

## ORIGINAL RESEARCH

## PAIN MANAGEMENT

# Effects of craniosacral therapy and sensorimotor training on pain, disability, depression and quality of life of patients with nonspecific chronic low back pain: a randomized clinical trial

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## Abstract

**Background:** Craniosacral therapy (CST) and sensorimotor training (SMT) are two recommended interventions for nonspecific chronic low back pain (NCLBP). This study compares the effects of CST and SMT on pain, functional disability, depression and quality of life in patients with NCLBP.

**Methodology:** A total of 31 patients with NCLBP were randomly assigned to the CST group (n=16) and SMT (n=15). The study patients received 10 sessions of interventions during 5 weeks. Visual analogue scale (VAS), Oswestry disability index (ODI), Beck depression inventory-II (BDI-II), and Short Form-36 (SF-36) questionnaires were used at baseline (before the treatment), after the treatment, and 2 months after the last intervention session. Results were compared and analyzed statistically.

**Results:** Both groups showed significant improvement from baseline to after treatment ( $p < 0.05$ ). In the CST group, this improvement continued during the follow-up period in all outcomes ( $p < 0.05$ ), except role emotional domain of SF-36. In the SMT group, VAS, ODI and BDI-II increased during follow-up. Also, all domains of SF-36 decreased over this period. Results of group analysis indicate a significant difference between groups at the end of treatment phase ( $p < 0.05$ ), except social functioning.

**Conclusions:** Results of our research confirm that 10 sessions of craniosacral therapy (CST) or sensorimotor training (SMT) can significantly control pain, disability, depression, and quality of life in patients with NCLBP; but the efficacy of CST is significantly better than SMT.

**Key words:** Craniosacral therapy; Sensorimotor training; Nonspecific chronic low back pain; Quality of life

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**Abbreviations:** CST=Craniosacral therapy; SMT=Sensorimotor training; NCLBP=Nonspecific chronic low back pain; VAS=Visual analogue scale; ODI=Oswestry disability index, BDI-II=Beck depression inventory-II, and SF-36=Short Form-36; CSF=cerebral spinal fluid; CSS=craniosacral system; PRM=primary respiratory movements

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## 1. Introduction

Low back pain (LBP) is one of the most common musculoskeletal disorders worldwide. About 80% of people experience LBP at least once during their lifetime. This disorder can cause human disability and cost highly for societies.<sup>1,2</sup> LBP for more than 3 months and without any clear etiology such as trauma, malignancy, and so on are categorized as nonspecific chronic LBP (NCLBP).<sup>3</sup>

Several potential causes have been proposed for NCLBP. Different pain practitioners have suggested different therapeutic interventions based on distinct theories. Some evidence suggests that patients with NCLBP present more proprioception impairment compared to healthy subjects.<sup>4</sup> Sensorimotor training (SMT) is a method for proprioception improvement, which increases muscle adjustment ability and coordination.<sup>5,6</sup>

Craniosacral therapy (CST) is an alternative approach that applies manual force to restore normal cerebral spinal fluid (CSF) and craniosacral system (CSS) movements. Craniosacral therapists believe that brain produces some rhythmic and involuntary movements within the skull. This movement circulates CSF in the brain. Based on this theory, fluctuation mechanism causes reciprocal tension on the membranes around the brain and spine and induce craniosacral movement. In this technique, the therapist finds any somatic dysfunction of the head and the remainder of the body and tries to mobilize abnormal restricted physiologic motion.<sup>7</sup> Preliminary experimental studies of Sutherland, an osteopath in the 1930s, were the outset for other studies on the role of CSS distribution and CST.<sup>8</sup> He claimed that the individual bones of the skull affect CSF. In this theory, primary respiratory movements (PRM) manifest mobility of cranial bones, sacroiliac joint, dura mater, CSF, etc. Therefore, any path mechanics of tissues around the lumbar spine including fascia, can influence CSS and this change can affect motor control and postural adjustment.

CST and SMT are two treatment methods for NCLBP with different theories. CST focuses on restoring CSS dysfunction that can be secondary to fascial disorders<sup>9-11</sup> and SMT concentrates on training sensorimotor dysfunction that can be secondary again to fascial disorders.<sup>12</sup>

This study compares the clinical effects of CST and SMT in patients with NCLBP on pain, functional disability, level of depression and quality of life.

## 2. Methodology

### 2.1 Study design

This study was designed as a randomized clinical trial with two parallel study groups. Thirty-one patients suffering from NCLBP were enrolled at physiotherapy clinic of School of Rehabilitation, Iran University of Medical Sciences (IUMS), Tehran, Iran, between September 2016 and November 2017. All participants were recruited by the convenience sampling method. This research protocol was approved by the Research Ethics Committee of IUMS, Tehran, Iran (Code: IR.IUMS.REC139509211342216). All potential participants received information about CST, SMT and research procedure. Written informed consent was obtained from all enrolled patients.

### 2.2 Inclusion and exclusion criteria

Inclusion criteria were as follows: patients of both sexes, aged 20 to 40 y, had had LBP below the costal margin and above inferior gluteal folds for more than 6 months, and able to understand and communicate with the research team. Patients with nerve root pain or specific neurological disorder, pregnant females, patients with any infection; tumor; seizure; history of lumbar fracture, lumbar surgery, or lumbar physiotherapy treatment less than 3 months ago were excluded from the study.

Participants, who encountered symptoms such as high level of disability, severe worsening pain, headache, vertigo etc., were excluded from the study. In addition, participants who were unwilling to continue the study due to any reason, were excluded.

### 2.3 Randomization

All eligible participants were randomly divided into two groups, CST (n=16) and SMT (n=15), using random number sequence obtained from Excel software. Allocation concealment was performed through putting random numbers in sealed opaque envelopes prepared by a researcher who was not involved in the sampling, randomization, treatment, or assessment. To group assignment, the therapist opened the envelopes immediately before treatment.

## 2.4 Interventions

All patients received 10 physiotherapy sessions during 5 weeks with 2 sessions per week. CST was carried out by a 5-year experienced craniosacral therapist. In this group, patients were treated by modified therapeutic protocol presented by Upledger and Vredevoogd (1996).<sup>13</sup> One CST session lasts about 45 min, which has 4 phases. In each phase, patients were in a specific position for 10 min. To feel and follow craniosacral movements, craniosacral therapist puts her hands on two regions or bones. These phases are;

In the prone position; dominant hand in the lower lumbar region, which moves slightly towards thoracic and cervical spine and occipital bone; non-dominant hand on sacrum.

In side-lying position (behind the therapist) with slight hip and knee flexion; dominant hand on occipital bone; non-dominant hand on sacrum.

In side-lying (in front of the therapist) with slight hip and knee flexion; dominant hand on frontal bone; non-dominant hand on occipital bone (web space on base of occipital).

In the supine position; both hands at temporal and parietal bones of two sides.

In these positions, both the therapist and the patient should be relaxed to feel rhythmic CSF and craniosacral movements. An important point of this technique is that the therapist should only sense and follow movements in its direction, not correct or adjust them.

In the SMT group, patients received 10 sessions of balance training based on global approach by Page (2006). According to this approach, patients progress through three stages of static, dynamic, and functional, during 10 sessions.<sup>14</sup> In each stage, patients experience different postures and base of support and their center of gravity is being challenged.

## 2.5 Outcome measures

Demographic information of all participants was recorded, including age, height, weight, and body mass index (BMI).

Pain intensity was measured using a 10-cm visual analog scale (VAS). This scale is a reliable and valid measurement tool for pain assessment in NCLBP.<sup>15</sup> All participants were instructed about the meaning of

0 and 10, which represent “no pain” and “worst imaginable pain” respectively. Participants were asked to score their pain at the test time.

Functional disability was measured using the Persian version of Oswestry functional disability questionnaire (ODQ).<sup>16</sup> This questionnaire includes 10 items to evaluate the effect of LBP on the patient’s ability to manage his daily life. Each question is scored from 0 to 5, therefore maximum possible score is 50, which should be doubled to express as a percentage. A higher score of Oswestry disability index (ODI) indicates a worse level of disability.

The Beck depression inventory-II (BDI-II) was used for depression evaluation. This questionnaire contains 21 questions that each of them has 4 sentences describing the patient’s condition. We asked participants to mark the most precise sentence describing their condition. The BDI-II score ranges from 0 to 63 and higher scores indicate more depression.<sup>17</sup> The validity and reliability of the Persian version of BDI-II have been reported.<sup>18</sup>

Quality of life was assessed using Persian version of 36-item Short Form health survey (SF-36).<sup>19</sup> This questionnaire contains eight domains (physical function, role physical, body pain, general health, vitality, social functioning, role emotional and mental health). Each domain is scored on a scale of 0 to 100, and higher scores indicate better health status.

All outcome measures were assessed on three time points: before, immediately after the last session, and two months after the end of treatment (follow-up). In addition, the therapist asked the patients about their symptoms to assess for adverse effects at each session.

## 2.6 Statistical analysis

The obtained data were analyzed using SPSS version 16.0. During statistical analysis, specific codes were assigned for each group. Therefore, the statistician was blinded to study samples.

The normality of the distribution of all variables was assessed by the Kolmogorov-Simonov (K-S) test. The chi-square test was used for comparing the sex distribution between groups. The independent sample *t*-test and Mann-Whitney *U* test were used to compare between groups at all assessment time points in normalized and non-normalized distributed variables, respectively.

To analyze within-group variables in normalized and non-normalized data distributed, paired sample *t-test* and Wilcoxon's signed-rank test were used, respectively.

Repeated measures analysis of variance (ANOVA, Wilks' Lambda test) was used to assess the effects of the group, time and their interaction for VAS, ODI, BDI-II and SF-36. Since no participant was excluded during intervention and assessment times, there was no need to conduct intention-to-treat analysis. Significance level was set at  $p < 0.05$ .

### 3. Results

At first, 75 patients were assessed for eligibility and finally 32 of them were enrolled in the study (CST group: 16 and SMT group: 15). One participant did not participate in the first assessment session and treatment. Other patients continued study until the follow-up phase. No participants reported any complications such as pain or dysfunction. Figure 1 displays subject's attrition.

The demographic characteristics of the participants are presented in Table 1. All patients were equivalent at the outset of treatment ( $p > 0.5$ ). Results of statistical analysis of all clinical outcomes present similarity at baseline except mental health domain of SF-36 (Tables 2 and 3). Patients had minimal severity of depression in both groups.<sup>20</sup>

In both groups, all outcome measures improved significantly from baseline to after treatment ( $p < 0.05$ ). In the CST group, this improvement continued during follow-up period in all outcomes ( $p < 0.05$ ), except role emotional domain of SF-36 that decreased non-significantly ( $p=0.15$ ). In the SMT group, VAS, ODI and BDI-II increased during follow-up (Table 2).

Also, all domains of SF-36 decreased during this period (Table 3).

Results of group analysis show a significant difference between groups at the end of treatment phase ( $p < 0.05$ ), except for social functioning that was better in the CST group than the SMT group, but the difference was not significant ( $p=0.17$ ). In addition, there were significant differences between groups in all outcome measures at follow-up assessment phase ( $p < 0.05$ ). Tables 2 and 3 present between group analyses for all outcome measurements.

Results of repeated measures of ANOVA show a significant effect for the measurement time. In addition, the interaction between time and group was significant ( $p < 0.05$ ) (Table 2).

### 4. Discussion

This randomized clinical trial was performed to compare the effects of CST and SMT in patients with NCLBP. Although some studies have examined the influence of CST and SMT on pain and functional disability in NCLBP patients,<sup>5, 6, 21-23</sup> but this was the first study that compared them. We compared these treatments, because they were representatives of two therapeutic interventions which are related to lumbosacral fascia disorders with two main differences: CST is a central therapeutic intervention with central stimulation and passive role of patient, but SMT applies peripheral stimuli and needs active patient role.

**Table 1: Demographic data of the participants in both groups. Dara presented as mean  $\pm$  SD or No.**

Characteristics	Intervention groups	
	CST	SMT
Male : Female	8 : 8	9 : 6
Age (y)	27.7 $\pm$ 4.8	27.4 $\pm$ 3.5
Height (cm)	172.3 $\pm$ 10.3	174.4 $\pm$ 8.7
Weight (kg)	70.6 $\pm$ 10.5	71.0 $\pm$ 9.4
BMI (kg/m <sup>2</sup> )	23.7 $\pm$ 2.4	23.2 $\pm$ 1.6

It seems that fascia tissue of body, especially thoracolumbar fascia are the link between CST and SMT. Wilke et al. (2017) concluded that the lumbosacral fascia (LF) is one of the potential sources of LBP.<sup>24</sup> They reported that histological studies

proved the presence of free nerve endings in LF and that its morphological properties changed after NCLBP. One of the potential mechanisms of the role of fascia in LBP is compromising the proprioception signaling after fascia deformation. In other words, the

**Table 2: Comparing VAS, ODI and BDI scores before, after and in follow-up phase assessment with the results of repeated measures of ANOVA (mean  $\pm$  SD)**

Outcome measurement	Phase assessment	of Intervention groups		P value
		CST	SMT	
VAS	Before intervention	6.9 $\pm$ 1.0	6.5 $\pm$ 1.0	0.22 <sup>a</sup>
	After intervention	1.3 $\pm$ 0.6	3.0 $\pm$ 0.8	<0.01 <sup>a</sup>
	2 months later	0.33 $\pm$ 0.5	4.1 $\pm$ 0.8	<0.01 <sup>b</sup>
Time difference	WL value	0.02		
	P value	<0.01		
Group*Time difference	WL value	0.12		
	P value	<0.01		
ODI (%)	Before intervention	34.5 $\pm$ 8.5	32.4 $\pm$ 10.9	0.55 <sup>a</sup>
	After intervention	5.3 $\pm$ 3.0	17.0 $\pm$ 7.2	<0.01 <sup>a</sup>
	2 months later	0.7 $\pm$ 1.4	22.1 $\pm$ 6.9	<0.01 <sup>b</sup>
Time difference	WL value	0.11		
	P value	<0.01		
Group*Time difference	WL value	0.29		
	P value	<0.01		
BDI	Before intervention	27.3 $\pm$ 8.6	25.6 $\pm$ 6.7	0.54 <sup>a</sup>
	After intervention	5.8 $\pm$ 4.1	15.6 $\pm$ 5.5	<0.01 <sup>a</sup>
	2 months later	2.1 $\pm$ 2.4	20.5 $\pm$ 5.8	<0.01 <sup>b</sup>
Time difference	WL value	0.13		
	P value	<0.01		
Group*Time difference	WL value	0.2		
	P-value	<0.01		
SF-36	Before intervention	35.3 $\pm$ 13.4	45.8 $\pm$ 18.2	0.07
	After intervention	89.8 $\pm$ 5.2	68.4 $\pm$ 14.9	<0.01 <sup>a</sup>
	2 months later	96.5 $\pm$ 34.5	58.8 $\pm$ 15.1	<0.01 <sup>a</sup>
Time difference	WL value	0.06		
	P value	<0.01		
Group*Time difference	WL value	0.24		
	P value	<0.01		

<sup>a</sup> Independent sample *t* test.

<sup>b</sup> Mann-Whitney *U* test.

fascia has major role in proprioception signaling and processing, which is disturbed after LBP.<sup>12,24</sup> Studies

indicate NSCLP correlation with the change of proprioception processing, anticipatory postural

**Table 3: Comparing the scores of SF-36 questionnaire domains before, after and follow-up phase assessment (mean  $\pm$  SD)**

Outcome measurement	Phase of assessment	Intervention groups		p- value
		CST	SMT	
Physical function	Before intervention	30.63 $\pm$ 18.24	40.0 $\pm$ 16.03	0.14
	After intervention	93.44 $\pm$ 3.96	62.33 $\pm$ 20.86	< 0.01 <sup>b</sup>
	2 months later	100.0 $\pm$ 0.0	59.33 $\pm$ 18.69	< 0.01 <sup>a</sup>
Role physical	Before intervention	20.3 $\pm$ 26.1	28.3 $\pm$ 31.1	0.52
	After the intervention	95.3 $\pm$ 10.0	65.0 $\pm$ 24.6	< 0.01 <sup>b</sup>
	2 months later	100.0 $\pm$ 0.0	53.3 $\pm$ 32.5	< 0.01 <sup>b</sup>
Body pain	Before intervention	40.9 $\pm$ 20.94	44.4 $\pm$ 15.2	0.35
	After intervention	87.7 $\pm$ 12.5	72.4 $\pm$ 13.5	< 0.01 <sup>b</sup>
	2 months later	100.0 $\pm$ 0.0	59.6 $\pm$ 12.2	< 0.01 <sup>a</sup>
General health	Before intervention	34.6 $\pm$ 13.2	47.6 $\pm$ 25.6	0.08
	After intervention	78.0 $\pm$ 6.5	64.9 $\pm$ 17.1	< 0.01 <sup>b</sup>
	2 months later	98.2 $\pm$ 2.76	51.9 $\pm$ 18.1	< 0.01 <sup>b</sup>
Vitality	Before the intervention	40.0 $\pm$ 17.12	50.0 $\pm$ 13.8	0.08
	After intervention	85.3 $\pm$ 7.8	64.3 $\pm$ 12.7	< 0.01 <sup>b</sup>
	2 months later	93.4 $\pm$ 4.7	55.6 $\pm$ 10.8	< 0.01 <sup>b</sup>
Social functioning	Before intervention	48.6 $\pm$ 19.3	58.6 $\pm$ 16.6	0.16
	After intervention	92.3 $\pm$ 10.0	85.1 $\pm$ 14.3	0.17
	2 months	100.0 $\pm$ 0.0	71.8 $\pm$ 12.8	< 0.01 <sup>b</sup>
Role emotional	Before intervention	20.8 $\pm$ 36.2	37.8 $\pm$ 33.1	0.14
	After intervention	95.8 $\pm$ 11.2	64.4 $\pm$ 29.7	< 0.01 <sup>b</sup>
	2 months later	87.5 $\pm$ 50.0	55.4 $\pm$ 32.6	< 0.01 <sup>b</sup>
Mental health	Before intervention	47.0 $\pm$ 18.3	60.2 $\pm$ 13.9	0.03
	After intervention	89.2 $\pm$ 5.6	69.3 $\pm$ 11.9	< 0.01 <sup>b</sup>
	2 months later	93.7 $\pm$ 5.8	63.4 $\pm$ 9.8	< 0.01 <sup>b</sup>
SF-Total physical	Before intervention	32.06 $\pm$ 10.7	42.0 $\pm$ 18.6	0.11
	After intervention	87.7 $\pm$ 5.8	65.7 $\pm$ 14.9	< 0.01 <sup>a</sup>
	2 months later	98.3 $\pm$ 5.8	56.0 $\pm$ 15.2	< 0.01 <sup>a</sup>
SF-Total mental	Before intervention	38.3 $\pm$ 16.1	50.8 $\pm$ 18.2	0.054
	After intervention	88.1 $\pm$ 5.0	69.7 $\pm$ 14.7	< 0.01 <sup>a</sup>
	2 months later	94.4 $\pm$ 9.6	59.7 $\pm$ 13.8	< 0.01 <sup>b</sup>

<sup>a</sup> Independent sample *t* test; <sup>b</sup> Mann-Whitney *U* test.

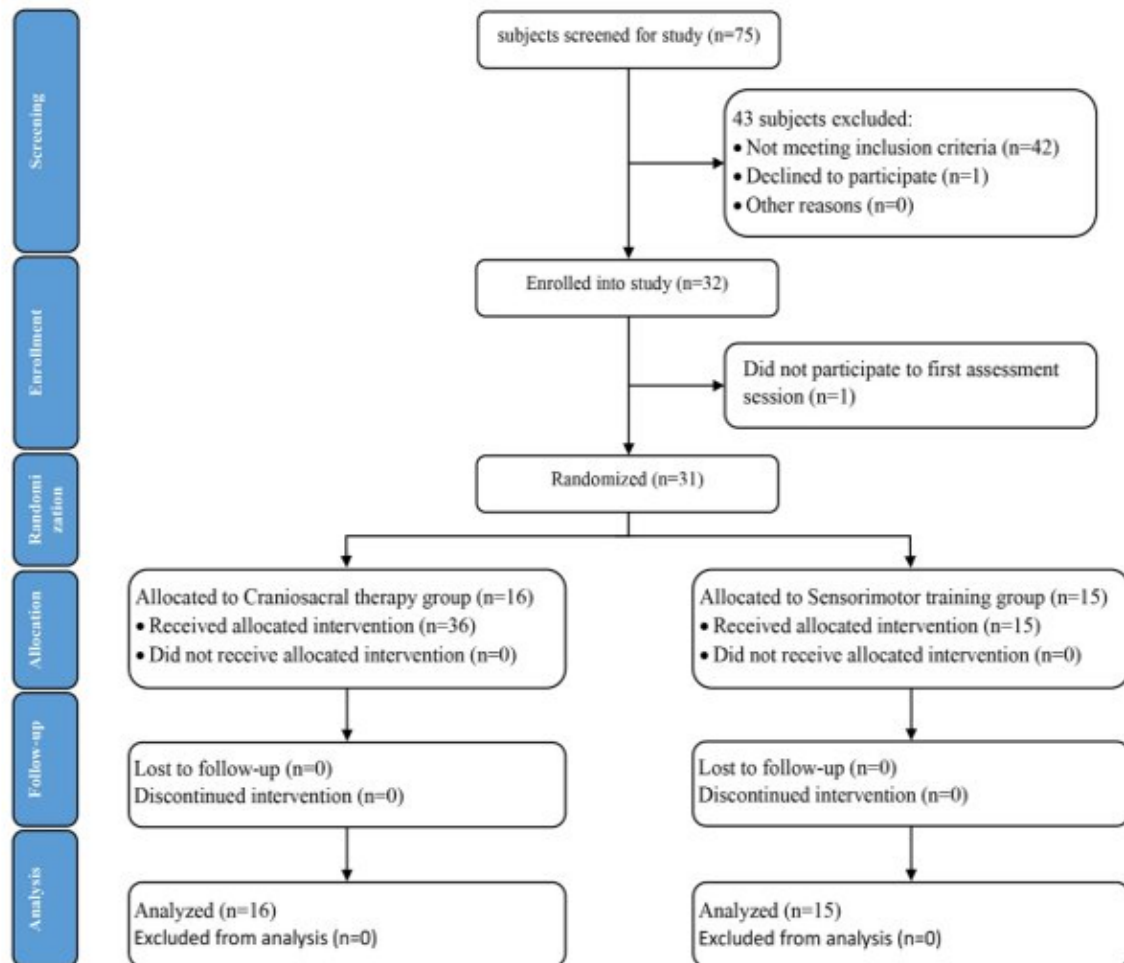


Figure 1: CONSORT study flowchart.

adjustment (APA) and muscles response delay.<sup>4,25</sup> The fascial tissue wraps, interpenetrates, and forms many tissues in the body including blood stream, bones, organs, muscles, etc. Other important tissues covered by fascia can be influenced by changes are dura mater, meninges and CSF surrounded around spinal cord.<sup>26,27</sup> These tissues have a global and systematic function that any change in one part of this system can influence other parts.

We selected CST as a central treatment approach, because it is more effective than a classic massage in NCLBP,<sup>21</sup> which can influence the fascia, dura mater, autonomic nervous system (ANS),<sup>28</sup> and all related tissues and systems. It has been shown that this treatment can improve proprioception, strength and postural stability.<sup>29</sup> Although, we chose these two

treatments in our trial, there are other central and peripheral treatments that should be compared in future studies.

Our results indicate that central treatment approach is more effective than the peripheral treatment. This effect can be because many patients accept a passive treatment more than an active intervention.

In a systematic review by Jake and Hauenschild, clinical benefits of CST were discussed. They included all studies, which had used CST for treating patients with various clinical conditions. Finally, they included three randomized controlled trials (RCTs) and four observational studies with different diseases, including fibromyalgia, child disabilities, multiple sclerosis, lateral epicondylitis, and dementia. Conclusion shows

positive results of CST in studies with moderate qualities.<sup>7</sup>

Castro-Sanchez et al. evaluated the effects of CST on disability, pain, quality of life, lumbar mobility, hemoglobin oxygen saturation, systolic and diastolic blood pressure, cardiac index, and biochemical estimation of interstitial fluid in patients with NCLBP. They randomly assigned participants to the CST group and classic massage group. Both groups received 10 treatment sessions. Although the procedure of CST in this study varies minimally with our study, they reported that 10 sessions of CST improved pain intensity, hemoglobin oxygen saturation, systolic blood pressure and magnesium level significantly compared to classic massage.<sup>21</sup>

In another study, Haller et al. compared the efficacy of 8 weeks CST and sham touch treatment with 12 weeks follow-up in 52 patients with chronic cervical pain. All patients in the CST group reported more pain reduction and disability improvement compared to the control group. Patients also reported continuous improvement after treatment until 12 weeks that is similar to our study.<sup>30</sup>

Regarding our study, it seems that both CST and SMT are effective modality for managing NCLBP, but CST seems a more effective treatment with longer duration persistence. This lasting effect of CST is due to its influence on tissues such as the dura mater and CSF. CST can change number of CSF and biomechanical properties of connective tissues around spinal cord.

There are two proposed possible mechanisms for CST. First, CST can improve articular restriction and enhance the amplitude of cranial rhythm. The second mechanism focuses on the changes of ANS.<sup>28</sup> In a quasi-experimental, crossover, pilot study by Girsberger et al., standard deviation of respiratory rate (RR) intervals and total power of RR-interval changed in the CST group as an indicator of ANS changes. These changes were not seen in the control group.<sup>31</sup>

## 5. Limitations

This study has some limitations too. First, we only evaluated effects of treatment by subjective outcome measurements. Although these outcome measurements are known as valid and reliable, it seems that future studies should evaluate ANS and balance changes after these treatments. Second, we did

not set blinding procedure in the assessment phases during the study. Blinding is known as an important methodological property in RCTs to minimize bias.<sup>32</sup> Third, we only used CST and SMT as central and peripheral interventions for NCLBP, respectively. Future studies should compare other central and peripheral interventions.

## 6. Conclusions

The results of this randomized clinical trial suggest that 10 sessions of craniosacral therapy and sensorimotor training can significantly alleviate pain, disability, depression, and quality of life in patients with NCLBP, but the efficacy of craniosacral therapy is significantly higher than sensorimotor training. Another difference between groups was that in patients in sensorimotor training group, outcome measures showed a decreasing trend during the follow-up period.

## 7. Funding

No funding was involved in this study.

## 8. Conflict of Interest

Authors declare no conflict of interest.

## 9. Authors' contribution

CG: Study design

AA: Concept

JS: Performed the study, manuscript writing

MD: Literature review, statistical analysis

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