Feasibility and Efficacy of Craniosacral Therapy on Sleep Quality in Fibromyalgia Syndrome: a Pre-Post Pilot Trial

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Background: Sleep disturbance is one of the key symptoms of fibromyalgia syndrome (FMS), which negatively affects the participants' quality of life. Craniosacral therapy (CST) is a gentle manual technique found to have significant effects on pain and function in chronic pain participants. However, limited evidence exists on its effectiveness on sleep quality in FMS participants.

Purpose: To evaluate the feasibility and effectiveness of CST on sleep quality in FMS participants.

Setting: Outpatient physiotherapy department of a hospital in Bangalore.

Participants: Participants diagnosed with FMS.

Research Design: A pre/post pilot trial.

Intervention: Once weekly, 45-minute sessions of CST for 12 weeks. The participants continued the standard medical care prescribed by the physician.

Main Outcome Measure: The sleep quality was evaluated using Pittsburgh Sleep Quality Index (PSQI) at baseline and 12 weeks. The data analysis was carried out using paired *t* test.

Results: 9 out of 10 included participants completed the treatment and were included for analysis. The results of the paired t test showed significant improvement in the global PSQI score ($p = .001$, mean difference = 5.44±3.28, 95% CI = 2.92-7.97), as well as the 5 components of PSQI ($p < .05$).

Conclusion: CST was feasible to deliver with high retention, acceptability, and minimal adverse events. It significantly improved sleep quality in FMS participants along with standard medical care. However, future studies with larger sample sizes and appropriate control groups are required to confirm the findings.

KEYWORDS: chronic pain; complementary therapies; craniosacral massage; fibromyalgia; sleep

INTRODUCTION

Fibromyalgia syndrome (FMS) is a chronic disorder with pain in at least 4 out of 5 regions of the body along with somatic symptoms such as fatigue, waking up unrefreshed, and difficulties in cognition.[1] It is prevalent among 2.7% of the global population.[2] Sleep impairment is one of the core symptoms in FMS participants, which impairs the health-related quality of life.[3,4] Poor sleep is seen in 90% of FMS participants.[5,6] The FMS participants commonly complain of difficulty initiating or maintaining sleep, reduced total sleep time, multiple awakenings at night, feeling unrefreshed and tired on waking up, and lack of deep sleep.[5,7] The objective features of impaired sleep include deprived "slow-wave sleep (SWS)", dominant alpha frequency in "non-rapid eye movement (NREM) sleep", extended "sleep latency", and recurrent switches between sleep phases. It is found that the disruption of synaptic transmission during impaired

SWS may disturb the inhibitory mechanisms of pain, resulting in heightened susceptibility to noxious and innoxious sensations. This phenomenon could explain the role of disturbed sleep in central sensitization and polysymptomatology in FMS.[3,8] Thus, treatment strategies focusing on identifying and intervening with sleep problems can curtail the morbidness in FMS.[5,7–9]

The usage of complementary and alternative therapies is highly prevalent in FMS participants.[10,11] These therapies' high acceptance rate and safety make their use recommendable in FMS management.[12,13]

Craniosacral therapy (CST) is a manual therapeutic technique that uses light touch over the body to evaluate the delicate craniosacral rhythm. The craniosacral (CS) system is composed of the meningeal, fascial, and bony structures of the cranium and spinal column. Presumably, the CST technique intends to unwind the restrictions or impairments in the CS system. Such processes are thought to influence the performance of the central nervous system, and the visceral, endocrinal, and immunological systems via the autonomic pathways.[14] The available evidence demonstrates the effects of CST in primary health care.[15] A qualitative study found that people usually opt for CST for numerous chronic disorders such as back pain, headache, chronic fatigue, anxiety, and depression.[16]

A recent meta-analysis by Haller et al. suggested that CST can have significant effects in chronic pain disorders such as neck pain, backache, migraine, fibromyalgia, and pelvic pain.[17] However, the study reported only two randomized controlled trials (RCTs)[18,19] conducted in FMS. Moreover, both studies were conducted at the same geographical location, and participants were recruited from a fibromyalgia association (non-probabilistic convenience sampling). Furthermore, only one study evaluated the sleep quality in which poor sleepers were not identified for inclusion in the study. The number of CST sessions also varied among the studies included in the review.[17]

Thus, the objective of the current study was to evaluate the feasibility of delivering a 12-week CST protocol in FMS participants identified as poor sleepers visiting a hospital setting, and to determine its effectiveness on sleep quality in FMS in the Indian population.

METHODS

The current study is a "pre/post pilot trial" conducted at the physiotherapy department of Manipal Hospital, Bangalore. The study was approved by the Manipal Hospital's ethics committee. The participants diagnosed with FMS using the "2016 Revisions to the 2010/2011 American College of Rheumatology (ACR) fibromyalgia diagnostic criteria"[1] were referred by the physician to the physiotherapy department. They were then evaluated for their eligibility for the study. Those found eligible were asked for their consent to participate in the study. The study procedure is illustrated in Figure 1.

Inclusion Criteria

Male and female FMS participants diagnosed for at least one year and identified as poor sleepers (Pittsburgh Sleep Quality Index > 5)[20] were enrolled.

Exclusion Criteria

Participants were excluded if they: a) had concomitant inflammatory rheumatic diseases, uncontrolled endocrine disorders, b) were engaged in mindfulness or meditative therapies such as Cognitive Behavioral Therapy (CBT), c) had diagnosed psychological or neurological disorders, or d) were contraindicated to CST. CST is contraindicated in conditions that may have concerns with intracranial/intraspinal fluid pressure changes such as acute stroke, cerebral aneurysm, hemorrhage, herniated medulla oblongata, and recent skull fracture.

Intervention

The intervention was delivered by a physiotherapist trained in CST with 10 years of experience practicing CST. The participants received once-a-week, 45 min CST sessions for 12 weeks. The intervention was delivered in an enclosed room with the patient lying in a supine position on the plinth. The therapist sat on a stool beside the patient. The CST protocol consisted of 10 steps: still point (at feet), diaphragms release (pelvic, respiratory, thoracic inlet, hyoid, occipital cranial base), sacral techniques, dural tube rock/glide, frontal lift, parietal lift, sphenobasilar compression-decompression, temporal bone techniques, temporomandibular joint compression-decompression, and

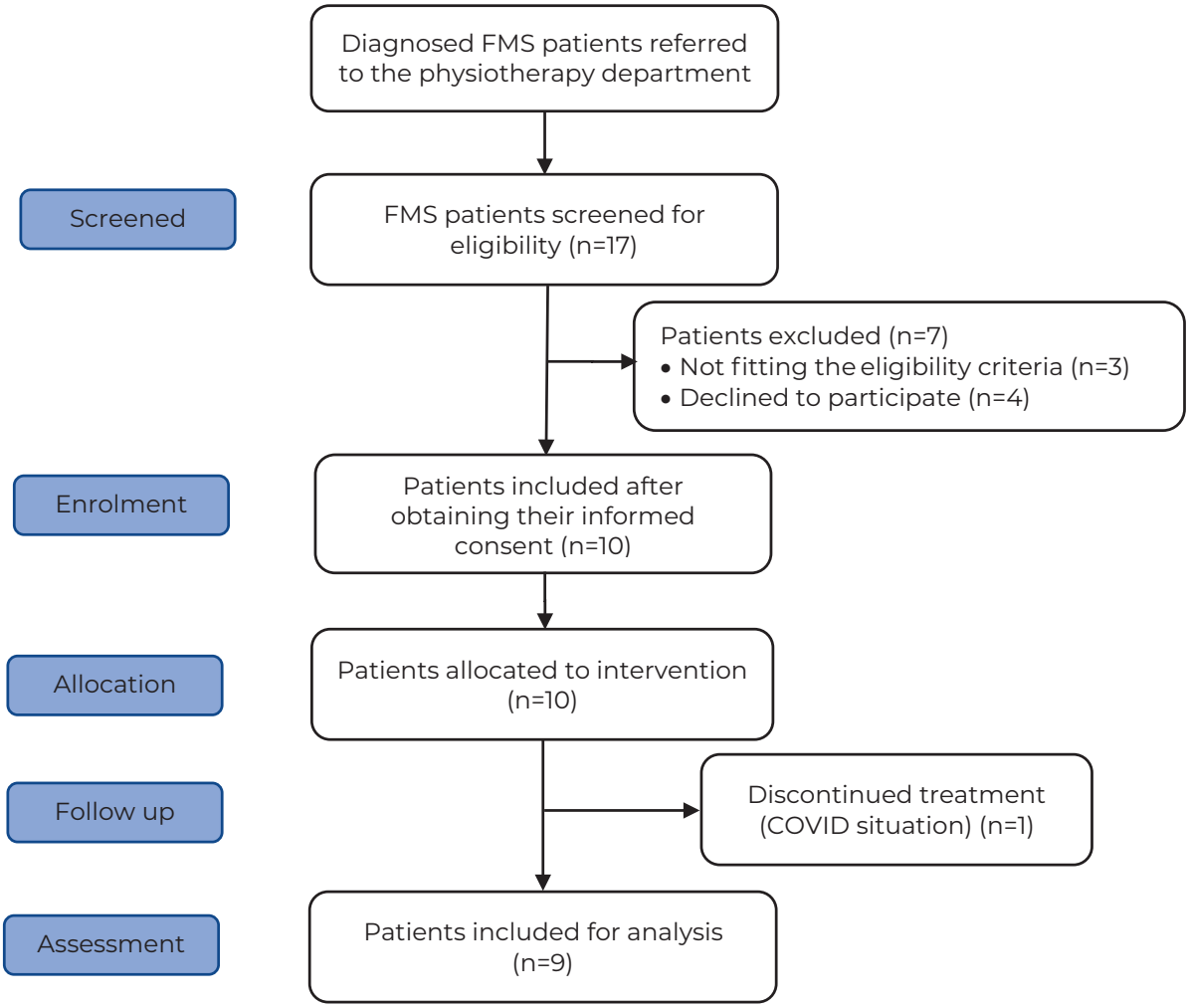

Figure 1. CONSORT flow chart

still point at occiput (CV-4).[21,22] At the end of the treatment session, the participants were allowed to lie on the plinth for 5 min. During the study period, the participants continued to receive the standard medical care as prescribed by the physician, which consisted of education about fibromyalgia, sleep hygiene, and medications.

Outcome

The outcomes were taken at baseline and the end of 12 weeks of intervention. The primary outcome of the study was the Pittsburgh Sleep Quality Index (PSQI). It has seven components: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbance, use of sleep medication, and daytime dysfunction. Its good clinimetric properties (Cronbach's alpha, α = 0.83 and test/retest reliability [Pearson's correlation coefficient, r = 0.85]) make it a reliable and valid tool to evaluate an individual's sleep quality and use it for research activities.[20] At the end of 12 sessions of the therapy, the therapist took an oral feedback from the participants regarding their acceptance and satisfaction by asking them to rate the same as poor, fair, good or very good.

The demographic data consisted of age, gender, height, weight, education, diet, addiction, marital and employment status, fibromyalgia duration, medications, associated illness, and physical activity level.

Statistical Analysis

Descriptive statistics were used to compute the mean and standard deviation (SD) for continuous variables and frequency and percentage for qualitative variables. The normality of the data was checked using the Shapiro-Wilk test. Pre/post differences

for the sleep variables were evaluated using paired *t* test for normally distributed data and Wilcoxon's signed-rank test for skewed data. A *p* value less than .05 was considered statistically significant.

RESULTS

Ten FMS participants were recruited for the study, out of which one patient dropped out after two CST sessions due to the COVID pandemic situation prevalent during that period. The mean age of the included participants was 34.22 ± 7.31 years, with a mean PSQI score of 12.44 ± 4.28 and a mean fibromyalgia symptom duration of 3.89 ± 3.38 years. The baseline characteristics of the included participants are presented in Table 1. Table 2 represents the results of the paired *t* test.

The global sleep score of PSQI improved significantly at the end of 12 weeks of CST sessions ($p = .001$, mean difference = 5.44, CI = 2.92–7.97). The component scores such as "subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, and daytime dysfunction" also showed significant improvement ($p < .05$) posttreatment. Figure 2 represents the mean paired differences of PSQI global and component scores.

The mean sleep duration increased by 63 min posttreatment, with a mean sleep latency reduction of 39 min. 77.8%

TABLE 1. Baseline Characteristics of FMS Participants (n=9)

Domain	*Mean (SD)*
Age (years)	34.22(7.31)
Gender (F: M)	9:0
BMI (Kg/m2)	24.37(3.09)
FMS duration (years)	3.89(3.38)
PSQI global (0-21)	12.44 (4.28)
Education (%) Bachelors/Masters	33.3/66.7
Employment (%) Working/non-working	77.8/22.2
Marital status (%) Married/Unmarried	66.7/33.3
Socioeconomic status (%) Good	100
Diet (%) Vegetarian/Non-vegetarian/Mixed	77.8/11.1/11.1
Physical activity level (%) Low/Moderate	77.8/22.2
Medications (%) Anti-convulsants/Analgesics/ Anti-depressants/Supplements	66.7/55.6/33.3/100
Comorbidities (%) Present/Absent	66.7/33.3

F = female; M = male; BMI = Body Mass Index; FMS = Fibromyalgia Syndrome; PSQI = Pittsburgh Sleep Quality Index.

TABLE 2. Results of Paired *t* Test

	Paired Sample t Test							
	Paired Differences							
				95% CI of the Difference				
Domain	*Mean*	*SD*	*Standard Error Mean*	*Lower*	*Upper*	*t*	*df*	*Sig. (2-tailed)*
PSQI	5.44	3.28	1.09	2.92	7.97	4.98	8	0.001[a]
SQ	1.22	0.83	0.28	0.58	1.86	4.40	8	0.002[a]
SL	0.78	0.97	0.32	0.03	1.53	2.40	8	0.043[a]
SDU	0.89	1.05	0.35	0.08	1.70	2.53	8	0.035[a]
HSE	1.22	1.30	0.43	0.22	2.22	2.82	8	0.023[a]
SD	0.22	0.44	0.15	-0.12	0.56	1.51	8	0.169
DD	0.89	0.93	0.31	0.18	1.60	2.87	8	0.021[a]

[a]$p < .05$ – significant
PSQI = Pittsburgh Sleep Quality Index; SQ = subjective sleep quality; SL = sleep latency; SDU = sleep duration; HSE = habitual sleep efficiency; SD = sleep disturbances; DD = daytime dysfunction.

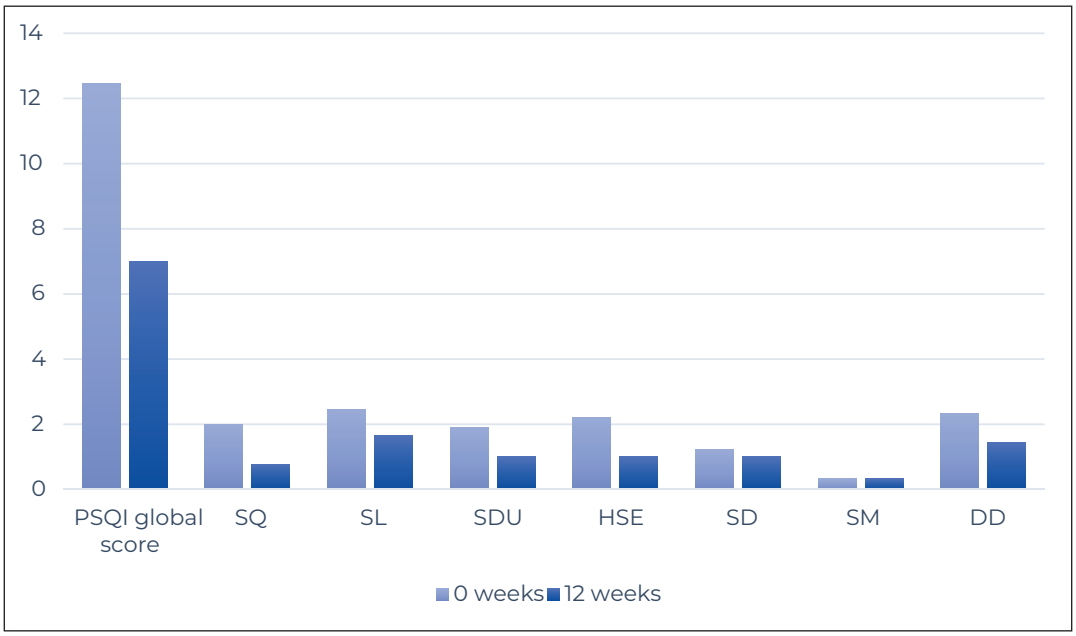

Figure 2. Mean sleep scores before and after intervention

PSQI = Pittsburgh Sleep Quality Index; SQ = subjective sleep quality; SL = sleep latency; SDU = sleep duration; HSE = habitual sleep efficiency; SD = sleep disturbances; SM = use of sleeping medication; DD = daytime dysfunction.

of participants had a sleep efficiency of >75% posttreatment as opposed to 22.2% pretreatment. The sleep efficiency of 22.2% of participants was > 85% posttreatment as opposed to 0% pretreatment, which demonstrated clinical improvement according to Edinger et al.[23] Fifty per cent of participants in our study reported a mean sleep duration of 6.5 hrs or more posttreatment. This result was considered clinically improved, as evidenced by Edinger et al.[23]

The recruitment rate in the study was 59% (10 out of 17 participants were recruited), and the retention rate was 90% (9 out of 10 participants completed all 12 CST sessions). The adverse event rate was 10%. One out of ten participants reported a mild increase in pain for two days after the therapy. On asking for feedback on their satisfaction with the therapy, six participants rated it as good, with three of the nine participants rating it as fair. Two out of nine participants volunteered this information.

DISCUSSION

Our study is one of the first studies conducted in India which aimed to evaluate the feasibility and efficacy of CST on sleep quality in FMS participants. The results of the pilot trial indicated significant positive effects of CST on the PSQI global and component scores after 12 weeks of intervention. The therapist found minimal difficulty with the implementation and delivery of the protocol. The participants found the intervention acceptable, which was demonstrated by their satisfaction with the intervention. The high retention rate and low minimal adverse events demonstrate the feasibility of the CST protocol. However, the low recruitment rate could be a challenge for the timely completion of a future RCT.

The results of our 12-week study were in line with those of a 25-week study conducted by Mataran-Panarrocha et al., which demonstrated significant improvements in PSQI total and component scores (sleep duration and sleep disturbance) posttreatment.[19] Similar results were also demonstrated in studies evaluating the effects of mindfulness[24,25] and CBT[26,27] on sleep quality in FMS participants.

The mean paired differences of the PSQI global score (5.44) in our study exceeded the minimum clinically significant difference of 3.[28] The sleep duration and sleep efficiency also improved clinically[23] in 50% and 22.2% of participants, respectively, posttreatment. Similar results were found in a study using CBT for insomnia in FMS participants, which demonstrated clinically

significant differences in total sleep duration (in 33.33% of participants) and sleep efficiency (in 36.6% of participants).[26]

The probable reason for the improvement in sleep quality could be the normalization of the autonomic nervous system (ANS) activity.[29] Autonomic dysfunction is a characteristic feature of FMS which correlates with FMS symptom severity.[30] The ANS holds a vital role in sleep physiology.[31] Evidence shows that CST might alter the ANS function by switching sympathetic overactivity to parasympathetic dominance.[29,32,33] CST modifies the rhythm of the craniosacral system and regulates and relaxes the physiological systems[14,17,34] and thus may influence sleep quality. The improvement in sleep quality could also be related to the natural progress of the condition, the placebo effect of touch, therapist-patient interaction, or the effect of the CST itself.

Although all participants followed the same treatment regime, certain variables could have influenced the study outcome. Two participants did not take FMS medications throughout the treatment duration of 12 weeks (one patient was planning for pregnancy, and the other patient stopped taking medicine after two weeks). The physical activity level was low in all participants except for two moderately active participants. Two participants underwent additional treatment sessions with a psychologist (one patient took 2 sessions, and the other took 6 sessions).

Limitations & Future Implications of the Research

The limitations of this pilot study were: a) there was no control group in the study, and a manual control group, such as a placebo touch, should be added in future trials; b) the study was limited to a small sample size, therefore future trials need to be conducted on a large sample; and c) PSQI is a subjective measure of sleep quality. Henceforth, polysomnograms and autonomic nervous system parameters can be used as objective measures in future trials to evaluate the effects of CST on sleep.

Clinical Relevance

The current pilot study gives insights into CST as an alternative treatment option to manage disturbed sleep in FMS participants. CST may be used in conjunction with other interventions to manage sleep and FMS symptoms.

CONCLUSION

The 12-week CST protocol was feasible to deliver with high retention, good acceptability, and minimal adverse events in FMS participants. CST, along with standard medical care, significantly improved sleep quality in FMS participants. Future RCTs with a large sample size and appropriate control group need to be conducted to confirm the findings.

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CONFLICT OF INTEREST NOTIFICATION

The authors declare there are no conflicts of interest.

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