Supplementary Material 10 – Evidence of effectiveness – complementary therapy synthesis – additional tables

Table 1: Characteristics of Excluded Studies

Study (n=26)	Aim	Reason for exclusion
Alcantara 2014 [1]	To realize the breadth and depth of chiropractic in the care of children with chronic constipation, we performed an integrative review of the literature to inform practice, research and policy.	Narrative review
Allen 2014 [2]	Examining use of massage to address paediatric digestive issues	Narrative review
Aquino 2017 [3]	Identify if osteopathic manipulation improves defecation frequency and reduces enema administration.	Single case study
Bayne 2002 [4]	Details the decision about banning Use of Aloe and Cascara Sagrada in OTC Drug Products	FDA's ruling that anything containing Aloe can't be used. Exclude as nothing pertaining to effectiveness.
Barber 2016 [5]	Improvement in functional constipation while under chiropractic care in a pediatric patient with primary vesicoureteral reflux: a case report.	Focus is on a child with vesicoureteral reflux, therefore exclude.
Bishop 2003 [6]	Efficacy of treating patients with encopresis and chronic constipation with reflexology	This study is included in the Chase 2011 review, which is included.
Cheng 2009 [7]	This review aimed to determine the efficacy and safety of Chinese Herbal Medicines for the treatment of functional constipation by summarizing current available randomized controlled trial	This review was classified as having a HIGH risk of bias due to inclusion of studies of poor quality and unclear risk of bias that they were not addressed adequately in data synthesis. In addition, it is unclear if multiple reviewers were involved in screening, data extraction and ROB/Quality assessment. As a result, this review was excluded. It is not clear if any of the included RCTs focus on children.
Clarke 2009b [8]	To investigate use of transcutaneous interferential electrical stimulation	Moved to our 'Level 2' synthesis
Connor 2014 [9]	This article describes the introduction of abdominal massage techniques by a community team as part of a total bowel management programme for people with learning disabilities	Audit - no data specific to children, all relates to "people"
Field 2019 [10]	This narrative review on paediatric massage literature from the last decade	Narrative review

	suggests that massage therapy has positive effects on several paediatric conditions	
Gardiner 2005 [11]	To establish, for GI complaints, which herbs and supplements spell relief?	Medical education for Physicians
Gurol 2019 [12]	To determine the herbal supplement product(s) frequently used by mothers to cope with some health problems among children.	Does not address children with CFC.
Yaqi 2020 [13] (CRD42018106589)	An evidence-based systematic review and meta-analysis of randomised controlled trials were conducted to investigate the effect of foot reflexology on functional constipation.	Review includes all ages and includes only one paediatric study
Koe 2009 [14]	To examine the use of complementary and alternative medicine (CAM) in children	Narrative review
Lee and Rickards-Tilley 2013 [15]	Describes a case study: 32-month-old male who had suffered from idiopathic chronic constipation for the past 2 years. Intervention: acupuncture.	Single case study, adult.
Li 2019 [16]	The aim of the present quantitative research was to collect evidence about the safety and efficacy of acupuncture at ST25 for FC in order to facilitate the clinical application of this treatment.	SR published in Nov 2020 – outwith our search dates. However, we note that the review includes 10 RCTs - adults only.
Martin-Marcotte 2018 [17]	Safety and efficacy of chiropractic manipulation.	Single case study
Motaharifard 2015 [18, 19]	This descriptive review based study evaluated the reliable books of traditional medicine, contexts and concepts related to this subject. Then, the data were collected and categorized.	Narrative review
Nath 2017 [20]	This case study examines some common complementary and alternative treatments used in the management of behavioral and gastrointestinal symptoms associated with autism including food selectivity, abdominal pain, nausea, gastro-esophageal reflux, constipation, and diarrhea.	Single case study
Nimrouzi 2014 [21]	Define constipation in traditional Persian medicine and contemporary medicine.	The literature survey relates to defining constipation and would be classed as a narrative review.
Paknejad 2019 [22]	This review aims to evaluate the efficacy and safety of complementary and alternative medicine methods for constipation in the pediatric population.	This study was classified as having a HIGH risk of bias because grey literature and hand searching were not performed, resulting studies excluded significant number of

		complementary and alternative techniques due to requirement for study design to be case series or a trial and although ROB/Quality performed, this was not accounted for when synthesising findings. As a result, this review was not included.
Sinclair 2011 [23]	This article reviews scientific evidence from 1999 to the present, regarding abdominal massage as an intervention for chronic constipation.	Narrative review
Soo 2018 [24]	Systematic review protocol to assess clinical evidence for or against massage as a management for symptoms of constipation	Study did not progress (confirmed by authors via email)
Vakili 2018 [25]	This review was conducted to report the medicinal plants effective for constipation	Narrative review
Woodward 2009 [26]	To attempt to answer the question: Does reflexology decrease physical or psychological morbidity and symptom distress and improve quality of life in patients with a diagnosis of chronic idiopathic (functional) constipation? The primary objective is to assess the efficacy and safety of reflexology for the treatment of chronic idiopathic constipation	Systematic review protocol. Authors confirmed by email that the review did not progress.
Zollars 2019 [27]	Aim: To assess improvement in the quality of life, function, and colonic motility before and after visceral and neural manipulation in five children with cerebral palsy and chronic constipation.	This is five single case reports – exclude.

Table 2: Characteristics of Ongoing Studies

Study (n=16)	Clinical trial / PROSPERO registry number (if available)	Aim	Study design	Anticipated completion date

Abarna 2019 [28]	CTRI/2019/06/019692	Prevalence and effectiveness of Siddha management in children with constipation.	Cohort study	Authors contacted to clarify, but no response received
Arman 2017 [29]	IRCT2017072535304N	To evaluate the anti-constipation effects of abdominal application of olive oil ointment in children 1-4 years old:	RCT	Trial registration. Authors contacted, but no response received
Cao 2012 [30]	Registered as a Cochrane review protocol	To assess the efficacy and safety of acupuncture therapy for chronic constipation	Review	Protocol paper. Authors contacted, but no response received.
Chan 2018 [31]	NCT03751267	To investigate the efficacy of pediatric tuina (massage) on the functional constipation of pre-school aged children.	RCT	Reported as completed on the clinical trial register. No data published. Authors contacted but no response received
Erdrich 2020 [32]	CRD42018096644	To systematically review the literature and analyse the methodological quality of all manual therapy studies, and to provide an overall level of evidence analysis	Systematic review	No information available. No publication found.
Ghanwat 2019 [33]	CTRI/2019/03/018241	To compare of Haritaki pippali avaleha and Aargwadha phalamajja avaleha in the treatment of constipation in the age group of 3 to 6 years.	RCT	Single arm trial registration. Authors contacted, but no response received
Hembade 2018 [34]	CTRI/2018/12/016752	To study the role of Haritaki-draksha avaleha and aaragwadha phalmajja avaleha in the management of constipation among children without any underlying disease	RCT	Registered 2018. No further details.
Lakshmeesh 2019 [35]	CTRI/2019/08/020576	To evaluate the Efficacy and Safety of HCLX031706 (Herbal Syrup) for the symptomatic relief of Functional Constipation in Pediatric Population	Trial	Email from authors confirm trial complete but results yet to be published
Radha 2020 [36]	CTRI/2020/01/022916	Clinical evaluation of the effect of	Trial	No data published. Authors

		aynkaaya chooranam for the treatment of kattu mantham	protocol	contacted but no response received
Sahana 2017 [37]	CTRI/2017/03/008095	This study is an open labeled single arm non-randomized prospective clinical trial to study the effect of Haritaki Khanda given at a dose of 6grams bid with warm milk for 14days in children with Vibandha (constipation	Trial protocol	No data published. Authors contacted but no response received
Sathya 2017 [38]	CTRI/2017/03/008145	In balavagadam and gunapadam mooligai vaguppu there is a sastric siddha formulation Ingi Ennai for kattumantham The drug is more cost effective and also efficacy is not yet scientifically validated ,so I selected the medicine Ingi Ennai as a trial drug for the treatment of kattumantham	Trial protocol	No data published. Authors contacted but no response received. Note: this clinical trial number has been allocated to two different clinical trials.
Wang 2019 [39]	CRD42019119722	To provide evidence of whether Tuina is an effective and safe intervention for FC.	Protocol (Review)	No data published. Authors contacted but no response received
Ravanbakhsh 2019 [40]	IRCT20190614043891N	To study the effect of visceral manipulation on children with chronic functional constipation	RCT	Not stated (study registered 12-04-2019)
Akhavan 2019 [41]	IRCT20190722044310N	Comparison of response to Quchi point massage therapy versus standard treatment in children with functional constipation	RCT	Not stated (study registered 30-09-2019)
Zhong 2015 [42]	CRD42015016260	To determine whether integrative medicine (IM), mainly including Chinese medicine and conventional medicine has better effectiveness and safety than conventional medicine or Chinese	Systematic review and meta-analysis protocol	No update on PROSPERO record and unable to find completed review.

		medicine alone for constipation patients		
Yue 2019 [43]	CRD42019142719	To determine whether aromatherapy can benefit functional constipation in patients	Systematic review protocol	Anticipated completion date: 14 May 2026

Table 3: Reported Outcomes of included primary studies

	Outcomes Addressed								
Study (n=15)	**Painful Defecation**	**QOL**	**Stool Frequency**	**Stool Consistency**	**Side Effects**	**Faecal Incontinence**	**Abdominal Pain**	**School Attendance**	**Additional outcomes**
Aslam 2021 [44]	x		x	x		x			Retentive posturing, drug compliance
Babaei 2018 [45]			x		x				Thirst, oral smell, gastric disorders, drooling
Bromley 2014 [46]		x	x	x				x	Diet, fluid intake, sleep pattern, behaviour
Cai 2018 [47]	x		x	x	x	x			Time of defecation, recurrence rate and compliance. Abdominal distension, decreased appetite, dry mouth, halitosis, feverish feeling in palms and soles, hypochromic urine.
Canbulat Sahiner 2017 [48]			x	x		x			
Chase 2011 [49]			x	x	x	x	x		
Duymaz 2020 [50]	x		x	x					Impact of constipation severity, functional independence, gross motor function
Elbasan 2018 [51]			x						
Mostamand 2018 [52]							x		Manometric tracings, passage of flatus or stool
Nimrouzi 2015 [53]			x	x	x	x	x		Retentive posturing, rectal bleeding
Orhan 2018 [54]	x	x	x	x					Feeling of incomplete evacuation, and changes in food and liquid consumption, straining during defecation, perceived severity, global rating of improvement
Qiao 2021 [55]	x		x		x	x			Global symptoms, satisfaction with bowel function, laboratory assessments

Shahamat 2016 [56]	x		x	x		x	x		Retentive posturing or excessive volitional stool retention.
Tavassoli 2021 [57]	x		x	x	x	x			Faecal retention
Zadpe 2020 [58]			x	x			x		Loss of appetite

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

	Domain 1: concerns regarding specification of study eligibility criteria	**Domain 2: Concerns regarding methods used to identify and/or select studies**	**Domain 3: Concerns regarding methods used to collect data and appraise studies**	**Domain 4: Concerns regarding the synthesis and findings**	**Overall risk of bias in the review**
Aslam 2021 [44]	LOW	LOW	UNCLEAR	UNCLEAR	LOW
Chase 2011 [49]	LOW	LOW	LOW	LOW	LOW

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

Study (N=8)	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Selective reporting (reporting bias)
Cai 2018 [47]	LOW risk	LOW risk	LOW risk	LOW risk	UNCLEAR risk
Canbulat 2017 [48]	UNCLEAR risk	UNCLEAR risk	HIGH risk	HIGH risk	UNCLEAR risk
Duymaz 2020 [50]	LOW risk	UNCLEAR risk	HIGH risk	HIGH risk	UNCLEAR risk
Orhan 2018 [54]	LOW risk	LOW risk	HIGH risk	LOW risk	LOW risk
Qiao 2021 [55]	LOW risk	LOW risk	LOW risk	LOW risk	LOW risk
Nimrouzi 2016 [53]	HIGH risk	HIGH risk	HIGH risk	HIGH risk	UNCLEAR risk
Shahamat 2016 [56]	LOW risk	UNCLEAR risk	HIGH risk	LOW risk	UNCLEAR risk
Tavassoli 2021 [57]	LOW risk	LOW risk	LOW risk	LOW risk	LOW risk

Table 6: Risk of bias judgements of studies for non-RCTs, using ROBINS-I ROB tool

Study	Bias due to confounding factors	Bias in selection of participants into the study	Bias in classification of interventions	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported result	OVERALL ASSESSMENT
Elbasan 2018 [51]	Moderate	Low	Low	Moderate	Low	Moderate	Low	Moderate

Table 7: Risk of bias judgements of studies with other designs, using WEIRD tool

Study	Is there a clearly stated aim, objective or purpose for the source material?	Is there a clear description of the source of the information reported (transparency)?	Is there a clear description of the programme or intervention or policy or reform on which the source material focuses?	Is there a clear description of the context/s to which the information described in the source material relates?	Is the information accurate (source materials other than empirical studies)?	Is the information accurate (empirical studies only)?	Is the evidence representative?	Are any limitations of the information and / or methods discussed in the source material?	Is evidence provided to support any findings or conclusions made?	Are relevant rights and ethics considerations described?	Are any interests declared and any potential conflicts of interest noted?	Overall Assessment
Non-comparative studies (n=4)												
Babaei 2018 [45]	Yes	Yes	Yes	Yes		Unclear	Yes	Yes	Unclear	Unclear	No	Minor concerns
Bromley 2014 [46]	Yes	Yes	Yes	Yes		Unclear	Unclear	Yes	Yes	Unclear	No	Minor concerns
Mostamand 2018 [52]	Yes	Unclear	No	No		Unclear	No	Yes	Yes	Unclear	No	Serious concerns
Zadpe 2020 [58]	Yes	Unclear	Unclear	Unclear		Unclear	Unclear	No	Unclear	Yes	Yes	Serious concerns

Table 8: Studies addressing questions relating to complementary therapy

Sub-heading	**Connective tissue massage**		**Musculoskeletal manipulations**		**Reflexology**	**Acupuncture**		**Complementary / alternative medicines**
Question	What is the effect of abdominal massage (in children with or without disabilities)?	What is the effect of connective tissue manipulation and kinesio taping in children with cerebral palsy?	What is the effect of chiropractic or osteopathic manipulation?	What is the effect of dry cupping therapy compared to laxatives?	What is the effect of reflexology?	What is the effect of acupuncture?	**What is the effectiveness of cassia fistula?**	What is the effect of herbal and/or traditional medicines?
Systematic review			Chase 2011 [49]		Chase 2011 [49]	Chase 2011 [49]	***Aslam 2021***	
RCT		Orhan 2018 [54]		Shahamat 2016 [56]	Canbulat-Sahiner 2017 [48] Duymaz 2020 [50]			Cai 2018 [47] Tavassoli 2021 [57] Zhang 2017 Nimrouzi 2016 [53] Qiao 2021 [55]
Other primary study	Bromley 2014 [46] Mostamand 2018 [52]				Elbasan 2018 [51]			Zadpe 2020 [58], Babaei 2018 [45]

Red = high ROB, Amber = Moderate ROB, Green = Low ROB, RCT=Randomized controlled trial.

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

Question	Study	Limitations	Inconsistency	Indirectness	Imprecision	Publication bias	Judgement of certainty in evidence	**Summary of findings**
What is the effect of abdominal massage (in children with or without disabilities)?	Bromley 2014 [46] Mostamand 2018 [52]	Downgrade once – no comparator and no long term follow up.	No downgrade	No downgrade	Two small studies with varied populations and different interventions. Downgrade twice	Low risk of bias	Insufficient evidence	Abdominal massage for children with CFC may result in equivalent or better outcomes than standard care, but there is insufficient evidence to support generalised conclusions.
What is the effect of connective tissue manipulation and kinesio taping in children with cerebral palsy?	Orhan 2018 [54]	Downgrade once due to low participant numbers. Downgrade once due to risk of bias of non-blinded treating physiotherapists.	No downgrade – consistent findings (only one study)	No downgrade – single study	No downgrade	No downgrade	Low	There is low certainty from one RCT that physiotherapy techniques of connective tissue manipulation and kinesiotaping may be beneficial components of a programme for children with cerebral palsy who have constipation and are receiving physiotherapy.

What is the effect of chiropractic or ostepathic manipulation?	Chase 2011 [49]	Downgrade twice – case study data only.	Downgrade once – inconsistencies and inaccurate reporting in studies.	No downgrade.	Low quality evidence around efficacy – downgrade once	Downgrade once	Insufficient evidence	There is insufficient evidence to support conclusions about the effectiveness of chiropractic or osteopathic manipulation.
What is the effect of dry cupping therapy compared to laxatives?	Shahamat 2016 [56]	Downgrade once – moderate risk of bias	No downgrade	Downgrade once – only one small study	Downgrade once-confounding factors	Downgrade once	Very low	There is very low certainty that dry cupping therapy of the abdominal wall may be as effective as laxatives. Further research is required to explore this finding.
What is the effect of reflexology?	Chase 2011 [49] Canbulat-Sahiner 2017 [48] Duymaz 2020 [50] Elbasan 2018 [51]	Downgrade once – SR includes one study which is judged to be high ROB, other studies judged to be moderate/high ROB	Downgrade once – inconsistent findings	Downgrade once – different populations studied	Downgrade once – confounding factors	No downgrade	Insufficient evidence	There is insufficient evidence to support conclusions relating to the effect of reflexology.
What is the effect of	Chase 2011 [49] relevant	Downgrade once –	No downgrade	Downgrade once –	Downgrade once – one small study	No downgrade	Insufficient evidence	There is insufficient

acupuncture?	study;	included study is cross-over design		unexplained results relating to physiological outcomes				evidence to support conclusions relating to the effect of acupuncture.
What is the effectiveness of cassia fistula?	Aslam 2021 [44]	Downgrade once as included studies have high ROB for some domains	Downgrade once – inconsistencies in results for different outcomes	Downgrade once – I2 indicates heterogeneity for some analyses	No downgrade	Downgrade once – search limited to open-access articles	VERY LOW	There is some very limited evidence that suggests cassia fistula may have some beneficial effects, but this is insufficient to support any generalised conclusions. We have very low confidence in this finding.
What is the effect of other herbal and/or traditional medicines?	Cai 2018 [47] Tavassoli 2021 [57] Qiao 2021 [55] Nimrouzi 2016 [53] Zadpe 2020 [58] Babaei 2018 [45]	Downgrade once – low numbers in 2 studies and no long term follow up in 3 studies.	Downgrade twice – all studies investigate different interventions	No downgrade	No downgrade	No downgrade	VERY LOW	There is low certainty that herbal/traditional medicine for children with CFC may result in equivalent or improved outcomes. However, studies have investigated different interventions, making it

								difficult to support clinical decisions.

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