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Effect of craniosacral therapy on the intensity of chronic back pain of nurses: A randomized controlled trial

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ABSTRACT

Background & Aim: Chronic low back pain is a common disease among nurses. According to the literature, complementary medicine can reduce low back pain, one of which is craniosacral therapy. This study was designed to investigate the effect of craniosacral therapy on the intensity of chronic back pain of nurses.
Methods & Materials: This randomized clinical trial study was conducted on 60 nurses with chronic back pain. The participants were randomly assigned into intervention and control groups. The intervention group's participants received eight individual sessions of craniosacral therapy. In the control group, a light-touch in the lumbar region was performed as a placebo. The therapist met each participant separately in a private room of the hospital. The two groups completed the McGill Pain Questionnaire at the baseline, immediately after the intervention, and one month after the intervention. The collected data was analyzed in SPSS (v.16) using descriptive and analytical tests such as t-test, Chi-Square, ANCOVA, and repeated measures ANOVA.
Results: The ANCOVA test results showed a significant difference between the two groups' mean scores of pain intensity and its subscales ($P<0.05$). The results of repeated measures ANOVA showed that the mean scores of pain intensity and its subscales (sensory, affective, pain evaluation, and miscellaneous) decreased over the three time points in the intervention group ($P<0.05$).
Conclusion: The findings affirmed the positive effects of the craniosacral therapy on the intensity of pain in nurses with chronic back pain. Therefore, it is recommended that this approach be performed as a complementary, effective, non-invasive intervention to decrease chronic back pain.

Introduction

Chronic back pain is one of the most challenging medical problems in industrialized and developing countries that, with a high prevalence, imposes high economic costs on the community (1). In general, the annual prevalence of back pain in nurses ranges from 15 to 45% (2). 75 to 85 percent of people experience some back pain during their lifetime (1). The prevalence of back pain in the United States is between 15% and 20%, 25 to 45% in Europe (3), 28.5% in Canada (4), and 65-70% in Iran, which is significant statistics (5). Back pain is the most common musculoskeletal disorder in the working population, while about one-third referred to orthopedic clinics is due to non-specific disorders. The group of patients, experiences pain between the twelve ribs and the Gluteal region in the back. They refer to the physician with a history of pain for more than three months without any pathological symptoms (6). Chronic back pain is the most important reason for work absence and job disability, and its financial cost is three times more than that of cancer (7). The risk of

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back pain prevalence is increased in some occupations, such as nursing, due to the need for prolonged standing, frequent changes in body status, lifting of objects, bending, and repeated turning of the body (8). According to the studies, the mean annual prevalence of back pain in nurses is 45-77% (9-10). Work-related back pain of nurses results in high treatment costs, work absence, and failure in the health care system (11). Pain often undermines the general health of nurses and reduces their professional performance. The evidence has shown that back pain is the most important reason for job change in nurses (12). Those nurses who suffer from back pain will not provide good care, such as physical and psychological support for patients. This exacerbates occupational mistakes and incidents, which, finally, have consequences for the patient and nurse (13).

The control of chronic back pain consists of two categories of medicine and non-medicine interventions. Medicine interventions include non-steroidal anti-inflammatory drugs and opioids, and non-medicine interventions include psychological techniques, electrical stimulation, and complementary and alternative medicine therapies. During the back pain period, various pain relief medicines are provided by physicians to patients, which, in addition to heavy financial burden, can cause relatively severe side effects in some cases (14). In recent years, the use of complementary medicine has been increased for the treatment of these patients due to the inability of the medical profession to treat chronic back pain, so the use of complementary medicine in advanced countries is increasing (15). One of the complementary medical therapies is craniosacral therapy. In this method, non-invasive techniques, using gentle manual palpation to release fascial restrictions between the cranium and the sacrum (16-17). Craniosacral therapy is a completely safe method with no side effects, which profoundly impacts the function of the brain and spinal cord (16). In a variety of studies, this technique has been implemented on various diseases. Haller et al. demonstrated that craniosacral therapy twice a week for eight weeks caused a significant reduction in chronic non-specific neck pain in patients referred to the treatment center (18). Also, Castro-Sánchez et al. reported that 10 sessions of craniosacral therapy significantly reduced pain intensity in patients with chronic back pain referred to craniosacral therapy but did not significantly affect general health and physical activity (19). However, the study results of Białoszewski et al. showed that the use of three sessions at 3-4 day intervals of craniosacral therapy did not have a significant effect on the control of back pain and muscle performance in 55 patients with non-specific chronic back pain (20). Haller et al. also reported that eight weekly craniosacral therapy sessions had no significant effect on pain relief in 50 patients with chronic neck pain (21).

Regarding the complications of chronic back pain, timely treatment and prevention of complications are essential. In recent years, several studies have been conducted on the effectiveness of craniosacral therapy on chronic back pain (18-19); however, the effectiveness of this technique on the treatment of chronic back pain is still ambiguous as further studies have been proposed in this regard (18, 20). Also, controversial studies on the effectiveness of craniosacral therapy on chronic back pain show the need for further research in this field. Therefore, this study was conducted to determine the effect of craniosacral therapy on the chronic back pain of nurses.

Methods

Study design

A single-blinded clinical trial study was conducted on 60 nurses with chronic back pain working in the central hospital of Kashan, Iran, from August to November 2018. In the intervention group, craniosacral therapy was performed by the first author. The data collection was completed by the third author, who was unaware of the participant group assignment. The statistical specialist was also unaware of the participant group assignment.

Sample size

The sample size in each group was calculated based on the same study (18) and assumptions: power=0.80, α=0.05, the minimum expected difference in standard deviations=2.4, and the minimum expected difference in means=4.2. Considering a possible attrition rate of 10%, the optimal sample size was estimated to be 30 participants in each group. At the beginning of the study, 95 nurses with chronic back pain were assessed for eligibility. Of the 95 nurses, 18 nurses did not meet the inclusion criteria, and 17 nurses declined to participate in the study (Figure 1).

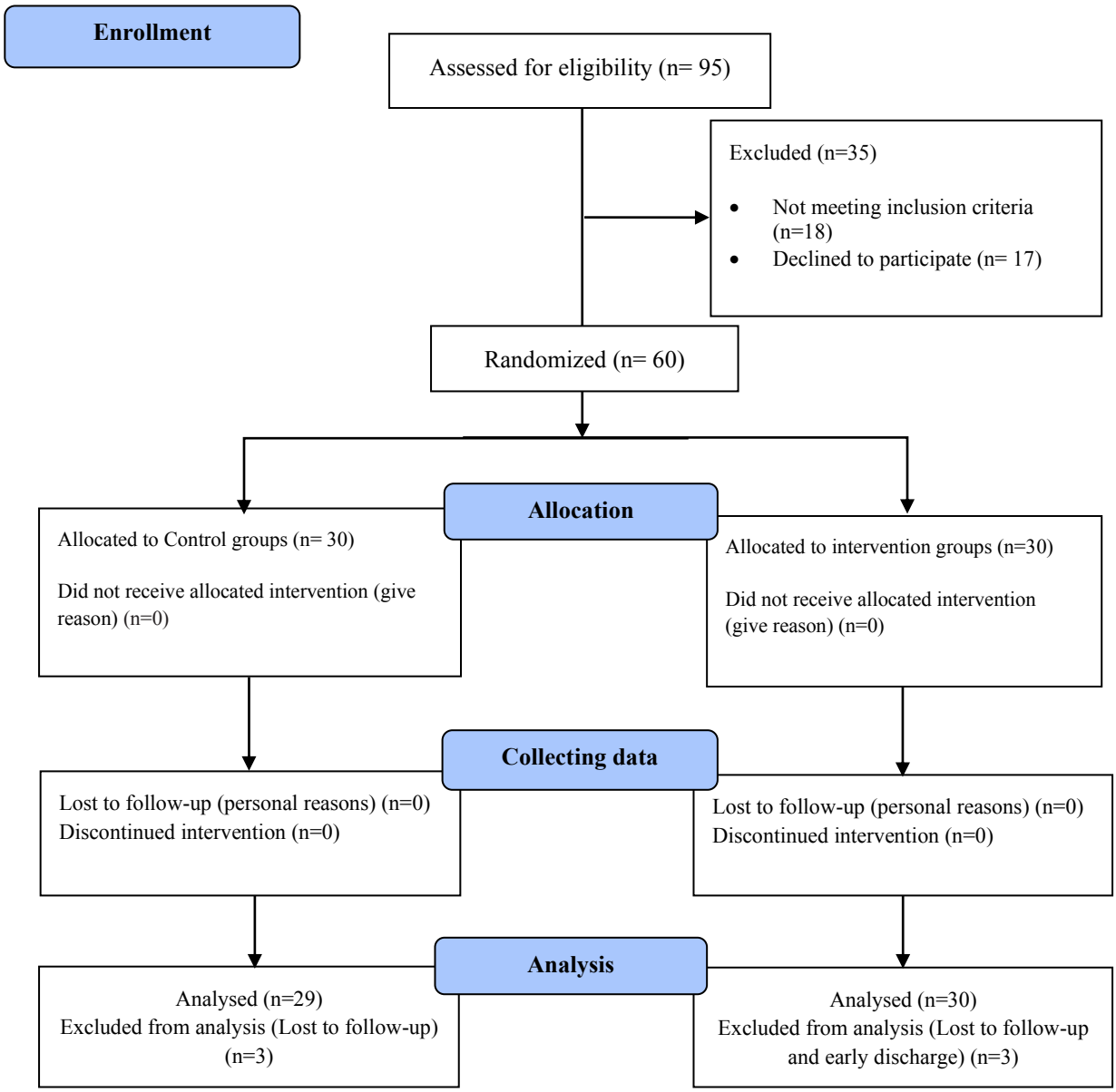

Figure 1. The flow diagram of the study, based on the Consort statement 2012.

Setting and participants

After coordination with the hospital authorities, a general call was made to the clinical departments that nurses with back pain can refer to the researcher to attend the study at a designated time inside the hospital. After referring and explaining the purpose of the study, those who tended to participate in the study with score 4 and above of visual analog of pain were introduced to the orthopedic specialist for the diagnosis of non-specific chronic back pain. So, The convenience sampling method

was used in this study. The study inclusion criteria included clinical activity in each department of the hospital, having complete satisfaction with participating in the study, obtaining a score over 4 in the visual analog scale, diagnosis of non-specific chronic back pain, and no injury in the back (skin, musculoskeletal, and skeletal damage) according to the examination of an orthopedic surgeon. The study exclusion criteria included the reluctance to continue participating in this study, more than two absences, and the use of other complementary therapies during the research for back pain (such as exercise, laser therapy, and swimming).

Randomization

A total of 60 nurses with chronic back pain were randomly assigned into intervention (n=30) and control (n=30) groups using the block randomization method (10 blocks of 6) that was performed via an online randomization software (i.e., https:// www. sealedenvelope. com/simple randomiser/v1/ lists) (22).

Data collection

The study measures included sociodemographic characteristics with nine questions age, gender, education level, marital status, body mass index (BMI), number of work shifts per month, type of unit, shift type, job position, and McGill Pain Questionnaire. Melzack designed the questionnaire to study the quality and intensity of the pain (23), which provides valuable information about sensory and affective subscales of pain and can differentiate between different types of pain. McGill Pain Questionnaire consisted of four main groups and 78 descriptive words in 20 subgroups comprised of three subscales of sense (sub-groups of 1-10), emotion (sub-groups of 11-15), cognitive evaluation (subgroup of 16), and different groups (subgroups of 17-20). In each subgroup, pain intensity increases from top to bottom, so the lowest word has the highest score. The patient can choose a word from each subgroup (24). The reliability of this questionnaire in Iran was obtained by Cronbach's alpha (α=0.89) in the Yazdanpanahi et al. study (25). In the present study, Cronbach's alpha was calculated at 0.86.

Intervention

The participants completed the self-report questionnaire. In the intervention group, craniosacral therapy was performed for eight sessions and 30-45 minutes each session in a room with mild light, proper air conditioning, and temperature in the treatment center (21). Craniosacral therapy is performed by the first researcher (nurse). She had a certificate in this field. In the control group, a light-touch in the lumbar region was performed as a placebo. McGill Pain Questionnaire was completed by the samples at the baseline, immediately after, and one month after the intervention.

This study was conducted based on previous studies (18-20). First, the patient was placed in a Prone Position. The Craniosacral therapy protocol was designed to release the limitations of the skull and spine up to the pelvis and sacrum using gentle fascial traction and release and unlock techniques in accordance with the relevant touch restrictions. The techniques applied included parietal and frontal lift, medial compression of the parietal bones, sagittal suture and the atlanto-occipital joint release, decompression-compression of the temporomandibular and the sphenobasilar joints, release cranial base, the thoracic inlet and the hyoid diaphragm release, release of the pelvic diaphragm and respiratory, dural tube traction, sacroiliac and lumbosacral decompression, release of the fascial neck/shoulders and lower limbs (18-20).

Data analysis

The information was analyzed using descriptive statistics (mean and standard deviation) and analytical statistics. Kolmogorov Smirnov test was used to check the normality of the data. In order to compare the quantitative demographic

variables in two groups, independent t-test and qualitative demographic variables were used in the two groups of X^2 (chi-square test). The repeated measures ANOVA test was used to perform within- and between-group comparisons regarding pain intensity and its subscales score before the intervention, immediately after the last session, and one month after the last session of the intervention. A Post-hook test was also used to compare times. Covariance (ANCOVA) was used to compare the mean scores of pain intensity and its subscales in two groups. Statistical analysis was performed using SPSS version 16 (SPSS Inc., Chicago, IL, USA). P-value < 0.0 was considered as significant for all results.

Ethical considerations

This study was approved by the Institutional Review Board and the ethics committee of Kashan University of Medical Sciences (approval number: 94013). The research objectives were explained to the participants, and written informed consent was obtained. The participants were informed about voluntary participation and the right to withdrawal at any time. They were assured that their anonymity would be protected and their personal information will be kept confidential. This study was registered at the Iranian Registry of Clinical Trials (no. IRCT20111210008348N37).

Results

In the present study, no sample loss was found due to the researcher's continuous follow-up. The mean age of the subjects in the intervention group was 33.11±3.20 years and 34.28± 3.28 years in the control group. No significant difference was found between the two groups in terms of sociodemographic characteristics, and the two groups were homogeneous (p>0.05) (Table 1).

Table 1. The intervention and control groups' sociodemographic characteristics

Variable		Groups		P value
		Intervention group (n=30)	Control group (n=30)	
		Mean ± SD	Mean ± SD	
Age (year)		34.28± 3.28	33.11± 3.20	0.11*
BMI		26.15 ± 3.81	25.84± 3.35	0.14*
Number of shifts in month		26.42 ± 2.35	25.27 ± 2.17	0.10*
Gender ***N* (%)** **	Female	26 (86.7)	26 (86.7)	0.97**
	Male	4 (13.3)	4 (13.3)	
Education level ***N* (%)**	Bachelor	29 (96.66)	30 (100)	0.98**
	Master of science	1 (3.33)	0	
Marital status ***N* (%)**	Single	6 (20)	2 (6.7)	0.81**
	Married	24 (80)	28 (93.3)	
Type of unit ***N* (%)**	Medical –surgical unit	15 (50)	16 (53.3)	0.63**
	Emergency unit	6 (20)	8 (26.7)	
	Intensive care unit	9 (30)	6 (20)	
Shift type	Rotation	27 (90)	27 (90)	0.99**
	Fixed morning or evening	3 (10)	3 (10)	
Job position	Supervisor	4 (13.3)	5 (16.7)	0.85**
	Nurse	26 (86.7)	25 (83.3)	

*Independent samples t-test; ** Chi-Square test

The result showed that baseline, immediately after the last session and one month after the intervention, the total score of pain intensity was 32.62±4.71, 21.30±4.22, and 15.35±4.21, respectively, and in the control group were 33.32±5.22, 34.24±4.91, and 35.37±5.20, respectively. The results of repeated measures ANOVA in the intervention group showed that the mean scores of pain intensity and its subscales (sensory, affective, pain evaluation, and miscellaneous) decreased over the three time points (P<0.05). Also, the comparison three times baseline, immediately after the last session and one month after the last session of the intervention in each group with the

post hoc test, showed a significant difference in pain intensity score and its subscales in different times in the intervention group. The results of the ANCOVA test also showed that there was a significant difference between the two groups' mean scores of pain intensity and its subscales (P<0.05) (Table 2).

Table 2. Comparison of mean pain intensity score before, immediately after the last session and one month after intervention in two groups

Variable	Group	Before	Immediately after	One month after the intervention	P value **			
		Mean±S.D*	Mean±S.D	Mean ±S.D	Post hoc test	Time	Time × Group	Group
Sensory	Intervention	16.51±2.20	12.45±2.01	9.33±1.84	T1 & T2, P=0.01 T1 & T3, P=0.01 T2 & T3, P=0.02	p<0.001	p<0.001	p<0.001
	Control	16.93±2.54	15.95±2.64	16.53±1.23	T1 & T2, P=0.31 T1 & T3, P=0.23 T2 & T3, P=0.54			
	ANCOVA	F=234.25, P=0.04			-			
Affective	Intervention	5.13± 1.54	4.53± 1.12	2.25 ± 0.26	T1 & T2, P=0.04 T1 & T3, P=0.01 T2 & T3, P=0.01	p<0.001	p<0.001	p<0.001
	Control	5.97 ± 0.44	5.87± 0.96	5.93±0.72	T1 & T2, P=0.32 T1 & T3, P=0.54 T2 & T3, P=0.24			
	ANCOVA	F=276.27, P=0.03			-			
Pain evaluation	Intervention	3.51±0.23	2.03±0.21	2.80±0.11	T1 & T2, P=0.02 T1 & T3, P=0.04 T2 & T3, P=0.04	p<0.001	p<0.001	p<0.001
	Control	3.75±0.35	4.52±0.40	4.57±0.42	T1 & T2, P=0.09 T1 & T3, P=0.21 T2 & T3, P=0.23			
	ANCOVA	F=199.52, P=0.02			-			
Miscellaneous	Intervention	6.28±0.65	4.54±0.46	3.13±0.21	T1 & T2, P=0.01 T1 & T3, P=0.00 T2 & T3, P=0.03	p<0.001	p<0.001	P<0.001
	Control	6.80±1.80	6.13±1.65	6.05±1.52	T1 & T2, P=0.63 T1 & T3, P=0.41 T2 & T3, P=0.15			
	ANCOVA	F=200.12, P=0.01			-			
Total score of pain intensity	Intervention	32.62±4.71	21.30±4.22	15.35±4.21	T1 & T2, P=0.01 T1 & T3, P=0.01 T2 & T3, P=0.01	p<0.001	p<0.001	p<0.001
	Control	33.32±5.22	34.24±4.91	35.37±5.20	T1 & T2, P=0.13 T1 & T3, P=0.91 T2 & T3, P=0.36			
	ANCOVA	F=246.52, P=0.04			-			

*Continuous data are presented using means ± standard deviations (SD) ; ** Repeated Measure ANOVA

Discussion

The present study showed that craniosacral therapy could reduce the intensity of chronic back pain in nurses after the intervention and one month after. The study results of Haller et al., which evaluated the effect of craniosacral therapy on the intensity of chronic neck pain (18), are consistent with that of the present study. In Haller's study, craniosacral therapy was performed for 8 weeks and three times per week. Also, in order to determine the effect of treatment, the patients were followed up to 20 weeks after the intervention. The results showed a significant reduction in pain intensity after 20 weeks. Jäkel & Von Hauenschild considers this method to have a

profound effect on the brain and spine and believes that craniosacral therapy can remove the patterns of pressure and compression in the communications anatomical spaces of the membrane and skull bones and reduce muscle pain (26). The study results of Castro-Sánchez et al. showed that 10 sessions of craniosacral therapy reduced pain intensity in patients with chronic back pain but did not significantly affect physical activity (19). His study is consistent with the present study to reduce pain intensity. The similarity of the present study with this study was in the number of sessions and intervention method.

In contrast, the study results of Białoszewski et al., to determine the effect of craniosacral therapy on chronic non-specific pain in patients, were not significantly different between the two groups in terms of pain and muscle function (20). It seems that the reason for inconsistency in the number of sessions is the duration of craniosacral therapy implementation and the type of pain evaluation tool. In Białoszewski et al., study, patients received three sessions of 30 minutes of craniosacral therapy, while craniosacral therapy was performed in 8 sessions and 45 minutes each time in the present study. Also, in order to evaluate the intensity of pain, McGill Pain Questionnaire was used, but in Białoszewski et al., study, VAS visual scale questionnaire was used (20). Therefore, with the increase in the number and length of sessions, it seems that the effectiveness of craniosacral therapy is more, and the difference in questionnaires can also affect the results. In another study, Haller et al. for patients with neck pain performed craniosacral therapy for eight weeks. Craniosacral therapy had no significant effect on neck pain reduction (18). The reason for this difference seems to be the age of the participant's samples, the tools used, and the follow-up period. The participants in the study included young people, while Haller's study participants were middle-aged.

Given that by increasing age, bone and joints pain is more (27), this could be a factor in the difference in the results of the two studies. Also, McGill questionnaire was used in this study, and Oswestry questionnaire was used in Haller's study. On the one hand, in the present study, the patients were followed up for one month after the end of the intervention to monitor the effectiveness of treatment, but this was not done in Haller's study (21). Therefore, according to the researchers' experiences during the study, such complementary medical interventions should be considered non-medicine approaches and other commonly used treatments and care for patients. It should be noted that doing such activities in hospitals, physicians' offices, and other health care institutions requires the knowledge of the care team members, including physicians, nurses, and other members. The provision of special rooms for complementary medical therapies, especially craniosacral therapy, is one of the most useful measures in hospitals and other treatment centers, which can be mentioned according to the study results. Because by doing interventions in complementary medicine, especially craniosacral therapy, nurses and other members of the treatment team are in a better position to meet the needs of their patients. It is recommended to conduct further studies on samples with different age ranges, varying duration of intervention, and further follow-up.

Limitations of the study

Failure to control confounding factors such as rest rate per day and the amount of walking distance per day is one of the limitations of the present study.

Conclusion

Regarding chronic back pain in nurses, performing craniosacral therapy technique is recommended as an intervention that effectively reduces chronic back pain. The study results showed that craniosacral therapy reduces the pain intensity of nurses with chronic back pain, especially in sensory perception. The study results can be used as an appropriate method for reducing back

pain in these patients. Considering the positive effect of craniosacral therapy on chronic back pain, it can be used as a treatment along with other back pain therapies.

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Conflict of interest

No conflict of interests has been reported by the authors or by any individuals in control of the content of this article.

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