory reflex	Additional information from study
Allergic proctitis	Retrospectiv		61 boys	-Anorectal	(RAIR) and histology results	Severe abdominal distension defined as
and abdominal	e case	Inclusion		manometry:		an abdominal wall that protruded, was
distention	series	criteria:	Mean age: 2.1 ±		-RAIR absent (N=48)	shiny and tense upon palpation
mimicking		Infants < 6	0.9 months	Performed by		
Hirschsprung's	Evidence	months of age		paediatricians	HD: 34	Reviewer comments:
disease in	level:	with severe	Country:	using a silicon	Normal histology: 10	Unclear how the reviewing process was
infants. 2007.	111	abdominal	Korea	rubber catheter	AP: 2	conducted
Acta		distension that		with an array of 8	IND: 2	
Paediatrica,	Study aim:	mimicked HD		channels of		Unclear what was the order in which
International	To evaluate	referred to		sensors. Sedation		investigations were carried out
Journal of	the	department of		with chloral	-RAIR present (N=57)	
Paediatrics	incidence	paediatrics and		hydrate for the		Source of funding:
96[12], 1784-	and clinical	division of		procedure was	HD: 5	Not stated
1789United	aspects of	paediatric		used	Normal histology: 43	
Kingdom.	allergic	surgery and			AP: 5	
	proctitis (AP)	underwent all		-Suction rectal	IND: 4	
	in patients	triple tests		biopsy:		
	with	including			Diagnostic variables for ARM	
	symptoms	barium enema,		Taken from 4	and rectal suction biopsy in HD	
	that mimic	anorectal		different sites	<u>(%):</u>	
	Hirschsprun	manometry and		using a rectal		
	g's disease	rectal suction		suction biopsy	-Biopsy:	
	(HD). In	biopsy. Some		tube. Biopsy sites		
	addition	patients had		were 3cm and 5	Sensitivity:	
	authors	associated		cm for anal verge.	92.31% (CI: 76.68 to 97.35)	
	determined	symptoms like		When ganglion	Specificity:	
	the	constipation,		cells were	100 % (94.50 to 100.00)	
	sensitivity	poor oral intake,		observed to be	Positive predictive value 100%	
	and	vomiting, poor		present with	Negative predictive value:	
	specificity of	weight gain and		normal	95.65%	
	anorectal	diarrhoea		appearance on		
	manometry			haematoxylin-	-ARM:	
	and	Exclusion		eosin staining HD		
	suction	criteria:		was excluded.	Sensitivity:	
	rectal biopsy	Coeliac disease		HD was finally	87.18% (CI: 73.29 to 94.90)	
	used for	and cystic		diagnosed with		
	evaluation of	fibrosis not		full thickness	78.79% (CI: 67.49 to 86.92)	

Bibliographic Information	Study type & Evidence level	Number of patients	Population Characteristics	Type of test (s)	Follow-up & Outcome Measures Effect Size	Reviewer comments
	Ievel HD	considered in the differential diagnosis because are extremely rare in Korea		biopsy	Effect Size Positive predictive value 70.83% Negative predictive value 91.23%	

Bibliographic	Study type	Number of	Population	Type of test (s)	Follow-up & Outcome	Reviewer comments
Information	& Evidence	patients	Characteristics		Measures	
	level				Effect Size	
Low et al.	Study type:	50 children	50 children	<u>Tests:</u>	Rectoanal inhibitory reflex	Additional information from study
Accuracy of	Prospective			-Anorectal	(RAIR) and histology results	5 children (10%) required repeat full-
anorectal	case series	Inclusion	(data available for	manometry		thickness biopsy for inadequate
manometry in		<u>criteria:</u>	45 children)		-RAIR absent (N=16)	sampling
the diagnosis of	<u>Evidence</u>	Children	31 male	Performed as a		
Hirschsprung's	<u>level</u> :	referred	14 female	side-room	HD: 15	All children underwent both manometry
disease. 1989.	111	consecutively to		procedure. All	Normal histology: 1	and biopsy.
Journal of		one of the	Age range birth to	children under 4		
Pediatric	Study aim:	authors for	11 months	years of age who	-RAIR present (N= 34)	Biopsy specimens prepared in paraffin
Gastroenterolog	To asses the	anorectal		were unable to		sections and stained with haematoxylin
y and Nutrition	accuracy of	manometric	Country:	cooperate were	HD: 4	and eosin. Up to 60 6-µm-thick serial
9[3], 342-346	anorectal	studies	Singapore	tested after oral	Normal histology: 30	sections of each specimen were
	manometry			sedation with		examined histologically by pathologist
	in the	Exclusion		chloral hydrate	Diagnostic variables for ARM,	for ganglion cells and hypertrophied
	diagnosis of	criteria:			total sample N=50 (%):	nerve bundles. Specimens not including
	Hirschsprun	Not stated				the submucosal layer were considered
	g's disease			-Suction	Accuracy: 90	inadequate and repeat full-thickness
	(HD) using			rectal biopsy	Sensitivity: 79	operative rectal biopsies were taken
	histological				Specificity: 97	
	aganglionosi			Suction rectal	Positive predictive value: 94	A normal reflex was present when
	s as the			biopsies obtained	Negative predictive value: 88	rythmicity of internal sphincter
	reference			without		contractility was totally inhibited by
	point for final			anaesthesia by	Diagnostic variables for ARM,	rectal distension accompanied by
	diagnosis			paediatric	neonates N=10 (%):	simultaneous drop in internal
				surgeon on		sphincteric pressure. Rythmicity and
				outpatient basis.	Accuracy: 90	tone recovered when rectal distension
				Biopsies taken at	Sensitivity: 86	was removed. When rythmicity and
				4 cms from the	Specificity: 100	internal sphincter pressure remained
				anal verge with a	Positive predictive value: 100	virtually unchanged after rectal
				Noblet or Quinton	Negative predictive value: 75	distension a negative response was
				biopsy set.		recorded
					Diagnostic variables for ARM,	
					infants N=18 (%):	No complications encountered with
						manometry in all 50 children studied
					Accuracy: 94.4	
					Sensitivity: 90	Reviewer comments:
					Specificity: 100	No definition of constipation/idiopathic
					Positive predictive value: 100	constipation given

Bibliographic Information	Study type & Evidence level	Number of patients	Population Characteristics	Type of test (s)	Follow-up & Outcome Measures Effect Size	Reviewer comments
					Effect Size Negative predictive value: 89	Unclear what "infant" meant for authors <u>Source of funding:</u> Research grant (RP53/81) from the National University of Singapore, Singapore

Bibliographic	Study type	Number of	Population	Type of test (s)	Follow-up & Outcome	Reviewer comments
Information	& Evidence	patients	Characteristics		Measures	
	level				Effect Size	
Kong et al.	Study type:	39 patients	39 patients	Tests:	Rectoanal inhibitory reflex	Additional information from study
Screening	Retrospectiv			-Anorectal	(RAIR) and histology results	A normal reflex (RAIR) was present
Hirschsprung's	e case	Inclusion	age range: 3 days	manometry:		when rythmicity of internal sphincter
disease by	series	criteria:	to 9 years		-RAIR absent (N=18)	contractility was totally inhibited by
anorectal		Children with	(no other details	Double lumen		rectal distension accompanied by a
manometry.	Evidence	constipation or	provided)	stainless steel	HD: 15	simultaneous drop of internal
1993. Chinese	level:	suspected HD		manometric	Normal histology: 3	sphincteric pressure fro 5mmHg or
Journal of	111		Country:	probes with		more. A positive rectoanal response
Gastroenterolog		Exclusion	Taiwan	internal diameter	-RAIR present (N=18)	consisted of 3 successive pressure
y 10[1], 29-	Study aim:	criteria:		of 6 mm used.		falls, each immediately following upon
32Taiwan,	To evaluate	Systemic		Entire system	HD: 0	rectal distension by balloon. When
Province of	the	diseases like		closed and water	Normal histology: 18	rythmicity and internal sphincter
China.	possibility of	hypothyroidism		filled. Multiple-		pressure remained unchanged following
	using	or neurologic		channel recorder	-RAIR inconclusive (N=3)	rectal distension, the amount of air was
	anorectal	disorders		used for		increased gradually to 10 cc fro
	manometry			recording results.	HD: 0	neonates and 50 cc for children. If RAIR
	(ARM) for			No previous	Normal histology: 3	was absent, a negative response was
	screening			bowel		recorded
	Hirschsprun			preparation.	Diagnosis variables ARM (%):	
	g's disease			Stimulus balloon		The final diagnosis of HD was made by
	(HD)			placed from 3 to 5	Accuracy: 90	patient's clinical history, barium enema
				cm from anal	Sensitivity: 100	and rectal suction biopsy
				verge, depending	Specificity: 86	
				on size of	PPV: 83	Inconclusive results with manometry
				patients. For	NPV: 100	due to poor tracing of internal sphincter
				uncooperative		contraction as a result of oversedation
				patients		(n=2) and to anal stenosis (n=1)
				intramuscular		
				injection with		Reviewer comments:
				mixture of		No definition of constipation given
				chlorpromazine,		
				promethazine and		Insufficient details on how HD was
				meperidine with		diagnosed
				or without		
				Intravenous		It is not completely clear whether or not
				diazepam was		all patients underwent rectal biopsy but
				given		It looks as this was probably the case

Bibliographic Information	Study type & Evidence level	Number of patients	Population Characteristics	Type of test (s)	Follow-up & Outcome Measures Effect Size	Reviewer comments
				- Rectal suction biopsy (no other details provided)		The 3 children in whom manometry was inconclusive were not included in the calculation of the diagnostic variables and this introduces bias <u>Source of funding:</u> Not stated

Bibliographic	Study type	Number of	Population	Type of test (s)	Follow-up & Outcome	Reviewer comments
Information	& Evidence	patients	Characteristics		Measures	
	level				Effect Size	
Penninckx et al.	Study type:	261 patients	261 patients	Tests:	Rectoanal inhibitory reflex	Additional information from study
Pitfalls and	Prospective			-Anorectal	(RAIR) and histology results	In no case the result of a rectal biopsy
limitations of	case series	Inclusion	-gender not	manometry		was known at the time of manometry
testing the		criteria:	reported for all		-RAIR equivocal result	
rectoanal	Evidence	Patients	patients	No special bowel	(absent?):	RAIR considered to be present if the
inhibitory reflex	level:	referred for		preparation given.	9 children	anal pressure decreased on rectal
in screening for	111	anorectal	-Age:	if a considerable		distension followed by recovery of the
hirschsprung's		manometry in	< 6 months: 94	amount of faecal	HD: 4	basal tone. RAIR was also considered
disease. 1990.	Study aim:	order to confirm	(36%)	impaction was	Normal histology: 5	to be present if the typical anal pressure
Pediatric	To better	or exclude	6 month to 6 years:	found, patients		waves were clearly abolished
Surgery	ascertain the	Hirschsprung's	106 (41%)	were sent back	-RAIR equivocal result	
International	traps and	disease. All	6 to 15 years: 47	for evacuating	(present?):	Confident interpretation of the RAIR
5[4], 260-	limitations of	patients had	(18%)	enema (s) and	8 children	was made in 232/261 patients (89%):
265Germany.	testing the	presented with	2 adolescents and	reexamination		RAIR present in 207 cases and absent
	rectoanal	constipation	12 adults (5%)	planned for the	HD: 2	in 25. The result of this first manometric
	inhibitory	varying from		next day.	Normal histology: 6	evaluation was verified either by biopsy
	reflex	slight to	Country:	Children not		or by repeated manometry in 54 cases.
	(RAIR), how	intractable, with	Belgium	sedated. Entire	-RAIR confident interpretation:	In other cases the clinical evolution did
	frequently	highly differing		system filled with	232 children	not warrant further investigation.
	they occur	durations		degassed water.		
	and the	ranging from		Multiple-channel	RAIR+: 207	Manometrically the following factors
	possible	neonatal ileus		recorder used for	RAIR-: 25	prevented examiners from reaching a
	explanations	to chronic		recording results		definite conclusion: low anal tone (n=8),
	fro equivocal	constipation in			Of the previous 54 children	restlessness of patient (n=7), reflex
	or false	adults		- Superficial	underwent either biopsy or	external sphincter contraction partially
	results			biopsy of rectal	repeated manometry. Only	or completely masking possible RAIR
		Exclusion		mucosa and	false results reported:	(n=4), presence of megarectum (n=3),
		criteria:		submucosa taken		artifacts (n=1), unstable RAIR (n=6)
		Not stated		with a laryngeal	-RAIR present and HD: 2	
				biopsy forceps.	children	Reviewer comments:
				Frozen section		Not all children underwent both
				biopsies stained	-RAIR absent and normal	manometry and biopsy: 261 patients
				for	histology: 4 children	underwent manometry and only 24
				acetylcholinestera		underwent biopsy
				se and	Incidence of false results and	
				nicotinamide	age of patients at first	Details of both the manometry and
				adenine	manometry	biopsy results were reported only in
				dinucleotide-		cases where the RAIR was equivocal in

Bibliographic Information	Study type & Evidence	Number of patients	Population Characteristics	Type of test (s)	Follow-up & Outcome Measures	Reviewer comments
	level				Effect Size	
				reduced	-In <1 month old: 5/22	the first manometry and in those
				diaphorase.	(22.7.8%)	children where the result proved to be
				Aganglionosis		false (either negative or positive).
				with hypertrophic	$-\ln > 1 \text{ month old: } 4/239 (1.7\%)$	Considering this it is not possible to
				bundles was		calculate the sensitivity, specificity,
				diagnostic for HD	Incidence of equivocal results	positive and negative predictive values
					and age of patients at first	of the anorectal manometry
					manometry	The incidence of folge regults in
					1n < 1 month old: $1/22$ (18.2%)	manometry performed by different
					ln > 1 month old: $4/22$ (10.276)	examiners is reported in the paper, but
					(10.4%)	there are missing data not accounted
					(,)	for and therefore we do not report it
						here
						Source of funding: Not stated

Diagnostic Value of the Plain Abdominal Radiography in Children with Chronic Idiopathic Constipation

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
	level	prevalence		standard		
Reuchlin-	Study type:	6 studies (3	Otherwise healthy	Test and	Diagnostic value:	MEDLINE searched from inception to
Vroklage et al.	Systematic	case series, 2	children aged from	<u>Reference</u>		April 2004, search terms reported and
Diagnostic	Review	case-control	1 to 18 years old	Standard (studies	(LR: Likelihood ratio)	comprehensive. Results of this search
value of		studies,	with signs and	could treat either		combined with search strategy specific
abdominal	Evidence	1 retrospective	symptoms related	test as the	-Ability of the abdominal	to identify diagnostic studies.
radiography in	level:	re-examination	to constipation.	reference	radiography to discriminate	References lists of reviews articles and
constipated	1+	of abdominal	Some studies	standard)	between clinically constipated	included studies checked for further
children: a		radiographs	included children		and non constipated children	relevant articles. Experts in the field
systematic	Study aim:		with soiling or	-Faecal loading	(4 studies):	contacted and asked to identify
review. 2005.	to evaluate	Inclusion	encopresis, while	on plain		published and unpublished studies. No
Archives of	the	criteria:	others exclude this	abdominal	1.	language restrictions applied
Pediatrics and	additional	Controlled,	group	radiography	Sensitivity: 76 (95% CI: 58 to	
Adolescent	diagnostic	observational		according to a	89)	Two reviewers independently screened
Medicine	value of the	studies	Country:	predefined	Specificity: 75 (95% CI: 63 to	the titles and abstracts f studies
159[7], 671-678	plain	investigating the	The Netherlands	scoring system	85)	identified by the searches for eligibility.
	abdominal	relationship		(reference test in	LR: 3.0 (95% CI: 1.6 to 4.3)	All potentially relevant studies were
	radiography	between faecal		3 studies)		retrieved as full papers and
	in the	loading on plain			2.	independently screened by two
	diagnosis of	abdominal		-Clinical	Sensitivity: 60 (95% CI: 46 to	reviewers. Any disagreements were
	constipation	radiography and		diagnosis of	72)	resolved through consensus or by
	in children	symptoms and		constipation	Specificity: 43 (95% CI: 18 to	arbitration of a third reviewer
		signs related to		according	71)	
		constipation in		to the presence	LR: 1.0 (95% CI: 0.5 to 1.6)	Methodological quality of studies
		otherwise		or absence of		assessed using the QUADAS tool. An
		healthy children		predefined	3.	overall methodological quality value
		aged from 1 to		symptoms and	Sensitivity: 80 (95% CI: 65 to	was assigned to studies by calculating
		18 years old		signs (reference	90)	the number of positive scores
				test in 3 studies)	Specificity: 90 (95% CI: 74 to	(maximum value 14). Studies with
		Exclusion			98)	scores of 9 or higher >60%) were
		criteria:		In the 6 studies	LR: 8.0 (95% CI: 0.7 to 17.1)	arbitrarily regarded as being of "high"

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
		Lack of control group, no data on diagnostic value presented, symptoms of constipation not related to the outcomes of a plain abdominal radiography <u>Setting:</u> all 6 studies hospital based		included, 3 different scoring systems for assessing impaction on abdominal radiography were used: 3 studies: Barr- score 2 studies: revised Barr-score 1 study: authors' own scoring system	 4.Accuracy 80% (95% CI: 50 to 100) Ability of the clinical examination to discriminate between radiographically constipated and non constipated children (1 study): Sensitivity: 77 (95% CI: 70 to 84) Specificity: 35 (95% CI: 27 to 44) LR: 1.2 (95% CI: 1.0 to 1.4) -Association between a history of hard stool and faecal impaction on radiography: LR: 1.2 (95% CI, 1.0 to 1.4) -Association between a finding of absence of rebound tenderness and faecal impaction on radiography: LR: 1.1 (95% CI, 1.0 to 1.2) -Association between stool present on rectal examination and faecal impaction on abdominal radiography: LR: 1.6 (95% CI, 1.2 to 2.0) LR: 1.5 (95% CI, 0.8 to 2.3) 	methodological quality. Two reviewers independently assessed the methodological quality of the independent studies. Any disagreements were resolved by consensus or through consultation with third reviewer. Reviewers scored 84 items and agreed on 65 item (77.4%, k=0.54) Structured data extraction performed independently by two reviewers and any disagreement resolved by consensus <u>Source of funding:</u> Not reported

Bibliographic Information	Study type & Evidence level	Number of patients & prevalence	Population Characteristics	Type of test and Reference standard	Sensitivity, Specificity, PPV and NPV	Reviewer comment
					Interobserver reliability: 5 studies: moderate to excellent (k range, 0.63 to 0.95) 1 study: poor to moderate (k=0.28 to 0.060) Intraobserver reliability: Evaluated in 3 studies, ranged from moderate (k=0.52) to excellent (k≥0.85)	

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
	level	prevalence		standard		
de Lorijn et al.	Study type:	89 non selected	89 children	Test:	Mean Leech score (using the	Children with clinical characteristics of
The Leech	Diagnostic.	consecutive		Leech method to	first score):	FAP and FNRFI were classified as the
method for	Case control	children	Median age: 9.8	diagnose		control group, because according the
diagnosing			years	constipation in	-Group 1 (constipation): 10.1	authors they have "little or no faecal
constipation:	Evidence	Inclusion		plain abdominal	-Group 2 (controls): 8.5	loading on an abdominal radiograph"
intra- and	level:	criteria: patients	Group 1	radiography		
interobserver	111	referred for the	(constipation):		p=0.002	Treatment with oral/rectal laxatives was
variability and		evaluation of	n=52 (28 boys)	Reference test:		discontinued in each patient for at least
accuracy. 2006.	Study aim:	abdominal pain,		Colonic Transit	Mean CTT:	4 days. Thereafter the patient ingested
Pediatric	to assess	constipation or	Group 2 (controls):	Time (CTT)	-Group 1 (constipation): 92 h	one capsule with 10 small radiograph
Radiology 36[1],	intra- and	faecal	N=37 (24 boys)		-Group 2 (controls): 37 h	opaque markers on 6 consecutive days,
43-49	interobserver	incontinence.				in order to determine the CTT.
	variability	Diagnosis of	31: FNRFI		p<0.0001	Subsequently, a plain abdominal
	and	constipation: at	6: FAP			radiograph was taken on day 7. this
	determine	least two of the		Leech scoring	Diagnostic accuracy of Leech	radiograph was both used in the Leech
	diagnostic	following was		method:	method vs. CTT method:	method and for CTT measurement
	accuracy of	present:	Diagnosis of	Colon divided into		
	the Leech	-defecation	functional non-	three segments:	-Leech method:	Three scorers independently scored the
	method in	frequency less	retentive faecal	right, left and	(cut-off point as per study	same radiography twice (4 weeks apart)
	identifying	than 3	incontinence	recto sigmoid	comparable to 9 as per	using the Leech method, which was
	children with	times/week	(FNRFI) based on:	Each segment	literature)	discussed amongst the three scorers
	functional	-2/more	1) two/more faecal	provided with a	Sensitivity: 75%	previous to both readings
	constipation	episodes of	incontinence	score from 0-5	Specificity : 59%	
		faecal	episodes/week with	0:no faeces		Scorers were three experienced doctors
		incontinence	no signs of	visible	(cut-off point 9 as per	(a 5"' year radiology resident, a
		per week	constipation 2)	1:scanty faeces	literature)	paediatric radiologist and a senior
		-production of	defecation	visible	Positive Predictive Value: 72%	paediatric gastroenterologist). No
		large amounts	frequency 3/more	2: mild faecal	Negative Predictive Value:	clinical information was about the
		of stool once	times/week 3) no	loading	63%	patients was made available to them.
		over a period of	periodic passage of	3: moderate		
		7-30 days	very large amounts	faecal loading		A Leech score of 9 or more was
		-presence of	of stool at least	4: severe taecal	(cut-off point 54h as per study)	considered as suggestive of
		palpable	once during a	loading	Sensitivity: 79%	constipation.
		abdominal or	period of 7-30 days	5: severe taecal	Specificity: 92%	
		rectal mass	4) no palpable	loading with		CIT were assessed once by a single
			abdominal or rectal	bowel dilatation	(cut-off point 62h as per	scorer. It was assumed that the
		(control children	mass on physical			counting of radiopaque markers would
		tultilled criteria	examination fro a	Colonic transit	Sensitivity: 71%	not lead to intra- or interobserver

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
	level	prevalence		standard		
		for functional	period of at least 1	<u>time:</u>	Specificity: 95%	variability
		abdominal pain	week during the	Determined by	Positive Predictive Value: 69%	
		(FAP) and for	preceding 12	the method of	Negative Predictive Value:	In 5% of cases the Leech scores of the
		functional non-	weeks. Faecal	Bouchoucha.	97%	same patient produced by different
		retentive faecal	incontinence	Radiography on		scorers could differ by 4 points or more
		incontinence	defined as the	day 7 used to	ROC analysis	
		(FNRFI))	voluntary/involuntar	count the number		Source of funding: not stated
			y loss of loose	of markers in the	-AUC (Leech method):	
		Exclusion	stools in the	colon. Number of	0.68 (95% CI 0.58-0.80)	
		<u>criteria:</u> not	underwear after the	markers x 2	-AUC (CTT method):	
		reported	age of 4 years	produced total	0.90 (95% CI 0.83-0.96)	
			Functional	CTT in hours.		
		Setting: tertiary	abdominal pain	Localization of	p=0.00015	
		gastroenterolog	(FAP) defined as	markers and CTT	AUC=Area Under the ROC	
		y outpatients	abdominal pain of	calculated	curve	
		clinic	at least 12 weeks	according to	ROC=Receiving Operator	
			duration 1)that was	previously	Characteristic	
			continuous or	described		
			nearly	formula. Normal	Intraobserver variability (Leech	
			discontinuous in a	range fro total	score)	
			school-aged child	transit time based		
			or adolescent 2)	on the upper	a. Systematic difference	
			that had no or only	limits (mean ±	<u>(Mean, 95% CI):</u>	
			an occasional	2xSD) from a	-Scorer 1	
			relationship with	study in healthy	0.7 (0.2-1.2)	
			physiological	children. Based	P=0.89	
			events 3) that was	on this study a		
			accompanied by	CTT > 62 h was	-Scorer 2	
			some loss of daily	considered	0.03 (-0.4-0.5)	
			functioning 4) that	delayed.	P=0.0005	
			was not feigned			
			and) for which		-Scorer 3	
			there were		-1.6 (-2.0-1.3)	
			insufficient criteria		P<0.0001	
			to indicate the			
			presence of		b. Variability (SD)	
			another functional		-Scorer 1:	
			gastrointestinal		2.2	

Bibliographic Information	Study type & Evidence level	Number of patients & prevalence	Population Characteristics	Type of test and Reference standard	Sensitivity, Specificity, PPV and NPV	Reviewer comment
Information	& Evidence level	patients & prevalence	Characteristics disorder <u>Country:</u> The Netherlands	Reference standard	and NPV Limits of agreement: -6.0-5.0 -Scorer 2 : 2.2 Limits of agreement: -7.0-7.0 -Scorer 3: 1.5 Limits of agreement: -5.0-3.0 Interobserver variability (using the first score): -Scorer 3 vs. scorer 1: Mean of differences 2.7 p<0.0001 -Scorer 3 vs. scorer 2: Mean of differences 2.9 p<0.0001 - Scorer 2 vs. scorer 1: no systematic differences found	
Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
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Information	& Evidence	patients &	Characteristics	Reference	and NPV	
	level	prevalence		standard		
van den Bosch	Study type:	40 patients	40 patients	Test and	Intraobserver variability (k	Masked abdominal radiographs of the
et al.	Diagnostic			<u>Reference</u>	values)	children were independently evaluated
Systematic	retrospective	Inclusion	Mean age 7 years	Standard (all		by two observers, both experienced
assessment of	case series	criteria:	(range 3-12)	tests compared to	-Observer 1:	paediatric radiologists. Observers
constipation on		consecutive	55% boys	each other)	Barr: 0.75	assessed each radiograph on two
plain abdominal	Evidence	patients	-		Blethyn: 0.61	separate occasions, 6 weeks apart.
radiographs in	level:	referred to	Country:	-Barr scoring	Leech: 0.88	Each abdominal radiograph was scored
children. 2006.	111	hospital for	The Netherlands	system		according to the three different scoring
Pediatric		assessment of		-Leech scoring	-Observer 2:	systems
Radiology 36[3],	Study aim:	constipation.		system	Barr: 0.66	
224-226	To assess	Patients		-Blethyn scoring	Blethyn: 0.65	Intraobserver variability was determined
	the	complained of		system	Leech: 1.00	for each scoring system by comparing
	reproducibilit	infrequent		_		data from the same observer at two
	y of there	defection,		Barr scoring	Interobserver variability (k	different reading sessions.
	scoring	soiling,		system:	<u>values)</u>	Interobserver reproducibility was
	systems	encopresis, or		Quantifies the		determined by comparing data from the
	(Barr, Leech	abdominal pain		amount of faeces	-Period 1	two observers on one occasion. Thus
	and Blethyn)			in four different	Barr: 0.45	two intraobserver and two interobserver
	for plain	Exclusion		bowel segments	Blethyn: 0.43	variabilities could be derived for each
	abdominal	criteria:		(ascending colon,	Leech: 0.91	parameter. Kappa coefficients were
	radiography,	None reported		transverse colon,		calculated as indicators of intra- and
	in order to			descending colon	-Period 2	interobserver variability.
	determine	<u>Setting:</u>		and rectum) and	Barr:0.71	
	which one is	hospital		also the	Blethyn: 0.31	
	most useful			consistency of the	Leech: 0.84	
	in clinical			faces i.e. granular		
	practice			or rocky stools	All k values are statistically	
				Constipation	significant (p<0.05)	
				defined as Barr		
				score>10	Kappa (k) coefficients (level of	
					agreement):	
				Blethyn system:	<0.20: poor	
				Rough scoring	021-0.40: fair	
				system used to	0.41-0.60: moderate	
				assess amount of	0.61-0.80: good	
				faeces in large	0.81-1.00: very good	
				bowel		
				-Normal, grade 0:		

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
	level	prevalence		standard		
				faeces in rectum		
				and cecum only		
				-Grade 1, mild		
				constipation:		
				faeces in rectum,		
				cecum and		
				discontinuous		
				elsewhere		
				-Grade 2,		
				moderate		
				constipation:		
				faeces in rectum,		
				cecum with		
				continuous		
				faeces affecting		
				all segments		
				-Grade 3, severe		
				constipation:		
				faeces in rectum		
				and caecum,		
				continuous		
				elsewhere with		
				dilated colon and		
				rectal impaction		
				Leech method:		
				The colon is		
				divided into there		
				segments:		
				1.ascending and		
				proximal		
				transverse colon		
				2.distal		
				transverse and		
				descending colon		
				3. rectosigmoid		
				Amount of faces		
				in each segment		

Bibliographic Information	Study type & Evidence level	Number of patients & prevalence	Population Characteristics	Type of test and Reference standard	Sensitivity, Specificity, PPV and NPV	Reviewer comment
				scored from 0 to 5. O indicates no faeces and 5 severe faecal loading and bowel dilatation. With a possible score of 0-15, > 8 considered to indicate constipation		

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
	level	prevalence		standard		
Giramonti et al.	Study type:	133 children	133 children	Test and	Correlation between symptoms	Authors defined constipation in the past
The association	Diagnostic		35 males	<u>Reference</u>	of constipation and faecal load	as "at least 2 weeks of hard, rock-like
of constipation	case control	Inclusion	Mean age: 5.6	Standard	on abdominal X-ray:	stools passed less than 3 times/week
with childhood		<u>criteria:</u> Cases:	years	(not clear which		without evidence of structural,
urinary tract	Evidence	Children with a	(range: from	one was what)	Correlation coefficient=0.08	endocrine or metabolic disease, other
infections.	<u>level</u> : III	history of UTIs	newborn to 14			useful association include: abnormally
2005. Journal of		who were	years)	-Abdominal		large stools, and difficult or painful
Pediatric	Study aim:	already		radiograph (KUB)		defecation, associated with stools
Urology 1[4],	To evaluate	undergoing a	Group 1 (history of			accidents or faecal smearing in
273-278United	the	VCUG(voiding	UTI	-Clinical		undergarments
Kingdom.	relationship	cystourethrogra	n=100	variables:		
	between a	m), who were				Abdominal X-rays reviewed blindly by
	history of	on medications	Group 2 (no history	Number of bowel		three physicians: two paediatric
	constipation,	for the	of UTI)	movements/week		radiologists an one paediatric urologist
	faecal	treatment of	n= 33			and score for faecal loading based on a
	loading on	constipation		Stools		previously validated scoring system
	X-rays and a	Controls:	Country:	consistency		(Leech)
	history of	Children	USA			
	UTIs in an	undergoing a				Data collected prospectively on several
	office	plain film of the				historical questions about constipation
	practice	abdomen for				shortly after the X-ray was performed,
		reasons that did				but before they were reviewed with the
		not include				family. An interviewer filled out the
		constipation/				history questionnaire using consensus
		UTIs (e.g. renal				of the child's and parents' responses.
		calculi,				Data were also obtained regarding a
		gastroesophage				history of UTI. No data on the
		al reflux)				interviewer are reported
		Exclusion				Constipation history responses were
		criteria:				scored from 1 to 3 and a total history
		Neurological				score was obtained scored were
		bowel and/or				grouped as:
		bladder				1-none or mild, 2-moderate, 3-severe
		dysfunction or				
		lower				Data derived from scores on faecal
		gastrointestinal				loading were averaged for each patient
		problems.				and the scores then grouped in the

Bibliographic Information	Study type & Evidence level	Number of patients & prevalence	Population Characteristics	Type of test and Reference standard	Sensitivity, Specificity, PPV and NPV	Reviewer comment
	level	prevalence Children with no history of UTI who were undergoing a plain film of the abdomen for constipation or encopresis <u>Setting:</u> office practice		standard		same way as previous. Questionnaire not piloted previous to the study As it was thought that children beyond toilet-training age would be more likely to have developed constipation related to overall elimination dysfunction and therefore UTIs as well, the data for children > 3 years were analysed separately

Bibliographic Stud Information & Ev	dy type Nur vidence pa	mber of Po atients Char	pulation racteristics	Type of test (s)	Follow-up & Outcome Measures	Reviewer comments
Bibliographic InformationStudy & Ev IdLewis et al.Study DiagnosingStudy Retro- e cohHirschsprung's disease: increasing the odds of a positive rectal biopsy result.Evide e coh2003. Journal of PediatricStudy To te Surgery 38[3], 	dy type Nur vidence pa evel 315 ch ospectiv criteria onort Inclus orite -Coho criteria -Coho conce -Coho consti preser v aim: diagno vaim: diagno vaim: diseas key diseas	mber of atientsPo Charhildren315 chion a:-265 ch hade uort 1:rectal bren nting with pation to ose sse (HD)-50 chi concur	byulation racteristics hildren: hildren who undergone biopsy ildren, rrent selected (cohort 2)	Type of test (s) Tests: Rectal biopsy	Follow-up & Outcome Measures Effect Size Clinical features in children with Hirschsprung's disease and idiopathic constipation (IC, n=40) -Onset of constipation <1 year old Delayed passage of meconium (%) HD: 65 IC: 13 P< 0.05	Additional information from study Questionnaires, telephone interviews and patients visits used to compile long- term data. In reporting features listed in the questionnaire only patients with definite information were included: the number of patients in each analysis varies to exclude those with missing data Delayed passage of meconium defined as failure to pass meconium in the first
featu the h physi exam and radio evalu would to av unne recta biops	res in -Coho istory, idiopa ical consti- nination <u>Exclus</u> graphic <u>criteria</u> uation Patien d allow underg oid evalua icessary consti- l sies throug proced HD	ort 2: thic pation <u>sion</u> <u>a:</u> nts going re- ation fro pation pull- gh dure for			Abdominal distension (%) HD: 80 IC: 42 P< 0.05 Vomiting (%) HD: 72 IC: 21 P< 0.05 Faecal impaction requiring manual evacuation (%) HD: 6 IC: 30 P< 0.05 Enterocolitis (%) HD: 13	48h of life. These data were available in 59% of cases Abdominal distension determined from parental response to questionnaire or data noted during patients visits Enterocolitis defined as diarrhoea associated with fever <u>Reviewer comments:</u> Data on clinical features not available for all children Unclear what kind of rectal biopsy was performed and how the diagnosis of HD was made <u>Source of funding:</u>

Diagnostic Value of the Rectal Biopsy in children with Chronic Idiopathic Constipation

Bibliographic Information	Study type & Evidence	Number of patients	Population Characteristics	Type of test (s)	Follow-up & Outcome Measures	Reviewer comments
	level				Effect Size	
					NS	
					Onset of constinution >1 year	
					old	
					Delayed passage of meconium	
					(%)	
					HD: 81	
					IC: 1	
					P< 0.05	
					Abdominal distension (%)	
					HD: 53	
					IC: 7	
					P< 0.05	
					Vomiting (%)	
					HD: 23	
					IC: 0	
					P< 0.05	
					Faecal impaction requiring	
					manual evacuation (%)	
					HD: 46	
					IC: 30	
					NS	
					Enterocolitis (%)	
					HD: 13	
					IC: 14	
					NS	
					Age at onset of symptoms	
					-Hirschsprung's (HD) (n=46)	
					Mean: 8 months (range 1 day	
					to 9 years)	
					1 rst month of life: 50 %	
					1rst vear of life: 87%	

Bibliographic	Study type	Number of	Population	Type of test (s)	Follow-up & Outcome	Reviewer comments
Information	& Evidence	patients	Characteristics		Measures	
	level				Effect Size	
					after 1 year of life: 13%	
					-Idiopathic constipation (IC)	
					(n=40)	
					Mean: 15 months (range 7	
					days to 16 years)	
					1rst week of life: 15%	
					1rst month of life: 55%	
					1rst year of life: 68%	
					after 1 year of life: 32%	
					At least 34% of HD patients	
					had the classic triad (delayed	
					passage of meconium +	
					vomiting + abdominal	
					distension). At least 1 feature	
					of the triad noted in 98% of	
					patients with HD. Only 60% of	
					patients with IC had a history	
					of delayed passage of	
					meconium, vomiting or	
					abdominal distension. 100 %	
					HD patients vs. 64% IC	
					patients had 1 or more of the	
					following: delayed passage of	
					meconium, vomiting,	
					abdominal distension and a	
					transition zone on contrast	
					enema. 36% of IC patients had	
					none of these features.	

Bibliographic	Study type	Number of	Population	Type of test (s)	Follow-up & Outcome	Reviewer comments
Information	& Evidence	patients	Characteristics		Measures	
	level			- ·	Effect Size	
Pini-Prato et al.	Study type:	141 patients	141 patients	lests:	Clinical variables	Additional information from study
Rectal suction	Retrospectiv		median age: 20	-Rectal suction	a. Meconium passage (%)	I otal number of biopsies: 1118
biopsy in the	e cohort	Inclusion	months	biopsy	-Failure/delay	performed on 429 patients (mean of 2.6
workup of		criteria:	mean 44 months ±		FC (n=45): 7	each). In 63 patients (14.7%) biopsies
childhood	<u>Evidence</u>	Patients with	67	-Clinical variables	HD (n=47): 87	inadequate for a reliable diagnosis
chronic	<u>level</u> :	intestinal		:	IND (49): 22.5	absence of submucosal layer) 143
constipation:	2+	dysganglinonos	<u>Country:</u>			patients (33.3%) received a diagnosis
indications and		es (ID)	Italy	a. Meconium	FC vs. HD p<0.001	of ID. 96/143 fulfilled inclusion criteria,
diagnostic	Study aim:	(Hirschsprung's		passage		being 49 IND and 47 HD. 45
value. 2007.	To describe	disease (HD)		 b. Symptoms 	-Normal	consecutive patients with a diagnosis of
Pediatric	the clinical	and intestinal		onset	FC (n=45): 93	FC (out of the remaining 286 patients)
Surgery	features of a	neuronal		c. Intestinal	HD (n=47): 13	fulfilled inclusion criteria and were
International	group	dysplasia (IND))		obstruction	IND (49): 77.5	consequently included, for a total
23[2], 117-122	patients with	who were		d. Abdominal		sample of 141
	intestinal	diagnosed in		distension	FC vs. HD p<0.001	
	dysganglino	the period		e. Reported		Rectal suction biopsies (RSB)
	noses (ID)	between		enterocolitis	b. Symptoms onset (%)	performed with the instrument Solo-
	(Hirschsprun	February 2000		f. Failure to thrive	- at < 1year old	RBT ©. Each patient underwent 2 to 4
	g's disease	and July 2005		g. Palpable faecal	FC (n=45): 80	biopsies 2 to 10 cms from the pectinate
	(HD) and			masses	HD (n=47): 96	line. Various histochemical staining
	intestinal	Exclusion		h. Soiling	IND (49): 94	(AChE, LDH, ANE, NADPH-diaphorase
	neuronal	criteria:				and Toluidine Blue) were used to
	dysplasia	Not stated			FC vs. HD p<0.02	diagnose HD and IND. All biopsies
	(IND)) along					were evaluated by a single, senior and
	with a group				- at > 1 year old	experienced pathologist.
	of				FC (n=45): 20	
	consecutive				HD (n=47): 4	HD diagnosed by demonstrating:
	patients with				IND (49): 6	- a dramatic increased in AChE-
	functional					positive nerve fibres in the
	constipation				FC vs. HD p<0.02	lamina propia and muscularis
	(FC), to					mucosae
	compare				c. Intestinal obstruction (%)	 - thick nerve trunks
	them and to				FC (n=45): 0	 absent ganglion cells in
	find out if the				HD (n=47): 49	submucosal
	clinical				IND (49): 26.5	
	criteria to					
	indicate				FC vs. HD p<0.001	In case on negative RSB functional
	rectal				-	constipation diagnosed according to

Bibliographic	Study type	Number of	Population	Type of test (s)	Follow-up & Outcome	Reviewer comments
Information	& Evidence	patients	Characteristics		Measures	
	level				Effect Size	
	suction				d. Abdominal distension (%)	Rome II criteria:
	biopsy in				FC (n=45): 20	At least 2 weeks of:
	constipated				HD (n=47): 85	-scybalous, pebble like, hard stools fro
	children do				IND (49): 26.5	a majority of stools
	exist					-firm stools 2 o less times/week
					FC vs. HD p<0.001	absence of any organic cause of
						constipation (IND, HD, anorectal
					e. Reported enterocolitis (%)	malformations, spinal dysraphism,
					FC (n=45): 9	metabolic disorders)
					HD (n=47): 10.5	
					IND (49): 20.5	Clinical variables retrospectively
						extracted from patients notes
					FC VS. HD, NS	Boviowar commenta:
					f Epiluro to thrive $(%)$	Lincloar how the reviewing process was
					FC (n = 45): 11	conducted
					HD $(n=47)$: 27 5	conducted
					IND (49): 22.5	Source of funding:
						Not stated
					FC vs. HD p<0.045	
					g. Palpable faecal masses (%)	
					FC (n=45): 22	
					HD (n=47): 17	
					IND (49): 20.5	
					FC vs. HD, NS	
					h, Soiling (%)	
					FC (n=45): 46.5	
					HD (n=47): 4	
					IND (49): 4	
					FC vs. HD p<0.001	
1						

Bibliographic	Study type	Number of	Population	Type of test (s)	Follow-up & Outcome	Reviewer comments
Information	& Evidence	patients	Characteristics		Measures	
	level				Effect Size	
Ghosh et al.	Study type:	141 children	141 children	<u>Tests:</u>	Features in history and	Additional information from study
Rectal biopsy in	Retrospectiv		age at biopsy: 1	-Rectal biopsy:	examination	Histological diagnosis usually made on
the investigation	e case	Inclusion	day to 13 years		-Hirschsprung's (n=17):	haematoxylin and eosin staining with at
of constipation.	series	<u>criteria:</u>	gender not reported	Noblett suction		least 100 serial sections looked at in
1998. Archives		All children who		biopsy in children	age at diagnosis: 1 day to 3	detail. Acetylcholinesterase used
of Disease in	Evidence	had rectal	Country:	younger than 1	years	occasionally but not as the main
Childhood	level:	biopsy to	UK	year	14 children: < 4 weeks	method of diagnosis
79[3], 266-268	3	exclude			1 child: 4 to 12 weeks	
		Hirschsprung's		Open transanal	1 child: 12 weeks to 1 year	Constipation defined as a decreased
	Study aim:	disease		rectal biopsy	1 child: > 1 year	frequency of bowel movement
	To develop	between		under general		s(<3/week), or a difficulty in defection
	criteria that	January 1, 1993		anaesthesia	history of delayed passage of	which is perceived by the parents as a
	would	and December		performed at	meconium (>48h after birth):	problem, requiring medication (oral or
	reliably and	31, 1995 at		least 1cm above	10 (58.8%)	rectal) or manual intervention by the
	consistently	Southampton		pectinate line, in		parents. This included anal stimulation
	identify	General		older children or	age of onset of constipation:	with cotton bud, holding the buttocks
	children with	Hospital		following	all 17 children: < 4 weeks	apart and manual evacuation
	Hirschsprun			repeated failure		
	g's disease	Exclusion		of Nobblet biopsy	bleeding per rectum: 0	History of onset of constipation was
	(HD) and	criteria:			anal fissures:0	available in 136 of the 141 children
	thereby	Not stated		- Clinical	sever behavioural/emotional	(96%). The 5 children in whom this
	avoid the			variables:	problems: 0	history could not be obtained from the
	trauma and			extracted from	soiling: 0	notes were all older than 1 year (3
	expense of			case notes	enterocolitis: 8 (47%)	teenagers) and none had HD
	unnecessary					
	rectal				-No Hirschsprung's (n=124)	A total of 186 biopsies performed, with
	biopsies in					22% failures. (Suction: total 74, 35%
	the others				age at biopsy: 1 day to 13	failures; Open: total 100, 14% failures,
					years	operative total 12, no failures)
					20 children: < 4 weeks	
					12 children: 4 to 12 weeks	Reviewer comments:
					14 children: 12 weeks to 1 year	Unclear how the reviewing process was
					78 children: > 1 year	conducted
					history of delayed passage of	Source of funding:
					meconium (>48h after birth):	Not stated
					17 (13.7%)	

Bibliographic Information	Study type & Evidence	Number of patients	Population Characteristics	Type of test (s)	Follow-up & Outcome Measures	Reviewer comments
	level	•••••			Effect Size	
					age of onset of constipation: 40 children: < 4 weeks 32 children: 4 to 12 weeks 22 children: 12 weeks to 1 year 25 children: > 1 year bleeding per rectum: 37 (30%) anal fissures: 14 (11%) sever behavioural/emotional problems: 10 (8%) soiling: 16 (13%) optorecolitio: 0	

Bibliographic	Study type	Number of	Population	Type of test (s)	Follow-up & Outcome	Reviewer comments
Information	& Evidence	patients	Characteristics		Measures	
	level				Effect Size	
Khan et al. The	Study type:	182 patients	182 patients	Tests:	-Total number of patients	Additional information from study
constipated	Retrospectiv			 Suction rectal 	diagnosed with HD: 25 (14%)	Clinical details, laboratory investigations
child: how likely	е	Inclusion	118 males	biopsy (SRB) and		and histopathological reports reviewed
is	case series	criteria:		full-thickness	-mean age of patients	retrospectively
Hirschsprung's		Patients who	Mean age 2.9 years	rectal biopsy	diagnosed with HD: 3.64	
disease? 2003.	Evidence	presented with	(range 2 days to 16		months (range 2 days to 4	The Great Ormond Street (GOS)
Pediatric	level:	chronic	years)	-Clinical	years)	suction instrument (modified Nobblet)
Surgery	3	constipation or		variables:		was used. 2 of 4 specimens were
International		intestinal	Country:		Clinical symptoms in children	obtained at 2, 3 and 4 cm above the
19[6], 439-442	Study aim:	obstruction and	UK	a. Meconium	with HD (number of children):	dentate line, in the ward or theatre
	To review	had rectal		passage		without anaesthesias. All suction biopsy
	author's	biopsy to		 b. Constipation 	Meconium passed> 48 h:	specimens were examined by routine
	experience	exclude HD in		since birth	-In total sample:	fixation with HE staining and AChE
	of rectal	the University		c. Intestinal	< 1 year old: 35	histochemistry. All full thickness
	biopsy to	Hospital of		obstruction	>1 year old: 6	biopsies were done under general
	exclude	Wales, Cardiff		d. Failure to thrive	-In HD children: 16	anaesthesia and examined by routine
	Hirschsprun			e. Chronic	% of clinical feature to HD: 39	fixation with HE staining. The
	g's disease	Exclusion		abdominal		histochemical criteria used for the
	(HD) by	<u>criteria:</u>		distension	Meconium passed< 24 h:	diagnosis of HD were those of Meier-
	haematoxyli	Not stated			-In total sample:	Ruge in 1972 i.e. the combination of an
	n-eosin (HE)				< 1 year old: 40	absence of submucosal ganglion cells
	staining and				>1 year old: 74	and an increased AChE activity with
	acetylcholine				-In HD children: 6	parasympathetic fibres of the
	sterase				% of clinical feature to HD: 5	muscularis mucosae and lamina propia
	(AChE)					mucosae. At least 60 sections were
	stains, and				Passage of meconium	examined from each block to find the
	author's				unknown:	submucosal ganglion cells
	clinical				-In total sample:	
	criteria to				< 1 year old: 29	Suction biopsy accepted as adequate
	perform				>1 year old: 17	even if only 1 out of 2 to 4 specimens
	rectal biopsy				-In HD children: 3	contained mucosa and sub-mucosa
	In these				% of clinical feature to HD: 11	
	children					182 patents who had rectal biopsies
					Constipation since birth:	provided355 specimens in which 79%
					-In total sample:	of suctions biopsies and 97% of full-
					< 1 year old: 33	thickness biopsies were adequate.
					>1 year old: 20	Adequate biopsies include rectal
					-In HD children: 17	mucosa and submucosal according to

Bibliographic	Study type	Number of	Population	Type of test (s)	Follow-up & Outcome	Reviewer comments
Information	& Evidence	patients	Characteristics		Measures	
	level					
					% of clinical feature to HD: 32	Noblett. In 20 children with HD the
					Intertinal chatructions	diagnosis was made at the first attempt
					Intestinal obstruction:	biopoion performed on 14 (8%) of 182
					-in total sample.	piopsies periorned on 14 (8%) of 182
					< 1 year old: 1	biopsy, clarification of atypical
					In HD childron: 0	incruation and confirmation of false
					% of clinical feature to HD: 60	nervation and commation of laise
					78 Of chillear leature to TID. 09	underwent SRB were > 1 year old
					Failure to thrive:	Because 5 children (12 specimens) who
					-In total sample:	were older than 1 year had inadequate
					< 1 year old: 10	suction biopsies at beginning of series.
					>1 year old: 8	it was decided that SRB was not
					-In HD children: 4	suitable fro children >1 year old. 3
					% of clinical feature to HD: 22	patients with HD (aged 6 days, 12 days
						and 6 weeks) has false negative AChE
					Chronic abdominal distension:	staining. In these the diagnosis were
					-In total sample:	later established from repeated
					< 1 year old: 6	biopsies: 1 full thickness biopsy, 1
					>1 year old: 7	laparotomy and 1 suction biopsy
					-In HD children: 3	
					% of clinical feature to HD: 23	Reviewer comments:
						Unclear how the reviewing process was
						conducted
						No definition of constinction or other
						No definition of constipation of other
						cinical symptoms given
						Authors explained that patients may
						have had more than one symptom but
						these figures were not reported in the
						paper
						· ·
						Source of funding:
						Not stated

Diagnostic Value of the Abdominal Ultrasound in Children with Chronic Idiopathic Constipation

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
	level	prevalence		standard		

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
Kliin et al. The	Study type:	19 patients	19 natients	Tost	Rectal diameter (cm)	Illtrasound done with the patient
diameter of the	Diagnostic		aged between 5-13	lower abdominal		supine 7.5 MHz probe applied on
rectum on	Case control	Inclusion	vears	ultrasound of	(Mean_standard deviation	abdominal skin approximately 2cm
ultrasonography	Cube control	criteria:	youro	rectum	95% CI)	above the symphysis Measurement
as a diagnostic	Evidence	Positive	Group 1:			performed with moderate (30-70 %
tool for	level:	diagnosis of	23 patient s with	Reference	-Group 1 (constipated, n=23):	capacity of for age) filled bladder at an
constipation in	111	constipation,	positive history of	Standard :	4.9 (1.01; 4.4 to 5.3)	angle of about 15 degrees downward
children with		made by patient	voiding dysfunction	None reported		from the transverse plane. The
dysfunctional	Study aim:	history and	and constipation		-Group 2 (control, n=26)	diameter of the rectum, behind the
voiding. 2004.	to prove the	physical			2.1 (0.64; 1.8 to 2.4)	bladder was measured twice.
Journal of	accuracy of	examination	Group 2:			
Urology 172[5	the	when the	26 urological		p<0.001	If stools had been passed in the last
Pt 1], 1986-	transverse	patient had at	patients without			two hours or patients had an urge to
1988	diameter of	least 2 positive	lower urinary tract			defecate during the investigation the
	the rectum	signs, including:	dysfunction and a			were not included in the study, but this
	on	-2 or fewer	normal defecation			situation did not occur
	ultrasonogra	bowel	pattern, diagnosed			
	phy as an	movements	with undescended			In all patients it was possible to obtain a
	additional	weekly without	testicle, periodic			reliable and repeatable measurement of
	parameter	laxative therapy	control for upper			the rectum if at least some bladder
	tor	-2 or more	urinary tract			filling was present
	diagnosing	episodes of	dilatation, etc.			It was not non-out-of-of-on-out-of-on-out-of-of-out-of-of-out-of-of-out-out-of-out-of-out-of-out-of-out-of-out-of-out-of-out-of-out-of-out-of-out-of-out-of-out-of-out-of-out-of-out-out-of-out-out-of-out-of-out-out-of-out-out-out-out-out-out-out-out-out-out
	constipation	faecal solling	Country			It was not reported who performed the
	in children	weekly	<u>Country:</u>			ultrasound, or whether this person was
	with lower		UK			bindea
	dycfunction	passage of a				No significant difference in age between
	uysiunction	stool once				the two groups $(p=0.20)$ or in period
		Studi Unice				between the last time a stool was
		dave				passed prior to the rectal measurement
		-nalnahle				(n=0.16)
		abdominal				(p=0.10)
		and/or rectal				In all patients with voiding dysfunction
		mass				and faecal constipation (Group 1) rectal
						examination confirmed stool in the
		Exclusion				rectum, but there are no data reported
		criteria: laxative				on this variable for the control group,
		therapy,				probably for ethical reasons

Bibliographic Information	Study type & Evidence	Number of patients &	Population Characteristics	Type of test and Reference	Sensitivity, Specificity, PPV and NPV	Reviewer comment
	level	prevalence		standard		
		constipation				
		due to				Source of funding: Not stated
		neurological				
		disease,				
		disease of the				
		gastrointestinal				
		tract based on				
		endocrinological				
		, metabolic,				
		disease or				
		connective				
		tissue disease				
		Setting: hospital				
		<u></u>				

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
	level	prevalence		standard		
Singh et al. Use	Study type:	177 children	177 children	<u>Test:</u>	Median rectal crescent (cm)	A portable US machine with a 5-MHz
of pelvic	Diagnostic.		-	Pelvic ultrasound		probe (falcon 2101 Ultrasound scanner
ultrasound in	Case control	Inclusion	Group 1:		Group 1 (healthy children):	with a transducer type 8803 [3.0-5.0
the diagnosis of		<u>criteria:</u>	82 children (median	Reference test:		MHz], B-K Medical, Copenhagen,
megarectum in	<u>Evidence</u>	Children	age 5.5 years,	none reported	2.4 (range 1.3 to 4.2; IQR	Denmark) was used.
children with	level:	referred after	range 0.30-15.30)		0.72)	
constipation.	111	failing to	with no history of			The same individual performed all the
2005. Journal of		respond to	constipation or		Group 2 (children with	US scans, but not other data on this
Pediatric	Study aim:	medical	other anorectal or		constipation):	were reported (as blinding, individual's
Surgery 40[12],	to establish	treatment.	gastrointestinal			experience in radiology, etc)
1941-1944	normal	Diagnosis of	problems and no		3.4 (range 2.10 to 7.0; IQR	
	values for	constipation	previous anorectal		1.0)	All children had a full or partially full
	the rectal	made once the	surgery			bladder at the time of measurement. In
	crescent in	child had 2 or			p<0.001	cases where the child was initially
	healthy	more of the	Group 2:			scanned and the bladder was noted to
	children,	following:	95 children (median		IQR= interquartile range	be empty, the US was abandoned and
	compare	-less than 3	age 6.5 years,			the child was offered liberal fluids orally.
	them with	bowel	range 0.40-16.40)		Receiver operating	The scan was repeated within an hour
	the rectal	movements/we	with a history of		characteristic analysis:	and in all cases, by then, the child had
	crescent in	ek	constipation of at			a full or partially full bladder
	children with	-periodic	least 6 months		-Area under the curve:	
	constipation	passage of a	duration, referred to		0.847	The US probe was applied on the
	and explore	large stool with	a tertiary referral		95% CI: 0.791 to 0.904	anterior abdominal wall in the midline,
	whether	discomfort or	centre			approximately 1-2 cm above the
	pelvic	pain				symphysis at a 90 degrees angle to the
	ultrasound	-a palpable	Country:		Cut-off point for establishing	abdominal wall. This showed the
	can hep in	abdominal	UK		the diagnosis of megarectum:	impression of the rectum behind the
	establishing	mass on				urinary bladder as a crescent which
	a diagnosis	physical			3.0 cm	was measured in centimetres
	of	examination				
	megarectum	-faecal soiling in				There were no significant differences
		the presence of				between the two groups in terms of
		any of the				age, weight and height (p values 0.114,
		above				0.198 and 0.131 respectively)
		Exclusion				Results were adjusted for confounders
		criteria:				(age, height and weight)
		Previous				

Bibliographic Information	Study type & Evidence level	Number of patients & prevalence	Population Characteristics	Type of test and Reference standard	Sensitivity, Specificity, PPV and NPV	Reviewer comment
	level	anorectal surgery (e.g. pull-through procedures for Hirschsprung's disease or anorectal myectomy) <u>Setting:</u> tertiary referral centre		standard		Age and rectal diameter were significantly related (p<0.0001): the older the child the bigger the rectal diameter Time to last evacuation was not ascertained and authors acknowledged this may influence the size of the rectal crescent <u>Source of funding</u> : not stated

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information		patients &	Characteristics	standard		
Bijos ot al. Tho	Study type:	225 childron	225 childron	Toot	Diamotors of roctal ampulla by	LIS assessment of steel retention and
bijus et al. The	Diagnostic	225 children		<u>Abdominal</u>	$\frac{\text{Diameters of fectal ampula by}}{\text{ILS (mm, moon + SD)}}$	colonic onlargement involved
ultracound	Case control	Inclusion	Group 1:	ultrasound	Δq_{0} (vers)	measurement of the transverse
evamination of	Case control	criteria:	120 children with	uitrasouriu	Age (years)	diameter of the rectal ampulla (by US)
the howel as a	Evidence	Referred	chronic constinution	Reference tests:	-Group 1 (constinated):	and pelvic width (externally using a
method of		hecause of	(72 hove mean are	Proctoscony (for	All ages:	measuring tape) Pelvic width was
assessment of		chronic	6 25 years range	diagnosing faecal	$13, 06 \pm 9, 68$ (range 30 to 82)	defined as the distance between the
functional		constination	1 6 to 17 0)	impaction)	$+3.00 \pm 3.00$ (range 50 to 02)	external margins of the anterior
chronic	Study aim:	based on	1.0 10 17.3)	impaction)	<3: 38 35 + 8 65	superior iliac spines. The ratio between
constinution in	to determine	history and	Group 2:		$31 \text{ to } 6: 4116 \pm 872$	the transverse diameter of the rectal
children 2007	whether a	nhysical	105 children with		6.1 to 12 : 46.15 ± 9.56	ampulla and transverse diameter of the
Pediatric	new method	evamination.	normal defecation		12 vers: 10.00 ± 0.00	pelvis was calculated to give the
Radiology	of ultrasound	defecation	nattern (mean age		>12 years. 40.00 ± 10.10	rectonelvic ratio
37[12] 1247-		disorders	8 25 years)		-Group 2 (control):	
1252	assessment	nersisting	0.20 youro)	Transit times	All ages:	US was performed using a Philips HDI
1202	of stool	longer than 6	Country.	(hours upper limit	31 83 + 824 (range not given)	4000 US unit (Philips Best The
	retention	months all	Poland	of 66 based on		Netherlands) equipped with three
	could be	patients fulfilled		literature)	≤3: 27.07 + 8.00	electronic transducers with various
	used as a	Rome II criteria		<u>interactor oy</u>	3.1 to 6: 29.25 + 6.86	frequencies from 2-14 MHz, children
	method of	for defecation		≤66: normal-	6.1 to $12:32.85 + 8.73$	were examined before food and had a
	identifving	disorders		transit	>12 years: 35.15 ± 7.18	slightly filled bladder. Patients who
	children with	(frequency of		constipation		passed stool on the day of the
	functional	bowel			p<0.001 for every age group	examination were temporarily excluded
	chronic	movements less		66-100: slow-		from the study until they became
	constipation,	than twice a		transit	Mean rectopelvic ratios for all	constipated again.
	and to	week,		constipation	ages (mean ± SD)	
	determine	consistency and			(Cut-off value to diagnose	Rectal ampulla width was measured
	whether	size of stool		>100: very	megarectum: 0.189)	with the probe applied to the anterior
	children with	caused pain		delayed slow-		abdomen above the symphysis.
	an enlarged	during		transit	-Group 1 (constipated):	Measurement was performed on
	rectum and	defecation,		constipation	All ages:	oblique transaxial scanning plane to
	colon (as	withholding			0. 22 ± 0.05	obtain transverse diameter of the
	seen on US)	behaviour)				ampulla. Measurement was taken
	should be				≤3: 0.24 ± 0.060	several times and the highest one
	referred for	Exclusion			3.1 to 6: 0.23 ± 0.05	recorded taken as the final
	further	criteria:			6.1 to 12: 0.22 ± 0.05	measurement
	procedures	anatomic			>12 years: 0.19 ± 0.04	
	such as	abnormality				Total and segmental colonic transit

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
	level	prevalence		standard		
	proctoscopy	(Hirschsprung's			-Group 2 (control):	time measured by the modified sixth
	and	disease,			All ages:	day Hinton method. Total and
	assessment	congenital			0.15 ± 0.04	segmental time obtained by multiplying
	of colonic	abnormalities of				the number of radiopaque markers
	transit time.	the anorectal			≤3: 0.17 ± 0.05	seen on the radiograph by 1.2 (time in
		region)			3.1 to 6: 0.16 ± 0.04	hours/number of markers swallowed by
		neurological			1 to 12: 0.15 ± 0.05	the patient)
		and psychiatric			>12 years: 0.14 ± 0.03	
		conditions				The same individual performed all the
		(cerebral palsy,			p<0.001 for age groups (years):	US scans, but not other data on this
		spina bifida,			≤3;	were reported (as blinding, individual's
		mental			3.1 to 6; 6.1 to 12	experience in radiology, etc)
		retardation,			p=0.002 for >12 years	
		anorexia				It is not clear what number of children
		nervosa)			US vs. proctoscopy in the	underwent each of the tests
		,metabolic			diagnosis of faecal impaction	
		conditions				It is not clear how the authors
		(diabetes			-Sensitivity: 88.3%	calculated the sensitivity of the US vs.,
		mellitus/insipidu				proctoscopy to diagnose faecal
		s) endocrine			Mean colonic transit times:	impaction, as the results of
		disorders			Children with faecal impaction	proctoscopy are not reported
		(hypothyroidism			(as per US) had significantly	
), previous			longer average segmental	It is difficult to know exactly how many
		thoracic or			transit time for the rectum,	children were diagnosed with faecal
		abdominal			sigmoid and left colon	impaction by US, as these data are
		surgery			(p<0.001, p=0.0015 and	reported only in the form of a bar
					p=0.0104 respectively) there	graph. Data on number of children
		(control			was not statistically significant	diagnosed with "overfilled colon" are
		patients: normal			difference for the right side of	not reported at all.
		defecation			the colon. Children with an	
		patterns,			overfilled splenic flexure on US	It is not clear whether "enlarged" and
		treated for			had a significantly longer transit	"overfilled" colon mean the same for
		various			time in the left side of the colon	the authors, as no measurements of
		symptoms like			(p=0.0029)	"enlarged" colon are reported.
		chronic				
		abdominal pain,			Definitions of:	Children apparently underwent DRE
		food allergies)				but no results are reported
					-Faecal impaction (as per US in	

Bibliographic Information	Study type & Evidence level	Number of patients & prevalence	Population Characteristics	Type of test and Reference standard	Sensitivity, Specificity, PPV and NPV	Reviewer comment
	level	prevalence Setting: gastroenterolog y outpatient clinic	Characteristics	standard	sagital plane): when pelvic structures were covered by stool masses and were not even partially visible. -Overfilled colon (as per US): Overfilled bowel at the splenic flexure: when it was impossible to visualise the entire length of the left kidney due to the lack of visibility of the lower pole of the kidney because of bowel contents. Probe applied to the long axis of the spleen. Overfilling of the transverse colon: when the superior mesenteric artery was not visible with the probe applied in the sagital plane over the aorta	Control group did not differ from patients regarding gender, the comparison regarding age is not clearly reported Source of funding: Not stated

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
	level	prevalence		standard		
Joensson et al.	Study type:	51 children	51 children, aged 4-	Test:	Rectal diameter (mm) (mean ±	For transabdominal measurements of
Transabdominal	Diagnostic.		12 years	Transabdominal	<u>2SD)</u>	rectal diameter: a 7.5 MHz probe
ultrasound of	Case control	Inclusion:		ultrasound of		applied to the abdomen approximately
rectum as a		Children	Group 1:	rectum	-Children with rectal impaction	2cm above the symphysis at 10 to15-
diagnostic tool	Evidence	referred to	27 children (mean		as per DRE (n=22, 20	degree downward angle. Diameter of
in childhood	level:	outpatient clinic	age 7.0±1.8 years)	Reference test:	constipated, 2 healthy):	the rectum measured in traverse plane.
constipation.	111	with either	diagnosed with	Digital rectal		At each session (n=3) diameters were
2008. Journal of		constipation or	chronic constipation	examination	40.5 ± 7.9	measured three times and mean value
Urology 179[5],	Study aim:	faecal	by Rome III criteria	(DRE)		was calculated. All children had a
1997-2002	To look into	incontinence,			-Children without rectal	partially full bladder range (28 to 450
	a possible	with or without	Group 2:		impaction as per DRE (n=26, 7	ml) corresponding to 20-155% of
	correlation	urinary	24 healthy children		constipated, 19 healthy):	expected bladder capacity for age at
	between a	incontinence	(mean age 9.1±2.7			the time of the measurement. In case
	dilated	and a history of	years)		21.0 ± 4.2	of empty bladder fluid was offered
	rectum	UTI. Patients				orally and scanning was repeated. If
	measured by	fulfilled Rome III	Country:		p<0.001	the child had a bowel movement within
	ultrasound	criteria, had at	the Netherlands			3 hours before the investigation or had
	and a faecal	least 2 of the			Cut-off value for the presence	an urge to defecate, the result was
	mass	following			of rectal impaction (average	excluded. All investigations were
	detected by	characteristics:			rectal diameter of children	performed by the same observer (a
	digital rectal	-fewer than 3			without impaction plus 2SD):	paediatric intern, who had no prior
	examination.	bowel				radiological experience) This observer
	To evaluate	movements/we			29.4 mm	was not reported blinded to the study
	whether this	ek				objectives and patient's characteristics
	method	-more than 1			Rectal diameter (mm) (mean ±	
	could	episode of			<u>2SD)</u>	There was no significant difference in
	diagnose	faecal				height and weight distribution between
	constipation	incontinence			Before treatment:	the 2 groups, but the healthy children
	according to	weekly			-Group 1 (Constipated, n=27):	were significantly older than the
	Rome III	-large stools in				constipated children
	criteria	rectum by DRE			39.6 ± 8.2	
		or palpable on				Constipated children received 3 days of
		abdominal			-Group 2 (Healthy):	disimpaction followed by 4 weeks of
		palpation				laxative treatment with polyethylene
		-occasional			21.4 ± 6.00	glycol and behavioural therapy. No
		passage of				other details reported
		large stools			p<0.001	
		-display of				No significant correlation between

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
	level	prevalence		standard		
		retentive			Alter treatment	bladder volume at the time of
		posturing and			-Group T (Constipated,	
		withholding			responded to treatment, n=15):	(1=0.04)
		Denaviour				These are rejectory data and accounted
		painiui			20.9 ± 5.0	for
		derecation			n (0.01 (as someored to some	101
		(heelth), eentrel			p<0.01 (as compared to same	Annerently bealthy shildren discussed
		(nealthy control			group before)	Apparently nealthy children diagnosed
		children were			p<0.05 (as compared to group	with faecal impaction did not receive
		recruited form			2)	any laxative treatment, which is
		employees of			4.4 shildren did net reen and to	worrying from an ethical point of view
		the Paediatrics			treatment and no significant	Authors calcovuladized the abdominal
					differences were cheeried in	Authors acknowledged the abdominal
		the hospital)			differences were observed in	
		Evolucion			their rectal diameter as	technical limitations related to arteracts
					compared to pre-treatment	like. acoustic enhancement, speed
		criteria: known			Intro obcony or veriability a	their passible influence on their results
		organic causes			intraobserver variability.	inell possible initialize on their results
		or constipation,			-coefficient of variation of the 3	is unclear
		Including			consecutive measurements:	No correlation was found between the
					E 90/ · 4 20/	No correlation was found between the
		disease, spinal			$5.0\% \pm 4.3\%$	heldron in either group
		and anal			7 of the constinuted children	children in eitner group
		congenital			(26%) had a ractal diameter	Source of funding
		abriornalities,			(20%) flau a fectal utaffeter	Supported by Karon Elico, Janaan
		pievious			smaller man me established	Supported by Nateri Elise Jensen
					impaction despite the fact that	
		inflammatory			they fulfilled the Rome III	
		howel disease			criteria for constinution 2	
		alleray			bealthy children with rectal	
		metabolic and			impaction had a markedly	
		endocrine			larger rectal diameter (29 and	
		dispases			31 mm) than the other healthy	
		children			controls	
		know to affect				
		howel function				
		organic causes of constipation, including Hirschsprung's disease, spinal and anal congenital abnormalities, previous surgery on the colon, inflammatory bowel disease, allergy, metabolic and endocrine diseases, children receiving drugs know to affect bowel function			Intraobserver variability: -coefficient of variation of the 3 consecutive measurements: 5.8% ± 4.3% 7 of the constipated children (26%) had a rectal diameter smaller than the established cut-off point for rectal impaction, despite the fact that they fulfilled the Rome III criteria for constipation. 2 healthy children with rectal impaction had a markedly larger rectal diameter (38 and 31 mm) than the other healthy controls.	their possible influence on their results is unclear No correlation was found between the rectal diameter and age or sex of the children in either group <u>Source of funding:</u> Supported by Karen Elise Jensen Foundation

Bibliographic Information	Study type & Evidence level	Number of patients & prevalence	Population Characteristics	Type of test and Reference standard	Sensitivity, Specificity, PPV and NPV	Reviewer comment
	level	during a 2-mont period before initiation (not specified which) <u>Setting:</u> outpatient clinic		standard		

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
	level	prevalence		standard		
Lakshminaraya	Study type:	500 children	500 children	<u>Test:</u>	Correlation between SSS and	Additional information from study
nan et al. A new	Diagnostic			Pelvic ultrasound	<u>US score</u>	-US scoring sheet (this score can be
ultrasound	prospective	Inclusion:	317 male			used even with an empty bladder)
scoring system	case series	All children,		Both transverse	-first visit (n=500)	
for assessing		both new	median age: 8	and longitudinal		Stool height (x): (bladder effect (y)):
the severity of	Evidence	referrals and	years (age range 8	planes	Mean SSS: 23.5 (SD 11.6)	
constipation in	level:	follow-up,	months to 18 years)			No stool: 1 (empty bladder: 0
children. 2008.	111	attending a		All scans done by	Mean US total score: 4.02 (SD	Retro bladder: 2 (n compression: 0)
Pediatric		constipation	Country:	same clinician	2.8)	Just above bladder: 3
Surgery	Study aim:	outpatient clinic	UK	after very brief		Nearly umbilicus: 4 (indented bladder:
International	To asses the			training	Pearson's correlation: 0.39	1)
24[12], 1379-	correlation	Exclusion			P<0.001	To umbilicus: 5 (Flattened bladder: 2)
1384	between	criteria:				Beyond umbilicus: 6 (displaced
	severity of	Children not		Reference test:	-second visit (n=226)	bladder: 3)
	constipation	compliant to		Clinical		Can't see upper edge: 7
	and	have		assessment:	Mean SSS: 19.9 (SD 12.6)	Uncooperative: 99
	ultrasound	assessment				Not available: 0
	(US)	done by US,		Standard	Mean US total score: 3.49 (SD	
	findings, the	cases when the		symptoms	2.6)	total =x+y
	correlation	US machine		severity scoring		
	between	was not		sheet (SSS),	Pearson's correlation: 0.49	-Symptom severity scoring sheet:
	clinical	available		completed by	P<0.001	
	examination			parent or child if		Filled in by parent, or child if old
	and US	Setting:		old enough	-third visit (n=62)	enough.
	findings and	Constipation				Q1 About the soiling problem (faecal
	the	outpatient clinic		Clinical	Mean SSS: 23.02 (SD 13.7)	incontinence/mess in underclothes) :
	correlation			assessment done		- none (0)
	between			by detailed	Mean US total score: 3.66 (SD	- rarely (1)
	findings at			history taking and	2.6)	- occasionally (2)
	serial out-			abdominal		- only is bowel loaded (5)
	patient			examination	Pearson's correlation: 0.26	- continuous day only (8)
	follow-up				P=0.04	- continuous day and night (10)
	visits to					
	assess				-fourth visit (n=12)	Q2 About the delay from passing one
	clinical					complete stool to the next:
	improvement				Mean SSS: 28.5 (SD 16.8)	- daily stool (0)
	s and US					- every 2 or 3 days (1)
	findings				Mean US total score: 4.9 (SD	- every 3-5 days (2)

Bibliographic	Study type & Evidence	Number of nationts &	Population Characteristics	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
internation	level	prevalence	Onaracteristics	standard		
		-			3.2)	- every 5-10 days (5),
						- greater than 10 (8)
					Pearson's correlation: 0.70 P=0.01	- never (10)
						Q3 About pain and difficulty with
					Pearson's correlation	passing stools:
					between US score and clinical	- none (0)
					examination of palpable faeces	- occasionally (1)
					per abdomen	- often (2)
						- with most stools (4)
					-first visit (n=500)	- with every stool (5)
					Mean palpable faeces score:	Q4 About the amount and types of
					1.42 (SD 1.6)	medicine needed regularly over the last
					Mean US total score: 4.02 (SD	- none (0)
					2 8)	- softeners only e.g. lactulose or
					2.0)	Docusate or daily Movicol or methyl
					Pearson's correlation: 0.89	cellulose (1)
					P<0.001	- softeners and daily stimulants e.g.:
						Senokot or picosulphate (2)
					-second visit (n=226)	- softeners and daily stimulants and
						weekend extra picosulphate or Movicol
					Mean palpable faeces score:	(4)
					1.10 (SD 1.6)	- medicines as well as extra weekend
						klenprep or high dose Movicol (8)
					Mean US total score: 3.49 (SD	- medicines as well as regular enemas
					2.6)	or suppositories (10)
					Pearson's correlation: 0.845	Q5 About how your child's general
					P<0.001	health has been affected by the bowel
						problem over the last month:
					-third visit (n=62)	- well (0)
						- occasionally III (2)
					Iviean palpable faeces score:	- otten III (3)
					1.10 (SD 1.6)	- III most days (4)
					Mean US total score: 3.66 (SD	- never well (5)

Bibliographic Information	Study type & Evidence level	Number of patients & prevalence	Population Characteristics	Type of test and Reference standard	Sensitivity, Specificity, PPV and NPV	Reviewer comment
		prevalence		standard	2.6) Pearson's correlation: 0.77 P<0.001 -fourth visit (n=12) Mean palpable faeces score: 1.92 (SD 1.7) Mean US total score: 4.9 (3.2) Pearson's correlation: 0.91 P<0.001	Q6 About behavior related to the bowel problem: - cooperative OK (0) - needs reminding to use the lavatory/pot (2) - refuses the lavatory or pot (3) - also refuses medicines (4) - also generally difficult behavior (5) Q7 overall, which best describes how the problems are now compared with the last time seen at hospital: - nearly completely OK (0) - much better (1) - some improvement (4) - still as difficult (8) - getting worse (12) Filled in by practitioner Amount of stool detected on clinical examination of abdomen score: - None palpable: 0 - Little: 1 - Suprapubic only: 2 - To umbilicus: 3 - Beyond umbilicus: 5 - Reaching ribs: 8 Reviewers comments No control/comparison group Very small sample size at the fourth visit Source of funding: Not stated
			1			

Diagnostic Value of Transit Studies in Children with Chronic Idiopathic Constipation

Radiopaque Markers

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
de l'arite et el		prevalence	100	standard	Total and a sum antal transit	
de Lorijn et al.	Study type:	169 consecutive	169 consecutive	<u>Test:</u> Calaria transit	times (hours) (median 25	Additional information from study:
Prognosis of	Diagnostic	patients		Colonic transit	times (nours), (median, 25	Significant baseline differences
constipation:	prospective	la alvalan	65% DOYS	time (CTT) with	tors centiles)	between boys and girls: median
clinical factors	case series	Inclusion	Median age 8.4	radiopaque	D ((20)	defecation frequency at intake lower in
and colonic		<u>criteria:</u>	years	markers	a. Boys (n=109)	girls than boys (1.0 vs. 2.0 times/week;
transit time.	Evidence	All referred		_ ·	-total colon: 60 (38 to 103)	p=0.03); encopresis frequency more
2004. Archives	level: III	patients ≥ 5	<u>Country:</u>	Reference:	-delayed >62 h: 49%	than twice weekly reported more often
of Disease in		years old, at	the Netherlands	Clinical variables:	-ascending colon: 10 (5 to 16)	in boys (94% vs. 73%; p=0.0002). More
Childhood	Study aim:	least two of the			-delayed >18 h: 23%	girls than boys reported no encopresis
89[8], 723-727	То	following:		-defecation	-descending colon: 11 (4 to 18)	at all (20% vs. 6% p<0.05)
	investigate	1) defecation		frequency	-delayed >20 h: 21%	
	the relation	<3/week 2)		-encopresis	-rectosigmoid: 37 (19 to 68)	At entry all children underwent CCT.
	between	encopresis		frequency	-delayed >34h: 53%	Treatment with oral/rectal laxatives
	symptoms of	episodes		-night-time		discontinued for at least 4 days before
	chronic	>1/week 3)		encopresis	b. Girls (n=60)	the test; during this period they took
	constipation	passing of very		-rectal mass	-total colon: 53 (37 to 74)	one sachet of fibre (Volcolon, 6g) each
	and colonic	large stools			-delayed >62 h: 43%	day. Then they ingested a capsule
	transit time	every7-30 days			-ascending colon: 11 (5 to 15)	containing 20 radiopaque markers on 3
	(CTT). To	4)a palpable			-delayed >18 h: 18%	consecutive mornings. Abdominal X ray
	evaluate the	abdominal or			-descending colon : 8 (5 to 18)	performed on days 4 and 7 in morning.
	possible	rectal faecal			-delayed >20 h: 23%	Additional abdominal x ray performed
	relation	mass			-rectosigmoid: 31 (17 to 47)	on days 10, 13 and 16 if more than 20%
	between				-delayed >34h: 38%	of markers remained on previous film. X
	symptoms	Exclusion				ray localisation of markers based
	and CTT	criteria:			c. Total group (n=169)	identification of bony landmarks and
	and the	Hirschsprung's			-total colon: 58 (37 to 92)	gaseous outlines. Markers counted in
	outcome	disease, spinal			-delayed >62 h: 47%	right, left and rectosigmoid region and
	after one	and anal			-ascending colon: 10 (5 to 16)	mean segmental transit time calculated
	vear of	abnormalities.			-delayed >18 h: 21%	according to previously described
	follow up	mental			-descending colon: 10 (5 to 18)	formula.
		retardation, use			-delayed >20 h: 22%	

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
mormation	level	prevalence	Characteristics	standard		
Bibliographic Information	Study type & Evidence level	Number of patients & prevalence of drugs other than laxatives Setting: gastrointestinal outpatient clinic	Population Characteristics	Type of test and Reference standard	Sensitivity, Specificity, PPV and NPV -rectosigmoid: 32 (18 to 63) -delayed >34h: 48% (no significant differences between boys and girls in the CTT and rectosigmoid transit time) Correlation between clinical parameters and transit time (hours) (RSTT: rectosigmoid transit time) 1. Defection frequency: a. 0 to1/week (n=79) CTT (median): 74 RSTT (median): 74 RSTT (median): 38 b. >1 to 3/week (n=55) CTT (median): 50 RSTT (median): 30 c. \ge 3/week (n=35) CTT (median): 49 RSTT (median): 28 CTT: p=0.001 a. vs. b and a vs. c RSTT: p= 0.009 a. vs. b and a vs. c 2. Encopresis frequency (day	Reviewer comment Normal ranges for total and segmental transit times based on upper limits (mean ± 2 SD) from a study in healthy children: CTT > 62 h considered delayed. Upper limits for right colon, left colon ad rectosigmoid transit time were 18, 20 and 34 hours respectively Reviewers' comments: Researchers not blinded No definition of encopresis given No control group Source of funding: not stated
					and night) <u>a. no encopresis (n=18)</u> CTT (median): 49 RSTT (median): 24	

Bibliographic Information	Study type & Evidence	Number of patients &	Population Characteristics	Type of test and Reference	Sensitivity, Specificity, PPV and NPV	Reviewer comment
	level	prevalence		standard		
					<u>b. <1/day (n=24)</u>	
					CTT (median): 52	
					RSTT (median): 31	
					· · ·	
					c. 1 to 2/day (n=48)	
					CTT (median): 50	
					RSTT (median): 30	
					d. ≥2/day (n=79)	
					CTT (median): 70	
					RSTT (median): 38	
					$CTT \cdot p = 0.003 dvs c dvs b$	
					and dive a	
					RSTT: p=0.03 dys c dys b	
					and dive a	
					3 Night time enconresis:	
					a not present $(n=106)$	
					CTT (median): 47	
					DSTT (median): 47	
					KSTT (median). 20	
					b propert $(n-62)$	
					CTT (modian): 74	
					DSTT (median): 74	
					KSTT (median). 40	
					CTT: p < 0.0001	
					PSTT = 0.0001	
					1.011. p< 0.0001	
					4 Rectal mass:	
					a not present $(n=118)$	
					CTT (median): 48	
					RSTT (median): 28	
					b present $(n=51)$	
					CTT (median): 86	
					RSTT (median): 64	
					CTT: p< 0.0001	

Bibliographic Information	Study type & Evidence level	Number of patients & prevalence	Population Characteristics	Type of test and Reference standard	Sensitivity, Specificity, PPV and NPV	Reviewer comment
					RSTT: p< 0.0001	

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	standard		
Yang et al.	Study type:	96 children	96 children	Tests:	Total transit time (hours, mean	Reviewers' comments:
Determination	Diagnostic			Colonic transit	± SD)	Researchers not blinded
of	case control	Inclusion	-Patients (n=28):	time (CTT) with		
gastrointestinal		criteria:	38 boys	radiopaque	-Patients (n=28)	No data available on diet, use of
transit time in	Evidence	-Patients:	Mean age: 6 years	markers	59.9 ± 2.3	laxatives previous to the measurement
functional	level: III	confirmed	(range 3 to 14)			of CTT
constipation in		functional		Reference:	-Controls (n=68)	
children. 2005.	Study aim: to	constipation		none	14.8 ± 0.8	Source of funding:
Chinese Journal	investigate	(FC). Two of	-Controls (n=68)			not stated
of Clinical	the	the following for	38 boys		p<0.01	
Rehabilitation	difference of	more than 3	Mean age: 6 years			
9[7], 236-	gastrointesti	months:	(range 3 to 13)		Segmental transit time (hours,	
237China.	nal transit	Evacuation less			<u>mean ± SD)</u>	
	time (GTT)	3 times/week,	Country:			
	between	evacuating	China		Right colon:	
	constipated	pains, faecal			-Patients (n=28)	
	and normal	soiling every			20.3 ± 1.2	
	nealtny	week or				
	controis to					
	elicit its	more 2			7.3 ± 1.1	
	significance	umes/week in			n -0.01	
	in assessing	over 5 years			p<0.01	
	dynamics of	olu, louchable			L off colon:	
	the whole	abdominal or			-Patients (n=28)	
	dastro-	anal			12.8 ± 1.7	
	intestine and	examination			12.0 ± 1.7	
	each	excessive			-Controls (n=68)	
	segment	defecation at			34+08	
	coginent	interval of 7 to				
		30 days. No			p<0.01	
		administration				
		of			Rectosigmoid:	
		gastrointestinal			-Patients (n=28)	
		dynamic and			26.8 ± 1.4	
		evacuation				
		drugs for 2			-Controls (n=68)	
		weeks			4.1 ± 1.2	

Bibliographic Information	Study type & Evidence level	Number of patients & prevalence	Population Characteristics	Type of test and Reference standard	Sensitivity, Specificity, PPV and NPV	Reviewer comment
	level	-Controls: normal height and weight, normal frequency and character of evacuation fro 3 months without administration of any gastrointestinal dynamic and evacuation drugs <u>Exclusion</u> <u>criteria:</u> organic ailment in alimentary tract and other organs ailment that would affect gastrointestinal function <u>Setting:</u> general		stanuaru	p<0.01	
		hospital				

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
	level	prevalence		standard		
de Lorijn et al.	Study type:	89 non selected	89 children	Test:	Mean Leech score (using the	Additional information from study
The Leech	Diagnostic.	consecutive		Plain abdominal	first score):	Diagnosis of functional non-retentive
method for	Case control	children	Median age: 9.8	radiography (read		faecal incontinence (FNRFI) based on:
diagnosing			years	using the Leech	-Group 1 (constipation): 10.1	1) two/more faecal incontinence
constipation:	Evidence	Inclusion		method)	-Group 2 (controls): 8.5	episodes/week with no signs of
intra- and	level:	criteria: patients	Group 1			constipation 2) defecation frequency
interobserver	111	referred for the	(constipation):	Reference test:	p=0.002	3/more times/week 3) no periodic
variability and		evaluation of	n=52 (28 boys)	Colonic transit		passage of very large amounts of stool
accuracy. 2006.	Study aim:	abdominal pain,		time (CTT) with	Mean CTT:	at least once during a period of 7-30
Pediatric	to assess	constipation or	Group 2 (controls):	radiopaque	-Group 1 (constipation): 92 h	days 4) no palpable abdominal or rectal
Radiology 36[1],	intra- and	faecal	N=37 (24 boys)	markers	-Group 2 (controls): 37 h	mass on physical examination fro a
43-49	interobserver	incontinence.				period of at least 1 week during the
	variability	Diagnosis of	31: FNRFI		p<0.0001	preceding 12 weeks. Faecal
	and	constipation: at	6: FAP			incontinence defined as the
	determine	least two of the			Diagnostic accuracy of Leech	voluntary/involuntary loss of loose
	diagnostic	following was	Country:		method vs. CTT method:	stools in the underwear after the age of
	accuracy of	present:	the Netherlands			4 years
	the Leech	-defecation			-Leech method:	Functional abdominal pain (FAP)
	method in	frequency less			(cut-off point as per study	defined as abdominal pain of at least 12
	identifying	than 3			comparable to 9 as per	weeks duration 1)that was continuous
	children with	times/week			literature)	or nearly discontinuous in a school-
	functional	-2/more			Sensitivity: 75%	aged child or adolescent 2) that had no
	constipation	episodes of			Specificity : 59%	or only an occasional relationship with
		faecal				physiological events 3) that was
		incontinence			(cut-off point 9 as per	accompanied by some loss of daily
		per week			literature)	functioning 4) that was not feigned and
		-production of			Positive Predictive Value: 72%) for which there were insufficient
		large amounts			Negative Predictive Value:	criteria to indicate the presence of
		of stool once			63%	another functional gastrointestinal
		over a period of				disorder
		7-30 days			-CCT:	Children with clinical characteristics of
		-presence of			(cut-off point 54h as per study)	FAP and FNRFI classified as the
		palpable			Sensitivity: 79%	control group: according to authors they
		abdominal or			Specificity: 92%	have "little or no faecal loading on an
		rectal mass				abdominal radiograph"
					(cut-off point 62h as per	_
		(control children			literature)	Treatment with oral/rectal laxatives
		fulfilled criteria			Sensitivity: 71%	discontinued in each patient for at least

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information 8	& Evidence	patients &	Characteristics	Reference	and NPV	
	level	prevalence for functional abdominal pain (FAP) and for functional non- retentive faecal incontinence (FNRFI)) <u>Exclusion</u> <u>criteria:</u> not reported <u>Setting:</u> tertiary gastroenterolog y outpatients clinic		standard	Specificity: 95% Positive Predictive Value: 69% Negative Predictive Value: 97% <u>ROC analysis</u> -AUC (Leech method): 0.68 (95% CI 0.58-0.80) -AUC (CTT method): 0.90 (95% CI 0.83-0.96) p=0.00015 AUC=Area Under the ROC curve ROC=Receiving Operator Characteristic	 4 days. Thereafter the patient ingested one capsule with 10 small radiograph opaque markers on 6 consecutive days, in order to determine the CTT. Subsequently, a plain abdominal radiograph was taken on day 7. this radiograph was both used in the Leech method and for CTT measurement CTT determined by the method of Bouchoucha. Radiography on day 7 used to count the number of markers in the colon. Number of markers x 2 produced total CTT in hours. Localization of markers and CTT calculated according to previously described formula. Normal range for total transit time based on the upper limits (mean ± 2xSD) from a study in healthy children. Based on this study a CTT > 62 h was considered delayed 3 scorers independently scored the same radiography twice (4 weeks apart) using the Leech method, discussed amongst the 3 scorers previous to both readings CTT assessed once by single scorer. Assumed the counting of radiopaque markers would not lead to intra- or interobserver variability Leech scoring method: Colon divided into three segments: right, left and recto sigmoid Each segment provided with a score from 0-5 uppa.
Bibliographic Information	Study type & Evidence level	Number of patients & prevalence	Population Characteristics	Type of test and Reference standard	Sensitivity, Specificity, PPV and NPV	Reviewer comment
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						 1:scanty faeces visible 2: mild faecal loading 3: moderate faecal loading 4: severe faecal loading 5: severe faecal loading with bowel dilatation Leech score of 9 or more: suggestive of constipation Scorers: 3 experienced doctors (a 5th year radiology resident, a paediatric radiologist and a senior paediatric gastroenterologist). No clinical information about the patients was made available to them. In 5% of cases the Leech scores of the same patient produced by different scorers could differ by 4 points or more
						Reviewer's comments: No data reported on type of diet given prior to the measurement of CTT Source of funding: not stated

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
-	level	prevalence		standard		
Zaslavsky et al.	Study type:	61 adolescents	61 adolescents	<u>Test:</u>	Colonic transit times patterns	Additional information from study:
Chronic	Diagnostic			Colonic transit	<u>(N, %):</u>	Radiographs interpreted by 2 of the
functional	case control	Inclusion	-Patients (n=48)	time (CTT) with		authors (no further data provided)
constipation in		<u>criteria:</u>	Mean age: 14 years	radiopaque	Normal colonic transit: 8 (17)	
adolescents:	<u>Evidence</u>	-patients: aged	(range 12 to 18)	markers	Slow colonic transit: 29 (60)	Adolescents told to keep their usual diet
clinical findings	level:	12 to 18 years,	13 boys		Pelvic floor dysfunction: 6 (13)	during examination and to discontinue
and motility	111	both sexes,		Reference:	Slow colonic transit and pelvic	use of laxatives 7 days before
studies. 2004.		normal sexual	-Controls (n=13)	Clinical variables	floor dysfunction: 5 (10)	examination
Journal of	Study aim: to	maturation and	9 boys			
Adolescent	evaluate	growth (Tanner	age not reported		Total transit time (hours, mean	Patients underwent plain abdominal
Health 34[6],	symptoms	staging), <3			<u>± SD, median and range)</u>	radiography as per Metcalf method
517-522	and clinical	evacuations/we	Country:			
	findings in a	ek, excessive	Brazil		Constipated:	-Slow CTT: delay of total CTT and
	prospective	straining,			62.9 ± 12.6	delay of markers in the right and/or left
	series of	complaints for 1			69 (62.9 to 12.6)	colon
	adolescents	year or longer				-Pelvic floor dysfunction: delay in the
	with	-controls: no			Non constipated:	rectosigmoid
	functional	digestive			30.2 ± 13.2	-Slow CTT associated with pelvic floor
	constipation	complaints,			27.5 (10.8 to 50.4)	dysfunction: delay in the colon and
	and to	more than 3			p<0.001	rectosigmoid together with delay in the
	identify	bowel				total CTT
	colonic	movements/we			Segmental transit time (hours,	
	disorders by	ek			<u>mean ± SD, range)</u>	Cut-off points for measurements: mean
	measuring	(participated in				value plus two SDs. Right colon (>14
	total and	previous study			-Right colon:	h); left colon (>24h), rectosigmoid (>>36
	segmental	by authors)			Constipated:	h) and total (>51 h)
	colonic				18.6 ± 15	
	transit times	Exclusion			13.2 (12 to 54)	Reviewers' comments:
	with	criteria:				Researchers not blinded
	radiopaque	neurologic/meta			Non constipated:	
	markers	bolic diseases,			6.7 ± 3.9	Cut-off points for total and segmental
		Hirschsprung's			4.8 (1.2 to 12)	transit times apparently taken from
		disease (barium			P=0.001	previous 1998 study by the authors
		enema), spinal				
		disease,			-Left colon:	Source of funding: not stated
		anorectal			Constipated:	
		anomalies,			24.3 ± 13.7	
		surgery of the			22.8 (2.4 to 51.6)	

Bibliographic Information	Study type & Evidence	Number of patients &	Population Characteristics	Type of test and Reference	Sensitivity, Specificity, PPV and NPV	Reviewer comment
	level	prevalence		standard		
		colon, mental				
		retardation, use			Non constipated:	
		of drugs that act			7.9 ± 7.8	
		on digestive			7.2 (0-28.8)	
		motility, no			P<0.001	
		clinical				
		evidence of			-Rectosigmoid:	
		bowel /systemic			Constipated:	
		disease that			20 ± 15.7	
		could cause			18 (0 to 54)	
		constipation				
					Non constipated:	
		Setting: hospital			15.6 ± 10.7	
		gastroenterolog			12 (3.6 to 36)	
		y outpatients			NS	
		clinic				
					Interval between evacuations:	
					-Slow colonic transit (n=29):	
					$7.7 \pm 6.6 \text{ days}$	
					Delvie fleer dyefunction $(n-6)$:	
					-7 = 0.001 dystatiction (II=0).	
					5.7 ± 2.4 days	
					p < 0.003	
					p<0.000	
					Faecal mass nalpable at initial	
					examination statistically	
					associated with slow colonic	
					transit ($p=0.03$)	
					(p=0100)	
					Other clinical variables not	
					statistically associated with	
					delay in colon or rectosigmoid	
					transit: onset of constipation.	
					scybalous faeces, large	
					volume, faecaloma, anal	
					bleeding, soiling, previous use	
					of	

Bibliographic Information	Study type & Evidence level	Number of patients & prevalence	Population Characteristics	Type of test and Reference standard	Sensitivity, Specificity, PPV and NPV	Reviewer comment
	level	prevalence		standard	laxative/suppositories/enemas, history of constipation in family, anal fissure, daily ingestion of fibre, sex, age, skin colour	

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
	level	prevalence		standard		
Gutierrez et al.	Study type:	68 children	68 children	<u>Test:</u>	Total transit time (hours)	Additional information from study:
Total and	Diagnostic		aged 2 to 14 years	Colonic transit	<u>(mean ± SD, ranges)</u>	Two children from patients group did
segmental	case control	Inclusion		time (CTT) with		not complete study: one refused to
colonic transit		<u>criteria:</u>	Patients (n=38)	radiopaque	Patients (n=38)	swallow the capsules; one did not
time and	Evidence	Patients: history		markers	49.57 ± 25.38 (15.6 to 122.4)	comply (not clear exactly with what)
anorectal	level:	of chronic	Controls (n=30)			
manometry in	111	idiopathic		<u>Reference:</u>	Controls (n=30)	No significant differences observed in
children with		constipation > 6	Country:	Frequency of	29.08 ± 8.30 (14.4 to 50)	mean daily fibre intake and calorie
chronic	Study aim:	months,	Spain	defecation		consumption between the 2 groups
idiopathic	to evaluate	with/without			p<0.001	
constipation.	the use of a	secondary				Measurements made while children
2002. Journal of	colonic	encopresis,			Segmental transit time (hours)	maintained their usual diets. Laxative
Pediatric	motility study	refractory to			(mean ± SD, ranges)	treatment discontinued 1 week before
Gastroenterolog	easily	conventional				the test and a cleansing enema
y and Nutrition	applied in	treatment of			-RC:	administered on the day before the test
35[1], 31-38	daily clinical	disimpaction,			Patients (n=38)	
	practice to	re-education of			9.53 ± 9.07 (2.4 to 36)	No differences observed in CTT in
	more clearly	defecatory				relation to either se or age. Statistically
	define	habits,			Controls (n=30)	significant inverse correlation observed
	patients with	measures to			7.52 ± 5.75 (2.4 to 15.6)	between total CTT and number of
	this disorder	increase dietary				weekly defecations (correlation
	and to	fibre content			p value NS	coefficient, r=0.68, p<0.001)
	improve	and				
	therapy and	administration			-LC:	Reviewer comments:
	follow-up	of mineral oil or			Patients (n=38)	Researchers not blinded
		osmotic-type			15.41 ± 13.13 (2.4 to 32)	
		laxatives				Source of funding: Janssen
		(lactulose or			Controls (n=30)	Pharmaceutical contributed the material
		Lactinol).			6.60 ± 6.20 (2.4 to 24)	required to determine the colonic transit
		Encopresis				time. No further details provided
		defined as non-			p=0.01	
		voluntary				
		defecation with			-RS:	
		a frequency of			Patients (n=38)	
		more than twice			24.20 ± 16.77 (4.8 to 69.6)	
		weekly in				
		children older			Controls (n=30)	
		than 4 years in			14.96 ± 8.70 (2.4 to 19.2)	

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
	level	prevalence		standard		
		the absence of				
		any underlying			p=0.01	
		organic cause				
		Controls:			Clinical characteristic of the	
		normal bowel			patients' group as a function of	
		habits (between			colonic transit time:	
		3 defecations				
		daily and 3			a) Age at onset of constipation	
		weekly, without			(y, mean, SD):	
		staring at stool,			-Total CTT within reference	
		and faces of			values (n=19): 2.54 (1.18)	
		normal			-Prolonged total CTT (n=19):	
		consistency for			1.77 (0.88)	
		at least 12			p<0.05	
		months before				
		the study, no			 b) Family history of 	
		history of			constipation:	
		previous			-Total CTT within reference	
		abdominal/majo			values (n=19): 21%	
		r extra-			-Prolonged total CTT (n=19):	
		abdominal			79%	
		surgery, not on			p<0.01	
		medication with				
		effects on			c) Abdominal mass	
		digestive tract,			-Total CTT within reference	
		normal diet, and			values (n=19): 60%	
		underwent			-Prolonged total CTT (n=19):	
		abdominal			93.8%	
		radiography as			p<0.05	
		part of clinical				
		study with			d) Encopresis episodes/night	
		normal results			(mean, SD)	
					-Total CTT within reference	
		Exclusion			values (n=19): 0.10 (0.44)	
		criteria:			-Prolonged total CTT (n=19):	
		Hirschsprung's			0.60 (0.91)	
		disease, spinal/			p<0.05	
		anal				

Bibliographic Information	Study type & Evidence	Number of patients &	Population Characteristics	Type of test and Reference	Sensitivity, Specificity, PPV and NPV	Reviewer comment
	level	prevalence		standard		
		malformations,			No significant differences	
		prior surgery of			found for age at diagnosis,	
		colon, metabolic			sex, defecations/week, pain at	
		diseases,			defecation, enuresis, anal	
		mental			fissure, rectal mass or	
		retardation			encopresis episodes/day	
		Setting:				
		gastroenterolog				
		y outpatients				
		CIINIC				

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
Zeelevelevetel	level	prevalence	00 a dala a anta	standard		
Zaslavský et al.	Study type:	26 adolescents	26 adolescents	lest:	lotal transit time (nours, mean	Additional information from study:
Total and	Diagnostic		aged 12-18 years		± SD, range)	No significant statistical differences
segmental	case control	Inclusion	Constipated (n=13)	time (CTT) with	-Constipated	between two groups regarding age,
colonic transit		<u>criteria:</u>	Nonconstipated	radiopaque	58.25 ± 17.46	weight and height
time with radio-	Evidence	-patients: hard	(n=13)	markers	68.4 (27.6 to 72)	
opaque markers	level: III	stools, difficulty	9 boys in each			Total and segmental CTT measured
in adolescents		in evacuating,	group	Reference:	-Non constipated	using Metcalf technique
with functional	Study aim:	less than 3		Clinical variables	30.18 ± 13.15	
constipation.	To measure	bowel	Country:		27.5 (10.8 to 50.4)	On the days the measurements were
1998. Journal of	total and	movements/we	Brazil			performed adolescents were advised
Pediatric	segmental	ek, no evidence			P<0.001	not to alter their diets and not to ingest
Gastroenterolog	colonic	of palpable				food that might alter bowel motility.
y and Nutrition	transit time	rectal mass,			Segmental transit time (hours,	Fibre intake standardised at 15g/day
27[2], 138-142	in	history of			<u>mean ± SD, range)</u>	but due to poor compliance, test was
	constipated	constipation of				performed on their normal diet. Any
	adolescents	at least one			-Right colon:	treatment with laxatives discontinued at
	and	year of duration			Constipated	least 7 days before test
	compared	-controls: no			15.97 ± 12.48	
	the results	digestive			13.7 (2.4 to 43.2)	All radiographs interpreted by the same
	with those in	complaints,				radiologist who did not know whether
	non	more than 3			Non constipated	the patient was constipated
	constipated	bowel			6.74 ± 3.91	
	children	movements/we			7.2 (1.2 to 12)	Patients with constipation considered to
		ek			P=0.03	have slow colonic transit when delay in
						transit through the right colon, the left
		Exclusion			-Left colon:	colon or both. They were considered to
		<u>criteria:</u>			Constipated	have distal obstruction when the delay
		neurologic/meta			24.74 ± 13.39	occurred in the rectosigmoid.
		bolic diseases,			25.7 (7.2 to 51.6)	
		Hirschsprung's				Normal values for total and segmental
		disease,			Non constipated	transit times taken from the 95"
		spinal/anal			7.94 ± 7.82	percentile of adolescents without
		anomalies,			7.2 (0 to 28.8)	constipation
		surgery of the			P<0.001	
		colon, mental				Reviewers' comments:
		retardation,			-Rectosigmoid:	Small sample size
		history of drug			Constipated	
		abuse			17.60 ± 16.25	Source of funding: not stated

Bibliographic Information	Study type & Evidence level	Number of patients & prevalence	Population Characteristics	Type of test and Reference standard	Sensitivity, Specificity, PPV and NPV	Reviewer comment
		<u>Setting:</u> hospital			16.6 (0 to 49.2) Non constipated 15.58 ± 10.69 12 (3.6 to 36) NS Interval between stools: -Constipated: 5.8 ± 2.3 days -Nonconstipated: Daily P<0.01 No significant differences between the 2 groups regarding: bulky or small stools, encopresis, rectal mass, intense use of laxatives, bowel movements/week and mean daily intake of fibres	

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
	level	prevalence		standard		
Bijos et al. The	Study type:	225 children	225 children	Test:	Mean colonic transit times:	Additional information from study:
usefulness of	Diagnostic			Abdominal		Faecal impaction (as per US in sagital
ultrasound	Case control	Inclusion	Group 1:	ultrasound	Children with faecal impaction	plane): when pelvic structures were
examination of		criteria:	120 children with		(as per US) had significantly	covered by stool masses and were not
the bowel as a	Evidence	Referred	chronic constipation	Reference:	longer average segmental	even partially visible.
method of	level:	because of	(72 boys, mean age	Colonic transit	transit time for the rectum,	
assessment of	111	chronic	6.25 years, range	time (CTT) with	sigmoid and left colon	-Overfilled colon (as per US):
functional		constipation,	1.6 to 17.9)	radiopaque	(p<0.001, p=0.0015 and	
chronic	Study aim:	based on		markers	p=0.0104 respectively) there	Overfilled bowel at the splenic flexure:
constipation in	to determine	history and	Group 2:		was not statistically significant	when it was impossible to visualise the
children. 2007.	whether a	physical	105 children with		difference for the right side of	entire length of the left kidney due to
Pediatric	new method	examination:	normal defecation		the colon. Children with an	the lack of visibility of the lower pole of
Radiology	of ultrasound	defecation	pattern (mean age	Transit times	overfilled splenic flexure on US	the kidney because of bowel contents.
37[12], 1247-	(US)	disorders	8.25 years)	(hours, upper limit	had a significantly longer	Probe applied to the long axis of the
1252	assessment	persisting		of 66 based on	transit time in the left side of	spleen.
	of stool	longer than 6	Country:	<u>literature)</u>	the colon (p=0.0029)	
	retention	months, all	Poland			Overfilling of the transverse colon:
	could be	patients fulfilled		≤66: normal-		when the superior mesenteric artery
	used as a	Rome II criteria		transit	Total CTT	was not visible with the probe applied in
	method of	for defecation		constipation	(mean values are estimates	the sagital plane over the aorta
	identifying	disorders			taken from a bar chart):	
	children with	(frequency of		66-100: slow-		US: children examined before food and
	functional	bowel		transit	-Patients with faecal impaction	had a slightly filled bladder. Patients
	chronic	movements less		constipation	on US: 67	who passed stool on the day of the
	constipation,	than twice a				examination were temporarily excluded
	and to	week,		>100: very	-Patients without faecal	from the study until they became
	determine	consistency and		delayed slow-	Impaction on US: 42	constipated again. Measurement was
	whether	size of stool		transit	0.004	taken several times and the highest one
	children with	caused pain		constipation	p<0.001	recorded taken as the final
	an enlarged	during				measurement
	rectum and	defecation,			Segmental CTT	
	colon (as	withholding			(mean values are estimates	I otal and segmental colonic transit time
	seen on US)	behaviour)			taken from a bar chart)	measured by the modified sixth day
	snould be	E			4. Disht salar	Hinton method. I otal and segmental
	referred for	Exclusion			1. Right colon	time obtained by multiplying the number
	further	criteria:			-Patients with faecal impaction	of radiopaque markers seen on the
	procedures	anatomic			on US: 9	radiograph by 1.2 (time in
	such as	abnormality				nours/number of markers swallowed by

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
	lever			stanuaru	Batianta without facal	the notiont)
	procloscopy				-Patients without faecal	the patient)
	anu	uisease,			impaction on 05. 8	Boviowar's comments:
	of colonic	abnormalities of			NS	Reviewer's comments.
	transit time	the anorectal			11.5	No data on diet or use of lavatives
					2 Left colon	previous to the measurement of CTT
		neurological			-Patients with faecal impaction	previous to the measurement of OTT
		and psychiatric			on LIS: 18	The same individual performed all the
		conditions			01 03. 18	IIS scans, but not other data on this
		(cerebral paley			-Patients without faecal	were reported (as blinding individual's
		spina hifida			impaction on US [•] 9	experience in radiology etc)
		mental				experience in radiology, etc)
		retardation.			p=0.0104	It is not clear what number of children
		anorexia			P 0.0.0	underwent each of the tests
		nervosa)			3. Rectosigmoid:	
		.metabolic			-Patients with faecal impaction	It is not clear whether "enlarged" and
		conditions			on US: 32	"overfilled" colon mean the same for the
		(diabetes				authors, as no measurements of
		, mellitus/insipidu			-Patients without faecal	"enlarged" colon are reported.
		s) endocrine			impaction on US: 16	
		disorders				Data on number of children diagnosed
		(hypothyroidism			p=0.0015	with "overfilled colon" are not reported.
), previous				
		thoracic or				It is not clear how many children were
		abdominal				diagnosed with faecal impaction by US
		surgery				
						Children apparently underwent DRE but
		(control				no results are reported
		patients: normal				
		defecation				Control group did not differ from
		patterns,				patients regarding gender, the
		treated for				comparison regarding age is not clearly
		various				reported
		symptoms like				
		chronic				Source of funding: Not stated
		abdominal pain,				
		tood allergies)				
	1					

Bibliographic Information	Study type & Evidence level	Number of patients & prevalence	Population Characteristics	Type of test and Reference standard	Sensitivity, Specificity, PPV and NPV	Reviewer comment
		<u>Setting:</u> gastroenterolog y outpatient clinic				

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
Denninge et el		prevalence	140 abildran	Standard		
Benninga et al.	Study type:	148 children	148 children	<u>Test:</u> Calaria transit	Total transit time (nours,	Additional information from study:
	Diagnostic	Inclusion	Detients (n. 04):	Colonic transit	<u>median, range)</u>	Total and segmental CTT done as
time in	case control	Inclusion aritaria	-Patients (n=94):	time (CTT) with	(104.4 to 280.4)	described by Metcali
	E vidence	<u>Criteria.</u>	- DOTO (nandiatria	radiopaque	189 (104.4 10 380.4)	Deceder unner limit (mean + 200) of
children: does	Evidence	-Patients:	a. PSTC (paediatric	markers		Based on upper limit (mean + 2SD) or
pediatric slow-	<u>ievei.</u>		Slow transit	Deference	-NDTC (T=70)	previous sludy in 63 constipated
transit	111	nealthy children	constipation):	<u>Reference</u>	46.8 (3.6 10 99.6)	children (Corazziari, 1985), children in
constipation	0	with complaints	24 children	-Clinical variables		current study arbitrarily separated in 2
exist? 1996.	Study alm:	of constipation	17 DOYS		Segmental transit time (nours,	groups:
Journal of	10	with/without	Mean age 8 years		median, range)	1. CTT>100 h: paediatric slow transit
Pediatric	Investigate	encopresis,	(range 5-14)			constipation (PSTC)
Gastroenterolog	the presence	encopresis			Right colon:	2. CTT<100 h: normal- or delayed-
y and Nutrition	of slow	alone or	b. NDTC (normal		-PSIC (n=24)	transit constipation (NDTC) (normal
23[3], 241-251	colonic	recurrent	delayed transit		27.0 (3.6 to 60)	transit ser at < 63h)
	transit in	abdominal pain.	constipation)			Further analysis of the NDTC group
	children with	They fulfilled at	70 children		-NDTC (n=70)	after separation into a group with total
	constipation	least 2 of the	46 boys		8.4 (0 to 32.4)	CTI<63h and one with total CTI
	using	following criteria	Mean age 8 years			between 63 and 100h showed same
	radiopaque	for paediatric	(range 5-14)		Left colon:	significant differences compared with
	markers	constipation: a)			-PSIC (n=24)	PSTC children as did the total PSTC
		2/fewer bower	-Controls (n=54):		37.2 (0 to 110.4)	group allowing the merge of these
		movements/we	15 children (for			children
		ek b)2/more	rectal manometry)		-NDTC (n=70)	
		solling or	10 boys		7.2 (0 to 36.0)	CTT performed on patients taking their
		encopresis	Mean age 11 years			normal diet, any treatment with
		episodes/week	(range 7-15)		Rectosigmoid:	laxatives discontinued at least 4 days
		c) passage of			-PSIC (n=24)	prior o test. No enemas given before
		very large	Country:		116.4 (49.2 to 226.8)	transit studies.
		amounts of	the Netherlands			
		stool once			-NDTC (n=70)	Reviewers' comments:
		every 7-30 days			27.0 (0 to 90.0)	Researchers not blinded
		d) a palpable				
		abdominal			Clinical variables:	Values for both total and segmental
		mass or rectal			-Daytime soiling (yes/no) (no.,	transit times expressed as medians in
		mass			(%)	the text and the heading of a table, and
		-Controls:			-PSIC (n=24)	as means in the table itself. We have
		healthy			22 (92)	chosen to report them as median
		children.	1		-NDTC (n=70)	values because authors stated in the

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
	level	prevalence		standard	40.(00)	
		Siblings and			48 (69)	statistical analysis section that results
		Thends of			p=0.05	for continuous variables
		paediatric			Doutimo opiling opicodos /	Tor continuous variables
		patients and modical staff			- Daytime solling episodes /	Source of funding: major grant from the
		medical stan			PSTC (n=24)	Stitching Kinderpostzegels Nederland
		Soiling defined			14.0 (0 to 7)	and from an endowment from Zyma
		as loss of loose			14.0 (0 10 7)	Nederland (Importal)
		stools			-NDTC $(n=70)$	
		encopresis as			50(0 to 56)	
		loss of formed			p<0.01	
		stools			P 10101	
		A palpable			-Nightime soiling (yes/no) (no.,	
		rectal mass			%)	
		defined as the			-PSTC (n=24)	
		presence of a			17 (71)	
		firm and large				
		faecal lump in			-NDTC (n=70)	
		the rectal			8 (11)	
		ampulla			p<0.01	
		Exclusion			- Nightime soiling episodes /	
		criteria:			week (median, range)	
		Hirschsprung's			-PSTC (n=24)	
		disease, spinal/			7 (0 to 7)	
		anal anomalies,				
		surgery of			-NDTC (n=70)	
		colon, metabolic			0 (0 to 7)	
		diseases,			p<0.01	
		mental				
		retardation, on			(n_1, ∞)	
		drugs other			-PSTC (1=24)	
		Inan laxalives			10 (73)	
		Setting:			-NDTC (n=70)	
		outpatient clinic			33 (49)	
		of tertiary			p=0.03	
		academic				

Bibliographic Information	Study type & Evidence	Number of patients &	Population Characteristics	Type of test and Reference	Sensitivity, Specificity, PPV and NPV	Reviewer comment
	level	prevalence		standard		
		teaching			-Pain during defecation (no.,	
		hospital			%)	
		•			-PSTC (n=24)	
					8 (33)	
					$-NDTC_{(n-70)}$	
					28 (60)	
					p=0.01	
					p=0.01	
					-No rectal sensation (no., %)	
					-PSTC (n=24)	
					8 (33)	
					-NDTC $(n-70)$	
					10(14)	
					10(14)	
					p=0.03	
					-Palpable abdominal mass	
					(no., %)	
					-PSTC (n=24)	
					17 (71)	
					-NDTC (n=70)	
					27 (39)	
					p=0.02	
					p=0.0 <u>-</u>	
					-Palpable rectal mass (no., %)	
					-PSTC (n=24)	
					17 (71)	
					NDTC $(n-70)$	
					(12)	
					9 (13)	
					p<0.01	
					No significant differences	
					regarding: sex, age, toilet	
					training statue, age at which	
					toilet training started. bowel	
					movements/week, large	
					amounts of stools very 7-30	

Bibliographic Information	Study type & Evidence level	Number of patients & prevalence	Population Characteristics	Type of test and Reference standard	Sensitivity, Specificity, PPV and NPV	Reviewer comment
					days, encopresis episodes/week, abdominal pain, poor appetite, daytime or nightime urinary incontinence Proportion of children with PSTC and rectal palpable mass, night time soiling or both: 0.34, 0.39 and 0.82 respectively. (multivariate analysis) only 7% of children without any of these characteristics had PSTC	

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
	level	prevalence		standard		
Benninga et al.	Study type:	211 children	211 children	<u>Test:</u>	Total CTT (hours, mean and	Additional information from study:
Defaecation	diagnostic			Colonic transit	range):	Significant differences in the study
disorders in	case control	Inclusion	Group 1 (PC)	time (CTT) with		population regarding clinical variables:
children, colonic		criteria:	N=129	radiopaque	-Group 1 (PC, n=129):	more PC children reported large
transit time	Evidence	complains of	64% boys	markers	79.3 (2.4 to 384)	amount of stools, a palpable abdominal
versus the Barr-	<u>level</u> : III	infrequent	Median age: 8			mass and rectal mass as compared to
score. 1995.		defection,	years (5-14)	Reference test:	-Group 2 (isolated ES, n=54):	RAP children (p<0.001). More PC
European	Study aim:	soling,		Plain abdominal	41.4 (16.6 to 104.4)	children reported abdominal pain and
Journal of	to	encopresis or	Group 2 (isolated	radiography (read		no rectal sensation as compared to ES
Pediatrics	objectivate	recurrent	<u>ES)</u>	using the Barr	-Group 3 (RAP, n=23):	children (p<0.05)
154[4], 277-284	the presence	abdominal pain	N=54	score)	32.5 (4.8 to 69.6)	
	or absence	(RAP)	81% boys			Two experienced paediatric radiologists
	of faecal	-Group 1:	Median age: 9		-Healthy controls (n=23, mean	familiar with the Barr criteria and
	retention in	patients who	years (5-17)	Barr scoring	+ 2SD) (Arhan <i>et al.)</i>	without any knowledge of the clinical
	each child	met at least 2 of		system:	29.0 (62)	condition of the patient, independently
	using CTT	the 4 criteria for	Group 3 (RAP)	Quantifies the		analysed in random order the first (day
	and compare	paediatric	N=23	amount of faeces	p=0.03 group 2 vs. group 3	4) and second (day 7) plain abdominal
	these	constipation	39% boys	in four different		radiographs of the markers studies of
	findings to	(PC): 1) stool	Median age: 9	bowel segments:	Segmental CTT (hours, mean	the initial 101 consecutive patients. Barr
	the Barr	frequency less	years (5-16)	ascending colon	and range):	scores were assessed in the different
	score	than 3		(0,1, or 2 points);,	-Right colon:	segments and total scores calculated. A
		times/week 2) 2	Country:	transverse colon	Group 1 (PC, n=129):	radiograph was considered positive if
		or more	the Netherlands	(0,3, 4 or 5	13.2 (<1.2 to 60)	Barr score>10
		soling/encopresi		points)		
		S		descending colon	Group 2 (isolated ES, n=54):	Normal range for segmental and total
		episodes/week		(0,3, 4 or 5	7.9 (<1.2 to 26.4)	CTT taken from upper limits obtained in
		periodic		points)		healthy controls (mean \pm 2SD), as
		passage of very		and rectum (0,2	Group 3 (RAP, n=23):	described by Arhan et al.
		large amounts		or 5 points) and	7.7 (1.2 to 21.6)	Total CTT > 62h: delayed
		of stools once		also the		Total CTT > 100h: slow transit
		every 7-30 days		consistency of the	-Healthy controls (n=23, mean	constipation (based on study by
		 a palpable 		faces i.e. scybala	+ 2SD) (Arhan <i>et al.)</i>	Corazziari et al.)
		abdominal or		(0,1,2 or 3	7.7 (18)	Normal limits for segmental transit
		rectal mass		points); granular		times (h): right colon (18), left colon
		-Group 2: only		(0,2, 4 or 5	p<0.01 group 1 vs. group 2	(20), rectosigmoid (34)
		encopresis		points)	and group 1 vs. group 3	
		and/or soiling				Colonic transit time assessment
		(ES), without			-Left colon:	method: Metcalf

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
	level	prevalence		standard		
		any of the other			Group 1 (PC, n=129):	
		criteria for PC.			16.1 (<1.2 to 110.4)	Measurements of CTT performed with
		Soiling defined				patients on their habitual diet.
		as the loss of			Group 2 (isolated ES, n=54):	Treatment with laxatives ([ills or
		loose stools.			6.8 (<1.2 to 25.2)	enemas) discontinued for at least 4
		Encopresis				days before the CTT study
		defined as			Group 3 (RAP, n=23):	
		(in)voluntary			7.0 (1.2 to 25.2)	5 patients excluded from study: 4 not
		passage of a				able to swallow capsule, 1 had
		normal bowel			-Healthy controls (n=23, mean	"uninterpretable" abdominal X-ray
		movement in			+ 2SD) (Arhan <i>et al.)</i>	
		the underpants			8.7 (20)	Comparison of the Barr-score with the
		or another				marker method performed using the
		unorthodox			p<0.01 group 1 vs. group 2	mean Barr-score of the two observers
		location with a			and group 1 vs. group 3	obtained on radiograph I. Similar
		frequency of 2				analysis using radiograph II revealed no
		or more			-Rectosigmoid	differences compared to radiograph I,
		times/week			Group 1 (PC, n=129):	therefore only results with radiograph I
		after the age of			49.7 (<1.2 to 226.8)	are presented in detail
		4 in the				
		absence of any			Group 2 (Isolated ES, $n=54$):	According to authors the radiopaque
		Organic cause			26.7 (4.8 to 93.6)	markers were no nindrance for the 2
		-Group 3: RAP			Croup 2 (PAD p=22)	observers in assessing the Barr-scores
		loost 2			Group 3 (RAP, II=23).	Boviowara' commenta:
		anisodos/wook			10.9 (1.2 10 49.2)	Thore are missing data not accounted
		of non specified			Healthy controls (n=22 mean	for: only 101 obdominal radiographs
					± 2 SD) (Arban et al.)	were available for analysis, but there is
		enough to			(-200) (Anian et al.)	no clear explanation for this
		interfere with			12.4 (34)	
		dav-to dav			p < 0.01 group 1 vs. group 2	Source of funding: not stated
		activities over at			and group 1 vs. group 3	<u>bource of funding</u> . Not stated
		least a 3-month				
		period, without			p=0.05 group 2 vs. group 3	
		any of the other				
		symptom of PC			сст	
		- , . .			-Interobserver agreement:	
		Exclusion				

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
information		patients &	Characteristics	standard		
	16761	criteria:		Standard	Radiograph 1 (n=101):	
		Hirschsprung's			Perfect agreement: 62%	
		disease spinal/			Difference of one marker: 25%	
		anal anomalies.			Radiograph 2 ($n=101$):	
		prior surgery of			Perfect agreement: 92%	
		colon, metabolic			Difference of one marker: 6%	
		diseases,			Barr scores (n=101) (mean of	
		mental			two observers)	
		retardation, use			-Group 1 (PC, n=57)	
		of drugs other			Radiograph 1:	
		than laxatives			≥10 : 60%	
					Radiograph 2:	
		Setting:			≥10 : 63%	
		gastroenterolog				
		y outpatients			-Group 2 (isolated ES, n=30)	
		clinic			Radiograph 1:	
					210:47% Rediagraph 2	
					$\sim 10 \cdot 60\%$	
					210.00%	
					-Group 3 (RAP $n=14$)	
					Radiograph 1:	
					≥10 · 47%	
					Radiograph 2:	
					≥10 : 63%	
					-Interobserver agreement	
					(agreement between the 2	
					observers for the different	
					segments on the same	
					radiograph):	
					k from 0.28 (fair) to 0.60	
					(moderate)	
					Intrachsonyor agroomost	
					difference in quantity and	
					quality of stool between	
					radiograph L and II as scored	

Bibliographic Information	Study type & Evidence level	Number of patients & prevalence	Population Characteristics	Type of test and Reference standard	Sensitivity, Specificity, PPV and NPV	Reviewer comment
					by same radiologist): k from 0.05 (poor) to 0.47 (moderate) for both observers -Intraobserver agreement (agreement on the existence of constipation as measured by a Barr-score of 10 or more points	
					between radiographs I and II): fair for both observers, k= 0.22 and 0.25 respectively <u>Correlation of the Barr-score</u> with Metcalf's makers method: Correlation between positive Barr score (≥10) and delayed total CTT (>62h): k=0.22 (fair) for all children.	
					K values by group: -PC group: 0.20 -ES group: 0.02 -RAP group: 0.46 Abnormal Barr scores found in at least 46% of patients with normal transit times. Positive Barr scores correlated only with total CTT exceeding 100 b	

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
	level	prevalence		standard		
Papadopoulou	Study type:	52 children	52 children	Test:	Patterns of transit time (n=52):	Additional information from study:
et al. The	Diagnostic		Median age: 8	Colonic transit	-normal transit: 21 (40%)	-To assess reliability of test
clinical value of	prospective	Inclusion	years (range 2-13.5	time (CTT) with	-mild delay: 4 (8%)	interobserver error between 2
solid marker	case series	criteria:	years)	radiopaque	-moderate delay: 9 (17%)	observers was measured: each
transit studies in		Constipation		markers	-severe delay: 18 (35%)	independently assessing 30 abdominal
childhood	Evidence	and/or soiling.	Sex distribution not			X-rays and interobserver error by
constipation	<u>level:</u> III	One patient had	reported	Reference:	Patterns of marker distribution:	carrying out duplicate estimations by
and soiling.		neurological		Frequency of	-pancolonic transit delay: 15	the same observer on the same 30
1994. European	Study aim: to	problems due to	Country:	bowel	(29%)	days
Journal of	assess the	ganglioneuroma	UK	movements and	-segmental transit delay: 5	
Pediatrics	acceptability,	tosis.		soiling	(10%)	-Assessment criteria of severity of
153[8], 560-564	the reliability	Constipation			-outlet obstruction: 11 (21%)	transit delay:
	of	defined as less				a. normal transit: < 12 markers in colon
	interpretation	3 bowel			Correlation between transit	(<40% of given markers)
	and the	movements/we			delay and clinical symptoms:	b. mild delay: 12-18 markers in colon
	clinical value	ek. Soling				(41-60% of given markers)
	of solid	defined as			a) Fewer than 2 bowel	c. moderate delay: 19-24 markers in
	marker	involuntary			movements/week (%):	colon (61-80% of given markers)
	transit	passage of fluid				d. severe delay: >24 markers in colon
	studies in	or semi-solid			-Children with severe delay	(>80% of given markers)
	children with	stools into			(n=18):	
	soiling and	clothing 2/more			87	-Assessment criteria of different
	spurious	times/week			-Children with normal transit	patterns of marker distribution:
	diarrhoea				(n=21): 27	a. pancolonic transit delay: no single
	(otherwise	Exclusion				segment contains >75% of markers
	known as	criteria:			p<0.001	remaining in colon
	overflow	Hirschsprung's				b. segmental transit delay: >75% of
	incontinence	disease			b) More than 3 soiling	markers remaining in colon clustered in
)*				episodes/week (%):	one segment
		Setting:				c. outlet obstruction: >60% of given
		hospital			-Children with severe delay	markers clustered in rectosigmoid
					(n=18):	
					92	-In 6 patients the transit studies were
						repeated after colonic washout.
					-Children with normal transit	Significant improvements in transit
					(n=21): 35	round after colonic emptying (p<0.05)
					0.005	(exact number not reported in text, just
					p<0.005	a bar graph)

Bibliographic Information	Study type & Evidence	Number of patients &	Population Characteristics	Type of test and Reference	Sensitivity, Specificity, PPV and NPV	Reviewer comment
	level	prevalence		standard		
	* reviewer's note				No correlation found between duration of symptoms and severity of delay	Laxative treatment not interrupted previous to measurements (97% were on laxatives)
					distribution and transit	Researchers not blinded
					-Children with severe delay	integentiers not binded
					(n=18): Outlet obstruction: 39% Pancolonic transit delay: 56% Segmental transit delay (in	No data on the type of diet children were on when measurements were made
					descending colon): 5% -Children with mild delay (n=4): Pancolonic transit delay: 25%	No data reported on the correlation between transit delay and clinical
					Segmental transit delay (in rectosigmoid): 75%	mild/moderate delay
					P<0.005	Source of funding: not stated
					Correlation between marker distribution and symptoms:	
					movements/week (%) :	
					a. Outlet obstruction: 100% b. Pancolonic transit delay: 83% c. Segmental transit delay : 33%	
					a vs. c and b vs. c: p<0.05	
					-More than 3 soiling episodes/week (%):	
					a. Outlet obstruction: 100% b. Pancolonic transit delay:	

Bibliographic Information	Study type & Evidence level	Number of patients & prevalence	Population Characteristics	Type of test and Reference standard	Sensitivity, Specificity, PPV and NPV	Reviewer comment
					57%	
					c. Segmental transit delay: 0%	
					a vs. c and b vs. c: p<0.05	
					Observer errors:	
					(coefficient of variation):	
					-interobserver: 2.1 %	
					intro cho on (on 2 4 0)	
					-Intraodserver: 3.1 %	

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
	level	prevalence	10 1 11 1	standard		
Staiano et al.	Study type:	42 children	42 children	lest:	I otal gastrointestinal transit	Additional information from study:
Colonic transit	diagnostic			- I otal	time (IGII) (hours, mean ±	Severe brain damage: spastic
and anorectal	case control	Inclusion	<u>Group1: children</u>	gastrointestinal	<u>SD):</u>	tetraparesis/diplegia, generalised
manometry in	study	<u>criteria:</u>	with brain damage	transit time		hypotonia
children with		-patients:	N=16	(TGITT)	-children with brain damage:	
severe brain	Evidence	children with	10 boys		106.4 ± 6.1	Children off all laxatives and/or
damage. 1994.	<u>level:</u> III	brain damage	Mean age 5.1 ± 3.5	-Colonic		suppositories during the measurement
Pediatrics 94[2		referred for	years (range 1.5 to	segmental	-children with functional faecal	of total and segmental transit times
Pt 1], 169-173	<u>Study aim:</u> to	gastroenterologi	12 years)	gastrointestinal	retention (FFR):	
	study colonic	c evaluation of		transit time	98.6 ± 5.1	Tracing coded and analysed by one of
	transit and	constipation	Group 2: children	(SGTT)		the authors unaware of the clinical
	anorectal	-Controls:	with functional		p value N.S	status of the child (not clear whether
	motility in	1. functional	faecal retention	<u>Reference</u>		this is CTT or manometry)
	children with	faecal retention:	<u>(FFR)</u>	standard:	Segmental gastrointestinal	
	severe brain	2.	N=15	None	<u>transit time (SGTT):</u> (mean,	Reviewers' comments:
	damage,	asymptomatic:	9 boys		SEM)	29 of the children originally undergoing
	looking for	normal	Mean age 6.0 ± 2.9			evaluation for severe brain damage
	differences	frequency of	years (range 2 to		Left colon:	were found to have constipation, but
	from	defecation and	11 years)		total number of markers at 48	only 16 were included in the study. It is
	asymptomati	no history of			h	not clear why the other 13 were
	c children	current/previous	Group 3: children		-brain damaged:	excluded
	and from	gastrointestinal	<u>with no</u>		7.3 ± 1.3	
	patients with	disease	gastrointestinal			Functional faecal retention not defined
	functional		problems		-functional faecal retention	
	faecal	Exclusion	N=11		(FFR):	Exact values for all segmental transit
	retention and	criteria:	7 boys		3.0 ± 1.0	times in the 2 groups not reported
	normal	secondary	Mean age 5.6 ± 3.9			
	neurologic	constipation	years (range 2 to		p< 0.05	Source of funding: not stated
	development	excluded by	12 years)			
		clinical			total number of markers at 72	
		interview,	Country:		h:	
		physical	Italy		-brain damaged:	
		examination,			3.3 ± 0.8	
		barium enema,				
		and anorectal			-functional faecal retention	
		manometry			(FFR):	
		studies and/or			0.5 ± 0.3	
		multiple suction				

Bibliographic Information	Study type & Evidence level	Number of patients & prevalence	Population Characteristics	Type of test and Reference standard	Sensitivity, Specificity, PPV and NPV	Reviewer comment
		rectal biopsies			p<0.01	
		<u>Setting:</u> hospital			Distribution of markers in right colon and rectum not significantly different between the two groups	

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
	level	prevalence	40.1111	standard	T () () ()	
Koletzko et al.	Study type:	48 children	48 children	lest:	I otal transit time (hours, mean	Additional information from study:
Is histological	Case series		25 boys	Colonic transit	<u>± SD)</u>	Hirschsprung's disease diagnosed in 9
diagnosis of	(multicentre)	Inclusion	Mean age: 6.4 ±	time (CTT) with	.	children excluded from further analysis
neuronal		<u>criteria:</u>	5.2 years	radiopaque	-Children with normal histology	
intestinal	<u>Evidence</u>	Initial symptoms		markers	(n=15):	Abortive neuronal intestinal dysplasia
dysplasia	<u>level:</u> III	of chronic	Country:			(NID) and classic NID diagnosed in 17
related to		constipation or	Switzerland	<u>Reference:</u>	70.0 ± 42.6	and 6 patients respectively.
clinical and	Study aim: to	soiling, or		none		
manometric	investigate	obstructive				Mean colonic transit times measured
findings in	the	symptoms in				using the Metcalf method, in only 30
constipated	relationship	early life				children of the total population
children?	of clinical,	suggestive of				
Results of a	manometric,	Hirschsprung's				Reviewers' comments:
pilot study.	and	disease				CTT results for children diagnosed with
1993. Journal of	histological					abortive and classic NID not reported
Pediatric	findings in a	Exclusion				for the purposes of this review as they
Gastroenterolog	group of	criteria:				are considered organic causes of
y and Nutrition	children with	Anorectal				constipation
17[1], 59-65	chronic	malformation or				
	constipation	mielomengonce				No data reported on diet, use of
	in order to	le				laxatives previous to the investigations
	evaluate the					
	role of	Setting: hospital				Segmental transit times results not
	anorectal					reported, and not clear whether they
	manometry					were measured
	in the					
	diagnosis of					Researchers not blinded
	neuronal					
	intestinal					Source of funding: not stated
	dysplasia					
	(NID) and					
	the					
	relationship					
	of					
	histological					
	and					
	manometric					
	findings to					

severity of	
and outcome	

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
	level	prevalence		standard		
Martelli et al.	Study type:	1182 children	1182 children	Test:	Total transit time (hours,	Additional information from study:
Can functional	Diagnostic		63% boys	Colonic transit	<u>median, range)</u>	Patients classified into 4 groups:
constipation	retrospective	Inclusion		time (CTT) with		-"Normal" transit time
begin at birth?	case series	criteria:	Group 1:	radiopaque	-C+E patients (n=168):	-"Pancolic" constipation: delay in the 3
1998.		Constipation	constipated	markers	67.2 (2 to 168)	sites
Gastroenterolog	Evidence	with/without	children without			-"Terminal" constipation: delay in the
y International	<u>level:</u> III	encopresis	encopresis (C	<u>Reference:</u>	-C+4 patients (n=112):	rectosigmoid with/without delay in right
11[1], 1-11Italy.		Constipation	patients)	none	54.6 (9 to 168)	or left colon
	Study aim: to	defined as less				-"Non terminal" constipation: right
	analyse	than 3	N=855		-C-4 patients (n=77)	and/or left delay but normal
	epidemiologi	spontaneous	59%boys		49.6 (8 to 161)	rectosigmoid transit time
	С,	stools/week				
	manometric	without any	65% < 4 years old		-Controls (n=21) Arhan et al.	Reviewers' comments:
	and	laxative or	(C-4 patients)		1983	Researchers not blinded
	radiologic	motility-	35% > 4 years old		22.8 (9.4 to 56.4)	
	data in a	influencing	(C+4 patients)			Not all children underwent CTT
	large	drug.			p<0.0001 C+4/C-4/C+E	
	population of	Encopresis	Median age at first		patients vs. controls	No data on diet or use of laxatives
	young	defined (in	evaluation:		p<0.05 C+E patients vs. C+4	previous to CTT measurement
	patients	France) as	C-4: 11 months		patients	
	presenting in	incontinent	(range 4 to 15			Source of funding: not stated
	a paediatric	associated with	years)		Segmental transit time (hours,	
	tertiary care	faecal	C+4: 7.7 years		<u>median, range)</u>	
	hospital in	impaction, at or	(range 4 to 15			
	order to	after the age of	years)		1-Right colon:	
	classify	3 years. Faecal			-Controls (n=21): Arhan et al.	
	different	impaction	Group 2:		1983	
	types of	considered to	constipated		7.2 (0.6 to 19.2)	
	idiopathic	be present	children with		-C-4 patients (n=77):	
	constipation	when	encopresis (C+E		14.8 (0 to 96)	
	according to	consistency of	patients)		-C+4 patients (n=168):	
	age of onset,	faeces			12 (0 to 48)	
	sex and	persisting in	N=327		-C+E patients (n=112):	
	pelvic floor	rectum more	78% boys		14 (0 to 144)	
	function	solid than that	Median age at first			
		of stools	evaluation: 8.5		p<0.0005 C+4/C-4 patients vs.	
		spontaneously	years (range 4 to		controls	
		emitted	15 years)		p<0.0001 C+E patients vs.	

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
	level	prevalence		standard		
			Country:		controls	
		Exclusion	France			
		<u>criteria:</u>			2-Left colon:	
		children aged <			-Controls (n=21): Arhan et al.	
		48 months.			1983	
		Local/general			7.4 (1.2 to 22.8)	
		causes of			-C-4 patients (n=77):	
		constipation:			12.4 (0 to 72)	
		anal lesions			-C+4 patients (n=168):	
		(anal fissures,			12 (0 to 96)	
		anal			-C+E patients (n=112):	
		malposition),			13.6 (0 to 96)	
		neurogenic				
		constipation			p<0.0005 C-4 patients vs.	
		(Hirschsprung's			controls	
		disease,			p<0.005 C+4/C+E patients vs.	
		neurointestinal			controls	
		dysplasia,				
		spinal cord			3-Rectosigmoid: Arhan et al.	
		disorders,			1983	
		chronic			-Controls (n=21):	
		intestinal			10.4 (1.21 to 34.2)	
		pseudobstructio			-C-4 patients (n=77):	
		n),endocrine			18.4 (0 to 106)	
		(hypothyroidism			-C+4 patients (n=168):	
), metabolic			26.4 (0 to 108)	
		disorders			-C+E patients (n=112):	
		(diabetes			30.2 (0 to 142)	
		mellitus, renal				
		acidosis,			p<0.005 C-4 patients vs.	
		hypercalcemia),			controls	
		still breast-fed			p<0.0001 C+4/C+E patients	
		patients with not			vs. controls	
		symptoms other				
		than fewer than			Classification of constipation	
		3 stools/week			according to segmental colonic	
					transit times (n, %):	
		Setting:				

Bibliographic	Study type	Number of	Population Characteristics	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
mormation	level	prevalence	Characteristics	standard		
		paediatric			1.Normal transit:	
		tertiary care			-C-4 patients (n=77): 33 (43)	
		hospital			-C+4 patients (n=168): 34	
					(30.5)	
					-C+E patients (n=112): 38	
					(22.3)	
					-101ar (11=357). $105 (29)$	
					p<0.001 C+E vs. C-4 patients	
					2.Non terminal constipation:	
					-C-4 patients (n=77): 18 (23)	
					-C+4 patients (n=168): 26 (23)	
					-C+E patients (n=112): 37 (22)	
					-Total (n=357): 81 (23)	
					3.Terminal constipation:	
					-C-4 patients (n=77): 17 (22)	
					-C+4 patients (n=168): 42	
					(37.5)	
					-C+E patients (n=112): 70	
					(41.5)	
					-Total (n=357): 129 (36)	
					p<0.05 C+4 vs. C-4 patients	
					p<0.005 C+E vs. C-4 patients	
					4Pancolic constipation:	
					-C-4 patients (n=77): 9 (12)	
					-C+4 patients (n=168): 10 (9)	
					-C+E patients (n=112): 23 (14)	
					-Total (n=357): 42 (12): 42 (12)	
					(p values not reported were not	
					significant)	

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
-	level	prevalence		standard		
Corazziari et al.	Study type:	141 children	141 children	Test:	Total gastrointestinal transit	Additional information from study:
Gastrointestinal	Diagnostic			Total	<u>time (TGITT) (hours, mean ±</u>	No patients receiving laxatives during
transit time,	case control	Inclusion	Patients:	gastrointestinal	<u>SD, range)</u>	investigation
frequency of		<u>criteria:</u>	N=63	transit time	-healthy controls (n=78)	
defecation, and	Evidence	-Patients: long-	40 boys	(TGITT) '	25.0 ± 3.7 (19 to 33)	Retention of contents in a given large
anorectal	<u>level:</u> III	standing	Mean age 5.4 ± 4.1			bowel segment considered abnormally
manometry in		constipation,	years (2 months to	Reference:	-patients with TGITT>33h	prolonged when transit index ≤60 (i/e
healthy and	<u>Study aim: to</u>	complaints of	4 years)	-Frequency of	(n=53)	when on average, ≥ 30% of markers
constipated	quantify	reduced bowel		defecation	81.4%	were retained in that given segment at
children. 1985.	bowel	frequency	Controls:			least 33 h after ingestion of radiopaque
Journal of	function in	associated with	N=78		-patients with TGITT<33h	pellets). Transit index of 60 chosen
Pediatrics	healthy	straining at	37 boys		(n=10)	because the lower confidence limit (?)
106[3], 379-382	children in	defecation, or	Mean age 5.5 ± 3.2		18.6%	of a normal adult population did not
	regard to	presence of	years (2 months to			exceed this value
	frequency of	visible fresh	12 years)		Segmental transit time	
	defecation,	blood on faeces			N=39 (out of 53 children with	Reviewers' comments:
	gastrointesti	or frequent use	Country:		prolonged transit time)	Not clear what type of diet patients
	nal transit	of mild laxatives	Italy			were following during investigation
	time and	-Controls:			Colon: lowest in 3 patients	
	manometric	healthy children				Segmental colonic transit times (right
	characteristi	free of bowel			Rectum: lowest in 24 patients	and left colon and rectosigmoid)
	cs of the	complaints				measured but results not reported
	anorectal				Colon and rectum: lowest in 12	
	tract and to	Exclusion			patients	Accurate figures for CTT in patients not
	compare	<u>criteria:</u>				reported
	variables of	secondary			Frequency of defecation	
	bowel	constipation			(times/week):	Segmental transit time not measured in
	function in	excluded after			-healthy controls (n=78)	controls
	children with	clinical interview			6.3 ± 1.3 (range 4 to 9)	
	chronic	and				Results reported for the healthy controls
	constipation	examination,			-patients with TGITT>33h	are not clearly stated in the paper that
	with those in	barium enema,			(n=53)	there actually belong to this group, but
	the normal	anorectal			2.5 ± 0.9 (range not reported)	as results for the patients group are
	population	motility studies,				explicitly related to them, it was
		rectosigmoidosc			-patients with TGITT<33h	assumed the others belonged to the

¹ Italian papers included in this review (Corazziari, Cucchiara, Staiano) measured "total gastrointestinal transit time (TGITT)". Because of the similarity in the figures with the other studies' CTTs we assumed that TGITT is the name by which CTT known in Italy.

Bibliographic Information	Study type & Evidence level	Number of patients & prevalence	Population Characteristics	Type of test and Reference standard	Sensitivity, Specificity, PPV and NPV	Reviewer comment
		opy, rectal biopsy. Metabolic and endocrinologic abnormalities. <u>Setting:</u> unclear			(n=10) 5.1 \pm 0.73 (range not reported) Stool frequency and TGITT significantly correlated in patients with prolonged transit time (r=0.75; p<0.001) and in healthy controls (r=0.78; p<0.001) In 7 of 53 patients with TGITT>33 h, the bowel frequency overlapped the range observed in the controls	controls Researchers not blinded <u>Source of funding:</u> not stated

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
Cucchiara et al	Study type:	00 childron	00 childron	Standard	Total transit time (hours, moan	Additional information from study:
Cucchiara et al.	Diagnostic	99 children	99 children	Total	+ SD range)	Additional information from study.
transit time and	case-control	Inclusion	-Patients (n-53)	astrointestinal	± SD, Tange)	but not sex with the constinated
anorectal		criteria:	40 hovs	transit time	a) Patients with soiling $(n=32)$	children
manometry in	Evidence	-patients:	mean age 8.3 years	(TGITT)	58 ± 14.3 (36 to 86)	
children with	level: III	constipation of	(range 4.8 to 12.9)	(1011)		TGITT measurements performed with
fecal soiling.	<u> </u>	several months	(ge	Reference:	b) Patients without soiling	children taking their usual diet
1984. Journal of	Study aim: to	of duration	-Controls (n=46)	none reported	(n=21)	<u> </u>
Pediatric	determine	with/without	24 boys		61.1 ± 15 (36 to 96)	Reviewers' comments:
Gastroenterolog	motility	soiling	mean age 8.1 years			No definitions of constipation/soiling
y and Nutrition	characteristi		(range 4.2 to 12)		c) Controls (n=46)	given
3[4], 545-550	cs of the	-controls:			25.6 ± 3.7 (19 to 33)	
	anorectum	healthy children	Country:			Researchers not blinded
	and to	without	Italy		a) vs. c) p < 0.001	
	measure	gastrointestinal			b) vs. c) p < 0.001	No data on use of laxatives previous to
	total	complaints				the CTT but a barium enema, without
	gastrointesti	referred to				previous cleansing of the colon and
	nal transit	outpatients				limited to the rectosigmoid was
	time (TGITT)	paediatric clinic				performed to demonstrate the presence
	in children	for routine				of stenosis, megarectum or
	with chronic	examination				Hirschsprung's disease
	constipation,	- · ·				
	with/without	EXCIUSION				Segmental transit times not measured
	Taecal	criteria: nistory				Courses of fundings, not stated
	overnow	or anorectai				Source of funding: not stated
		surgery, spinal				
		abriornalities,				
		disorders				
		Settina:				
		outpatients				
		paediatric clinic				

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
	level	prevalence		standard		
Arhan et al.	Study type:	176 patients	176 patients	<u>Test:</u>	Segmental transit time of one	Additional information from study:
Idiopathic	Diagnostic		aged 2 to 15 years	Colonic transit	radiopaque marker (hours,	Markers ingested 24h after beginning a
disorders of	case control	Inclusion	64% boys	time (CTT) with	<u>min; mean ± SD)</u>	diet containing 0.5g/kg of crude fibres
fecal continence		<u>criteria:</u>		radiopaque		
in children.	<u>Evidence</u>	-Patients: one	Controls:	markers	1. Ascending colon:	Functional studies performed when
1983. Pediatrics	<u>level</u> :	of the following:	23 children (no		-normal children (n= 23):	rectum free of stool either
71[5], 774-779	111	 history of 	further data	-Reference: none	7:10 ± 1:4	spontaneously or as a result of
		less than 3	reported)		-constipated children	cleansing enemas
	Study aim: to	spontaneous			(with/without spina bifida	
	describe the	stools/week 2)	Country:		occulta) (n=176):	Reviewers' comments:
	clinical	evidence of	France		13:24 ± 1:5	No clear definition of constipation given
	presentation	faecaloma				
	of children	(stools of harder			p<0.05	Researchers not blinded
	with	consistency				
	idiopathic	than those			2. Descending colon	Not clear how many children underwent
	disorders of	passed			-normal children (n= 23):	CTT
	faecal	spontaneously)			7:37 ± 1:3	
	continence	at rectal			-constipated children	Total transit time not measured
	and to	examination 3)			(with/without spina bifida	
	demonstrate	presence of			occulta) (n=176):	As no data are reported on the
	that they	faecal material			13:49 ± 1:37	characteristics of the control group it is
	have	in the entire				not possible to tell whether they could
	functional	descending			p<0.05	be significantly different from the
	abnormalitie	colon or				patients
	s of large-	faecaloma in			3. Rectum	
	bowel	the			-normal children (n= 23):	Source of funding: partially by the
	motility	rectosigmoid			11:4 ± 1:5	Institut national de la Sante et de la
		area diagnosed			-constipated children	Recherche Medicale (INSERM), CRL
		radiologically			(with/without spina bifida	No.80-7002, grant MT-3511 from the
		-Controls:			occulta) (n=176):	CRM, and by the French Canadian sub
		children with no			30:22 ± 2:42	commission for health matters
		intestinal				
		abnormalities			p<0.05	
		who had to				
		undergo a			No significant differences	
		radiography of			between children with and	
		the abdomen			without spina bifida occulta	
		for medical				

Bibliographic Information	Study type & Evidence level	Number of patients & prevalence	Population Characteristics	Type of test and Reference standard	Sensitivity, Specificity, PPV and NPV	Reviewer comment
		reasons				
		Exclusion				
		criteria: none				
		Sidled				
		<u>Setting:</u> hospital				

Radioisotopes Markers

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
On all at all	level	prevalence	404 shildren	Standard	Manage suggest 600 for the st	
Cook et al.	Study type:	101 consecutive	101 children	<u>Test:</u>	Wean sum of GC for the 4	Additional information from study:
Radionuclear	Diagnostic	nuclear transit	00 h au a	Colonic transit	imaging periods (mean ± SD,	Four imaging periods: 6, 24, 30 and 48n
transit to assess	retrospective	time performed	62 DOYS	time (CTT) with	range)	Intellig of love there at an and Calevia
sites of delay in	case series	on children with	Maan	radioisotopes		Intake of laxatives stopped 5 days
large bowel	E vidence	severe	Mean age 7.3 ±	Deference	1-Normal transit time (n=24):	before the transit time and patients
	Evidence	constipation	3.7 years	<u>Reference</u>		lasted for 4 n before start of test. Rectai
children with	<u>ievei</u> : III	over a 2-year	O sum tan u	Standard :	15.7±3.3 (7.3-19.1)	disimpaction not carried out before
chronic	Otrack a stress	period	Country:	None stated		study in any patient.
Idiopathic	Study alm:		Australia	-	2-501 (n=50):	Radiopharmaceutical technetium 99m-
constipation.	To review	Inclusion		I hree categories		calcium phytate colloid, suspended in
2005. Journal of	the authors	criteria:		of colonic transit	11.2±1.9 (7.5-16.3)	20mL of milk was administered by
Pediatric	results of	All patients		according to	0.004	mouth.
Surgery 40[3],	scintigraphic	seen by the		visual	p<0.001 as compared to	
478-483	studies on	senior author or		assessment	normal transit time and FFR	A nuclear medicine radiologist from the
	children with	а		-Normal transit	groups	hospital performed qualitative visual
	severe	gastroenterologi		time: tracer		assessment of the images acquired at
	chronic	st paediatrician.		reached the	3-FFR (n=22):	each time interval. Colonic transit times
	constipation	All had		caecum by 6		was estimated by analysis of the
	and to	symptoms of		hours, passed	15.1±1.5 (12.7-18.2)	images acquired between 6 and 48
	assess the	severe chronic		through the colon		hours
	use of the	constipation		and was largely	4-Borderline (n=5)	
	geometric	and/or		excreted by 6	not reported	Geometric centre (GC): six regions of
	centre (GC)	encopresis that		hours		interest were defined:
	and visual	had not			GC at each of the 4 imaging	1-precolonic region
	interpretation	responded to at		-Slow colonic	periods (mean ± SD, range)	2-caecum and ascending colon as far
	of images in	least six months		transit time		as the hepatic flexure
	categorising	of medical		(SCI): when the	1-Normal transit time (n=24):	3-transverse colon from hepatic to
	these	therapy with		tracer reached	6h: 2.0±0.5 (1-3.5)	splenic flexure
	children	laxatives,		the caecum at 6	24h: 3.9±1.1 (1-5.9)	4- descending colon from splenic
		dietary		hours but most	30h: 4.6±1.2 (2-5.9)	flexure to start of sigmoid
		alterations and		radioactivity was	48h: 5.2±0.9 (2.3-6)	5-sigmoid colon
		behaviour		retained in the		6-TARCES
		modification		proximal colon at	2-SCI (n=50):	GC refers to the median point of the
				24, 30 and 48 h	6h: 1.8±0.3 (1-2.5)	distribution of activity within the colon. It
		Exclusion			24h: 2.6±0.5 (1.9-4.4)	was calculated by multiplying the
		criteria:		-Functional faecal	30h: 3.1±0.6 (1.8-4.5)	traction of the administered activity in a
		Obviously		retention/outlet	48h: 3.7±0.9 (1.9-5.7)	region, by a region number and the 6
		palpable		obstruction		numbers for each image episode were
Bibliographic Information	Study type & Evidence	Number of patients &	Population Characteristics	Type of test and Reference	Sensitivity, Specificity, PPV and NPV	Reviewer comment
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	level	prevalence		standard		
		faecaloma in		(FFR): the tracer	p<0.05 at 6h and p<0.001 at	added
		rectum or		reached the	24, 30 and 48 h, as compared	
		sigmoid colon.		rectosigmoid by	to normal transit and FFR	Reviewers' comments:
		Anorectal		24 to 30 h but	groups	No control group, or comparison with a
		malformation,		was not passed		reference test
		spinal		at 48 h	3-FFR (n=22):	
		deformity,			6h: 2.0±0.4 (1.2-3)	Not clear definition of constipation
		Hirschsprung's		-Borderline:	24h: 3.6±0.7 (2.5-5)	reported
		disease, bowel		according to	30h: 4.4±0.5 (3.5-5.4)	
		washout or		authors "more like	48h: 5.1±0.3 (4.4-5.7)	No diagnosis prior to the application of
		enema in the		functional		the test was made
		week before		retention than	4-Borderline (n=5)	
		study to remove		slow transit	not reported	Researchers not reported blinded
		faecaloma		trough the colon"		
					No significant difference in the	Source of funding: Not stated
		Setting:			GC at any imaging time when	
		continence			comparing patients with normal	
		clinic			transit with those with FFR.	
					T	
					I wo of the 101 children (not	
					clear in which group) had a GC	
					of 1.0 at 6 h indicating that	
					100% of the tracer was located	
					in the small bowel, suggesting	
					impairment.	

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
	level	prevalence	07 1 1	standard		
Chitkara et al.	Study type:	67 adolescents	67 adolescents	lest:	Colonic transit time (n=41)	Additional information from study:
The role of	Diagnostic		Mean age: 14.7±	Colonic transit	(FC=12; FFR=8; C-IBS=21)	Patients were classified in three groups
pelvic floor	retrospective	Inclusion	3.3 yr	time (CII) with		according to paediatric Rome II criteria
dysfunction and	case series	criteria:	67% female	radioisotopes	-Geometric centre at 24 h	based on the symptoms and diagnoses
slow colonic		-constipation			$1 \text{ otal: } 2.03 \pm 0.99$	provided by the clinician who evaluated
transit in	Evidence	unresponsive to	Group 1:		FC: 1.73 ± 0.29	the patient prior to the ARM and BE I
adolescents	<u>level</u> : III	first line,	(n=16) Functional	Reference tests:	FFR: 2.04 ± 0.38	
with refractory		symptomatic	constipation (FC)	-Clinical variables		Patients instructed to discontinue all
constipation.	Study aim:	treatments		(nausea,	-Slow colonic transit (%)	medications known to affect intestinal
2004. American	to examine	- completion of	Group 2:	vomiting,	Total: 30	motility 48 h prior to study. Patients
Journal of	the	clinically	(n=18) Functional	bloating, weight	FC: 42	given the radioisotope after overnight
Gastroenterolog	symptoms	indicated ARM	faecal retention	loss and	FFR: 14	fast
y 99[8], 1579-	and pelvic	and BEI for	(FFR)	incomplete rectal		
1584	floor function	the evaluation		evacuation)	-Fast colonic transit (%)	A geometric centre at 24h of \leq 1.6 was
	by anorectal	of constipation	Groups 3:		Total: 7.5	classified as slow colonic transit and >
	manometry	-age ≤ 18 yr	(n=33)		FC: 0	3.8 considered fast colonic transit.
	(ARM) and	-able and willing	Constipation-		FFR: 0	
	balloon	to follow	predominant			Reviewers' comments:
	expulsion	instructions in	irritable bowel		No significant association of	Methodology poorly described.
	test (BET) in	the balloon	syndrome IBS(C-		abnormal GC at 24h (fast or	Researchers not reported blinded.
	adolescents	expulsion study	IBS)		slow) and individual	Intrarater/interrater reliability
	≤ 18 years of	as judged by	_		gastrointestinal symptoms (no	measurements not reported
	age referred	experienced	Country:		further details reported)	
	to a tertiary	test operator	USA			Only 61% of total sample underwent
	care centre	-presence of				colonic transit time, but not clear
	for	gastrointestinal				explanation for this
	symptoms of	complaints in				
	refractory	the absence of:				Not clear on what basis the cut off
	constipation,					points for the geometric centre were
	and to	Exclusion				determined
	describe the	criteria:				
	results of	colonic				Insufficient data to allow calculation of
	scintigraphic	resection or				other parameters of diagnostic value of
	colonic	systemic				CTT (Sensitivity, Specificity, PPV and
	transit	organic disease				NPV)
	measuremen	(diabetes				
	ts in the	mellitus,				Results for C-IBS patients not reported,
	patients who	hypothyroidism,				as population outside the remit of this

Bibliographic Study type Information & Evidence level	Number of patients & prevalence	Population Characteristics	Type of test and Reference standard	Sensitivity, Specificity, PPV and NPV	Reviewer comment
also underwent this test	mielomeningoc ele, mental retardation/deve lopmental delay, Hirschsprung's disease) <u>Setting:</u> tertiary care centre				guideline <u>Source of funding:</u> In part by the GlaxoSmithKline Institute of Digestive General Research Award to D. Chiktara ad NIH grants to M. Camilleri

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	& Evidence	patients &	Characteristics	Reference	and NPV	
	level	prevalence		standard		
Shin et al. Signs	Study type:	180 children	180 children	Test:	FFR (n=19)	Additional information from study:
and symptoms	Retrospectiv		92 boys	Colonic transit	STC (n=161)	Clinical stories reviewed retrospectively
of slow-transit	e case	Inclusion	Mean ages: 10.5	time (CTT) with		and augmented by interview or
constipation	series	criteria:	years (STC); 6	radioisotopes	FFR vs. SCT	questionnaire
versus		Severe,	years (FFR)		(Clinical variables (%))	
functional	Evidence	intractable		Reference:		No gender differences between both
retention. 2002.	level: III	constipation	Country:	-Clinical variables	-Constipation: 89 vs.91	groups
Journal of		which did not	Korea & Australia	-Stool	-Soling: 42 vs.64	
Pediatric		respond to at		characteristics	-Bloating: 26 vs. 46	Normal CCT defined as the presence of
Surgery 37[12],	Study aim:	least 6 months			-Abdominal pain: 42 v. 51	tracer in the caecum by 6 h, in the
1762-1765	to correlate	of medical			-Anal pain: 16 vs. 19	rectosigmoid by 30 h and passed in the
	symptoms,	therapy			-Vomiting: 7 vs. 16	faces by 48h. Slow CCT defined as
	signs, transit	instituted by a			-Failed toilet training:	global colonic delay with hold-up of
	times and	general			-Poor appetite: 42 vs. 22	tracer proximal to the rectosigmoid at
	immunohisto	practitioner or			-Behavioural problems: 21 vs.	30 and 48 h (with no rectal faecaloma).
	chemistry to	paediatrician			22	FFR identified by hold-up of tracer
	determine				-Prematurity: 6 vs. 5	proximal to the rectosigmoid at 48 h
	the	Exclusion			-Meconium passage > 24 after	preceded by normal transit
	diagnostic	criteria:			birth: 41 vs. 33 (35% unknown)	
	differences	None reported			-Family history of constipation:	Visual inspection of collected
	between				61 vs. 52	radiographic images augmented by use
	slow transit	Setting: unclear			-Constipation present at birth:	of a "colonic transit index" (sum of the
	constipation				11 vs. 26 (p=0.17)	geometric centres of radioactivity at 6,
	(STC) and					24, 30 and 48 h)
	functional				(p values not reported are not	
	faecal				significant)	Normal values for CTT derived from
	retention					several studies of transit time in healthy
	(FFR)				FFR vs. SCT	children
					(Stool characteristics (%))	
						Slow-transit constipation, STC: slow
					-Volume:	transit through the colon
					Small moderate: 68 vs. 47	FFR: chronic constipation caused by
					Large: 26 vs. 52	delay of anorectal release
					Not known: 5 vs. 2	
						Reviewers' comments:
					-Consistency:	Exclusion criteria not reported
					Hard/firm: 78 vs. 58	
					Soft/variably soft: 16 vs. 39	Questionnaires not piloted. No data on

Bibliographic Information	Study type & Evidence level	Number of patients & prevalence	Population Characteristics	Type of test and Reference standard	Sensitivity, Specificity, PPV and NPV	Reviewer comment
					(p<0.001) Not known: 5 vs. 3 -Frequency: >1 week: 56 vs. 40 1/week: 26 vs. 22 <1 week: 11 vs. 28 Not known: 5 vs. 10	intrarater/interrater reliability No data on diet or use of laxatives previous to CTT No data of individual(s) performing readings: blinding, etc. Actual figures for CTT not reported <u>Source of funding:</u> Not reported

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
mormation	level	prevalence	Characteristics	standard		
Vattimo et al.	Study type:	39 children	39 children	Test:	Total transit time (hours, mean	Additional information from study:
Total and	Diagnostic.		23 females	Colonic transit	± SD)	-RC: right colon from caecum to mid-
segmental	Prospective	Inclusion	Age range: 2-13	time (CTT) with		transverse
colon transit	case series	criteria:	vears	radioisotopes	-Normal transit time (n=13)	-LF: left colon from mid-transverse to
time in		Constipation	,		27.79 ± 4.10	descending colon-sigmoid junction
constipated	Evidence	defined as 2 or	Country:	Reference test:		-RS: rectosigmoid from the sigmoid
children	level: III	fewer bowels	Italy	none reported	-Mainly rectosigmoid retention	junction to rectum
assessed by		motions/week			(n=5)	
scintigraphy	Study aim:	or straining for			53.36 ± 29.66	From the point of view of radiation
with 111In-	Not clearly	more than 25%				dosimetry the most heavily irradiated
DTPA given	stated, it	of the			-Prolonged transit time in all	organs were the lower large intestine
orally. 1993.	might read	defecating time			segments (n=14)	and the ovaries and the level of
Journal of	like: to				62.09 ± 7.23	radiation burden depended on the colon
Nuclear Biology	present the	Exclusion				transit time
and Medicine	results of	criteria:			-More prolonged transit time in	
37[4], 218-222	children	Normal children			rectosigmoid tract (n=7)	Reviewers' comments:
	referred for	(no other details			92.36 ± 24.16	
	constipation	given)				No data reported on diet or use of
	who	0			Segmental transit time (nours,	laxatives previous to the measurement
	underwent	Setting: unclear,			$\frac{\text{mean} \pm \text{SD}}{1}$	oruli
	total and	but children			Normal transit time (n. 12)	It is upplear whether the children
	segmental	were			-Normal transit time $(n=13)$	auffored from acuero (intractable
		oulpalients			Right colon. 9.11 ± 2.53	constinution. Otherwise if might be
	by				$1 \text{ oft colors: } 0.80 \pm 3.50$	difficult to justify this study
	with 1111p-				Left colori. 9.80 ± 5.50	
					Rectosignoid: 8.88 ± 4.09	No data on the researchers or their
	BIIX				1000 ± 4.00	performance was reported
					-Mainly rectosigmoid retention	
					(n=5)	Results for children with dolichocolon
					Right colon: $10.38 + 2.34$	(n=7) not reported as this would be
						secondary constipation
					Left colon: 10.40 ± 4.00	
						Source of funding: not stated
					Rectosigmoid: 32.58 ± 29.64	
					-Prolonged transit time in all	
					segments (n=14)	

Bibliographic	Study type	Number of	Population	Type of test and	Sensitivity, Specificity, PPV	Reviewer comment
Information	level	prevalence	Characteristics	standard		
		•			Right colon: 21.81 ± 5.29	
					Left colon: 23.32 ± 6.14	
					Rectosigmoid: 16.95 ± 4.52	
					-More prolonged transit time in rectosigmoid tract (n=7) Right colon: 19.78 ± 9.03	
					Left colon: 21.05 ± 5.70 Rectosigmoid: 51.53 ± 17.82	
					Interval between defecations: (hours, mean \pm SD)	
					-Normal transit time (n=13) 23.38 ± 5.42	
					-Mainly rectosigmoid retention (n=5) 35.60 ± 14.54	
					-Prolonged transit time in all segments (n=14) 53.00 ± 15.97	
					-More prolonged transit time in rectosigmoid tract (n=7) 85.71 ± 32.25	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Youssef et al.	Study Type:	41 children	41 children	Intervention:	Follow-up	Clearance of faecal	Additional information from study:
Dose response	RCT		27 male	Polyethylene	<u>period:</u> 5 days	impaction (number of	Functional faecal retention: difficulty
of PEG 3350 for		Inclusion	median age 7.5	glycol PEG 3350	after starting	patients, %)	passing stools >3 months (straining,
the treatment of	<u>Evidence</u>	criteria:	years (3.,3 to		treatment (48		grunting, stool "getting stick") and
childhood fecal	level:	children with	13.1)	Comparisons (4	hour after their	-Achieved	passage of stools <3 times/week
impaction.	1-	functional		<u>arms):</u>	last drug use)	total: 30 (75)	
2002. Journal of		faecal	<u>Country:</u> USA				Planned to enrol 10 children in each
Pediatrics	Study aim: to	retention as		1) 0.25 g/kg per	<u>Outcome</u>	(Values for each	group
141[3], 410-414	investigate	defined by		day	Measures:	group are estimates	
	the efficacy	Rome criteria,		2) 0.5 g/kg per	a. Primary	taken from a Bar	All medications for constipation
	and safety of	aged 3 to 18,		day	outcome:	chart.):	discontinued 7 days before baseline
	4 different	male or		3) 1.0 g/kg per			examination and also during the
	doses of	female, with		day	-clearance of	a) 0.25 g/kg per day	duration of study
	polyethylene	evidence of		4) 1.5 g/kg per	faecal	(n=10): 5	
	glycol (PEG)			day	Impaction		Faecal impaction: a palpable mass in
	3350 in the	impaction at				b) 0.5 g/kg per day	the left abdomen and/or a dilated rectum
	treatment of	physical		Each of them to	b. Secondary	(n=10): 4	filled with a large amount of hard stool
	childhood	examination		be taken for 3	outcomes:		on rectal examination
	Taecal	E		consecutive days,	a complete a set	c) 1.0 g/kg per day	
	disimpaction	Exclusion		premixed with a	-number of	(n=10): 9	Presence or absence of faecal
		<u>criteria:</u>		solution havoured	Dowel	d) 1 E alka por dov	Impaction assessed by abdominal and
		previous		In orange Crystal	movements	a) 1.5 g/kg per day	rectal examination. Physical
		gastrointestin		Light (Krait Food,	abaraatariatiaa	(n=9): 10	examinations performed by 2 examiners
		al surgery, no		morning with		p = 0.05 a and $d = (0.50())$	to commin presence of faecal impaction
		allergy		hrockfoot of o		p < 0.05 C and $u (95%)$	Investigators blinded to rendemination
		PEC colution		doco of	cofoty	vs. a anu b (55%)	
		rEG Solution		10ml /kg/day If	-salety	Number of bowel	maintained until patients enrolled
		nhocnhotoc		volumo oxcoodod		movements in 5 days:	completed
		signs and		2/0 ml the		movements in 5 days.	completed
		symptoms		remaining daily		>3 howel movements	All medications dispensed to families in
		suggestive of		dose was equally		during the 5-day	a clear container labelled with only a
		obstruction		divided		study: 33 (83%) of	random sequence number deperated by
		(vomiting		throughout the		total sample	manufacturer All containers initially
		abdominal		remaining meals			contained PEG 3350: 50g 100g 200g
		distension		Maximum dose		(Values for each	or 300g. Each container was then

Pharmacological and Surgical Interventions for Disimpaction in Children with Chronic Idiopathic Constipation

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
		and		100 g daily		group are estimates	constituted to a 2000 ml solution for
		abdominal				taken from a Bar	respective four doses
		mass that				chart. Baseline value	
		extended				is less than 2 for all	Characteristics of stools measured by
		beyond the				groups):	diaries provided to parents. Diaries had
		level of the					visual analog scales marked from 0 to
		umbilicus)				a) 0.25 g/kg per day	10, each mark evenly spaced 1 cm
						(n=10): 6	apart, 0 minimum and 10 maximum.
							Children and parents asked to report
						b) 0.5 g/kg per day	each defecation and its associated
						(n=10): 8	straining (0, very easy and no pushing; 1
							to 10, very difficult and much effort),
						c) 1.0 g/kg per day	consistency of stool (0, too loose and
						(n=10): 11	watery; 1 to 10 very hard), amount of
							stools per defecation (0, very little; 1 to
						d) 1.5 g/kg per day	10, a lot) associated gas (0, none; 1 to
						(n=9): 12	10 too much) and cramping (0, none; 1
							to 10 very painful)
						p<0.005 for each	-th the second s
						group compared to	5" day after initiation of treatment
						the others	chosen for follow-up visit because of
							author's previous clinical experience
						-time of first bowel	with PEG 3350 showed initial effect
						movement after	between 1 and 2 days after beginning
						initiation of treatment	use of medication
						(mean ± SD) 1.89 ±	
						0.46 days (total	Clearance of faecal impaction defined
						sample)	as rectal valit that was either empty or
							had a small amount of soft stools. In
						Characteristics of	those with abdominal examination
						stools and symptoms	findings, resolution of the left lower
						auring treatment	quadrant mass in addition to an empty
						No oignificant	rectai vault was defined as successful
							disimpaction. Clearance of faecal
						differences in any of	Impaction confirmed by 2 examiners
						the following	
						parameters among	Success of disimpaction not significantly
						the 4 groups:	related to the independent factors of

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures	a ta a la la la	
						straining,	age, duration of constipation, current
						consistency, stool	use of medication for constipation and
						amount, gas and	baseline constipation score
						cramping (copy actual	One shild receiving 1 E g/kg/day did not
						results)	che child receiving 1.5 g/kg/day did not
						Adverse effects:	snow up at ronow-up visit
						Nausoa (5%)	Reviewer comments:
						-Nausea (576)	Small sample, no sample size
						-Vorniting (570)	calculation
						18%	
						-Pain/cramping: 5%	Methods of randomisation and allocation
						-Loose stools (13%)	concealment not described
						-Diarrhoea: higher	
						doses groups (5/20)	Examiners performing physical
						vs. lower doses group	examination not clearly reported blinded.
						(2/20); p<0.02	Unclear whether the two examiners who
						Acceptability of study	confirmed clearance of faecal impaction
						medication by	were the same who assessed children
						children:	at baseline
						95% of children took	Unclear who prepared the 2000 ml
						PEG 3350 on the first	solution for respective four doses
						attempt	
							Source of funding: supported by
						<u>Iviean daily volumes</u>	Braintree Laboratories Incorporated,
						appropriate study	Children's Heapital of Dittaburgh
						dooo: no oignificant	Children's Hospital of Fillsburgh,
						difforences between	rennsylvania
						droupe	
						groups	
						All children said they	
						would repeat a 3-day	
						regimen of PEG3350	
						to help treat future	
						faecal impaction	
						Duration of	

Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
	Level		S		Measures	constipation at baseline significantly longer for the group receiving 1.5 g/kg per day as compared to the group receiving 0.5 g/kg per day (p<0.03)	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Tolia et al. A	Study Type:	48 children	48 children	Intervention:	Follow-up	Frequencies (%)	Additional information from study:
prospective	RCT			2-8 tablespoons	<u>period:</u> 2 days	(total sample for all	Constipation defined as the passage of
randomized		Inclusion	Data available	of mineral oil in 2		outcomes, n=36)	infrequent, large sized, firm to hard
study with	Evidence	criteria:	for 36 patients	divided doses for	Outcome	1.History:	stools with or without associated rectal
mineral oil and	level:	children aged	who completed	2 days. Dose	Measures:		pain or bleeding
oral lavage	1-	> 2 years with	study:	empirically	1.History:	a. number of bowel	
solution for		constipation,		determined (30		movements after	Randomisation performed by a
treatment of	Study aim:	normal growth	-Group I	ml/10 kg of body	-number of	treatment (>5 / 1 to 5/	computer-generated table
faecal impaction	to compare	and	(mineral oil):	weight)	bowel	none):	
in children.	the efficacy	development,	11 males		movements	-Group I (mineral oil,	Significantly more patients in the lavage
1993.	and	absence of	Mean age: 6.88	If parents had	after treatment	n=17): 2/10/5	group gave a history of previous
Alimentary	acceptability	Hirschsprung'	± 3.26 years	difficulty in	-vomiting		treatment with mineral oil (p<0.05). No
Pharmacology	of the	s disease		administering the	-compliance	-Group II (lavage	significant differences at baseline
and	treatment of	excluded on	-Group II	oil they were	-	solution, n=19): 9/8/2	between 2 groups regarding: duration of
Therapeutics	faecal	the basis of	(flavoured	asked to disguise	cramps/bloating	p<0.005	constipation, frequency of stooling,
7[5], 523-529	impaction	history and	lavage	it by blending it	-first bowel		associated encopresis, rectal bleeding,
	using either	physical	solution):	with 120-180 ml of	movement after	b. vomiting	previous treatments with enemas/fibre
	mineral oil or	examination	6.44 ± 2.36	orange juice	treatment	(none/occasional/a	diet, palpable abdominal masses,
	pineapple	by the	years		consider same	lot):	abdominal distension, anal fissure,
	isotonic	presence of		Comparison:	treatment	-Group I (mineral oil,	perineal soiling, sphincter tone and
	intestinal	firm to hard	Country: USA	pineapple		n=17):17/0/0	consistency of stool.
	lavage	faecal		flavoured	2.Physical		
	solution	impaction in		balanced oral	examination:	-Group II (lavage	Parents kept diaries assessing:
	containing	the anal canal		lavage solution		solution, n=19):	compliance of child with medication,
	polyethylene	and rectal		containing	-palpable	12/6/1	time of first bowel movement after
	glycol-3350	ampulla on an		polyethylene	abdominal	p<0.005	treatment, number of bowel movements
	(Colyte)	otherwise		glycol-3350	masses		on each day, consistency of bowel
		normal;		(Colyte)	-abdominal	c. compliance	movements, abdominal distension,
		complete		(sweetened with	distension)	(good/fair/poor):	cramps, nausea and vomiting, and
		physical		Nutra-Sweet) to	-consistency of	-Group I (mineral oil,	willingness to repeat the same treatment
		examination		drink in the dose	Stool	n=17): 14/3/0	in the future if impaction recurred
		Evolucion		or 20 mi/kg/n for 4	-anal fissure		
				n once dally on 2	-anai sphincter	-Group II (lavage	After treatment patients re-evaluated by
		<u>ciliena:</u>		Consecutive days.		solution, n=19): 6/7/6	the same physician who repeated the
		history			-perineal solling	p<0.01	abuominal and rectal examination in the
		requireest		amount/nour. 1		d oromno/blocting	Same way as belore
		vomiting		nue		u. cramps/bloating	12 patients failed to return for
		vomiting				(none/ a rew/a lot):	12 patients falled to return for

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Levei	and/or	5	In addition	Measures	-Group I (mineral oil	reassessment in two days
		aspiration.		patients received		n=17): 13/4/0	reassessment in two days
		central		a single oral dose		,	Post-treatment history and physical
		nervous		of		-Group II (lavage	examination further analysed after
		system		metoclopramide		solution, n=19):	stratifying for previous use of mineral
		problems or		(0.1 mg/kg) before		10/8/1	oils and stratified results did not differ
		known history		dinking the lavage		N.S a first howal	significantly from unstratified analysis.
		of liver, kidney and		days to prevent		e. IIISt Dowel	Results presented are unstratilied
		heart disease		nausea and		treatment (< 1 day/>1	Reviewer comments:
				vomiting		day/none):	Small sample size. No sample
				Ŭ		-Group I (mineral oil, n=17): 6/6/5	calculation made
						,	Method of allocation concealment not
						-Group II (lavage	described
						solution, n=19):	
						14/3/2	Physician-researchers not reported
						p<0.01	blinded
						f. consider same	Intention to treat analysis not performed
						(ves/maybe/no):	Unclear how descriptive outcomes
						-Group I (mineral oil, n=17): 12/3/2	converted to numerical before analysis
						,	Source of funding: Block Drug
						-Group II (lavage	Company, Inc. (Jersey City, NJ, USA)
						solution, n=19):	provided the supplies for the study
						11/6/2	
						N.5	
						2 Physical	
						examination:	
						-palpable abdominal	
						masses (none/a	
						rew/many):	
						n=17): 10/4/3	

Bibliographic Information	Study Type & Evidence	Number of Patients	Patient Characteristic	Intervention & Comparison	Follow-up & Outcome	Effect Size	Reviewer Comments
	Level		S		Measures		
						-Group II (lavage solution, n=19): 17/1/1 p<0.005	
						-abdominal distension (none/some): -Group I (mineral oil, n=17): 11/6	
						-Group II (lavage solution, n=19): 11/8 N.S	
						-consistency of stool (soft/firm/hard): -Group I (mineral oil, n=17): 12/3/2	
						-Group II (lavage solution, n=19): 14/3/2 N.S	
						-anal fissure (none/healing): -Group I (mineral oil, n=17): 15/2	
						-Group II (lavage solution, n=19): 15/4 N.S	
						-anal sphincter tone (normal/decreased): -Group I (mineral oil, n=17): 14/3	

Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
						-Group II (lavage solution, n=19): 15/4 N.S -perineal soiling (absent/present): -Group I (mineral oil, n=17): 10/7 -Group II (lavage solution, n=19): 13/6 N.S	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Guest et al.	Study Type:	224 children	224 children	Intervention:	Follow-up	Percentage of	Additional information from study:
Clinical and	Multicentre		aged 2 to 11	macrogol 3350	period:	patients disimpacted	Clinical data contained in patients' case
economic	retrospective		years	plus electrolytes	12 weeks	within 5 days (%,	notes transcribed onto case report forms
impact of using	cohort	Inclusion			(including	Confidence limit)	designed specifically for this study by
macrogol 3350		criteria: aged	5 centres in	Comparison 1:	maintance		one independent nurse, who examined
plus electrolytes	<u>Evidence</u>	between 2	England and	enemas and	treatment) ²	-macrogol 3350 plus	the case notes of all patients at all
in an outpatient	level:	and 11 years,	Wales	suppositories		electrolytes (n=5	centres
setting	2-	suffering from			<u>Outcome</u>	centres): 97% (94%,	
compared to		intractable		Comparison 2:	Measures:	100%)	Patients stratified according to centre
enemas and	Study aim: to	constipation		manual	-Percentage of		and initial treatment for disimpaction.
suppositories	estimate the	and initially	-macrogol 3350	evacuation of the	patients	-enemas and	Individual clinical outcomes quantified
and manual	clinical and	disimpacted	plus electrolytes	bowel under	disimpacted	suppositories (n=5	for each treatment at each centre.
evacuation to	economic	between	n=112 children	anaesthesia	within 5 days	centres): 73% (58%,	Clinical centre was the unit of analysis
treat paediatric	impact of	01/01/01 and	n=5 centres			89%)	
faecal impaction	using	31/01/06			-Time to initial		Reviewer comments:
based on actual	macrogol		-enemas and		disimpaction	-manual evacuation	No clear definition of "intractable
clinical practice	3350 plus	Exclusion	suppositories			of the bowel under	constipation" given
in England and	electrolytes	criteria: not	n=101 children		-time for	anaesthesia (n=2	
Wales. 2007.	(macrogol	initially	n=5 centres		disimpaction for	centres): 89% (67%,	Very small sample size for the manual
Current Medical	3350;	disimpacted			those who did	100%)	evacuation of the bowel
Research and	Movicol,	between	-manual		not disimpact		
Opinion 23[9],	Movicol	previous	evacuation of		within 5 days	p<0.001	Not reported which enemas and
2213-2225	Paediatric	dates or had	the bowel under				suppositories children were treated with
	Plain) in an	any condition	anaesthesia		-reported	lime to initial	for disimpaction
	outpatient	contraindicati	n=11 children		adverse effects	disimpaction and time	
	setting	ng the use of	n= 2 centres			tor disimpaction for	Having another nurse (or other
	compared to	macrogol				those who did hot	professional) independently examining
	enemas and	3350	Country: UK			disimpact within 5	the case notes or reviewing the
	suppositories					days:	transcriptions might have decreased the
	and manual					N	risk of potential blas
	evacuation to					INO SIGNIFICANT	
	treat					differences amongst	According to the reported results it is
	paediatric					the 3 groups	unclear that clinical centre was the unit
	inaecal						
	impaction					Doses required for	
						SUCCESSIUI	Source of funding: sponsored financially

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
						disimpaction within 5	by Norgine Pharmaceuticals Ltd,
						days (mean, 95% CI):	Harefiled, UK, manufactures of Movicol
							(macrogol 3350 plus electrolytes)
						-macrogol 3350 plus	
						electrolytes (sachets):	
						29 (13 to 44)	
						-enemas (units):	
						2 (1 to 3)	
						-suppositories (units):	
						1 (1 to 2)	
						Percentage of	
						patients on different	
						treatments during the	
						week belore miliai	
						<u>ireaimeni.</u>	
						Significantly more	
						children disimnacted	
						with manual	
						evacuation were	
						taking lactulose and	
						senna compared with	
						other 2 groups	
						(p<0.001)	
						u ,	
						Significantly more	
						children disimpacted	
						with Macrogol were	
						taking picosulphate	
						compared with other	
						2 groups (p<0.01)	
						Significantly more	
						children disimpacted	
						with enemas and	
						suppositories were	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
						taking lactulose and	
						other combinations	
						(p<0.01), other	
						laxatives (p<0.001) or	
						were not treated	
						((p<0.001) when	
						compared with other	
						2 groups	
						No significant	
						differences between	
						the 3 groups for	
						patients taking	
						lactulose only or	
						those taking Senna	
						Adverse effects:	
						a. Vomiting (%):	
						-macrogol 3350 plus	
						electrolytes (n=112	
						patients): 2	
						-enemas and	
						suppositories (n=101	
						patients): 2	
						-manual evacuation	
						of the bowel under	
						anaesthesia (n=11	
						patients): 18	
						p<0.01	
						No significant	
						differences among 3	
						groups for: urinary	
						tract infection,	
						dermatitis around	
						anus, thrush and	
						gastric illness	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Candy et al.	Study Type:	65 children	65 children	Intervention:	Follow-up	1. Successful	Additional information from study:
Treatment of	Prospective			Polyethylene	period:	disimpaction (No, %):	Definition of impaction was functional or
faecal impaction	case series	Inclusion	Mean age: 5.7	glycol 3350 (13.8	9 days	-total (n=63)	procedural: Children were eligible if they
with	(phase 1 of	criteria:	years(56%	g powder		yes: 58 (92)	would, in the normal course of events,
polyethelene	the study)*	children aged	children 5 to 11	dissolved in at	<u>Outcome</u>	no: 5 (8)	have been admitted and treated for
glycol plus		2 to 11 years	years)	least 125 ml water	Measures:		faecal impaction
electrolytes	Evidence	with		per sachet) plus		-age 2 to 4 (n=28)	
(PGE + E)	level:	intractable	68% boys	electrolytes (PEG	1. Successful	yes: 25 (89)	Phase 1 of the study planned as
followed by a	3	constipation		+ E; Movicol ®)	disimpaction	no: 3 (11)	noncomparative because of good
double-blind		that had failed	Country: UK	administered	without any		success rate obtained at initial
comparison of	Study aim: to	to respond to		orally in hospital	additional	-age 5 to 11 (n=35)	experience in treating impacted children
PEG + E versus	assess the	conventional		according to an	intervention	yes: 33 (94)	with PEG + E in the authors' unit: it was
lactulose as	efficacy of	treatment and		escalating dosing		no: 2 (6)	considered unethical to randomise the
maintenance	polyethylene	would require		regime until	2. Time to		children to an alternative treatment
therapy. 2006.	glycol 3350	hospital		disimpaction was	disimpaction	2. Time to	
Journal of	plus	admission for		achieved (up to 7	(primary	disimpaction (days)	Sample size: intended to recruit 60
Pediatric	electrolytes	disimpaction		days)	efficacy	(mean, SD; median,	children to obtain approximately 45
Gastroenterolog	(PEG + E;	(otherwise			endpoint)	range):	children continuing to end of phase 2
y and Nutrition	Movicol ®) as	been admitted		-PEG + E dosing		-total (n=63)	
43[1], 65-70	oral	for enemas,		regime	Maximum	5.7 ± 1.2	Successful disimpaction indicated by the
	monotherapy	manual			dose required	6.0 (3 to 7)	passage of watery stools.
	in the	removal or		No. PEG + E	to achieve		
	treatment of	intestinal		sachets :	disimpaction	-age 2 to 4 (n=28)	Dose regime chosen because it had
	faecal	lavage with				5.8 ± 1.2	shown to be effective in a previous study
	impaction in	PEG + E		a. 2 to 4 years	4. Safety	6.0 (3 to 7)	from the same unit
	children and	solutions)		Day 1: 1			
	to compare			Day 2: 2		-age 5 to 11 (n=35)	After disimpaction children continued to
	PEG + E with	Exclusion		Day 3: 2		5.6 ± 1.1	received PEG + E at the dose that
	lactulose as	<u>criteria</u> : any		Day 4: 3		6.0 (3 to 7)	achieved disimpaction for 2 more days
	maintenance	condition		Day 5: 3			to ensure that complete disimpaction of
	therapy in a	contraindicati		Day 6: 4		3. Maximum dose	the bowel had occurred
	randomised	ng the use of		Day 7: 4		required	
	trial	PEG+E or				(sachets/day):	Use of additional interventions
		lactulose,		b. 5 to 11 years		-total (n=63): 6	necessary to achieve disimpaction

^{*} Study comprised two phases. Outcomes for the second phase (RCT) regarding maintenance therapy will be presented at the next review

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level	in also din a	S	Davida 0	Measures		
		including		Day 1: 2		-age 2 to 4 (n=28): 4	(laxatives, suppositories, enemas,
		intestinal		Day 2: 3			washouts of manual removal) necessary
		perforation or		Day 3: 4		-age 5 to 11 (n=35): 6	to achieve disimpaction was also
				Day 4. 5 Day 5: 6		4. Wean number (SD)	recorded
		allergy to any		Day 5: 6		or sachets required to	2 shildren withdrew before resolving any
		or the		Day 6. 6		total (a C2): 10 C	s children withdrew before receiving any
		ingreatents of		Day 7: 6		-total (n=63): 19.6	study medication and 2 children failed to
		the trial		Compariant papa		(7.5)	disimpact within the time allowed, but
		products,		Comparison: none			they were included in results
		paralytic lieus,				-age 2 to 4 (n=28):	Deviewer commenter
						14.3 (4.5)	Reviewer comments.
		Hirochonrung'				a = 5 + 11 (n - 25)	no explicit definition of watery stools
						-age 5 (0 11 (n=35)).	given
		s disease,				23.0 (0.8)	It is not clear who accorded the
		severe				No oignificant	it is not clear who assessed the
		howol				differences between	outcome passage of watery stools,
		disease				the two age groups	annough it looks like it was probably the
		uisease,				for any of the	researchers
		ropal/bopatic/					Individual accessing outcomes not
		cardiac				outcomes measured	reported blinded to study objectives
		disease.				The 2 children who	
		uncontrolled				failed to disimpact in	Not reported whether there were any
		endocrine				the 7 days specified	differences between the children who
		disorder or				in the study protocol	withdrew before receiving any
		anv				were continued on	medication, those who failed to
		neuromuscula				PEG+E	disimpact and the ones who completed
		r condition				administration and	the study and disimpacted during the
		affecting the				eventually	time allowed
		bowel				disimpacted	
							Not clear whether vomiting affected the
		Setting:				4. Safety:	dose required to achieve disimpaction
		hospital				-Number of children	or whether children receive any
						experiencing adverse	medication to prevent / stop vomiting
						effects: 39 (62%).	· · · · · · · · · · · · · · · · · · ·
						(non of these judged	Source of funding: supported by Norgine
						by investigator to be	Pharmaceuticals Ltd.
						serious)	

Bibliographic Information	Study Type & Evidence	Number of Patients	Patient Characteristic	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
						Most commonly reported events: gastrointestinal (51% children) (abdominal pain, nausea, pruritus, ani / proctalgia and vomiting) No differences in the overall incidence of adverse effects or of gastrointestinal effects for the two age groups, except for vomiting (32% of age 2 to 4 children vs. 9% of aged 5 to 11 children)) results showed a direct correlation between incidence of vomiting and day of dosing	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Pashankar et al.	Study Type:	24 children	(data available	Intervention:	Follow-up	Soiling frequency	Additional information from study:
Efficacy and	Prospective		for only 20	PEG solution,	period: 8 weeks	(n=9) (mean ± SEM) :	Diagnosis of constipation based on
optimal dose of	case series	Inclusion	children who	initial dose ~1g/kg			symptoms of at least 3 months' duration
daily		criteria:	completed	body weight per	<u>Outcome</u>	before treatment:	including at least 2 of: hard stools,
polyethylene	Evidence	constipated	study)	day (14 ml/kg/d	Measures:	10.0 ± 2.4	painful defection, withholding of stools,
glycol 3350 for	level: 3	children		solution) given in		during treatment:	faecal soiling, palpable faecal mass and
treatment of		between ages	9 boys	2 divided doses	-soiling	1.3 ± 0.7	fewer than 3 bowel movements/week
constipation	Study aim: to	of 18 months	aged 18 months	for 8 weeks	frequency	p= 0.003	
and encopresis	examine the	and 12 years	to 11 years				Administration of all other medications
in children.	efficacy and		Mean age 6.09	Parents instructed	-presence of	Total resolution of	for constipation stopped on enrolment.
2001. Journal of	dosing of	Exclusion	± 4.2 years	to dissolve 17 g of	abdominal	soiling: 4 patients	No enemas or cathartics given either.
Pediatrics	PEG in	criteria:		PEG powder in	faecal mass	(44.4%)	Initial doses of PEG prescribed based
139[3], 428-432	children with	history of	11 children:	each 240 ml (8			on authors' previous experience with
	constipation	Hirschsprung'	constipation	ounces) of water,	-presence of	Presence of	this agent
		s disease,	alone	juice or other	faecal rectal	abdominal faecal	
		anorectal		clear-liquid	impaction	<u>mass (n=18)</u>	Stool consistency assessed by history
		malformations	9 children:	beverage, families			on a scale of 1 to 5 as follows: 1, hard;
		, abdominal	constipation +	allowed free	-dilated rectal	before treatment:	2, firm; 3, soft; 4, loose and 5, watery
		surgery or	soiling	choice of clear	vault	44%	
		any systemic		liquid beverage.		during treatment: 0%	Patients examined on enrolment and at
		illness that	<u>Country:</u> USA	For determination	-painful	p<0.0029	the end of 8 weeks of therapy for the
		could lead to		of best dose for	defecation		presence or absence of a palpable
		constipation		each child,		Presence of faecal	faecal mass, faecal impaction and rectal
				parents asked to	-fear of	rectal impaction	dilatation
				increase or	defecation	<u>(n=18)</u>	
				decrease volume	/stool		Children of appropriate developmental
				of PEG solution	withholding	before treatment:	status advised to sit on toilet for 5
				by 20% every 3		83%	minutes after each meal
				days as required		during treatment:	
				to yield 2 soft-to-		22%	Patients bowel habits before PEG
				loose stools		p<0.0006	treatment compared with those recorded
				(consistency			on diary forms during the last 2 weeks
				score of 3 to 4)		Dilated rectal vault	(weeks / and 8) of treatment
				per day		<u>(n=18)</u>	
				0		hafana (na star su)	4 subjects dropped from study because
				Comparison: none		perore treatment:	or railure to return required symptoms
						18%	diaries: 2 of these had an excellent
						during treatment:	response to therapy by parent report

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures	110/	and two wore last to follow up
						n < 0.0001	
						p 10.000 i	Reviewer comments:
						Painful defecation	Small sample size, no sample size
						<u>(n=20)</u>	calculation
						before treatment:	
						75%	No data reported on who performed
							at the end of 8 weeks of therapy
						p<0.0001	at the end of 6 weeks of therapy
						Fear of defecation	Not clear why data on physical
						/stool withholding	examination available for only 18
						<u>(N=20)</u>	children
						before treatment:	Source of funding: not stated
						during treatment: 5%	Source of funding. Not stated
						p<0.0001	
						Final effective dose	
						during last 2 weeks of	
						$\frac{\text{treatment (mean } \pm}{\text{SEM}}$	
						<u>OLW) (g/kg/day).</u>	
						0.84 ± 0.27 (range	
						0.27 to 1.42)	
						Deletekilitur ell	
						children reported	
						willingness to take	
						PEG and found it	
						highly palatable (to	
						prepare PEG patients	
						used sweeteners, fruit	
						juices, water and	
						Adverse effects: no	
						significant except for	

Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
	Level		S		Measures	diarrhoea during adjustment of dose. Flatulence (n=2) Abdominal pain (n=10)	

Pharmacological Interventions for	r Ongoing Treatment/ Maintenance in Cl	hildren with Chronic Idiopathic Constipation
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Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Candy et al.	Study Type:	65 children	-Phase 1:	Intervention:	Duration of	Number of successful	Additional information from study:
Treatment of	Double-blind		65 children	Polyethylene	treatment	defecations/week	Sample size: intended to recruit 60
faecal impaction	RCT**	Inclusion		glycol 3350 (13.8	12 weeks	(last on-treatment	children to obtain approximately 45
with		criteria:	-Phase 2:	g powder		<u>value)</u>	children continuing to end of phase 2
polyethelene	Evidence	children aged	58 children	dissolved in at	Assessment	Mean, SD, range	
glycol plus	level:	2 to 11 years		least 125 ml water	point (s):		Children and investigators blinded to
electrolytes	1+	with	67% boys	per sachet) plus	Immediately	-PEG+E (n=27):	medication which was dispensed
(PGE + E)		intractable		electrolytes (PEG	after treatment		according to randomisation list
followed by a	Study aim:	constipation	Mean age: 5.7 ±	+ E; Movicol ®)	finished	9.4 (4.56; 2 to 24)	generated by the study sponsor
double-blind	to assess the	that had failed	2.6 years				
comparison of	efficacy of	to respond to	(range 2 to 11	Comparison:	Follow-up	-Lactulose (n=26):	Blindness reasonably maintained as
PEG + E versus	polyethylene	conventional	years)	Lactulose (10 g	period:		appearance of 2 products very similar
lactulose as	glycol 3350	treatment and		powder dissolved	No follow-up	5.9 (4.29; 2 to 23)	and both packed in sachets of an
maintenance	plus	would require	Country: UK	in at least 125 mL	made after		identical size
therapy. 2006.	electrolytes	hospital		water)	treatment	Difference in means:	
Journal of	(PEG + E;	admission for			finished	3.5	5 children did not complete phase 1: 3
Pediatric	Movicol ®) as	disimpaction		For both		95% CI: 1.0 to 6.0	children withdrew before receiving any
Gastroenterolog	oral	(otherwise		medications	<u>Outcome</u>	p=0.007	study medication and 2 children failed to
y and Nutrition	monotherapy	been		children received	Measures:		disimpact within the time allowed
43[1], 65-70	in the	admitted for		oral maintenance		Reimpaction rate (n,	
	treatment of	enemas,		doses	1. Primary	<u>% children):</u>	58 children entered phase 2. 5 were
	faecal	manual		commencing with	efficacy	-PEG+E (n=27): 0	excluded from the ITT population as
	impaction in	removal or		1/2 of the numbers	endpoint:		they did not provide any on-treatment
	children and	intestinal		of sachets	-number of	-Lactulose (n=26): 7	efficacy data.
	to compare	lavage with		required for	successful	(23%)	10 children (17%) did not complete
	PEG + E with	PEG + E		disimpaction/day	defecations/we		phase 2: 7 on lactulose reimpacted, 2 on
	lactulose as	solutions)			ek	p=0.011	lactulose did not want to continue, 1 on
	maintenance			Disimpaction			PEG+E did not complete the diary card
	therapy in a	Exclusion		regime (n		Number of sachets	
	randomised	<u>criteria</u> :		sachets):	2.Secondary	used each day:	No significant differences at baseline
	trial	any condition			efficacy	-PEG+E (n=27): 0.91	between 2 groups regarding: age, sex,
		contraindicati		a. 2 to 4 years	endpoints:	(0.41)	height and weight
		ng the use of		Day 1: 1			
		PEG+E or		Day 2: 2	-reimpaction	-Lactulose (n=26):	No children withdrew form the study for

** This is phase 2 of the study. Phase 1 was a prospective case series already discussed in the review for disimpaction

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
		lactulose,		Day 3: 2	rate	2.41 (0.91)	safety reasons
		including		Day 4: 3			
		intestinal		Day 5: 3	-number of	Use of senna as	Reviewer comments:
		perforation or		Day 6: 4	sachets used	rescue medication	No clear definition of constipation given
		obstruction,		Day 7: 4	each day	-PEG+E (n=27): 0	
		allergy to any					Method of allocation concealment not
		of the		b. 5 to 11 years	-use of senna	-Lactulose (n=26): 8	described
		ingredients of		Day 1: 2	as rescue	(31%)	
		the trial		Day 2: 3	medication	p=0.002	Results not controlled for confounders
		products,		Day 3: 4			
		paralytic		Day 4: 5	-amount of stool	No significant	Missing data on 2 children who did not
		ileus, toxic		Day 5: 6		differences in mean	enter phase 2 of the study
		megacolon,		Day 6: 6	-predominant	values per patient	
		Hirschsprung'		Day 7: 6	bowel	between 2 groups	Source of funding:
		s disease ,			movement form	with respect to:	supported by Norgine Pharmaceuticals
		severe				amount of stool,	Ltd.
		inflammatory		Additional laxative	-pain	predominant bowel	
		bowel		treatment with		movement form, pain,	
		disease,		senna allowed as	-straining	straining, rectal	
		uncontrolled		rescue medication		bleeding, abdominal	
		renal/hepatic/		if the response to	-rectal bleeding	pain, soiling and	
		cardiac		a single agent		overall assessment of	
		disease,		alone was judged	-abdominal pain	treatment	
		uncontrolled		inadequate by			
		endocrine		investigator	-soiling	Safety (% children)	
		disorder or				<u>(n=58):</u>	
		any			-overall	-PEG+E: 64	
		neuromuscula			assessment of	-Lactulose: 83	
		r condition			treatment		
		affecting the				Similar incidence in	
		bowel				each age group. Most	
					3. Safety	commonly reported	
						events	
						gastrointestinal and	
						resolved during the	
						study. No clinically	
						significant abnormal	
						values observed in	

Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
	Level		S		Measures	urine and plasma electrolytes after 12 weeks of maintenance therapy	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Dupont et al.	Study Type:	96 children	96 children	Intervention:	Duration of	Stool frequency	Additional information from study:
Double-blind	RCT		51 male	PEG 4000	treatment:	(number of stools/wk,	Constipation defined as less than 1
randomized		Inclusion			3 months	median (interquartile	stool/day for > 1 month in children 6 to
evaluation of	Evidence	criteria:		-Starting dose:		range)	12 months old and less than 3
clinical and	level:	children with	-Age (months)	1 sachet (4g) and	<u>Assessment</u>		stools/week for > 3 months in children
biological	1+	constipation	median (25 [™] to	1 placebo to be	point (s):	-D42	aged 13 months to 3 years
tolerance of		despite their	75th	taken at breakfast	Day 42 (D42)	NS in babies	
polyethylene	Study aim: to	usual dietary	percentiles)		and day 84	Toddlers:	PEG 4000 and lactulose packaged in a
glycol 4000	assess the	treatment for		Comparison:	(D84) after	PEG 4000 (n=51):	double-blind and double-dummy design,
versus lactulose	safety of a	at least 1	PEG 4000:	Lactulose	starting	8 (6–10)	by means of coupled sachets, according
in constipated	polyethylene	month, aged	28 (19.5–33.7)		treatment	Lactulose (45):	to a randomisation list. Double dummy
children. 2005.	glycol (PEG)	6 months to 3		-Starting dose:		6 (5–7)	design required because of the
Journal of	4000 laxative	years,	Lactulose:	1 sachet (3.33g)	Follow-up	(P=0.013).	difference of taste between the drugs.
Pediatric	without	ambulatory	25.8 (12.3–33)	and 1 placebo to	period:		Numbered boxes provided to
Gastroenterolog	additional			be taken at	No follow-up	-D84	investigators at each site in equal
y and Nutrition	salts in	Exclusion	Country:	breakfast	performed after	NS in babies or	numbers. Investigators randomly
41[5], 625-633	paediatric	criteria:	France		treatment	toddlers	allocated either PEG 4000 or lactulose
	patients	history of			finished		to the children for a 3-month period, with
		intractable		For both drugs,		Frequency of hard	the same strategy for dose adaptation
		faecaloma,		dose could be	<u>Outcome</u>	stools	
		Hirschsprung'		doubled if	Measures:		3 children not included because of a
		s disease,		ineffective in		-D42	baseline laboratory value ONR (out of
		neurologic,		children aged 13	-Efficacy:	PEG 4000: 9%	normal range) before amendment
		endocrine or		months to 3 years		(4 of 46)	applied. 2 children in PEG 4000 group
		metabolic		If maximum	stool frequency	Lactulose (45): 34%	dropped out before any study drug
		disorders,		authorised dose	frequency of	(14 of 41)	intake, so the intention to treat
		allergic		unsuccessful, one	hard stools	P = 0.003	population included 51 children (10
		disease or		micro-enema of	enema use		babies and 41 toddlers) in the PEG
		allergies		glycerol per day	faecal	-D84	4000 group and 45 (12 babies and 33
				could be	impaction	PEG 4000 (n=51):	toddlers) in the lactulose group. 76 of
				prescribed for a	abdominal pain	6% (3 of 47)	these children included in the per
				maximum of 3	appetite	Lactulose (45): 28%	protocol analysis and 20 excluded by
				consecutive days.		(11 of 40)	the independent scientific committee for
				If child not	-Biological	P = 0.008	at least one major deviation, 11 in the
				produced stools	tolerance:		PEG 4000 group and 9 in the lactulose
				after treatment 2		Enema use	group. Reasons for exclusion were no
				enemas could be	ion		laboratory test at D84, one or more one
				administered at a	electrolytes	-D42:	missing laboratory results at D84,

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
				48-h interval. This	total protein	PEG 4000: 30% (14	delayed laboratory test at D84 (n = 12),
				procedure only	albumin	of 48)	inadequately long exposure to the study
				allowed twice	vitamin A	Lactulose: 43% (19 of	drug (n = 2), personal reasons (n = 5)
				during the study,	vitamin D	44)	and unauthorized concomitant treatment
				If child produced	folates		(n = 1)
				liquid stools for >1		-D84:	
				day or > 2 or 3	-Clinical	PEG 4000: 17% (8 of	No clinically relevant differences
				stools/day	tolerance:	48)	between 2 treatment groups at baseline
				depending on		Lactulose: 41% (17 of	for clinical or biologic parameters
				age, dose could	body height	42)	Stool frequency, abdominal pain,
				be decreased by	body weight	P = 0.012	vomiting, and nausea recorded on Self-
				1 pair of	adverse effects		Diary Evaluation Booklet
				sachets/day to a		Faecal impaction	
				minimum of 1 pair			Reviewer comments:
				of sachets every		PEG 4000 (n=51): 1	Methods of randomisation and allocation
				other day and		(2%)	Concealment not cleany described
				possibly to		Laciulose (45). 6	No sample calculation performed
				interruption		(13%)	
				Interruption		F=0.049	comounders
						Abdominal nain	Source of funding:
						disannearance.	not stated
						disappearance.	
						-D42	
						PEG 4000: 82% (9	
						out 11 at baseline)	
						Lactulose: 38% (3	
						out of 8 at baseline)	
						P<0.08	
						-D84	
						PEG 4000: 55% (6	
						out 11 at baseline)	
						Lactulose: 63% (5 out	
						of 8 at hasaling)	
						P<1.00	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Level	Patients	Characteristic	Comparison	Outcome Measures		
						Appetite score	
						<u>improvement</u>	
						PEG 4000 (n=51):	
						+19%	
						Lactulose (45):	
						-4%	
						p<0.003	
						Clinical tolerance	
						(ITT population)	
						-6 adverse effects (all	
						non serious):	
						5 diarrhoea (5	
						episodes in 2 children	
						groups)	
						1 anorexia (on	
						lactulose)	
						-median (interquartile	
						range) duration of	
						either new onset or	
						(davs):	
						PEG 4000: 3 (1 to	
						Lactulose: 5 (3 to	
						19.5)	
						P=0.005	
						-median (interquartile	
						range) duration of	
					1	either new onset or	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
						worsened vomiting	
						episodes (days):	
						PEG 4000: 1 (1 to 2)	
						Lactulose: 2 (1 to 6)	
						P<0.05	
						-anal irritation: 5% (2	
						out of 40 children,	
						both on lactulose)	
						-no difference	
						between PEG 4000	
						and lactulose groups	
						with regards to other	
						digestive tolerance	
						outcomes	
						-Body height and	
						body weight	
						unaffected during the	
						3-monnt treatment for	
						both boys and girls	
						Biological tolerance	
						(ITT population):	
						NO Significant	
						difference between	
						the % of children with	
						ONR values on Do4	
						status. No troatmont	
						related changes	
						found in serum iron	
						electrolytes	
						total protein albumin	
						and vitamine A D and	
						folatos	
						tolates	

Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
	Level		5		MedSures	Dose used (sachets/day) (median (interquartile range)) -Babies: 1 (0.9 to 1) PEG 1 (1 to 1.3) lactulose P = 0.67 -Toddlers 1 (1 to 1.3) PEG 1.1 (0.9 to 1.5) lactulose P = 0.58 Treatment stopped in 1 child because of lack of efficacy (lactulose group).	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Voskuijl et al.	Study Type:	100 children	91 children	Run-in phase (1	Duration:	Defecation	Additional information from study:
PEG 3350	RCT		49 male	week before	8 weeks (RCT)	frequency/week	Childhood constipation defined as
(Transipeg)		Inclusion		treatment):	18 weeks (case		having at least 2 to 4 of the following
versus lactulose	Evidence	criteria:	age range: 6	No laxatives	series)	-PEG 3350: 7.12	symptoms for the last 3 months: less
in the treatment	level:	children aged	months to 15	allowed.		(5.14)	than 3 bowel movements/week,
of childhood	1+	6 months to	years	At the end all	Assessment	-Lactulose: 6.43	encopresis more than once/week, large
functional		15 years with		patients received	point (s):	(5.18)	amounts of stool every 7 to 30 days
constipation: a	Study aim:	constipation	Age (y) (mean	1 enema daily for	1, 2, 4 and 8	N.S	(large enough to clog the toilet) and
double blind,	to compare		(SD)) PEG	3 days:	weeks after		palpable abdominal or rectal mass on
randomised,	the clinical	Exclusion	3350 6.5 (3.2)	-Children ≤ 6	starting	Encopresis	physical examination
controlled,	efficacy and	criteria:		years: 60 ml Klyx	treatment	frequency/week:	
multicentre trial.	safety of PEG	organic	Lactulose 6.5	(sodium			Estimated that a total sample of 90
2004. Gut	3350	causes for	(3.4)	dioctylsulfosuccin	Follow-up	-PEG 3350: 3.11	patients would be adequate to show a
53[11], 1590-	(Transipeg;	defecation		ate and sorbitol)	period:	(5.41)	difference of at least 30% more success
1594	polyethylene	disorders,	Country: the	-Children > 6	26 weeks after	-Lactulose: 2.84	at 8 weeks using PEG 3350 compared
	glycol with	including	Netherlands	years: 120 ml Klyx	entering case	(3.59)	to lactulose, with a 2 tailed alpha level of
	electrolytes)	Hirschsprung'			series phase	N.S	0.05 with a power of 80%
	and lactulose	s' disease,		 Initial phase: 			
	in paediatric	spina bifida			Outcome	Success percentages	Unlabelled number boxes with
	constipation	occulta or		Intervention:	Measures:	<u>(95% CI)</u>	unlabelled sachets prepared by the
		hypothyroidis		PEG 3350			AMC pharmacy and handed out to
		m			1. Efficacy:	PEG 3350: 56 (39 to	patients after randomisation. The box
				-children aged 6		70)	contained 180 sachets containing either
				months to 6 years	-frequency of		lactulose 6g/sachet or PEG 3350 2.95g
				(inclusive): one	stools	Lactulose: 29 (16 to	per sachet.
				sachet (2.95g) per		44)	
				day	-frequency of		Toilet training advised after each meal
					encopresis	P=0.02	(5 minutes) and small gifts and praise
				-children older			used to enhance compliance
				than 6 years: 2	-overall	Overall treatment	
				sachets (5.9g) per	treatment	success independent	No significant differences at baseline
				day	success	of age (< 6 years and	between the 2 groups with respect to:
						≥ 6 years) and use of	age, sex, defecation frequency,
				Comparison:	2. Safety	laxatives for more	encopresis, large amounts of stool and
				Lactulose		than 1 year prior to	faecal impaction
					-Incidence and	the start of the study.	
				-children aged 6	severity of	In children treated for	9 dropouts: 4 on PEG 3350, 5 on
				months to 6 years	gastrointestinal	less than 1 year a	lactulose. 2/each group lost to follow-up,

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
				(inclusive): one	adverse effects	significant difference	1/each group reason unknown. 2 on
				sachet (6g) per		in success found	lactulose were helicobacter positive, 1
				day		between those	on PEG due to bad palatability of study
						treated with PEG	medication
				-children older		3350 (63%) or	
				than 6 years: 2		lactulose (31%),	Overall treatment success defined 3 or
				sachets (12g) per		p=0.02	more bowel movement/week and 1
				day			encopresis episode or less every 2
				<u>2. Follow-up</u>		Medication	weeks
				<u>phase</u>		<u>(sachet/day):</u>	
							Reviewer comments:
				Intervention:		-PEG 3350: 1.99 (0.3)	Method of randomisation and allocation
				PEG 3350			concealment not described
						-Lactulose: 2.4 (0.4)	Case series phase outcomes not
				-children aged 6		0.00	reported for the purpose of this review
				months to 6 years		p=0.03	III analysis not performed
				(Inclusive): one		ne significant	Course of funding a not stated
				sachet (2.95g) per		no significant	Source of funding: not stated
				uay		amerences between	
				childron oldor		2 groups at 1, 2, 4	
				than 6 years: 2		dofecation and	
				sachets (5 9g) per			
				dav		encopresis nequency	
				uuy		Side effects:	
				Comparison [.]		No serious or	
				none		significant side effects	
						recorded	
						Significantly more	
						adverse effects	
						(abdominal pain, pain	
						at defecation and	
						straining at	
						defecation) in	
						patients taking	
						lactulose as	
						compared to PEG	
						(p<0.05). No	

Bibliographic Information	Study Type & Evidence	Number of Patients	Patient Characteristic	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
						significant differences between 2 groups regarding: bloating, diarrhoea, flatulence, nausea, hard stool consistency and vomiting. Significantly more children complained of bad palatability of PEG compared to lactulose and this caused the premature withdrawal of 1 patient.	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Gremse et al.	Study Type:	44 children	44 children	Intervention:	Duration of	Mean number of	Additional information from study:
Comparison of	RCT			PEG 3350 without	treatment:	bowel movements	7 patients withdrew during the first 2-
polyethylene	(crossover)	Inclusion	Age range: 2 to	electrolytes	2 weeks each		week treatment period due to lack of
glycol 3350 and		<u>criteria:</u>	16 years (mean	(MiraLax)	period	-PEG 3350 (n=37):	efficacy of the assigned intervention: 6
lactulose for	Evidence	patients aged	7.8 ± 3.7)	10g/m2/d orally		14.8 ± 1.4	patients taking lactulose at time of
treatment of	level:	2 to 16 years,		for 2 weeks	<u>Assessment</u>		withdrawal
chronic	1-	referred for	<u>Country:</u> USA		<u>point (s):</u>	-Lactulose (n=37):	
constipation in		subspecialty		Mean weight	Immediately	13.5 ± 1.5	Stool form scoring: 0 hard, 1 firm, 2 soft,
children. 2002.	Study aim:	evaluation of		adjusted dose: 0.3	after each		3 loose, 4 watery
Clinical	to compare	constipation		g/kg/d (range 0.2	treatment	Stool form (mean	
Pediatrics 41[4],	the efficacy of			to 0.5)	period	sum of scores)	Stool passage scoring: 0 hard, 1 difficult,
225-229	PEG 3350	Exclusion					2 easy, 3 urgency, 4, no control
	and lactulose	<u>criteria:</u>		Comparison:	Follow-up	-PEG 3350 (n=37):	
	in the	organic		Lactulose 1.3	<u>period:</u>	25.9 ± 3.0	Stool frequency, form and easy of
	treatment of	disease of the		g/kg/d orally for 2	No follow-up		passage recorded by parent or guardian
	chronic	large or small		weeks	made after	-Lactulose (n=37):	in symptom diary
	constipation in	intestine,			treatment	27.9 ± 1.5	
	children	known allergy			completed		Reviewer comments:
		to PEG or		(no washout	_	Stools passage	No definition of constipation given
		lactulose,		period)	Outcome	(mean sum of scores)	Baseline characteristics between groups
		previous			Measures:	-PEG 3350 (n=37):	not compared
		gastrointestin				28.5 ± 4.2	Method of randomisation and allocation
		al surgery,			-Stool		concealment not described
		renal; or heart			frequency	-Lactulose (n=37):	Non blinded study
		failure, bowel				26.2 ± 5.1	Small sample size, no sample size
		obstruction,			-Stool form		calculation
		ileus,			_ ,	Effectiveness (%	No follow-up period
		pregnancy,			-Easy of	effective)	Intention to treat analysis not performed
		lactation,			passage	-PEG 3350 (n=37):	15.9 % dropout rate
		galactosemia,				84	Results not controlled for potential
		diabetes			-Effectiveness		confounders
		mellitus			(global	-Lactulose (n=37): 46	
					assessment, as	p=0.002	Source of funding:
					reported by	Lauration and taxas	not stated
					parent or	Laxative preference	
					guardian)		
					1	-PEG 3350 (n=37):	
					-Laxative	73	
Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
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					preference (based on efficacy, ease of administration and side effects)	-Lactulose (n=37): 27	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Loening-	Study Type:	49 children	-Miralax group:	Intervention:	Duration of	Bowel movement	Additional information from study:
Baucke.	Prospective		28 children	MiraLax	treatment:	frequency (mean,	Initial dose of Miralax 0.5 g/kg daily
Polyethylene	cohort	Inclusion	20 boys	17 dissolved	12 months	results are estimates	suggested for children whose rectums
glycol without		criteria:	Mean age ± SD:	in 240 mL of a		taken form bar chart	were loaded with stool but who had no
electrolytes for	Evidence	children ≥4	8.7 ± 3.6 years	beverage such as	<u>Assessment</u>	as not reported in	fecal abdominal masses at the initial
children with	level:	years of age	Range 4.1 to	juice or Kool-Aid	point (s):	text)	physical examination and no history of
constipation	2+	referred for	17.5 years	initial dose:	1, 3, 6, and 12		long intervals between huge bowel
and encopresis.		functional		0.5 to 1 g/kg/daily	months after	-baseline:	movements. Those with
2002. Journal of	Study aim:	constipation	-MOM group:		initiating	PEG: 3.2	palpable abdominal fecal masses or
Pediatric	to determine	and	21 children	Comparison:	treatment	MOM: 2.5	history of infrequent huge bowel
Gastroenterolog	the efficiency,	encopresis	17 boys	MOM			movements started on 1 g/kg daily
y and Nutrition	acceptability,	Functional	Mean ± SD: 7.3	Initial dose:	Follow-up	-1 month	
34[4], 372-	and treatment	constipation	± 3.0 years	1 to 2.5 mL/kg	period:	PEG: 9.0	Milk of Magnesia given if family could
377United	dosage of	defined as	Range: 4.0 to		No follow-up	MOM: 6.5	afford only the use of a cheaper laxative
States.	MiraLax	delay/difficulty	13.9 years		made after		or if child had previously received MOM
	(polyethylene	in defecation			treatment	-3 months	without refusal. For these children, MOM
	glycol 3350	and	Country:		finished	PEG: 9.5	reintroduced or adjusted to adequate
	without	encopresis	USA			MOM: 7.0	dosage. Parents told how to improve the
	electrolytes)	(≥1/week) for			Outcome		taste by mixing the child's preferred
	during a 12-	more than 1		Large laxative	Measures:	-6 months	flavoring with plain MOM. Initial daily
	month	year		dosages divided		PEG: 8.8	dosage of 1 mL/kg body weight
	treatment			into 2 daily doses.	-bowel	MOM: 6.3	suggested for children with rectal fecal
	period in	Exclusion		Parents told to	movement		masses only at initial evaluation and if
	children with	<u>criteria:</u>		adjust the dose of	frequency	-12 months	no history of infrequent large bowel
	functional	Children <4		medication by 30		PEG: 6.8	movements. Dosage of 2.5 mL/kg
	constipation	years of age;		mL for MiraLax	-consistency of	MOM: 7.2	prescribed for those with fecal
	and	children who		and by 7.5 mL	stools		abdominal masses at the initial
	encopresis	refused the		(one-half		P<0.01 when	evaluation or history of huge, infrequent
		toilet for		tablespoon) for	-soiling	comparing values at	bowel movements.
		stooling but		MOM every 3	frequency	every assessment	
		who had no		days to a dosage		point to baseline for	Regular stool sittings for 5 minutes after
		constipation,		that resulted in 1	-abdominal pain	both treatments	each meal required for initial months
		Hirschsprung'		to 2 soft bowel	frequency		
		s disease,		movements/day		Soiling frequency	Patients and parents provided with diary
		chronic		and prevented	-medication	(mean, results are	sheets to record each outcome
		intestinal		soiling and	dosage	estimates taken form	measured
		pseudo-		abdominal pain.		bar chart as not	
		obstruction,		It child retained	-clinically	reported in text)	Doing well defined as 3 or more bowel

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
		or		stools despite	significant side		movements/week and 2 or fewer soiling
		previous		compliance with	effects	-baseline:	episodes / month. Improved defined as
		surgery of the		assigned laxative,		PEG: 12.0	3 or more bowel movements / week and
		colon or anus		daily senna added	-compliance	MOM: 8.5	more than 75% decrease in soiling but
				to treatment.	with medication		not more than 1 soiling / week. Not
						-1 month	doing well defined as fewer than 3 bowel
						PEG: 3.0	movements / week, less than 75%
						MOM: 0.5	decrease in soiling frequency, use of senna, or refusal to take the assigned
						-3 months	laxative. Recovered defined as 3 or
						PEG: 1.8	more bowel movements / week and 2 or
						MOM: 0.2	fewer soiling episodes / month while not taking laxatives.
						-6 months	5
						PEG: 1.0	No significant baseline differences
						MOM: 0.8	between 2 groups
						-12 months	Reviewer comments:
						PEG: 0.9	No sample size calculation performed
						MOM: 0.1	
							Outcomes for consistency of stools not
						P<0.01 when	reported
						comparing values at	
						every assessment	Not reporting on the clinically significant
						point to baseline for	side effects (or lack of them) for MOM
						both treatments	
						P<0.01 when	Source of funding:
						comparing values	Dr. Loening-Baucke recipient of grant
						between 2 groups at	support from Brainfree Pharmaceuticals,
						1 and 12 months	Braintree, MA, U.S.A., for continuing
						Childron with	studies on childhood constipation
						abdominal nain (%)	
						haseline	
						PFG: 61	
						MOM: 81	
						-1 month	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
						PEG: 14	
						MOM: 14	
						_	
						-3 months	
						PEG: 13	
						MOM: 5	
						-6 months	
						PEG: 8	
						MOM: 11	
						-12 months	
						PEG: A	
						$P_{<}0.01$ when	
						comparing values at	
						overy accessment	
						every assessment	
						point to baseline for	
						both treatments	
						Madiaation dagage	
						Medication dosage	
						(wean doses and	
						range for children	
						who were doing well	
						or improved) (PEG,	
						g/kg; MOM, mL/kg)	
						1 magneth	
						$0.6 \pm 0.2 (0.3 \text{ to } 1.1)$	
						MOM:	
						1.4 ± 0.6 (0.6 to 2.6)	
						3 months	
						PFG	
						$0.6 \pm 0.3 (0.3 \pm 0.1.4)$	
						MOM:	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
						1.2 ± 0.5 (0.6 to 2.4)	
						12 months	
						PEG:	
						$0.4 \pm 0.1(0.1 \text{ to } 0.7)$	
						MOM:	
						only 2 children still	
						required MOM. Their	
						dosages were 0.4	
						and 1.6 mL/kg, both	
						less than the initial	
						treatment dosage.	
						and a set of the set o	
						mean doses for both	
						treatments at 12	
						months	
						did not differ	
						significantly between	
						children with or	
						af the netionte	
						of the patients	
						decoge of either	
						dosage of either	
						medication over time	
						5 children received a	
						stimulant laxative in	
						addition to PEG and	
						1 child received a	
						stimulant laxative	
						in addition to MOM (P	
						> 0.2)	
						Clinically significant	
						side effects	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
						PEG: no significant	
						clinical side effects.	
						Some children had	
						diarrhea. None of the	
						children in the PEG	
						group became	
						dehydrated. Children	
						receiving PEG and	
						their parents did not	
						report increased	
						flatus, abdominal	
						distention, or new	
						onset of abdominal	
						pain	
						Compliance with	
						medication:	
						-PEG: No children	
						reported disliking the	
						taste, no parents	
						reported that child	
						refused to take it in	
						Juice or Kool-Aid	
						Derentel	
						noncompliance with	
						lavative and	
						toilot uso: 14%	
						childron	
						-MOM [.] 33% children	
						refused to take it	
						Parental	
						noncompliance with	

Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
	Level		S		Measures	administering the laxative and supervising toilet use: 4% children	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Loening-Baucke	Study Type:	79 children	79 children	General:	Duration of	Improvement rate (%)	Additional information from study:
et al. A	RCT		65 boys	disimpacted with	treatment:	-at 12 months:	Functional constipation defined by
randomized,		Inclusion	age range: 4 to	1 or 2 phosphate	12 months	PEG (n=34): 62	duration of \geq 8 weeks and \geq 2 of the
prospective,	Evidence	<u>criteria:</u> age ≥	16.2 years	enemas in the		MOM (n=21): 43	following: frequency of bowel
comparison	level:	4 years and	(median 7.4;	clinic on the day	Assessment		movements <3 stools/week, >1 episode
study of	1-	presence of	mean 8.1 ± 3.0)	of the visit, if	point (s):	NS	of faecal incontinence/week, large stools
polyethylene		functional		necessary and	1, 3, 6 and 12		noted in rectum or felt during abdominal
glycol 3350	Study aim: to	constipation	Country: USA	started laxative	months after	Recovery rate (%)	examination, passing of stools so large
without	compare the	with faecal		therapy that	initiating	-at 12 months:	that they obstructed the toilet
electrolytes and	efficacy,	incontinence		evening	treatment	PEG (n=34): 33	
milk of	safety and					MOM (n=21): 23	Randomisation performed by children
magnesia for	patient	Exclusion		Intervention:	Follow-up		drawing a sealed envelope with and
children with	acceptance of	<u>criteria:</u> stool		polyethylene	period:	NS	enclosed assignment
constipation	polyethylene	toileting		glycol (PEG) 3350	No follow-up		
and fecal	glycol (PEG)	refusal, faecal		without added	made after	Bowel movement	Investigators, children and their parents
incontinence.	3350 without	incontinence		electrolytes 0.7	treatment	frequency (mean ±	aware of the study group assignment
2006. Pediatrics	added	but no		g/kg body weight	finished	<u>SD,</u>	
118[2], 528-535	electrolytes	constipation,		daily for 12		episodes/week)	Estimated that 38 subjects required in
	vs. milk of	previous		months	Outcome	-Baseline:	each group to be able to detect a
	magnesia	refusal of one			Measures:	PEG (n=39): 3.5 ± 3.7	difference in failure rates between the 2
	(MOM) over	of study		capful of PEG (17		MOM (n=40): 3.5 ± 6	groups of 30% in 12 months (40% vs.
	12 months	medications,		g) mixed in 8 oz of	1. Primary		10%), at the .05 significance level with
		children who		beverage (juice,	outcomes:	-at 12 months:	.80 power. Authors hypothesized that
		came from far		Kool-Aid, Crystal		PEG (n=34): 6.8 ± 3.1	PEG would be as successful as MOM in
		away for a		Light or water)	-improvement	MOM (n=21): 8.2 ±	treating chronic constipation and faecal
		second		making a solution		3.9	incontinence. Authors' previous study
		opinion,		of ~2g/30 mL	-recovery		showed that 33% of children refused to
		Hirschsprung'				P<0.005 for both	take MOM during the first 12 months of
		s disease,		Comparison:	2. Secondary	groups compared to	treatment.
		chronic		milk of magnesia	outcomes:	baseline	
		intestinal		(MOM) 2mL/kg			Children treated with minimal effective
		pseudobstruct		body weight daily	-improvement in	Faecal Incontinence	dosage of PEG or MOM, allowing for a
		ion, previous		for 12 months	stool frequency	frequency (mean ±	daily stool and preventing abdominal
		surgery			per week	<u>SD,</u>	pain and faecal incontinence. Parents
		involving		plain MOM could		episodes/week)	instructed to aim for 1 or 2 stools of
		colon or anus		be mixed into	-improvement in	-Baseline:	milkshake consistency each day.
				apple sauce or	episodes of	PEG (n=39): 12.2 ±	Parents asked to increase dosage if
				milkshakes, or	taecal	13	stools too hard or not frequent enough

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
				chocolate and	incontinence	MOM (n=40): 13.5 ±	and to decrease the dosage if stools
				other flavouring	per week	15.5	watery or too numerous. Small changes,
				could be added			such as 2 oz of PEG or 0.5 tbsp of MOM
					-resolution of	-at 12 months:	every 3 days, were recommended.
				Large doses of	abdominal	PEG (n=34): 1.4 ± 3.5	Regular stool sittings for 5 minutes after
				both medications	pain	MOM (n=21): 0.5 ±	each meal required initially. Toilet sitting
				could be divided		1.6	frequency reduced after children
				into 2 doses	-safety profile		recognized urge to defecate and
						P<0.005 for both	initiated toilet use themselves.
					-patient's	groups compared to	
					acceptance and	baseline	No significant differences at baseline
					compliance		between the 2 groups regarding: age,
						Abdominal pain (%)	sex, primary faecal incontinence,
						-Baseline:	previous treatment with laxatives, history
						PEG (n=39): 71.8	of retentive posturing, frequency of
						MOM (n=40): 52.5	bowel movements, bowel movements
							obstructing the toilet, frequency of faecal
						-at 12 months:	incontinence, presence of abdominal
						PEG (n=34): 3	pain, presence of abdominal faecal
						MOM (n=21): 0	mass and presence of rectal faecal mass
						P<0.005 for both	
						groups compared to	By 12 months a total of 27 dropouts/lost
						baseline	to follow-up. PEG: 2 children lost to
							follow-up monitoring, 2 (5%) had refused
						At 12-month	PEG, 1 child allergic to PEG, 2 children
						frequency of bowel	were receiving senna. These 7 children
						movements,	counted as not improved and not
						frequency of	recovered. MOM: 2
						episodes of faecal	Children lost to follow-up monitoring, 3
						incontinence, and	children had discontinued study
						percentage of	participation, 14 children (35%) had
						children	refused to take MOM, and 1 child was
						with abdominal pain	receiving senna
						not significantly	
						different	Efficacy analyses performed with
						between PEG and	intention to treat population, other
						MOM group	outcomes calculated from available

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome Measures		
	Level		3		Measures		follow-up data
						Patient Acceptance Several children complained about taste of PEG and MOM. 2 children (5%)	Reviewer comments: Results not controlled for potential confounders High drop-out / lost to follow-up rate: 30.4%
						continued to refuse PEG vs. 14 children (35%) continued to refuse MOM during the 12 months of the study (P < .001	<u>Source of funding:</u> Braintree Laboratories (Braintree, MA) supported study with an unrestricted research grant. According to authors, the funding source had no involvement in the study
						<u>Treatment doses</u> (mean ± SD): -PEG (g/kg body weight)	interpretation of data, writing of the report or decision to submit the article for publication
						1 month: 0.7 ± 0.2 3 months: 0.6 ± 0.3 additional senna at some point: 3 children	
						-MOM (mL/kg body weight)	
						1 month: 1.2 ± 0.7 3 months: 1.2 ± 0.8 additional senna at some point: 1 child	
						mean doses similar in children who improved and who did not improve for both treatments	

Bibliographic Study Type & Information Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
					safety profiles PEG: 1 child allergic No other significant clinical effects for either medication, apart from transient diarrhoea disappearing with dose reduction -Laboratory tests: PEG: 1 child with elevated platelets before and after treatment, 1 child with decreased sodium levels at 6 months, but normal at 12 months MOM: 1 child high platelet count, 1 low serum sodium level, elevated AST, 1 elevated ALT	

Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Perkin.	Study Type:	21 children	21 children	Intervention:	Duration:	Number of patients	Additional information from study:
Constipation in	RCT			Senna syrup	1 week each	passing stools of any	Patients given either treatment
childhood: a	(crossover)	Inclusion	Country: UK	10 to 20 ml daily	period with 1	kind each day:	according to a code-list of random
controlled		criteria:	-	for 1 week	week no	Lactulose vs. Senna	numbers, placed in a series of sealed
comparison	Evidence	children aged			treatment in	N.S	envelopes, one of which was opened
between	level:	<15 years		Comparison:	between		each time a child entered the trial
lactulose and	1-	with a history		Lactulose		Number of patients	
standardized		of		10 to 15 ml daily	Assessment	passing normal stools	1 dropout: 1 patient on senna at the
senna. 1977.	Study aim:	constipation		for 1 weeks	point (s):	each day (mean)	beginning of study failed to attend at the
Current Medical	to compare	treated at			immediately		end of 1 st week
Research and	effectiveness	home for 3		Each preparation	after treatment	-Lactulose: 13.4	
Opinion 4[8],	and side	months or		given throughout	completed	-Senna: 8.43	No written or oral indication of any
540-543	effects	more		the appropriate		p <0.01	medical preference for other preparation
	between a			treatment week in	Follow-up		given and patients presented with single
	standardised	Exclusion		a daily dose	period:	Adverse effects (n	bottle of one or other of the preparations
	senna syrup	criteria:		varied according	No follow up	patients):	according to the coded instruction at
	and lactulose	any cause of		to the age of the	made after	a- senna week:	start of trial. On 3 ^{ra} week a bottle of
	in the	constipation		patient	treatment	12 (8 colic, 1	alternative preparation was given
	treatment of	requiring			finished	diarrhoea, 2 colic+	
	childhood	surgical or		1 intermediate		diarrhoea, 1 colic +	Outcomes recorded by parents in written
	constipation	medical		week with not	<u>Outcome</u>	distension)	diaries
		correction in		treatment	Measures:		
		addition to				b- no treatment week:	4-point scale of stool consistency: loose,
		laxation			-stool	4 (3 colic, 1 colic +	normal, hard, none
					consistency	distension)	
							Reviewer comments:
					-number of	c- lactulose week	No clear definition of constipation given
					stools passed	1 (colic)	Very small sample size, no sample size
					each day		calculation
						p<0.001 (a vs. c)	Inadequate method of allocation
					-adverse effects	NS (b vs. c)	concealment
							Patients' baseline characteristics not
							reported
							Study not reported as blinded
							Results not controlled for confounders
							Very short treatment period
							According to authors the number of
							stools passed each day was recorded,

Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
							but is not reported <u>Source of funding:</u> not stated

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Farahmand. A	Study Type:	247 children	247 children	General:	Duration of	Stool frequency	Additional information from study:
randomised trial	RCT			1 or 2 enemas	treatment:	<u>(mean +</u> SD)	Diagnosis of chronic functional
of liquid paraffin		Inclusion	127 male	daily for 2 days to	8 weeks	-before treatment (per	constipation based on having at least 2
versus lactulose	Evidence	criteria:		clear any rectal		week):	of the following symptoms for the last 3
in the treatment	level:	chronic	aged 2 to 12	impaction (30	Assessment	Liquid paraffin	months: less than 3 bowel
of chronic	1-	functional	years old (mean	cc/10 kg of	point (s):	(n=127)	movements/week, faecal soiling more
functional		constipation	4.1±2.1 years)	paraffin oil)	4 and 8 weeks	1.6 ± 1	than once/week, large amounts of stool
constipation in	Study aim:				after treatment	Lactulose (n=120)	every 7 to 30 days and palpable
children. 2007.	to compare	Exclusion	Country: Iran	Intervention:	started	1.8 ± 1.2	abdominal or faecal mass on physical
Acta Medica	the clinical,	criteria:		Liquid paraffin		p=0.155	examination
Iranica 45[3],	efficacy and	organic		orally, 1 to 2	Follow-up		
183-188Iran,	safety of liquid	causes for		ml/kg, twice daily	period:	-during first 4 weeks	Apart form laxative treatment, parents
Islamic	paraffin and	defecation		for 8 weeks	12 weeks after	(per week):	given instructions to increase their daily
Republic of.	lactulose in	disorders			treatment	Liquid paraffin	fibre intake to an amount of grams equal
	the treatment	including		Comparison:	finished	(n=127)	to their age plus 10. Toilet training after
	of functional	Hirschsprung'		Lactulose orally, 1		12.1 ± 3.2	each meal advised to enhance
	childhood	s' disease,		to 2 ml/kg, twice	<u>Outcome</u>	Lactulose (n=120)	compliance
	constipation	spina bifida		daily for 8 weeks	Measures:	9.2 ± 2.1	
		occulta,				p<0.001	Treatment success defined as 3 or more
		hypothyroidis			-stool frequency		bowel movements/week and encopresis
		m, cystic				-during last 4 weeks	episodes less than 2/week
		fibrosis,			-encopresis	(per week):	
		neurological		For determination	frequency	Liquid paraffin	No significant baseline differences
		abnormalities,		of best dose for		(n=127)	between the 2 treatment groups
		intestinal		child, parents	-success rate	13.1 ± 2.3	regarding: age, sex, duration of
		pseudo		asked to increase		Lactulose (n=120)	constipation, defection frequency,
		obstruction		the volume of	-optimal dose of	8.1 ± 3.1	number of patients with history of
				each drug by 25%	drug	p<0.001	encopresis, large amount of stool, faecal
				every 3 days as			impaction in rectum, rectal bleeding, lost
				required to yield 1	-side effects	Encopresis frequency	to follow-up after 8 weeks, bad
				or 2, firm-loose		<u>(mean ±</u> SD)	palatability of study medication
				stools		-Before treatment	
						(per week):	Reviewer comments:
						Liquid paraffin	Method of randomisation and allocation
						(n=127)	concealment not described
						10 ± 4.7	Non blinded study
						Lactulose (n=120)	No sample calculation performed
						9 ± 4.85	No withdrawals/dropouts reported

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
						p=0.1	Results not controlled for potential
							confounders
						-during first 4 weeks	
						(per week):	Source of funding:
						Liquid paraffin	not stated, but authors reported "no
						(n=127)	conflicts of interests"
						1 ± 4.3	
						Lactulose (n=120)	
						2 ± 4.6	
						p=0.07	
						-during last 4 weeks	
						(per week):	
						Liquid paraffin	
						(n=127)	
						0 ± 0	
						Lactulose (n=120)	
						3 ± 4.1	
						p<0.001	
						Success rate (%, CI	
						<u>95%)</u>	
						-during first 4 weeks:	
						Liquid paraffin	
						(n=127)	
						90	
						Lactulose (n=120)	
						52	
						p<0.001	
						-at end of 8 weeks:	
						Liquid paraffin	
						(n=127)	
						85	
						Lactulose (n=120)	
						29	
						p<0.001	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
						Optimal dose of drug	
						-Final effective dose	
						(mean, ml/kg/day):	
						Liquid paraffin	
						(n=127)	
						1.72 ± 0.13	
						Lactulose (n=120)	
						2.08 ± 0.21	
						p<0.001	
						Side effects (during 4	
						to 12 week) (not clear	
						whether, n or %, but	
						probably %)	
						estimates taken from	
						bar chart, outcomes	
						not reported in text):	
						Lactulose (n=120)	
						Abdominal pain: 10	
						Bad palatability: 15	
						Pain at defecation: 10	
						Bloating: 10	
						Diarrhoea: 10	
						Anal oil leakage: 20	
						Flatulence: 10	
						Nausea: 10	
						Hard stool: 20	
						Vomiting: 0	
						Liquid paraffin	
						(n=127)	
						Abdominal pain: 50	
						Bad palatability: 40	
						Pain at defecation: 50	
						Bloating: 20	
						Diarrhoea: 30	

Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
	Level		S		Measures	Anal oil leakage: 40 Flatulence: 20 Nausea: 5 Hard stool: 6 Vomiting: 0	

Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Urganci et al. A	Study Type:	40 patients	40 patients	Intervention:	Duration of	Stool consistency	Additional information from study:
comparative	RCT		22 male	Liquid paraffin	treatment:	<u>(mean ± SD)</u>	Diagnosis of constipation based on
study: the		Inclusion	mean age 3.7 ±		8 weeks		symptoms of ay least 3 months duration
efficacy of liquid	Evidence	criteria:	2.7 years	Comparison:		-first 4 weeks:	including at least 2 of the following: hard
paraffin and	level:	children 2 to		Lactulose	Assessment	Liquid paraffin (n=20):	stool, painful defecation, rectal bleeding,
lactulose in	1-	12 years old			point (s):	2.17 ± 0.5	encopresis and < 3 bowel
management of		referred for				Lactulose (n=20):	movements/week
chronic	Study aim:	evaluation of	Country:	Medication	4 and 8 weeks	1.71 ± 0.5	
functional	to determine	constipation	Turkey	administered	after initiation of	p<0.01	Open-label randomised study
constipation.	and compare	with evidence		orally as a	treatment		
2005. Pediatrics	efficacy,	of faecal		suspension at 1		-last 4 weeks:	Children also met with a nutritionist,
International	safety and	impaction		mL/kg, twice daily	Follow-up	Liquid paraffin (n=20):	were given instructions to increase daily
47[1], 15-19	optimal dose			for each drug	period:	2.29 ± 0.2	fibre intake to amount of gram equal to
	of liquid	Exclusion			No follow-up	Lactulose (n=20):	their age plus 10, parent asked to have
	paraffin and	criteria:		For determination	made after	2.21 ± 0.4	children sit on the toilet 4 times daily
	lactulose in	Hirschsprung'		of best dose for	treatment	N.S	after meals
	children with	s disease,		each child,	finished		
	chronic	hypothyroidis		parents asked to		Stool frequency	Stool frequency and stool consistency
	functional	m, mental		increase or	<u>Outcome</u>	<u>(mean ± SD) (per</u>	recorded by parents in daily diary forms.
	constipation	deficiency,		decrease the	Measures:	<u>week)</u>	Stool consistency scoring: 1, hard; 2,
		chronic		volume of each			firm; 3, loose
		debilitating		drug by 25%	-stool	-first 4 weeks:	
		diseases,		every 3 days as	consistency	Liquid paraffin (n=20):	No significant baseline differences
		neurological		required, to yield		13.3 ± 4.2	between 2 groups
		abnormalities,		2 firm-loose stools	-stool frequency	Lactulose (n=20):	
		previous		per day.		10.2 ± 4.4	Effective treatment defined as clearance
		surgery of		Maximum dose	-optimal dose of	p<0.05	of impaction: more than 3 bowel
		colon		used throughout	drugs		movements/week and improvement in
				the study: 3 mL/kg		-last 4 weeks:	stool consistency
				per day for each	-compliance	Liquid paraffin (n=20):	
				drug	rate	16.1 ± 2.2	Patients considered compliant if $\ge 80\%$
						Lactulose (n=20):	of prescribed dose taken correctly.
						12.3 ± 6.6	Patients instructed to take both empty
						p<0.05	and full containers to calculate amount
							of medication taken
						Optimal dose of drugs	
						<u>(mean ± SD)</u>	Reviewer comments:
						(mL/kg/day)	Randomisation method not described

Bibliographic Study Type & Nur	lumber of Patient	& Number of	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Level	S	Fatients	comparison	Measures		
Information Evidence Pa	Patients Characteristic S		Comparison	Measures	-data reported in table, assumed that for the whole study period: Liquid paraffin (n=20): 1.88 ± 0.27 Lactulose (n=20): 2.08 ± 0.27 N.S -data reported in text for the last 4 weeks of treatment: Liquid paraffin (n=20): 1.72 ± 0.18 Lactulose (n=20): 1.82 ± 0.57 Compliance rate (%) -first 4 weeks: Liquid paraffin (n=20): 95 Lactulose (n=20): 90 N.S -end of 8 weeks: Liquid paraffin (n=20): 90 Lactulose (n=20): 90 Lactulose (n=20): 90	No sample size calculation performed No clear definition of "evidence of faecal impaction" given Apparently no children dropped out the study/were lost to follow-up Study not controlled for potential confounders <u>Source of funding:</u> not stated
					p=0.02 Adverse effects:	

Bibliographic Information	Study Type & Evidence	Number of Patients	Patient Characteristic	Intervention & Comparison	Follow-up & Outcome	Effect Size	Reviewer Comments
	Level		S		Measures		
						No patient stopped	
						treatment because of	
						adverse effects	
						(adverse effects not	
						reported). During first	
						4 weeks, taste	
						aversion in 1 child on	
						liquid paraffin and	
						abdominal distension	
						in 2 patients on	
						lactulose influenced	
						compliance. During	
						last 4 weeks, poor	
						symptom control in 5	
						patients, side-effects	
						(abdominal distension	
						and cramping) in 3	
						on lactulose, and	
						watery stools in 2 on	
						liquid paraffin	
						influenced	
						compliance	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Sondheimer et	Study Type:	37 children	37 children	General:	Duration:	Daily bowel	Additional information from study:
al. Lubricant	RCT			5-day course of	Unclear,	movement (%	Diagnosis of chronic functional
versus laxative		Inclusion	26 male	oral bisacodyl	probably 6	<u>patients)</u>	constipation made on basis of historical
in the treatment	Evidence	<u>criteria:</u>		(most patients)	months		features and physical exam
of chronic	level:	patients	age range: 3 to	and daily enema		at 1 month: N.S	demonstrating dilated rectum, excessive
functional	1-	treated for	12 years	for 3-5 days in	Assessment		retained stool directly within anal verge
constipation of		chronic		addition (a	<u>point (s):</u>	at 3 months:	and in most cases, evidence of perianal
children: a	Study aim: to	functional	Country:	minority)	1, 3 and 6		soiling
comparative	compare the	constipation	USA		months after	-Mineral oil (n=18):	
study. 1982.	efficacy of	in specialist		Intervention:	initiating	100	Children assigned to 1 of 2 treatment
Journal of	mineral oil	clinic		Mineral oil orally	treatment	-Senokot (n=18): 72	groups according to the last digit of their
Pediatric	and			twice daily in		p<0.05	hospital number. All patients seen by
Gastroenterolog	standardised	Exclusion		doses sufficient to	Follow-up		same physician. Parents informed that 1
y and Nutrition	senna	<u>criteria:</u>		induce loose	period:	latest follow-up:	of 2 acceptable medications would be
1[2], 223-226	concentrate in	neurological		stools and	-Mineral oil		used to accomplish the discussed
	the treatment	impairment,		leakage of oil per	group, mean	-Mineral oil (n=18): 89	objectives
	of functional	faecal soiling		rectum. After 1rst	10.1 months	-Senokot (n=18): 50	
	constipation in	in the		week of		p<0.05	No significant baseline differences
	children	absence of		treatment, dose	-Senokot group,		between 2 groups regarding mean age,
		retained stool		reduced until	mean 10.5	Daily soiling (%	median age at onset of symptoms and
				leakage ceased.	months	<u>patients)</u>	percent of patients who had received
				This dose (range			prior treatment with constipation, sex
				1.5 to 5.0	Outcome	at 1 month:	ratio, faecal soiling, overt retentive
				cc/kg/day)	Measures:		behaviour, enuresis, "difficult" toilet
				maintained for		-Mineral oil (n=18): 11	training and primary failure of toilet
				minimum 3	-dally bowel	-Senokot (n=18): 39	training.
				months.	movements	p<0.05	
				0	de lle e e lle e	- (0	Patients allowed to discontinue
				Comparison:	-dally solling	at 3months:	medications after 3 months if symptom
				Senokot (tablet or			
				syrup), doses	-compliance		4 notions on minaral ail last a fallow un
					with medication	-Senokot (n=18): 50	after 2 month visit and not considered in
				howel movement		p<0.05	aner 3-month visit and not considered in
				doily during first 0		lataat fallow up:	ethor group
				ually during first 2		ialest ioliow-up.	
				trootmont This		Minoral ail (n-19): 6	During 1rst month nationts/parents kent
				doog maintained		$\frac{1}{2} = \frac{1}{2} = \frac{1}$	reporte of modioation, stool fraguency
				uose maintained		-Senokot (n=18): 44	records or medication, stool frequency

Bibliographic Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information Evidence	Patients	Characteristic	Comparison	Outcome		
		5	for 3 months. Tapering accomplished by changing from daily to every other day and then every 3 rd day medication	Weasures	p<0.05 <u>Compliance with</u> <u>medication (% reliably</u> <u>compliant)</u> -Mineral oil (n=19): 68 -Senokot (n=18): 78 <u>% successfully</u> <u>discontinued regular</u> <u>medication at latest</u> <u>follow-up:</u> -Mineral oil (n=18): 22 an additional 33% discontinued Senokot because of unacceptable symptom control 45% in each group remained on regular medication <u>Episodes of</u> <u>symptoms recurrence</u> <u>/treatment/ month</u> (Mean ± SD): -Mineral oil (n=18): 0.09 ± 0.08 -Senokot (n=18): 0.34 ± 0.36	and faecal soiling. From then on outcomes measured by telephone interviews and during consultations <u>Reviewer comments:</u> Study inadequately randomised. Allocation concealment not described Clinicians/researchers not blinded. Blinding procedures for parents/patients not clearly described No sample size calculation performed Results not controlled for potential confounders Definition of "reliably compliant" not given <u>Source of funding:</u> not stated

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Thomson et al.	Study Type:	51 children	51 children	Intervention:	Duration of	Number of complete	Additional information from study:
Polyethylene	RCT (cross		29 girls	PEG + E (6.9 g	treatment:	defecations per week	Chronic constipation defined according
glycol 3350 plus	over,	Inclusion	mean age 5.4	powder/sachet)	2 weeks each	(Mean (SD), range)	to Rome criteria as fewer than 3
electrolytes for	multicentre)	criteria:	years (range:		treatment	(data do not include	complete bowel movements/week, and
chronic		chronic	24 months to 11	Comparison:	period	washout period)	at least 1 of the following: pain on
constipation in	Evidence	constipation	years)	Placebo (6.9 g	separated by a		defecation on at least 25% of days; at
children: a	level:	for at least 3		powder/sachet)	2-week placebo	a. ITT population	least 25% of bowel movements with
double blind,	1+	months	Country: UK		washout		straining, and at least 25% of bowel
placebo			-			-PEG+E (n = 47):	movements with hard or lumpy stools
controlled,	Study aim: to	Exclusion		Washout period in	Assessment	3.12 (2.050)	
crossover	assess the	criteria:		between: 2 weeks	point (s):	0.00-8.87	Random sequence group computer
study.[erratum	efficacy and	current or			immediately		generated before start of recruitment
appears in Arch	safety of	previous		Dosing regime for	after each	-Placebo (n = 48)	using block size of 4 patients and study
Dis Child. 2008	polyethylene	faecal		both PEG + E and	treatment	1.45 (1.202)	medication labelled accordingly.
Jan;93(1):93].	glycol 3350	impaction		placebo (number	period,	0.00–3.73	Random blocks (with numbers stored in
2007. Archives	plus	decided by		sachets/day):	including		sealed code-break envelopes) sent to
of Disease in	electrolytes	either			washout	Treatment difference:	investigator sites as required. As
Childhood	(PEG + E) for	physical		-children aged 2		1.64	children enrolled, sites allocated
92[11], 996-	the treatment	examination		to 6 years	Follow-up		treatment supplies sequentially, started
1000	of chronic	or abdominal		days 1-2: 1	period:	p Value (95% CI)	with lowest possible number. Both the
	constipation in	X-ray,		days 3-4: 2 (taken	No follow-up	<0.001 (0.99 to 2.28)	children (and their parents/guardians)
	children	previous		together)	made after		and those administering treatment were
		intestinal		days 5-6: 3 (2	treatment	 b. PP population 	blinded to allocation schedule
		perforation/ob		morning, 1	completed		
		struction,		evening)		-PEG+E (n = 36):	A sample size of 50 children was
		paralytic		days 7-8: 4 (2	Outcome	3.63 (1.980)	planned to achieve 40 evaluable
		ileus,		morning, 2	Measures:	0.00-8.87	children, giving 90% power to detect a
		Hirschsprung'		evening)			true treatment difference of 0.3 bowel
		s disease,			1. Primary	-Placebo (n = 36):	movements/week using a two-tailed
		severe		-children aged 7	efficacy	1.63 (1.229)	significance test at the 5% level. As
		inflammatory		to 11 years	endpoint:	0.00–3.73	dropout rate was higher than originally
		conditions of		days 1-2: 2 (taken			estimated, recruitment target was
		the intestinal		together)	-number of	Treatment difference:	increased to 60 children
		tract, severe		days 3-4: 2 (taken	complete	1.96	
		gastroesopha		together)	defecations per		At baseline, clinically significant
		geal reflux,		days 5-6: 5 (2	week	<0.001 (1.19 to 2.72)	abnormalities
		diabetes,		morning, 3			on physical examination (mainly
		receiving		evening)	Secondary	(95% CI, 95%	associated with faecal loading but not

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
		doses of		days 7-8: 6 (3	efficacy	confidence interval;	impaction) recorded for 8 children (5/27
		stimulant		morning, 3	outcomes:	ITT, intention to treat;	in the PEG+E/placebo group, 3/24 in the
		laxatives		evening)		PP per protocol)	placebo/PEG+E group). Before
		considered by			-total number of		randomisation, 47 children taking other
		local		For both groups if	defecations	Secondary efficacy	laxatives (most frequently lactulose)
		observers to		diarrhoea, doses		outcomes, ITT	
		be at higher		was decreased by	-pain on	population (mean,	13/51 children (7/27 in the
		end of their		2 sachets or miss	defecation	<u>SD)</u>	PEG+E/placebo
		own doses		a day. If loose			group, 6/24 in the placebo/PEG+E
		spectrum		stools doses	-straining on	a. Total number of	group) recorded at least one deviation
				decreased by 1	defection	defaecations	from the study protocol (1 child recorded
				sachet			2 protocol deviations). Main reason for
					-stool	PEG+E (n = 47): 5.68	deviation was non-compliance with
					consistency	(2.771)	study medication (7/51 children),
						Placebo $*$ (n = 47):	followed by failure to supply sufficient
					-percentage of	4.10 (2.503)	bowel movement data (4/51 children),
					hard stools	Treatment difference:	and taking concomitant non-study
						1.58	laxative medication after randomisation
					-abdominal pain	p Value (95% CI)=	(3/51 children).
					on defecation	0.003 (0.55 to 2.60)	
							Reviewer comments:
					-taecal	b. Pain on	Blinding procedures not clearly
					incontinence	defaecation	described
						PEG+E (n = 47): 0.49	Unclear whether outcomes assessors
					3. Adverse	(0.727)	were also blinded to treatment allocation
					events	Placebo $(n = 47)$:	Study not controlled for potential
						0.77 (0.863)	contounders
						reatment difference:	Source of funding
							Source of funding.
						p value (95% CI):	Norgine Ltd. One of the authors was an
						0.041 (-0.52 to -	employee of Norgine Ltd at the time the
						0.01)	study was written. The others declared
						c Straining on	that they had nothing to declare
						defensation	
						$DEC_{\pm}E (n = 17) \cdot 0.72$	
						(0.780)	
						(0.709)	
						Placebo (n = 47):	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
						1.37 (1.041)	
						Treatment difference:	
						-0.65	
						p Value (95% CI):	
						0.001 (-0.97 to -	
						0.33)	
						d. Stool consistency	
						PEG+E (n = 47):	
						1.73 (0.497)	
						Placebo (n = 47):	
						2.21 (0.556)	
						Treatment difference:	
						-0.48	
						p Value (95% CI):	
						0.001 (–0.68 to –	
						0.27)	
						e. Percentage hard	
						stools	
						PEG+E (n = 47):	
						14.64 (26.041)	
						Placebo (n = 47):	
						38.19 (39.508)	
						Treatment difference:	
						-23.55	
						p Value (95% CI):	
						<0.001	
						f Abdeminel neis	
						T. Abdominal pain on	
						P = G + E (n = 47): 0.67	
						(U.789)	
						(n = 47):	
						U.19 (U.9U3)	
						11eauneni uillerence:	
						20.12 n) (alua (05% Ol)	
1			1		1	Ip value (95% CI)	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
						NS	
						g. Faecal	
						incontinence	
						PEG+E (n = 47): 4.70	
						(6.344)	
						Placebo (n = 47):	
						4.85 (7.863)	
						Treatment difference:	
						20.15	
						p Value (95% CI)	
						NS	
						Mean effective dose	
						of PEG 3350	
						<u>(g/kg/day):</u>	
						0.6 (2 to 6-year-old)	
						0.7 (7 to 11-year-old)	
						Adverse events:	
						PEG+E (31/49, 63%)	
						Placebo (28/49, 57%)	
						during periods I and	
						III. None serious,	
						most judged by	
						investigator to be	
						moderate or mild in	
						severity	
						20 children (41%) on	
						PEG+E: 41 events	
						22 children (45%) on	
						placebo: 45 events,	
						judged by investigator	
						to be at least possibly	
						related to the study	
						treatment. Most	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
						gastro-intestinal	
						disorders (particularly	
						abdominal pain),	
						PEG+E (39%, 39	
						events); placebo	
						(45%, 41 events). 1	
						child in	
						placebo/PEG+E	
						group withdrawn at	
						week 3 because of	
						abdominal pain,	
						assessed by	
						investigator as being	
						related to treatment,	
						this child was taking	
						placebo at the time of	
						withdrawal. New	
						clinically significant	
						abnormalities on	
						physical examination	
						(mainly associated	
						with faecal loading):	
						13 children (8/27 in	
						the PEG+E/placebo	
						group, 5/24 in the	
						placebo/	
						PEG+E group). When	
						analysed for what	
						these children were	
						taking for the 2 weeks	
						before the physical	
						examination, 23 out	
						of the 24 reports	
						(95.8%) occurred	
						when child taking	
						placebo. Only 1	
						report of an abnormal	
						abdominal	

Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic S	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
Information	Evidence Level	Patients	Characteristic S	Comparison	Outcome Measures	examination while patient on PEG+E Mean weight similar before and after treatment, no significant difference found between the 2 groups for change in weight while on treatment (p=0.357)	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Nurko et al.	Study Type:	103 children	103 children	General:	Duration of	Proportion of children	Additional information from study:
PEG3350 in the	RCT			Behavioural	treatment:	who responded to	Chronic constipation diagnosed when
treatment of	(multicentre)	Inclusion	69 boys	treatment:	3 weeks	treatment (%	for at least 3 months there was a history
childhood		criteria:		instructions to sit		children)	of <3 spontaneous bowel
constipation: a	Evidence	Children aged	mean age: 8.5 ±	on toilet for 10	Assessment	Group 1 (n=26): 77	movements/week and ≥ 1 associated
multicenter,	level:	4 to 16 years	3 years	minutes twice	point (s):		symptoms including: straining, hard
double-blinded,	1+	with chronic		after meals,	7 and 14 days	Group 2 (n=27): 74	stools sensation of incomplete
placebo-		constipation.	Country:	positive	after medication		evacuation, production of large bowel
controlled trial.	Study aim:	Patients	USA	reinforcement	started	Group 3 (n=26): 73	movements that may obstruct the toilet
2008. Journal of	To establish	taking other		using age-			or painful defecation
Pediatrics	the efficacy	laxatives only		appropriate	Follow-up	Placebo (n=24): 42	
153[2], 254-261	and best	included if		printed calendars	period:		Faecal impaction defined as presence of
Nurko et al.,	starting dose	they had <3		and special	N.A	P<0.04 each group	faecal hypogastric mass palpable on
2008	of	bowel		stickers for days		vs. placebo	abdominal examination and presence of
	polyethylene	movements/w		without episodes	Outcome	P=0.026 all	hard stool on rectal examination.
	glycol (PEG)	eek while		of faecal	Measures:	treatments groups vs.	diagnosis of faecal impaction made by 2
	3350 in the	taking the		incontinence and		placebo	independent observers, no
	short-term	laxative		others with bowel	Efficacy:	NS between	disagreement found in the assessment
	treatment of			movements		treatment groups	of any patient
	children with	Exclusion			-primary		
	functional	criteria:		Intervention	outcome:	Weekly number of	Sample size calculation performed
	constipation	Taking a		(Group 1):		bowel movements	
		stable dose of		Polyethylene	proportion of	<u>(BM)</u>	Patient randomly assigned in blinded
		PEG3350,		glycol (PEG) 3350	children who	Group 1 (n=26):	fashion in a 1:1:1:1 ratio within each
		evidence of		Miralax):	responded to	Before 1.7±0.9	participant site. Randomisation schedule
		faecal		0.2g/kg per day-	treatment		at each site constructed by using
		impaction,		single dose		Group 2 (n=27):	random blocks of 20 patients, which
		guiac-		Maximum: 8.5 g	-secondary	Before 1.5±1.0	provided balanced treatment
		positive stool,		per day	outcomes:		assignments in order to ensure the
		anorectal				Group 3 (n=26):	specified treatment ratio
		malformations		Comparison 1	weekly number	Before 1.5±0.5	
		,		<u>(Group 2):</u>	of bowel		Miralax and placebo provided as a
		Hirschsprung'		Polyethylene	movements	Placebo (n=24):	powder containing flavouring in
		s disease,		glycol (PEG) 3350		Before 1.6±0.7	identically labelled bottles reconstituted
		myelomening		Miralax):	weekly number		with water to 4000 mL by study
		ocele,		0.4g/kg per day-	of faecal	Overall difference	personnel in the pharmacy. Dosing
		hypothyroidis		single dose	incontinence	between treatment	calculated by pharmacy staff and water
		m or other		Maximum: 17 g	episodes	groups and placebo	added. All dose calculated to be given

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
		organic		per day		p=0.017	on a 10-mL/kg basis by pharmacy staff.
		causes of			changes in	P=0.015 dose-	The blinded research team received the
		constipation		Comparison 2	stool	response trend	reconstituted identical jugs, which were
				<u>(Group 3):</u>	consistency		distributed to patient's
				Polyethylene		Weekly number of	parents/caregivers. No difference in
				glycol (PEG) 3350	straining	faecal incontinence	colour, appearance r taste amongst
				Miralax):		episodes mean ± SD)	different doses. Patients took single
				0.8g/kg per day-	proportion of		dose per day. No adjustment of study
				single dose	children who	Group 1 (n=26):	medication allowed during study. No
				Maximum: 34 g	responded to	Before 3.8±4.8	other laxatives allowed during study
				per day	treatment in the	After 3.0±4.6	
					second week		Families completed daily diary that
				Comparison 3:		Group 2 (n=27):	included number and characteristics of
				Placebo	Safety:	Before 3.5±4.9	bowel movements an documentation of
						After 1.8±2.6	episodes of faecal incontinence
					-incidence and		
					severity of	Group 3 (n=26):	Response to treatment defined as ≥3
					adverse effects	Before 7.2±18.7	bowel movements during the second
						After 3.5±7.8	week of treatment. Patients considered
							failures and withdrawn from study if they
						Placebo (n=24):	had no bowel movements (BIVI) for 7
						Before 2.4±3.8	days or developed faecal impaction at
						After 1.4±3.7	any point.
						NS amongst different	No significant differences in baseline
						arouns	characteristics between the 4 groups
						groups	characteristics between the 4 groups
						Changes in stool	14 patients did not complete the 2-week
						consistency (mean +	treatment:
						SD)	-8 because of treatment failure (5 with
							impaction (2 Group 1, 3 Group 2), and
						Group 1 (n=26):	3 with > 7 days without a BM) (2 Group
						Before 2.8±0.8	1, 1 Group 3)]
						After 2.1±0.7	- 3 because of adverse events (1
							increased abdominal pain (placebo), 1
						Group 2 (n=27):	fever, malaise, headache (placebo), 1
						Before 2.6±0.9	exacerbation bipolar (placebo))
						After 1.7±0.6	- 1 withdrawal (lack of response

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Level	Patients	Characteristic	Comparison	Outcome Measures		
Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect SizeGroup 3 (n=26):Before 2.9 ± 0.7 After 1.5 ± 0.7 Placebo (n=24):Before 3.0 ± 0.8 After 2.4 ± 0.9 P<0.003 each groupvs. placeboP<0.003 overalldifference betweentreatment groupsStraining scores(mean \pm SD)Group 1 (n=26):Before 2.3 ± 1.1 After 1.0 ± 1.0 Group 2 (n=27):Before 2.0 ± 1.0 After 1.0 ± 1.0 Group 3 (n=26):Before 2.0 ± 1.0 After 0.9 ± 0.6 Placebo (n=24):Before 2.7 ± 1.2 After 1.5 ± 1.2	Reviewer Comments (placebo)) 2 non compliance (1 Group 2, 1 Group 3) - 3 serious adverse events occurred requiring hospitalisation (2 cases impaction, 1 case of exacerbation of bipolar/depression) IIT analysis performed There were no significant predictors of success by controlling for age, duration of constipation, prior laxative use, presence of stool in rectum, sex and presence of faecal incontinence at baseline Source of funding: Supported in part by Braintree Laboratories Inc.
						P<0.003 each group vs. placebo P<0.003 test for trond	
						P<0.003 overall	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Level	Patients	Characteristic	Comparison	Measures		
			-			difference between	
						treatment groups	
						Droportion of childrop	
						who responded to	
						treatment in the	
						second week	
						Group 1 (n=26): 58%	
						(with ho faecal	
						Group 2 (n=27): 48%	
						(with no faecal	
						Incontinence 26%)	
						Group 3 (n=26): 62%	
						(with no faecal	
						incontinence 31%)	
						Placebo (n=24): 29%	
						(with no faecal	
						incontinence 8%)	
						$P_{<0.27}$ aroup 3 vs	
						placebo	
						Incidence and	
						severity of adverse	
						Group 1 (n=26): 9	
						(34.6%)	
						Group 2 (n=27): 16 (59.3%)	
						(00.070)	
						Group 3 (n=26): 17	
						(65.4%)	
					1		

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
						Placebo (n=24): 14	
						(58.3%)	
						NS difference	
						amongst groups	
						No differences in the	
						type of non-	
						gastrointestinal	
						related events, most	
						common was	
						headache. Higher	
						incidence of GI-	
						related events in	
						patients receiving	
						PEG vs. placebo. As	
						dose of PEG	
						increased, it also	
						increased incidence	
						of flatulence,	
						abdominal pain,	
						nausea and	
						diarrhoea.	
						No electrolyte	
						abnormalities or	
						differences in	
						laboratory values	
						amongst groups	
						Ireatment Failures	
						Group 1 (n=26): 6 (4	
						BM frequency criteria,	
						2 with stool	
						impaction)	
						Group 2 (n=27): 7(3	
						BM frequency criteria,	
						4 with stool	

Bibliographic Information	Study Type & Evidence	Number of Patients	Patient Characteristic	Intervention & Comparison	Follow-up & Outcome	Effect Size	Reviewer Comments
	Level		S		Measures	impaction)	
						Group 3 (n=26): 7 (6 BM frequency criteria	
						1 with stool	
						impaction)	
						Placebo (n=24): 14	
						(all related to BM	
						inequency enterior	
Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
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Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Wald et al.	Study Type:	50 children	50 children	Intervention:	Duration of	Children in remission	Additional information from study:
Evaluation of	RCT			Biofeedback , one	treatment:	or markedly improved	At baseline 2 groups comparable
biofeedback in		Inclusion	40 boys	25 to 30-minute	12 weeks	(%)	respect to age, sex, duration and
childhood	Evidence	criteria:	Age range 6 to	session		(results are estimates	severity of soiling, anorectal motility
encopresis.	level:	encopresis of	15 years (mean		Assessment	taken from a bar chart	parameters and expulsion patterns
1987. Journal of	1-	at least 6	8.4)	Children with	point (s):	as exact figures not	
Pediatric		months of		abnormal	Immediately	reported in text)	Single blinded design
Gastroenterolog	Study aim:	duration	Country: USA	expulsion pattern	after treatment		
y and Nutrition	to evaluate			taught a	completed	-3 months:	Initial and follow-up office visits at 2, 4
6[4], 554-558	the efficacy of	Exclusion		technique to		biofeedback (n=24):	and 8 weeks similar in duration for both
	biofeedback	criteria:		normalise their	Follow-up	54	groups. All outcomes recorded by
	for childhood	not stated		patterns and they	period:		parents in written calendar. Follow-up
	encopresis			and children with	6 and 12	mineral oil (n=26): 54	interviews by telephone performed at 3,
				normal expulsion	months after		6 and 12 months by investigator
				pattern told to use	treatment	-6 months:	unaware of treatment or results of
				the technique	finished	biofeedback (n=24):	anorectal studies
				whenever they		50	
				attempted to	<u>Outcome</u>		Based on outcomes, children placed in
				defecate	Measures:	mineral oil (n=26): 62	groups at each assessment: 1-some
					-frequency of		improvement, 2-some improvement, but
				Reinforcement	defecation	-12 months:	major soiling (<1/week), 3-marked
				sessions at 2, 4		biofeedback (n=24):	improvement (rare major soiling
				and 8 weeks	-frequency of	50	<1/week or minor soiling) 4-complete
					gross		remission
				Comparison:	incontinence	mineral oil (n=26): 59	
				Mineral oil orally			2 dropouts at 3 months (1 from each
				in graded	-frequency of	NS for any treatment	group), 3 additional dropouts at 6
				amounts (range 1	staining or	period	months (2 biofeedback) and 5 lost to
				to 4	minor soiling		follow-up at 12 months (3 biofeedback).
				tablespoons/day),		No significant	All dropouts designated as treatment
				designed to	-parental	differences in	failures for each subsequent
				induce a soft	perception of	outcomes for children	assessment point
				bowel movement	clinical status	with abnormal	
				daily	and overall	expulsion pattern vs.	Reviewer comments:
					satisfaction	children with normal	No clear definition of encopresis given
						expulsion patterns	Method of randomisation and allocation
							concealment not described
							No sample size calculation. ITT analysis

Bibliographic S Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
							apparently performed Unclear how the 4 outcomes groups were defined from the clinical variables <u>Source of funding:</u> not stated

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Berg et al. A	Study Type:	44 children	40 children	General:	Duration of	Severity of soiling:	Additional information from study:
controlled trial	Quasi RCT			Behavioural	treatment:		Children randomly allocated to 1 of 3
of 'Senokot' in		Inclusion	mean age: 7.9	treatment,	3 months	-At 3 months:	treatment groups, A, B and virtually in a
faecal soiling	Evidence	criteria:	years (S.D. =	focusing on use of		Senokot (n=14)	random fashion
treated by	level:	children who	2.3)	the toilet and	Assessment	Placebo (n=11)	
behavioural	1-	had soiling as		freedom from	point (s):	No tablets (n=15)	No significant baseline differences
methods. 1983.		a main	gender not	soiling	3 months after		between the 3 groups
Journal of Child	Study aim:	complaint	reported		starting	NS between the 3	
Psychology and	to see	and		Intervention:	treatment	groups (outcomes	Psychiatrist and psychologists did not
Psychiatry and	whether	uncomplicate	Country: UK	Senokot		not reported by	know which tablets actually contained
Allied	behaviour	d functional			Follow-up	group)	the laxative. Tablets made up in packs
Disciplines	therapy would	faecal		Comparison 1:	period:		labelled A and B.
24[4], 543-549	suffice on its	incontinence		placebo tablets in	6 months to 1	Number of soiling-	
	own in the	after an initial		similar dosage to	year after first	free children	Methods used in behavioural treatment:
	treatment of	assessment		Senokot	entering trial		identifying targets, discussing use of
	severe and	and physical			(but after 3	-Relieved (less than	rewards, star charting, reinforcement of
	persistent	examination		Comparison 2:	months the	once/week or not at	using the toilet appropriately and staying
	faecal soiling			No medication	study was a	all)	clean, mainly by Mothers advised to
	or would be	Exclusion			case series for		avoid castigating children. Initially,
	improved by	criteria:		Children started	Senokot only,	Senokot (n=14): 5	children taken to toilet 3 times a day,
	employing a	not clearly		on 1 tablet at	therefore not	(35%)	then prompted to go unaccompanied,
	laxative	stated		night. On the next	reported here)	Placebo (n=11): 2	then expected to go on own initiative
	as well			visit to the clinic, if		(18%)	
				no improvement	<u>Outcome</u>	No treatment (n=15):	4 children dropped out after only 1 or 2
				in 'use of the	Measures:	9 (60%)	visits
				toilet' and 'being			
				clean' on the	-severity of	-Not relieved	Severity of soiling rating: 0 = none, 1 =
				charts dosage	soiling		less than once a week, 2 = at least once
				increased to 2		Senokot (n=14): 9	a week but less than daily, 3 = daily
				tablets. Number of	-number of	Placebo (n=11): 9	
				tablets increased	soiling-free	No treatment (n=15):	Reviewer comments:
				to 3 on following	children	6	No definitions of soiling/functional faecal
				visit if			incontinence given
				improvement had		NS between the 3	Inadequate randomisation
				still not occurred.		groups	Allocation concealment not described
				When soiling			Soiling frequently apparently assessed
				getting better and			by interviewing parent at time of
				child using toilet			consultation

Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
				dosage kept the same. Once child going regularly to toilet and not soiling tablets stopped altogether			No sample size calculation performed Not clear whether the 4 children who dropped out had already received any study medication There is a mistake in the paper regarding outcomes for the "no tablets" groups, therefore not reported here Results not controlled for potential confounders <u>Source of funding:</u> Messrs Reckitt and Coleman provided the medication and gave their support in carrying out this trial

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Bu et al.	Study Type:	45 children	45 children	Intervention:	Duration of	Defecation frequency	Additional information from study:
Lactobacillus	RCT		23 male	MgO 50 mg/kg	treatment:	(times/day)	Chronic constipation defined as a stool
casei		Inclusion		per day, twice a	4 weeks	-MgO (n=18)	frequency of <3 times/week for >2
rhamnosus	Evidence	<u>criteria:</u>		day		0.55 ± 0.13	months and at least 1 of the following
Lcr35 in	level:	children	Age (months,		Assessment		minor criteria: anal fissures with
children with	1+	under 10	mean, SD)	Comparison 1:	point (s):	-probiotic (n=18)	bleeding due to constipation, faecal
chronic		years old with		Lcr35 8 X 10^8	Immediately	0.57 ± 0.17	soiling or passage of large and hard
constipation.	Study aim:	chronic	MgO group	c.f.u/day	after treatment		stool
2007. Pediatrics	to investigate	constipation		(Antiobiophilus	completed	-placebo (n=9)	
International	the effect of		Probiotic group	250 mg, 2		0.37 ± 0.10	Children randomly assigned into the 3
49[4], 485-490	Probiotics	Exclusion		capsules, twice a	Follow-up		groups according to a computer -
	(Lactobacillus	<u>criteria:</u>	Placebo group	day)	period:	MgO vs. probiotic NS	generated randomisation list
	case	organic			No follow up	Placebo vs. probiotic	
	rhamnosus,	causes of		Comparison 2:	made after	P=0.006	Blinding achieved by the use of 3
	Lcr35) alone	constipation	Country:	Placebo (starch in	treatment	MgO vs. placebo	interventions with similar appearances
	in the	like	Taiwan	content)	finished	p=0.01	and placed into identical capsules,
	treatment of	Hirschsprung'					which were either swallowed o as a
	chronic	s disease,			Outcome	Hard stool (%)	whole or opened and the contents of the
	constipation in	spina bifida			Measures:	-MgO (n=18)	capsule administered in milk or fluid
	children and	(occulta),				23.5 ± 7.9	
	to compare	hypothyroidis		Lactulose use	-frequency of		Throughout the duration of study all
	the effect with	m, or other		(1mL/kg/day)	defecation	-probiotic (n=18)	investigators, participants and data
	magnesium	metabolic/ren		allowed when no		22.4 ± 14.7	analysts were blinded to the assigned
	oxide (MgO)	al		stool passage	-consistency of		treatment
	and placebo,	abnormalities,		noted for 3 days.	stools	-placebo (n=9)	
	respectively	drugs		Glycerin enema		75.5 ± 6.1	Sample size determined by doing
		influencing		used only when	-episodes of		primary trial with 9 patients using non-
		gastrointestin		no defecation for	soiling	MgO vs. probiotic NS	inferiority to test. Equivalent margin
		al function		>5days or		Placebo vs. probiotic	chosen with reference to effect of active
		other than		abdominal pain	-episodes of	p=0.02	control in the data of preliminary trial.
		laxatives		suffered due to	abdominal pain	MgO vs. placebo	Unbalance design of allocation number
		(calcium		stool impaction		p=0.03	used for more interest in the new drug
		cnannel			-use of		(Lcr35): allocation rate set at 2:2:1. One
		DIOCKERS,			lactulose or	Abdominal pain	sided significance level set at 0.05 and
		antidysrythmi			enema	(times)	power was 80%. Under these
		c agents,					assumptions the smallest sample size
		anticonvulsiva				4.8 ± 3.7	was 45 and the sample size of MgO,
		nts,		l		1	Lcr35 and placebo was 18, 18 and 9

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures	nachistic (n. 40)	koon ooti yohy
		antidepressan					respectively
		anticholinerai				1.9 ± 1.0	No significant differences at baseline
		c agents)				-placebo (n=9)	amongst the 3 group regarding, sex age
		o ugonio)				6.7 ± 3.3	of enrolment, age of onset of
						MgO vs. probiotic	constipation, duration of constipation,
						p=0.04	previous treatment, defecation period,
						Placebo vs. probiotic	stool consistency, abdominal pain,
						p=0.01	faecal soiling, bleeding during
						MgO vs. placebo NS	defecation, use of enema, taking fruit or vegetable daily
						Use of glycerine	
						enema (times)	Patients asked to discontinue any
						-MgO (n=18)	laxatives previously prescribed 3 days
						1.3 ± 1.9	before entering protocol, and also asked
						probiotic (p. 10)	to avoid any other problotics, yogurt or
						-probiolic (n=10)	least 2 weeks before treatment and
						1.0 ± 1.5	during therapy
						-placebo (n=9)	
						4.0 ± 2.1	All outcomes measures recorded by
						MaQ va probiotio NC	parents in a stool diary
						Placebo vs. probiotic NS	A patients discontinued medication
						n=0.04	during study period: 2 in MaO 1 in
						MaO vs. placebo	probiotic, 1 in placebo group (2 patients
						p=0.03	suffered from acute gastroenteritis and
							2 patients lost to follow-up)
						No significant	
						differences regarding	Reviewer comments:
						use of lactulose,	Allocation concealment not described
						taecal soiling and	Not clear whether the 2 patients who
						change of appetite	suffered from acute gastroenteritis had it
						amongst 5 groups	Study not controlled for potential
						Patients with	confounders
						treatment success	
						(%)	Source of funding: not stated

Bibliographic Information	Study Type & Evidence	Number of Patients	Patient Characteristic	Intervention & Comparison	Follow-up & Outcome	Effect Size	Reviewer Comments
Information	Evidence Level	Patients	Characteristic S	Comparison	Outcome Measures	-MgO (n=18): 72.2 -probiotic (n=18): 77.8 -placebo (n=9): 11.1 MgO vs. probiotic NS Placebo vs. probiotic p=0.01 MgO vs. placebo p=0.01 no adverse effects noted in probiotic and placebo groups, only 1 patient in the MgO group suffered from mild diarrhoea	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Thomson et al.	Study Type:	51 children	51 children	Intervention:	Duration of	Mean effective dose	Additional information from study:
Polyethylene	RCT (cross		29 girls	PEG + E (6.9 g	treatment:	of PEG 3350	Chronic constipation defined according
glycol 3350 plus	over,	Inclusion	mean age 5.4	powder/sachet)	2 weeks each	<u>(g/kg/day):</u>	to Rome criteria as < 3 complete bowel
electrolytes for	multicentre)	<u>criteria:</u>	years (range:		treatment	0.6 (2 to 6-year-old)	movements/week, and at least 1 of the
chronic		chronic	24 months to 11	Comparison:	period	0.7 (7 to 11-year-old)	following: pain on defecation on at least
constipation in	<u>Evidence</u>	constipation	years)	Placebo (6.9 g	separated by a		25% of days; at least 25% of bowel
children: a	level:	for at least 3		powder/sachet)	2-week placebo	Adverse events:	movements with straining, and at least
double blind,	1+	months	<u>Country:</u> UK		washout		25% of bowel movements with hard or
placebo						PEG+E (31/49, 63%)	lumpy stools
controlled,	Study aim:	Exclusion		Washout period in	Assessment	Placebo (28/49, 57%)	
crossover	to assess the	<u>criteria:</u>		between: 2 weeks	<u>point (s):</u>	during periods I and	Random sequence group computer
study.[erratum	efficacy and	current or			immediately	III. None serious,	generated before start of recruitment
appears in Arch	safety of	previous		Dosing regime for	after each	most judged by	using block size of 4 patients and study
Dis Child. 2008	polyethylene	faecal		both PEG + E and	treatment	investigator to be	medication labelled accordingly.
Jan;93(1):93].	glycol 3350	impaction		placebo (number	period,	moderate or mild in	Random blocks (with numbers stored in
2007. Archives	plus	decided by		sachets/day):	including	severity	sealed code-break envelopes) sent to
of Disease in	electrolytes	either			washout		investigator sites as required. As
Childhood	(PEG + E) for	physical		-children aged 2		20 children (41%) on	children enrolled, sites allocated
92[11], 996-	the treatment	examination		to 6 years	Outcome	PEG+E: 41 events	treatment supplies sequentially, started
1000	of chronic	or abdominal		days 1-2: 1	Measures:	22 children (45%) on	with lowest possible number. Both the
	constipation in	X-ray,		days 3-4: 2 (taken		placebo: 45 events,	children (and their parents/guardians)
	children	previous		together)	Adverse events	judged by investigator	and those administering treatment were
		intestinal		days 5-6: 3 (2		to be at least possibly	blinded to allocation schedule
		perforation/ob		morning, 1		related to the study	
		struction,		evening)		treatment. Most	A sample size of 50 children was
		paralytic ileus,		days 7-8: 4 (2		gastro-intestinal	planned to achieve 40 evaluable
		Hirschsprung'		morning, 2		disorders (particularly	children, giving 90% power to detect a
		s disease,		evening)		abdominal pain),	true treatment difference of 0.3 bowel
		severe				PEG+E (39%, 39	movements/week using a two-tailed
		inflammatory		-children aged 7		events); placebo	significance test at the 5% level. As
		conditions of		to 11 years		(45%, 41 events). 1	dropout rate was higher than originally
		the intestinal		days 1-2: 2 (taken		child in	estimated, recruitment target was
		tract, severe		together)		placebo/PEG+E	increased to 60 children
		gastroesopha		days 3-4: 2 (taken		group withdrawn at	
		geal reflux,		together)		week 3 because of	At baseline, clinically significant
		diabetes,		days 5-6: 5 (2		abdominal pain,	abnormalities

Adverse Effects of medium- to long-term use of Laxatives in Children with Chronic Idiopathic Constipation

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
		receiving		morning, 3		assessed by	on physical examination (mainly
		doses of		evening)		investigator as being	associated with faecal loading but not
		stimulant		days 7-8: 6 (3		related to treatment,	impaction) recorded for 8 children (5/27
		laxatives		morning, 3		this child was taking	in the PEG+E/placebo group, 3/24 in the
		considered by		evening)		placebo at the time of	placebo/PEG+E group). Before
		local				withdrawal. New	randomisation, 47 children taking other
		observers to		For both groups if		clinically significant	laxatives (most frequently lactulose)
		be at higher		diarrhoea, dose		abnormalities on	
		end of their		was decreased by		physical examination	13/51 children (7/27 in the
		own doses		2 sachets or miss		(mainly associated	PEG+E/placebo group, 6/24 in the
		spectrum		a day. If loose		with faecal loading):	placebo/PEG+E group) recorded at least
				stools dose		13 children (8/27 in	1 deviation from the study protocol (1
				decreased by 1		the PEG+E/placebo	child recorded 2 protocol deviations).
				sachet		group, 5/24 in the	Main reason for deviation was non-
						placebo/	compliance with study medication (7/51
						PEG+E group). When	children), followed by failure to supply
						analysed for what	sufficient bowel movement data (4/51
						these children were	children), and taking concomitant non-
						taking for the 2 weeks	study laxative medication after
						before the physical	randomisation (3/51 children)
						examination, 23 out	
						of the 24 reports	Safety monitored by adverse events
						(95.8%) occurred	recording, physical examination findings,
						when child taking	and weight changes
						placebo. Only 1	
						report of an abnormal	Reviewer comments:
						abdominal	Blinding procedures not clearly
						examination while	described
						patient on PEG+E	Unclear whether outcomes assessors
							were also blinded to treatment allocation
						Mean weight similar	Study not controlled for potential
						before and after	contounders
						liealment, no	Source of funding:
						significant difference	Source of funding:
						around between the 2	amployee of Norgine Ltd. At the time the
						groups for change in	study was written. The others declared
						trootmont (n=0.257)	that they had nothing to declare
						groups for change in weight while on treatment (p=0.357)	employee of Norgine Ltd. At the time the study was written. The others declared that they had nothing to declare

Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Dupont et al.	Study Type:	96 children	96 children	Intervention:	Duration of	Clinical tolerance	Additional information from study:
Double-blind	RCT		51 male	PEG 4000	treatment:	(ITT population)	Constipation defined as <1 stool/day for
randomized		Inclusion			3 months	-6 adverse effects (all	>1 month in children 6 to 12 months old
evaluation of	Evidence	criteria:	Age (months)	-Starting dose:		non serious):	and <3 stools/week for > 3 months in
clinical and	level:	ambulatory	(median, (25th-	1 sachet (4g) and	Assessment	5 diarrhoea (5	children aged 13 months to 3 years
biological	1+	children with	75th	1 placebo to be	point (s):	episodes in 2 children	
tolerance of		constipation	percentiles)	taken at breakfast	Day 42 (D42)	in both treatment	PEG 4000 and lactulose packaged in a
polyethylene	Study aim:	despite their			and day 84	groups)	double-blind and double-dummy design,
glycol 4000	to assess the	usual dietary	-PEG 4000:	Comparison:	(D84) after	1 anorexia (on	by means of coupled sachets, according
versus lactulose	safety of a	treatment for	28 (19.5–33.7)	Lactulose	starting	lactulose)	to a randomisation list. Double dummy
in constipated	polyethylene	at least 1			treatment		design required because of the
children. 2005.	glycol (PEG)	month, aged	-Lactulose:	-Starting dose:		-median (interquartile	difference of taste between the drugs.
Journal of	4000 laxative	6 months to 3	25.8 (12.3–33)	1 sachet (3.33g)	<u>Outcome</u>	range) duration of	Numbered boxes provided to
Pediatric	without	years		and 1 placebo to	Measures:	either new onset or	investigators at each site in equal
Gastroenterolog	additional		Country: France	be taken at		worsened flatulence	numbers. Investigators randomly
y and Nutrition	salts in	Exclusion		breakfast	-Biological	(days):	allocated either PEG 4000 or lactulose
41[5], 625-633	paediatric	criteria:			tolerance:		to the children for a 3-month period, with
	patients	history of				PEG 4000: 3 (1 to	the same strategy for dose adaptation
		intractable		For both drugs,	ion	4.5)	
		faecaloma,		dose could be	electrolytes	Lactulose: 5 (3 to	3 children not included because of a
		Hirschsprung'		doubled if	total protein	19.5)	baseline laboratory value ONR (out of
		s disease,		ineffective in	albumin	P=0.005	normal range) before the amendment
		neurologic,		children aged 13	vitamin A		was applied. 2 children in PEG 4000
		endocrine or		months to 3 years	vitamin D	-median (interquartile	group dropped out before any study
		metabolic		If maximum	folates	range) duration of	drug intake, so the intention to treat
		disorders,		authorised dose		either new onset or	(ITT) population included 51 children (10
		allergic		unsuccessful, one	-Clinical	worsened vomiting	babies and 41 toddlers) in the PEG
		disease or		micro-enema of	tolerance:	episodes (days):	4000 group and 45 (12 babies and 33
		allergies		glycerol per day			toddlers) in the lactulose group. 76 of
				could be	body height	PEG 4000: 1 (1 to 2)	these children included in the per
				prescribed for a	body weight	Lactulose: 2 (1 to 6)	protocol analysis and 20 excluded by
				maximum of 3	adverse effects	P<0.05	the independent scientific committee for
				consecutive days.			at least 1 major deviation, 11 in the PEG
				If child not		-anal irritation: 5% (2	4000 group and 9 in the lactulose group.
				produced stools		out of 40 children,	Reasons for exclusion were no
				atter treatment 2		both on lactulose)	laboratory test at D84, 1 or more one
				enemas could be			missing laboratory results at D84,
				administered at a		-no difference	delayed laboratory test at D84 (n = 12),

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
				48-h interval. This		between PEG 4000	inadequately long exposure to the study
				procedure was		and lactulose groups	drug (n = 2), personal reasons (n = 5)
				only allowed twice		with regards to other	and unauthorized concomitant treatment
				during the study,		digestive tolerance	(n = 1). There were no clinically relevant
				If child produced		outcomes	differences between the 2 treatment
				liquid stools for			groups at baseline for clinical or biologic
				more than 1 day		-Body height and	parameters.
				or more than 2 or		body weight	Stool frequency, abdominal pain,
				3 stools/day		unaffected during the	vomiting, and nausea recorded by
				depending on		3-month treatment for	parents on Self-Diary Evaluation Booklet
				age, dose could		both boys and girls	
				be decreased by		Biological tolerance	Reviewer comments:
				1 pair of		(III population):	Methods of randomisation and allocation
				sachets/day to a			Concealment not cleany described
				of apphoto overv		treatment groups for	No sample calculation performed
				of Sachels every		the % of children with	
				possibly to		ONP values on D84	comounders
				transitory		compared to baseline	Source of funding: not stated
				interruntion		status No treatment-	Bource of funding. Not stated
				Interruption		related changes	
						found in serum iron	
						electrolytes.	
						total protein, albumin	
						and vitamins A. D and	
						folates	
						Dose used	
						(sachets/day)	
						(median (interquartile	
						range))	
						-Babies:	
						1 (0.9 to 1) PEG	
						1 (1 to 1.3) lactulose	
						P = 0.67	
						T a shall a wa	
						- I oddlers	

Bibliographic Study Information Evi	y Type & Nu idence P evel	umber of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
			5		Measures	1 (1 to 1.3) PEG 1.1 (0.9 to 1.5) lactulose P = 0.58 Treatment stopped in 1 child because of lack of efficacy (lactulose group)	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Loening-	Study Type:	49 children	-Miralax group:	Intervention:	Duration of	Medication dosage	Additional information from study:
Baucke.	Prospective		28 children	MiraLax	treatment:	(Mean doses and	Initial dose of Miralax 0.5 g/kg daily
Polyethylene	cohort	Inclusion	20 boys	17 dissolved	12 months	range for children	suggested for children whose rectums
glycol without		criteria:	Mean age ±	in 240 mL of a		who were doing well	were loaded with stool but who had no
electrolytes for	Evidence	children ≥4	SD:	beverage such as	Assessment	or improved) (PEG,	fecal abdominal masses at the initial
children with	level:	years of age	8.7 ± 3.6 years	juice or Kool-Aid	point (s):	g/kg; MOM, mL/kg)	physical examination and no history of
constipation	2 +	referred for	Range 4.1 to	initial dose: 0.5 to	1, 3, 6, and 12		long intervals between huge bowel
and encopresis.		functional	17.5 years	1 g/kg/daily	months after	1 month	movements. Those with
2002. Journal of	Study aim:	constipation			initiating	PEG:	palpable abdominal fecal masses or
Pediatric	to determine	and	-MOM group:	Comparison:	treatment	0.6 ± 0.2 (0.3 to 1.1)	history of infrequent huge bowel
Gastroenterolog	the efficiency,	encopresis	21 children	MOM		MOM:	movements started on 1 g/kg daily
y and Nutrition	acceptability,	Functional	17 boys	Initial dose 1 to	<u>Outcome</u>	1.4 ± 0.6 (0.6 to 2.6)	
34[4], 372-	and treatment	constipation	Mean ± SD: 7.3	2.5 mL/kg	Measures:		Milk of Magnesia given if family could
377United	dosage of	defined as	± 3.0 years			3 months	afford only the use of a cheaper laxative
States.	MiraLax	delay/difficulty	Range: 4.0 to		-medication	PEG:	or if child had previously received MOM
	(polyethylene	in defecation	13.9 years		dosage	0.6 ± 0.3 (0.3 to 1.4)	without refusal. For these children, MOM
	glycol 3350	and				MOM:	reintroduced or adjusted to an adequate
	without	encopresis	Country:		-clinically	1.2 ± 0.5 (0.6 to 2.4)	dosage. Parents told how to improve the
	electrolytes)	(≥1/week) for	USA		significant side		taste by mixing the child's preferred
	during a 12-	more than 1			effects	12 months	flavoring with plain MOM. Initial daily
	month	year		Large laxative		PEG:	dosage of 1 mL/kg body weight
	treatment			dosages divided	-compliance	$0.4 \pm 0.1(0.1 \text{ to } 0.7)$	suggested for children with rectal fecal
	period in	Exclusion		into 2 daily doses.	with medication	MOM:	masses only at initial evaluation and if
	children with	criteria:		Parents told to		only 2 children still	they had no history of infrequent large
	functional	Children <4		adjust the dose of		required MOM. Their	bowel movements. Dosage of 2.5 mL/kg
	constipation	years of age;		medication by 30		dosages were 0.4	prescribed for those with fecal
	and	children who		mL for MiraLax		and 1.6 mL/kg, both	abdominal masses at the initial
	encopresis	refused the		and by 7.5 mL		less than the initial	evaluation or history of huge, infrequent
		toilet for		(one-half		treatment dosage	bowel movements
		stooling but		tablespoon) for			
		who had no		MOM every 3		mean doses for both	Regular stool sittings for 5 minutes after
		constipation,		days to a dosage		treatments at 12	each meal required for initial months.
		Hirschsprung'		that resulted in 1		months	
		s disease,		to 2 soft bowel		did not differ	Patients and parents provided with diary
		chronic		movements/day		significantly between	sheets to record each outcome
		intestinal		and prevented		children with or	measured
		pseudo-		solling and		without initial	
		obstruction, or		abdominal pain.		palpable abdominal	Global assessment of whether child was

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
		previous		If child retained		faecal masses. None	"doing well," "improved," or "not doing
		surgery of the		stools despite		of the patients	well" was recorded. Doing well defined
		colon/anus		compliance with		required an increased	as 3 or more bowel movements/week
				assigned laxative,		dosage of either	and 2 or fewer soiling episodes / month.
				daily senna added		medication over time	Improved defined as 3 or more bowel
				to treatment			movements / week and a more than
						5 children received a	75% decrease in soiling but not more
						stimulant laxative in	than 1 soiling / week. Not doing well was
						addition to PEG and	defined as fewer than 3 bowel
						1 child received a	movements / week, a less than 75%
						stimulant laxative	decrease in soiling frequency, use of
						in addition to MOM (P	senna, or refusal to take the assigned
						> 0.2)	laxative. Recovered defined as 3 or
							more bowel movements / week and 2 or
						Clinically significant	fewer soiling episodes / month while not
						side effects	taking laxatives.
							No significant becaling differences
						PEG: no significant	No significant baseline differences
						Clinical side effects.	between 2 groups
						Some children had	Deviewer commonter
						children in the DEC	Ne comple size coloulation performed
							no sample size calculation performed
						debydrated Children	Outcomes for consistency of stools not
						receiving PEG and	reported
						their parents did not	reported
						report increased	Not reporting on the clinically significant
						flatus abdominal	side effects (or lack of them) for MOM
						distention, or new	
						onset of abdominal	Source of funding:
						pain	Dr. Loening-Baucke recipient of grant
						1 T	support from Braintree Pharmaceuticals.
						Compliance with	Braintree, MA, U.S.A., for continuing
						medication:	studies on childhood constipation
						-PEG: No children	
						reported disliking the	
						taste, no parents	

Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
Information	Evidence Level	Patients	Characteristic S	Comparison	Outcome Measures	reported that child refused to take it in juice or Kool-Aid Parental noncompliance with administering the laxative and supervising toilet use: 14% children -MOM: 33% children refused to take it Parental noncompliance with administering the laxative and supervising toilet use: 4% children	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Erickson et al.	Study Type:	46 children	46 children	Intervention:	Duration of	Side effects:	Additional information from study:
Polyethylene	Retrospective			Polyethylene	treatment		Diagnosis of constipation based on
glycol 3350 for	case series	Inclusion	35 girls	glycol 3350		-Diarrhoea: 9/46	history of
constipation in		<u>criteria:</u>	mean age: 7.7	without	Mean: 194.3	children, all female	Infrequent bowel movements (less than
children with	<u>Evidence</u>	Children	years (range	electrolytes	days (SD		very other day) and/or hard, large or
dysfunctional	level:	diagnosed	4.5 to 11.2	(MiraLax)	133.5)	age at start of PEG	painful bowel movements. Most children
elimination.	3	with	years)			(mean ± SD, years):	also had confirmatory abdominal x-ray
2003. Journal of		dysfunctional		17 gm (1 capful)	Assessment		demonstrating accumulation of stool in
Urology 170[4	Study aim:	voiding and	11 boys	mixed with 8	<u>points</u>	patients with	the rectum and throughout the colon
Pt 2], 1518-	To review the	constipation	mean age: 7.6	ounces of fluid of		diarrhoea (n=9):	
1520	efficacy of	who received	years (range	parent's choice	Not clear	6.8 ± 1.1	25 patients also underwent biofeedback,
	PEG as a	polyethylene	4.4 to 11.1		-		and 8 patients began anticholinergic
	single agent	glycol 3350	years)	Starting dose: 8	Outcome	patients without	medication during the course of PEG
	for the	between		ounces of mixture	Measures:	diarrhoea (n=37):	treatment
	treatment of	January 2000		each day with		8.2 ± 1.8	
	constipation in	and July 2002	Country:	instructions to	side effects		Reviewer comments:
	children with	- · ·	USA	adjust the amount		p=0.04	Not clear how side effects measured in
	dysfunctional	Exclusion		consumed by 1 to			the first place
	elimination	<u>criteria</u> :		2 ounces every 3		duration of follow-up	
	and asses	Known		days to achieve		(mean ± SD, days):	Not clear now the reviewing process
	bladder	neurological		the goal of 1 to 2		4: 4 : : 41-	was conducted
	function	impairments		SOIT DOWEI		patients with	
	tractment			movements per			Source of funding:
	treatment			day Final daga		330 ± 153	not stated
				Final dose		potionto without	
				normalised to		diarrhage (n. 27)	
				Average linal		100 ± 11	
				(reported in		n-0.0028	
				(reported III		p=0.0020	
				an/kg (reported in		1 child stopped taking	
				tovt)		PEG because of side	
						effects	
				Comparison:			
				None			
				<u>Comparison</u> : None			

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Loening-Baucke	Study Type:	75 children	75 children	Intervention:	Duration of	Adverse effects	Additional information from study:
et al.	Retrospective			PEG 3350 without	treatment		Constipation defined according to
Polyethylene	case series	Inclusion	36 boys	electrolytes	(months, mean	a. ≤ 4 months (n=71)	NASPGHAN criteria
glycol 3350		criteria:		(MiraLax)	<u>+ SD)</u>		
without	Evidence	Children with	mean age 17		-short term:	5 children (7%): runny	Reviewer comments:
electrolytes for	level:	constipation	months (range	Starting average	2.3 ± 1.3	stools	Authors reviewed charts from their own
the treatment of	3	<2 years of	1 to 21 months)	dose 1g/kg body	(range: 1 to 4)		clinics. Not clear how the reviewing
functional		age at start of		weight/day		(Dose of PEG (g/kg	process was conducted
constipation in	Study aim:	PEG therapy	Country: USA		-long term:	body weight/day):	
infants and	to evaluate			Parents asked to	10.6 ± 8.1	Range 0.4 to 2.3	Not completely clear how side effects
toddlers. 2004.	the safety and	Exclusion		adjust dose to	(range 6 to 37)	Mean 1.1 ± 1.2	were measured in the first place, it
Journal of	efficacy of	criteria:		yield 1 to 2 soft		Median (0.82)	seems that parents were asked about
Pediatric	PEG 3350	Hirschsprung'		painless	<u>Assessment</u>		the at the time of consultation
Gastroenterolog	without	s disease,		stools/day	<u>points</u>	b. ≥ 6 months (n=47)	
y and Nutrition	electrolytes	chronic			-short term:		Source of funding: not stated
39[5], 536-539	for the	intestinal			≤ 4 months	1 child (2%): watery	
	treatment of	pseudo-		Comparison:	(mean 2	stools (he was only	
	constipation in	obstruction,		none	months)	brought by his mother	
	children < 2	previous				for a 6-month follow-	
	years of age	surgery of			-long term:	up). The diarrhoea	
		colon/anus,			≥ 6 months	disappeared after	
		disease			(mean 11	lowering the dose of	
		states that			months)	PEG.	
		place			-	(Dose of PEG (g/kg	
		limitations on			<u>Outcome</u>	body weight/day):	
		the act of			Measures:	Range 0.3 to 2.1	
		defecation				Mean 0.8 ± 0.4	
		such as			Adverse effects	Median (0.67)	
		hypotonia,					
		cerebral palsy				Parents did not report	
		and severe				increased flatus,	
		mental				abdominal distension,	
		retardation				vomiting or new onset	
						abdominal pain. None	
						stopped PEG	
						because of adverse	
						enects.	

Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
						Complete blood counts (in 24 children), electrolytes (in 9 children), renal functions (in 8 children) and liver functions (in 8 children) occasionally done in children on long-term PEG treatment, and all were within normal limits.	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Michail et al.	Study Type:	28 children	28 children	Intervention:	Duration of	Side effects:	Additional information from study:
Polyethylene	Retrospective			PEG 3350	treatment	Total: 5 (17.9%) of	Diagnostic criteria for functional
glycol for	case series	Inclusion	-age at initiation	administered	Mean 6.2 ± 5	patients	constipation in infants and preschool
constipation in		criteria:	of therapy:	orally, mixed in a	months (range,		children adapted from Rasquin-Weber
children	Evidence	children		ratio of 17 g to	3 weeks to 21	1 (3.6%) infant	and included: 2 weeks of hard stools
younger than	level:	younger	3 children: age	240 mL of fluid, as	months)	experienced	(the majority of stools), or firm stools 2
eighteen	3	than 18	0 to 5 months	recommended by		increased passage of	or fewer times a week in the
months old.		months	9: age 6 to11	the manufacturer.	Assessment	gas per rectum	absence of structural, endocrine, or
2004. Journal of	Study aim:	treated for	months	Caregivers for	points		metabolic disease
Pediatric	to determine	constipation	16: age 12 to	small infants	at initial visit	4 (14.3%) infants	
Gastroenterolog	safety,	with PEG	17 months	mixed PEG 3350	and subsequent	experienced transient	No patient placed on a clean-out
y and Nutrition	efficacy, and	powder		in formula if it was	visits every 8 to	diarrhoea that	protocol using any other drug
39[2], 197-199	optimal		gender not	the sole diet. After	12 weeks	resolved after dose	
	dose of	Exclusion	reported	initial dose,		adjustment	Duration of therapy and side effects
	polyethylene	criteria:		families asked to	<u>Outcome</u>		retrieved from the patient's chart.
	glycol powder	organic	Country:	titrate the dose to	Measures:		Information not available in the chart
	for treatment	aetiology for	USA	obtain at least one			was obtained by telephone interview.
	of	constipation:		nonformed bowel	Side effects		Only 1 family needed to be contacted by
	constipation	Hirschsprung'		movement daily.			telephone
	in patients	s disease,		Change in dose			
	younger than	anorectal		permitted within			Reviewer comments:
	18 months	malformation,		24 hours, if			Authors reviewed charts from their own
		bowel		necessary			clinics. Not clear how the reviewing
		obstruction, or					process was conducted
		systemic		Mean initial			
		illness		Dose: 0.88			Source of funding: not stated
		(hypothyroidis		g/kg/day (range,			
		m, cystic		0.26-2.14			
		fibrosis, or		g/kg/day)			
				M G C			
		poisoning		Mean effective			
		associated		maintenance			
		with					
		Taking		g/kg/uay (range,			
		raking		0.20 - 1.20			
		thet could		g/kg/uay)			
		nat could		Comparison			
		potentially		<u>comparison</u> :			

Bibliographic Stud Information Ev	ly Type & Number ridence Patient Level	of Patient s Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
	change th frequency or consistend bowel movemen	ey of s	none			

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Pashankar et al.	Study Type:	74 children	74 children	Intervention:	Duration of	Average dose of PEG	Additional information from study:
Long-term	Retrospective		40 boys	PEG 3350 without	treatment	at time of evaluation:	Diagnosis of chronic constipation based
efficacy of	cohort	Inclusion		electrolytes	Mean 8.4		on symptoms of at least 3 months'
polyethylene		criteria:	mean age:	(MiraLax)	months (range	0.73 g/kg/day (range	duration including at least 2 of the
glycol 3350 for	Evidence	children > 2			3 to 30)	0.3 to 1.8) following	following: hard stools, painful defection,
the treatment of	level:	years of age	-constipation	0.8 g/kg/day		adjustment of dose	encopresis or fewer than 3 bowel
chronic	2-	with chronic	only: 6.6 years	administered	Assessment	by caretakers	movements/week
constipation in		constipation	(range 2 to	orally, as	points		
children with	Study aim:	treated at	16.9)	recommended by	Unclear	Adverse effects:	Encopresis defined as constipation with
and without	to report	authors' clinic		the manufacturer			involuntary loss of stools into the
encopresis.	efficacy of	daily with	-constipation	mixed in a ratio of	<u>Outcome</u>	no major clinical	underwear beyond a developmental age
2003. Clinical	PEG therapy,	PEG 3350	and encopresis:	17 g of powder to	Measures:	adverse effects	of 4 years
Pediatrics 42[9],	effective dose	without	8.4 years (4.3	240 mL of water	Adverse effects	observed	
815-819	and patient	electrolytes	to 12.8)	or other beverage.			Reviewer comments:
	compliance	(MiraLax) for		Families allowed			Authors reviewed charts from their own
	separately for	> 3 months		free choice of			clinics. Not clear how the reviewing
	children with		Country:	beverage			process was conducted. Some
	constipation	Exclusion	USA				outcomes variables gathered by
	and children	<u>criteria</u> :		Parents asked to			interviewing patients/parents and
	with	history of		adjust the dose as			examining patients. Unclear how data
	constipation	Hirschsprung'		required to yield 2			on adverse effects were obtained
	and	s disease,		soft painless			
	encopresis	anorectal		stools per day			Source of funding:
	over the long	malformations					Financial assistance provided in part by
	term	, abdominal					Braintree Laboratories, Braintree, MA
		surgery, or		Comparison:			
		any systemic		Behaviour			
		illness leading		modification			
		to		programme			
		constipation					

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Hardikar et al.	Study Type:	81 children	77 children	Intervention:	Duration of	Mean numbers of	Additional information from study:
Macrogol 3350	Prospective			Macrogol 3350	treatment	sachets/day during	Chronic constipation defined as fewer
plus electrolytes	case series	Inclusion	44% boys	plus electrolytes	Mean 75.5 days	treatment period:	than 3 complete bowel movements per
for chronic		criteria:	mean age:	(Movicol)		1.3 (6.9 g)	week over previous14 days in
constipation in	Evidence	Children aged	4.9 ± 2.6 years		Assessment		association with either straining or
children: a	level:	24 months to		Each sachet	points	Adverse effects	passage of hard stools in at least a
single-centre,	3	11 years with		(6.563 g	Adverse effects	<u>(n=78)</u>	quarter of bowel movements
open-label		chronic	Country:	Macrogol)	monitored	72 children (92%)	
study. 2007.	Study aim:	constipation	Australia	dissolved 62.5 mL	throughout the	reported a total of	If investigator considered it to be
Journal of	To evaluate	for at least 6		of water	study, venous	318 events	clinically necessary patients could be
Paediatrics and	the safety and	months,			samples for		given another laxative provided they had
Child Health	efficacy of a	which was		Number of	laboratory taken	241 (76%) assessed	failed to respond to the maximum dose
43[7-8], 527-	macrogol	either		sachets first 5	at baseline, 28	as unrelated to study	for 3 days
531	3350-based	untreated or		days	days and 84	treatment	
	electrolyte	inadequately		-Children aged 2	days. Vital		No other therapeutic interventions,
	containing	treated by		to 6 years:	signs measured	262 (82%): mild	including an increase in oral fluids or
	preparation in	laxatives		Days 1 & 2: 1/day	at baseline and	302 (95%): resolved	dietary fibre were instituted
	the treatment			Days 3 & 4: 1	84 days	by end of study	
	of chronic	Exclusion		twice a day			Any child who developed faecal
	constipation in	criteria:		Day 5: 1 three	<u>Outcome</u>	6 serious adverse	impaction (faecal loading) which
	children	children		times/day	Measures:	events in 4 children: 4	required treatment was withdrawn from
		treated for				affected	study and classified as treatment failure
		faecal		-Children aged 7	-Safety :	gastrointestinal	
		impaction with		to 11 years		system. All assessed	78 (96%) patients included in safety
		bowel		Day 1 & 2:	adverse effects	by investigator as	analysis.
		washouts		1 twice a day		unrelated or unlikely	65 (80%) patients completed study. 16
		during the		Day 3, 4 & 5:	laboratory tests	to be related to study	patients withdrew prematurely: 6 unable
		previous 2		2 twice a day		medication and	or refused to take medication, 4 protocol
		months, or			changes in vital	resolved at end of	deviation, 3 poor compliance, 1 failed to
		had a past		Thereafter and	signs	study. 1 serious	return for final visit, 1 parent refused to
		history of		until end of study		adverse event (faecal	give medication, 1 serious adverse
		intestinal		dosage titrated		impaction) led to	effect
		perforation/ob		according to		patient's premature	
		struction,		faecal form. This		withdrawal from study	Reviewer comments:
		Hirschsprung'		dose increased by		as child was admitted	6 serious adverse events in 4 children: 4
		s disease,		1 sachet/day in		as impatient for bowel	affected gastrointestinal system,
		paralytic		the event of		washout	remaining 2 not reported
		ileum, toxic		continued hard			

Bibliographic	Study Type &	Number of	Patient Characteristic	Intervention &	Follow-up &	Effect Size	Reviewer Comments
mormation	Level	Fallents	S	Companson	Measures		
		megacolon, severe inflammation of the intestinal tract, urinary tract infection,, uncontrolled renal, hepatic or cardiac diseases, endocrine disorders, or any other severe unstable coexisting disease during he previous 30 days		stools/no bowel movements, and decreased by 1 to 2 sachets/day in the event of loose stools or diarrhoea <u>Comparison</u> : None		Changes in vital signs: No clinically significant changes as result of study medication	Not clear how clinical adverse effects were asked for <u>Source of funding:</u> Movicol sachets supplied by Norgine Ltd. Uxbridge, UK. Study supported by a research grant from Norgine Ltd. Uxbridge, UK and Norgine PTY, Sydney, Australia

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome Measures		
Adler. Effective Treatment of Constipation and Encopresis with Movicol (Macrogol 3350 with Electrolytes) in Children and Adolescents. 2005. Gut 54[Suppl VII], A217 Adler, 2005	Study Type & Evidence Level Study Type: Prospective Case series Evidence level: 3 Study aim: to assess the effectiveness of Movicol (macrogol 3350 with electrolytes), over the course of long term treatment in children with constipation	Number of Patients 134 patients Inclusion criteria: children referred with constipation and/or encopresis to The Queen Silvia Children's Hospital, Sweden Exclusion criteria: Not stated	Patient Characteristic s 134 patients 88 males age not clearly reported Country: Sweden	Intervention & Comparison Intervention: Movicol (macrogol 3350 with electrolytes,13.8g sachets) -Mean starting dose: Age 2 to 6: 0.58 sachets Age 7 to 11: 0.51 sachets Doses adjusted in each patient to achieve symptom relief with the minimally effective dosage	Follow-up & Outcome Measures Duration of treatment: Mean: 50 weeks (SD ±50 weeks; range 1 to 211 weeks) Assessment point (s): unclear Outcome Measures: -final treatment dose -side effects	Leffect Size Mean dose at end of observational period Age 2 to 6: 0.42 sachets Age 7 to 11: 0.49 sachets -overall mean change: 0.553 to 0.477 sachets/day Side-effects were reported in 10 (7.5%) patients and these were generally mild and transient	Reviewer Comments Reviewer's' comments It is difficult to asses the quality criteria and to make comments on this study because we have only been able to review the abstract. This abstract was included because it provides some evidence on long-term treatment with Movicol Source of funding: Not stated
				Comparison: None			

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Loening-Baucke	Study Type:	79 children	79 children	General:	Duration of	Patient Acceptance	Additional information from study:
et al. A	RCT		65 boys	disimpacted with	treatment:	Several children	Functional constipation defined by
randomized,		Inclusion	age range: 4 to	1 or 2 phosphate	12 months	complained about	duration of \geq 8 weeks and \geq 2 of the
prospective,	Evidence	criteria:	16.2 years	enemas in the		taste of PEG and	following: frequency of bowel
comparison	level:	age ≥ 4 years	(median 7.4;	clinic on the day	Assessment	MOM.	movements <3 stools/week, >1 episode
study of	1-	and presence	mean 8.1 ± 3.0)	of the visit, if	point (s):	2 children (5%)	of faecal incontinence/week, large stools
polyethylene		of functional		necessary and	1, 3, 6 and 12	continued to refuse	noted in rectum or felt during abdominal
glycol 3350	Study aim:	constipation	Country: USA	started laxative	months after	PEG vs. 14 children	examination, passing of stools so large
without	to compare	with faecal		therapy that	initiating	(35%) continued to	that they obstructed the toilet
electrolytes and	the efficacy,	incontinence		evening	treatment	refuse MOM during	
milk of	safety and					the 12 months of the	Randomisation performed by children
magnesia for	patient	Exclusion		Intervention:	<u>Outcome</u>	study	drawing a sealed envelope with and
children with	acceptance of	criteria:		polyethylene	Measures:	(P < 0.001)	enclosed assignment
constipation	polyethylene	stool toileting		glycol (PEG) 3350			
and fecal	glycol (PEG)	refusal, faecal		without added	-safety profile	Treatment doses	Investigators, children and their parents
incontinence.	3350 without	incontinence		electrolytes 0.7		<u>(mean ± SD):</u>	aware of the study group assignment
2006. Pediatrics	added	but no		g/kg body weight	-patient's		
118[2], 528-535	electrolytes	constipation,		daily for 12	acceptance and	-PEG (g/kg body	It was estimated that 38 subjects were
	vs. milk of	previous		months	compliance	weight)	required in each group to be able to
	magnesia	refusal of one					detect a difference in failure rates
	(MOM) over	of study		capful of PEG (17		1 month: 0.7 ± 0.2	between the 2 groups of 30% in 12
	12 months	medications,		g) mixed in 8 oz of		3 months: 0.6 ± 0.3	months (40% vs. 10%), at the 0.05
		children who		beverage (juice,		additional senna at	significance level with 0.80 power.
		came from far		Kool-Aid, Crystal		some point: 3 children	Authors hypothesized that PEG would
		away for a		Light or water)			be as successful as MOM in treating
		second		making a solution		-MOM (mL/kg body	chronic constipation and faecal
		opinion,		of ~2g/30 mL		weight)	incontinence. Authors' previous study
		Hirschsprung					showed that 33% of children refused to
		s disease,		Comparison:		1 month: 1.2 ± 0.7	take MOM during the first 12 months of
		chronic		milk of magnesia		3 months: 1.2 ± 0.8	treatment.
		intestinal		(MOM) 2mL/kg		additional senna at	
		pseudobstruct		body weight daily		some point: 1 child	Children treated with minimal effective
		ion, previous		for 12 months			dosage of PEG or MOM, allowing for a
		surgery				mean doses similar in	daily stool and preventing abdominal
		involving		plain MOM could		children who	pain and faecal incontinence. Parents
		colon or anus		be mixed into		improved and who	instructed to aim for 1 or 2 stools of
				apple sauce or		did not improve for	milkshake consistency each day.
				milkshakes, or		both treatments	Parents asked to increase dosage if

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
				chocolate and other flavouring could be added Large doses of both medications could be divided into 2 doses		safety profiles PEG: 1 child allergic No other significant clinical effects for either medication, apart from transient diarrhoea disappearing with dose reduction -Laboratory tests: PEG: 1 child with elevated platelets before and after treatment, 1 child with decreased sodium levels at 6 months, but normal at 12 months MOM: 1 child high platelet count, 1 low serum sodium level, elevated AST, 1 elevated ALT	stools too hard or not frequent enough and to decrease the dosage if stools watery or too numerous. Small changes, such as 2 oz of PEG or 0.5 tbsp of MOM every 3 days, were recommended. Regular stool sittings for 5 minutes after each meal required initially. Toilet sitting frequency reduced after children recognized urge to defecate and initiated toilet use themselves. No significant differences at baseline between the 2 groups regarding: age, sex, primary faecal incontinence, previous treatment with laxatives, history of retentive posturing, frequency of bowel movements, bowel movements obstructing the toilet, frequency of faecal incontinence, presence of abdominal pain, presence of abdominal faecal mass By 12 months a total of 27 dropouts/lost to follow-up. PEG: 2 children lost to follow-up monitoring, 2 (5%) had refused PEG, 1 child allergic to PEG, 2 children were receiving senna. These 7 children counted as not improved and not recovered. MOM: 2 Children lost to follow-up monitoring, 3 children had discontinued study participation, 14 children (35%) had refused to take MOM, and 1 child was receiving senna Efficacy analyses performed with intention to treat population, other

Bibliographic Study Type & Nu Information Evidence F Level	Number of Patient Patients Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
Level	S		Measures		outcomes calculated from available follow-up data Patients and parents questioned with respect to side effects during each visit <u>Reviewer comments:</u> Results not controlled for potential confounders High drop-out / lost to follow-up rate: 30.4% <u>Source of funding:</u> Braintree Laboratories (Braintree, MA) supported study with an unrestricted research grant. According to authors, the funding source had no involvement in the study design, collection, analysis, interpretation of data, writing of the report or decision to submit the article for publication

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Pashankar et al.	Study Type:	83 children	83 children	Intervention:	Duration of	Clinical adverse	Additional information from study:
Safety of	Prospective			PEG 3350 without	treatment	effects Minor and	Diagnosis of chronic constipation based
polyethylene	case series	Inclusion	Male/female:	electrolytes	mean 8.7	acceptable over	on symptoms of at least 3 months'
glycol 3350 for		criteria:	48/35	(MiraLax)	months (range,	mean duration of	duration, including at least 2 of the
the treatment of	Evidence	Children >			3 to 30	therapy	following: hard stools, painful defecation,
chronic	level:	than 2 years	Mean age 7.4	Initial dose: 0.8	months		encopresis, or fewer than 3 bowel
constipation in	3	old with	years (range	g/kg per day		8 patients (10%):	movements per week
children. 2003.		chronic	2.0 to 16.9	According to	Assessment	frequent watery stools	
Archives of	Study aim:	constipation	years)	manufacturer's	points	sometime during	All other laxative treatments stopped
Pediatrics and	to assess the	who were		directions, parents		therapy. Diarrhoea	before starting PEG
Adolescent	biochemical	treated daily	Country:	instructed to	Outcome	disappeared with	
Medicine	and	with PEG	USA	dissolve 17 g of	Measures:	reduction of dose	Parents interviewed using structured
157[7], 661-664	clinical safety	>3 months		PEG powder in			questionnaire and asked about dose of
	profile of long-			240 mL of water	Adverse effects:	5 children (6%):	PEG given, medication compliance, any
	term PEG	Exclusion		or other beverage		bloating or flatulence	possible adverse effects of PEG, and
	3350	criteria:		and to give	-clinical		particularly about excessively loose or
	treatment in a	history of		prepared solution		2 children (2%):	frequent stools, abdominal pain,
	large cohort of	Hirschsprung'		in 2 divided	-laboratory	abdominal pain	flatulence, bloating, and nausea.
	children and	s disease,		doses. Families			Parents asked about overall
	also	anorectal		allowed choice of		1 patient each (1%):	improvement in bowel movement
	paediatric	malformations		beverage to suit		thirst, fatigue, and	pattern regarding stool frequency and
	patient	, or any		child's preference.		nausea after	consistency with PEG therapy.
	acceptance	systemic		Parents asked to		receiving PEG	Following interview and physical
	of long-term	illness		adjust dose of		solution on	examination, 4 mL of blood obtained for
	PEG therapy	potentially		PEG solution as		an empty stomach	measurement of different parameters
		leading to		required to yield 2			
		constipation		soft painless		None of the patients	Results of blood tests considered
				stools per day.		stopped treatment	abnormal if outside (even by 1 point) the
				Over time,		due to adverse	age- and sex appropriate reference
				parents instructed		effects and all were to	range established in authors' hospital. If
				to gradually		continue PEG	results abnormal, blood tests repeated
				decrease		therapy.	within 8 weeks while patient continued
				dose of PEG if			to receive therapy
				symptoms of		General physical	
				constipation and		examination findings	
				encopresis		revealed no new	Source of funding:
				showed		significant	Study financially assisted by Braintree
				improvement		abnormalities	Laboratories

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
						compared with the	
				Comparison:		pre-treatment	
				None			
						Laboratory evaluation	
						results:	
						Haemoglobin,	
						haematocrit, serum	
						electrolytes, blood	
						urea nitrogen, serum	
						creatinine, serum	
						albumin, and	
						osmolality, normal in	
						all patients (10	
						patients did not have	
						serum osmolality	
						measured)	
						9 patients (11%) had	
						slightly elevated ALT	
						level (<1.5 times the	
						upper limit of normal;	
						range, 31 to 45 U/L).	
						8 of these patients	
						had ALT levels	
						remeasured within 8	
						weeks, 7 of whom still	
						receiving PEG	
						therapy. 7 of these 8	
						patients had values in	
						the reference range,	
						1 had slightly	
						elevated ALT level	
						(<1.2 times normal;	
						28 U/L).	
						3 patients (4%) had	
						an elevated aspartate	
						aminotransferase	

Bibliographic Information	Study Type & Evidence	Number of Patients	Patient Characteristic	Intervention & Comparison	Follow-up & Outcome	Effect Size	Reviewer Comments
						level (<1.5 times normal; range, 42-52 U/L), and all had normal values when remeasured while still receiving PEG therapy Dose and duration of PEG therapy not significantly different in patients with abnormal values compared with those with laboratory values in the reference range	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Clark et al.	Study Type:	25 children	25 children	Intervention:	Duration of	Serum levels	Additional information from study:
Serum beta-	Prospective			Following initial	treatment	(micromols/L	Vitamin supplementation not prescribed
carotene,	case series	Inclusion	mean age: 7.83	disimpaction (not	4 months	(micrograms/dL)	
retinol, and		criteria:	years (range	reported with		<u>(mean ± SEM):</u>	Normal serum values for authors'
alpha-	Evidence	Children with	1.75 to 14.27	what), mineral oil,	Assessment		laboratory:
tocopherol	level:	encopresis,	years)	45 mL twice daily	points	-Month 1 (n=25):	-Serum beta-Carotene: >0.6
levels during	3	over 1 year		between meals		Serum beta-carotene:	micromols/L (>30 micrograms/dL)
mineral oil		old with no	gender not		1, 2, 3 and 4	Baseline: 1.0 ± 0.5	-Retinol: 0.70 micromols/L (20
therapy for	Study aim:	previous	reported	Dose gradually	months	(55.7 ± 26.0)	micrograms/dL)
constipation.	to	treatment with		decreased on		Treatment: 0.7±0.4	-Alfa tocopherol: >9 micromols/L (>0.4
1987. American	prospectively	mineral oil	Country:	monthly basis	Outcome	(35.9 ± 22.1)	micrograms/dL)
Journal of	monitor		USA	(usually 30	Measures:	P<0.01	
Diseases of	children	Exclusion		mL/mo)			Since number of patients returning for
Children	receiving	criteria:		depending on	Serum beta-	Retinol: NS as	subsequent visits gradually decreased,
141[11], 1210-	large doses of	not stated		patient's reported	carotene level	compared to baseline	basal levels were recalculated for each
1212	mineral oil			performance and			month of treatment using the remaining
	throughout			results of serial	Retinol level	-Month 2 (n=17):	patients as their own controls
	the early			rectal		Serum beta-carotene:	
	phase of			examinations	Alfa tocopherol	Baseline: 1.1 ± 0.6	
	treatment				level	(59.5 ± 30.6)	Source of funding: not stated
				-Mean ± SEM:		Treatment: 0.7 ± 0.5	
						(38.2 ± 28.4)	
				Month 1: 4.0 ± 1.4		P<0.05	
				Month 2: 2.9 ± 1.2			
				Month 3: 2.1 ± 0.5		Retinol: NS as	
				Month 4: 1.4 ± 0.4		compared to baseline	
				Comparison		Month $2(n-10)$	
				<u>companson</u> .		-ivionin 5 ($n=10$).	
				none		Basolino: 1 1 + 0 6	
						(60.4 + 20.0)	
						$Treatment: 0.6 \pm 0.2$	
						(34.7 ± 12.3)	
						$P_{-0.05}$	
						1 20.00	
						Retinol:	
						Baseline: 1.48 ± 0.84	
						(42.3 ± 24.1)	

Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
						Treatment: 2.22 ± 0.77 (63.5 ± 22.1) P<0.01 -Month 4 (n=5): Serum beta-carotene: NS as compared to baseline Retinol: NS as compared to baseline Serum alfa tocopherol levels remained relatively unchanged throughout study. No statistical significant difference between baseline levels and those obtained throughout the 4 months of therapy	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Perkin.	Study Type:	21 children	21 children	Intervention:	Duration:	Adverse effects (n	Additional information from study:
Constipation in	RCT		(age and	Senna syrup	1 week each	patients):	Patients given either treatment
childhood: a	(crossover)	Inclusion	gender not	10 to 20 ml daily	period with 1	a- senna week:	according to a code-list of random
controlled		criteria:	reported)	for 1 week	week no	12 (8 colic, 1	numbers, placed in a series of sealed
comparison	Evidence	children aged			treatment in	diarrhoea, 2 colic+	envelopes, one of which was opened
between	level:	<15 years	Country: UK	Comparison:	between	diarrhoea, 1 colic +	each time a child entered the trial
lactulose and	1-	with a history		Lactulose		distension)	
standardized		of		10 to 15 ml daily	<u>Assessment</u>		1 dropout: 1 patient on senna at the
senna. 1977.	Study aim:	constipation		for 1 weeks	<u>point (s):</u>	b- no treatment week:	beginning of study failed to attend at the
Current Medical	to compare	treated at			immediately	4 (3 colic, 1 colic +	end of 1 st week
Research and	effectiveness	home for 3		Each preparation	after treatment	distension)	
Opinion 4[8],	and side	months or		given throughout	completed		No written or oral indication of any
540-543	effects	more		the appropriate		c- lactulose week	medical preference for other preparation
	between a			treatment week in	<u>Outcome</u>	1 (colic)	given and patients presented with single
	standardised	Exclusion		a daily dose	Measures:		bottle of one or other of the preparations
	senna syrup	criteria:		varied according		p<0.001 (a vs. c)	according to the coded instruction at
	and lactulose	any cause of		to the age of the	-adverse effects	NS (b vs. c)	start of trial. On 3 ¹⁰ week a bottle of
	in the	constipation		patient			alternative preparation was given
	treatment of	requiring					
	childhood	surgical or		1 intermediate			Outcomes recorded by parents in written
	constipation	medical		week with not			diaries
		correction in		treatment			
		addition to					4-point scale of stool consistency: loose,
		laxation					normal, hard, none
							Reviewer comments:
							Very small sample size, no sample size
							calculation
							Inadequate method of allocation
							concealment
							Patients' baseline characteristics not
							Study probably non blinded
							Results not controlled for confounders
							very short treatment period
							According to authors the number of
							stools passed each day was recorded,
							but is not reported

Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
							Source of funding: not stated

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Farahmand. A	Study Type:	247 children	247 children	General:	Duration of	Optimal dose of drug	Additional information from study:
randomised trial	RCT			1 or 2 enemas	treatment:	-Final effective dose	Diagnosis of chronic functional
of liquid paraffin		Inclusion	127 male	daily for 2 days to	8 weeks	(mean, ml/kg/day):	constipation based on having at least 2
versus lactulose	Evidence	criteria:		clear any rectal		Liquid paraffin	of the following symptoms for the last 3
in the treatment	level:	chronic	aged 2 to 12	impaction (30	<u>Assessment</u>	(n=127)	months: <3 bowel movements/week,
of chronic	1-	functional	years old (mean	cc/10 kg of	point (s):	1.72 ± 0.13	faecal soiling >once/week, large
functional		constipation	4.1±2.1 years)	paraffin oil)	4 and 8 weeks	Lactulose (n=120)	amounts of stool every 7 to 30 days and
constipation in	Study aim:				after treatment	2.08 ± 0.21	palpable abdominal or faecal mass on
children. 2007.	to compare	Exclusion	Country: Iran	Intervention:	started	p<0.001	physical examination
Acta Medica	the clinical,	criteria:		Liquid paraffin			
Iranica 45[3],	efficacy and	organic		orally, 1 to 2	Outcome	Side effects (during 4	Apart from laxative treatment, parents
183-188Iran,	safety of liquid	causes for		ml/kg, twice daily	Measures:	to 12 week) (not clear	given instructions to increase their daily
Islamic	paraffin and	defecation		for 8 weeks		whether, n or %, but	fibre intake to an amount of grams equal
Republic of.	lactulose in	disorders			-optimal dose of	probably %)	to their age plus 10. Toilet training after
	the treatment	including		Comparison:	drug	(estimates taken from	each meal advised to enhance
	of functional	Hirschsprung'		Lactulose orally, 1		bar chart, outcomes	compliance
	childhood	s' disease,		to 2 ml/kg, twice	-side effects	not reported in text):	
	constipation	spina bifida		daily for 8 weeks		Lactulose (n=120)	Treatment success defined as 3 or more
		occulta,					bowel movements/week and encopresis
		hypothyroidis				Abdominal pain: 10	episodes < 2/week
		m, cystic				Bad palatability: 15	
		fibrosis,				Pain at defecation: 10	No significant baseline differences
		neurological		For determination		Bloating: 10	between the 2 treatment groups
		abnormalities,		of best dose for		Diarrhoea: 10	regarding: age, sex, duration of
		intestinal		child, parents		Anal oil leakage: 20	constipation, detection frequency,
		pseudo		asked to increase		Flatulence: 10	number of patients with history of
		obstruction		the volume of		Nausea: 10	encopresis, large amount of stool, faecal
				each drug by 25%		Hard stool: 20	impaction in rectum, rectal bleeding, lost
				every 3 days as		Vomiting: 0	to follow-up after 8 weeks, bad
				required to yield 1			palatability of study medication
				or 2, firm-loose		Liquid parattin	
				Stools		(n=127)	Parents received chart to record side
							effects
						Abdominal pain: 50	
						Bad palatability: 40	Keviewer comments:
						Planting 20	iviethod of randomisation and allocation
						Bioating: 20	conceaiment not described
						Diarrhoea: 30	INON DIINAEA STUAY
Bibliographic Study Ty Information Eviden Leve	e & Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments	
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					Anal oil leakage: 40 Flatulence: 20 Nausea: 5 Hard stool: 6 Vomiting: 0	No sample calculation performed No withdrawals/dropouts reported Results not controlled for confounders <u>Source of funding:</u> not stated, but authors reported "no conflicts of interests"	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Urganci et al. A	Study Type:	40 patients	40 patients	Intervention:	Duration of	Optimal dose of drugs	Additional information from study:
comparative	RCT		22 male	Liquid paraffin	treatment:	<u>(mean ± SD)</u>	Diagnosis of constipation based on
study: the		Inclusion	mean age $3.7 \pm$		8 weeks	(mL/kg/day)	symptoms of ay least 3 months duration
efficacy of liquid	Evidence	criteria:	2.7 years	Comparison:			including at least 2 of the following: hard
paraffin and	level:	children 2 to		Lactulose	Assessment	-data reported in	stool, painful defecation, rectal bleeding,
lactulose in	1-	12 years old			point (s):	table, assumed that	encopresis and fewer
management of		referred for				for the whole study	
chronic	Study aim:	evaluation of	Country:	Medication	4 and 8 weeks	period:	Open-label randomised study
functional	to determine	constipation	Turkey	administered	after initiation of		
constipation.	and compare	with evidence		orally as a	treatment	Liquid paraffin (n=20):	Children also met with a nutritionist,
2005. Pediatrics	efficacy,	of faecal		suspension at 1		1.88 ± 0.27	were given instructions to increase daily
International	safety and	impaction		mL/kg, twice daily	Outcome	Lactulose (n=20):	fibre intake to amount of grams equal to
47[1], 15-19	optimal dose			for each drug.	Measures:	2.08 ± 0.27	their age plus 10, parent asked to have
	of liquid	Exclusion				N.S	children sit on the toilet 4 times daily
	paraffin and	criteria:		For determination	-optimal dose of		after meals
	lactulose in	Hirschsprung'		of best dose for	drugs	-data reported in text	
	children with	s disease,		each child,		for the last 4 weeks of	Stool frequency and stool consistency
	chronic	hypothyroidis		parents asked to	-compliance	treatment:	recorded by parents in daily diary forms.
	functional	m, mental		increase or	rate		Stool consistency scoring: 1, hard; 2,
	constipation	deficiency,		decrease the		Liquid paraffin (n=20):	firm; 3, loose
		chronic		volume of each		1.72 ± 0.18	
		debilitating		drug by 25%		Lactulose (n=20):	No significant baseline differences
		diseases,		every 3 days as		1.82 ± 0.57	between 2 groups
		neurological		required, to yield			
		abnormalities,		2 firm-loose stools		Compliance rate (%)	Patients considered compliant if $\ge 80\%$
		previous		per day.			of prescribed dose taken correctly.
		surgery of		Maximum dose		-first 4 weeks:	Patients instructed to take both empty
		colon		used throughout		Liquid paraffin (n=20):	and full containers to calculate amount
				the study: 3 mL/kg		95	of medication taken
				per day for each		Lactulose (n=20):	
				drug		90	Reviewer comments:
						N.S	Randomisation method not described
							No sample size calculation performed
						-end of 8 weeks:	No clear definition of "evidence of faecal
						Liquid paraffin (n=20):	impaction" given
						90	Apparently no children dropped out the
						Lactulose (n=20):	study/were lost to follow-up
						60	Study not controlled for potential

Bibliographic Information	Study Type & Evidence	Number of Patients	Patient Characteristic	Intervention & Comparison	Follow-up & Outcome	Effect Size	Reviewer Comments
						p=0.02 No patient stopped treatment because of adverse effects (adverse effects not reported). During first 4 weeks, taste aversion in 1 child on liquid paraffin and abdominal distension in 2 patients on lactulose influenced compliance. During last 4 weeks, poor symptom control in 5 patients, side-effects (abdominal distension and cramping) in 3 on lactulose, and watery stools in 2 on liquid paraffin influenced compliance	confounders Source of funding: not stated

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Bongers et al.	Study Type:	38 children	38 children	Intervention:	Duration of	Clinical efficacy	Additional information from study:
The clinical	Double-blind			Nutrilon Omneo	treatment	after period 1	Constipation defined as the presence of
effect of a new	RCT (cross-	Inclusion	19 boys	(new formula, NF)	2 periods of 3	Defecation frequency	at least 1 of the following symptoms: 1)
infant formula in	over)	criteria:	median age: 1.7		weeks each	(mean ± SD)	frequency of defecation < 3/week; 2)
term infants		Otherwise	months	-Nutrients per 100			painful defecation (crying); 3) abdominal
with	<u>Evidence</u>	healthy, term		:	<u>Assessment</u>	SF (n = 15): 4.9 ± 2.5	or rectal palpable mass
constipation: a	level:	infants with		ml:	<u>point (s):</u>	NF (n = 20): 5.6 ± 2.8	
double-blind,	1+	constipation,	Country:		After period 1		Infants randomised by a computer
randomized		between 3 to	The	Energy (kcal) 70	and period 2	Difference of means	program to either NF or SF in period 1
cross-over trial.	Study aim:	20 weeks of	Netherlands			(95% CI):	and crossed-over after 3 weeks to
2007. Nutrition	To test the	age, who		Protein (g) 1.7	Follow-up	0.7 (-0.8 to 2.3)	treatment period 2
Journal 6, 8	hypothesis	received at		Casein -	period:	N.S	
	that Nutrilon	least 2 bottles		Intact whey	No follow-up		In order to mimic the taste of Nutrilon
	Omneo (new	of milk-based		protein -	conducted after	Improvement of hard	Omneo, the whey-based control formula
	formula, NF)	formula per		Whey protein	treatment	to soft stools (n)	was partly mixed with a formula based
	will have a	day		hydrolysate 1.7	finished		on hydrolyzed whey protein (mixture of
	positive effect					SF (n = 15): 50%	75% Nutrilon 1 and 25% Aptamil HA I).
	on stool	Exclusion		Fat (triglycerides)	Outcome	(5/10)	Formula cans were labelled with codes
	characteristics	criteria:		(g) 3.3	Measures:	NF $(n = 20)$: 90%	to mask identity of the study feedings.
	in constipated	Hirschsprung		Palmitic acid 0.6	_ .	(9/10)	Neither the parents nor the physicians
	children	s disease,		- at the sh-2	Primary		were aware of the composition of the
		spinal or anal		position (%) 41.0	efficacy	RR (95% CI):	formula until the entire study was
		anomalies,		Linoieic acid 0.4	outcomes:	1.8 (0.9 to 3.5)	completed
		previous		a-linolenic acia	 d) defensetien 	N.5	Drive to start of the study, some la size
		COIONIC		0.08	1) defecation		Prior to start of the study, sample size,
		surgery,		Carbaby drates (a)	Trequency		based on a cross-over design, was
		metabolic,		Carbonydrates (g)	> 3/week	<u>(n)</u>	calculated to allow detection of a 30%
		cerebrai and		8.4 Lastage 2.0			amerence in improvement between NF
		renal		Laciose 2.9	2) normalization	SF(n = 15): 33%	and SF. Under the assumption of a
		abriormanties,		Mailouexinn 4.0	OI SIOOI	(0/10)	significance level of 0.05 with
		children who		Startin 1.5	consistency	NF(11 = 20).35%	a power of 0.80, and 2-sided hypothesis
		were treated		Γ ibro (a) 0.9		(7/20)	testing, a minimal sample size of 34 with
		at oprollmost		Cligospocharidas			determined
		atenionnent			defection	(30% CI).	
				(30 % GUS, 10%	uelecation	N C	Only 24 children (62%) completed the
	1	1		10-03/0.0	1	11.0	Tority 24 children (05%) completed the

Effectiveness of Diet and Lifestyle modifications in Children with Chronic Idiopathic Constipation

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
					Secondary		cross-over study. In period 1, 3 SF
				Minerals and	outcome:	Clinical efficacy	patients dropped out; 2 patients stopped
				trace elements		after cross-over	because of severe constipation; 1
				(mg)	-safety	(period 1 and 2)	patient switched to hypoallergenic
				Calcium 53		Defecation frequency	feeding, because of suspected cow's
				Phosphorus 29		(mean)	milk protein allergy. Parents of 1 patient
				Sodium 23			decided that they did not want to cross-
				Potassium 82		SF (n =12): 5.9/week	over because she was free of symptoms
				Chloride 44		NF (n =12): 5.5/week	and they started openly with NF instead.
				Iron 0.5			3 patients dropped out after switching to
				Zinc 0.5		Difference of means	NF; 2 patients stopped after less than 1
						(95% CI):	week because of recurrence of
				Comparison:		- 0.5 (-1.6 to 0.6)	constipation symptoms. 1 patient was
				Standard formula		N.S	lost to follow-up. 7 patients dropped out
				(SF, mixture of			after switching to SF; 6 patients stopped
				75% Nutrilon I		Frequency of soft	after 1 week because of recurrence of
				and 25% Aptamil		stools:	constipation symptoms. 1 patient was
				HA I)		17% (n = 4) of infants	lost to follow-up
						had soft stools when	
				Energy (kcal) 67		receiving NF but hard	Data analysis based on the group of 35
						stools with SF,	patients that completed period 1 and a
				Protein (g) 1.5		compared to no infant	subgroup analysis of 24 patients who
				Casein 0.5		with soft stools when	completed the cross-over
				Intact whey		receiving SF and no	
				protein 0.6		infant with hard stools	No significant differences in baseline
				Whey protein		with NF (p = 0.046)	characteristics between 2 groups
				hydrolysate 0.4			
						Painful defecation	During both periods parents asked to
				Fat (triglycerides)		not significantly	daily record in a diary details on formula
				(g) 3.5 3.3		different between the	intake, formula tolerance (vomiting,
				Palmitic acid 0.6		periods	flatulence, colic, rash), passage of stools
				- at the sn-2		on NF and SF	and stool
				position (%) 11.5			consistency compared to 4 validated
				Linoleic acid 0.4		Safety	photographs of runny, mushy soft,
				α-linolenic acid		I hroughout the study	formed soft and hard stools
				0.07		there were no serious	
				.		adverse effects in	Reviewer comments:
				Carbohydrates (g)		either group. Both	Allocation concealment method not

Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
				7.3 Lactose 7.2 Maltodextrin - Starch – Fibre (g) - Oligosaccharides (90% GOS, 10% IcFOS) – Minerals and trace elements (mg) Calcium 53 Phosphorus 29 Sodium 22 Potassium 69 Chloride 42 Iron 0.5 Zinc 0.5		formulas were well tolerated	described Study not controlled for potential confounders <u>Source of funding:</u> study supported by a grant of Nutricia Nederland BV, Zoetermeer, The Netherlands
				Feeding patterns not described			

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Savino et al.	Study Type:	604 children	604 children	Intervention:	Duration of	Stool frequency	Additional information from study:
"Minor" feeding	Prospective		(232 with	New formula (NF)	treatment	232 infants with	Constipation defined as a stool
problems during	case series	Inclusion	constipation)		14 days	constipation	frequency of less than 1 stool a day
the first months		criteria:		Composition per			
of life: Effect of	Evidence	Formula-fed	age at entry	100 ml	<u>Assessment</u>	-increase in number	Parents given a questionnaire in order to
a partially	level:	healthy term	(months, total		point (s):	of stools per day	monitor frequency of symptoms, feeding
hydrolysed milk	3	infants up to 3	population):	Energy: 70 kcal	On days 1, 7	during study period:	volume and side effects. Number of
formula		months of	1.35 ± 0.77	Protein equivalent	and 14	147 infants (63.4%)	stools were recorded daily
containing	Study aim:	age seen by		(g): 1.7			
fructo- and	To investigate	paediatrician	gender not	Casein: whey:	Follow-up	-average increase:	A total of 932 infants enrolled: 604
galacto-	whether a	because of	reported	100% whey	period:	0.42 (CI 95%: 0.55 to	completed the study protocol. A total of
oligosaccharide	new infant	colic and/or		hydrolysate	No follow-up	0.27; p<0.005)	358 infants excluded from study: 154
s. 2003. Acta	formula	constipation	Country:		conducted after		completed only the first step and did not
Paediatrica	commercially	and/or	Italy	Carbohydrate (g):	treatment	-average increase	return for the visit on day 14, 131 infants
Supplement	available in	regurgitation.		8.4	finished	between day 1 and	excluded because of incomplete data.
91[441], 86-	Italy is useful	Normal birth		Lactose:2.9		day 7: 0.41 (CI 95%:	73 infants required medication during
90Norway.	as a dietary	weight (>2500		Maltodextrine: 4.0	<u>Outcome</u>	0.51 to 0.23; p<0.05)	the 1rst week of study and were
	option in	g), normal		Starch: 1.5	Measures:		therefore excluded
	infants with	weight gain (≥				-average increase	
	minor feeding	150g/week)		Prebiotic	-stool frequency	between day 7 and	Reviewer comments:
	problems	and normal		oligosaccharides		day 14: 0.04 (NS)	No description of the scoring system
		physical		(g): 0.8	-parents'		used to evaluate parent's satisfaction
		examination		_	evaluation of	-no improvement of	was provided
				Fat (g): 3.3	formula	symptoms: 85 infants	
		Exclusion		Palmitic acid:0.60		(26.6%)	Source of funding:
		criteria:					Not stated
		Neonatal		Minerals (mg)		Mean parent	
		problems, use		Sodium: 23		evaluation of formula	
		of any kind of		Potassium: 66			
		medication		Chioride: 50		7.9 ± 1.8	
		the week		Calcium: 53		550 (040()	
		before the		Phosphorus: 31		550 parents (91%)	
		beginning of		Iron: 0.5		gave a positive	
		the study or		ZINC: 0.5		judgement (score 6 to	
		auring the		Feeding veloces		10)	
		study period		reeaing volume			
				based on a			
				reeding ad libitum			

Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
				procedure. Feeding frequency decided by the parents and not influenced by the study protocol			

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Pina et al.	Study Type:	3487 children	604 children	Intervention:	Duration of	91.6% of cases of	Additional information from study:
Prevalence and	Prospective	(total	(with	Novalac Anti-	treatment	constipation resolved	Study on effectiveness included 2069
dietetic	case series	population)	constipation)	Constipation:	30 days	within 7 days	infants with MGDs. Effectiveness was
management of				formula with			evaluated among 1441 infants who
mild	Evidence	Inclusion	52.2% boys (of	adapted	Assessment	Number of daily	completed follow-up. Premature study
gastrointestinal	level:	criteria:	the total	concentration of	point (s):	stools (mean ± SD)	termination due to adverse events in
disorders in	3	Infants up to	population)	magnesium and	Immediately	Baseline: 0.6 ± 0.7	2.7% cases, parent decision in 6.9%,
milk-fed infants.		4 months of	age at	lactose	after treatment	At 30 days: 1.7 ± 0.8	loss to follow-up in 1.64%, protocol
2008. World	Study aim:	age fed with	consultation: 1		was completed		violations in 2.46% and non-specified
Journal of	To assess the	artificial milk	week to 17	No other details		Type of stools (%	reasons in 16.62%
Gastroenterolog	prevalence of	formulas,	weeks (total	regarding feeding	Follow-up	<u>children)</u>	
y 14[2], 248-	mild	presence of	population)	volume/frequency	period:		A questionnaire addressing the different
254China.	gastrointestin	MGDs,		were provided	No follow-up	-Normal:	symptoms and their intensity was
	al disorders	possibility of	Country:		made after	Baseline: 33.40	designed for each disorder
	(MGDs) in	feeding	Spain	Comparison:	treatment	At 30 days: 95.60	
	milk-fed	infants with		N.A	finished		Satisfaction of parents/tutors with the
	infants in	some product				-Hard	formulas assessed on final visit by
	paediatric	of the			Outcome	Baseline: 66.60	means of a Likert-type scale with 5
	practice and	Novalac line			Measures:	At 30 days: 4.40	possible answers: from very satisfied to
	to evaluate	of formulas,					very dissatisfied
	the	continuation			-type of stools	Presence of pain or	
	effectiveness	of these				discomfort (%	Reviewer comments:
	and	formula on an			-presence of	<u>children)</u>	No definition of constipation given
	satisfaction	exclusive			pain or		
	with dietetic	basis for at			discomfort	-Yes:	Not completely clear how outcomes
	treatment:	least 30days				Baseline: 90.00	were measured and who measured
	specifically	with no			-external help	At 30 days: 10.40	them
	elaborated	incorporation			needed for		
	formulas	of other foods			defecation	-No:	No definition of "resolved case" given
	belonging to	to the diet				Baseline: 10.00	
	the Novalac				-satisfaction of	At 30 days: 89.60	Source of funding:
	line of	Exclusion			parents/tutors		Not stated
	products	criteria:				External help needed	
		Not clearly			-adverse events	for defecation	
		stated				-Yes:	
						Baseline: 76.10	
						At 30 days: 8.80	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
						-No:	
						Baseline: 23.90	
						At 30 days: 91.20	
						-satisfaction of	
						parents/tutors:	
						90.0% of parents	
						satisfied with	
						treatment	
						Adverse events (for	
						<u>all formulas, no</u>	
						subgroup analysis):	
						Reported in 3.9%	
						infants of total	
						population. Most	
						frequent affected	
						digestive tract (1.4%),	
						including diarrhoea	
						and constipation, and	
						respiratory apparatus	
						(0.7%) (E.g.	
						bronchiolitis and	
						bronchitis). 10 infants	
						(0.5%) required	
						nospital admission for	
						septicaemia (n=1),	
						denydration $(n=2)$,	
						vomiting (n=1), nernia	
						(n=1) and bronchitis	
						or bronchiolitis (n=2)	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Chao et al.	Study Type:	93 children	93 children	Intervention:	Duration of	Improved (number	Additional information from study:
Therapeutic	Open label		47 boys	Magnesium-	treatment	and % of children)	Study non-blinded, according to authors
effect of	RCT	Inclusion	mean age 3.8 ±	enriched infant	2 months	-At 2 weeks:	this was not possible because all infants
Novalac-IT in		criteria:	1.7 months	formula, Novalac-		Novalac-IT (n=47):	were included in 1 centre
infants with	Evidence	Children aged		IT	Assessment	31 (66)	
constipation.	level:	2 to 6 months	Country:		point (s):		Randomisation performed applying an
2007. Nutrition	1-	referred to	Taiwan	Composition per	At 2 weeks, 1	Strengthened formula	envelope drawing system
23[6], 469-473		paediatric		100 mL:	month and 2	(n=46): 23 (50)	
	Study aim:	gastroenterol			months	N.S	Assigned nurse educated the family to
	To evaluate a	ogy clinic at		Energy (cal/100			prepare the 20% strengthened formula
	commercialise	medical		mL): 70.7	Follow-up	-At 1 month:	(20% extra formula) (regular
	d formula,	centre with			period:	Novalac-IT (n=47):	concentration of the formula is 13%)
	Novalac-IT	constipation ≥		Protein (g): 1.70	No follow-up	39 (83)	
	(Intestinal	2 weeks, fed		Whey/casein:	conducted after		No significant differences in baseline
	Transit, Paris,	exclusively		60/40	treatment	Strengthened formula	characteristics (clinical or demographic)
	France)	with formula.			finished	(n=46): 23 (50)	between the 2 groups
	against a	Participation		Fat (g): 3.54		P=0.002	
	"strengthened	in trial			<u>Outcome</u>		Intake of formula and clinical parameters
	regular	proposed		Carbohydrates	Measures:	-At 2 months:	regarding constipation and weight and
	formula", the	before a		(g): 8.06	Remission /	Novalac-IT (n=47):	all relevant information recorded by
	traditional	more		100 % Lactose	improvement /	42 (89)	family daily in a diary during the entire
	approach in	complete			failure		intervention period
	infants with	diagnostic		Major minerals	according to	Strengthened formula	
	digestive	workup for		(mg)	severity scoring	(n=46): 25 (54)	Severity scoring system developed and
	problems in	cow's milk		Sodium 17.46	system based	P<0.001	evaluated in pilot study:
	Taiwan	protein		Potassium 61.58	on stool		Hard stool: 0, no hard stool; 1, hard and
		allergy,		Chloride 43.40	consistency,	Good response	long form, 2;
		Hirschsprung'		Calcium 60.87	frequency and	(number and % of	Difficulties with defecation: 0, no
		s disease and		Phosphate 31.46	volume of	<u>children)</u>	difficulties; 1, irritability; 2, crying
		others		Magnesium 9.12	stools and	-At 2 weeks:	Frequency of defecation: 0, >3
					difficulties in	Novalac-IT (n=47):	times/week; 1, 1 to 3 times/week; 2, <1
		Exclusion		Osmolality: 300	defecation (1 to	17 (36)	time/week
		criteria:			3 mild		Stool weight (g//kg/week): 1, >35; 2, 20
		unclear		Comparison:	constipation; 4	Strengthened formula	to 35; 3, <20
				20% strengthened	to 6 moderate;	(n=46): 13 (28)	
				Novalac regular	7 or 8 severe)		Reviewer comments:
				infant formula		-At 1 month:	No sample size calculation performed
					-Remission:	Novalac-IT (n=47):	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
				Composition per	asymptomatic	22 (47)	Irrelevant reason given for non-blinding
				100 mL			the study
					-Good	Strengthened formula	
				Energy (cal/100	response:	(n=46): 11 (24)	Unclear how both formulas were
				mL): 78	decrease in		administered
					severity of ≥ 2	Fair response	
				Protein (g): 1.89	F -:	(number and % of	No dropouts/lost to follow-up reported
				wney/casein:	-Fair response:	<u>children)</u>	Cturly not controlled for notontial
				50/50	decrease in	-At 2 weeks:	Study not controlled for potential
				$E_{ot}(a): 2.06$	sevenity of 1 to	(n=47):	confounders
				rai (y). 3.90	3	14 (30)	Source of funding:
				Carbohydrates	-Failure: if score	Strengthened formula	Not stated
				(a) · 8 69	did not change	(n-46)· 10 (22)	Intestinal Transit provided free samples
				70% Lactose	or increased	(11-40). 10 (22)	of Novalac-IT formula According to
				30%		-At 1 month	authors there was no other grant from
				Maltodextrin		Novalac-IT (n=47):	the company, which was neither
						17 (36)	involved in the design of the study
				Maior minerals		()	, , , , , , , , , , , , , , , , , , ,
				(mg)		Strengthened formula	
				Sodium 21.24		(n=46): 23 (50)	
				Potassium 70.20			
				Chloride 46.80		Not improved	
				Calcium 70.20		(number and % of	
				Phosphate 42.12		<u>children)</u>	
				Magnesium 7.02		-At 2 weeks:	
						Novalac-IT (n=47):	
				Osmolality: 300		16 (34)	
						Strengthened formula	
						(n=46): 23 (50)	
						At 1 month:	
						-At 1 month. Novalae $IT (n=47)$:	
						(1) = (1)	
						Strengthened formula	
						(n=46): 23 (50)	

Bibliographic S Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
						Symptoms free (number and % of children) -At 2 weeks: Novalac-IT (n=47): 18 (38) Strengthened formula (n=46): 12 (26) N.S -At 1 month: Novalac-IT (n=47): 28 (60) Strengthened formula (n=46): 16 (35) P=0.029 -At 2 months: Novalac-IT (n=47): 35 (75) Strengthened formula (n=46): 18 (39) P<0.001	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Savino et al.	Study Type:	123 children	95 children	Intervention:	Duration of	Stool frequency	Additional information from study:
Advances in the	Open label		50 boys	New formula (NF)	treatment	(number/day) (mean	Constipation defined as a stool
management of	RCT	Inclusion			14 days	<u>+ SD)</u>	frequency of less than 1 stool a day
digestive		criteria:	age at study	Composition per		-at study entry	
problems during	Evidence	Formula-fed	entry (months)	100 ml (Omneo /	<u>Assessment</u>	NF group (n=55):	Parents given a structured questionnaire
the first months	level:	healthy term		Conformil):	point (s):	0.53 ± 0.5	in order to monitor frequency of
of life. 2005.	1-	infants up to 4	-intervention		On days 1, 7		symptoms, feeding volume and side
Acta		months of	group:	Energy: 70 kcal	and 14	SF group (40):	effects
Paediatrica	Study aim:	age with	1.55 ± 0.88	Protein equivalent		0.60 ± 0.5	
94[SUPP 449],	To evaluate	constipation		(g): 1.7	Follow-up	N.S	No significant differences in baseline
120-	the efficacy		 -control group: 	Casein: whey:	period:		characteristics between the 2 groups
124Norway.	on digestive	Exclusion	1.28 ± 0.66	100% whey	No follow-up	-on day 7	
	problems of a	criteria:		hydrolysate	conducted after	NF group (n=55):	When an infant eligible to study came to
	formula based	Neonatal	<u>Country:</u>		treatment	1.79 ± 0.96	the doctor, child was randomly assigned
	on palmitic	problems	Italy	Carbohydrate (g):	finished		to the study or the control group, the
	acid	and/or any		8.4		SF group (40):	next infant with the same symptoms was
	predominantly	assumption of		Lactose:2.9	<u>Outcome</u>	1.31 ± 0.89	matched to the previous infant and
	esterified at	any kind of		Maltodextrine: 4.0	Measures:		assigned to the other group
	the β -position,	medication		Starch: 1.5		difference:	
	oligosaccharid	the week			-stool	0.48 (CI 95%: 0.09;	28 children excluded after randomisation
	es (GOS and	before the		Prebiotic	characteristics :	0.87)	because at entry they had more than 1
	FOS) with a	beginning of		oligosaccharides	frequency and	p=0.02	evacuation
	prebiotic	the study and		(g): 0.8	consistency		
	activity,	during the		_		-on day 14	Reviewer comments:
	partially	study period		Fat (g): 3.3		NF group (n=55):	Sample size calculation not performed
	hydrolysed			Palmitic acid:0.60		2.04 ± 1.04	
	protein, low						Inadequate randomisation
	lactose			Minerals (mg)		SF group (40):	
	content and			Sodium:23		1.64 ± 0.99	Allocation concealment not described
	higher density			Potassium: 66			
				Chloride: 50		difference:	Study not reported as blinded
				Calcium: 53		0.40 (CI 95%: -0.03;	
				Phosphorus: 31		0.83)	Stool consistency post- treatment not
				Iron: 0.5		p=0.07	reported
				∠inc: 0.5			
						Mean difference in	No aropouts/lost to follow-up children
				Comparison:		stool frequency	reported
				Standard formula		between the 2 groups	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Measures		
Information	Level	Patients	S	Comparison (SF) (composition not reported in paper) Feeding volume based on a feeding <i>ad libitum</i> procedure. Feeding frequency decided by the parents and not influenced by the study protocol	Outcome Measures	adjusted for gender, age at entry, maternal instruction, parity, birth weight , number of feedings/day and stool frequency at entry -Days 0 to 7: 0.60 (CI 95%: 0.19; 1.01) p=0.004 -Days 0 to 14: 0.53 (CI 95%: 0.11; 0.90) p=0.015	Source of funding: not stated

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Kokke et al. A	Study Type:	135 children	97 children	Intervention:	Duration of	Defecation	Additional information from study:
dietary fiber	Double-blind			Yogurt drink with	treatment	frequency/week(Randomisation performed by use of
mixture versus	RCT	Inclusion	fibre mix group	mixed dietary fibre	8-week	<u>mean)</u>	sequential numbers allocated to patients
lactulose in the		criteria:	(n=42):	(10g/125mL)	intervention	-At 8 weeks:	at study entry and coordinated by the
treatment of	Evidence	Constipated	20 boys		period	Fibre (n=42): 7	logistic manager of Numico Research
childhood	level:	children	median age: 5.5	-Fibre mixture			using a block design
constipation: a	1+	referred to	years (1 to 12	(per 100mL):	4-week	Lactulose (n=55): 6	
double-blind		hospital	years)	3.0 g	weaning period	N.S	Bottles with yogurt prepared and packed
randomized	Study aim:	outpatient		transgalacto-			by Numico Research and transported to
controlled trial.	To assess the	clinic for	lactulose group	oligosacharides	<u>Assessment</u>	Number of patients	hospital. Treatment products could not
2008. Journal of	clinical	constipation	(n=55):	3.0 g inulin	<u>point (s):</u>	with ≥ 1 faecal	be distinguished from each other with
Pediatric	efficacy and	who fulfilled	23 boys	1.6 g soy fibre	At 3, 8 and 12	incontinence	respect to colour, taste or consistency
Gastroenterolog	safety of a	at least 2 of 4	median age 5.0	0.33g resistant	weeks	episodes/week	
y and Nutrition	dietary fibre	criteria for	years (1 to 12	starch 3		-At 8 weeks:	Sample size based on primary outcome
47[5], 592-597	mixture and	constipation:	years)		Follow-up	Fibre (n=42): 9	variable, defecation frequency. It was
	compare it	stool	_	Comparison:	period:		calculated that a random allocation of
	with lactulose	frequency <3	Country:	Yogurt drink	No follow-up	Lactulose (n=55): 5	150 children would allow for the
	in the	times/week,	The	containing	conducted after	N.S	detection of a mean difference in
	treatment of	faecal	Netherlands	lactulose(10g/125	treatment		defecation of 1.0/week between the 2
	childhood	incontinence		mL) (Duphalac	finished	Stool consistency	groups
	constipation	≥2		Lactulose)		(mean)	
		times/week,			<u>Outcome</u>	-At 3 weeks:	No significant differences found in
		periodic			Measures:	Fibre (n=42): 3.5	baseline characteristics between the 2
		passage of					groups with a power of 80% and
		large		Both products	1. primary	Lactulose (n=55): 4.5	alfa=0.05
		amounts of		taken at breakfast	outcome:	P<0.01	
		stool at least		and in case of ≥ 2			Defecation noted on a daily basis during
		once very / to		bottles also at	-defecation	-At 8 weeks:	treatment period. Faecal incontinence
		30 days, or a		lunch	frequency/week	Fibre (n=42): 3.6	each day assessed "yes" or "no", stool
		palpable			a 1		consistency according to Bristol Stool
		abdominal or		Amount of	2. secondary	Lactulose (n=55): 4.0	Form Scale. Data recorded daily in
		rectal mass		fibre/fluid intake	outcomes:	P=0.01	bowel diary by parents or patients.
		Evelue:		daily depended on	faces	Number of a start	
				patient's body	-iaecal	inumber of patients	Adverse effects defined as any adverse
		<u>criteria</u> :		weight:		using step-up	change from baseline (pre-treatment)
		organic		Intoriontics	each day	At 2 weeks:	condition, which occurred during the
		causes of		intervention	ataal	-AL 3 WEEKS:	course or the study after treatment
		derecation		perioa:	-51001	Fibre (n=42): 13	started, whether it was considered to be

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
		disorders		<15 kg: 1 bottle	consistency		related to treatment
		including		(125 mL, 10g		Lactulose (n=55): 7	
		Hirschsprung'		fibres)	-use of step-up	P=0.028	33 patients dropped-out during study
		s disease,			medication		period: 22 in fibre group after 1 to 56
		spina bifida,		15 to 20kg: 2		-At 8 weeks:	days (median 7) and 11 in lactulose
		hypothyroidis		bottles (250 mL,	-adverse effects	Fibre (n=42): 20	group after 1 to 51 days (median 8)
		m or other		20g)			(p=0.020). Those patients refused to
		metabolic/ren				Lactulose (n=55): 21	drink the yogurt. 3 patients lost to follow-
		al		>20 kg: 3 bottles		N.S	up: 1 fibre, 2 lactulose. 2 exclusions
		abnormalities,		(375 mL, 30g)			after randomisation in lactulose group: 1
		mental				-At 12 weeks:	coeliac disease, 1 spina bifida occulta
		retardation,		Weaning period:		Fibre (n=42): 21	
		use of drugs		<15 kg: 0.5			Reviewer comments:
		influencing		bottle/day (week 9		Lactulose (n=55): 26	Method of allocation concealment not
		gastrointestin		& 10); 0.5 every		N.S	described
		al function		other day (week			
		other than		11 &12)		Adverse effects	Study not controlled for potential
		laxatives, use				No serious or	confounders
		of lactulose,		15 to 20kg: 1		significant side effects	
		other		bottle/day (week 9		recorded	Unclear how adverse effects were
		laxatives,		& 10); 1 every			recorded.
		prebiotics,		other day (week		Fibre (n=42): 1 dose-	
		probiotics or		11 &12)		related persistent	ITT analysis not performed
		antibiotics in				diarrhoea	
		the previous 4		>20 kg: 2			Source of funding:
		weeks before		bottles/day (week		Lactulose (n=55): 2	The Scientific Research Foundation
		the first visit		9 & 10); 1		dose-related	project SW) 2001.
				bottle/day (week		persistent diarrhoea	One author received financial support
				11 &12)			throught project no.9.001, which is a
							subproject of Business aimed
				If persistent			Lechnological Cooperation project
				diarrnoea			00176. 2 authors were researchers and
				reported, original			employees of Danone Research BV
				ause reduced by			(Iormerly Numico Research BV)
				50%			
				If clinical			
				noremetere			
				parameters			

Bibliographic Information	Study Type & Evidence	Number of Patients	Patient Characteristic	Intervention & Comparison	Follow-up & Outcome	Effect Size	Reviewer Comments
	Level		S	compared to baseline did not improve 3 weeks after start of intervention period, step-up medication (Macrogol 3350) given per protocol	Measures		
				1			

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Loening-Baucke	Study Type:	31 children	31 children	General	Duration of	Children with <3	Additional information from study:
et al. Fiber	Double-blind			Disimpaction with	treatment	BMs/week (%)	Constipation defined as a delay or
(glucomannan)	RCT (cross-	Inclusion	16 boys	1 or 2 phosphate	2 treatment	Placebo (n= 31): 52%	difficulty in
is beneficial in	over)	<u>criteria:</u>		enemas if rectal	periods of 4	Fibre (n= 31): 19%	defecation, present for >2 weeks, and
the treatment of		Otherwise	age: 4.5 to 11.7	impaction felt	weeks each	P<0.05	sufficient to cause significant distress to
childhood	Evidence	healthy	years (mean:	during rectal			child
constipation.	level:	children older	7.1 ± 2.0 years)	examination	Assessment	Stool consistency	
2004. Pediatrics	1+	than 4 years		(58% of patients	point (s):	Initial (n= 31): 0.3 ±	Encopresis defined as the involuntary
113[3 Pt 1],		who had	Countries:	continued with	At 4 and 8	0.9	loss of formed, semiformed, or liquid
e259-e264	Study aim:	chronic	USA & Italy	their	weeks	Placebo (n= 31): 1.2	stool into the child's underwear in the
	to evaluate	functional		preevaluation		± 0.9	presence of functional constipation after
	whether fiber	constipation		laxative during	Follow-up	Fibre (n= 31): 1.5	the child
	supplementati	for ≥6 months		whole study	period:	±0.9	has reached the age of 4 years
	on with	with or		period)	No follow-up	P<0.05 as compared	
	glucomannan	without			conducted after	to initial data	It had been previously calculated that at
	is beneficial in	encopresis		Intervention:	treatment		α =0.05; 26 subjects would allow a power
	the treatment			Glucomannan B:	finished	Children with	of approximately 0.95 to detect a
	of children	Exclusion		capsule		encopresis	difference of 0.7 versus 0.2 in achieving
	with functional	<u>criteria</u> :		containing	<u>Outcome</u>	Initial (n= 31): 58%	normal bowel patterns in the crossover
	constipation	Hirschsprung'		glucomannan, a	Measures:	Placebo (n= 31): 48%	design
		S		polysaccharide of	-efficacy:	Fibre (n= 31): 42%	
		disease,		d-glucose and d-			Patients randomized by envelope into 1
		hypothyroidis		mannose, equal	changes in	Frequency of soiling	of 2 treatment arms. Blinding done by
		m, mental		to 450 mg of	frequency of	episodes/wk (n=18)	having the medication labelled
		deficiency,		alimentary fibre.	bowel	Initial (n=18): <u>9.9 ±</u>	glucomannan A and glucomannan B
		chronic			movements	12.3	with the code kept by the company until
		debilitating		Comparison:	(BMs)	Placebo (n= 18): 4.2	study was completed and analyzed.
		diseases,		Glucomannan A:		± 4.8	Glucomannan A was a capsule
		neurological		capsule	soiling	Fibre (n= 18): 4.0 ±	containing maltodextrins as placebo.
		abnormalities,		containing	frequency	6.3	Glucomannan B was a capsule
		previous		maltodextrins as		P<0.05 as compared	containing glucomannan, a
		surgery of the		placebo.	-successful	to initial data	polysaccharide of d-glucose and d-
		colon or anus			treatment		mannose, =450 mg of alimentary fibre
				Group 1: placebo		Successful treatment	
				first and then	-parents' global	Placebo (n= 31): 13%	Patients and their parents kept diary
				glucomannan	assessment	Fibre (n= 31): 45%	sheets during the 8 weeks of study.
						P<0.05 as compared	They recorded daily each BM, soiling
				Group 2:	-overall	to placebo treatment	episode, abdominal pain episode, and

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
				glucomannan first	tolerance and		medication used and reported at the end
				and then placebo	palatability	Improved (parent	of each treatment period the associated
						rating)	subjective symptoms such as stool
				-Placebo and	-safety: side	Placebo (n= 31): 13%	consistency, new occurrence of
				glucomannan	effects	Fibre (n= 31): 68%	abdominal pain, bloating, abdominal
				doses:		P<0.05 as compared	distension, excessive gas, or diarrhoea.
				100 mg/kg body		to placebo treatment	Stool consistency was assessed rating
				weight daily			the stool consistency as hard like rocks,
				(maximal 5		Outcomes controlled	pellets= 0, firm = 1, soft like banana = 2,
				g/day), rounded to		for confounders	loose like milkshake = 3 , and watery = 4
				the nearest 500		-successful treatment	
				mg, because each		(physician rating) and	Successful treatment rated by physician
				capsule contained		improvement (parent	and defined as \geq 3 bowel movements
				500 mg. Each		rating)independent of	per week and \leq 1 soiling episode in the
				capsule either		low or acceptable	last 3 weeks with no abdominal pain.
				opened and		fibre intake (P>0.6)	Parents' global assessments: whether
				sprinkled on food			they believed that the child was better
				given with 50 mL		- more children with	during the first or second treatment
				of fluid per		encopresis in the	period
				capsule; given as		laxative group (78%	
				a solution,		vs. 31%; P<0 .02),	No significant differences in baseline
				whereby the		and significantly more	characteristics between the 2 groups
				content of each		children in the	
				500-mg capsule		laxative group were	46 children originally recruited. 13
				was mixed with 50		treated successfully	children did not show up for the 4-week
				mL of fluid of the		with fibre than with	follow-up: 7 children randomized to
				child's choice; or		placebo	placebo first and 6 children randomized
				swallowed as a		(P <0 .01)	to fibre first. 2 constipated girls
				capsule with 50			completed the first 4 weeks of the study
				mL of fluid for		- Children with	only: 1 received placebo and 1 received
				each capsule.		constipation only	fibre; both recovered from chronic
						were significantly	constipation and abdominal pain during
				in addition,		more likely to be	the first 4 weeks of treatment and did
				parents instructed		treated successfully	the 42 shildren who entered the study
				to nave the child		WITH TIDIE	the 13 children who entered the study
				sit on the tollet 4		(09%) than those with	and were randomized but did not come
				times daily after		constipation and	for follow-up and the 2 children who did
				meals and to keep		encopresis (28%;	not complete the study were excluded

Bibliographic	Study Type &	Number of Patients	Patient Characteristic	Intervention &	Follow-up &	Effect Size	Reviewer Comments
internation	Level	i atiento	S	Companson	Measures		
				a stool diary. No enemas given during each treatment period, unless rectal disimpaction felt during rectal examination at assessment visits		P<0.04) <u>Safety</u> No significant side effects such as new onset of abdominal pain, bloating, abdominal distension, excessive gas, diarrhoea, or anaphylactic symptoms reported	from the analysis. Initial data of these 15 children not significantly different from the data of the 31 children who completed the study, except soiling frequency per week was significantly less (4.0 ± 1.4; P<0 .001). Data analysis includes 31 children with functional constipation with or without encopresis <u>Reviewer comments:</u> No definition of soiling given. Unclear how different this would be from the authors' definition of encopresis High dropout rate: 28%. ITT analysis not performed <u>Source of funding:</u> DicoFarm (Rome, Italy) provided research support and the medications for the study

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Castillejo et al.	Study Type:	56 children	56 children	Intervention:	Duration of	No. of bowel	Additional information from study:
A controlled,	Double-blind			cocoa husk	treatment	movements per week	Chronic functional constipation defined
randomized,	RCT (pilot	Inclusion	22 boys	supplement rich	4 weeks	(mean ± SD)	in accordance with Rome II diagnostic
double-blind	study)	criteria:	Mean age 6.3 ±	in dietary fibre +		Difference (95% CI):	criteria, by the presence, for at least 12
trial to evaluate		Children aged	2.2 years	standardized toilet	Assessment		(not necessarily consecutive) weeks in
the effect of a	Evidence	3 to 10 years		training	point (s):	0.67 (-0.76 to 2.10)	the preceding 12 months, of at least 2 of
supplement of	level:	referred to	Country:	procedures	Immediately	p=0.780	the following symptoms: straining in
cocoa husk that	1+	pediatric	Spain		after treatment		>25% of defecations; lumpy or hard
is rich in dietary		gastroenterol		1 sachet (5.2 g):	finished	-Cocoa husk group	stools in >25% of defecations; a
fiber on colonic	Study aim:	ogy		4 g cocoa husk +		Basal (<i>n</i> =24): 3.86	sensation of incomplete
transit in	to evaluate	outpatients'		1 g	Follow-up	±2.05	evacuation in >25% of defecations; a
constipated	the effect of a	clinic between		betafructosans	period:	Final (<i>n=</i> 24): 6.16	sensation of anorectal
pediatric	palatable	January 2004			No follow-up	±3.35	obstruction/blockage in >25% of
patients. 2006.	cocoa husk	and April		(53.2 g of fibre	made after	Difference (95% CI):	defecations; a need for manual
Pediatrics	supplement	2005 with		(39.6 g of total	treatment	2.40±3.16	maneuvres to facilitate >25% of
118[3], e641-	that is rich in	chronic		fibre and 13.6 g of	finished		defecations (e.g., digital evacuation,
e648	fibre on	constipation		betafructosans)		-Placebo group	support of the pelvic floor); and <3
	intestinal			per 100 g of	Outcome	Basal (<i>n=</i> 24): 3.18±	defecations per week
	transit time	Exclusion		product. Insoluble	Measures:	1.93	
	and other	criteria:		fibre 37.2% and	-number of	Final (<i>n=</i> 24): 5.08	Treatment was blinded to both patients
	indices of	presence		soluble fibre 2.4%	bowel	±2.10	and investigator until the study was
	constipation	of fecal		of total fibre	movements per	Difference (95% CI):	completed and analyzed. Patients
	in children	impaction that		Cellulose and	week	1.73 ±1.73	randomly assigned to treatment 1 or 2 in
	with idiopathic	required		uronic acids the			a ratio of 1:1. A randomization list was
	chronic	enema in the		main type of	-stool	Hard stool	designed by the manufacturers of the
	constipation	7 days		insoluble fibre and	consistency	consistency (%	supplement and the placebo (Madaus
		before the		soluble fibre,		<u>children)</u>	SA) using a computer random-number
		start of the		respectively)	-pain with	-Cocoa husk group	generator in 20 blocks of 4 patients
		study,			defecation	Basal (<i>n=</i> 24): 95.8	each. The details of the randomization
		treatment with		Comparison:		Final (<i>n=</i> 24): 41.7	codes were kept in sealed envelopes
		dietary fibre,		placebo +	-safety		away from the investigators. Only in
		bulk-forming		standardized toilet		-Placebo group	cases of the utmost necessity (eg,
		agents, or		training		Basal (<i>n=</i> 24): 95.8	serious adverse events) did the
		laxatives in		procedures		Final (<i>n=</i> 24): 75.0	coordinator of the study allow the
		the 2 weeks				P=0.017	investigator to know the treatment
		before the		1 sachet (5.2 g):			assigned to the patient
		start of the		glucose, cocoa		Subjective	
		study,		flavouring, and		improvement in stool	Because of lack of previous studies and

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
		constipation		excipients		consistency (n	likelihood of methodological difficulties
		attributable				<u>children)</u>	(in the evaluation of the main
		to organic or		-doses for both		P=0.039	parameters)
		anatomic		products:			in carrying out a study on this kind of
		causes				Cocoa husk group	population, authors designed a pilot
		(Hirschsprung		Children aged 3 to		(<i>n</i> =24)	study with a minimum sample from the
		's disease,		6 years: 1 sachet		Improvement : 14	statistical point of view
		hypothyroidis		before lunch and		No Improvement: 10	
		m, mental		1 sachet before			Fibre supplement and placebo
		deficiency,		dinner		Placebo group (<i>n</i> =24)	administered as a soluble powder in
		psychiatric				Improvement : 6	sachets of identical weight (5.2 g) and
		illnesses,		Children aged 7 to		No Improvement: 18	presentation
		chronic		10 years: 2		Subjective	
		debilitating		sachets		improvement in pain	At baseline and after 4 weeks of
		diseases,		before lunch and		P=0.109	treatment, investigators evaluated bowel
		neurologic		dinner		Cocoa husk group	movement habits and stool consistency
		abnormalities,		-		(<i>n</i> =24)	using a diary completed by patients
		or previous		Parents instructed		Improvement : 16	parents; and received a subjective
		surgery of the		to dissolve		No Improvement: 8	evaluation from the parents regarding
		colon or		content of the		Placebo group	the efficacy of the treatment. Adherence
		anus), renal		sachets in 200 mL		(<i>n=24</i>)	to the intervention evaluated by the
		insufficiency,		of whole milk		Improvement : 11	same investigator using a visual
		nypocaicemia		before ingestion		No Improvement: 13	analogical scale (In the case of
		, humanicalanaia				Catati	standardized tollet training procedures)
		nyperkalemia,				<u>Salety</u>	and counting the empty sachets that
						NU SIGNINCAN	were returned
		diagona at				adverse ellects, such	No significant differences in baseling
		the start of				as a new onset of	characteristics between the 2 groups
		the study:				bloating abdominal	characteristics between the 2 groups
		long-term use				distansion excessive	8 children withdrew from study before its
		of drugs that				disterision, excessive	completion (5 children discontinued
		affect				ananhylactic	study because of the difficulty of the
		astrointestin				symptoms reported	protocol and 3 were excluded because
		al motility (eq				during the 4-week	of the presence of positive antigliadin
		imipramine				period with either	and antiendomysium
		iron or				treatment	antibodies). Data refer only to 48
		calcium				No significant	participants who completed the study

Bibliographic Information	Study Type & Evidence	Number of Patients	Patient Characteristic	Intervention & Comparison	Follow-up & Outcome	Effect Size	Reviewer Comments
		supplements, anticonvulsan ts), inability to adhere to the study's medications or procedures				changes between groups in relation to hemoglobin concentrations; hematocrit; serum ferritin; or plasma levels of zinc, iron, or calcium	Reviewer comments: Study not controlled for potential confounders ITT analysis not performed Source of funding: Study supported by Madaus, SA, and by grants from the Instituto de Salud Carlos III, Red de Centros RCMN (C03/08), and Red de Grupos (G03/140), Madrid, Spain. One author had received consulting or lecture fees from Madaus Laboratories and another one belonged to Madaus Laboratory

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Staiano et al.	Study Type:	20 children	20 children	General:	Duration of	Number of stools per	Additional information from study:
Effect of the	Case series			Disimpaction with	treatment	week (mean ± SD)	Children fed by mouth with semi-liquid
dietary fiber		Inclusion	14 boys	enemas for 2 or 3	12 weeks	-at 4 weeks	diet including formula and pureed food
glucomannan	Evidence	criteria:	mean age 5.7 ±	days (not clear		Glucomannan (n=9):	
on chronic	level:	Severe	4.2 years	what medication	Assessment	4.0 ± 1.3	No significant differences in baseline
constipation in	3	neurologic		used)	point (s):	Placebo (n=10):	characteristics between 2 groups
neurologically		damage,	Country:		At 4, 8 and 12	1.1 ± 0.2	
impaired	Study aim:	constipation	Italy	Intervention:	weeks		1 patient receiving glucomannan
children. 2000.	To evaluate	of at least 12		Glucomannan		-at 8 weeks	withdrawn from study after 3 weeks of
Journal of	the efficacy of	months. In		100mg/kg 2 times	Follow-up	Glucomannan (n=9):	treatment because of concomitant
Pediatrics	glucomannan	most patients		a day	period:	3.3 ± 1.0	increase in seizure frequency
136[1], 41-45	as a treatment	evacuation			No follow-up	Placebo (n=10):	associated with blood level of
	for chronic	not possible		Comparison:	conducted after	2.5 ± 1.2	Phenobarbital below the therapeutic
	constipation in	without		Placebo	treatment		range
	children with	enema. All		100mg/kg 2 times	finished	-at 12 weeks	
	severe	patients had		a day		Glucomannan (n=9):	During study period a daily diary card
	neurologic	severe			<u>Outcome</u>	3.8 ± 0.9	was completed for recording symptoms,
	damage	/profound			Measures:	Placebo (n=10):	dietary fibre intake, number of bowel
		mental		Both		2.0 ± 0.6	movements per week, stool consistency,
		retardation		glucomannan and	Stool frequency		presence of painful defecation and use
		(IQ level < 35)		placebo consisted		p<0.01 for	of laxative (lactulose 1g/kg/dose) or
		and exhibited		of a 500-mg	Stool	glucomannan group	glycerol suppository. Arbitrary scoring
		severe clinical		capsule. Oral	consistency	at all periods as	system used for assessment of
		manifestation		dose given by	_	compared to baseline	symptoms:
		s of brain		mixing the	Presence of		-stool consistency: 1, pellets; 2, hard; 3,
		damage		contents of one	painful	Stool consistency	soft; 4, loose; 5, liquid
		etiologically		capsule with 100	defecation	score (mean ± SD)	-presence of painful defecation: 1, often;
		related to		mL of water		-at 4 weeks	2, occasionally; 3, none
		prenatal or			Laxative use	Glucomannan (n=9):	
		perinatal				2.4 ± 0.5	Reviewer comments
		hypoxia: 12				Placebo (n=10):	No definition of constipation given
		patients had				1.3 ± 0.6	
						at 0 was als	very small sample size. Sample size
		tetraplegia, 6				-at & weeks	calculation not performed
		severe				Giucomannan (n=9):	
		spastic				2.8 ± 0.7	Randomisation and allocation
		diplegia, 2				Placebo (n=10):	concealment
		persistent				1.3 ± 0.5	methods not described

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
		hypotonia					
		·				-at 12 weeks	Blinding procedures poorly described
		Exclusion				Giucomannan (n=9):	
		criteria:				2.7 ± 0.7	Unclear who measured study outcomes
		unclear					Study not controlled for notontial
						1.4 ± 0.7	confounders
						p<0.01 for	
						glucomannan group	Source of funding:
						at all periods as	One of the authors supported by a grant
						compared to baseline	from Dicofarm, Italy. No other details provided
						Painful defecation	
						score(mean ± SD)	
						-at 4 weeks	
						Glucomannan (n=9):	
						1.4 ± 1.1 (N.S as	
						compared to	
						baseline)	
						Placebo (n=10):	
						0.9 ± 0.8	
						-at 8 weeks	
						Glucomannan (n=9):	
						1.7 ± 1.4 (N.S as	
						compared to	
						baseline)	
						Placebo (n=10):	
						1.2 ± 0.8	
						-at 12 weeks	
						Giucomannan (n=9):	
						1.9 ± 1.2 Placebo (n=10):	
						12+00	
						1.2 ± 0.9	
						alucomannan aroun	
						as compared to	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures	h a a a l'a a	
						baseline	
						Lavative use (number	
						per week. (mean +	
						SD)	
						-at 4 weeks	
						Glucomannan (n=9):	
						0.3 ± 0.8	
						Placebo (n=10):	
						2.0 ± 0.6	
						p<0.01 for	
						glucomannan group	
						as compared to	
						baseline	
						-at 8 weeks	
						Glucomannan (n=9):	
						0.5 ± 0.8 (N.S as	
						compared to	
						baseline)	
						Placebo (n=10):	
						1.8 ± 1.6	
						-at 12 weeks	
						Glucomannan (n=9):	
						0.3 ± 0.5	
						Placebo (n=10):	
						2.1 ± 0.4	
						p<0.01 for	
						glucomannan group	
						as compared to	
						baseline	
						All outcomes for	
						placebo group at all	
						points were N.S as	

Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
						compared to baseline	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Tse et al.	Study Type:	20 children	20 children	Intervention:	Duration of	Number of laxatives	Additional information from study:
Dietary fibre	Prospective			Fibre	treatment	<u>per week</u>	Definition of constipation: in the centre
intake and	case series	Inclusion	age range 3 to	supplementation:			where the study was conducted if a child
constipation in	(pilot study)	<u>criteria:</u>	17 years	wheat bran (All	-	-at baseline:	does not have a spontaneous bowel
children with		severe	gender not	Bran ® , Kellogg)	supplementatio	1.22 (SD 0.36)	movement for 2 consecutive days a
severe	Evidence	developmenta	reported	added in	n		laxative is administered. Those who
developmental	level:	lly disabled		breakfast	stage 1: 20	-at end of stage 1:	need more than 1 laxative per week are
disabilities.	3	children able	Country:		days	0.9 (SD 0.75)	defined as having constipation
2000. Journal of		to take oral	Hong Kong	-Stage 1: 15 g	-normal diet, no	p<0.05 as compared	
Paediatrics and	Study aim:	feeding and		added to each	supplementatio	to baseline	Baseline fibre intake around 2g/day
Child Health	To evaluate	medically		serving of	n:10 days		
36[3], 236-	fibre intake of	stable		breakfast (total	-	-at end of stage 2:	Reviewer comments:
239Australia.	severe			fibre intake, 17g)	supplementatio	0.7 (SD 0.40)	Unclear who measured study outcomes
	developmenta	Exclusion		_	n	p<0.01 as compared	and how
	lly disabled	criteria:		-Stage 2: 19 g	stage 2: 6	to baseline	
	children living	Not stated		added to each	weeks		Outcomes for bowel movements not
	in a			serving of		N.S comparing stage	reported in paper
	residential			breakfast (total	Assessment	1 and 2	
	institution and			fibre intake, 21g)	point (s):		Source of funding:
	the possibility				At the end of		Study sponsored by the Society for
	of reducing			Comparison:	stages 1 and 2		Relief of Disabled Children, Pokfulam,
	the use of			N.A			Hong Kong. 'All Bran' ® sponsored by
	laxatives by				Follow-up		Kellogg's Asia Ltd Wanchai, Hong Kong
	increasing				period:		
	their fibre				No follow-up		
	intake				conducted after		
					treatment		
					finished		
					<u>Outcome</u>		
					Measures:		
					-bowel motions		
					-use of		
					laxatives		

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
MAFFIA.	Study Type:	200 children	200 children	Intervention:	Duration of	Returned to normality	Additional information from study:
Treatment of	Open label			Prune-Malt ®	treatment	(number of children)	Diagnosis of constipation made on the
functional	non-RCT	Inclusion	age range: 3	added to diet	3 weeks	Prune-Malt ®: 28	following: 1) decreases in frequency of
constipation		<u>criteria:</u>	months to 8			Controls: 16	stools as compared to the child's usual
with prune-malt.	Evidence	Infants and	years	-Infants 3 weeks	Assessment		bowel habits, 2) passage of hard, dry
1955. Archives	level:	children aged	gender not	to 1 year old:	point (s):	Improved (number of	stools
of Pediatrics	1-	3 months to 8	reported	2 tablespoonfuls	Immediately	<u>children)</u>	
72[10], 341-346		years with		daily added to	after treatment	Prune-Malt ®: 51	Wherever possible, cases of equal
	Study aim:	functional	Country:	milk or juice	completed	Controls: 25	severity and ages were equally divided
	To evaluate	constipation	USA				between the 2 groups
	the			-children 1 to 4	Follow-up	Not improved	
	effectiveness	Exclusion		years:	period:	(number of children)	All mothers given a card to record daily
	in the	criteria:		3 tablespoonfuls	No follow-up	Prune-Malt ®: 21	number and description of stools, all
	treatment of	Organic		daily added to	made after	Controls: 59	associated findings if any and
	functional	constipation		milk or food	treatment		acceptability of Prune Malt by the child
	constipation in	ruled out			finished	Acceptability (number	
	infants and	clinically and		-children 4 to 8		of parents)	Reviewer comments:
	children of a	if necessary,		years:	Outcome	Good: 132	No sample size calculation performed
	palatable	after		4 tablespoonfuls	Measures:	Fair: 47	
	mixture	laboratory		daily added to		Poor: 21	No comparison made between baseline
	containing	and radiologic		milk or food	-improvement /		characteristics
	prune and fig	studies			no improvement		
	concentrate				/ return to		No definitions/scoring system given for:
	and non-			(no changes	normality		"improvement", "no improvement",
	diastatic malt			made in usual			"return to normality", "good", "fair" and
	syrup			diet, no drugs	-acceptability		"poor"
	neutralised			given)			
	with						No dropouts/lost to follow-up children
	potassium			Comparison:			reported
	carbonate			No intervention			
							Study not controlled for potential
							confounders
							Source of funding:
							Prune-Malt provided by the Benson-
							Nuen Laboratories Inc., New York
							No other details provided

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Bu et al.	Study Type:	45 children	45 children	Intervention:	Duration of	Defecation frequency	Additional information from study:
Lactobacillus	double-blind		23 male	MgO 50 mg/kg	treatment:	(times/day)	Chronic constipation defined as a stool
casei	RCT	Inclusion		per day, twice a	4 weeks	-MgO (n=18)	frequency of <3 times/week for >2
rhamnosus		criteria:		day		0.55 ± 0.13	months and at least 1 of the following
Lcr35 in	Evidence	children	Age (months,		Assessment		minor criteria: anal fissures with
children with	level:	under 10	mean, SD)	Comparison 1:	point (s):	-probiotic (n=18)	bleeding due to constipation, faecal
chronic	1+	years old with		Lcr35 8 X 10^8	Immediately	0.57 ± 0.17	soiling or passage of large and hard
constipation.		chronic	-MgO group	c.f.u/day	after treatment		stool
2007. Pediatrics	Study aim:	constipation	32.4 ± 13.9	(Antiobiophilus	completed	-placebo (n=9)	
International	to investigate			250 mg, 2		0.37 ± 0.10	Children randomly assigned into the 3
49[4], 485-490	the effect of	Exclusion	-Probiotic group	capsules, twice a	Follow-up		groups according to a computer -
	Probiotics	criteria:	36.7 ± 14.5	day)	period:	MgO vs. probiotic NS	generated randomisation list
	(Lactobacillus	organic			No follow up	Placebo vs. probiotic	
	case	causes of	-Placebo group	Comparison 2:	made after	P=0.006	Blinding achieved by the use of 3
	rhamnosus,	constipation	35 ± 14.7	Placebo (starch in	treatment	MgO vs. placebo	interventions with similar appearances
	Lcr35) alone	like		content)	finished	p=0.01	and placed into identical capsules,
	in the	Hirschsprung'	Country:		_		which were either swallowed o as a
	treatment of	s disease,	Taiwan		Outcome	Hard stool (%)	whole or opened and the contents of the
	chronic	spina bifida			Measures:	-MgO (n=18)	capsule administered in milk or fluid
	constipation in	(occulta),		Lactulose use		23.5 ± 7.9	
	children and	hypothyroidis		(1mL/kg/day)	-frequency of		Throughout the duration of study all
	to compare	m, or other		allowed when no	defecation	-probiotic (n=18)	investigators, participants and data
	the effect with	metabolic/ren		stool passage		22.4 ± 14.7	analysts were blinded to the assigned
	magnesium	al		noted for 3 days.	-consistency of		treatment
	oxide (MgO)	abnormalities,		Glycerin enema	stools	-placebo (n=9)	
	and placebo,	drugs		used only when		75.5 ± 6.1	Sample size determined by doing
	respectively	influencing		no defecation for	-episodes of		primary trial with 9 patients using non-
		gastrointestin		>5days or	soiling	MgO vs. probiotic NS	interiority to test. Equivalent margin
		al function		abdominal pain		Placebo vs. probiotic	chosen with reference to effect of active
		other than		suffered due to	-episodes of	p=0.02	control in the data of preliminary trial.
		laxatives		stool impaction	abdominal pain	MgO vs. placebo	Unbalance design of allocation number
		(calcium				p=0.03	used for more interest in the new drug
		channel			-use of		(Lcr35): allocation rate set at 2:2:1. One
		DIOCKERS,			lactulose or	Abdominal pain	sided significance level set at 0.05 and
		antidysrythmi			enema	(times)	power was 80%. Under these
		c agents,				$-ivig \cup (n=18)$	assumptions the smallest sample size
		anticonvuisiva				4.8 ± 3.1	was 45 and the sample size of MgO,
		nts,					LCr35 and placebo was 18, 18 and 9

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level	antidanraaan	S		Measures	probiotic (p. 10)	reenestively
		te				-probiolic (n=10)	respectively
		anticholinerai				1.9 ± 1.0	No significant differences at baseline
		c agents)				-placebo (n=9)	amongst the 3 group regarding; sex, age
						6.7 ± 3.3	of enrolment, age of onset of
						MgO vs. probiotic	constipation, duration of constipation,
						p=0.04	previous treatment, defecation period,
						Placebo vs. probiotic	stool consistency, abdominal pain,
						p=0.01	faecal soiling, bleeding during
						MgO vs. placebo NS	defecation, use of enema, taking fruit or vegetable daily
						Use of glycerine	
						enema (times)	Patients asked to discontinue any
						-MgO (n=18)	laxatives previously prescribed 3 days
						1.3 ± 1.9	before entering protocol, and also asked
						probiotic (p. 10)	to avoid any other problotics, yogurt or
						-probiolic (n=10)	least 2 weeks before treatment and
						1.0 ± 1.5	during therapy
						-placebo (n=9)	
						4.0 ± 2.1	All outcomes measures recorded by
						Mar o un anabiatia NO	parents in a stool diary
						NIGO VS. problotic INS	A nationta discontinued mediaction
						$r_{-0.04}$	during study period: 2 in MaO 1 in
						MaQ vs. placebo	probiotic 1 in placebo group (2 patients
						p=0.03	suffered from acute gastroenteritis and
						p 0.00	2 patients lost to follow-up)
						No significant	
						differences regarding	Reviewer comments:
						use of lactulose and	Allocation concealment not described
						faecal soiling	
						amongst 3 groups	Not clear whether the 2 patients who
						Detients with	suffered from acute gastroenteritis had it
						treatment success	as consequence of the study medication
						(%)	Study not controlled for potential
						-MgO (n=18): 72.2	confounders

Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
						-probiotic (n=18): 77.8 -placebo (n=9): 11.1 MgO vs. probiotic NS Placebo vs. probiotic p=0.01 MgO vs. placebo p=0.01 no adverse effects noted in probiotic and placebo groups, only 1 patient in the MgO group suffered from mild diarrhoea	Source of funding: not stated

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Banaszkiewicz	Study Type:	84 children	84 children	General:	Duration of	Treatment success	Additional information from study:
et al.	Triple-blind			Rectal	treatment	<u>(%)</u>	Allocation sequence and randomisation
Ineffectiveness	RCT	Inclusion	mean age	disimpaction	12 weeks	-At 12 weeks:	list computer generated by investigators
of Lactobacillus		criteria:	(months)	with phosphate		LGG (n=43): 72	
GG as an	Evidence	Children aged	-lactulose +	and saline enema	(from weeks 13	Placebo (n=41): 68	Blinding achieved by the use of study
adjunct to	level:	2 to 16 years	LGG group	in all patients	to	N.S	products with similar appearances and
lactulose for the	1+	with	79 ± 47	before study	24, patients		tastes, packed identically and
treatment of		constipation		treatment	instructed to	-At 24 weeks:	indistinguishable from each other.
constipation in	Study aim:	defined as < 3	-lactulose +		continue the	LGG (n=43): 64	Throughout duration of study all
children: a	To assess the	bowel	placebo group	Intervention:	use of lactulose	Placebo (n=41): 65	investigators, participants, outcomes
double-blind,	effectiveness	movements	65 ± 36	Lactulose 70%, 1	or other	N.S	assessors and data analysts were
placebo-	of	per week for		mL/kg/day (in 2	laxatives as		blinded to the assigned treatment
controlled	lactobacillus	at least 12	gender not	divided doses) +	needed	Spontaneous bowel	
randomized	rhamnosus	weeks	reported	10^9 colony		movements per week	No significant differences in baseline
trial. 2005.	GG (LGG) as			forming units	Assessment	(mean±SD)	characteristics between the 2 groups
Journal of	and adjunct to	Exclusion	Country:	(CFU) of	point (s):	-At 4 weeks	
Pediatrics	lactulose in	criteria:	Poland	lactobacillus	At 4, 8, 12	LGG (n=43):	All patients received stool diaries to
146[3], 364-369	the treatment	Constipation		rhamnosus GG		5.9 ± 2.3	record frequency of daily bowel
	of	caused by		(LGG)	Follow-up	Placebo (n=41):	movements, faecal soling, straining,
	constipation in	neuromuscula			period:	7.7 ± 5.4	stool consistency as well as any
	children	r, anatomic or		Comparison:	At 24 weeks	N.S	symptoms they consider important (e.g.
		metabolic		Lactulose 70%, 1	after study		abdominal pain, bloating, diarrhoea)
		diseases (as		mL/kg/day (in 2	treatment	-At 8 weeks	
		established		divided doses) +	finished	LGG (n=43):	I reatment success defined as ≥3
		by medical		placebo	0	6.1 ± 2.3	spontaneous bowel movements per
		nistory, an			Outcome		week with no episodes of faecal solling
		abnormai			<u>Measures:</u>	7.2 ± 3.8	5 shildren in LOO server discontinued
		thyroid				N.5	5 children in LGG group discontinued
		normone level			-primary	At 10 weaks	Intervention (4 clinical improvement, 1
		or prior			outcome:	-At 12 weeks	abdominal pain) vs. 3 patients in
		anorectal			treatment	LGG (n=43):	placebo group (2 refused to participate,
		harium ar			success	0.1 ± 1.0	r provided other reason)
		banum or			a a a a a a da m (Beviewer commenter
					-secondary	0.0 ± 3.1	<u>Reviewer comments:</u>
		examination)			outcomes:	0.81	Sample size calculation not performed
					number of	Enisodes of faecal	Study not controlled for potential
					howel	soiling per week	confounders
					DOWEI	Soming per week	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S	-	Measures		
					movements per	(mean± SD)	ITT analysis performed
					week	-At 4 weeks	
						LGG (n=43):	Outcomes for stool consistency not
					number of	0.9 ± 2.1	reported
					episodes of	Placebo (n=41):	
					faecal soiling	0.7 ± 1.5	Source of funding:
					per week	N.S	Not stated
					-		
					stool	-At 8 weeks	
					consistency	LGG (n=43):	
						0.8 ± 2.2	
					straining	Placebo (n=41):	
					frequency per	0.3 ± 0.8	
					week	N.S	
					percentage of	-At 12 weeks	
					patients using	LGG (n=43):	
					laxatives	0.8 ± 1.8	
						Placebo (n=41):	
					adverse events	0.3 ± 0.9	
						N.S	
						Straining frequency	
						per week (mean± SD)	
						-At 4 weeks	
						LGG (n=43):	
						1.6 ± 1.9	
						Placebo (n=41):	
						1.4 ± 1.9	
						N.S	
						-At 8 weeks	
						LGG (n=43):	
						1.4 ± 1.7	
						Placebo (n=41):	
						1.4 ± 1.8	
						N.S	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
						-At 12 weeks	
						LGG (n=43):	
						1.3 ± 1.5	
						Placebo (n=41):	
						1.6 ± 1.8	
						N.S	
						Patients using	
						laxatives (%)	
						-At 24 weeks:	
						LGG (n=43): 44	
						Placebo (n=41): 43	
						N.S	
						Adverse effects (%	
						patients)	
						LGG (n=43): 9	
						Placebo (n=41): 14.6	
						N.S	
						LGG well tolerated.	
						Side effects profile of	
						LGG Similar to that of	
						placebo. 3 patients in	
						LGG gloup vs. 5	
						group developed	
						group developed	
						abuominal pain. T	
						aroun developed	
						vomiting and 1 in the	
						nlacebo aroun	
						experienced	
						headache	
Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
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Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Bekkali et al.	Study Type:	20 children	20 children	General:	Duration of	Frequency of bowel	Additional information from study:
The role of a	Prospective			Disimpaction:	treatment	movements (BMs)	Constipation defined by Rome III criteria
probiotics	case series	Inclusion	10 boys	rectal enema	4 weeks	per week, total	as having at least 2 out of 6 of the
mixture in the	(pilot study)	criteria:	Median age: 8	(Klyx: sodium-		sample	following
treatment of		Children	years (4 to 16)	dioctylsulfosuccin	<u>Assessment</u>	-Baseline:	symptoms: bowel movements <3
childhood	Evidence	between 4 to		ate and sorbitol)	point (s):	2.0 (1.0 to 5.0)	times/week; faecal incontinence >2
constipation: a	level:	16 years of	Country:	once daily for 3	At 2 and 4		times/week; large amounts of stools
pilot study.	3	age referred	The	days	weeks	-Week 2:	obstructing the toilet once in 10 days;
2007. Nutrition		to outpatient	Netherlands			4.2 (0.0 to 16.0)	painful defecation; withholding
Journal 6, 17	Study aim:	clinic with		Intervention:	Follow-up	p = 0.10	behaviour; palpable abdominal or rectal
	to determine	constipation		Daily probiotics	period:		mass on physical examination
	the			mixture of	No follow-up	-Week 4:	
	therapeutic	Exclusion		4 × 109 colony	conducted after	and 3.8 (2.1 to 7.0)	7 days prior to baseline assessment and
	effect of a	criteria:		forming units	treatment	p = 0.13	during treatment period all children
	combination	use of any		(CFU), containing	finished		recorded frequency of bowel
	of probiotics	oral laxative <		Bifidobacteria		Frequency of bowel	movements, number of faecal
	strains,	4 weeks		(B.) bifidum, B.	<u>Outcome</u>	movements (BMs)	incontinence episodes, stool
	containing the	before intake,		infantis, B.	Measures:	per week in 12	consistency, abdominal pain, flatulence
	bifidobacteria	mental		longum,		children presenting	and pain during defecation as well as
	B. bifidus, B.	retardation,		Lactobacilli (L.)	Primary	with <3 BMs per	adverse effects such as vomiting and
	infantis and B.	metabolic		casei, L.	outcomes:	week at baseline:	diarrhoea in a standardized bowel diary
	longum and	disease,		plantarum and L.		-Baseline:	
	the lactobacilli	functional		rhamnosus	-frequency of	1.0 (0.0 to 2.0)	Stool consistency rated by patients as
	L. casei, L.	non-retentive			bowel		hard, normal or watery
	plantarum and	incontinence,		Comparison:	movements per	-Week 2:	
	L. rhamnosus,	and a history		N.A	week	3.0 (0.0 to 7.0)	During treatment period children
	on childhood	of gastro-				p = 0.01	instructed to start toilet training. Toilet
	constipation	intestinal			-stool		training consisted of sitting on the toilet
		surgery			consistency	-Week 4:	3 times per day for 5 minutes after each
						3.0 (0.0 to 10.0)	meal with the intention of trying to
					Secondary	p = 0.009	defecate. Use of laxatives not allowed
					outcomes:		during treatment period
						Stool consistency	
					-number of	Hard stools (n	Reviewer comments:
					faecal	children):	No dropouts/lost to follow-up children
					incontinence	-Baseline: 7	were reported
					episodes per		
					week	-Week 2 : 4	Source of funding:

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
						p = 0.23	Not stated
					-incidence of	•	
					adverse effects	-Week 4: 6	
					such as	p = 1.00	
					vomiting and		
					diarrhoea	At week 4, hard	
						stools appeared in 5	
						children who also had	
						hard stools at	
						baseline. 1 child with	
						normal stools at	
						baseline, reported	
						hard stools only at	
						the end of the study.	
						2 of the 7 children	
						who	
						presented with hard	
						stools, reported	
						normal stools at the	
						end of the study	
						Number of faecal	
						incontinence	
						episodes per week	
						Baseline:	
						4.0 (0.0 to 35.0)	
						Week Or	
						VVEEK 2.	
						1.5 (0.0 to 14.0)	
						p = 0.007	
						Week 4.	
						0.3(0.0 to 7.0)	
						p = 0.001	
						P = 0.001	
						Side effects	
						There were no side	

Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
	Level		S		Measures	effects such as vomiting, bloating and increased flatulence during the study period	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Young et al.	Study Type:	108 children	90 children	Intervention:	Duration of	Stool frequency	Additional information from study:
Increasing oral	Open label			Increased water	treatment	<u>(mean)</u>	Constipation Assessment Score based
fluids in chronic	RCT	Inclusion	31 boys	intake: group	2 weeks	H2O (water)	on 8 variables assessed during the past
constipation in		criteria:	(47.46%)	instructed to		HiOsm (high	3 days: abdominal distension or
children. 1998.	Evidence	Prepubertal		increase water	Assessment	osmolality)	bloating, change in amount of gas
Gastroenterolog	level:	children with	mean age 7.5	intake by 50% on	point (s):		passed rectally, less frequent bowel
y Nursing 21[4],	1-	moderate to	years (range	the basis of total	At week 2 and 3	-baseline:	movements, oozing liquid stools, rectal
156-161		severe simple	2.5 to 12.5	measured oral		Control: 3.45	fullness or pressure, rectal pain with
	Study aim:	constipation	years)	liquid intake	Follow-up	H2O: 3.52	bowel movement, smaller stool size,
	To determine	as assessed		during1st baseline	period:	HiOsm: 3.75	urge but inability to pass stool. Each
	whether or not	by the	Country:	week	No follow-up		variable scored as 0, no problem; 1,
	increasing	Constipation	USA		made after	-week 2:	some problem and 2, severe problem.
	liquid intake	Assessment		Comparison 1:	treatment	Control: 4.05	
	by either	Score		Hyperosmolar	finished	H2O: 3.57	A gift certificate to a toy store was used
	excess water			liquids: group		HiOsm: 4.31	as incentive to return data collection
	intake or	Exclusion		administered	Outcome		forms
	excess	<u>criteria</u> :		supplemental	Measures:	-week 3:	
	hyperosmolar	Post pubertal		liquid in the form		Control: 3.40	The concentration of 600 mOsm/L
	liquid intake	children,		of Kool-Aid, juice,	-stool frequency	H2O: 3.70	chosen because it was considered to be
	would	hypercalcemi		soda pop or other		HiOsm: 3.44	a level above which a significant osmotic
	significantly	a,		liquids know to	-stool		load in the small bowel would result in
	alter the	Hirschsprung'		contain more than	consistency	Stool consistency	significant plasma to lumen flux. The
	course of	s disease,		600 mOsm/L		<u>(mean)</u>	50% increase arbitrarily chosen as being
	simple	hypothyroidis			-difficulty of	-baseline:	feasible , >50% considered potentially
	constipation in	m, cardiac or		Comparison 2:	stool passage	Control: 6.30	burdensome for children/caregiver and
	children	renal		Control group: no		H2O: 6.13	probably not therapeutically obtainable
		disorders,		intervention			under normal situations
		children				-week 2:	
		receiving				Control: 6.33	Stool frequency, consistency and
		specialised				H2O: 5.99	difficulty with passage assessed daily by
		diets,					parents using a simple form. The Stool
		malnourished				-week 3:	Consistency Continuum previously
		children				Control: 6.30	developed by Bergstrom chosen to
		already				H2O: 5.79	evaluate stool form. Difficulty of passage
		receiving					scored as: 0, no problem; 1, some
		stool				Difficulty of stool	problem; 2 severe problem
		softeners or				passage (mean)	
		laxative				-baseline:	A second round of analysis excluded all

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
		preparations,				Control: 0.96	subjects who failed to comply with at
		children who				H2O: 0.78	least 75% of assigned intervention, and
		were				HiOsm: 0.77	this did not change the study outcomes
		physically or					
		intellectually				-week 2:	Reviewer comments:
		challenging				Control: 0.95	Sample size calculated on the basis of
		(?) or who				H2O: 0.84	preliminary power analysis but no details
		had an				HiOsm: 0.74	provided. Non probability convenience
		underlying					sample was used
		central				-week 3:	
		nervous					No comparison made of baseline
		system				H2U: 0.87	characteristics
		uisease					Mathada of randomisation and allocation
						Neither increasing	concealment not described
						water intake nor	
						increasing	108 children originally included, but only
						hyperosmolar liquid	90 completed the entire study as
						intake significantly	assigned, 18 children failed to comply
						increased stool	with 75% of the intervention, but there
						frequency or	are no clear explanations as to why that
						decreased stool	happened
						consistency or	
						difficulty with stool	Outcomes for stool consistency in the
						passage within	HiOsm group not reported
						groups when	
						comparisons were	Study not controlled for potential
						made with previous	contounders
						weeks, or between	
						the 3 groups during	
						the same week	Source of funding:
							NOT Cleany Stated
			1			1	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Eisenberg et al.	Study Type:	22 children	22 children	Intervention:	Duration of	Prevalence of	Additional information from study:
Contribution of	Non-RCT			Trial of David Hart	treatment	constipation (number,	Intervention and control children
stepping while		Inclusion	Intervention	Walker (HW)	6 months	% of children)	matched for age and sex
standing to	Evidence	criteria:	group (n=11):	device (to			
function and	level:	Aged	6 males	encourage active	<u>Assessment</u>	-At entry:	HW device – The David Hart Walker
secondary	1-	between 3.5	mean age (yr)	stepping while	point (s):		(HW) Orthosis, a hands free walker
conditions		and 10 years	6.1±2.1	standing) in	at 6 months	HW: 6 (54.5)	provides weight-bearing support and leg
among children	Study aim:	at first visit,		addition to	after treatment	SF: 6 (54.5)	alignment while allowing upper extremity
with cerebral	To explore the	CP spastic	Controls (n=11)	physical therapy	initiated		freedom, aiming to allow the action of
palsy. 2009.	feasibility and	quadriplegia	:	sessions.		NS	stepping while standing
Pediatric	efficacy of	with gross	6 males	Beginning with 30	Follow-up		
Physical	stepping while	motor	mean age (yr)	minute sessions 4	period:	-at 6 months:	Constipation defined as 2 bowel
Therapy 21[1],	standing and	function	6.7±1.6	times a week,	None after		movements per week, or 2 of the
79-85	its effect on	classification		parents and	intervention	HW: 1 (9.1)	following on more than 1 of 4 occasions:
Einsberg et al.	function and	system	Country:	children	period finished	SF: 6 (54.5)	straining, hard stools and a feeling of
2009	the	(GMFCS)	Israel	encouraged to			incomplete evacuation
	prevalence of	level 4 or 5,		use device at	<u>Outcome</u>	p = 0.02	
	secondary	inability to		home	Measures:		Diary of bowel function kept by parent
	conditions	stand and			Prevalence of		and/or the physical therapist and
	among	walk with		Comparison:	constipation		maintained throughout follow-up period
	children with	traditional		Program in			used to assess for constipation
	severe	walker/rollator		standing frame			
	cerebral palsy	due to		(SF) (passive			At baseline children in the HW group
	(CP)	insufficient		standing) as part			had higher significant mean scores in
		upper		of physical			the self-care and social function domain
		extremity		therapy session.			of the Paediatric Evaluation of Disability
		control,		30-minute			Inventory (PEDI) score than children in
		attempts		sessions 4 times			the SF group
		steps when in		a week, parents			
		a supported		and children			Reviewer comments
		standing		encouraged to			
		position,		use SF at home			Very small study population
		flexion					
		contractures					No dropouts/loss to follow-up reported
		of the hips					
		and knees of					PEDI scores may have confounded the
		less than 30°					effects of the intervention and this was
							not accounted for

Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
		Exclusion criteria: Not stated					Source of funding: Not stated

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
lacono et al.	Study Type:	65 patients	Age (mo)	Intervention:	Follow-up	Observation period	The order of treatment was randomly
Intolerance of	Cross over		34.6+-17.1	Excluding cow's	period: Mean:	<u>(n=65)</u>	assigned by a computer-generated
cow's milk and	randomised	33 patients		milk and its	10 months		method with the individual patient as the
chronic	controlled trial	received	Sex M/F 29/36	derivatives from	(range 3 to 20)	Number of bowel	unit of randomisation. The researchers
constipation in		cow's milk		the diet of children		movements: 4	were unaware of the order of the
children. 1998.	<u>Evidence</u>	and 32 soy		with constipation	<u>Outcome</u>	Median: 3-5	treatment.
New England	<u>level:</u> 1+	milk during			Measures:	25th to 75th	
Journal of		the fist study		Comparison:	Number of	percentile	At baseline and end of two study periods
Medicine		period		Cow's milk vs. soy	bowels		children were examined by a researcher
339[16], 1100-				milk	movements	Qualitative faecal	who was unaware of laboratory test results
1104United		32 patients			Children with	score	and histological findings
States.		received		Weeks 1-2:	eight or more	1:0	
		cow's milk		observation	bowel	2: 0	To ensure that children did not receive any
		and 33 soy		period	movements	3: 65	other kind of milk-containing food during
		milk during		all medication	during a		the study periods parents were given a list
		the second		stopped	treatment	Weeks 3-4 and 6-7	of most common milk-containing food to
		study period			period were	-Cow's milk group:	be avoided
				Weeks 3-4: one	considered to		
		Inclusion		group received	have a	Number of bowel	6 patients were withdrawn from the study
		criteria:		cow's milk and	response	movements:	during the cow's-milk study period (on
		consecutive		unrestricted diet		Median: 4	days 9-12) because of the reappearance
		children		and the other had	Qualitative	25th to 75th	of constipation and other related disorders.
		referred by		cow's milk and its	faecal score	percentile: 3-5	For these children the number of bowel
		family		derivatives	1: mushy or		movements per period was prorated.
		paediatricians		excluded from diet	liquid stool	Qualitative faecal	Intention to treat analysis was used
		to a paediatric		and received soy	2: soft faeces	score	
		gastroenterol		milk instead	and no pain in	1: 0	The mean (±SD) daily consumption was
		ogy clinic			passing stools	2:0	450±120 ml of soy milk and 470±135 ml of
		diagnosed		Week 5: washout	3: hard faeces	3: 65	cow's milk. Analysis of the main
		with chronic		period for both	and difficulty		constituents of the diet (proteins,
		constipation.		groups,	and pain on	 Soy milk group: 	carbohydrates and fibres) did not show
		Chronic		unrestricted diet	passing stools		any qualitative or quantitative variation
		constipation		and intake of soy		Number of bowel	during the study period (data not shown).
		defined as		or cow's milk and	Both Number of	movements	
		chronic faecal		its derivatives	bowels	Median: 10	Patients were highly selected and this
		retention (one			movements and	25th to 75th	might have led to overestimate the

Effectiveness of excluding Cow's Milk from the Diet in Children with Chronic Idiopathic Constipation

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
		bowel		Week 6-7:	qualitative	percentile: 4-12	frequency of cow's milk intolerance as a
		movement		patients switched	faecal score		cause of constipation. Paediatricians who
		every 3 to 15		to the other type	were recorded	Qualitative faecal	referred the patients may have preselected
		days) often		of milk	by parents	score	them having being the centre where the
		associated				1: 2	study was conducted experience in the
		with		Total amount of		2: 42	treatment of food allergies. The inclusion
		abdominal		milk given to the		3: 21	of patients with no response to laxatives
		symptoms		patient during the			may have also contributed to this issue.
		(abdominal		two weeks: 5-10		p values were <	
		pain, painful		litres		0.001 for all variables	
		defecation					
		and so forth)		Bottles coded A or		Challenge with cow's	
				B by hospital		<u>milk (n=44)</u>	
		Exclusion		dispensary			
		criteria:		Infants < 15		-Placebo group (soy	
		Anatomical		months age:		milk): 0 clinical	
		causes		formula based on		reactions	
		(Hirschsprung		cow's milk			
		's disease,		(Transilat,		-Cow's milk group: 0	
		spinal		Plasmon, Milan,		acute reaction, but in	
		disease)		Italy) or formula		all patients	
		another		based on soy		constipation	
		disorder		(Plasmonsoy,		associated with hard	
		(hypothyroidis		Plasmon).		stools and discomfort	
		m,		Children > 15		on defecation	
		psychomotor		months age:		reappeared after 5-10	
		retardation),		commercially		days on the diet.	
		prior anal		available whole		Cow's-milk-free diet	
		surgery,		cow's milk or soy		was recommenced,	
		medication		milk		with a consequent	
		that can				normalisation of	
		cause		After the two		bowel movements in	
		constipation		study periods		all patients	
		(cnlorpromazi		children with a			
		ne) and		response to		Follow-up:	
		reterral for		cow's-milk free			
		other reasons		diet were given		0 children with	
				the soy-milk diet		response had	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
				for another month		constipation	
				and then			
				underwent a 2-		Cow's milk	
				week double-blind		reintroduced into the	
				challenge with		diets of 15 children	
				cow's milk at		after 8-12 of cow's	
				hospital. Children		milk-free diet and in	
				were randomly		all cases constipation	
				assigned to		returned within 5-10	
				receive cow's milk		days	
				or a placebo			
				containing soy		Children with no	
				milk. If no clinical		response to soy-milk	
				reactions were		diet were treated with	
				observed within		high doses of	
				12 hours, patients		laxatives, with	
				were discharged		subsequent	
				and the challenge		improvement in stool	
				continued at		frequency. In all	
				home with bottles		cases symptoms	
				coded A or B by		returned once	
				the hospital		treatment with	
				dispensary.		laxatives was stopped	
				Challenge was			
				stopped when a			
				clinical reaction			
				occurred, in			
				particular when			
				there were not			
				bowel movements			
				the petient had			
				the patient had			
				abuominai pain,			
				perianal lessons			
				or both.			
1			1				

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Carroccio et al.	Study Type:	52	Age (months) :	Intervention:	Follow-up	Observation period:	Qualitative faecal score previously
Chronic	Case series	consecutive	51.2±18	Cow's milk-free	period:		validated according to authors
constipation	and	infants and		diet, with the	None reported	-Patients with food	
and food	embedded	children with	Sex (M/F):	exclusion of cow's		intolerance (n=30)	Randomisation method used during the
intolerance: A	randomised	chronic	22/30	milk and all its	<u>Outcome</u>		cow's milk challenge not described
model of	controlled	constipation		derivatives	Measures:	Number of bowel	
proctitis causing	challenge	unresponsive			Number of	movements/week:	To ensure that children did not receive any
constipation.		to previous		Comparisons:	bowels	Median: 1.5	other kind of milk-containing food during
2005.	<u>Evidence</u>	treatments		1. Cow's milk-free	movements/we	25th to 75th	the study periods parents were given a list
Scandinavian	<u>level</u> :	examined at		diet vs. soy milk	ek	percentile: 1-2	of most common milk-containing food to
Journal of	3	the		2. Cow's milk vs.			be avoided. Furthermore, they were asked
Gastroenterolog		outpatients		ass's milk	Qualitative	Qualitative faecal	to record the amount and type of food their
y 40[1], 33-		clinic of a			faecal score	score	children had eaten every day. Frequent
42Norway.		hospital.			1: mushy or	1: 0	telephone contacts helped to ensure
		Chronic		1. Cow's milk-free	liquid stool	2: 0	adherence to the diet
		constipation		diet vs. soy milk	2: soft faeces	3: 30	
		defined as			and no pain in		Patients with chronic constipation caused
		chronic faecal		-2 weeks	passing stools	- Patients with	by food intolerance showed at baseline a
		retention (one		observation	3: hard faeces	constipation	higher frequency of a personal history of
		bowel		period: all	and difficulty	unrelated to food	previous food intolerance (p=0.02) and
		movement		medications	and pain on	intolerance (n=22):	concomitant signs of food intolerance
		every 3 days		stopped	passing stools		(bronchospasm five cases, rhinitis four
		or more) with		and at the end a		Number of bowel	cases, dermatitis two cases) (p=0.03) than
		painful		clean-out with	both number of	movements/week:	patients with constipation unrelated to food
		elimination of		single dose of	bowels	Median: 1.5	Intolerance.
		hard stools		polyethylene	movements/we	25th to 75th	No difference was observed between the
		associated			ек	percentile: 1-2	24 patients with CM intolerance and the 6
		with		(0.75g/kg).	and qualitative		patients with multiple food intolerance for
		abdominal		Normal diet, no	taecal score	Qualitative faecal	outcome measures considered (number of
		pain		restrictions	were recorded	score	bowel movements and qualitative faecal
					by parents	1:0	score), either at baseline or on elimination
		Inclusion		-4 WEEKS OT COW'S	Obildres with	2:0	diet. However in comparison with patients
		<u>criteria:</u>		milk free diet	Children with	3: 22	intolerant to Civi alone, patients suffering
		-a nistory of			eight or more	Elimination dist	(n 0/04) and had a higher fragment of
		Chronic		tool	DOWEI		(p=0/04) and had a higher frequency of
				100)	during	penoa:	Tarming history of atopic disease (p=0.03)
		lasting at		Infonto - 15	during a	Detients with face!	Analysis of the main constituents of the
		least b		101a0ts < 15	treatment	-Patients with food	Analysis of the main constituents of the

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
		months		months age: soy-	period were	intolerance (n=30)	diet (proteins, carbohydrates and fibres)
		-lack of		based (Nutrilon-	considered to		did not show any qualitative or quantitative
		response to a		soya, Nutricia,	have a	Number of bowel	variation during the study period (data not
		previous		Milan, Italy)	response	movements/week:	shown)
		increase in		.		Median: 5	
		dietary fibre		Children > 15	Normalised	25th to 75th	Patients with food intolerance (to CM only
		intake and/or		months age:	stools habits:	percentile: 4-7	or multiple) were treated as a group for the
		to laxative		commercially	bowel		purpose of analysing the data, therefore it
		treatment		available soy milk	frequency of at	Qualitative faecal	is not possible to offer specific data for the
		(milk of			least five	score	CM group only
		magnesia 1-2		Patients	evacuations/we	1:2	
		ml per kg		unresponsive to	ek with the	2: 28	The high frequency of chronic constipation
		bodyweight,		CM-free diet	elimination of	3: 0	owing to food intolerance likely due to a
		polyethylene		placed on	soft stools,		selection bias, as mainly food-intolerant
		glycol 4000		oligoantigenic diet	without painful	- Patients with	patients are treated at the centre where
		mean dose		4 weeks (also	defecation	constipation	study was conducted.
		0.75 g per kg		excluding cow's		unrelated to food	
		dally)		milk): exclusively		intolerance (n=22):	Funding source: partly supported by a
		attempted for		rice, lamb,			grant from MURST and from the MIPAF
		at least one		carrots, ass's		Number of bowel	(progetto "ALICE", D.D. n 86 dated
		month		milk, olive oil and		movements/week:	30.01.2002)
		-regular		sugar		Median: 1.5	
		dietary intake				25th to 75th	
		of cow's milk		2. Cow's milk vs.		percentile: 1-2	
		and		ass's milk		Qualitation (a seal	
		derivatives		Dauch Iach Bard		Qualitative faecal	
		EXClusion		Double-blind		score	
		criteria:		placebo-controlled		1:0	
		-prior anal		challenge with		2:0	
		surgery		cow s milk, after		3: 22	
		-use of		1∠ weeks, to all		Cow's mills shaller re-	
		theteen		patients cured on		Cow s milk challenge:	
		mat can		Civi-iree Or		reported apart from	
		cause		diat		neponed apart from	
		referred for		Diacobo: coo'o		saying marin an	
		roacona othar		milk		roadministration	
		then obronic		ITTIIK If no olinical			
		man chronic		n no clinical		caused the	

Bibliographic Information	Study Type & Evidence	Number of Patients	Patient Characteristic	Intervention & Comparison	Follow-up & Outcome	Effect Size	Reviewer Comments
	Level		S		Measures		
		constipation		reactions after 12		reappearance of	
		-anatomical		hours, patients		constipation within 5	
		/neurological		were discharged		days after	
		causes of		and challenge		commencing the	
		constipation		continued at		challenge (median 2	
		(Hirschsprung		home with bottles		days, range 1-5 days)	
		's disease,		coded A or B.			
		spinal		Challenge was			
		uisease,		slopped when a			
		retardation)					
		-another		occurred			
		disease					
		causing					
		constipation					
		(hypothyroidis					
		m, coeliac					
		disease)					

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S	-	Measures		
lacono et al.	Study Type:	27 infants	15 boys	Intervention:	Follow-up	Mean number (+-SD)	Analysis of the patient's dietary diaries did
Chronic	Case series			Excluding cow's	period: monthly	of stools per day	not show any significant variations in daily
constipation as		Inclusion	Mean age: 20.6	milk and its	for a mean	during unrestricted	fibre and liquid intake during the various
a symptom of	Evidence	criteria:	+- 13.4 months	derivatives from	period of 18	diet (UD) and during	study periods
cow milk	level: 3	referred to a	(range 5 to 36	the diet of children	months (range	CMP-free diet	
allergy. 1995.		paediatric	months)	with chronic	10 to 30		It is not reported whether any medication
Journal of		gastroenterol		constipation	months)	Stools from patients	was stopped at the beginning of the study
Pediatrics		ogy clinic				on CMP-free diet	
126[1], 34-39		during the 12		Comparisons:	<u>Outcome</u>	-Cured (n=21)	Funding: not reported
		months		1. Cow's milk-free	Measures:		
		preceding the		diet vs. soy milk/		a. UD: 0.24+-0.10	
		study and		ass's milk	-Number of	b. 1rst CMP-free diet:	
		considered to		Cow's milk vs.	stools/day	1.04+-0.12	
		have		ass's milk		c. 1rst CMP	
		idiopathic			 Description of 	challenge: 031+-0.14	
		constipation.		1. Cow's milk-free	stools +	d. 2nd CMP-free diet:	
		Diagnosis of		diet vs. soy milk/	Difficulty in	1.05+-0.11	
		constipation		ass's milk	passing them =		
		made on the			Qualitative	Significance: b and d	
		basis of a		-First 7 days: All	score	vs. a and c, p<0.0005	
		history of		patients were			
		reduced		being fed the	Qualitative	-Unimproved (n=6)	
		frequency of		same diet as at	score:		
		stools (one		the time of	hard faeces,	UD: 0.18+-0.12	
		evacuation		diagnosis: various	difficulty and	1rst CMP-free diet:	
		every 3 to 7		form of	pain in passing	0.20+-0.13	
		days- and on		commercial	stools	CMP challenge: -	
		pain in the		formula derived	2: soft faeces,	CMP-free diet: -	
		passage of		from cow milk or	no pain		
		hard stools. In		whole cow milk	1: mushy or	Qualitative score:	
		all patients		and its derivatives	liquid stool		
		the frequency			During the	-Cured (n=21)	
		of stools per		-For the next	various study		
		day was lower		month: all patients	periods (as	a. UD: 2.85+-0.05	
		than the 3rd		started a cow's	recorded by	b. 1rst CMP-free diet:	
		percentile of		milk protein-free	parents):	1.90+-0.08	
		the values		diet. Three		c. 1rst CMP	
		observed in a		patients aged <		challenge: 2.75+-0.11	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
		large		12 months were		d. 2nd CMP-free diet:	
		population of		fed a formula		1.85+-0.10	
		healthy		containing soy			
		subject		protein and the		(p<0.001)	
		participating		others received			
		in an Italian		soy milk or ass's		-Unimproved (n=6)	
		multicentre		milk (eight cases)			
		study		and all milk		UD: 3	
		Exclusion		derivatives were		1rst CMP-free diet: 3	
		criteria:		excluded		CMP challenge: -	
		Hirschsprung'				CMP-free diet: -	
		s disease,		After a month:			
		mental		-Patients whose		Difficulty in passing	
		retardation		symptoms abated:		stools:	
				cow milk			
				challenge. Cow		-Cured (n=21)	
				milk given for a			
				maximum of 10		a. UD:	
				days, again an		B. 1rst CMP-free diet:	
				exclusion diet for		none had difficulty	
				1 month and then		C. 1rst CMP	
				a second cow milk		challenge: Painful	
				challenge. All		d. 2nd CMP-free diet:	
				challenges were		none had difficulty	
				performed in		During the second	
				nospital. Before		During the second	
				the challenge a		challenge symptoms	
				prick test was		reappeared within 24	
				performed with		to 48 h: all 21	
				CIVIP. In patients		patients had painful	
				with a negative		passage of stools and	
				challenge was		challenge was	
				periorned by		suspended on the	
				giving whole cow		uniu day	
				fooding: if thore		$ $ n improved $(n - 6)$	
				were no elinies!		-ommproved (n=6)	
				were no clinical			

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
				reactions, the		Control: ?	
				same food was		1rst CMP-free diet: no	
				given the		changes	
				following days. In		CMP challenge: -	
				patients with a		CMP-free diet: -	
				positive test			
				result, the		Follow-up period:	
				challenge was		Reintroduction of cow	
				performed by		milk was cautiously	
				giving a formula		attempted in 16	
				containing CMP,		children 6-9 months	
				beginning with an		after the diagnosis of	
				initial quantity of		CMPA-dependant	
				10 ml and		constipation. In eight	
				gradually		children CMP did not	
				increasing the		cause the onset of	
				amount to reach		any problems and it	
				the dose		was reintroduced on	
				equivalent to a full		a permanent basis; in	
				feeding after 48		eight patients CMP	
				hours. No other		led to the	
				change in diet		reappearance of	
				was made.		constipation within 2	
						to 3 days after	
				Reintroduction of		introduction, and	
				cow milk		these infants were	
				cautiously		still following CMP-	
				attempted in 16		free diet at the time	
				children 6-9		the paper was written.	
				months after the			
				diagnosis of			
				CMPA-dependant			
				constipation			
				-Patients with no			
				abatement in			
				symptoms:			
				permanently given			

Bibliographic Information	Study Type & Evidence	Number of Patients	Patient Characteristic	Intervention & Comparison	Follow-up & Outcome	Effect Size	Reviewer Comments
	Level		S	•	Measures		
	Level		S	an unrestricted diet, except for one infant who had episodes of recurrent bronchospasm related to ingestion of cow milk	Measures		

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
lacono et al.	Study Type:	36	20 females	Intervention:	Follow-up	Observation period:	To ensure that all children observed a
Food	Case series	consecutive		Cow's milk-free	period:		correct elimination diet, parents were
intolerance and	and	infants and	Aged 9 months	diet, with the	Not reported	-Patients with food	asked to record the amount and type of
chronic	embedded	children with	to 10 years	exclusion of cow's		intolerance (n=17)	food their children had eaten each day.
constipation:	randomised	chronic	(median 3.6	milk and all its	Outcome		These diaries were analysed at the end of
manometry and	controlled	constipation	years)	derivatives	Measures:	Number of bowel	the study to evaluate adherence to the diet
histology study.	challenge	unresponsive			Number of	movements/week:	and the quantity of milk consumed
2006. European		to previous		Comparisons:	bowel	Median: 1.5	
Journal of		treatments,		1. Cow's milk-free	movements/we	25th to 75th	Neither the parents nor the children were
Gastroenterolog	Evidence	examined at		diet vs. soy milk	ek	percentile: 1-2	able to distinguish whether the bottles
y and	level:	the outpatient		Cow's milk vs.			contained asses' or cows' milk.
Hepatology	3	clinic of a		ass's milk	Appearance of	Qualitative faecal	
18[2], 143-150		hospital			stools + child's	score	According to the authors the qualitative
		Paediatric		1. Cow's milk-free	degree of	1: 0	faecal score had been previously validated
		Gastroenterol		diet vs. soy milk:	difficulty in	2:0	
		ogy Division.			passing stools =	3: 17	Randomisation method used during the
		Chronic		2-week	Qualitative		cow's milk challenge not described
		constipation		observation	faecal score:	- Patients with	
		defined as		period: all		constipation	Specific data related to number of bowel
		less than 3		medications	1. Mushy or	unrelated to food	movements and qualitative faecal score
		bowel		stopped	liquid stools	intolerance (n=19):	were not reported for the challenge period.
		movements/r			2. Soft faeces		
		week with		4 weeks: all	and no pain in	Number of bowel	Analysis of the main constituents of the
		painful		patients on cow's	passing stools	movements/week:	diet (proteins, carbohydrates and fibres)
		elimination of		milk free diet.	Hard stools	Median: 1.5	did not show any qualitative or quantitative
		hard stools		Infants < 15	and difficulty	25th to 75th	variation during the study period (data not
				months old	and pain on	percentile: 1-2	shown)
		Inclusion		received a	passing stools		
		criteria:		formula based on		Qualitative faecal	Patients with food intolerance (to CM only
		 a history of 		soy (Nutrilon-	(All outcomes	score	or multiple) were treated as a group for the
		chronic		soya, Nutricia,	measures were	1:0	purpose of analysing the data, therefore it
		constipation		Milan, Italy),	recorded by	2:0	is not possible to offer specific data for the
		lasting at		children>15	parents)	3: 19	CM group only
		least 3		months old a			
		months		commercially	Normalised	Elimination diet	Funding: partly supported by a grant from
		-lack of		available soy milk.	stool habits: a	period:	MIUR and MiPAF: project "Alimetazione e
		response to a			bowel		celiachia (ALICE)", D.D. n 86 dated
		previous		Patients	frequency of at	-Patients with food	30.01.2002)

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
		increase in		unresponsive to	least three	intolerance (n=17)	
		dietary fibre		CM-free diet	evacuations per		
		intake or to		placed on	week, with the	Number of bowel	
		laxative		oligoantigenic diet	elimination of	movements/week:	
		treatment		4 weeks (also	soft stools,	Median: 5	
		(milk of		excluding cow's	without painful	25th to 75th	
		magnesia 1-2		milk): exclusively	defecation	percentile: 3-7	
		ml/ kg of body		rice, lamb,			
		weight)		carrots, ass's		Qualitative faecal	
		-a regular		milk, olive oil and		score	
		dietary intake		sugar		1: 1	
		of cow's milk				2: 16	
		and		2. Cow's milk vs.		3: 0	
		derivatives		ass's milk:			
						 Patients with 	
		Exclusion		After 12 weeks:		constipation	
		criteria:		patients cured on		unrelated to food	
		-previous		cow's milk-free		intolerance (n=19):	
		evaluation for		diet and			
		chronic		oligoantigenic		Number of bowel	
		constipation		underwent a 2-		movements/week:	
		-anatomical		week double-blind		Median: 1.5	
		/neurological		placebo-controlled		25th to 75th	
		causes		challenge with		percentile: 1-2	
		(Hirschsprung		cow's milk. Asses'			
		's disease,		milk was used as		Qualitative faecal	
		psychomotor		placebo. If no		score	
		retardation)		clinical reactions		1:0	
		-another		after 12 hours,		2:0	
		disease		patients were		3: 19	
		(coeliac		discharged and			
		disease,		challenge		Cow's milk challenge	
		hypothyroidis		continued at		period	
		m)		nome with bottles			
		-previous anal		coded A or B.		Reappearance of	
		surgery		Challenge was		constipation in all	
		-use of		stopped when a		cases (n=17), very	
		medication		clinical reaction		often associated with	

Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
	Level	that causes constipation -referral for reasons other than constipation	S	occurred	Measures	painful defecation, within 5 days after the commencement of the challenge (median 2 days, range 1-5 days).	

Psychological/Behavioural Interventions	for Ongoing Tre	atment/Maintenance in Children	with Chronic Idiopathic	Constipation
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Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Loening-	Study Type:	43 children	43 children	Intervention:	Duration of	Recovery rate	Additional information from study:
Baucke.	Parallel-RCT			Conventional	treatment	<u>(number</u>	Constipation and encopresis defined as
Modulation of		Inclusion	33 boys	treatment alone	6-month	recovered, %)	having ≥ 2 soiling episodes/week and
abnormal	Evidence	criteria:		(CT)	protocol.		evidence of a huge amount of faecal
defecation	level:	Children 5 to	Mean age: 8.9			-at 7 months:	material in the rectal ampulla at rectal
dynamics by	1+	16 years with	years (range 5	CT: use of	Assessment		examination. In many patients stool
biofeedback		chronic	to 16)	laxatives,	point (s) and	CT (n=19): 1(5)	evacuation was incomplete as
treatment in	Study aim:	constipation		increase of dietary	follow-up		evidenced by periodic passage of very
chronically	To determine	and	Country:	fibre and	period:	BF (n=22): 12 (55)	large amounts of stools (every 7 to 30
constipated	whether	encopresis	USA	scheduled			days), often clogging the toilet
children with	outcome in	and abnormal		toileting	7 & 12 months	P<0.001	
encopresis.	chronically	defecation					Abnormal defecation dynamics defined
1990. Journal of	constipated	dynamics		Disimpaction with	<u>Outcome</u>	Recovery rates did	as abnormal contraction of the external
Pediatrics	and			enemas (type and	Measures:	not differ between	anal sphincter and pelvic floor during
116[2], 214-222	encopretic	Exclusion		dose not reported)		boys and girls in	defecation attempts, as determined by
	children with	<u>criteria</u> :			Recovery rate	general and within	anorectal manometry
	abnormal	Hirschsprung'		Maintenance: milk		the biofeedback	
	defecation	s disease,		of magnesia ~		group in particular.	Sample size and calculation: 2 pairs of
	dynamics	hypothyroidis		2ml/kg body		Prior unsuccessful	subjects would be needed per group to
	could be	m, mental		weight daily to		treatment no related	allow a power of approximately 0.9 to
	improved with	deficiency,		induce at least 1		to treatment outcome	detect a difference of 0.7 vs. 0.2 in
	biofeedback	chronic		bowel movement		in either group	achieving normal bowel habits (recovery
	training	debilitating		daily and prevent			from constipation and encopresis)
		diseases,		faecal retention.		Patients with an initial	
		neurologic		Doses decrease		abdominal faecal	Sealed envelopes with cards indicating
		abnormalities,		gradually to		mass (severe	either conventional therapy alone or
		previous		maintain daily		constipation)	conventional therapy with biofeedback
		surgery of the		bowel movement		significantly more	training used for randomisation
		colon		and prevent		likely to recover with	
				faecal retention		BF training than with	1 boy in the conventional treatment
				and soiling		CT alone (46% vs.	group was lost to follow-up 1 month after
						0%, p<0.02)	treatment began. At that visit he was
				Patients			taking milk of magnesia and his soiling
				instructed to		-at 12 months :	had resolved. 1 boy was lost to follow-up
				discontinue			in the biofeedback group
				laxative therapy at		CT (n=19): 3 (16)	after the first biofeedback session

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
intornation	Level	Fallents	S	Comparison	Measures		
				6 ± 0.5 months after initiation of therapy <u>Comparison</u> : Conventional treatment (CT) + biofeedback (BF) Up to 6 sessions of biofeedback therapy 7 +/- 2 days apart. 1 session included approximately 30 to 35 defecation trials and lasted approximately 45 minutes Patients instructed to discontinue laxative therapy at 6 ± 0.5 months after initiation of therapy		BF (n=22): 11 (50) P<0.05 A 14-yeor old boy in the BF group had a relapse. He had severe faecal impaction with enormous abdominal distension initially. Faecal impaction recurred 4 months after successful discontinuation of milk of magnesia. at time study was written he had no soiling but required intermittent treatment for constipation	Baseline characteristics not significantly different between both groups apart from gender: more girl in the BF group than in the CT group (41% vs. 5%, p<0.02). During initial evaluation the following significantly more frequent in girls than in boys: severe constipation (an abdominal faecal mass present) (90% vs. 48%, p<0.03), daytime urinary incontinence (70% vs. 23%, p<0.02) and a history of previous urinary tract infection (60% vs. 6%, p<0.001) Patients considered to have recovered if they had ≥3 bowel movements/week and soiling ≤ 2 episodes/month while not receiving laxatives for 4 weeks. Patients considered not to have recovered if they had <3 bowel movements/week or were soiling >2 times/month or had been started on a regime of laxatives again Re-evaluation of patients included review of last month's stool, soiling and medication dairy. Follow-up interview by questionnaire at 12 months <u>Reviewer comments:</u> Not completely clear who measured outcomes and how, and whether questionnaires were piloted ITT analysis not performed <u>Source of funding:</u> Supported by grant No. M01-RR-00059 from the General Clinical Research

Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
	Level		S		Measures		Centre Program,, Division of Research Resources, National Institute of Health; the Children's Miracle Network Telethon and the Spelman-Rockefeller Child and Parenting Seed Grant

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
van der Plas et	Study Type:	192 children	192 children	Intervention:	Duration of	Treatment success	Additional information from study:
al. Biofeedback	Parallel-RCT			Conventional	intervention	(number of children	A faecal mass defined as a large hard or
training in		Inclusion	126 boys	laxative treatment	6 weeks	<u>cured, %)</u>	soft stool in the rectum which completely
treatment of	<u>Evidence</u>	criteria:		(CT)			filled the rectal vault. Soiling defined as
childhood	level:	Patients with	-age range		Assessment	-at 6 weeks	loss of loose stools in underwear.
constipation: a	1+	paediatric	(total	5 outpatient	point (s) and	CT (n=94):	Encopresis defined as voluntary or
randomised		constipation	population): 5 to	visits lasting	follow-up	31/94 (33%)	involuntary passage of a quantitatively
controlled	Study aim:	who fulfilled	16 years	approximately 30	period:		normal bowel movement in underwear in
study. 1996.	To evaluate	at least 2 of		min during which	after the last	CT+BF (n=98):	children over the age of
Lancet	the effect of	these 4	-median age for	laxative	visit of the	31/98 (32%)	4, occurring on a regular basis without
348[9030], 776-	biofeedback	criteria: stool	both groups: 8	treatment and	intervention		any organic cause. A large amount of
780	training and	frequency <3	years	information from a	period at 6	NS	stool was estimated to be twice the
	conventional	per week, ≥2		diary containing	weeks, then at		standard shown in a clay model
	treatment on	soiling and/or	Country:	defaecation	6 months, 1	-at 6 months	
	defaecation	encopresis	The	frequency and	year, and 1 1/2	CT (n=94):	High percentage of non compliance
	dynamics and	episodes per	Netherlands	encopresis and/or	years	48/93 (52%)	reported by parents if the child was
	outcome in	week,		soiling episodes			asked to attempt toilet training 15–30
	chronically	periodic		were discussed	Outcome	CT+BF (n=98):	min after the meal to profit from the
	constipated	passage of			Measures:	44/94 (47%)	gastro—colic reflex
	children	very large		High-fibre diet			
		amounts of		advised but	Treatment	NS	Treatment was considered successful if
		stool at least		additional fibre	success		the patients achieved ≥3 bowel
		once every 7-		supplements		-at 1 year	movements per week and < 2 soiling or
		30 days, or a		not prescribed		CT (n=94):	encopresis episodes per month while
		palpable				54/92 (59%)	not receiving laxatives for 4 weeks
		abdominal or		Patients			
		rectal mass.		instructed to try to		CT+BF (n=98):	It was estimated that a sample of 180
		Children		defecate on the		46/92 (50%)	patients would be adequate to show a
		needed to be		toilet for 5 min			difference of at least 70% success at 6
		at least 5		immediately after		NS	months for CT+BF compared to 45%
		years		each meal			success using CT with a two-tailed alfa
		old to				-at 1 1/2 year	2 of 0.05 with a power of 90%
		understand		During the first 3		CT (n=94):	
		the		days patients		52/92 (57%)	At baseline patients were comparable
		manometric		were to use daily			for gender, age, and frequency of
		procedures		enemas (120 mL		CT+BF (n=98):	gastrointestinal complaints, and urinary
		and		sodiumdioctylsulfo		44/92 (48%)	problems
		instructions		succinate, 1 mg			

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
		and had to		sorbitol, 250 mg			At 6 months, 5 patients were lost (4
		have had		per mL, Klyx) at			patients in the CT+BF and 1 patient in
		treatment with		home. If, on day			the CT group), and at 1 year 8 patients
		laxatives for a		3, enemas still			were lost to follow up (another 2 in the
		minimum of 1		resulted in large			CT+BF and 1 in the CT group). Patients
		month before		amounts of stool,			lost to follow up were withdrawn from
		randomisation		enemas were			further analysis
				continued for a			
		Exclusion		maximum of 7			During the intervention period, 3 patients
		criteria:		days. After the			in the CT group refused manometry at
		Hirschsprung'		initial 3-day			the end of the treatment period: 1
		s disease,		enema treatment,			patient was successfully treated and the
		spina bifida		patients started			parents refused permission for
		occulta,		oral laxatives with			manometry; 1 patient was
		hypothyroidis		Importal (lactitol			unsuccessfully treated and refused
		m or other		betagalactoside			manometry; and 1 patient was lost to
		metabolic or		sorbitol, 1 sachet			follow-up after two visits. 2 patients of
		renal		of 5 g/10 kg body			the CI+BF group discontinued
		abnormalities,		weight per day			treatment: one 5-year-old patient did not
		mental		divided in 2			cooperate and another patient
		retardation,		doses). Enemas			discontinued treatment because his
		and		given whenever			parents could not afford the cost of
		children using		spontaneous			transport.
		arugs		defaecation was			
		influencing		delayed for more			At the beginning and end of the 6-week
		gastrointestin		than three days.			treatment period, each patient had a
		al function		Motivation			detailed medical history, abdominal and
		otner		ennanced by			rectal examination, and anorectal
		than laxatives		praise and small			manometry. The child and parents were
				gifts			asked about bowel function, frequency
				Companiaon			or deraecation solling and/or encopresis,
				Comparison:			consistency and size of stool, pain
							ouring defaecation, and associated
				5 outpatient visits,			symptoms such as abdominal pain,
				including the			appente, and enuresis. Follow up
				Sallie			atopdard quastionpairs or by talashara
				conventional			standard questionnaire or by telephone
				treatment as			

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
				described above, in combination with 5 biofeedback training sessions. As far as possible, both groups received equal attention.			Because other studies have selected patients for evaluation according to the presence of abnormal defaecation dynamics at the start of the study, authors compared defaecation dynamics at randomisation and after treatment, and found no correlation between achievement of normal defaecation dynamics and success. Analysis of all patients showed no relationship between post-treatment defaecation dynamics and success. Log-linear modelling showed significant relationships between pre-treatment and post-treatment defaecation dynamics (x2= 13·91, p<0·001) and between treatment and post-treatment defaecation dynamics (x2=28·38, p<0·001). There was no association between post-treatment defaecation dynamics and treatment success after 6 weeks (x2=2·41, p=0·12). The results at 6 months and 1 year were similar <u>Reviewer comments:</u> Randomisation and allocation concealment methods not reported Not completely clear who measured outcomes and how ITT analysis not performed <u>Source of funding:</u> Not stated

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Nolan et al.	Study Type:	29 children	29 children	Intervention:	Duration of	Treatment outcome	Additional information from study:
Randomised	Parallel-RCT			EMG biofeedback	treatment		Originally, it was planned to recruit 25
controlled trial		Inclusion	24 boys	training and	CT: Unclear	-Full remission:	subjects into each group, which would
of biofeedback	Evidence	criteria:		conventional		BFT+CT (n=14):	mean that, at the alfa = 0.05 level (one
training in	level:	Children aged	age range: 4.8	medical treatment	BFT: up to 4	2 (14%)	tailed), there would be 80% power to
persistent	1+	≥4 years,	to 14.9 years	(BFT+CT)	weeks		detect at least a 38% point advantage of
encopresis with		judged to be				CT (n=15):	biofeedback (32% against 70% or
anismus. 1998.	Study aim:	of adequate	-mean age	Up to 4 sessions	Assessment	2 (13%)	better) in the comparison group. An
Archives of	To determine	maturity to	(years) (SD):	at weekly intervals	<u>point (s):</u>		interim analysis conducted when it
Disease in	whether	cooperate		conducted for	6 months	95% CI on difference,	became clear that successful and
Childhood	surface	with	BFT+CT :	each patient, each		-24% to 26%	sustained biofeedback outcomes were
79[2], 131-	electromyogra	biofeedback	9.2 (2.7)	session consisting	Follow-up		not occurring. A revised sample size
135United	phic (EMG)	treatment and		of ~ 30–35	period:	-Improved:	calculation was based on argument that
Kingdom.	biofeedback	had received	CT:	defecation	None	BFT+CT (n=14):	if no successful outcomes were to be
	training	3 months or	8.4 (2.3)	attempts. Aim was		2 (14%)	achieved in 15 subjects
	produces	more of		to achieve 10	<u>Outcome</u>		randomised to biofeedback, there would
	sustained	conventional	Country:	relaxations of the	Measures:	CT (n=15):	be a 95% confidence that the true rate
	faecal	multimodal	Australia	external anal		4 (27%)	of successful outcome could not be
	continence in	therapy; had		sphincter without	Treatment		greater than 18%. The precision of the
	medical	continuing		visual feedback in	success	p = 0.7; 95%Cl on	final result was expressed in the
	treatment	soiling with or		2 successive		difference, −46% to	confidence interval (CI) around the
	resistant	without		sessions.		23% (for remission	difference in remission rates
	and/or	laxative		If this occurred in		and improvement	
	treatment	treatment		less than 4		combined)	Procedure to determine whether
	dependent	(more than		sessions then			anismus was present involved the use of
	children with	once a		biofeedback was		-No improvement:	a balloon filled with 50 ml warm water.
	anismus	month) or had		discontinued.		BF1+C1 (n=14):	After a tuition period to explain what was
		achieved		At completion of		10 (71%)	required to achieve correct straining and
		remission		training, subjects			squeezing, patient asked to make 5
		from soiling		followed at		CI (n=15):	alternating attempts each to squeeze
		but could not		monthly intervals		9 (60%)	and strain. Normal strain response
		sustain		by			defined as a persistent decrease in
		continence		a single		3/14 patients in the	external anal sphincter activity
		without		paediatrician, who		BFI group completed	(measured by a decrease in amplitude
		continued		gave verbal		the training in 3	of the electromyographic recording and
		laxative		reinforcement of		sessions, and the	an increase in rectal pressure of at least
		treatment;		the skills learned		remainder underwent	50 mm Hg) in at least 3 of 5 attempts. A
		and had		during training		4 sessions. Only 1	persistent increase in external anal

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
		anismus on				patient was unable to	sphincter activity with a corresponding
		EMG during		Comparison:		demonstrate	increase in rectal pressure in at least
		anorectal		Conventional		relaxation of the	four of five attempts were
		manometry		medical treatment		external anal	deemed as indicating anismus
				alone (CT)		sphincter with	
		Exclusion				attempted defecation.	Randomisation carried out using a
		<u>criteria</u> :		 Laxative therapy 		Only 1 patient (same	stratified, blocked schedule, with
		known		in 2 phases:		one) was unable to	subjects stratified on the basis of
		structural		1. Initial		defecate the	whether they were soiling or were in
		congenital		disimpaction		biofeedback balloon	laxative dependent remission. Each
		or		phase: 3-day		by the time of their	treatment allocation was recorded on a
		postoperative		cycles of 5 mL		final session. All	card in an opaque numbered and sealed
		anatomical		'Microlax' enemas		complied well with	envelope and stored sequentially. An
		defect (such		(sodium citrate)		instructions and	individual not connected with the clinic
		as		on day 1, one 5		procedures involved	or the study carried out the
		spina bifida or		mg bisacodyl		in the training. 2	randomisation plan
		anorectal		tablet after school		complained of	
		malformation)		and 1 in evening		transient discomfort	Full remission defined as no medication
		, or		of day 2. Up to 4		when the biofeedback	and no soiling for at least 4 weeks; full
		Hirschsprung'		cycles (12 days)		apparatus was	remission on medication was defined as
		s disease		undertaken.		inserted. No other	on
		(excluded by		Further cycles		adverse effects seen	medication and no soiling for at least 4
		rectal		prescribed if later		or reported	weeks; partial remission defined as
		biopsy only if		evidence of stool			soiling no more than once a week,
		clinically		reaccumulation			regardless of medication used. The use
		indicated)					of medication was attempted by all
				2. Maintenance			those not in full remission, not only
				phase: liquid			those who were worse or not improved.
				parattin 5 to 30 ml			The remainder were those who were
				once or twice a			solling more than once a week,
				day, senna			regardless of medication use.
				granules and or			Improvement defined as progression by
				bisacodyl tablets.			at least one level from baseline status,
							but without achieving full remission
				Medication			Descent an above of the b
				use decreased to			Presence or absence of continued
				a level consistent			solling ascertained on the basis of
				with			parental report, assisted by daily diary

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
				maintenance of			record. Patient data recorded
				continence as			prospectively in a relational database
				monitored by			was also used for appointment
				bowel			scheduling and data quality control
				diary			
							At baseline there were slightly more
				-Standard			subjects with primary encopresis in the
				paediatric			biofeedback group than in the control
				behaviour			group
				modification:			
				clarification during			Reviewer comments:
				joint parent-child			No definition of constipation given
				interview of the			
				postulates			Small sample size
				underlying			
				physiological			Unclear how the use of medication was
				basis for			measured
				encopresis. Bowel			
				training			No dropouts/lost to follow up reported
				programme used			
				positive			Results not controlled for potential
				reinforcement for			confounders
				successful			
				defection in toilet			Source of funding:
				and additional			grants from the National Health and
				reinforcement for			Medical Research Council (grant
				each 24h without			910621) and the Royal Children's
				soiling.			Hospital Research Foundation
				Reinforcement			
				consisted of			
				parental praise			
				and use of start-			
				chart diary (fitness			
				training card) to			
				indicate soiling-			
				free days. Regular			
				sitting programme			
				of 5 to 10 minutes			

Bibliographic	Study Type &	Number of Patients	Patient Characteristic	Intervention &	Follow-up &	Effect Size	Reviewer Comments
mormation	Level	i atiento	S	Companson	Measures		
				toilet-time within 30 minutes of each meal was basis of the programme. -Dietary advice, general counselling and support provided by paediatrician. Psychiatric assessment or treatment initiated when indicated clinically			

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Borowitz et al.	Study Type:	87 children	87 children	Intervention:	Duration of	Soling	Additional information from study:
Treatment of	Parallel-RCT			Intensive medical	treatment	frequency(mean, SD)	Using a random number generator,
childhood		Inclusion	72 boys	therapy (IMT)	Unclear	-at 3 months:	blocks of six consecutive children were
encopresis: A	Evidence	criteria:				IMT: 0.54 (0.68)	randomly assigned to one of 3 treatment
randomized trial	level:	Children	Mean age at	1 of 2 paediatric	Assessment		groups
comparing three	1+	aged between	time of	gastroenterologist	point (s) and	ETT: 0.22 (0.21)	
treatment		5 and 15	enrollment: 8.6	s directed	follow-up period		All data were collected using the
protocols. 2002.	Study aim:	years	± 2.0 years	treatment: colonic		BF: 0.34 (0.51)	Automated Patient Symptom Monitor
Journal of	To compare	of age who	(range, 5 to 13	disimpaction with	When subjects		system, a computerized voice-mail
Pediatric	short- and	had	years)	a series of	had been	-at 6 months:	system that telephones the families
Gastroenterolog	long-term	experienced		enemas followed	enrolled in the	IMT:0.44 (0.52)	each day. With each telephone call, the
y and Nutrition	effectiveness	encopresis for	Country:	by sufficient	study, data		computer asked parents the same 8 pre-
34[4], 378-	of	a minimum of	USA	laxative therapy to	concerning	ETT: 0.38 (0.45)	recorded questions relating to bowel
384United	three additive	6 months,		produce at least 1	toileting habits		habits during the previous 24 hours.
States.	treatment	defined as at		soft stool each	were collected	BF:0.20 (0.26)	After parents had answered all
	protocols in	least weekly		day without	for 14		questions, the computer checked
	children	episodes of		associated pain.	consecutive	-at 12 months:	responses to ensure all items were
	experiencing	faecal soiling		Laxatives	days before	IMT:0.33 (0.48)	answered and that responses were
	chronic	for at least 6		prescribed: Milk of	and after the		within acceptable ranges. If the
	encopresis	months		Magnesia and/or	initial outpatient	ETT: 0.36 (0.53; 95%	computer detected an error, the
				senna (Senokot,	visit, and again	confidence interval,	questionnaire was repeated
		Exclusion		Ex-Lax, or	at 3 months,	0.05 to 0.47)	
		criteria:		Fletcher	6 months, and		No significant differences in baseline
		any chronic		Castoria).	12 months after	BF:0.27 (0.37)	clinical or demographics characteristics
		underlying		Laxative dosages	initiation of		between the 3 groups
		medical		adjusted regularly	therapy	NS among the 3	
		conditions or		to produce 1 to 3		groups at any time	Treatment considered successful if the
		developmenta		soft bowel	<u>Outcome</u>		child experienced no episodes of faecal
		l disabilities		movements daily.	Measures:	Improvement rate (%	soiling during the 2-week assessment
				An enema or	-soling	<u>children)</u>	12 months after initiation of therapy
				suppository	frequency	-at 2 weeks:	
				administered if		IMT: 41	Reviewer comments:
				child had not	-improvement	FTT 40	No definition of constipation given
				produced a bowel	rate	E11:48	
				movement during			No sample size calculation performed
				a 48-nour period.	-cure rate	BF: 62	
				INO SPECIFIC dietary	a combine of		ivietnod of allocation concealment not
				recommendations	-number of	NS between 3 groups	reportea

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
				or manipulations	bowel		
				undertaken.	movements	-at 3 months:	No drop outs/lost to follow up children
				Families received	passed in the	IMT: 45	reported
				specific	toilet each day		
				instructions and		ETT: 85	Source of funding:
				written brochure	-self-initiated		supported by National Institutes of
				detailing	toileting each	BF: 61	Health grant RO1 HD 28160
				treatment protocol	day		
				and need for		-at 6 months:	
				children to attend	-laxative use	IMT: 41	
				the toilet at least			
				twice dally,		ETT: 74	
				preferably after			
				breakfast and		BF: 58	
				supper			
						-at 12 months:	
				Comparison 1:		IMT: 41	
				Intensive medical			
				therapy +		ETT: 78	
				enhanced toilet			
				training (ETT)		BF: 61	
				.			
				Similar enema		At 3 months, 6	
				and laxative		months, and 12	
				therapy, with 1		months, the number	
				clinical		of children who	
				psychologist		responded in the ETT	
				adjusting laxative		group was	
				dose. Only		significantly greater	
				difference from		than in either the IM I	
				previous therapy		or the BF group ($P < 1$	
				was that laxative		U.U5), and these	
				therapy was		results were very	
				decreased		stable over time (P <	
				gradually when		0.001). With all 3	
				children		regimens, response	
				demonstrated		to treatment during	
				stable bowel		the first 2 weeks of	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
				frequency with no		therapy strongly	
				soiling episodes.		correlated with	
				As long as child		response to treatment	
				had daily bowel		at 3, 6, and 12	
				movements of		months (r > 0.90, P <	
				normal size for a		0.0001 in all cases).	
				week, laxative		Of those children who	
				dose was		had significant	
				decrease by one		improvement	
				quarter. This		after 2 weeks of	
				process was		therapy, 86 continued	
				continued until		to improve at 3	
				laxative therapy		months, 83 at 6	
				was discontinued.		months, and 81 at 12	
				If child did not		months	
				pass daily bowel			
				movements of		Cure rate (number of	
				normal size,		children cured)	
				laxative dose was		-at 12 months:	
				increased.			
				Parents and child		IMT: 10/29 (34.5%)	
				instructed on the			
				psychophysiology		ETT: 12/27 (44.4%)	
				of constipation			
				and encopresis,		BF: 11/31 (35.5%)	
				and how			
				responding to		chisquare=0.9488	
				early rectal			
				distention cues		p=0.7005	
				along with regular			
				toileting was		Number of bowel	
				critical to avoid		movements passed in	
				reimpaction and		the toilet each day	
				to establish		(mean, SD)	
				regular bowel		-at 3 months:	
				nabits. Various		INTE:1.44 (0.57)	
				incentive			
				programs		ETT: 1.21 (0.49)	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
				established,			
				depending on the		BF: 1.25 (0.64)	
				developmental			
				age and the		-at 6 months:	
				motivation of the		IMT:1.36 (0.61)	
				child. Target			
				behaviours:		ETT:1.31 (0.63)	
				spontaneous trips			
				to the toilet and		BF:1.12 (0.60)	
				clean pants.			
				Toilet training was		-at 12 months:	
				"enhanced"		IMT:1.30 (0.61)	
				because			
				instructions were		ETT:1.01 (0.51)	
				given on the role			
				of paradoxic		BF:1.16 (0.67)	
				constriction of the			
				external anal		NS among the 3	
				sphincter, and		groups at any time	
				because			
				appropriate		Self-initiated toileting	
				defecation		<u>each day (times/day,</u>	
				straining was		<u>mean, SD)</u>	
				modeled. The		-at 3 months:	
				therapist sat on a		IMT: 1.53 (0.77)	
				portable toilet and			
				demonstrated		ETT: 1.62 (0.82)	
				how to relax the			
				legs and feet, how		BF:1.40 (0.71)	
				to take in a deep			
				breath and hold it		-at 6 months:	
				while sitting up		INT:1.49 (0.60)	
				straight, and how			
				to push down with		ETT:1.67 (0.95)	
				the held breath			
				and pull in from		BF:1.34 (0.72)	
				the lower			
				abdomen (rectus		-at 12 months:	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
				abdominous		IMT:1.40 (0.76)	
				muscle) to propel			
				out a stool. The		ETT:1.31 (0.83)	
				child then			
				replicated this		BF:1.31 (0.69)	
				while sitting on a			
				portable toilet.		NS among the 3	
				The child		groups at any time	
				received "hand			
				feedback" by		Laxative use (number	
				placing one hand		of children using)	
				on the abdomen		-at 12 months:	
				just below the		IMT: 17/29 (58.6%)	
				navel to feel the			
				abdomen move		ETT: 9/27 (33.3%)	
				out when the			
				breath was		BF: 17/31 (54.8%)	
				pushed down, and		(chi-square= 4.1414,	
				placing the		P= 0.1261)	
				second hand just			
				below the first to			
				feel inward			
				movement with			
				contraction of the			
				rectus			
				abdominous.			
				Parents instructed			
				to prompt these			
				behaviours at			
				home.			
				Additionally, 8 to			
				12 minutes of			
				"toilet time" was			
				scheduled daily,			
				beginning 15 to			
				30 minutes after			
				the same two			
				meals.			

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
				During these			
				times, children			
				were instructed to			
				practice tensing			
				and relaxing the			
				external anal			
				sphincter for the			
				first 4 minutes,			
				with the objective			
				of localizing			
				control of and			
				fatiguing the			
				external anal			
				sphincter, and to			
				mechanically			
				stimulate the			
				rectum. To			
				desensitize			
				children to toilet			
				sitting, the second			
				4 minutes were			
				spent "having fun"			
				while being read			
				to or playing			
				games. During the			
				final 4 minutes,			
				the child was to			
				strain and attempt			
				to have a bowel			
				movement while			
				relaxing his or her			
				legs and feet. This			
				routine toilet			
				sitting was			
				discontinued 2			
				weeks after the			
				last scheduled			
				treatment session			
Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
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				Comparison 2: Intensive medical therapy + enhanced toilet training + anal sphincter biofeedback (BF) Same instructions that previous 2 groups and simultaneously received surface electromyographic biofeedback training. Same 2 psychologists who worked with the ETT group also worked with the BF group			

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Sunic-Omejc et	Study Type:	49 children	49 children	Intervention:	Duration of	Therapeutic success	Additional information from study:
al. Efficiency of	Parallel-RCT			Conventional	treatment	(number of children	Treatment considered successful if a
biofeedback		Inclusion	27 male	treatment (CON)	12 weeks	<u>cured)</u>	frequency of \geq 3 stools /week and < 2
therapy for	Evidence	criteria:					episodes of soling or encopresis per
chronic	level:	Children aged	Mean age	Per oral	Assessment	-CON: 15/24 (62.5%)	month were achieved without laxatives
constipation in	1+	>5 years who	(CON):	administration of	point (s):		
children. 2002.		met at least 2	94 ± 33 months	Portalak	At 12 weeks	-BFB: 21/25 (84%)	Therapeutic success evaluated by use
Collegium	Study aim:	of the		(lactulosis, 240			of questionnaires distributed on weekly
Antropologicum	To asses the	following	Mean age	mg/day or 10 mL	Follow-up	P<0.05	visits
26 Suppl, 93-	success of	criteria fro	(BFB):	syrup) with dose	period:		
101	biofeedback	chronic	92 ± 35 months	titration for the	None		No significant differences in baseline
	method vs.	constipation:		patient to have at			characteristics between 2 groups
	conventional	defecation	Country:	least 3	<u>Outcome</u>		
	method in the	frequency < 3	Croatia	stools/week.	Measures:		All children completed treatment
	treatment of	times/week, ≥		When			
	chronic	2 episodes of		spontaneous	Therapeutic		Reviewer comments:
	constipation in	soiling and/or		defecation failed	success		Small sample size, no sample size
	childhood	encopresis		to occur for > 3			calculation
	over a 12-	/week,		days in spite of			
	week period	periodic		appropriate			Randomisation and allocation
	and to follow-	evacuation of		therapy an enema			concealment methods not described
	up the effect	large volume		was used. In			
	of	stools at least		addition a fibre-			Insufficient details on who measured
	biofeedback	once every /		rich diet and			outcomes and how
	treatment on	to 30 days		attempting			
	defecation	and paipable		detecation after			Results not controlled for potential
	dynamics and	abdominal or		meal were			contounders
	otner	faecal mass		advised			
	anorectai	Evolucion		Companiana			Source of funding:
	manometric	EXClusion		Comparison:			Not stated
	parameters	<u>criteria</u> : Hirochonrung'		Conventional			
		Hirschsprung		treatment (CON,			
		s ulsease,		as previous) +			
		spilla billua,					
		m motobolic					
				Drosouro			
		dioordoro		toobniquo			
		uisoraers,		technique.			

Bibliographic	Study Type &	Number of Patients	Patient Characteristic	Intervention &	Follow-up &	Effect Size	Reviewer Comments
internation	Level	1 ulionito	S	Companioon	Measures		
		mental retardation, taking drugs for	3	Child and parents instructed on how to perform Kegel exercises at home. Exercises include alternating 10-second contraction and relaxation of sphincter and pubo-rectal muscle, performed 5 times a day in 20 cycles	Measures		

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Loening-	Study Type:	129 children	129 children	Intervention:	Duration of	Stool frequency/week	Additional information from study:
Baucke.	Retrospective			Conventional	treatment	<u>(mean ± SD)</u>	Parents and children instructed to keep
Biofeedback	cohort	Inclusion	97 boys	treatment (CT) +	BF: between 2		diary of bowel movements, faecal soiling
treatment for		criteria:		biofeedback (BF)	and 6 weeks	BF (n=63): 5 ± 3	and medication used
chronic	Evidence	Children 5 to	Mean age			CT (n=66): 6 ± 3	
constipation	level:	18 years with	(years):	At least 2 and up	CT: unclear	N.S	Of 64 patients who originally received
and encopresis	2+	chronic		to 6 weekly			biofeedback 1 patient did not return after
in childhood:		constipation	-CT group	training sessions	Follow-up	% of children soiling	the first unsuccessful biofeedback
long-term	Study aim:	and	Initial:	given. 1 session	period:		session and was lost to follow-up. The
outcome. 1995.	To evaluate if	encopresis	9.1 ± 3.3	included	-CT group:	BF (n=63): 35	63 patients included in the biofeedback
Pediatrics 96[1	patients who	(≥1 soiling		approximately 30	4.2 ± 2.5 years	CT (n=66): 24	group were combined from 2 studies
Pt 1], 105-110	received	episode per	Follow-up:	to 35 defecation		N.S	(clinical characteristics of both groups
	biofeedback	week)	13.4 ± 3.3	trials and lasted	-BF group:		were similar): 21 patients from an RCT
	treatment			approximately 45	4.1 ± 2.4 years	Soiling	(included already in this review, see
	(BF)	Exclusion	-BF group	to 60 minutes.		frequency/week	Loening-Baucke, 1990) and 42 patients
	continued with	criteria:	Initial:	Number of	Outcome	(mean ± SD)	who had not recovered after at least 6
	improved	Hirschsprung'	10.4 ± 3.2	training sessions	Measures:		months of conventional treatment.
	outcome	s disease,		given depended		BF (n=63):1 ± 2	Patients were charged for this service.
	compared	hypothyroidis	Follow-up:	on how soon child	-stool frequency	CT (n=66):1 ± 2	Because of cost, inability to return for
	with patients	m, mental	14.5 ± 3.3	learned to relax		N.S	weekly biofeedback training or parent's
	who received	deficiency,		external sphincter.	-presence of		and children's satisfaction with the
	conventional	chronic	Country:	Sessions stopped	soiling	Recovery rate	marked improvement of constipation
	treatment	debilitating	USA	after 10		(number of children,	and encopresis with conventional
	alone (CT)	diseases,		relaxations of the	-soiling	<u>%)</u>	treatment these patients chose to
		neurologic		external sphincter	frequency		continue with conventional treatment. 23
		abnormalities,		without visual		BF (n=63): 28 (44)	patients have been originally included in
		previous		feedback could be	-recovery rate	CT (n=66): 41 (62)	the RCT but 1 boy was lost to follow-up
		surgery of the		accomplished in		N.S	after the first biofeedback session and a
		colon		each of 2	-laxative use		second patient received a central
				successive		Laxative use (%	nervous system shunt during the follow-
				training sessions		children using	up period and was exclude from
						laxatives)	analysis
				Comparison:			
				Conventional		BF (n=63): 25	In May 1993 parents requested by email
				treatment alone		CT (n=66): 18	to fill out with the help of their children a
				(CT)		N.S	structured questionnaire eliciting
							information on the presence of soiling
				CT: use of			and frequency and amount of soiling per

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S	la va ti va a	Measures		
				laxatives,			week, the frequency and size of bower
				fibro and			Inovertients per week and the use of
				schodulod			auestionnaires again were mailed to non
				toiloting (child			responders and to those families
				instructed to			evaluated between January and May
				defecate fro 5			1993 non responders were contacted
				minutes after			by telephone
				each meal and			by telephone
				after returning			Patients considered to have recovered if
				from school for			they had \geq 3 bowel movements/week
				the initial months.			and solling ≤ 2 episodes/month while off
				and try to			laxatives for at least 1 month. Patients
				defecate at least			considered not to have recovered if they
				daily once they			had <3 bowel movements/week or were
				could recognise			soiling >2 times/month or had been
				the urge to			started on a regime of laxatives again
				defecate			
							Baseline characteristics were
				Disimpaction with			comparable between both groups
				enemas (type and			except for the presence of an abdominal
				dose not reported)			faecal mass (number of children, BF: 60
							vs. CT: 41; p<0.05)
				Maintenance: milk			
				of magnesia ~			Age and follow-up age were not related
				2ml/kg body			to outcome in either group. The length of
				weight daily to			follow-up was significantly related to
				induce at least 1			recovery for the biofeedback group
				bowel movement			(p<0.02) and for all patients $(p<0.01)$ but
				daily and prevent			showed no relationship for the
				faecal retention.			conventionally treated group
				Doses decreased			Boviowor commente:
				gradually to			No clear definition of constinution given
				howel movement			Into clear deminion of consupation given
				and prevent			Source of funding:
				faecal retention			Supported by grant No. M01-RP 00050
				and soiling			from the General Clinical Research
				faecal retention and soiling.			Supported by grant No. M01-RR-00059 from the General Clinical Research

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Level	Patients	S	Comparison	Measures		
	Level		5	Occasionally mineral oil or senna used instead of milk of magnesia	MedSures		Centre Program,, Division of Research Resources, National Institute of Health; the Children's Miracle Network Telethon and the Spelman-Rockefeller Child and Parenting Seed Grant

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
van Dijk et al.	Study Type:	134 children	134 children	General:	Intervention	IRR: incidence rate	Additional information from study:
Behavioral	Parallel-RCT			-Disimpaction:	period:	ratio	At entry, patients had to meet at least
therapy for		Inclusion	76 boys	daily Klyx enemas	For both CT	RR: relative risk	2 of 4 criteria: defecation frequency< 3
childhood	Evidence	criteria:		(sodium-	and BT 12 visits	CT (n=67)	times per week, faecal incontinence ≥ 2
constipation: a	level:	Children with	age range: 4 to	dioctylsulfosuccin	during 22	BT (n=67)	times per week, passage of large
randomized,	1+	functional	18 years	ate and sorbitol;	weeks with		amounts of stool at least once every 7 to
controlled trial.		constipation		60 mL/day for	similar intervals	Defecation frequency	30 days (large
2008. Pediatrics	Study aim:	aged 4 to 18	-mean age:	children ≤ 6 years	between	per week, mean (95%	enough to clog the toilet), or a palpable
121[5], e1334-	To evaluate	years referred		of age; 120	treatment	<u>CI)</u>	abdominal or rectal faecal mass
e1341	the clinical	to the	CT group: 6.5	mL/day for	sessions		
	effectiveness	gastrointestin	(2.1)	children > 6 years		-Post-treatment	After baseline measurement and if
	of	al outpatient		of age) for 3	<u>Assessment</u>		written informed consent was given, a
	behavioural	clinic at the	BT group: 6.9	consecutive days	point (s) &	CT: 7.2 (6.1 to 8.5)	research assistant performed a
	therapy with	Emma	(2.5)	was prescribed by	follow-up	BT: 5.4 (4.3 to 6.7)	telephone call to a randomization centre
	laxatives	Children's		paediatric	period:		and revealed the allocation to parents
	compared	Hospital	Country:	gastroenterologist		-Follow-up	immediately. A computer-based system
	with	between 11/	The	s before starting	At the last visit		used to generate a sequence of random
	conventional	2002 and	Netherlands	treatment	(posttreatment	CT: 6.6 (5.0 to 8.8)	group assignment for consecutive
	treatment in	August 2004			time point) and	BT: 5.3 (4.4–6.3)	patients. Random assignment stratified
	treating			-Maintenance:	6 months after		by age (4 to 8 years or ≥8 years) and
	functional	Exclusion		polyethylene	the 22-week	Group (main effect of	gender. Within 2 weeks after random
	constipation in	<u>criteria</u> :		glycol 3350, 1	treatment	BT):	assignment, patients received their 1rst
	childhood	Having		sachet (10 g) per	ended (follow-		treatment session
		received a		day, and if	up).	IRR=0.75 (0.59 to	
		comprehensiv		treatment	Time between	0.96) p=0.021	Sample size calculated to allow
		e BT in the		considered to	baseline		detection of a 25% difference in the
		previous 12		have insufficient	assessment	Group x time	proportion of success between BT and
		months, use		effect dose	and follow-up:	(interaction effect of	CT. It was estimated that CT reached
		of drugs		increased by 1	~1 year	BT with measurement	success in 35% of the children at follow-
		influencing		sachet. If		at follow up):	up. Under the additional assumption of a
		gastrointestin		spontaneous	<u>Outcome</u>		significance level of .05, a power of .80,
		al function		defecation	Measures:	IRR= 1.06 (0.75 to	and 2-sided hypothesis testing, a
		other than		delayed for >3		1.50) p=0.758	minimal sample size of 124 with 62
		laxatives,		days, parents	-Primary		children in each group was determined
		organic		advised to give an	outcomes	Faecal incontinence	
		causes for		enema or		per week, mean (95%	During treatment 2 (3.1%) of 64 in the
		detecation		bisacodyl	a. detecation		CI group and 9 (13.8%) of 65 in the BT
		disorders, e.g		suppository of 5	trequency		group discontinued intervention

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures	_	
		Hirschsprung'		mg. In BT	per week	-Post-treatment	(P=0.054). At follow-up, 4 patients
		s disease,		preferred to give			dropped out in CT. There was 1 loss of
		spina bifida		oral bisacodyl	b. faecal	CT: 2.1 (0.8 to 5.8)	contact, and 3 children were referred for
		occulta,		tablets of 5 mg	incontinence	BT: 5.0 (2.1 to 12.0)	BT directly after CT, making them
		hypothyroidis		instead of rectal	frequency per		unsuitable for follow-up measurements.
		m, or other		laxatives. During	week	-Follow-up	Questionnaires were not returned by 3
		metabolic		BT, paediatric			patients in both intervention arms at
		or renal		psychologists	c. successful	CT: 6.4 (3.5 to 11.7)	posttreatment and by 9 patients (CT: 6;
		abnormalities		adjusted laxative	treatment	BT: 8.6 (4.0 to 18.3)	BT: 3) at follow-up
				dose and			
				consulted	-Secondary	Group (main effect of	Except for painful defecation (65.0% CT
				paediatric	outcomes:	BT):	vs. 43.1% BT, P=0 .014), no significant
				gastroenterologist			differences between the 2 groups in
				when necessary.	a. stool	IRR=2.36 (0.77 to	baseline sociodemographic factors or for
				In both treatment	withholding	7.31) p=0.135	clinical characteristics
				groups, patients	behaviour		
				kept a bowel diary		Group x time	Intent-to-treat analyses conducted.
						(interaction effect of	Because of withdrawal before treatment
				Intervention:		BT with measurement	start, dropouts during the study, failure
				Protocolised		at follow up):	to fill out questionnaires, or research
				behavioural			procedure violations, missing data
				therapy (BT)		IRR= 0.57 (0.12 to	occurred. Imputation of missing values
						2.61) p=0.467	used to make intent-to-treat analyses
				-developed by			feasible
				paediatric		<u>Success, % (95% CI)</u>	
				psychologists of			I reatment considered successful if
				the psychosocial		-Post-treatment	patients achieved a defecation
				department of our		C1: 62.3 (51.1 to	trequency of ≥3
				hospital. Basic		76.1) BT: 51.5 (39.7	times per week and a faecal
				assumption that		to 66.9)	incontinence frequency of ≤ 1 times per
				phobic reactions			2 weeks, irrespective of laxative use
				related to		RR= 0.83 (0.60 to	
				defecation		1.14) p=0.249	Reviewer comments:
				can be reduced			Insufficient details on how outcomes
				and that adequate		-Follow-up	were measured
				toileting behaviour		C1: 57.3 (46.6 to	
				and appropriate		70.4) BT: 42.3 (31.8	Results controlled for confounders
				defecation		to 56.4)	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S	atraining can be	Measures		Courses of funding:
				straining can be		PP- 0.74 (0.52 to	Source of funding: funded in part by the Dutch Digestive
				(re)acquired by		RR = 0.74 (0.52 10)	Disease Equadation (SWO 02.16)
				behavioural		1.05) p=0.095	Disease Foundation (SWO 02-10)
				procedures and		Stool withholding	
				by behavioural		behaviour at follow-	
				by benavioural		up (% children with	
				the child in		behaviour)	
				nresence of his or			
				her parents. The		CT: 13.8	
				notocol consists		BT: 10.6	
				of 2 age-related		NS	
				modules:			
				a module for			
				children aged 4 to			
				8 vears and a			
				module for			
				children aged ≥8			
				years. Learning			
				process for child			
				and parents: 5			
				sequential steps			
				(know, dare can,			
				will, and do). This			
				approach is			
				derived from a			
				multidisciplinary			
				BT to treat			
				children with			
				defecation			
				disorders.			
				For all involved			
				psychologists, a			
				detailed manual			
				rolotod modules			
				available to			
				avaliable ID			
				ensule a standalu			

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
				delivery of			
				therapy. Visits			
				lasted ~45			
				minutes			
				Comparison:			
				Conventional			
				treatment (CT)			
				-conducted by			
				paediatric			
				gastroenterologist			
				s, visits lasted ~20			
				to 30 minutes,			
				laxative treatment			
				and bowel diary			
				discussed.			
				Patients and their			
				parents received			
				education to			
				explain that			
				symptoms are not			
				harmful and are			
				common in			
				children with			
				functional			
				constipation and			
				that a positive,			
				non-accusatory			
				approach is			
				essential.			
				Children			
				instructed not to			
				withhold stool			
				when they feel			
				urge to defecate.			
				Motivation			
				enhanced by			

Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
	Levei		5	praise and small gifts from the paediatric gastroenterologist s	Measures		

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Ritterband et al.	Study Type:	24 children	24 children	Intervention:	Duration of	Percentage change	Additional information from study:
An Internet	Parallel-RCT			Laxatives + Web	intervention:	from pre- to post-	Computer and internet access provided
intervention as	(multicentre)	Inclusion	19 boys	intervention	3 weeks	assessment	to all families who contacted the
adjunctive		/exclusion					research centre and met the inclusion
therapy for	Evidence	criteria:	mean age: 8.46	Comparison:	<u>Assessment</u>	Number of faecal	criteria
pediatric	level:	Children aged	years (SD1.81)	Laxatives only	point (s):	accidents per week	
encopresis.	1+	between 6			3 weeks after	<u>(mean, SD)</u>	Participants received a \$25 gift
2003. Journal of		and 12 years,	-Web group: 12	Laxatives: all	initial home visit	-Web group: 0.50	certificate to a local toy sore for
Consulting and	Study aim:	soling at least	children (10	children instructed		(.85)	completing the pre-treatment
Clinical	To examine	once a week	boys)	to start with a	Follow-up		assessment and another \$25 gift
Psychology	the utility and	and have no		basic regime of	period:	-No-Web group: 8.27	certificate for completing the post-
71[5], 910-917	effectiveness	medical	-No-Web group:	one square of Ex-	None	(13.83)	treatment assessment
	of an Internet-	diagnosis	12 children (9	Lax (senna), twice			
	based version	other than	boys)	a day	<u>Outcome</u>	Number of bowel	Information regarding BM assessed by
	of enhanced	constipation			Measures:	movements (BM)	parent report on the Child Information
	toilet training	that could		-The Web site:	-number of	passed in the toilet	Form. Question regarding child's bowel
		explain their	Country:	Web-based	faecal accidents	<u>per week</u>	habits included such as number of BMs
		faecal	USA	program for the	per week	-Web group: +152%	in toilet and use of toilet with / without
		incontinence		treatment of			parental prompts. Questions regarding
				paediatric	-number of	-No-Web group: -16%	use of internet programme also included
				encopresis (U-	bowel	p=0.001	in post-treatment form for the
				CAN-POOP-TOO	movements		intervention group. The Virginia
					(BM) passed in	Bathroom use without	Encopresis/Constipation Apperception
				Child-focused	the toilet per	prompts	Test (VECAT) also administered. It
				programme,	week	-Web group: +109%	assesses bowel specific problems
				targets primarily 5			related to the process of encopresis,
				to 10 years old	 bathroom use 	-No-Web group: -	such as avoidance of the toilet, non
				children but was	without prompts	37%	responsiveness to rectal distension cues
				designed to be		p=0.021	and fear of defecation pain. A generic
				used by child and	-bathroom use		subscale included as a comparison
				parent (s)	with prompts	Bathroom use with	measure, addresses problem
				together		prompts	behaviours not related to bowel issues.
					-internet use	-Web group: +47%	The VECAT consists of 18 pairs of
				3 core modules	(most/least		drawings (9 pairs bowel-specific and 9
				take 60 to 90	useful aspect of	-No-Web group: -45%	parallel generic events) and child selects
				minutes to	the programme;	NS	the picture in each pair that best
				complete, all	preference		describes him/herself
				users instructed to	questions	Internet use (Web	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
				review them	regarding	group only)	No significant differences in baseline
				during the first	individual cores		characteristics between the 2 groups
				week:	an modules)	1. Most useful aspect	(age, gender, race, stage of bowel
				1. The body		of the programme:	movement training, length of current
				(anatomy,		-the step by step	laxative regime or any of the outcomes
				physiology and		program to get the	measured)
				pathophysiology		child regulated	
				of digestion)		-understanding why	CM1: anatomy and pathophisiology
				2. How to poop		his body does what it	CM2: medication (enemas/laxatives)
				(behavioural		needs to do	CM3: behavioural intervention
				techniques for		everyday-and what	
				treatment of		happens when he	Reviewer comments:
				encopresis)		doesn't have a BM	No definition of constipation / soling
				Medication		and health	given
				(clean-out and		consequencesinfor	Small sample size, no sample size
				laxative		mation was	calculation
				treatment)		tremendously useful	Randomisation and allocation
						-developing a feeling	concealment method not described
				New modules		that he can control	No dropouts/lost to follow up reported
				assigned each		his own body	
				week based on a		-realising that he's not	Results not controlled for potential
				follow-up		the only child with this	confounders
				assessment the		problemthat was	
				user completes		reassuring	Source of funding:
				about their child's			National Institutes of Health Grant RO1
				status. Not all		2. Least useful aspect	HD28160
				modules		of the programme	
				necessarily used		1.66. 14 141	
				by all users, only		-difficulty with	
				those modules		connections	
				identified as		-modules regarding	
				relevant are		rear of tollet and	
				assigned and		monsters	
				leviewed.		-an work of the body	
						ala not print out	
				viewed by all		-ivilialax should have	
				viewed by all		been included (as a	
				users. Follow-up		choice of laxative)	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
				comprised of 17		-nutrition portion was	
				to 20 questions,		too limited	
				depending on the			
				week. System		Internet experience:	
				contains a total o		parents' views /	
				22 modules, each		satisfaction	
				takes 5 to 10			
				minutes to review		-found material	
						understandable	
						(mean 5.00, SD 0.00,	
						N = 20	
						found it apply to upo	
						(mean 4.62 SD 0.74)	
						(1100114.02, 500.14, 100)	
						N - 21)	
						-believed their child	
						liked the program	
						(mean 4.05, SD 1.28,	
						N = 21	
						 believed their child 	
						found it	
						understandable	
						(mean 4.32, SD 0.89,	
						N = 19)	
						- believed their child	
						found it easy to use	
						(mean 4.47, SD 0.77,	
						N = 19)	
						3. Preference	
						regarding cores	
						modules (CM) (mean,	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
						SD)	
						(score 0 to 4)	
						- 11	
						a. How useful:	
						CIVIT: 3.84 (0.38)	
						CIVIZ. 3.94 (0.24)	
						CIVIS. 4.00(0.00)	
						h. How well did you	
						understand the	
						material	
						CM1: 3.89 (0.32)	
						CM2: 3.89 (0.32)	
						CM3: 3.92 (0.28)	
						· · · · · ·	
						c. how well did your	
						child understand the	
						material	
						CM1: 3.53 (0.61)	
						CM2: 3.28 (1.07)	
						CM3: 3.54 (1.13)	
						d. How much did you	
						enjoy using the	
						CIVIT. 3.00 (0.40)	
						CN2: 3.67 (0.49)	
						01010. 3.08 (0.40)	
						e How much did your	
						child enjoy using the	
						module	
						CM1: 3.63 (0.76)	
						CM2: 3.61 (0.98)	
						CM3: 3.46 (1.13)	
						, ,	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Taitz et al.	Study Type:	47 children	47 children	General	Duration of	Treatment success	Additional information from study:
Factors	Quasi-RCT			In cases where	treatment	did not differed	One year after the beginning of
associated with		Inclusion	26 boys	constipation was	-BhM: 6 weekly	between both groups.	treatment parents sent a postal
outcome in	Evidence	<u>criteria:</u>		severe with large	intervals for		questionnaire, which sought to elicit the
management of	level:	children who	age not	faecal masses	between 3	It is not possible to	response to treatment. This survey
defecation	1+	presented	reported	children initially	months	report the figures	included all patients who 'dropped out' of
disorders. 1986.		with faecal		admitted to the	and 1 year	here, as they were	this study at any stage. They were
Archives of	Study aim:	soiling, with	Country:	ward for		only analysed by the	asked whether they considered the child
Disease in	To report our	or without	UK	defecation was	Assessment	authors according to	cured, improved, or unchanged and
Childhood	experience	constipation		made impossible	<u>point (s):</u>	compliance with	asked how often the child defecated;
61[5], 472-477	with children			by severe	1 year after	treatment and with	whether and how often soiling occurred;
	who	Exclusion		impaction. They	initiating	children social class,	and whether and how often laxatives
	presented	<u>criteria</u> :		were then	treatment	but not according to	were needed. These answers were
	with faecal	identified		continued on		treatment groups	made as objective as possible by
	soiling, with or	organic bowel		whatever laxative	Follow-up		requesting parents to place ticks in
	without	disease or		they had been on	period:		appropriate boxes. This response was
	constipation,	neurological		before referral.	None		then graded into three categories-cured,
	who were	handicaps		Where no laxative	_		improved, and no response, on the
	treated by			had previously	Outcome		basis of the parents' answers to the
	incentive			been used the	Measures:		questionnaire, compared with the clinical
	based			child was offered			assessment before allocation to
	behavioural			a twice	Treatment		treatment groups. Assessment of results
	modification,			daily dose of	success		were thus made by the parents at home
	plus or minus			lactulose. If no			and not by the professionals involved
	psychotherap			accumulation of			
	y, and			faeces no			Criteria for the classification of the
	consider			laxatives			results of treatment:
	factors that			prescribed. No			(1) Cured. At least 5 normal stools each
	might predict			other			week without soiling. Only occasional
	the outcome			laxatives used in			use of laxatives (less than once a week)
	for a non-			this study, and in			(2) Improved. At least three stools each
	intensive			general their			week and solling less than once a week
	approach and			use was			(3) Non-responders. Less than three
	in particular,			minimised, with			stools each week or solling more than
	to draw			the parents			once a week. These children were
	attention to			encouraged to			considered as failing to improve, despite
	social			stop the treatment			the fact that in most cases there was
	background			with laxatives as			less solling than at the beginning of

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Levei		5	soon as a regular	measures		troatmont
	as a			bowel babit			liealment
	indicator			established In			4 children dropped out from the study
	Indicator			none of the			and 13 failed to keep adequate 'star
				children			charts' The 'drop outs' occurred at 1 2
				were			3. and 4 months. 2 children were
				suppositories			subsequently found to be cured
				used at any time.			
				All the children			Reviewer comments:
				were encouraged			No definition of constipation given
				to take a high			
				residue diet and in			Small sample size, no sample size
				particular were			calculation
				asked to			
				take bran with			Baseline characteristics not compared
				their breakfast			
				cereal			Randomisation and allocation
				Internetien.			concealment methods not reported
				<u>Intervention.</u>			ITT analysis not parformed
				modification			in r analysis not penormed
				(RhM)			Source of funding:
							Grants from the Hawley Trust National
				Carried out by			Health Service Locally Organised
				paediatrician. All			Research Grant (Trent RHA) and
				children placed on			CHRIS Fund. Children's Hospital
				a star chart			
				regimen. Children			
				offered varying			
				coloured stars for			
				'sitting on the			
				toilet' and			
				'remaining			
				unsoiled for a full			
				day'. In			
				some cases stars			
				awarded to			
				encourage			

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
				children			
				who were			
				reluctant to take			
				bran in their diet.			
				Contract			
				negotiated			
				between child and			
				parent (usually			
				father) for an			
				award to be made			
				at the discretion of			
				the paediatrician.			
				Child was to			
				understand that			
				the giving of the			
				award would			
				depend on			
				response to			
				treatment.			
				'Demystification',			
				alleviation of guilt,			
				and use of			
				explanatory			
				diagrams			
				generally followed			
				the lines			
				recommended			
				by Levine and			
				Bakow.			
				Children seen at 6			
				weekly intervals			
				by paediatrician			
				for between 3			
				months			
				and 1 year and			
				subjected to			
				shows of affection			
				and interest,			

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S	-	Measures		
				which included			
				careful and			
				serious inspection			
				of the charts.			
				Failure to keep a			
				star chart on 2			
				successive visits			
				resulted in firm			
				statement of			
				displeasure. 2			
				further failures at			
				6			
				week intervals led			
				to the stopping of			
				treatment and			
				discharge with the			
				option of			
				psychiatric			
				referral.			
				Discharge of			
				cured patients			
				was at discretion			
				of the parents			
				Comparison:			
				Behaviour			
				modification (as			
				previous) +			
				psychotherapy			
				(BhM +Psy)			
				Bayabatharany"			
				-r-sycholnerapy:			
				the child			
				nevchiatriet at			
				roughly monthly			
				intervals for			
				nariods batwaen			
				perious perween			

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S	-	Measures		
				two and 12			
				months.			
				Treatment was			
				organised along			
				the following lines:			
				(1) At each			
				appointment			
				mother (and also			
				father in 4 cases)			
				seen for 15-30			
				minutes to explore			
				her feelings in			
				respect of the			
				child's bowel			
				problem and its			
				effect on the			
				family and her			
				own relationship			
				with the child.			
				Whenever			
				possible mother's			
				own history			
				explored and			
				other emotional			
				problems			
				discussed where			
				relevant e.g.			
				expressions of			
				grief, anger,			
				depression, etc.			
				(2) Child seen for			
				between 15-30			
				minutes for play,			
				including picture			
				drawing, games,			
				and sharing of			
				their own toys and			
				belongings. Their			

Bibliographic	Study Type &	Number of Patients	Patient Characteristic	Intervention &	Follow-up &	Effect Size	Reviewer Comments
internation	Level	i utonto	S	Companicon	Measures		
				feelings concerning their problem also explored. Behavioural star chart also often brought, and reviewed and child praised and encouraged according to progress (3) Mother and child seen together sometimes early in treatment, sometimes later, depending on their relationship and success with management of the problems to assess to overall progress			

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Silver et al.	Study Type:	108 children	108 children	Intervention:	Duration of	EXT (n=54)	Additional information from study:
Family therapy	Retrospective	and their		Externalizing	treatment	OTH (n=54)	162 sets of notes of all referrals for
and soiling: An	audit	families	3 to 5 years: 45	Treatment (EXT)	(mean, months)		soiling over a four-year period were
audit of			>6 years: 63		-EXT: 7.8	Not all children	audited
externalizing	Evidence	Inclusion		Families were	-OTH: 6.6	assessed for all	
and other	level:	criteria:	mean age	only included if		outcomes	Some children clearly diagnosed in the
approaches.	3	Children	(years):	the approach	Assessment		referral letter as 'constipated' or 'not
1998. Journal of		treated for	-EXT: 6.98	included:	point (s) &	Parent assessment of	constipated', but in some referral letters
Family Therapy	Study aim:	soiling	-OTH: 6.68		follow-up period	treatment (number of	it was not stated whether the referring
20[4], 413-422	To asses the	problems.		1 Externalizing	At a minimum	parents)	doctor had checked for constipation
	effectiveness	Referrals	Country:	the poo from the	of 6 months	-EXT:	
	of	included	UK	first interview with	(mean 28	Helpful: 24	The treatment given depended only on
	Externalizing	'faecal		the child and	months) after	Unhelpful: 5	the current approach of the therapist
	Treatment	soiling',		family (based on	treatment		who received the referral. All the families
	EXT) as	'encopresis',		White, 1984 and	Ended	-OTH:	had received either 'externalizing' or
	compared to	'psychological		White and Epston,		Helpful: 10	'other treatments'
	traditional	soiling', 'failed		1990)	Outcome	Unhelpful: 20	
	treatments in	toileting',			Measures:		No significant differences between the
	children with	'constipation		2 Developing a	-Parent	p = 0.0001	groups on baseline variables
	soiling	with overflow'		narrative with the	assessment of		
	problems	and		child and family	usefulness of	End of treatment	At a minimum of 6 months' follow-up
		'deliberate		where they could	treatment	outcome (from notes)	(mean 23 months), all parents (including
		soiling'.		see themselves		-EXT:	those who dropped out) sent a
				as capable, skilful	-Soiling	No soiling/improved:	questionnaire
		Exclusion		and determined to	presence	42	with a letter from the secretary,
		criteria:		teach the poo a	/frequency	Soiling: 5	explaining that we could learn a great
		Families who		lesson, outwit the	(parents'		deal from their responses, whether
		failed to		poo or defeat the	assessment	-OTH:	negative or positive, with no names
		attend or		роо	/GP	No soiling/improved:	being recorded. Parents asked whether
		cancelled			assessment	30	there had been any further soiling
		their first		3 Not using	/paediatric	Soiling: 13	incidents since they were last seen and
		appointment,		rewards,	notes		frequency of these incidents in the past
		the problem		interpretation,		p = 0.02	month. Parents asked whether they had
		had been		confrontation or	-Number of		found their treatment helpful or unhelpful
		resolved, the		paradoxical	appointments	GP follow-up	and what was helpful or unhelpful and to
		children were		interventions as		-EXT:	offer other comments. Where children
		put into care		therapeutic		No soiling: 29	had returned for paediatric consultation,
		or sent to		manoeuvres.		Soiling: 8	frequency of soiling stated in paediatric

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
		boarding		4 Attempting to			notes was recorded even if parents did
		school very		see the whole		-OTH:	not reply to the audit. GPs asked
		early in		family at least		No soiling: 24	whether they were aware of any further
		treatment or		once.		Soiling: 18	soiling after treatment had ended
		the soiling					
		had a medical		Comparison:		p = 0.045	Reviewer comments:
		cause		Other Treatments		Parent follow-up	No definition of constipation given
		(Hirschsprung		(OTH)		-EXT:	
		's disease).				No soiling/stains: 24	Unclear exactly how many children
		Children who		Mixed group of		Soiling: 14	dropped out/ were lost to follow up
		had full		traditional		OTH	
		control, but		treatments with		-OTH:	Source of funding:
		would insist		predominantly		No solling/stains: 13	Not stated
		on a nappy		(but not only) a		Solling: 22	
		for a bower		benavioural		n 0.026	
		movement.		approach in a		p = 0.026	
		familias		context There		Number of	
		whore a		wore no elemente		appointments (mean)	
		thoropist		of oxtornalizing in		appointments (mean)	
		who usually		or externalizing in		-FXT·82	
		used		OTH sessions		-OTH: 10	
		externalizing		0111303310113		NS	
		switched to a				110	
		behavioural				Externalizing proved	
		approach in a				to	
		systems				be superior for boys.	
		context in the				for children aged ≥ 6	
		belief that				years, for those with	
		externalizing				frequent soiling at the	
		would not				outset, for those with	
		work. Within				over 2 years'	
		the remaining				continuous soiling	
		families in the				and those diagnosed	
		audit there				as constipated on	
		was no				referral	
		known					
		selection for a					

Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
		particular therapy					

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
Bishon et al	Study Type:	50 children	50 children	Intervention:	Duration of	Soiling frequency	Additional information from study:
Reflexology in	Prospective	oo onnaron		Reflexology:	treatment	(n=48)	With the help of their parents, children
the	case series	Inclusion	age range 3 to	6 sessions, 30	6 weeks	% children	completed questionnaires on bowel
management of		criteria:	14 years	minutes each at		-Before:	motions and soling patterns before,
encopresis and	Evidence	Children	-	weekly intervals	Assessment	at least daily: 78	during and after treatment
chronic	level:	diagnosed	64% boys	(no other details	point (s):		
constipation.	3	with		provided)	Immediately	1 to 3 times/week: 16	Parents completed questionnaires on
2003. Paediatric		encopresis /	Country:		after treatment		their attitude towards reflexology
Nursing 15[3],	Study aim:	chronic	UK	Comparison:	was completed	no soiling/week: 6	
20-21	To investigate	constipation		N.A			Existing medications were unaltered
	the efficacy of				Follow-up	-After:	
	treating	Exclusion			period:	at least daily: 20	2 children only attended the first session
	patients with	criteria:			No follow-up		
	encopresis	Not stated			made after	1 to 3 times/week: 30	Reviewer comments:
	and chronic				treatment	na aailing/waaku 49	ino definition of constipation/encopresis
	constipation				Inisned	no solling/week. 46	given
	villi				Outoomo	n -0.05 (upploor for	Questionnaire not reported as piloted
	reliexology				Measures:	p<0.05 (unclear for which comparisons)	Questionnaire not reported as piloted
					INEASULES.	which compansons)	Results not controlled for potential
					-soiling	Frequency of howel	confounders
					frequency	movements	comounders
					nequency	(BM)(n=48)	Baseline outcomes for the 2 children
					-frequency of	% children	who only attended the first session were
					bowel	-Before:	reported but it is unclear whether they
					movements	No BM/week: 36	were included in the analysis
					(BM)		· · · · · · · · · · · · · · · · · · ·
					· /	1 to 4 BMs/week: 46	Source of funding:
					-parents'		Not stated
					attitude towards	daily BMs: 18	
					reflexology	-	
						-After:	
						No BM/week: 2	
						1 to 4 BMs/week: 72	

Complementary Therapies for Ongoing Treatment/Maintenance in Children with Chronic Idiopathic Constipation

Bibliographic Information	Study Type & Evidence	Number of Patients	Patient Characteristic	Intervention & Comparison	Follow-up & Outcome	Effect Size	Reviewer Comments
	Level		S		Measures		
Information	Evidence Level	Patients	Characteristic s	Comparison	Outcome Measures	daily BMs: 24 p<0.05 (unclear for which comparisons) <u>Parents' attitude</u> <u>towards reflexology</u> 70% parents keen to try treatment, 72% satisfied with outcome	

Surgical Interventions for Maintenance	: Effectiveness of the ACE	procedure in Children with	Chronic Idiopathic Constipation
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Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
King et al. The	Study Type:	56 children	42 children	Intervention:	Follow-up	ACE usage	Additional information from study:
antegrade	Retrospective			appendicostomy	period:		Independent investigator conducted
continence	cohort	Inclusion	31 boys	(ACE):	Mean: 48	a. ACE regimes	confidential telephone interviews using a
enema		<u>criteria:</u>		laparoscopy or	months (median		modified questionnaire
successfully	<u>Evidence</u>	patients with	mean age at	mini-laparotomy	39, range 3 to	-median initial	
treats idiopathic	level:	appendicosto	interview: 13.1		118)	regimes used (%	Continence score: modified
slow-transit	2+	my for	years (median	Comparison: none	_	children):	Holschneider (maximum score 12).
constipation.		idiopathic	12.4; range 6.9		<u>Outcome</u>	.	Modification required because the
2005. Journal of	Study aim:	constipation	to 25.0)		Measures:	Golytely (79)	criterion of "frequency of defecation" not
Pediatric	to determine	formed		Enemas:		Liquorice (12)	appropriate for the cohort
Surgery 40[12],	whether ACE	between	mean age at		-ACE usage	Water (2)	
1935-1940	are successful	Jan/95 and	procedure: 9.1	-median initial		Other (7)	Quality of life score: modified Templeton
	for idiopathic	Oct/04, who	years (median	regimes used:	-ACE efficacy		and loogood
	paediatric	satisfied	7.8, range 3.1			-outcome (%	
	slow transit	Rome II	to 18.5)	Golytely (PEG	-ACE	children):	Frequency score used for all frequency
	constipation	criteria for		3350 and	complications	Excellent (29)	measures: daily=6, 3 to 6 d/wk=5, 1 to 2
	(SIC)	functional	-recurrent	electrolytes): 250		G000 (36)	d/wk=4, 1 to 2 d/fortnight=3, 1 to 2
		constipation,	solling: 29/42	to 500 mi every		Average (7)	d/mo=2, once every 2 to 3 months=1
			(69%)	second day,		Poor (28)	and never=0)
		inecal	in chility to	Infused over 20 to		modion regime at	Deviewer commenter
		incontinence	-maphily to	30 mins IOF 1 to 3		-median regime at	<u>Reviewer comments.</u>
		undergene e	adequatery	monuns		time of interview.	originally 56 children met the inclusion
		prolongod	(17%)	Liquorico 250 to		Colutoly: (bow many	were interviewed without a clear
		protoriged	(1770)	Equorice, 200 to		childron 2): Defection	evelopation for that
			rocurront	infused over 10 to		confidence). Defecation	
		medical	hospital	20 mins infused		mins after ACF	Source of funding:
		management	admissions for	$a_{\text{VPr}} = 10 \text{ to } 20$		finished with 20 to 30	Dr. King funded by scholarships from
		management	nasonatric	mins for 1 to 3		mins spent on toilet	the NHMRC (Australia) and the Royal
			washouts: 6/42	months			Australian College of Surgeons
		Exclusion	(14%)	monaio		Majority of patients	
		criteria:	(1170)	-median regime at		(25/42, 60%) either	
		not stated		time of interview.		using the initial	
			Country:	Golvtely (PEG		regime or had tried	
			Australia	3350 and		one regimen change.	
				electrolytes): 500		No correlation	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
				to 750 ml every		between numbers of	
				second day,		ACE regimens tried,	
				infused over 10 to		patient satisfaction or	
				20 mins with no		length of ACE usage.	
				need for		Many families	
				disimpaction		believed regimes	
						changes were a	
						necessary response	
						to increased	
						tolerance to a	
						particular ACE	
						solution	
						b. patient input into	
						ACE regimen (n	
						children)	
						-completely	
						independent: 7 (all	
						older 10 years)	
						-requiring supervision	
						only: 5	
						-needing help setting	
						up and cleaning up:	
						15	
						-completely	
						dependent: 15	
						c. patients	
						satisfaction with ACE	
						(n children)	
						-very satisfied or	
						satisfied: 37 (88%)	
						-families would	
						recommend ACE to	
						other children: 41	
						(98%	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures	familian falt	
						-iamilies ieit	
						improvement in	
						quality of child's life:	
						39 (93%)	
						-mean optimal age for	
						appendicostomy	
						formation, as felt by	
						families: 4.9 years	
						(median 4, range 2 to	
						12)	
						d. effectiveness	
						-effective: 41 (98%)	
						e symptoms	
						resolution (n patients)	
						-ceased ACE: 15	
						(36%): in 7 symptoms	
						resolved, in 4 a	
						colostomy was	
						formed, in 2 an	
						lieostomy was formed	
						and 2 patients	
						conservative	
						management	
						-successful ACE: 34	
						(81%)	
						ACE efficacy (mean,	
						meulan anu lange).	
						-continence score:	
						pre-ACE: 2.5 (2; 0 to	
						8)	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Levei		5		weasures	post-ΔCE:: 5.2 (5: 1	
						to 12)	
						p<0.0001	
						-quality of life score:	
						pre-ACE: 1.4 (1.5; 0.5	
						10 3.0 post- $\Delta CE^{2} 2.2 (2.5)$	
						0.5 to 3.0)	
						p<0.0001	
						-soiling frequency	
						SCORE:	
						6)	
						post-ACE: 3.0 (3: 0	
						to 6)	
						p<0.0001	
						a hada an ina ha a in	
						-abdominal pain	
						pre-ACE: 7.4 (8: 0 to	
						10)	
						post-ACE: 3.0 (3; 0 to	
						8)	
						p<0.0001	
						-abdominal nain	
						frequency score:	
						pre-ACE: 5 (6; 0-6 to	
						3-6 d/week)	
						post-ACE: 2.5 (2.5;	
						0-6 to 1-2 d/month)	
						ACE complications:	
						a. symptoms at some	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
						stage of treatment:	
						Total: 30/42 (71%)	
						cramping: 18/30	
						nausea: 17/30	
						vomiting: 7/30	
						sweating: 14/30	
						dizziness: 10/30	
						pallor. 10/30	
						(3 or more symptoms	
						present in 12/30	
						patients)	
						F	
						b. Long-term	
						complications (n, %),	
						N=42:	
						-granulation tissue:	
						33 (79), unresolved:	
						15%	
						-anxiety about ACE:	
						21 (50), unresolved:	
						29%	
						-stomal infection: 18	
						(43), Unresolved: 11%	
						-stomal leakage (ACE	
						uays). 10 (30),	
						ombarracement	
						-embarrassment	
						upresolved: 87%	
						-dislikes device: 12	
						(29) unresolved 58%	
						-stomal leakage (non	
						ACE days): 12 (29)	
						unresolved: 8%	
						-stomal pain: 11 (26),	

Bibliographic Information	Study Type & Evidence	Number of Patients	Patient Characteristic	Intervention & Comparison	Follow-up & Outcome	Effect Size	Reviewer Comments
						unresolved: 45% -stomal stenosis: 8 (19), unresolved: 0 -new behavioural disturbance: 7 (17), unresolved: 72% -stomal prolapse: 6 (14), unresolved: 33% -stomal bleeding: 6 (14), unresolved: 0 -limited activity: 4 (10), unresolved: 75% -weight loss: 2 (5), unresolved: 0 -perforation: 2 (5), unresolved: 0	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Cascio et al.	Study Type:	49 children	49 children	Intervention:	Follow-up	Soiling (n children in	Additional information from study:
MACE or	Retrospective		15 boys	Malone antegrade	period:	which stopped	One patient with CB and one with MACE
caecostomy	cohort	Inclusion		enema (MACE)	Mean, 18	completely)	moved to another region and were lost
button for		criteria:	-MACE:		months		to follow-up
idiopathic	Evidence	children who	37 children	Antegrade		MACE (n=37): 30	
constipation in	level:	underwent	15 boys	enemas started	Outcome	(81%)	Success criteria:
children: a	2+	MACE or CB		on the 4 th	Measures:	CB (12): 9 (75%)	-full: totally clean or minor or minor
comparison of		between June	-CB:	postoperative day			rectal leakage on the night of the
complications	Study aim:	1998 and	12 children	and Foley	-Soiling	Occasional soiling still	washout;
and outcomes.	to compare	August 2002	9 boys	catheter left in		present in 1 child with	-partial: clean, but significant stomal or
2004. Pediatric	the results	for intractable		appendicostomy	-Failure	MACE and 2 with CB.	rectal leakage, occasional major leak,
Surgery	complications	idiopathic	Country: UK	for 6 weeks		1 child with CB	still wearing protection but perceived by
International	and outcomes	constipation			-Surgical	resumed regular	the child or parent to be an improvement
20[7], 484-487	of the Malone	and faecal		Comparison:	complications	activity and CB was	-failure: regular soiling or constipation
	antegrade	soiling that		Caecostomy		removed	persisted, no perceived improvements,
	enema	had failed		button (CB)			procedure abandoned usually to a
	(MACE) with	conventional				Failure	colostomy
	the	treatment		Enemas started		-MACE (n=37): 6	
	caecostomy			on 4 th		(16.2%)	Source of funding:
	button (CB) in	Exclusion		postoperative day			not stated
	children with	criteria: not		and MIC-KEY		4 patients' colonic	
	intractable	clearly stated,		gastrostomy tube		washouts ineffective.	
	constipation	but all rectal		changed to		1 patient: colonic	
		biopsies were		standard		washout associated	
		aganglionic.		gastrostomy		with abdominal pain	
				button after 6		during enema. 1	
				weeks		patient required	
						revision for	
						perforation of	
				Enemas		appendicostomy and	
				performed by		the fibrotic-ischaemic	
				administering		appendix was	
				saline (20ml/kg) to		replaced with a CB	
				empty the entire			
				colon at a		-CB (12): 1 (8.3%)	
				convenient time		Reason for failure	
				for patient.		was leaking faecal	
				Children not		content around the	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
				responding to		button, converted to	
				saline wash-out		MACE after 20	
				used Klean-Prep.		months	
				Frequency and		P >0.05	
				volume of enemas			
				individualised to		Surgical	
				each patient to		complications %):	
				achieve		a. requiring operative	
				cleanliness and		intervention	
				stop soiling		MACE (n=37)	
						-total: 9 (24%)	
						-stoma stenosis: 11%	
						-iatrogenic perforation	
						appendicostomy: 5%	
						-difficult	
						catheterization: 5%	
						-adhesive obstruction:	
						3%	
						CB (n=12)	
						-total: 0	
						-adhesive obstruction:	
						0	
						Others N.A	
						P=0.009 for total	
						b. not requiring	
						operative intervention	
						MACE (n=37)	
						-total: 7 (19%)	
						-pain/difficult	
						catheterisation: 11%	
						-stoma granulosa: 5%	
						-stoma stenosis: 3%	
						-faecal leakage: 0	
						-pain around button:	

Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic S	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
						N.A CB (n=12) -total: 11 (92%) -pain/difficult catheterisation: N.A -stoma granulosa: (33%) -stoma stenosis: N.A -faecal leakage: 42% -pain around button: 92% p<0.001 for total	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Mousa et al.	Study Type:	31 children	-total population	Intervention:	Duration of	(all values are	Additional information from study:
Cecostomy in	Retrospective		31 children	Caecostomy	study period:	median)	Standardised questionnaire used to
children with	cohort	Inclusion	58% boys	performed	4 years		obtain data on outcomes measured
defecation		criteria:		percutaneously by		Type of antegrade	
disorders. 2006.	Evidence	Children who		interventional	Follow-up	enemas used	Frequency of bowel movements scored
Digestive	level:	received a	-9 children with	radiologist	period:	No subgroup analysis	as: 1, <5 bowel movements/week; 2,
Diseases and	2+	caecostomy	functional		Median 11	performed	5/week to 3/day; 3, 3/day
Sciences 51[1],		fro	constipation	Comparison:	months (range		
154-160	Study aim:	constipation,		Caecostomy	1 to 45) after	Bowel movement	Soling frequency scoring: 1, none; 2,
	To report	faecal soiling	median age at	performed by	caecostomy	frequency (n=9)	occasional, 3, few episodes/week; 4.
	authors' 4-	or a	time of	open surgical		Pre: <5/week	few episodes/week to daily; 5,
	year	combination	caecostomy: 12	approach	<u>Outcome</u>	Post: 5/week to 3/day	constantly
	experience	of both.	years old		Measures:	P<0.01	
	with 2	Underlying	(range 3 to 16)				Quality of life assessed by scoring
	different	conditions			-type of	Soiling frequency	limitations of activity (none, mild,
	techniques of	included	Country:		antegrade	<u>(n=9)</u>	moderate and severe), global health
	the	functional	USA		enemas used	Pre: constant	score, and global emotional score (poor,
	caecostomy	constipation,				Post: none	fair, good, very good and excellent)
	procedure	Hirschsprung'			-bowel	P=0.01	
	and to	s disease,			movement		Reviewer comments:
	compare the	imperforate			frequency	Number of	Not clear who interviewed the parents
	clinical	anus,				medications (n=9)	
	outcome of	imperforated			-soiling	Pre: 4	Source of funding:
	caecostomy in	anus			frequency	Post: 1	study supported in part by the Ter
	children with	combined				P=0.01	Meulen Fund, Royal Netherlands
	defection	with tethered			-number of		Academy of Arts and Sciences
	disorders	spinal cord			medications	Number of physician	
	secondary to	syndrome and				visits related to	
	functional	spinal			-number of	defecation problems	
	constipation,	abnormalities			physician visits	<u>(n=9)</u>	
	imperforate				related to	Pre: 6	
	anus and	Exclusion			detecation	Post: 2	
	spinal	criteria:			problems	P<0.01	
	abnormalities	Not stated					
					-number of	Number of hospital	
					nospital	admissions for	
					admissions for	disimpaction (n=9)	
					disimpaction	Pre: 4	
Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
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Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S	-	Measures		
						Post: 0	
					-number of	P<0.01	
					missed school		
					davs per month	Number of missed	
					, ,	school days per	
					-guality of life	month (n=9)	
						NS	
					-complications		
						Global health score	
						(n=9)	
						Pre: poor	
						Post: good	
						P=0.01	
						Global emotional	
						score (n=9)	
						Pre: poor	
						Post: good	
						P=0.01	
						Limitations of activity	
						<u>(n=9)</u>	
						Pre: moderate	
						Post: mild	
						P<0.01	
						Complications	
						No major	
						complications like	
						perforation, stoma	
						stenosis, or stoma	
						prolapse. No	
						difference found in	
						occurrence of number	
						of complications	
						between different	
						procedures/technique	
						S	

Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic S	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
						Other outcomes not reported here as no subgroup analysis performed	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Jaffray. What	Study Type:	80 children	80 children	Intervention:	Follow-up	53 children:	Additional information from study:
happens to	Prospective			Antegrade	period:	conventional ACE	
children with	case series	Inclusion	44 boys	continent enema	6 months to 10		In the first 32 cases the diagnosis was
idiopathic		<u>criteria:</u>		(ACE) procedure	years (median	27 children:	confirmed by the use of marker studies
constipation	Evidence	All children	median age at		6.2 years)	laparoscopic ACE	using an established protocol. However
who receive an	level:	with idiopathic	surgery: 9.6	Children followed			because the marker studies did not alter
antegrade	3	constipation	years (range	up in a nurse-led	<u>Outcome</u>		treatment decisions and to avoid
continent		undergoing	3.4 to 18.7	continence clinic	Measures:	- ACE lavage failed in	unnecessary radiation exposure, this
enema?. An	Study aim:	ACE surgery	years)			12 children:	practice was stopped
actuarial	to perform an	by 1 surgeon.		Lavage regime	-Ongoing		
analysis of 80	actuarial	In all children	Country:	was supervised	lavage	4 children were	Draviaua traatment waa beterageneeue
consecutive	analysis of the	symptoms	UK	by specialist		identified where the	and had always included prelonged
cases. 2009.	outcomes of	had persisted		nurses and used	Failura: aithar	appendicostomy was	treatment with levelives, usually with
Journal of	antegrade	despite		a solution of	the percente	not being used.	noriode of in patient administration of
Pediatric	continent	medical		saline prepared	have stopped	Although these	surgical bowel cleansing solutions
Surgery 44[2],	enema (ACE)	management		by parents at a	have slopped	children could be	frequent manual disimpaction and often
404-407United	procedure in	supervised by		volume of	tochniquo	lavaged, parent's had	involvement of a clinical never longy
States.	children who	paediatrician		20mL/kg body	because colonic	not found it to be of	service
	have	for at least 3		weight	lavage has not	help in the child's	Service
	idiopathic	years			been found to	bowel management	
	constipation			Comparison:	improve the	and had ceased use	In calculating the Kaplan Meier
	and who did	Exclusion		N.A	child's howel		probability of an ACE being reversed or
	not respond to	criteria:			habit or the	In 8 children,	failing, the following times were
	3 years of	Hirschsprung			child's colon	deterioration of	calculated:
	medically	s disease			had not proved	symptoms occurred	
	supervised	(excluded by			to be	despite ACE lavage	-ongoing lavage: length of follow up
	conservative	rectal biopsy			lavageable and	and required	calculated as time from the date of
	management	in all cases)			symptoms had	alternative treatment	formation of ACE to current date
					deteriorated	of symptoms. These	
					actonoratoa	children could not be	-time to failure calculated as the time
					0 11	lavaged	from creation of the ACE to the clinic
					-Cure: the		letter stating that the parents had
					appendicostom	Kaplan Meier	ceased using the ACE or the date of
					y was	probability of an ACF	commencement of alternative
					ciosed/reversed	failing:	treatment
					because the		
					child achieved	0.0 -+ 0.5	and the state of t
					normai bowel	0.3 at 8.5	-cure: the date of the operation to

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
					nabit	years; estimated	reverse the ACE was used as the
						mean failure time:	censoring time
						0.0 years (95% CI 7.9	
						10 9.2)	A minimum of 6 months follow-up
						40 shildasa kasi	judged to be appropriate because a
						-12 children had	decision regarding cure would take no
						normal bower nabit,	
						colonic lavage and	
						underwent closure of	Children who could not be lavaged
						appendicostomy. The	a howel evacuation despite an
						Kaplan Meier	appropriate volume of lavage fluid
						probability of an ACE	These children were assessed by
						being reversed was	performing continuous lavage though
						0.2 at 6.2 years,	the appendicostomy over several days
						estimated mean time	while in hospital. Typically such children
						to reversal (9.1 years (0.5%) CI: 8.4 to 0.7)	accommodate very large volumes of
						(95% CI. 0.4 (0 9.7)	fluid in their colon, often in excess of 10
						50 1 11 1	L without bowel evacuation
						-56 children currently	
							Criteria for ACE reversal: for at least the
						lavaye	previous 6 months, child had stopped
							using their ACE, was stooling
							spontaneously at least every other day,
						(CTT), age at surgery	was not requiring laxative therapy and
						follow-up were not	dissecting the appendix to the caecal
						significantly	wall and ligating and removing it
						associated with ACE	
						failure, but sex was	No natient was discharged, and none
						(p=0.04) the higher	was lost to follow up
						failure rate amongst	
						girls was significant	Source of funding:
						(p=0.02)	Not stated
						in prodicting foilure in	
						In predicting failure in	

Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
						children who accommodated very large volume of lavage fluid (>10 L) in their colon without bowel evacuation. Median CTT for this subset significantly longer than for children who could be lavaged (141 h (SD 30) vs. 73 h (SD 17); 95% CI difference 9 to 74 h; p=0.01)	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Youssef et al.	Study Type:	12 children	12 children	Intervention:	Follow-up	Bowel	Additional information from study:
Management of	Retrospective		9 boys	Caecostomy	period:	movements/week	A questionnaire used to interview
intractable	case series	Inclusion	mean age: 8.7	(surgically and by	13.5 ± 8.5	before: 1.4 ± 0.7	caregivers
constipation		criteria:	± 4.4 years	interventional	months	after: 7.1 ± 3.8	13.5 ± 8.5 months after caecostomy
with antegrade	Evidence	children		radiology)		p<0.005	placement. No caregiver refused to
enemas in	level:	referred to a	Country: USA		Outcome		participate in interview
neurologically	3	tertiary care		Comparison:	Measures:	Soiling	
intact children.		motility centre		none		episodes/week	Scoring for episodes of abdominal pain:
2002. Journal of	Study aim:	for further			-Bowel	before: 4.7 ± 3.2	0 = none, 1=once or twice, 2=a few
Pediatric	to assess the	evaluation of			movements/we	after: 1.0 ± 1.4	times, 3=fairly often, 4=very often, 5=
Gastroenterolog	benefit of	intractable		Choice of	ek	p<0.01	everyday
y and Nutrition	antegrade	constipation,		irrigation solution			
34[4], 402-405	colonic	who had		used after	-Soiling	Number of	Scoring for overall health and
	enemas	undergone		caecostomy	episodes/week	medications used for	emotional state: 1=poor, 2=fair, 3=good,
	through	caecostomy		varied, based on		constipation	4=very good, 5=excellent
	caecostomy	placement for		preference of	-Number of	before: 4.0 ± 1.0	
	catheters in	administration		treating physician.	medications	after: 0.8 ± 0.6	Reviewer comments:
	children with	of antegrade		Most patients	used for	p<0.005	Very small sample
	severe	enemas		began with low	constipation		
	constipation			volume		Abdominal pain	Not clear who performed the review of
	who were	Exclusion		infusions of	-Episodes of	score:	the clinical records
	referred to a	criteria:		solution, which	abdominal	before: 2.9 ± 1.6	
	tertiary care	neurologic		were increased	pain/week	after: 0.9 ± 1.0	Not clear who interviewed the parents
	centre	handicap and		according		p<0.005	
		other organic		to therapeutic	-Missed school		Researchers not reported blinded
		causes of		response. 67% of	days/month	Missed school	
		constipation		patients used 200		(days/month)	Questionnaire not reported
				mL to 1,000 mL	-Emotional	before: 7.5 ± 6.9	piloted/validated
				(mean 478 mL ±	health	after: 1.5 ± 2.5	
				262 mL)		p<0.02	Source of funding:
				polyethylene	-Overall health		not stated
				glycol irrigation	D	Emotional health	
				solution, daily to	-Physician	score	
				every other day.	office visits/year	Defore: 1.9 ± 0.8	
				25% of patients		atter: 3.6 ±1.1	
				used a		p<0.005	
				combination of			
				saline and		Overall health score:	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
				glycerin, mixing		before: 1.7 ± 0.9	
				60 mL to 75 mL of		after: 3.6 ± 0.9	
				glycerin in 240 mL		p<0.005	
				to 300 mL of			
				saline. 1 patient		Physician office	
				received 90 mL		visits/year	
				phosphate soda		before: 24.0 ± 19.1	
				solution followed		after: 9.2 ± 14.2	
				by 300 mL of		p<0.05	
				saline. Evacuation		No acute adverse	
				occurred within 1		events	
				hour			
				of enema		Postoperative	
				administration in 7		adverse events (n	
				children and		<u>children):</u>	
				occurred within 3		-skin breakdown	
				hours in the other		and development of	
				5 children.		granulation tissue: 1	
						-leakage of irrigation	
						solution: 1	
						-accidental removal of	
						the catheter with	
						subsequent easy	
						catheter replacement	
						by the interventional	
						radiologist: 2	
						No adverse event led	
						to discontinuation	
						of antegrade enema	
						use.	
						No child has required	
						admission to a	
						hospital because of	
						faecal impaction	
						since starting	
						antegrade enemas.	
						5 patients	

Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
						discontinued antegrade enemas with removal of the caecostomy at a mean of 14.6 ± 9.1 months after beginning treatment. None has redeveloped problems with constipation or faecal soiling.	

Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Curry et al. The	Study Type:	273 children	273 children	Intervention:	Follow-up	Overall success rate	Additional information from study:
MACE	Retrospective			Malone Antegrade	period:	Including both full and	Results included figures from authors'
procedure:	survey		Mean age: 12.3	Continence	Mean 2.4 years	<u>partial):</u> 79%	previous study, reported figures from
experience in		Inclusion	years	Enema (MACE)	(range 0.3 to 6)		one other UK centre and replies to
the United	Evidence	criteria:					proformas sent by authors to BAPS
Kingdom. 1999.	level:	MACE	Country:	Comparison:	<u>Outcome</u>	Success rate based	members
Journal of	3	procedures	UK	None	Measures:	<u>on diagnosis (%):</u>	
Pediatric		performed by					102 proformas sent, 58 returned
Surgery 34[2],	Study aim:	UK members			-children	Constipation (n=23)	
338-340	to find out the	of the British			diagnoses		Success criteria:
	current status	Association of				Full: 52	-full: totally clean or minor or minor
	of the Malone	Paediatric			-success rate	Partial: 10	rectal leakage on the night of the
	Antegrade	Surgeons (or				Failure: 38	washout;
	Continence	their units) up			 complications 	Unknown: 1	-partial: clean, but significant stomal or
	Enema	to the end of			encountered		rectal leakage, occasional major leak,
	(MACE)	1996					still wearing protection but perceived by
							the child or parent to be an improvement
		Exclusion					-failure: regular soiling or constipation
		criteria:					persisted, no perceived improvements,
		not clearly					procedure abandoned usually to a
		stated					colostomy
							Reviewer comments:
							Retrospective study
							Low response rate to the proforma
							Populto for potients with diagnoses other
							than constipation not reported here
							because they are outside the remit of
							this review.
							Main complications not related in paper
							to the clinical diagnosis and therefore
							not reported here
							Source of funding:
							not stated

				Clinic-based I	nterventions		
Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Burnett et al.	Study Type:	102 children	102 children	Intervention:	Intervention	Primary outcomes	Additional information from study:
Nurse	RCT		55 males	Nurse led clinic	period:		Constipation defined as (1) decreased
management of		Inclusion		(NLC)	30 months	Time to cure at last	frequency of bowel movements
intractable	<u>Evidence</u>	<u>criteria:</u>	median age at			visit or later confirmed	(that is, decreased from the individual's
functional	level:	All children	study entry: 4.6	Comparison:	<u>Assessment</u>	by telephone	previous pattern); and/or (2) harder stool
constipation: a	1+	aged 1	(NLC) and 4.8	Consultant led	<u>point (s):</u>		consistency; and/or (3) subjective
randomised		to 15 years	years (PGC)	paediatric	Unclear	-Number cured, %	difficulty, including pain and distress
controlled trial.	Study aim:	presenting to		gastroenterology		NLC (n = 52):	associated
2004. Archives	To evaluate	the paediatric	age range: 13	clinic (PGC)	Follow-up	34 (65.4%)	with defecation
of Disease in	the	gastroenterol	months to 14.7	_	period:	PGC (n = 50):	
Childhood	effectiveness	ogy service at	years	-Assessment:	Median: 16.6	25 (50.0%)	Interpretation of abdominal radiograph
89[8], 717-722	of a nurse led	the John	-	Nurse led clinic	months for both		obtained at the time of initial
	clinic (NLC)	Radcliffe	Country:	designed to be a	groups	-Time to event	assessment made though a validated
	compared	Hospital,	UK	follow up clinic for		(median (95% CI,	scoring system (Leech) using scores
	with a	Oxford, UK		children who had	<u>Outcome</u>	months)	ranging from 0 (no stool) to 5 (gross
	consultant led	with		undergone a full	Measures:		faecal loading with bowel dilatation) in
	paediatric	constipation		and detailed	1. Primary	NLC (n = 52):	three areas of the colon, giving a total
	gastroenterolo			medical	outcomes:	18.0 (8.5 to 27.5)	severity score ranging from 0 to 15.
	gy clinic	Exclusion		assessment in the	-	PGC $(n = 50)$:	Using this system a radiographic score
	(PGC) in the	<u>criteria</u> :		paediatric	- I ime to cure at	23.2 (17.3 to 29.2)	of >9 has been shown to have a high
	management	Organic or		gastroenterology	last visit or later		specificity and sensitivity in the
	of chronic	neurological		clinic leading to a	confirmed by	Hazard ratio(one	diagnosis of childhood constipation
	constipation	disease		diagnosis of	telephone	sided 95% CI):	
				laiopathic	Time to sume of	1.332 (0.860 to ∞)	I ne primary outcome of cure at last visit
					- Time to cure at	Time rotio (one aided	or later commed by telephone used to
				consupation	last visit.		assess sample size. For non-interiority
				Investigations	Dramatura	95% (1):	To be concluded between NLC and
				-Investigations:	-Premature	0.616 (0.10 1.032)	he required for a new or of 20% and a
				where it was	study	Time to ours at last	be required for a power of 80% and a
						vicit	accuming the success rate of the BCC
				appropriate, all	2 Secondary	VISIL	to be 50%. The range of clinical
				radiograph		Number ourod %	aquivalence was defined to be within
				obtained at the	outcomes.	NIC $(n - 52)$	15% therefore non-informative was
				time of initial	number of	$1 \times 10^{-1} (11 = 32).$	defined on the ruling out of a beyond
				time of initial	-number of	27 (51.9%)	defined as the ruling out of a nazard

Information and Support for Children with Chronic Idiopathic Constipation and their families

Clinic-based Interventions									
Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic S	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments		
	Levei		5	assessment both as a diagnostic tool and as a semi-quantitative marker of the severity of constipation -Treatment: a standardised treatment algorithm (constructed for the study, similar to a number of published guidelines) provided the basis for management decisions in all consultations in both clinics -initial phases: involved child and parent education about diet (fibre and fluid), exercise, toilet training, and the actions of the laxatives prescribed. Laxative therapy comprised a	clinic visits -number requiring additional medication/in- patient procedures during the scheduled treatment period	PGC (n = 50): 22 (44.0%) -Time to event (median (95% CI, months) NLC (n = 52): 22.1 (15.1 to 29.2) PGC (n = 50): 25.1 (17.0 to 33.2) Hazard ratio(one sided 95% CI): 1.207 (0.749 to ∞) Time ratio (one sided 95% CI): 0.855 (0 to 1.112) <u>Premature study</u> termination -Number, % NLC (n = 52): 5 (9.6) (2 lost to follow-up, 3 withdrew) PGC (n = 50): 14 (28) (10 lost to follow- up, 4 withdrew) -Time to event (median (95% CI, months)	ratio less than 0.85 on the basis of the lower limit of the one sided 95% confidence interval. Conversely, for an outcome where a reduction of events is preferable, non-inferiority is defined as the ruling out of a hazard ratio greater than 1.176 on the basis Allocation concealment facilitated by using sequentially numbered sealed envelopes produced by an external source for consecutive and eligible study patients. Randomisation performed using block randomisation with fixed blocks of size four Time to cure at last visit or later confirmed by telephone relates to all those children confirmed cured either at their last visit, or subsequently, confirmed over the telephone. Children who were close to achieving the definition of "cured" at their last visit but who were still being weaned off medication, were not required to attend for a further follow up appointment but received their follow up via the telephone. Time to cure at last visit relates to only those children confirmed cured at their last visit (a subset of the previous outcome). Premature study termination comprises those patients who were either lost to follow up or withdrawn for whatever reason		
				stool softeners		$ \mathbf{U} = \mathbf{U}_{j} \cdot \mathbf{U}_{j}$	presentation characteristics as well as		

				Clinic-based Ir	terventions		
Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
	Level		S	(for example, lactulose, docusate sodium) and stimulants. Stimulants of different potencies (senna, bisacodyl, sodium picosulphate) were prescribed according to the clinical response as indicated by the bowel diaries. If there was an inadequate clinical response to this initial phase, the patient moved on to an advanced treatment regime which might include, enemas, intestinal lavage, manual removal of faeces under general anaesthesia, or psychological referral as was appropriate in each case	Measures	PGC (n = 50): NA Hazard ratio(one sided 95% Cl): 0.334 (0 to 0.788) Time ratio (one sided 95% Cl): NA Secondary outcomes Number of clinic visits -Median number of visits in each clinic: 6.0 -Median number of inter-visit contacts: NLC: 6.0 (range 2 to 16) PGC: 0.0 (range 0.0 to 29) Number requiring additional medication/in-patient procedures during the scheduled treatment period No significant differences between both groups	previous laxative usage well balanced across clinics ITT analysis conducted for all outcomes. Survival analysis conducted for the primary time-to-event outcomes Reviewer comments: Unclear who measured outcomes Results not controlled for potential confounders Source of funding: Research grants from Norgine Ltd and from WellChild
				/follow-up: Bowel			

				Clinic-based In	terventions		
Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic S	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
				diaries, which		10 children (5 NLC, 5	
				report the		PGC) completed	
				frequency, size,		study as per the	
				and consistency		protocol but were not	
				of stools,		cured (treatment	
				presence or		failures):	
				absence of			
				soiling, and a		-8/10: formally	
				record of daily		referred for	
				laxative		psychological /	
				medication, were		psychiatric	
				used in both		management	
				clinics to monitor		-9/10: had	
				progress and		documented serious	
				response to		behavioural problems	
				treatment.		-3/10: also referred	
				Dedicated case		for surgical	
				report forms were		assessment and	
				used for each		management	
				study participant		-	
				and, together with		A total of 15/102	
				detailed clinical		children still	
				history (including		undergoing follow up,	
				a detailed dietetic		as they are not cured.	
				history) and		In this group, 7/15	
				clinical findings on		children are followed	
				initial assessment,		up in the PGC and 8/	
				documented		15 in the NLC. 7/15	
				details of bowel		children had	
				habit and drug		documented	
				therapy at all		psychosocial	
				subsequent		problems associated	
				outpatient visits.		with poor compliance	
				Any other contact		in attending clinic	
				with the families,		appointments	
				e.g. on the			
				telephone or a			

				Clinic-based Ir	terventions		
Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
				home visit, was documented using inter-visit contact forms -Discharge: Child defined as having been "cured" of their constipation when, for a period of at least 1 month, they had been opening their bowels, producing a normal formed stool without difficulty at least 3 times per week and without any laxative therapy			

Bibliographic InformationStudy Type & Evidence LevelNumber of PatientsPatient Characteristic sIntervention & ComparisonFollow-up & Outcome MeasuresEffect SizeReviewer CommentsSullivan et al. Parent satisfaction in a nurse led clinic compared with a paediatric gastroenterolog y clinic for the management of intractable,Study Type & Study Type: Study Type: Study Type: Survey-RCT102 children 102 children to 2 children to 2 children to 2 children study entry: 4.6 (NLC) and 4.8 y ears (PGC)Intervention & ComparisonDuration of treatment As previous RCTProvision of information scores (median) NLC: 8.7 PGC: 7.5 P<0.001Additional information from study: Satisfaction with care defined as "the degree to which parents perceive the needs of their children are met"Study aim: management of intractable,Study aim: parent'sTo assess agastroenterolog parent'sIntervention: the paediatric age range: 13 months to 14.7Intervention: nurse led clinic (NLC)Provision of information scores (MEC)Provision of information scores (MLC)Provision of information scores (MLC)Provision of information scores (MEC)Provision of information scores<					Clinic-based I	nterventions		
Sullivan et al. ParentStudy Type: Survey-RCT102 children102 childrenIntervention: Survey-RCTDuration of treatmentProvision of information scoresAdditional information from study: Satisfaction with care defined as "the degree to which parents perceive the needs of their children are met"Parent satisfaction in a nurse led clinic compared with a paediatric y clinic for the management of intractable,Evidence tevel: to 15 years parent's102 children stidy entry: 4.6 to 15 years102 children 55 malesIntervention: Nurse led clinic (NLC)Duration of treatment As previous RCTProvision of information scores NLC: 8.7 PGC: 7.5Additional information from study: Satisfaction with care defined as "the degree to which parents perceive the needs of their children are met"Value parent'sEvidence the paediatric gastroenterolCriteria: All children to 15 years presenting to the paediatric gastroenterolIntervention: NLC: and 4.8 years (PGC)Duration of NLC: and 4.8 paediatric gastroenterologyProvision of information scores PGC: 7.5Additional information from study: Satisfaction with care defined as "the degree to which parents perceive the needs of their children are met"Value management of intractable,102 children parent'sIntervention: nonths to 14.7Duration of NLC: PGCProvision of treatment As previous Comparison: Consultant led paediatric gastroenterologyProvision of information scores PGC: 7.5Number parent'sIntervention: parent'sIntervention: nonths	Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
Parent satisfaction in a nurse led clinic compared with a paediatric y clinic for the management of intractable,Survey-RCT inclusion criteria: All children a gastroenterolSolution inclusion criteria: All children a gastroenterolNurse led clinic (NLC)treatment As previous RCTinformation scores (median) NLC: 8.7 PGC: 7.5Satisfaction with care defined as "the degree to which parents perceive the needs of their children are met"Parent satisfaction in a nurse led clinic compared with a paediatric 	Sullivan et al.	Study Type:	102 children	102 children	Intervention:	Duration of	Provision of	Additional information from study:
satisfaction in a nurse led clinic compared with a paediatric y clinic for the management of intractable,Inclusion criteria: All children aged 1 to 15 yearsmedian age at study entry: 4.6 (NLC) and 4.8 years (PGC)(NLC)As previous RCT(median) NLC: 8.7 PGC: 7.5degree to which parents perceive the needs of their children are met"Parent satisfaction measured using a gastroenterol intractable,1+aged 1 to 15 years presenting to the paediatric gastroenterol(NLC) and 4.8 years (PGC)(NLC) omparison: Comparison: Consultant led paediatric gastroenterologyAs previous RCT(median) NLC: 8.7 PGC: 7.5degree to which parents perceive the needs of their children are met"All children aged 1 to 15 years management of intractable,To assess parent'snonths to 14.7As previous median age at study entry: 4.6 (NLC) and 4.8 years (PGC)As previous Comparison: Consultant led paediatric gastroenterologyAs previous PGC: 7.5Parent satisfaction measured using a validated instrument based on the Lee Satisfaction Questionnaire (LDQ), whi has been shown to be easy and quick complete sensitive to change, reliable	Parent	Survey-RCT		55 males	Nurse led clinic	treatment	information scores	Satisfaction with care defined as "the
nurse led clinic compared with a paediatric gastroenterologEvidence level:criteria: All children aged 1 to 15 yearsmedian age at study entry: 4.6 (NLC) and 4.8 years (PGC)RCTNLC: 8.7 PGC: 7.5needs of their children are met"NLC: 8.7 PGC: 7.5Parent satisfaction measured using a validated instrument based on the Lee gastroenterologyParent satisfaction Questionnaire (LDQ), whi has been shown to be easy and quick compared with a gestroenterologyNLC: 8.7 PGC: 7.5Needs of their children are met"	satisfaction in a		Inclusion		(NLC)	As previous	<u>(median)</u>	degree to which parents perceive the
compared with a paediatric gastroenterologLevel: 1+All children aged 1 to 15 yearsstudy entry: 4.6 (NLC) and 4.8 years (PGC)Comparison: Consultant led paediatric gastroenterologyPGC: 7.5 P<0.001Parent satisfaction measured using a validated instrument based on the Lee Satisfaction Questionnaire (LDQ), whi has been shown to be easy and quick compared with	nurse led clinic	Evidence	criteria:	median age at		RCT	NLC: 8.7	needs of their children are met"
a paediatric gastroenterolog1+aged 1 to 15 years presenting to intractable,(NLC) and 4.8 to 15 yearsConsultant led paediatric gastroenterologyAssessment point (s): After 12 months to 14.7P<0.001Parent satisfaction measured using a validated instrument based on the Lee Satisfaction Questionnaire (LDQ), whi has been shown to be easy and quick complete sensitive to change, reliable	compared with	level:	All children	study entry: 4.6	Comparison:		PGC: 7.5	
gastroenterologto 15 yearsyears (PGC)paediatricpoint (s):validated instrument based on the Leey clinic for theStudy aim:presenting topresenting togastroenterologyAfter 12Empathy with patientSatisfaction Questionnaire (LDQ), whimanagement ofTo assessparent'sgastroenterolmonths to 14.7Clinic (PGC)NLC: 9.0NLC: 9.0validated instrument based on the Lee	a paediatric	1+	aged 1	(NLC) and 4.8	Consultant led	Assessment	P<0.001	Parent satisfaction measured using a
y clinic for the <u>Study aim:</u> presenting to the paediatric age range: 13 intractable, parent's age troenterol months to 14.7 gastroenterol months to 14.7 After 12 <u>Empathy with patient</u> Satisfaction Questionnaire (LDQ), whith so been shown to be easy and quick complete sensitive to change, reliable	gastroenterolog		to 15 years	years (PGC)	paediatric	point (s):		validated instrument based on the Leeds
management of To assess the paediatric age range: 13 clinic (PGC) months' follow- intractable, parent's gastroenterol months to 14.7 clinic (PGC) up or before NLC: 9.0 has been shown to be easy and quick complete sensitive to change, reliable	y clinic for the	Study aim:	presenting to		gastroenterology	After 12	Empathy with patient	Satisfaction Questionnaire (LDQ), which
intractable, parent's gastroenterol months to 14.7 up or before NLC: 9.0 complete sensitive to change, reliable	management of	To assess	the paediatric	age range: 13	clinic (PGC)	months' follow-	scores (median)	has been shown to be easy and quick to
	intractable,	parent's	gastroenterol	months to 14.7		up or before	NLC: 9.0	complete sensitive to change, reliable
functional satisfaction ogy service at years Intervention as this if the child PGC: 7.3 and reproducible. Questions in the LD	functional	satisfaction	ogy service at	years	Intervention as	this if the child	PGC: 7.3	and reproducible. Questions in the LDQ
constipation. with a nurse the John described in has been P<0.001 were pertinent to a rheumatology clinic	constipation.	with a nurse	the John		described in	has been	P<0.001	were pertinent to a rheumatology clinic
2006. Archives led clinic Radcliffe Country: previous study "cured" and thus adapted for the purposes of	2006. Archives	led clinic	Radcliffe	Country:	previous study	"cured"		and thus adapted for the purposes of
of Disease in (NLC) for Hospital, UK Technical quality and this constipation clinic. Questionnaire	of Disease in	(NLC) for	Hospital,	UK			Technical quality and	this constipation clinic. Questionnaire
Childhood children with Oxford, UK Outcome competence scores covered 6 separate domains in 48	Childhood	children with	Oxford, UK			Outcome	competence scores	covered 6 separate domains in 48
91[6], 499-501 intractable, with <u>Measures:</u> (median) statements: provision of information,	91[6], 499-501	intractable,	with			Measures:	(median)	statements: provision of information,
functional constipation NLC: 9.1 empathy with the patient, access to an		functional	constipation				NLC: 9.1	empathy with the patient, access to and
constipation 1. Parent PGC: 8.0 continuity with the caregiver and over		constipation				1. Parent	PGC: 8.0	continuity with the caregiver and overall
compared <u>Exclusion</u> satisfaction, 6 P<0.001 satisfaction. The "overall satisfaction"		compared	Exclusion			satisfaction, 6	P<0.001	satisfaction. The "overall satisfaction"
with a criteria: domains: component was added for the purpose		with a	<u>criteria</u> :			domains:		component was added for the purposes
consultant led Organic or <u>Attitude towards the</u> of validation. 5 point Likert scales user		consultant led	Organic or				Attitude towards the	of validation. 5 point Likert scales used
padiatric neurological -provision of <u>patient scores</u> fro responses ranging from strongly		paediatric	neurological			-provision of	patient scores	fro responses ranging from "strongly
gastroenterolo disease information (median) agree to "strongly disagree", stability		gastroenterolo	disease			information	(median)	agree" to "strongly disagree", stability of
gy clinic NLC: 8.7 The instrument tested using the test-		gy clinic					NLC: 8.7	the instrument tested using the test-
(PGC) Permpathy with PGC: 7.3 retest method		(PGC)				-empatny with	PGC: 7.3	retest method
patient P<0.001						patient	P<0.001	An attempt was made to report all
An attention in the visit contact to the telephone or						tachnical	Access to and	An allempt was made to record all
-technical <u>Access to and</u> inter-visit contacts (by telephone of						-lechnical	Access to and	Inter-visit contacts (by telephone of
quality and <u>contractive vertice</u> day watch attendances) indee by the							<u>continuity with the</u>	day ward allendances) made by parents
competence <u>categration</u> outside their schedules outpatients						competence	(modion)	
appointment						-attitude		
towards the PGC: 6.7 A total of 00 questionnaires returned						towards the	PGC · 6 7	A total of 90 questionnaires returned
iowards the FGC. 0.7 A total of 90 questioninalies feturited						nationt	P<0.001	from 107 families canvassed (84%)
AU(51 (78%) from the PGC and 50/56						Paden		40/51 (78%) from the PGC and $50/56$
-access to and Overall satisfaction (80%) from the NIC Robustness and						-access to and	Overall satisfaction	(89%) from the NLC. Robustness and
continuity with scores (median) high reliability of the questionnaire						continuity with	scores (median)	high reliability of the questionnaire

				Clinic-based I	nterventions		
Bibliographic Information	Study Type & Evidence	Number of Patients	Patient Characteristic	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
					the caregiver -overall satisfaction 2. Number of inter-visit contacts	NLC: 8.7 PGC: 7.3 P<0.001 Number of inter-visit contacts (mean (SD)) NLC: 2.37 ± 4.17 PGC: 1.70 ± 4.79 NS	demonstrated by calculating the internal consistency for each domain; lowest Cronbach's alpha: 0.81 <u>Reviewer comments:</u> This study is an evaluation of the previous RCT ITT analysis performed for all outcomes <u>Source of funding:</u> Research grant form WellChild

				Clinic-based I	nterventions		
Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
Poenaru et al.	Study Type:	114 patients	114 patients	Intervention:	Duration of	Stool frequency per	Additional information from study:
The Pediatric	Prospective			Bowel	treatment	month, mean (n=26)	Children considered constipated when
Bowel	case series	Inclusion	Mean age: 5.4 ±	Management	Mean time span	1rst visit: 11.73	they had persistent symptoms (soling,
Management		criteria:	3.8 years	Clinic	between first	last visit:: 29.77	pain, bleeding, etc) related to bowel
Clinic: initial	Evidence	Children up to	(range 4		and last visit to	p=0.00026	movements which tend to be infrequent
results of a	level:	19 years old	months to 19	-Clinic staff: a	clinic: 4.5		
multidisciplinary	3	referred to the	years)	physician (rotating	months	Stool consistency	Total number of visits was 257 with
approach to		clinic with		between 2		<u>(n=55)</u>	average of 6 patients per clinic. 62
functional	Study aim:	constipation	51.4% boys	paediatricians, 1	Assessment	(Unclear whether the	patients seen more than once with a
constipation in	To present	after a 3-		paediatric	point (s):	following are number	mean of 3.1 visits per patient and a
children. 1997.	the	month	Country:	gastroenterologist	2 and 4 months	of children or %)	mean time span between the first and
Journal of	experience of	unsuccessful	Canada	and 1 paediatric	after initial clinic		the last visit to clinic of 4.5 months
Pediatric	the first 16	course of		general surgeon),	visit	-liquid	
Surgery 32[6],	months of a	treatment		a nurse		1rst visit: 0	Sample size varies in each category of
843-848	multidisciplina			practitioner, a	<u>Outcome</u>	last visit:1	symptoms because of incomplete
	ry clinic for	Exclusion		dietician, an	Measures:		observations and stool frequencies were
	the treatment	criteria:		enterostomal		-soft	only included for non-soiling patients
	of functional	Obvious		therapist/nurse	-stool frequency	1rst visit: 4	
	constipation	associated		educator and a	per month	last visit: 13	13 children appeared to be lost to follow-
		anomalies		psychosocial			up (no return to clinic in over 6 months)
		causing		nurse specialists	-stool	-formed	and 11 were discharged Among the
		constipation			consistency	1rst visit: 16	discharges the mean number of clinics
		or encopresis		-Assessment: new		last visit: 13	visits was 3.5
				patients always	-occurrence		
				assessed by clinic	and frequency	-hard	Patient data collected prospectively from
				nurse and	of symptoms	1rst visit: 10	the families and the clinic staffBefore
				physician	(soiling, rectal	last visit: 3	initial clinic visit families filled out several
				assessment to	pain, rectal		mailed questionnaires covering medical,
				identify potential	bleeding)	p=0.00004	psychological and social issues
				organic causes of		· ·	surrounding the child's problem. These
				constipation and	-satisfaction	Occurrence of	included a medical information
				to establish	with care, 5	symptoms (%)	questionnaire, a family information
				components of	scales:	-Solling (n=42)	questionnaire, the Family Assessment
				individualised	respectful and	Trst Visit: 57	Device (FAD), the Chronic Illness
				management.	supportive care,	last visit: 43	psychosocial inventory (CI-PSI) and a
				Further referral to	enabling and	NS	knowledge quiz. Parents also required
				other BMC staff	partnership,		to complete a "constipation/soiling diary"

Bibliographic Information Study Type & Evidence Number of Patients Patient Characteristic Intervention & Comparison Foldocome Measures Effect Size Reviewer Comments Importation as needed providing general information, or lorganic cause information, of organic cause information of organic cause information of constipation or lack of -Rectal pain (n=51) information, or providing specific information, of constipation or lack of -Rectal bleeding information, of constipation or lack of -Rectal bleeding information, or constipation or lack of -Rectal bleeding information, comments and knowledge quiz inst visit: 4 Very result Figure 1 Figure 2 -Rectal bleeding information or lack of -Rectal bleeding information, comments and knowledge quiz inst visit: 2 -Rectal bleeding questionnaire and a skeet to continue daries throughout. The FAD, CI-PSI questionnaire and knowledge quiz intravention (abdominal radiograph with umbosacral spine, barium enema, anorectal manometry and rectal mucosa biopsy) -Rectal pain (n=23) ints visit: 12.8 Frequency of respectful and supportive care. enabling and pattership. providing general information, cordinated and comprehensive care.] The scores for last visit: 0.2 Rectal bleeding impaction, to provide social continence fro children with provide social continence fro children with Source of fundi					Clinic-based I	nterventions		
as neededproviding general (n=51)fro one week, detailing the child's sto and symptoms. At the first clinic visit and symptoms. At the first clinic visit and symptoms. At the first clinic visit structured history/physical examinati pe-0.003Investigations: of constipation or of constipation or lack of improvement after adequate intervention (abdominal radiograph with lumbosacral biopsy)-Rectal bleeding up families completed a short progre questionnaire and asked to continue ocordinated and comprehensive (n=54)Frequency of enema, anorectal monomity reatment educationRectal pin (n=51) last visit: 22 p=0.003fro one week, detailing the child's sti and symptoms. Part of the part of the structure of history/physical examinati part of the structure of the parents' perceptions: the structure of the parents' perceptions: the extent to which 5 behaviours of the extent to which 5 behaviours of the extent to which 5 behaviours of the study group were compared with treatment meduation, providing specific information, roviding specific information, providing general information, providing <b< th=""><th>Bibliographic Information</th><th>Study Type & Evidence Level</th><th>Number of Patients</th><th>Patient Characteristic s</th><th>Intervention & Comparison</th><th>Follow-up & Outcome Measures</th><th>Effect Size</th><th>Reviewer Comments</th></b<>	Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
		Level	ralients	S	as needed -Investigations: only performed if there is suspicion of organic cause of constipation or lack of improvement after adequate intervention (abdominal radiograph with lumbosacral spine, barium enema, anorectal manometry and rectal mucosa biopsy) -Treatment: only compulsory treatment modality is patient education. Enemas only used in initial treatment if faecal impaction, to provide social continence fro children with paraidata	providing general information, providing specific information, coordinated and comprehensive care	-Rectal pain (n=51) 1rst visit: 53 last visit: 22 p=0.0003 -Rectal bleeding (n=54) 1rst visit: 26 last visit: 4 p=0.00035 <u>Frequency of</u> <u>symptoms per month</u> Soiling (n=26) 1rst visit: 30.7 last visit: 12.8 p=0.015 Rectal pain (n=23) 1rst visit: 9.5 last visit: 2.0 N.S Rectal bleeding (n=11) 1rst visit: 0.6 last visit: 0.2 N.S <u>Satisfaction with care</u> Results only reported	fro one week, detailing the child's stools and symptoms. At the first clinic visit a structured history/physical examination completed by physician. At each follow up families completed a short progress questionnaire and asked to continue diaries throughout. The FAD, CI-PSI questionnaires and knowledge quiz were repeated at 2 and 4 months after initial clinic visit. A Measure of Processes of Care (MOPC) questionnaire was also administered at the 4-month point. MPOC is a self report measure of the parents' perceptions of the extent to which 5 behaviours of health care professionals occur (respectful and supportive care, enabling and partnership, providing general information, providing specific information, coordinated and comprehensive care). The scores from the study group were compared with those from a normative group of 653 patients <u>Source of funding:</u> Educational grant from Janssen Pharmaceutica through Queen's GI Motility Education Centre
encopresis and avoid undue rectal distension until					encopresis and avoid undue rectal distension until		it is difficult to extract estimates	

Bibliographic InformationStudy Type & Evidence LevelNumber of PatientsPatient CharacteristicIntervention & ComparisonFollow-up & Outcome MeasuresEffect SizeReviewer Comments					Clinic-based In	terventions		
	Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
I taking effect. or higher that the Choice of enemas norm for: are phosphate respectful and and tap water or supportive care, saline, High enabling and colonic saline partnership and colonic saline coordinated and severe cases, coordinated and severe cases, coordinated and routinely coordinated and routinely coordinated and or compliance information and and nature of providing specific symptoms. Most information patients treated with senna, Docusate sodium and mineral oil. Multiple laxatives avoided. Patient started on recommended dosses, then increased by 50% every 4 to 5 days until symptomatic improvement noted. Individualised dosage then maintained maintained minut, during which dietary and psychosocial identary and					taking effect. Choice of enemas are phosphate and tap water or saline. High colonic saline irrigations used in severe cases, suppositories not routinely employed. Choice of laxative based on compliance and nature of symptoms. Most patients treated with senna, Docusate sodium and mineral oil. Multiple laxatives avoided. Patient started on recommended dosages, then increased by 50% every 4 to 5 days until symptomatic improvement noted. Individualised dosage then maintained minimum 3 to 6 months, during which dietary and psychosocial increased by		or higher that the norm for: respectful and supportive care, enabling and partnership and coordinated and comprehensive care Scores were lower than the norm for providing general information and providing specific information	

				Clinic-based In	terventions		
Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
				with. Patient is then slowly weaned off medications -Follow-up: arranged by each health care professional as needed. Visits used to monitor progress and continue education process. Patients who show no progress are reassessed by physician and may become candidates for diagnostic testing -Discharge: when patient is asymptomatic and off medications. Patient referred back to the referring physician, with information for maintaining healthy bowel routine Comparison: N.A			

				Web-based In	terventions		
Bibliographic	Study Type &	Number of	Patient	Intervention &	Follow-up &	Effect Size	Reviewer Comments
Information	Evidence	Patients	Characteristic	Comparison	Outcome		
	Level		S		Measures		
Ritterband et al.	Study Type:	24 children	24 children	Intervention:	Duration of	Percentage change	Additional information from study:
An Internet	RCT			Web intervention	intervention:	from pre- to post-	Computer and internet access provided
intervention as	(multicentre)	Inclusion	19 boys		3 weeks	assessment	to all families who contacted the
adjunctive		/exclusion		Comparison:			research centre and met the inclusion
therapy for	<u>Evidence</u>	criteria:	mean age: 8.46	No-Web	Assessment	Number of faecal	criteria
pediatric	level:	Children aged	years (SD1.81)	intervention	<u>point (s):</u>	accidents per week	
encopresis.	1+	between 6			3 weeks after	<u>(mean, SD)</u>	Participants received a \$25 gift
2003. Journal of		and 12 years,	-Web group: 12	-The Web site:	initial home visit	-Web group: 0.50	certificate to a local toy sore for
Consulting and	Study aim:	soling at least	children (10	Web-based		(.85)	completing the pre-treatment
Clinical	To examine	once a week	boys)	program for the	Follow-up		assessment and another \$25 gift
Psychology	the utility and	and have no		treatment of	period:	-No-Web group: 8.27	certificate for completing the post-
71[5], 910-917	effectiveness	medical	-No-Web group:	paediatric	None	(13.83)	treatment assessment
	of an Internet-	diagnosis	12 children (9	encopresis (U-			
	based version	other than	boys)	CAN-POOP-TOO	<u>Outcome</u>	p=0.18	Information regarding BM assessed by
	of enhanced	constipation			Measures:		parent report on the Child Information
	toilet training	that could	_	(please refer to	-number of	Number of bowel	Form. Question regarding child's bowel
		explain their	Country:	Ritterband, 2008	faecal accidents	movements (BM)	habits included such as number of BMs
		faecal	USA	for a description	per week	passed in the toilet	in toilet and use of toilet with / without
		incontinence		of the program)		<u>per week</u>	parental prompts. Questions regarding
					-number of	-Web group: +152%	use of internet programme also included
					bowel		in post-treatment form for the
					movements	-No-Web group: -16%	Intervention group. The Virginia
					(BM) passed in	p=0.001	Encopresis/Constipation Apperception
					the toilet per		Test (VECAT) also administered. It
					week	Bathroom use without	assesses bowel specific problems
						prompts	related to the process of encopresis,
					- bathroom use	-web group: +109%	such as avoidance of the tollet, non
					without prompts		responsiveness to rectal distension cues
					h athra ana wa a	-INO-VVED group: -	and fear of defecation pain. A generic
					-bathroom use	31%	subscale included as a comparison
					with prompts	p=0.021	Ineasure, addresses problem
					internet use	Bothroom use with	The VECAT consists of 19 pairs of
					-internet use	Damiouni use with	drawings (0 poirs bowel apositis and 0
						<u>prompts</u>	urawings (9 pairs power-specific and 9
					luseful aspect of	-vveb group: +47%	parallel generic events) and child selects

Information and Support for Children with Chronic Idiopathic Constipation and their families

				Web-based In	terventions		
Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
					the programme; preference questions regarding individual cores an modules)	-No-Web group: -45% NS Internet use (Web group only) 1. Most useful aspect of the programme: -the step by step program to get the child regulated -understanding why his body does what it needs to do everyday-and what happens when he doesn't have a BM and health consequencesinfor mation was tremendously useful -developing a feeling that he can control his own body -realising that he's not the only child with this problemthat was reassuring 2. Least useful aspect of the programme -difficulty with connections -modules regarding fear of toilet and	the picture in each pair that best describes him/herself No significant differences in baseline characteristics between the 2 groups (age, gender, race, stage of bowel movement training, length of current laxative regime or any of the outcomes measured) CM1: anatomy and pathophisiology CM2: medication (enemas/laxatives) CM3: behavioural intervention <u>Reviewer comments:</u> No definition of constipation / soling given Small sample size, no sample size calculation Randomisation and allocation concealment method not described No dropouts/lost to follow up reported Results not controlled for potential confounders <u>Source of funding:</u> National Institutes of Health Grant RO1 HD28160

			Web-based In	terventions		
Bibliographic Study Type & Information Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
					"monsters" -art work of the body did not print out -Miralax should have been included (as a choice of laxative) -nutrition portion was too limited Internet experience: parents' views / satisfaction -found material understandable (mean 5.00, SD 0.00, N = 20) -found it easy to use (mean 4.62, SD 0.74, N = 21) -believed their child liked the program (mean 4.05, SD 1.28, N = 21) - believed their child found it understandable (mean 4.32, SD 0.89, N = 19) - believed their child found it easy to use (mean 4.47, SD 0.77, N = 19) 3. Preference regarding cores modules (CM) (mean, SD)	

				Web-based In	terventions		
Bibliographic S Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
						(score 0 to 4) a. How useful: CM1: 3.84 (0.38) CM2: 3.94 (0.24) CM3: 4.00 (0.00) b. How well did you understand the material CM1: 3.89 (0.32) CM2: 3.89 (0.32) CM3: 3.92 (0.28) c. how well did your child understand the material CM1: 3.53 (0.61) CM2: 3.28 (1.07) CM3: 3.54 (1.13) d. How much did you enjoy using the module CM1: 3.68 (0.48) CM2: 3.67 (0.49) CM3: 3.69 (0.48) e. How much did your child enjoy using the module CM1: 3.63 (0.76) CM2: 3.61 (0.98) CM3: 3.46 (1.13)	

				Web-based In	terventions		
Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments
Ritterband et al. Using the internet to provide information prescriptions. 2005. Pediatrics 116[5], e643- e647	Level Study Type: RCT-Survey Evidence level: 1+ (RCT component) 3 (survey component) Study aim: To determine if families of children	83 patients and their families Inclusion/excl usion criteria: Families with a child who was being seen for the first time in the paediatric gastroenterol ogy clinic at the University	s 83 patients and their families -Children's mean age: 7 years 10 months (94 ± 38 months) (range: 25 months to 14.5 years <u>Country:</u> USA	Intervention: E-mail-prompt group (n=43) <u>Comparison</u> : No E-mail-prompt group (n=40) At the conclusion of the patient's clinic visit, 1 of the 2 attending gastroenterologist	Measures Duration of intervention 1 week Assessment point (s): 1 week Follow-up period: None Outcome Measures:	Number of families who visited the prescribed Web site within 1 week of their clinic visit (N=83) 54 (65%) Perceived barriers to accessing the Web site 18 interviewed subjects did not go to	Additional information from study: On the Web page, users read the following instructions: "We hope you find the information in this website to be helpful. Before you can begin, please enter the ID number you were given in the space below, and then click the button to begin." When the "submit" button was clicked, the 2-digit identification number and the date and time were logged in a database. The 2- digit identification number identified the family as a member of the e-mail-prompt group or no-prompt group. This was the only information captured in the
	suffering from chronic constipation and/or encopresis will visit an educational Web site that is specifically prescribed by their physician and whether an e-mail reminder increases the likelihood that they will visit the Web site. In addition, barriers to accessing the prescribed	of Virginia with a chief complaint of chronic constipation and/or encopresis. To be eligible, families had to have access to the Internet in their home and have an active e-mail account		s provided a form with the Web-site address and a log-in identification number. The handout, signed by the physician, stated: "It is important to learn as much as you can about bowel problems and how to manage them. As part of your child's care, I want you to go to this Web site and review the relevant material. This should be beneficial to your	-Number of families who visited the prescribed Web site within 1 week of their clinic visit -Perceived barriers to accessing the Web site	 the Web site because (n, %): 1. Personal / family / behaviour: -just forgot: 11 (61) -didn't have much time: 11 (61 -lost flyer: 6 (33) -interrupted: 3 (17) -computer in use by another: 2 (11) -did not think it would be useful: 2 (11) -did not want to go: 1 (6) -did not like typing in URLs: 1 (6) -did not know how to type in URLs: 1 (6) -child not 	Approximately 1 week after the clinic visit, the study coordinator attempted to contact the primary caretaker of each patient by telephone or e-mail to ask about their experience accessing the Web site. Families who did not access the Web site. They were presented with a

Web-based Interventions									
Bibliographic Study Type & Num Information Evidence Pat Level	iber of Patient ients Characteristic	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments				
Web site were identified		child's treatment." Families were assigned randomly into a "prompt" group or "no- prompt" group. 2 business days after the clinic visit, an e-mail containing the Web-site address and a reminder to visit the Web site was sent to those in the "prompt" group -The Web site: an abbreviated version of a larger Web-based program for the treatment of paediatric encopresis (U- CAN-POOP-TOO) -3 modules: (1) "How to Strain": reviewed proper defecation dynamics, including proper positioning, straining and		cooperating: 0 -did not know how to use internet: 0 -family thought it was a bad idea: 0 2. Technical issues/obstacles -computer broken: 4 (22) -internet connection broken: 2 (11) -difficulty logging on: 1 (6) -too long to log on:1 (6) No significant differences in identified obstacles between the families who received the e-mail reminder and those who did not	list of potential barriers and were asked whether the item had been a barrier for them to accessing the Web site. Individuals were able to select multiple barriers, if applicable Of the 83 families, 67 (81%) were contacted by telephone (n= 57) or e-mail (n= 10) No significant differences were found in identified obstacles between the families who received the e-mail reminder and those who did not <u>Reviewer comments:</u> No definition of chronic constipation or encopresis given No sample size calculation performed Randomisation and allocation concealment methods not described Results controlled for potential confounders <u>Source of funding:</u> Partially supported by National Institutes of Health grant RO1 HD28160				

	Web-based Interventions										
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				muscle control/ strength-building exercises (2) "Giving and Getting Enemas": reviewed techniques for administering enemas (3) "The SuperCleanout game": An arcade-style game for children with a learning message. Parents and children were able to view as much of the site as they wanted and could come back as often as they liked							

Web-based Interventions										
Bibliographic InformationStudy Type & Evidence LevelNumber of PatientsPatient Characteristic sIntervention & ComparisonFollow-up & Outcome MeasuresEffect SizeReviewer Com Reviewer Com	iments									
Ritterband et al. Study Type: 49 children 49 children and Intervention: Duration of Motivation scores Additional information from the second statement of the second statement	<u>om study:</u>									
Examining the Single sample and their their families Modified modules intervention (lower score reflects Families who agreed to reflect the state of	participate									
added value of cross-over families including audio, Each module more motivation) received a										
audio, graphics, RCT 32 boys graphics and with or without \$25 gift certificate forma	a local toy store									
and interactivity Multicentre Inclusion interactivity each -Audio										
in an internet criteria: mean age: 7.98 component Parents asked to complete	ete the									
intervention for (and these Children aged years Comparison: presented once 1. Audio-computer motivation and readinese	s to change									
pediatric are the results 5 to 12 years (SD=1.88) Modules without items from their child's p	erspective:									
encopresis. of 3 individual who were audio, graphics or <u>Assessment</u> a. Child										
2006. Children's studies for being see for <u>Country:</u> interactivity <u>point (s):</u> Pre: 6.00 -Motivation: a 3-item par	allel drawing									
Health Care each encopresis at USA Immediately Post: 5.13 selection measure was of	reated in the									
35[1], 47- [component] 2 paediatric after each P≤0.004 same manner as the Vire	ginia									
59United gastroenterol 2 modules of the module was Encopresis-Constipation	Apperception									
States. <u>Evidence</u> ogy clinics original U-CAN- presented b. Parent lest for both the enema	and proper									
level: POOP-TOO Pre: 7.56 defecation dynamics mo	dules.									
1+ <u>Exclusion</u> intervention were <u>Follow-up</u> Post: 6.25 Respondents select the	image in each									
criteria: revised: <u>period:</u> P=0.06 pair which they feel is clo	osest to									
Study aim: Not stated represent now they might	it act given the									
1 o determine - Giving and 2. Audio-person scenario presented in the	e picture (e.g.									
the Getting Enternas : Outcome child for the	nema vs. child									
useruiness reviewed <u>Measures:</u> a. Child wants an enema, child te	els urge to									
and user rectingues for rectingues for recting Previous for poop but keeps on playing poop but keeps on playing	ig vs. go right									
preference for administering Post: 5.63 away to sit on tollet). Re-	spondents are									
adulo (Use of a life) adult (Use of a life)										
sound), now to Strain . Change h Parent Pro part a nucle ince the initial ince the initial strain and the sound property in the soun	aye selected.									
of images)										
and dynamics Det: 7.13 dynamic modules were	66 and 83									
interactivity induction proper PC0.2 respectively.	00 anu.05									
Interactivity including proper F30.02 respectively										
avents by the straining and straining and straining and straining and	1-item scale									
user causing with / response ontions v	vas created to									
various	of change as									
actions i e exercises	d DiClemente									
clickable a Child 1983) with respect to bo	h receiving an									
buttons) in a Design was Pre: 5.69 enema and proper defec	ation dynamics									
paediatric significantly Post: 5.19	and a griannoo									

	Web-based Interventions									
Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments			
	Internet-			improved with		N.S	Reviewer comments:			
	based health			special emphasis			No definition of chronic constipation or			
	intervention			given to graphical,		b. Parent	encopresis given			
	specifically			animation and		Pre: 7.13				
	designed for			interactive		Post: 6.06	No sample size calculation			
	patients with			elements. For		P≤0.03				
	encopresis			each of the 3			Baseline characteristics not compared			
				studies		2. Graphics -				
				conducted, the 2			Randomisation and allocation			
				modules were		a. Child	concealment methods not described			
				modified to either		Pre: 5.75				
				include the 3		Post: 5.94	No dropouts/lost to follow up reported			
				constructs of		N.S				
				interest (audio,			Results controlled for potential			
				graphics and		b. Parent	confounders			
				interactivity) or		Pre: 8.06				
				not.		Post: 7.19	Source of funding:			
				For the study		P=0.06	National Institutes of Health grant RO1			
				examining audio			HD28160			
				both modules		-Interaction				
				were created with						
				and without		1. Interaction +				
				sound. For the		.				
				study examining		a. Child				
				graphics both		Pre:6.00				
				modules were		Post: 4.71				
				created with		P=0.03				
				graphics and						
				completely text		b. Parent				
				based; and for the		Pre: 8.35				
				study examining		Post: 6.88				
				Interactivity both		NS				
				modules were						
				created with		2. Interaction -				
				Interaction (use						
				the mouse to click		a. Child				
				various aspects of		Pre: 5.18				

Web-based Interventions									
Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments		
				the screen and navigation) and as a movie (where no interaction was necessary and the participant could just watch the module play from beginning to end		Post: 4.41 P=0.02 b. Parent Pre: 7.76 Post: 7.29 NS			
						Stage of change scores -Audio			
						a. Child Pre: 2.88 Post: 3.00 N.S			
						b. Parent Pre: 2.19 Post: 2.69 N.S			
						2. Audio-person			
						a. Child Pre: 2.69 Post: 2.63 N.S			
						b. Parent Pre: 2.25 Post: 2.75 P=0.04			

Web-based Interventions										
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						-Graphics				
						1. Graphics +				
						a. Child Pre: 3.38 Post: 3.31 NS				
						b. Parent Pre: 2.44 Post: 2.88 P=0.01				
						2. Graphics -				
						a. Child Pre: 3.38 Post: 3.25 NS				
						b. Parent Pre: 2.75 Post: 3.13 NS				
						-Interaction				
						1. Interaction +				
						a. Child Pre: 2.47 Post: 2.71 NS				

	Web-based Interventions										
Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments				
						b. Parent Pre: 2.18 Post: 1.94 NS 2. Interaction - a. Child Pre: 2.53 Post: 2.53 NS b. Parent Pre: 1.82 Post: 1.94 NS					

				Web-based In	terventions		
Bibliographic	Study Type &	Number of Patients	Patient Characteristic	Intervention &	Follow-up &	Effect Size	Reviewer Comments
mormation	Level	Fatients	S	Companson	Measures		
Ritterband et al.	Study Type:	22 children	22 children	Intervention:	Duration of	Number of faecal	Additional information from study:
Real world use	Prospective			Internet-based	intervention	accidents over a 2-	Of 46 patients originally provided with
of an Internet	case series	Inclusion	13 males	intervention for	2 weeks	week period (mean)	the Web-based information prescription
intervention for		criteria:		childhood		-initial period:	10 could not be reached by phone or
pediatric	Evidence	Children with	mean age: 8.10	encopresis: U-	Assessment	13.86 (SD 10.40,	email for interview, of the remaining 36 3
encopresis.	level:	а	years (SD 2.3	CAN-POOP-TOO	point (s) and	median 13.00)	did not provide consent, 3 stated that
2008. Journal of	3	documented	years) range		follow-up period		they never received the initial email with
Medical Internet		diagnosis of	5.1 years to	Child-focused		-follow-up period:	their personalised log-in information, 5
Research 10[2],	Study aim:	encopresis as	12.11 years	programme,	-initial period: 2	2.14 (SD 2.21,	never logged on and 3 logged but never
e16	To examine	noted in their		targets primarily 5	weeks before	median 1.00)	viewed any of the intervention material.
	the utility and	medical	Country:	to 10 years old	children were	<i>P</i> < .001	No subsequent data was collected on
	impact of an	records and	USA	children but was	enrolled in the		these patients
	Internet	their families,		designed to be	program	Number of bowel	
	intervention	seen at the		used by child and		movements (BM)	Number of faecal accidents, number of
	for childhood	Paediatric		parent (s)	-follow-up	passed in the toilet	bowel movements passed in the toilet
	encopresis as	Gastroenterol		together	period: 2 weeks	over a 2-week period	and average amount of perianal pain
	part of	ogy Clinic at			immediately	<u>(mean, SD)</u>	experienced during defection were
	standard	the University		3 core modules	before phone	-initial period (n=21,	obtained from children's medical charts
	medical care	of Virginia		take 60 to 90	interview	missing data)	and though a phone interview with
	in a "real	Children's		minutes to		14.62 (10.68)	parents. Interview also included open-
	world" setting	Hospital		complete, all	<u>Outcome</u>		ended questions about what the parents
		between .		users instructed to	Measures:	-follow-up period:	believed were the most helpful and least
		all children		review them		14. 82 (8.65)	helpful components of the programme. 3
		had been		during the first	-number of	NS	structured questionnaire mostly
		given access		week:	faecal accidents		developed for this interview were also
		to the		1. The body	over a 2-week	Average amount of	completed: U-CAN-POOP-TOO Utility
		paediatric		(anatomy,	period	perianal pain	Questionnaire administered to all
		encopresis		physiology and		experienced during	parents who had used the program
		Internet		pathophysiology	-number of	defection over a 2-	(extent to which the parent and child
		intervention		of digestion)	bowel	week period (mean,	found program useful, enjoyable,
		as part of		2. How to poop	movements	<u>SD)</u>	understandable and easy to use); U-
		their		(behavioural	(BM) passed in		CAN-POOP-IOO Impact Questionnaire
		treatment		techniques for	the toilet over a	-initial period:	administered to all parents who had
				treatment of	2-week period	0.56 (0.78) (n=18,	used the program (parents to rate how
		Exclusion		encopresis)		missing data)	much they perceived the programme
		criteria:		3. Medication	-average		helped their child) and Internet
		Not stated		(clean-out and	amount of	-follow-up period:	Intervention Adherence Measure

Web-based Interventions									
Bibliographic Study Type & Information Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments			
			laxative treatment) New modules assigned each week based on a follow-up assessment the user completes about their child's status. Not all modules necessarily used by all users, only those modules identified as relevant are assigned and reviewed. However all modules can be viewed by all users. Follow-up comprised of 17 to 20 questions, depending on the week. System contains a total o 22 modules, each takes 5 to 10 minutes to review <u>Comparison</u> : N.A	perianal pain experienced during defection over a 2-week period -utility and impact of the programme :parents' views/satisfacti on -adherence	0.14 (0.47) NS <u>Utility and impact of</u> the programme :parents' <u>views/satisfaction</u> -liked program (mean 4.62, SD 0.50, N = 21) -found it understandable (mean 5.00, SD 0.00, N = 20) -found it easy to use (mean 4.62, SD 0.74, N = 21) -believed their child liked the program (mean 4.05, SD 1.28, N = 21) - believed their child found it understandable (mean 4.32, SD 0.89, N = 19) - believed their child found it easy to use (mean 4.47, SD 0.77, N = 19) -most helpful components of the program: tutorials about anatomy and pathophysiology, liked that the program	administered to patients who stopped using the programme for some reason other than that their problem was "resolved". Those who responded "not applicable" to items on the U-CAN-POOP-TOO Utility Questionnaire were not included in the analysis for that item (explaining the varying sample sizes) The U-CAN-POOP-TOO Impact Questionnaire was administered to examine how much the parents believed the program affected outcome. Those who responded "not applicable" were not included in the analysis for that item No significant correlations found between computer/Internet usage and the change from initial to follow-up period for accident frequency ($r = .09, P$ < .69, N = 22), BMs passed in the toilet ($r = .38, P < .09, N = 21$), or amount of pain associated with defecation ($r = .08, P$ < .76, N = 18). Internet comfort and connection speed were also not significantly correlated to changes in any of the bowel-related outcome variables (r values ranged from17 to .27; P values ranged from .25 to .59) Of the 22 patients who used U-CAN- POOP-TOO, 18 (82%) completed all three assigned cores (main treatment components). All 22 patients completed the Anatomy Core; 20 completed the Medication Core; and 18 completed the Medication Core; and 18 completed the			

Web-based Interventions								
Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic s	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments	
						the child, but that it was comprehensive and non-judgemental -least helpful components of the program: no clear themes emerged -How much parents believed the program helped them and their children: On average, 19/25 items (76%) rated at least "somewhat helpful," no item described as "not at all helpful." On the 1- to 5-point scale, average responses ranged from a low of 2.33 (the program helped reduce the number of times parents had to remind their child to use the bathroom) to a high of 4.2 (the program helped the child feel more comfortable using the toilet at home). <u>Adherence</u> 16/22 patients examined, stopped using the program for some reason other	(55%) completed one follow-up, four (18%) completed a second and third follow-up, and two of these four (9%) completed more than three follow-ups. Modules were individually assigned based on responses to follow-ups; however, patients had access to all the modules. The average number of modules completed was 7.23 (SD 9.64); 14 patients (64%) completed at least one module <u>Reviewer comments:</u> Unclear how encopresis was defined/diagnosed Small sample size, no sample size calculation Unclear whether questionnaires were piloted <u>Source of funding:</u> Partially supported by NIH grant RO1 HD28160	

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						than that their problem was "resolved." -Obstacles to using the program (only 2 items with a mean score of 2 or greater (on a 1- to 3-point scale)): I just forgot [to go to the website]" (mean 2.00, SD 0.89) "I didn't have time in my schedule" (mean 2.06, SD 0.85)					
Web-based Interventions											
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Bibliographic Information	Study Type & Evidence Level	Number of Patients	Patient Characteristic S	Intervention & Comparison	Follow-up & Outcome Measures	Effect Size	Reviewer Comments				
Borowitz et al.	Study Type:	1142	1142	Intervention:	Outcome	The tutorial received	Additional information from study:				
Using the	Online survey	participants	participants	Multimedia tutorial	Measures:	157 326 successful	The tutorial also includes a one-page				
Internet to teach					-clarity and	page requests from	feedback form comprised of 6 multiple-				
parents and	<u>Evidence</u>	Inclusion	only 887 (78%)	Directed primarily	easiness of	38 012 distinct hosts	choice questions and one open-ended				
children about	level:	criteria:	answered the	at parents and	information		comment field. Questions were				
constipation	4	Children and	questions	older children.	presented in	Was the information	developed in consultation with the				
and encopresis.		parents who	categorising the	Includes	tutorial	presented in the	university division of survey research. All				
2001. Medical	Study aim:	accessed a	reader:	information about		tutorial clear and easy	completed form were sent via email				
Informatics and	I o described	tutorial about	700 (000)	differential	-usefulness of	to understand?	directly to the main author				
the Internet in	the feedback	childhood	-789 (89%):	diagnosis,	tutorial: helping	<u>(N=883)</u>					
Medicine 26[4],	received	constipation	parents and	aetiology,	parents to	N/ 1 040	Responses to multiple-choice questions				
283-295	regarding a	and .	guardians of a	treatment and	understand why	-Very clear: 812	were tabulated. One author reviewed all				
	web-based	encopresis,	child with	potential side	children	(92%)	free text comments and identified the				
	tutorial about	developed	constipation or	effects, method of	develop	-Pretty clear: 71 (8%	central them of each comment.				
	chronic	and installed	encopresis	tollow-up	constipation	-Nobody chose not	Comment were categorised as:				
	childhood	on the web	44 (50())	including regular	and/or	very clear or not	-appreciation for making the information				
	constipation	pages of the	-44 (5%):	monitoring,	encopresis,	clear at all	available				
	and	Children's	granoparent or	natural history	making parents	Did the tuterial halm	-question (s) about a particular child s				
	encopresis	Nedical	other family	and prognosis	better able to	Did the tutorial help	symptoms or treatment				
	auring 20	Centre at the	members	and a list of	take care of	you to understand	-a general question not specific to any				
	months	University of	20 (20/)	references	their child	why children develop	particular child				
	Detween	virginia, and	-30 (3%).	Comparison	upofulnoss of	constipation and/or	-a request for distant recommon detions				
	January 1996	also	leachers	<u>Companson</u> .	-userumess or		-a request for additional online				
	2000	online	-9 (1%)	N.A	and way to	-Completely: 17/	information such as online forum or a				
	2000	feedback	-5 (170).		teach neonle	(25%)	frequently asked questions (EAO) site				
		form No	priysiciaris		about health	-Somewhat: 174	-specific recommendations as to how to				
		internal or	-35 (4%): other		nrohlems	(25%)	improve the tutorial				
		external	healthcare		problems	-A little: 13 (2%)					
		announceme	providers		-questions or	-Not al all: 0	Definition of constination in the tutorial: a				
		nt made to	providere		comments or		child is constinated when he or she				
		communicate	Country:		suggestions as	After completing the	passes bowel movements less than				
		the availability	USA		to how to	tutorial, do vou think	every other or every third day and when				
		of the tutorial			improve the	vou are better able to	he or she passes a bowel movement it				
		but access to			tutorial	take care of a child	often is large and hard and perhaps				
		the website				suffering from	more important, it hurts"				
		was not				constipation and/or	,				

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		limited in any way. These pages can be found by a link in the university homepage called "tutorials for families" <u>Exclusion</u> <u>criteria</u> : Not stated				encopresis? (N=696) -Very much: 408 (59%) -Somewhat: 226 (32%) -A little: 42 (6%) -Not at all: 20 (3%) Do you think this type of tutorial is a good way to teach people about health problems? (N=691) -Very good: 599 (87%) -Pretty good: 89 (13%) -Not very good: 0 -Not good at all: 3 (0.4%) Do you have any questions or comments or suggestions as to how to improve the tutorial? (N=845) -appreciation for making the information available: 443 (52%) -question (s) about a particular child's symptoms or treatment: 167 (20%)	Reviewer comments: Not all participants answered all the questions in the feedback form Source of funding: Not stated	

Web-based Interventions								
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						 -a general question not specific to any particular child: 96 (11%) -a referral request: 46 (5%) -a request for dietary recommendations: 34 (4%) -a request for additional online information, such as online forum or a frequently asked questions (FAQ) site: 21 (2%) -specific recommendations as to how to improve the tutorial: 38 (4%) 		