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Does a Manual Therapy Approach Improve the Symptoms of Functional Constipation? A Systematic Review of the Literature.

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Does a manual therapy approach improve the symptoms of functional constipation?

A systematic review of the literature.

Background: Functional constipation is highly prevalent and places a significant burden on healthcare systems around the world. Manual therapy is a commonly used intervention, however to date there has not been a systematic review that critically appraises a wide range of manual therapy disciplines.

Objectives: To systematically review the literature and analyse the methodological quality of all included studies, and to provide an overall level of evidence analysis.

Methods: A database search was completed to identify eligible studies that were published from database creation to July 2018. The relevant characteristics of each study were extracted, and each study was assessed for methodological quality with a modified version of the Downs and Black appraisal tool.

Results: Seven studies fulfilled the inclusion criteria and were assessed for methodological quality. One study was found to have 'strong' methodological quality, five were of 'moderate' quality, and one was of 'low' quality. All studies reported consistent findings regarding their individual primary outcome measures. Overall level of evidence for the use of manual therapy as an intervention for constipation was found to be 'moderate'.

Conclusions: There is moderate quality evidence for the use of manual therapy as an intervention for constipation. The review identified several themes that can guide future research on this topic, including intervention type and frequency, reporting quality, mechanism of effect, and variability of outcome measures.

Keywords: constipation, manual therapy, physical therapy, massage, systematic review

Introduction

Functional constipation (FC) is a highly prevalent condition around the world¹ and is one of the most common issues seen in gastroenterology clinics². FC belongs to a group of functional gastrointestinal disorders (FGIDs) that are characterised by changes to gastrointestinal function without an identified structural or biomechanical abnormality^{3,4}. Due to the lack of objective findings, clinical tools such as the Rome criteria⁵ are widely used by healthcare practitioners to establish the presence of FC. The most recent Rome IV diagnostic criteria for FC are presented in Figure 1.

FC is associated with changes in intestinal motility, visceral sensitivity, gut microbiota, mucosal and immune function, and changes to the central nervous system⁶. In addition to this, psychological factors such as stress and depression, are likely involved in the development and maintenance of FC³. Although traditionally regarded as a benign condition⁷ FC significantly impacts an individual's quality of life⁸, places a significant burden on healthcare systems⁹, and is possibly linked to risk of reduced life expectancy⁷.

The first line of intervention for FC often includes increasing fluid and fibre intake in addition to lifestyle modifications such as exercise and/or changes to bowel habits as these methods are considered low-risk and relatively cost-effective¹⁰. Unfortunately, these modifications are not always successful for people with constipation suggesting that for some individuals the underlying cause may not be related to fluid, fibre or exercise levels¹¹. Laxatives are often recommended for patients who do not respond to dietary and lifestyle modifications¹² and their usage, along with lifestyle changes, is currently supported by NICE guidelines for constipation in children and young people¹³. Despite this, many patients are dissatisfied with laxatives due to

concerns surrounding efficacy and safety¹⁴ and long-term laxative usage has been associated with a range of adverse effects^{15,16} indicating a need for other treatment options.

Manual therapy is commonly used as an intervention for a variety of musculoskeletal and non-musculoskeletal complaints¹⁷ and may be an effective intervention for the treatment of FC. The mechanical stimulus associated with manual therapy techniques is hypothesised to cause a variety of neurophysiological responses which may influence gastrointestinal function through a range of physiological mechanisms^{18,19,20,21}. Stimulation of the autonomic nervous system via the parasympathetic, sympathetic, or enteric divisions is one of the most commonly proposed mechanisms for improving visceral function and has been hypothesised to improve blood flow¹⁷, increase visceral motility^{14,15} and stimulate peristalsis¹⁶.

Previous reviews on this topic indicate an established interest in this field and provide a foundation for further investigation. In 1999 a systematic review on the effectiveness of massage for constipation was published¹⁶ which concluded massage could be a beneficial therapy for patients with constipation, however this conclusion was based on just four studies of limited methodological quality. A narrative review from 2011 also supported the use of massage for constipation¹⁸, however the studies included in the review had participants with specific conditions such as spinal cord injury, making the results difficult to interpret as the study population may not represent the majority of constipated patients. In 2014 Alcantara et al.,¹⁷ published a review which supported the use of chiropractic treatment for infants and children with constipation, but the conclusion appears to be based on anecdotal evidence from multiple case reports of undetermined quality and as such should be interpreted

cautiously. As these reviews were either limited by power, scope of the literature, or methodological quality, an updated and broader systematic review using the Downs and Black tool²² is warranted to further the evidence base in this field.

Symptom onset more than 6 months prior to the diagnosis, with the following criteria fulfilled for the past 3 months:

(1) Two or more of the following criteria must be met:

- Less than 3 spontaneous bowel movements per week
- Manual manoeuvres necessary to facilitate defecation more than one-fourth of defecations (eg, digital evacuation, support of pelvic floor)
- Hard or lumpy stools (1-2 on Bristol Stool Form Scale) more than one-fourth of defecations
- Sensation of incomplete evacuation more than one-fourth of defecations
- Sensation of anorectal obstruction/blockage more than one-fourth of defecations
- Straining with defecation more than one-fourth of defecations

(2) Loose stools rarely present without the use of laxatives

(3) Insufficient criteria met to establish a diagnosis of irritable bowel syndrome

Figure 1: Rome IV criteria for functional constipation adapted from Lacy et al.⁵

Methods

Protocol and registration

A review protocol does not exist for this systematic review. This review was registered with the PROSPERO international register for systematic reviews on the 9/7/2018 under the title “Is manual therapy an effective intervention for constipation?” The registration

ID for this systematic review is: CRD42018096644.

Eligibility criteria

The following inclusion criteria were applied to select primary research studies relevant to meet the aim of this review:

- Studies with the following methodologies: randomised controlled trials, cohort studies, pilot studies, prospective studies, and case series.
- Studies that identify a manual therapy as being the primary intervention. For the purposes of this review, manual therapy can include techniques such as: mobilisation, manipulation, high-velocity low-amplitude thrusts, myofascial techniques, balanced ligamentous tension techniques, massage, stretching, passive articulation, soft tissue techniques, and practitioner-resisted movements. In addition to this, studies that employed non-manual approaches often used by manual therapists (such as exercise prescription, muscle strengthening and breathing exercises) in addition to application of a manual technique were included for review.
- Study participants with a diagnosis of functional constipation made in accordance with validated diagnostic criteria
- Full-text publications in English language
- Any year of publication

The following exclusion criteria were applied:

- Study participants with a known comorbidity
- Identification of acupuncture, acupressure, biofeedback, cranial therapy, or reflexology as the primary intervention
- Lack of clear outcome measures
- Case studies, grey literature and published work not subject to peer review, such as expert opinions, commentaries, and theses
- Studies where participants are under 12 years of age.

Information sources

A literature search was undertaken by the primary investigator (LE) in from June-July 2018 using electronic databases that were accessible via Unitech library databases. This included Scopus, Science Direct and Google Scholar, with Sportdiscus, AMED, Health Source: nursing/academic, MEDLINE and CINAHL plus being searched collectively via EBSCO health databases. All databases were searched from inception with the final search being concluded on the 29/7/2018. Reference lists of included studies were searched identify any eligible studies that may have been missed by the database searches. Where full text was not available authors were contacted directly to obtain these.

Database search

EBSCO health databases was searched without filters using the following syntax:
(chiropract* OR osteopath* OR physiotherap* OR “physical therapy” OR “manual

therapy” OR manipulation OR massage) W/15 (constipat*).

Science Direct was searched with the filter of ‘titles, abstracts, and keywords’ using the following syntax: (osteopathy OR chiropractic OR physiotherapy OR "physical therapy" OR "manual therapy" OR massage OR manipulation) AND (constipation).

Scopus was searched with the filter of ‘titles, abstracts, and keywords’ using the following syntax: (chiropract* OR osteopath* OR physiotherap* OR “physical therapy” OR massage OR manipulation OR “manual therapy”) W/15 (constipat*).

Google Scholar was searched without filters using the following syntax: (chiropractic AND constipation) OR (osteopathy AND constipation) OR (massage AND constipation) OR (manipulation AND constipation) OR (physiotherapy AND constipation) OR ("physical therapy" AND constipation) OR ("manual therapy" AND constipation).

Citation tracking was not used during the search process and citation alerts were not created to find new literature as the review was in progress.

Study selection

Once the search was complete, all results were either included or excluded for review in accordance with the PRISMA²³ study selection process for systematic reviews (see Figure 2). Initially, duplicates were removed from the pool of studies with the titles and abstracts of remaining studies being screened for relevance. Full-texts were retrieved for any study that appeared relevant to the aim of this review. Once full-texts were attained the inclusion and exclusion were applied.

Data collection process

A data extraction sheet was developed and used to record the key characteristics of each included study such as: population; intervention; comparison; outcome; and study design. The data collection process was piloted on one randomly selected included study and refined accordingly. The primary researcher (LE) extracted all the data from included studies.

Data items

Data was extracted from each included study on: (1) characteristics of study participants (including age, gender, method of diagnosis), (2) comparison or control groups (3) intervention(s) including dose/frequency; (4) outcome measures; (5) results.

Risk of bias in individual studies

Each study will be individually assessed for risk of bias with a modified Downs and Black checklist²². The assessment of study power was different from that of the original Downs and Black tool. In this review study power was assessed in the same manner as in a recent systematic review²⁴ which scores study power as either '0' (the study did not report on power) or '1' (the study did report on power). This differs from the original Downs & Black tool²² that scores a study between 0-5 depending on a more complex power calculation. Given this, the highest possible score of a study assessed in this review could obtain was 28 instead of 32. The two primary authors (LE & DR) were blinded and scored each paper independently with the third author (JM) available to resolve any disagreement between the initial authors. There was full agreement on all scored papers between the two primary authors.

Additional analyses

In addition to risk of bias assessment, overall quality of included studies was ascertained in accordance with criteria as recommended by van Tulder et al.,²⁵. The purpose of this process was to provide an indication regarding the strength of the evidence for the effectiveness of an intervention, with levels of evidence ranging from no evidence to strong evidence (see Figure 4). This analysis is made based on the information available from included studies, and considers study participants, interventions, controls, outcomes, and methodologic quality. 'Consistent findings' were defined as >75% of the studies reporting the same trend in findings across each of the main variables²⁶.

Results

Study selection

The study selection process is outlined in Figure 2. Database searches of Science Direct, Scopus and EBSCO Health Databases retrieved 794 results. Two additional studies were found searching Google Scholar.

After removing duplicates, 533 studies remained. In total, 533 records were screened for eligibility. Of these, 500 were discarded after reviewing the title and abstract as they were either irrelevant to the aim of the review or would clearly not meet eligibility criteria. Three additional studies were discarded because the full-text of the study was unavailable and attempted contact with the author(s) yielded no success. The full-texts of the remaining 30 studies were retrieved and examined in more detail. Of these, 23 studies were excluded based on the predetermined eligibility criteria. No additional

studies were found by checking reference lists or contacting study authors. A total of 7 studies met the final inclusion criteria in the review

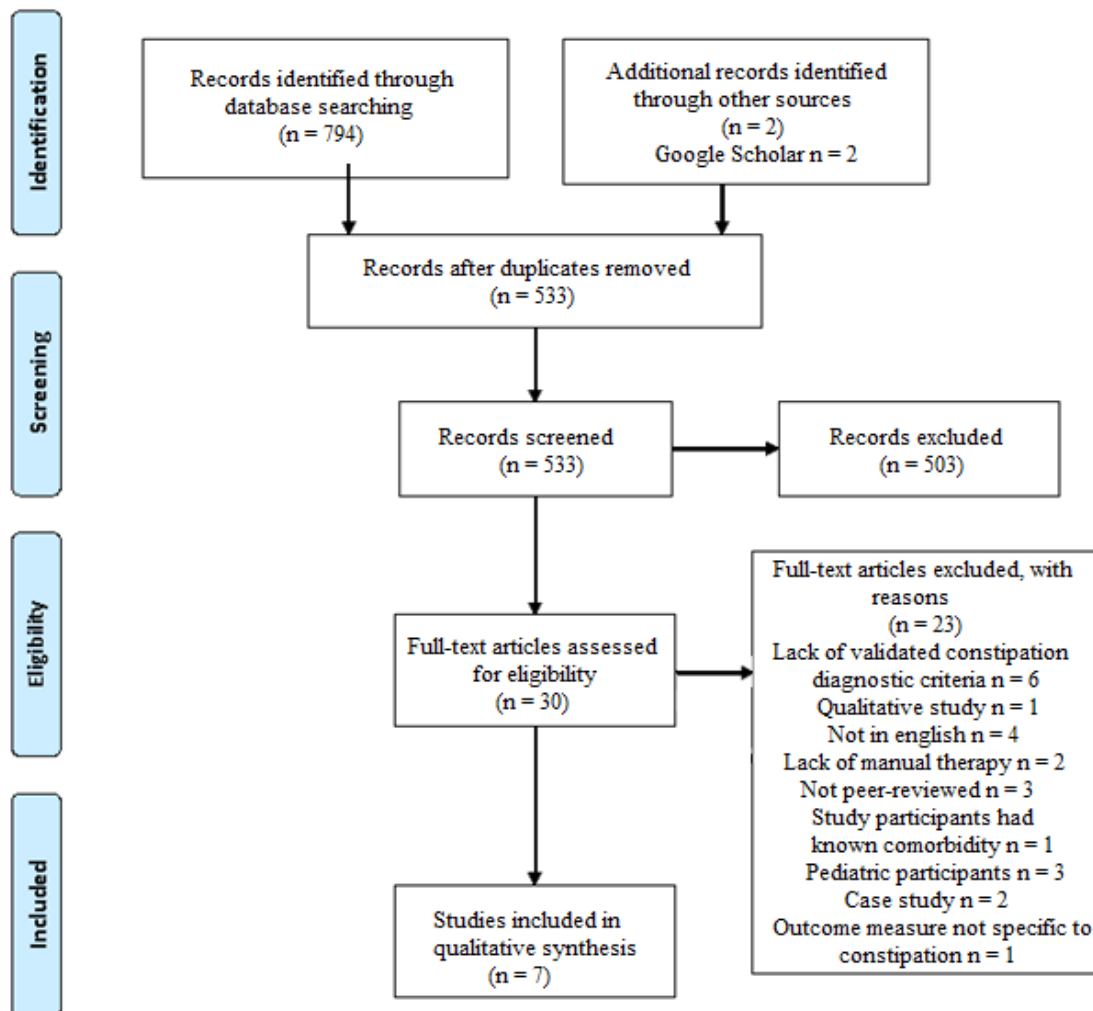


Figure 2: Flow diagram illustrating study selection process

Study characteristics

The characteristics of each study are summarised in Table 1. Included for review were two randomised controlled trials, three randomised uncontrolled trials, and two pilot studies.

Methodological quality

The methodological quality of the studies and the quality index (% and categorisation) are presented in Table 2. The mean score of the reviewed studies was 16.2/28 (range 12-21). The mean quality index percentage of the seven included studies was 58.19% (range 42.9%-78.6%). One study²⁷ scored between 75 and 100% on the quality index and are considered to have ‘strong’ methodological quality. Five studies²⁸⁻³² scored between 50 and 74% on the quality index, which determines them to have ‘moderate’ methodological quality. The remaining study³³ scored between 25 and 49% on the quality index and is therefore considered to have ‘limited’ methodological quality. No studies scored lower than 25%. All studies scored well in the Reporting section (7-10/10) and Internal validity-bias sections (5-7/7), however only two studies^{27,32} obtained a score in the External validity section. Scores were varied in the Internal validity–confounding section, with three studies^{28,32,33} scoring 0-2/6, and four studies^{27,29-31} scoring 3-4/6. Only two out of the seven studies^{27,32} reported on study power.

Total score of modified Downs and Black checklist	Percentage of total score	Quality index
21+	75%	Strong
14-20	50-74%	Moderate
7-13	25-49%	Limited
<7	<25%	Poor

Figure 3: Quality index scores from Downs and Black²²

Strength of Evidence

Due to clinical heterogeneity of the included studies, a meta-analysis of the data was not possible. As such, a qualitative synthesis was conducted in accordance with criteria from Van Tulder et al²⁵ (see Figure 4). Consistent findings were reported by one high quality RCT²⁷ and one moderate quality RCT³². Findings were also consistent among four moderate quality uncontrolled studies²⁵⁻²⁸ and one low quality study³³. Based on the overall quality of the studies and the consistency in findings, qualitative analysis indicates the level of evidence to be ‘moderate’.

Level of Evidence	Requirement
Strong	Consistent findings among multiple high quality RCTs
Moderate	Consistent findings among multiple low quality RCTs and/or CCTs and/or one high quality RCT
Limited	One low quality RCT and/or CCT
Conflicting	Inconsistent findings among multiple trials (RCTs and/or CCTs)
No evidence	No RCTs or CCTs

Figure 4: Overall levels of evidence from van Tulder et al²¹

Participants

There was a total of 236 subjects in the included studies. The average age of participants across the included studies at study onset was 43.2 years. The age range across all studies at study onset was 20-94 years. Constipation was diagnosed with the

Rome II criteria in two studies,^{28,32} with the Rome III criteria in three studies,^{27,29,33} and with the Rome III criteria in addition with a constipation assessment scale in the remaining two studies^{30,31}. One study³⁰ did not report the gender of participants. Across the other six studies, there were a total of 58 (29.6%) males and 138 (70.4%) females in the pooled data. The number of participants per study ranged from 8-58.

Interventions

The interventions used are also summarised in Table 1. Two studies^{28,33} specified osteopathy as the intervention, two specified massage^{29,32}, two specific Maitland orthopaedic manual therapy (MOMT)^{30,31}, and one specified physiotherapy²⁷. The specific techniques and clinical strategies used varied considerably between the studies.

Two of the studies using osteopathy as an intervention^{28,33} employed semi-standardised treatments that would differ based on assessment of the subject. In one of these studies,³³ subjects received one session per week for four weeks. Sessions consisted of a combination of the following techniques: soft-tissue techniques, direct visceral mobilisation, exercise, muscle energy techniques (METs), indirect ligamentous techniques and myofascial techniques. The other semi-standardised osteopathic intervention²⁸ was comprised of two sessions per week for two weeks, then reduced frequency to one session per week for two weeks. In this study, the intervention consisted of soft-tissue techniques, inhibition, passive joint mobilisation, myofascial release, direct visceral mobilisation, HVLAT (high-velocity low-amplitude thrust), METs, and strain counter-strain techniques.

Both massage studies employed standardised treatment sessions^{29,32}. In the first study²⁹ each subject received the same treatment consisting of techniques such as

stroking, fascial manipulation, displacement, kneading and abdominal massage was used. Sessions were given twice a week for three weeks. In the second study³² each subject received gentle stroking and light massage of the abdomen and hands. These sessions were given five times per week for eight weeks.

In both MOMT studies, the MOMT group received the same single technique of spinal mobilisation to the T9-L2 segments. In one study³¹, MOMT subjects received three sessions a week for eight weeks. In the other³⁰, MOMT subjects received three sessions a week for four weeks.

In the physiotherapy study²⁷, the intervention consisted of connective tissue manipulation to the lumbosacral, thoracic, scapular and cervical regions. This manipulation was applied five times per week for four weeks.

Controls

Two studies with control groups were identified^{27,32} and four studies^{29-31,33} with comparison groups were identified. One study did not include a control or comparison group²⁵. Refer to Table 2 for more information.

Primary outcome measures

A wide range of primary outcome measures were used across the included studies to assess the effectiveness of the intervention. One study²⁹ measured change based on bowel frequency and either straining or faecal incontinence. Five of the studies measured changes in various scales and tools to assess constipation severity/symptoms such as the Knowles-Eccersley-Scott-Symptom (KESS) score³³, Cleveland criteria²⁸, Constipation severity instrument²⁷ (CSI), Constipation assessment scale³⁰ (CAS), and the Gastrointestinal symptoms rating scale³² (GSRS). One study³¹ measured changes in

total and segmental colonic transit time.

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Table 1: Characteristics of included studies

Author	Study type	Participant demographic	Intervention	Control or comparison	Frequency and volume	Outcome measures	Results	Overall result
Belvaux et al. (2017) ³³	Pilot study	Participants N=21 Constipation diagnosis based on Rome III criteria FC group N=11 DD group N=10 Average age at onset 48.6 ± 14 years. 21 female: 0 male	Both FC and DD group received semi-standardised osteopathic treatment including some or all of the following techniques: soft tissue techniques, direct visceral mobilisation, exercise, METs, BLTs and myofascial techniques	Comparison group	One session per week for 4 weeks	(1) Primary: KESS score (2) Secondary: CTT, SF36, PAC-QOL, PAC-SYM, stool frequency and stool consistency, constipation intensity, drug intake, abdominal bloating and abdominal pain VAS	(1) Significant Kess score decrease for whole population (p=0.020) and for each group separately (DD p=0.05, FC p=0.014) (2) Significant changes found with regards to CTT, PAC-QOL, PAC-SYM, stool frequency, stool consistency, abdominal bloating VAS and reduction of drug intake.	Positive
Brugman et al. (2010) ²⁸	Pilot study	Participants N =8 Constipation diagnosis based on Rome II criteria Average age at onset 48.5 ± 14.1years. 7 female: 1 male	Participants received semi-standardised osteopathic treatment including some or all of the following techniques: soft tissue techniques, inhibition, passive joint mobilisation, myofascial release, direct visceral mobilisation, HVLAT, MET and SCS	None	Two sessions per week for 2 weeks. Then 1 session per week for 2 weeks	(1) Constipation severity (Cleveland criteria) (2) CTT, PAC-SYM, PAC-QOL	(1) Significant reduction of constipation severity found (p<0.001) (2) Significant changes found for CTT, PAC-SYM and PAC-QOL	Positive
Gürsen et al. (2015) ²⁷	Randomised controlled trial	Participants N = 50 Constipation diagnosis based on Rome III criteria Intervention group (IG) N=25 Average age 40 (range 23-49). 22 female: 8 male Control group N=25 Average age 38 (range 33-46). 24 female: 1 male	IG received connective tissue manipulation by physiotherapist	Control group	Five sessions per week for 4 weeks	(1) CSI (2) PAC-QOL, BSS, bowel diary, patient perception of improvement, patient compliance VAS	(1) Significant changes found for total CSI score in IG compared to control group (p<0.001) (2) Significant changes found in IG group for PAC-QOL, BSS, defecation frequency, defecation time and patient perception of improvement	Positive

Author	Study type	Participant demographic	Intervention	Control	Frequency and volume	Outcome measures	Results	Overall result
Kassolik et al.(2015) ²⁹	Randomised uncontrolled trial	Participants N = 29 Constipation diagnosis based on Rome III criteria Tensegrity massage group (TMG) N = 15 AAO 59.8 years (range 24-94) 13 female: 2 male Classical abdominal massage group (CAMG) N=14 AAO 55.7 years (range 23-83) 13 female: 1 male	TMG received massage techniques such as: stroking, fascial manipulation, displacement, and kneading. CAMG received abdominal massage	Comparison group	TMG received 20min sessions twice a week for 3 weeks CAMG received 10min sessions twice a week for 3 weeks	(1) Number of bowel movements, straining during defecation (2) Patient perception of physical/mental state	(1) Significant increase found in number of bowel movements between subsequent weeks in both groups (TMG p<0.00001; CAMG p<0.001). A significant decrease in the number of participants experiencing straining during defecation was found across both groups (p=0.049) (2) Significant difference found in patient perception of physical/mental state between TMG and CAMG	Positive
Koo, Choi and Kim (2016) ³¹	Randomised uncontrolled trial	Participants N= 30 Constipation based on Rome III criteria and constipation assessment scale Maitland orthopaedic manual therapy group (MOMTG) N=15 Average age at onset 21.6±12.7, 15 female Fibre group (FG) N=15 Average age at onset 21.1±10.71, 15 female	MOMTG received facet joint mobilisation T9-L2 DFG received psyllium husk as dietary fibre	Comparison group	20min sessions. Three times per week for 8 weeks	(1) CTT (right, left, rectosigmoid and total CTT)	(1) MOMTG showed significant decrease in left, right and total colonic transit time (p<0.05). DFG showed significant decrease in rectosigmoid and total colonic transit time (p<0.05). MOMTG showed significantly larger change in recto and total colon transit compared to DFG (p<0.05). Right and Left transit times show no significant difference between groups	Positive
Koo, Kim and Kim (2016) ³⁰	Randomised uncontrolled trial	Participants N=40 Constipation based on Rome III criteria and constipation assessment scale. Maitland orthopaedic manual therapy group (MOMTG) N=10 Average age at onset 21.5±2.73 Silver spike point therapy group (SSPG) N = 10 Average age at onset 20.69±0.70 Gymnastics exercise group (GEG) N =10 Average age at onset 21.0±0.82 Dietary fibre group (DFG) N=10 Average age at onset 21.06±0.68	MOMTG received joint mobilisation SSPG received electrical stimulation GEG received exercises DFG received dietary fibre	Comparison groups	MOMTG, SSPG and GEG received 20min sessions 3 times a week for 4 weeks DFG received intervention twice a day, 3 times a week for 4 weeks	(1) CAS (2) Weekly bowel frequency	(1) Significant decreases in CAS scores were found in MOMTG when compared to DFG (p<0.05) (2) No significant changes for MOMTG	Positive

Author	Study type	Participant demographic	Intervention	Control	Frequency and volume	Outcome measures	Results	Overall result
Lämås et al. (2009) ³²	Randomised controlled trial	Participants N = 58 Constipation based on Rome II criteria Intervention group (IG) N=29 Average age at onset 64±10.4 (range 47-85). 26 male: 3 female Control group N=29 Average age at onset 63±10.6 (range 36-79). 24 male: 5 female	IG received skin stroking and massage techniques	Control group	15min sessions. Five times per week for 8 weeks	(1) GSRS (2) BSS, laxative intake	(1) Significant changes found from baseline to week 8 in IG compared to control with regard to abdominal pain (p=0.038), total GSRS score (p=0.003) and constipation syndrome (p=0.014). A significant interaction was found between the baseline value of GSRS total score and massage effectiveness at week 8(p=0.001). (2) No significant changes	Positive

Key:

BSS: Bristol stool scale

BLT: Balanced ligamentous tension

CAS: Constipation assessment scale

CSI: Constipation severity instrument

CTT: Colonic transit time

DD: Defecation disorder

FC: Functional constipation

GSRS: Gastrointestinal symptom rating scale

HVLAT: High-velocity low-amplitude thrust

KESS: Knowless Eccersley Scott Symptom score

MET: Muscle energy technique

PAC-QOL: Patient assessment of constipation quality of life questionnaire

PAC-SYM: Patient assessment of constipation-symptoms

SCS: Strain counter-strain

Table 2 Modified Downs and Black scores of included studies

	Belvaux et al. ³³	Brugman et al. ²⁸	Gursen et al. ²⁷	Kassolik et al. ²⁹	Koo,Choi & Kim ³¹	Koo, Koo & Kim ³⁰	Lamas et al. ³²
Reporting							
1. Is the hypothesis/aim/objectives of the study clearly described (yes = 1, no = 0)	1	1	1	1	1	1	1
2. Are the main outcomes to be measured clearly described in the introduction or methods section? (yes = 1, no = 0)	1	1	1	1	1	1	1
3. Are the characteristics of the patients included in the study clearly described? (yes = 1, no = 0)	1	1	1	1	1	1	1
4. Are the interventions of interest clearly described? (yes = 1, no = 0)	1	1	1	1	1	1	1
5. Are the distributions of principal confounders in each group of subjects to be compared clearly described? (yes = 2, partially = 1, no = 0)	0	0	0	0	0	0	1
6. Are the main findings of the study clearly described? (yes = 1, no = 0)	1	1	1	1	1	1	1
7. Does the study provide estimates of the random variability in the data for the main outcomes? (yes = 1, no = 0)	1	1	1	1	1	1	1
8. Have all important adverse events that may be a consequence of the intervention been reported? (yes = 1, no = 0)	0	0	1	1	0	0	0
9. Have the characteristics of patients lost to follow-up been described? (yes = 1, no = 0)	0	1	1	1	0	0	1
10. Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001? (yes = 1, no = 0)	1	1	1	1	1	1	1
Reporting score (x/11)	7	8	9	9	7	7	9
External validity							
11. Were the subjects asked to participate in the study representative of the entire population from which they were recruited? (yes = 1, no = 0, unable to determine = 0)	0	0	1	0	0	0	0
12. Were those subjects who were prepared to participate representative of the entire population from which they were recruited? (yes = 1, no = 0, unable to determine = 0)	0	0	1	0	0	0	0
13. Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive? (yes = 1, no = 0, unable to determine = 0)	0	0	0	0	0	0	1
External Validity Score (x/3)	0	0	2	0	0	0	1
Internal validity – bias							
14. Was an attempt made to blind study subjects to the intervention they have received? (yes = 1, no = 0, unable to determine = 0)	0	0	0	1	0	0	0
15. Was an attempt made to blind those measuring the main outcomes of the intervention?	0	0	1	0	0	0	0

(yes = 1, no = 0, unable to determine = 0)							
16. If any of the results of the study were based on 'data dredging', was this made clear? (yes = 1, no = 0, unable to determine = 0)	1	1	1	1	1	1	1
17. In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls? yes = 1, no = 0, unable to determine = 0)	1	1	1	1	1	1	1
18. Were the statistical tests used to assess the main outcomes appropriate? (yes = 1, no = 0, unable to determine = 0)	1	1	1	1	1	1	1
19. Was compliance with the intervention/s reliable? (yes = 1, no = 0, unable to determine = 0)	1	1	1	1	1	1	1
20. Were the main outcome measures used accurate (valid and reliable)? (yes = 1, no = 0, unable to determine = 0)	1	1	1	1	1	1	1
Internal Validity - Bias Score (x/7)	5	5	6	6	5	5	5
Internal validity – confounding (selection bias)							
21. Were the patients in different intervention groups (trials and cohort studies) or were the Cases and controls (case-control studies) recruited from the same population? (yes = 1, no = 0, unable to determine = 0)	0	0	1	1	1	1	0
22. Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time? (yes = 1, no = 0, unable to determine = 0)	0	0	0	1	1	1	0
23. Were study subjects randomised to intervention groups? (yes = 1, no = 0, unable to determine = 0)	0	0	1	1	1	1	1
24. Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable? (yes = 1, no = 0, unable to determine = 0)	0	0	1	0	0	0	0
25. Was there adequate adjustment for confounding in the analyses from which the main findings were drawn? (yes = 1, no = 0, unable to determine = 0)	0	0	0	0	0	0	0
26. Were losses of patients to follow-up taken into account? (yes = 1, no = 0, unable to determine = 0)	0	1	1	1	0	0	1
Internal Validity – Confounding Score (x/6)	0	1	4	4	3	3	2
Power							
27. Was a power calculation used and described? (yes=1, no=0)	0	0	1	0	0	0	1
Total score x/28	12	14	21	19	15	15	18
Quality index %	42.9%	50%	75%	67.9%	53.6%	53.6%	64.3%
Quality index category	Limited	Moderate	Strong	Moderate	Moderate	Moderate	Moderate

Discussion

This review has found that a ‘moderate’ level of evidence exists to support the effectiveness of manual therapy as an intervention for constipation. This analysis is based on the van Tulder²⁵ criteria of “consistent findings among multiple low quality RCTs and/or CCTs and/or one high quality RCT”. Overall, the literature that exists on the use of manual therapy as an intervention for FC is of moderate methodological quality, however this review has found that significant variability exists between studies with regards to technique choice and outcome measures used. The inclusion of multiple manual therapy disciplines and interventions has allowed for this review to include a wider range of studies than previous reviews^{20,21,34} and the requirement of included studies to use validated diagnostic criteria helps to ensure homogeneity of study populations, making any findings more translatable to clinical practice. In addition, some themes emerged and are worth of discussion including: intervention and frequency; intervention description; mechanism of effect; and heterogeneity of outcome measures.

Intervention and frequency

The large variation of interventions used across the included studies was not unexpected, having been mentioned in previous reviews on constipation^{17,20,21} as well as other reviews³⁵⁻³⁷ on other non-musculoskeletal complaints. Such heterogeneity across manual therapy has been attributed to differences in individual experience and training¹⁷ and is thought to reflect the individualised and patient-centric nature of manual therapy²¹. Variability was also found within two of the studies^{28,33} included in this review, both of which used a semi-standardised intervention with specific techniques

chosen at the practitioner's discretion. These studies are pragmatic in nature, so while they may suffer when assessed for risk of bias, they are more readily generalisable to clinical practice than efficacy studies and are likely to be more representative of treatments patients receive. Such treatments are also more patient-centric and may be beneficial as techniques can be chosen based on the characteristics of the target tissues³⁴ in addition to the perception of patient's needs. Additionally, findings from other manual therapy reviews^{38,39} suggest that a multi-modal style treatment may actually be associated with favourable clinical outcomes.

The majority of included studies provided the intervention at a frequency of 2-5 times per week for the length of the intervention period, which, considering the associated financial cost and time commitment is perhaps an unachievable course of treatment for many people, an issue that has been acknowledged in previous reviews on massage^{20,34}. To address the issue of cost a full economic evaluation would be required to assess the cost of manual therapy versus standard medical care.

Intervention description

A distinct lack of exact technique description was noted across most of the included studies. Although the names of some manual techniques such as massage, manipulation or stretching are likely to be well known by most manual therapists, reporting specific details regarding the application of the intervention is necessary for reproducibility. Such details include force, direction, duration and patient positioning,

It has been highlighted that manual therapy studies often lack well-detailed descriptions of interventions⁴⁰, which becomes an issue when looking at the generalisability of results. Previous authors⁴⁰ have admitted manual therapy is complex and that poor

reporting can compromise the validity of the results, which indicates the need for manual therapy studies to follow comprehensive guidelines when reporting on their intervention(s).

Mechanism of effect

FGIDs are likely to be linked to stress and autonomic nervous system (ANS) dysfunction^{1,5,41}, which is the intended mechanism of effect given in most of the included studies. Using manual techniques to influence the ANS was proposed to influence muscle tone and motility of the gastrointestinal tract^{28,29,31}, increase digestive secretions, and relax gastro-intestinal sphincters^{30,32}. Other studies proposed more mechanical frameworks to improve constipation, such as improving the load-bearing capacity of the spine²⁹ or improving abdominal wall and pelvic floor function^{14,30}. Despite the fact that the exact mechanisms in which manual therapy could exert an effect are unproven⁴² and often speculative, a comprehensive mechanistic model¹² of manual therapy suggests that mechanical forces, such as those applied by a practitioner, can initiate a complex interaction between the peripheral and central nervous systems. This interaction can result in a chain of neurophysiological responses which may influence autonomic function, pain modulation, and inflammatory response⁴², factors that are all associated with constipation^{1,6}.

Outcome measures

The current review found a lack of consistency of primary outcome measures being used across the included studies. This variation in outcome measures was not mentioned in previous reviews on chiropractic²¹ or massage^{20,34} for constipation, however this issue has been pointed out in reviews published on other non-musculoskeletal

conditions^{35-37,43,44}. It seems evident that standardised outcome measures do not exist for manual therapy interventions for constipation, possibly because simple objective measures of constipation have been difficult for researchers to devise⁴⁵. This could be due to the number and range of subjective symptoms and objective findings that could be associated with this condition⁵.

Despite the heterogeneity in outcome measures, statistically significant results favouring the use of manual therapy was reported by all included studies. Given the consistency of diagnostic criteria and the lack of obvious confounding variables, manual therapy appears to be effective as an intervention for treating the symptoms of FC. Although the average intervention period of 3-8 weeks was clinically effective, none of the included studies collected data during a follow-up period making it impossible to determine the length of effect. As FC is regarded as a long-standing manifestation of symptoms⁴) and requires symptom onset at least 6 months prior to diagnosis,⁵ collecting data over a follow-up period of at least 3 months could provide clinically relevant information.

Conclusion

This review systematically analysed primary research assessing the effectiveness of manual therapy for treating the symptoms of constipation. Overall, the methodological quality of the included studies was found to be moderate. Qualitative assessment determined the level of evidence to support the use of manual therapy as an intervention for constipation to be moderate. Given the strict inclusion criteria and the consistency of significant clinical findings reported in the studies reviewed, manual therapy may have an effect on the symptoms of constipation. Despite the large heterogeneity of

interventions and outcome measures used in the included studies, some common themes were identified which may influence clinical practice as well as guide future research.

Recommendations for future research

Future studies should consider the following points:

- Use of consistent interventions, delivered at a frequency representative of clinical practice.
- Follow robust reporting guidelines when describing interventions to ensure reproducibility.
- Use specific, well-defined outcome measures so that depth is added to the research pool instead of breadth.
- Include a follow-up period of at least 3 months to evaluate duration of effect.

Limitations

Due to the large heterogeneity between the included studies, direct comparisons of interventions and outcomes is difficult, precluding meta-analysis. Because the review only included studies with clear diagnostic criteria that were published in the English language, this review may not be a complete representation of the available literature.

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Conflict of interest statement for the review titled:

**Does a manual therapy approach improve the symptoms of functional constipation?
A systematic review of the literature**

(1) Conflict of interest

None

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(3) Ethical approval

This research was granted exemption by the Unitec Research Ethics Committee.