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A systematic review to evaluate the clinical benefits of craniosacral therapy

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Craniosacral therapy;
Systematic review;
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Summary
Objective: Craniosacral therapy (CST) is an alternative treatment approach, aiming to release restrictions around the spinal cord and brain and subsequently restore body function. A previously conducted systematic review did not obtain valid scientific evidence that CST was beneficial to patients. The aim of this review was to identify and critically evaluate the available literature regarding CST and to determine the clinical benefit of CST in the treatment of patients with a variety of clinical conditions.
Methods: Computerised literature searches were performed in Embase/Medline, Medline® In-Process, The Cochrane library, CINAHL, and AMED from database start to April 2011. Studies were identified according to pre-defined eligibility criteria. This included studies describing observational or randomised controlled trials (RCTs) in which CST as the only treatment method was used, and studies published in the English language. The methodological quality of the trials was assessed using the Downs and Black checklist.
Results: Only seven studies met the inclusion criteria, of which three studies were RCTs and four were of observational study design. Positive clinical outcomes were reported for pain reduction and improvement in general well-being of patients. Methodological Downs and Black quality scores ranged from 2 to 22 points out of a theoretical maximum of 27 points, with RCTs showing the highest overall scores.
Conclusion: This review revealed the paucity of CST research in patients with different clinical pathologies. CST assessment is feasible in RCTs and has the potential of providing valuable outcomes to further support clinical decision making. However, due to the current moderate methodological quality of the included studies, further research is needed.

Contents

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Introduction

The craniosacral system is defined as a recognised, functioning physiological system, including the membranes and cerebrospinal fluid surrounding the spinal cord and brain, the bones to which these membranes attach and connective tissue related to these membranes.[1] It is intimately related to and influenced by the nervous, musculoskeletal, vascular, lymphatic, endocrine and respiratory system of the body.[1] The craniosacral system is characterised by rhythmic, mobile activity, being distinctively different from the physiological motions related to breathing and cardiovascular activity.[1] These observations date back to the 1930s to experimental studies of Sutherland, an osteopath who claimed that the individual bones of the skull reflect mobility.[2] An important component of craniosacral mobility is referred to as the primary respiratory mechanism (PRM), which manifests as palpable motion of the cranial bones, sacrum, dural membranes, central nervous system and cerebrospinal fluid (CSF).[3] With advances in technology and science research evidence is mounting which supports the craniosacral concept. Several studies show brain tissue and spinal cord motion, which appears to be related to the cardiac cycle.[4–7] The blood flow in the brain was shown to be responsible for the circulation of CSF.[8] Cranial bone motion was demonstrated on human subjects[9–11] and the mobility of the sacrum has been displayed in several studies, as reviewed by Walker and colleagues.[12] An association between the treatment of the cranial bones and the movement of cranial dural membranes has been demonstrated in human cadaver studies.[13]

Craniosacral therapy (CST) is mostly applied by trained craniosacral therapists but can also be performed by osteopaths and other healthcare practitioners who have undergone the appropriate training. CST is commonly described as an alternative treatment approach, applying a gentle manual force to address somatic dysfunctions of the head and the remainder of the body. The interplay of diagnosis and treatment is aimed at mobilising the cranial sutures which are abnormally restricted to physiologic motion. Restrictions in the craniosacral system are manually identified which include the bones, membranes and cerebrospinal fluid (CSF) that surround the brain and spinal cord.[14] With manual palpation and manipulation of this system, sensory, motor, cognitive and emotional processes in the nervous system can be affected.[14–16] CST is a widely used approach in different clinic settings and conditions, in adults as well as children.[17–20] It is thought to reduce the use of conventional pain medications and to improve daily functioning in a variety of conditions.[21]

A previously conducted systematic review explored the clinical effectiveness of CST, highlighting that the few studies which were found failed to show a decent effectiveness, which partly was attributed to poor study design.[21] The aim of this current systematic review was to identify randomised controlled trials (RCTs) and observational studies assessing the clinical benefit of CST in patients with a variety of clinical conditions and to provide evidence of added value to support clinical decision making.

Review methods

Search strategy for identification of studies

Computerised searching of the following literature databases was performed from database start up to April 2011: Embase/Medline, Medline® In-Process, The Cochrane library, CINAHL (Cumulative Index to Nursing and Allied Health Literature), and AMED (Alternative Medicine). The following clinical keywords were used to search for the intervention of interest: 'craniosacral' OR 'cranio sacral'. Candidate articles were then screened for possible inclusion in this review.

Criteria for considering studies for this review

To be included in this review, studies had to meet the eligibility criteria as defined in Table 1. There was no date limitation on studies. CST was defined as any form of alteration of the craniosacral system as defined by the practitioners and researchers providing primary data.

Exclusion criteria included non-English articles, studies not relevant to CST, animal studies, studies where no clear indication of the use of CST was described and studies where CST was not performed by a craniosacral therapist or where the practitioner profile was unclear. Studies describing mixed treatment methods which included CST together with other treatments were also excluded.

Table 1 Inclusion criteria.

	Description
Study design	Studies must be published RCTs or observational studies
Population	Studies must be conducted in human patients (no age restriction)
Disease	No limitation on disease
Intervention	Studies must report any form of craniosacral therapy as the only treatment modality provided, performed by a craniosacral therapist and defined as CST by the authors themselves
Indication	Studies must investigate the effectiveness of craniosacral therapy
Language restrictions	Only English language papers are considered

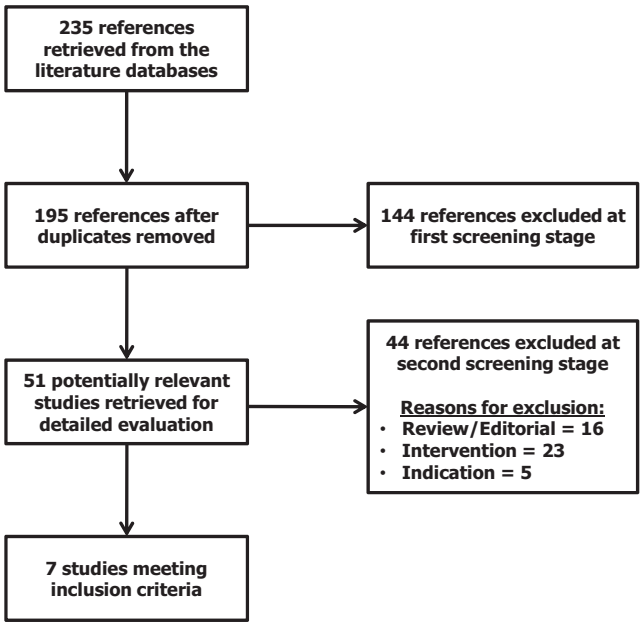

Figure 1 Study flow.

Citation screening and data extraction

Citations were first screened based on the title and abstract supplied with each citation. Each citation was screened by two independent reviewers, and any discrepancies between reviewers were resolved by discussion between the two reviewers. Citations that did not match the eligibility criteria were excluded at this 'first pass,' and where unclear, citations were included. Duplicates of citations (due to overlap in the coverage of the databases) were also excluded at this stage. Full-text copies of all references that could potentially meet the eligibility criteria were obtained at this stage.

Each full-text was screened by two independent reviewers, and any discrepancies between reviewers were resolved by discussion between the two reviewers. Data presented in the studies still included after this stage was extracted into tables by one reviewer and checked by a second reviewer, with any discrepancies between reviewers resolved by discussion.

For each included study, the following data were extracted: general study information (study size, study design, practitioner profile), participants data (conditions reported, treatment duration and frequency, type of treatment) and outcomes (e.g. quality of life, pain, emotional state, safety). Outcomes were reported in a descriptive manner rather than actual values, highlighting whether any differences between treatment groups or compared to baseline values were observed.

Quality assessment

In the current systematic review, the Downs and Black scoring system was used.[22] This check list is designed for critically evaluating experimental and non-experimental studies.[23,24] Each article was assessed by two independent reviewers using this scoring system based on 27 questions relating to reporting, internal and external validity, and subsequently was categorised as being of strong (score $\geq$21/27), moderate (score 14—20/27), limited (score 7—13/27) or poor quality (score < 7/27), as previously described.[25,26] Any discrepancies between reviewers were resolved by discussion between the two reviewers.

Results

Two hundred thirty five potentially relevant articles were identified in the literature searches. Of those, 42% were identified on Embase/Medline, 30% on AMED, 17% on CINAHL, 8% on the Cochrane library and 3% on Medline® In-Process.

Following a first review of the abstracts, 51 potentially relevant references were identified. Full-text reports of these citations were obtained for more detailed evaluation. Following detailed examination of the full text reports, 44 studies were excluded leaving 7 citations that met the inclusion criteria for this review. The flow of studies through the review is shown in Fig. 1.

Included clinical studies

The seven studies that met the inclusion criteria of this review evaluated the effectiveness of CST in different pathological conditions (Table 2). Of those, three randomised controlled trials (RCTs) were identified and four studies were of observational design, with two studies reporting data before and after the intervention and two studies used retrospective surveys to retrieve outcome data.

Trial design characteristics

Table 3 presents basic demographic information and brief clinical details, including a summary of treatment outlines and practitioner profile. Out of seven studies identified, two RCTs investigated the clinical benefit on patients with

Table 2 Overview of included studies.

Study	Design	Objective of study
Randomised controlled trials		
Castro-Sanchez[27]	RCT	• To determine the effects of CST on sensitive tender points and heart rate variability in patients with fibromyalgia
Mataran-Penarrocha[28]	RCT	• To determine the effects of CST on anxiety, depression, pain, sleep quality and quality of life in patients with fibromyalgia
Nourbakhsh[29]	RCT	• To investigate the effects of oscillating-energy Manual Therapy on pain, grip strength and functional abilities in adults with chronic lateral epicondylitis
Observational studies		
Gerdner[30]	Before and after observational study	• To explore the effects of Craniosacral still point technique in individuals with dementia, with an emphasis on agitation
Raviv[31]	Before and after observational study	• To examine whether CST improves lower urinary tract symptoms of multiple sclerosis patients
Harrison[32]	Retrospective survey	• To describe the impact of CST treatment on both symptoms and lives of patients with different conditions
McManus[33]	Retrospective survey	• To explore effects of CST on children with physical disabilities

fibromyalgia.[27,28] Other patient cohorts were adults with lateral epicondylitis,[29] dementia,[30] multiple sclerosis,[31] or a range of different conditions[32] and children with several disabilities.[33] The sample size of trials ranged from 23 patients[29] to 92 patients[27] in the RCTs and from 9 patients[30] to 130 patients[32] in the observational studies. The follow-up period, treatment frequency and duration varied extensively among the studies. One study did not report data on treatment frequency and duration.[32] The intervention was clearly described in the RCTs, in contrast to the observational studies, where no clear definition of the treatment was given. In all studies the treatment was performed by trained craniosacral therapists.

Clinical benefits and safety

The most commonly used outcome measurements were general wellbeing/quality of life and pain. Additional outcomes evaluated included emotional state (depression, agitation), sleep, motor function, ANS function, and safety. Quality of life improvement was reported in 4/4 studies, with 3 studies using questionnaires with patient-reported outcomes[28,31,32] and one study representing parent-reported outcomes for children with disabilities.[33] Three studies investigated pain after the application of CST, showing that in all three studies the pain levels significantly decreased, compared with the control group.[27–29] The positive effect of CST on emotional state was shown in two studies, with one study reporting a significant reduction in aggressive behaviour in patients with dementia.[30] However, there were no improvements seen in depression scores in patients with fibromyalgia compared with the control group.[28] Alterations in the ANS in terms of urinary function were observed in one study.[31] No changes in heart rate variability in patients with fibromyalgia could be observed.[27] Other findings included significant improvement in sleep duration in patients with fibromyalgia[28] and a positive effect seen in grip strength in patients with lateral epicondylitis.[29] Only two studies reported on the safety of CST, with no negative effect on children and adults shown.[31,33]

A summary of outcomes is presented in Table 4.

Quality of studies

The checklist score for each included study is reported in Table 5. Methodological Downs and Black quality scores ranged from 2 to 22 points out of a theoretical maximum of 27 points. The three RCTs gained a strong-quality rating (20—22 points),[27–29] whereas the remaining four observational studies varied in their quality, showing scores between 2[32] and 17 points.[30] Amongst those, the before-and-after studies ranked higher in quality than the retrospective surveys. Reporting was best in the RCTs, followed by the before-and-after studies. The reporting in the retrospective surveys generally was poor. The other categories external validity, internal validity (bias) and internal validity (confounding) ranked also highest in the RCTs, whereas the scores of the other study designs were generally lower. This might have been attributed to a large extent to the generally worse reporting in these studies, which made it impossible to answer these questions adequately.

Table 3 Patient cohorts and types of intervention.

Study	Patient population	Follow-up	Assigned groups	*N*	Frequency and duration of treatment sessions	Length of treatment period	Practitioner profile	Type of intervention
Randomised controlled trials								
Castro-Sanchez[27]	Adults with fibromyalgia	1 year	Cases	46	2× per week for 1 h	20 weeks	Craniosacral therapist	Sequence: Still point (feet), pelvic diaphragm release, scapular girdle release, frontal life, parietal lift, compression/decompression of sphenobasilar fascia, decompression of temporal fascia, compression/decompression of TMJ and evaluation of dural tube (balance of dura mater)
			Controls	46	2× per week for 30 min	20 weeks		Sham ultrasound to cervical area (10 min), dorsal (10 min) and lumbar region (10 min)
Mataran-Penarrocha[28]	Adults with fibromyalgia	1 year	Cases	43	2× per week for 1 h	25 weeks	Craniosacral therapist	Sequence: Still point (occipital), compression/decompression of TMJ, decompression of temporal fascia, compression/decompression of sphenobasilar joint, parietal lift, frontal lift, scapular waist and pelvic diaphragm release
			Controls	41	2× per week for 30 min	25 weeks		Sham ultrasound to cervical area (10 min), lumbar region (10 min) and both knees (10 min)
Nourbakhsh[29]	Adults with lateral epicondylitis	6 months	Cases	11	2—3× per week for 20—30 min	2—3 weeks	Orthopaedic clinic specialist trained in CST	V-shaped hand placement around detected tender point, gentle pressure and oscillating energy provided by therapist
			Controls	12	2—3× per week for 20—30 min	2—3 weeks		V-shaped hand placement away from the located tender point and no oscillating energy was directed to the affected area, very gentle pressure to the tissue and imparted periodic short-duration oscillation to non-affected areas

Table 3 (*Continued*)

Study	Patient population	Follow-up	Assigned groups	*N*	Frequency and duration of treatment sessions	Length of treatment period	Practitioner profile	Type of intervention
Observational studies								
Gerdner[30]	Adults with dementia	12 weeks	Cases	9	30 s—10 min, mean 5 min, daily	6 weeks	Craniosacral therapist	Craniosacral still point technique
Raviv[31]	Adults with Multiple sclerosis	4 weeks	Cases	28	1 × per week for 50 min	4 weeks	Craniosacral therapist	10-step protocol of CST previously reported by Upledger and Vredevoogt[1]
Harrison[32]	Patients with different conditions	6 months	Cases	130	NR	NR	Upledger Craniosacral therapist	Upledger craniosacral therapy (not further defined)
McManus[33]	Disability service users (children)	1 year	Cases	46	1 h per week or per month	Average: 15—20 h therapy per annum	Craniosacral therapist	CST (not defined)

Abbreviations used: CST — craniosacral therapy; TMJ — temporomandibular joint; NR — not reported.

Discussion

The main finding of this systematic review is that there are only a few studies evaluating the effectiveness of CST in a variety of pathological conditions. Using defined selection and eligibility criteria, seven studies were identified. The majority of these have been published after the year 2000. Results of the analysis indicate that the available evidence is substantially heterogeneous in terms of techniques used and sample size, which makes it difficult to draw general conclusions. However, the results of this review highlight that the most reported outcomes, pain and quality of life/general well-being, can be improved by the use of CST. For other outcomes, such as change in ANS function, the evidence is heterogeneous and insufficient in order to conclude accordingly. In general, a majority of positive outcomes are shown in the reviewed studies, adding to the current belief for CST being effective in the treatment of patients with a variety of pathologies. By focusing on RCT and observational study settings, this review aimed at providing robust evidence regarding the impact of this treatment approach on patient wellbeing and the possible added value in support of clinical decision making.

The overall quality of the reported trials seems fairly moderate. However, distinction has to be made between the quality of RCTs, which can be categorised as strong methodological quality, compared to the observational studies, which varied between poor and moderate quality. Poor reporting was particularly identified in the retrospective surveys.

The need for the investigation into the widely used CST was indicated, as this area of manual therapy is generally ill-defined. When compared to a previously conducted systematic review,[21] it is evident that the number of studies is still poor but that the methodology has slightly improved over time, including the use of RCTs. Additionally, in comparison to the findings in the current review, this previous systematic review did not identify sufficient evidence for the clinical benefit of CST. In order to capture the highest number of relevant studies possible, the search terminology was kept relatively broad and the most important databases were searched. The application of a valid and reliable critical appraisal tool ensured an extensive assessment of the methodological quality of the studies. However, some limitations of this work have to be discussed. Authors of original articles were not pursued for additional information on identified data gaps in the study methodology. Only English-written articles were included, which might have lead to the exclusion of other studies relevant for this review. Furthermore, a statistical analysis was not performed for the results obtained which may weaken their interpretation. Despite these potential limitations, this systematic review provides an improvement and an update on existing evidence in the field of CST in terms of quality of trial methodology as well as the finding that CST assessment in RCT settings is feasible and has the potential to provide invaluable data for patients suffering from a variety of pathological conditions. However, future research needs to further improve on methodological quality of trials in order to improve the evidence base, as currently it is of moderate level.

Table 4 Outcomes reported, by categories.

Outcome and methods used	Condition	Effect/result in comparison to control group and/or baseline	Study
General well-being/quality of life			
Glasgow Homeopathic Hospital Outcome Score (Scale −4 to +4)	Variety of conditions	• Improvement in their presenting problem reported by 74% of patients • Improvement in general well-being in 67% of patients • Medication decreased or was discontinued in 70% of patients • Practitioner consultation rate fell by 60% in the 6 months following treatment	Harrison[32]
Short From (SF)-36	Fibromyalgia	• In the intervention group there was significant improvement in SF-36 dimensions (physical function, physical role, body pain, general health, vitality and social function) compared to baseline at 25 weeks and significant improvement in physical function at 6 months post-therapy • No significant changes in placebo group compared to baseline at 25 weeks and 6 months post-therapy • Significant differences in intervention group compared to placebo group in physical function, physical role, body pain, general health, vitality and social function at 25 weeks and significant differences in physical function and vitality at 6 months post-therapy • One year post-therapy no significant differences were seen between intervention and placebo group and in neither group compared to baseline	Mataran-Penarrocha[28]
20-Item questionnaire (reported by parents)	Children with a variety of disabilities	• The majority of patients showed gross improvements (highest possible scale) on general health, elimination, sleep pattern, appetite, flexibility, vocalisation, relaxation, muscle tone, circulation and alertness • Less stress between siblings and in the family set up reported	McManus[33]
Overactive bladder (OAB)-V8 Questionnaire	Multiple sclerosis	• Mean quality of life score improved after treatment	Raviv[31]
Pain			
Tender point evaluation (pressure algometry)	Fibromyalgia	• Significant reductions in the number of tender points in the intervention group compared to placebo group after 20 weeks of therapy • Significant reduction in pain in the intervention group at 13 of the 18 tender points after 20 weeks of therapy compared to baseline values • At two months and 1 year post-therapy significant differences in pain at 4 out of 18 tender points in the intervention group compared to baseline values	Castro-Sanchez[27]
VAS (scale 0—10)	Fibromyalgia	• At 25 weeks VAS-measured pain was significantly improved in the intervention group compared to baseline and placebo group • No significant differences were reported in the intervention group compared to baseline and placebo group at 6 months and 1 year post-therapy	Mataran-Penarrocha[28]
Numeric rating scale (0—10)	Lateral epicondylitis	• Significant improvement in pain intensity in the intervention group compared to placebo group and baseline at post-test analysis • No significant difference between post-test and 6 month follow-up in pain intensity in the intervention group (73% of subjects remained pain free for at least 6 months)	Nourbakhsh[29]

Table 4 (*Continued*)

Outcome and methods used	Condition	Effect/result in comparison to control group and/or baseline	Study
Sleep			
Pittsburgh Sleep Quality Index	Fibromyalgia	• Significant improvement in the intervention group compared to placebo group in Pittsburgh sleep quality index score, sleep duration and sleep disturbance at 25 weeks • Significant differences in intervention group compared to placebo group in sleep duration, habitual sleep efficiency and sleep disturbance at 6 months post-therapy • Significant differences in intervention group compared to placebo group in sleep duration, habitual sleep efficiency and daily dysfunction at 1 year post-therapy	Mataran-Penarrocha[28]
Emotional state (depression, agitation, anxiety)			
Cohen-Mansfield Agitation Inventory (score 1—7), recorded by certified nursing assistants	Dementia	• Significant reduction in mean total and subscale scores (physically aggressive, physically non-aggressive, verbal agitation) during weeks 1—6 and continued throughout 3-week post-intervention for physically non-aggressive and verbal agitation but not physically aggressive agitation	Gerdner[30]
Beck Depression Inventory, State Trait Anxiety Inventory	Fibromyalgia	• No significant difference in depression scores at 25 weeks, and 6 months and 1 year post-therapy compared to placebo group or baseline • Significant differences in state anxiety and trait anxiety at 25 weeks in the intervention group compared with baseline • Significant differences in trait anxiety in the intervention group compared to placebo group at 25 weeks • No significant differences observed at 6 months and 1 year post-therapy for intervention group compared to placebo group or baseline	Mataran-Penarrocha[28]
Motor function			
Grip strength (Jamar Hand Dynamometer), patient specific functional scale (PSFS)	Lateral epicondylitis	• Significant improvement in grip strength and functional activities in the intervention group compared to placebo group and baseline at post-test analysis	Nourbakhsh[29]
ANS function (urinary, cardiovascular function)			
PVR, urinary frequency, urinary urgency	Multiple sclerosis	• Significant improvement in all variables measured was seen after the intervention compared to baseline	Raviv[31]
ECG (heart rate)	Fibromyalgia	• No significant changes in heart rate variability in the intervention or placebo group were observed, compared to baseline values after 20 weeks of therapy	Castro-Sanchez[27]
Safety			
20-Item questionnaire (reported by parents)	Children with a variety of disabilities	• No parent reported any worsening effect in their children's condition after CST	McManus[33]
Method not reported	Multiple sclerosis	• No worsening in quality of life following CST reported	Raviv[31]

Abbreviations used: CST — craniosacral therapy; VAS — Visual Analog Scale; PVR — post void residual; ECG — electrocardiogram; ANS — autonomic nervous system.

Table 5 Summary of critical appraisal score of the included studies (Downs and Black checklist).

Study name	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	Total score
	Reporting										External validity				Bias							Confounding						
Castro-Sanchez [27]	Y	Y	Y	Y	P	Y	Y	N/U	N/U	Y	Y	Y	Y	N/U	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N/U	Y	N/U	21
Mataran-Penarrocha [28]	Y	Y	Y	Y	Y	Y	Y	N/U	N/U	Y	Y	Y	Y	N/U	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N/U	Y	N/U	22
Nourbakhsh [29]	Y	Y	Y	Y	P	Y	Y	N/U	N/U	Y	Y	Y	Y	N/U	Y	Y	Y	Y	Y	Y	Y	Y	N/U	Y	N/U	Y	N/U	20
Gerdner [30]	Y	Y	Y	Y	Y	Y	Y	N/U	Y	Y	N/U	N/U	Y	N/U	N/U	N/U	Y	Y	Y	Y	Y	N/U	Y	N/U	N/U	N/U	Y	17
Raviv [31]	Y	Y	Y	Y	P	Y	Y	Y	N/U	Y	N/U	N/U	Y	N/U	N/U	N/U	Y	Y	Y	Y	Y	N/U	N/U	N/U	N/U	N/U	N/U	14
Harrison [32]	N/U	N/U	N/U	N/U	P	N/U	N/U	N/U	N/U	N/U	N/U	N/U	N/U	N/U	N/U	N/U	Y	N/U	N/U	N/U	Y	N/U	N/U	N/U	N/U	N/U	N/U	2
McManus [33]	Y	Y	Y	N/U	P	Y	Y	Y	Y	N/U	N/U	N/U	Y	N/U	N/U	N/U	Y	N/U	N/U	N/U	Y	N/U	N/U	N/U	N/U	N/U	N/U	10

Abbreviations used: Y — yes; N/U — no/unable to determine; P — partially.
Reporting: 1. Is the hypothesis/aim/objective of the study clearly described? 2. Are the main outcomes to be measured clearly described in the Introduction or Methods section? 3. Are the characteristics of the patients included in the study clearly described? 4. Are the interventions of interest clearly described? 5. Are the distributions of principle confounders in each group of subjects to be compared clearly described? 6. Are the main findings of the study clearly described? 7. Does the study provide estimates of the random variability in the data for the main outcomes? 8. Have all important adverse events that may be a consequence of the intervention been reported? 9. Have the characteristics of patients lost to follow-up been described? 10. Have the actual probability values been reported?
External validity: 11. Were the subjects asked to participate in the study representative of the entire population from which they were recruited? 12. Were those subjects who were prepared to participate representative of the entire population from which they were recruited? 13. Were the staff, places, and facilities where the patients were treated representative of the treatment the majority of patients received? 14. Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance was less than 5%?
Internal validity — bias: 15. Was an attempt made to blind study subjects to the intervention they have received? 16. Was an attempt made to blind those measuring the main outcomes of the intervention? 17. If any of the results of the study were based on ''data dredging,'' was this made clear? 18. 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? 19. Were the statistical tests used to assess the main outcomes appropriate? 20. Was compliance with the intervention/s reliable? 21. Were the main outcome measures used accurate (valid and reliable)?
Internal validity — confounding (selection bias): 22. 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? 23. Were the study subjects in different intervention groups (trial and cohort studies) or were the cases and controls (case—control studies) recruited over the same time period? 24. Were the study subjects randomised to intervention groups? 25. Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable? 26. Was there adequate adjustment for confounding in the analysis from which the main findings were drawn? 27. Were losses of patients to follow-up taken into account?

In conclusion, this systematic review provides an update on the available evidence of the clinical benefits of CST, with positive results shown for a range of clinical outcomes. Progress has been seen over the last decade in the methodological quality of studies; however, the current moderate quality of the studies and scarcity of available data indicates that further research into this area is needed.

Conflict of interest

The authors have no conflict of interest or financial disclosure relevant to the topic of the submitted manuscript.

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