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Original Research Article

# Effectiveness of craniosacral therapy, Bowen therapy, static touch and standard exercise program on sleep quality in fibromyalgia syndrome: A randomized controlled trial

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ABSTRACT

*Background:* Sleep disturbance is commonly seen in fibromyalgia syndrome (FMS); however, high quality studies involving manual therapies that target FMS-linked poor sleep quality are lacking for the Indian population.

*Objective:* Craniosacral therapy (CST), Bowen therapy and exercises have been found to influence the autonomic nervous system, which plays a crucial role in sleep physiology. Given the paucity of evidence concerning these effects in individuals with FMS, our study tests the effectiveness of CST, Bowen therapy and a standard exercise program against static touch (the manual placebo group) on sleep quality in FMS.

*Design, setting, participants and intervention:* A placebo-controlled randomized trial was conducted on 132 FMS participants with poor sleep at a hospital in Bangalore. The participants were randomly allocated to one of the four study groups, including CST, Bowen therapy, standard exercise program, and a manual placebo control group that received static touch. CST, Bowen therapy and static touch treatments were administered in once-weekly 45-minute sessions for 12 weeks; the standard exercise group received weekly supervised exercises for 6 weeks with home exercises until 12 weeks. After 12 weeks, all study participants performed the standard exercises at home for another 12 weeks.

*Main outcome measures:* Sleep quality, pressure pain threshold (PPT), quality of life and fibromyalgia impact, physical function, fatigue, pain catastrophizing, kinesiophobia, and positive–negative affect were recorded at baseline, and at weeks 12 and 24 of the intervention.

*Results:* At the end of 12 weeks, the sleep quality improved significantly in the CST group ($P = 0.037$) and Bowen therapy group ($P = 0.023$), and the PPT improved significantly in the Bowen therapy group ($P = 0.002$) and the standard exercise group ($P < 0.001$), compared to the static touch group. These improvements were maintained at 24 weeks. No between-group differences were observed for other secondary outcomes.

*Conclusion:* CST and Bowen therapy improved sleep quality, and Bowen therapy and standard exercises improved pain threshold in the short term. These improvements were retained within the groups in the long term by adding exercises. CST and Bowen therapy are treatment options to improve sleep and reduce pain in FMS.

*Trial registration number:* Registered at Clinical Trials Registry of India with the number of CTRI/2020/04/024551.

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## 1. Introduction

Fibromyalgia syndrome (FMS) is a multi-symptom chronic condition featuring widespread pain accompanied by symptoms such as fatigue, sleep disturbance, cognitive dysfunction, anxiety, depression and somatic symptoms with varying degrees of severity [1]. The global FMS prevalence varies from 0.20% to 6.60% [2] with a mean of 1.78% [3] to 2.10% [4]. The mean prevalence in Asia is 1.64% [4]. The FMS prevalence in India ranges from 0.04% to 3.24% in the urban and 0.14% to 4.34% in the rural population [5,6]. It is higher in females, with a female to male ratio of 4:1 [3,4]. FMS more commonly arises between the ages of 30–50 years or after the age of 50 years [7].

FMS has emerged as one of the most prevalent musculoskeletal disorders after osteoarthritis [5,6,8,9]. The heterogeneity of FMS symptoms results in reduced function, work output and quality of life. This makes FMS an economic burden to those who suffer from it and to the medical system. Thus, effective management of FMS can help to curtail the costs associated with the disorder [10].

About 90% of FMS patients complain of sleep disturbance [11,12], which negatively affects their health-related quality of life. The patients find it difficult to fall or stay asleep; they wake up frequently at night and thus are unrefreshed; they feel tired throughout the day or unable to achieve deep sleep. These problems result in "poor sleep quality, reduced sleep duration, increased sleep onset latency and reduced sleep efficiency, affecting total wake time" [13,14]. Slow-wave sleep is reduced in FMS, during which the inhibition of synaptic transmission is impaired. Thus, the descending inhibitory pain mechanisms are disrupted, causing an increased response to pain and other sensations. This mechanism explains how sleep disruptions contribute to central sensitization and polysymptomatology in FMS [14–16]. Hence, identifying and managing sleep disturbances may contribute to more effective treatment of FMS [15,16].

FMS management includes education and an individually tailored multimodal approach, comprising pharmacological and non-pharmacological treatments [17,18]. Complementary and alternative therapies (CATs) are frequently chosen by individuals with FMS [19,20]. The modest, short-term efficacy of drugs, which also are associated with adverse effects, encourages FMS individuals to try CATs [21–23]. Furthermore, these therapies are highly accepted by FMS individuals and reported to be safe [24,25]. Thus, integrating CATs into conventional approaches may contribute to the holistic and effective management of FMS symptoms [20]. Despite the common usage of these therapies in FMS, the evidence for their efficacy is poor and inconclusive [26–28].

Craniosacral therapy (CST) is a gentle, manual technique that employs light touch over several body regions (feet, back and head) to evaluate the craniosacral system's delicate rhythmic motions. It is hypothesized to unwind the restrictions in the craniosacral system, composed of the meninges, the fascia and the bones of the skull and vertebral column. It is also thought to improve the performance of central nervous system and help release physical and emotional stress, thus contributing to an individual's overall well-being [29]. CST has been used to treat chronic pain, depression, seizure and headaches to improve pain and function [29,30].

Bowen therapy is another gentle release approach that involves finger or thumb sequences over muscles or tendons. It stimulates the mechanoreceptors in the fascia, namely the Golgi tendon organ, Ruffini corpuscles and interstitial receptors. The slow, steady muscle movement reduces the sympathetic tone, increases the vagal activity, and produces a great sense of relaxation. The technique results in the re-organization of the nervous pathways, thus enhancing repair [31–33]. A systematic review reported the beneficial effects of Bowen therapy in chronic pain, frozen shoulder and migraine [34].

Touch influences the physical, emotional, intellectual and behavioral development of individuals in various ways [35–37]. Evidence shows that treatment modalities using interpersonal touch may lower the emotional and biological stress in intensive care patients [38]. Thus, static touch can act as a manual placebo group to control for the effectiveness of manual interventions involving touch.

Exercise is a strongly recommended non-pharmacological approach in FMS management [39]. Exercises are believed to stimulate the hypothalamus, increase the plasma levels of neurotransmitters such as β-endorphins and lipotrophins, improve mood, and reduce pain, fatigue, anxiety and depression [40–44]. Several studies have suggested that exercises can be effective for FMS management [45–47].

Autonomic and hypothalamic–pituitary–adrenal axis alterations are characteristic features of FMS [48]. The autonomic nervous system plays a crucial role in sleep physiology by regulating the sleep/wake cycle via its sympathovagal balance [49,50]. CST, Bowen therapy and aerobic exercises may influence the autonomic nervous system, establishing a balance between sympathetic-parasympathetic activity [51–53].

CST and Bowen therapy are manual therapies that have beneficial effects on pain and function in chronic pain [30,34]. Nonetheless, there is limited evidence on the effects of these interventions on sleep quality in FMS and studies targeting poor FMS sleepers. Moreover, the effects of these therapies have not been compared with a standard treatment, like exercise, and a manual control group, like static touch in FMS. Hence, the present study evaluates the effects of CST, Bowen therapy, static touch and a standard exercise program (SEP) on sleep quality in FMS.

## 2. Methods

The study was a randomized parallel-group placebo-controlled trial and lasted for 24 weeks, including a 12 week intervention period and a follow-up at 24 weeks. The Institutional Research Committee and the Scientific and Ethics Committee of Manipal Hospital, Bangalore approved the study. The study was registered at the Clinical Trials Registry of India (CTRI/2020/04/024551). Participants were recruited from July 2020 to June 2022. The study was completed in December 2022. The consulting physician referred the study participants to the outpatient physiotherapy department of Manipal Hospital, Bangalore, where the intervention was administered.

### 2.1. Study participants

Male and female study participants aged 18–60 years, who had suffered from FMS for at least 1 year, as diagnosed using the "2016 Revisions to the 2010/2011 Fibromyalgia Diagnostic Criteria" from

the American College of Rheumatology [54], and were identified as poor sleepers, with a Pittsburgh Sleep Quality Index (PSQI) > 5 [55] were enrolled. Participants were excluded if they: (a) had concurrent inflammatory rheumatic diseases or uncontrolled endocrine disorders; (b) were engaged in mindfulness or meditative therapies such as cognitive behavioral therapy for the past 6 months; (c) had been diagnosed with psychological or neurological disorders; (d) had contraindications for CST, Bowen therapy or exercises.

### 2.2. Randomization and allocation

The participants were randomly allocated to one of the four groups: CST and Bowen therapy groups (intervention groups), static touch group (placebo group) and SEP group (control group). An investigator uninvolved in the trial conducted the randomization process using computer-generated block randomization (11 blocks of 12 participants) with a 1:1 allocation ratio. The allocation sequence was placed in sequentially numbered opaque sealed envelopes.

### 2.3. Study procedure

The FMS participants visiting the physiotherapy department of Manipal Hospital, Bangalore were screened for eligibility. The principal investigator explained the study's purpose to the eligible participants and obtained written informed consent from those willing to participate. The participants were briefed about the evaluation procedure. Baseline information, including demographic data and outcomes, was recorded. The participants were randomly allocated to one of the four groups, and the treating therapist administered the treatment according to the random group allocation. The outcomes were taken at baseline, at the end of the 12th week and again at the end of week 24.

### 2.4. Interventions

The interventions were delivered by a certified physiotherapist (with more than 15 years of clinical experience) who was trained in CST and Bowen therapy and had practiced these therapies for 5 years [56]. The participants in the manual treatment groups (CST, Bowen therapy and static touch) received 45-minute, once-a-week supervised sessions for 12 weeks. The standard exercise participants received 6 supervised exercise sessions over the course of the first 12 weeks of the study (the 1st, 2nd, 3rd, 5th, 9th and 12th weeks) and carried out two additional home exercise sessions during the weeks in which they received exercise instruction. During the rest of the 12-week intervention period they performed these home exercises three times a week. All the outcomes were evaluated at the end of the 12-week intervention, and participants in all groups were instructed to do the SEP at home for an additional 12 weeks. They were also instructed to record their exercises in an exercise log sheet. Thus, exercise logs and telephone communications (every 2 weeks) were used to monitor exercise adherence in each group. Exercise videos were shared with all the participants to assist with exercise performance at home. After the 24th week, the participants had a follow-up assessment and exercise adherence was noted.

All the participants received standard care, including education about FMS, sleep hygiene and physician-prescribed medicines. We called the participants on different days to prevent contamination of the treatments. The participant's physical activity was assessed through the WHO Global Physical Activity Questionnaire [57] and noted throughout the study period. Any changes in treatments or medications were noted to assess how they affected the results. The investigator asked the participants to report any adverse event they experienced during the study period. The adverse event (if any) was reported to the ethics committee and the consulting physician, and any necessary actions were taken.

#### 2.4.1. CST

The CST protocol involved applying light touch (approximately 5 g) at different body regions and palpating and manipulating the craniosacral rhythm. A ten-step sequence was followed: still point (at feet), diaphragms release (pelvic, respiratory, thoracic inlet, hyoid and occipital cranial base), sacral techniques, dural tube rock/glide, frontal lift, parietal lift, sphenobasilar compression-decompression, temporal bone techniques, temporomandibular joint compression-decompression, and still point at occiput (fourth ventricle, CV-4) [58–60].

#### 2.4.2. Bowen therapy

The Bowen therapy consisted of sequential thumb and finger moves interspersed with a 2-minute pause between the moves. The protocol comprised the following sequence of muscles: erector spinae (left and right), gluteus medius (left and right), biceps femoris (left and right), iliotibial band (left and right), longissimus thoracis (4 points), lower trapezius (left and right), rhomboids major (left and right) and rhomboids minor (left and right), levator scapulae (left and right), latissimus dorsi (left and right), erector spinae (8 points), posterior and middle scalene (left and right), semispinalis capitis (left and right), upper trapezius (left and right), levator scapulae (left and right) and the head procedure [61].

#### 2.4.3. Static touch

It comprised placing a hand over landmarks common to CST and Bowen therapy. The following sequence was used: sacrum, lumbar region (L3–L4) (left and right), thoracic region (T10–T12) (left and right), neck, thigh (left and right), scapula (left and right), posterolateral hip (left and right), forehead, lateral aspect of the head (left and right) and occiput. The therapist held their hand for 3 min at each position without any movement or intention to manipulate. The intervention started with the sacrum and ended with the head procedure (9–10 min) so that the total duration of each session was the same as other manual interventions (45 min).

#### 2.4.4. SEP

The SEP consisted of aerobic, stretching and strengthening exercises prescribed by the American College of Sports Medicine's FITT (frequency, intensity, time and type of exercise) recommendations for individuals with FMS [62]. The exercise program included 5 min of warm-up, 30–60 min of aerobic exercise training, 10 min each of stretching and strengthening exercises, and 5 min of cool down. The exercises were performed three times a week, increasing to 4 or 5 days depending on the participant's capacity. The exercises were started with light intensity, increasing to a moderate level, as scored by the Borg's rate of perceived exertion scale, ranging from 6 to 20 [62].

The aerobic part of the exercise program included brisk walking, swimming or cycling, depending on the participant's preference. Stretching exercises consisted of triceps, pectorals, calf, hamstring, quadriceps, erector spinae, trapezius and levator scapulae. Strengthening exercises started with static exercises of deep cervical flexors, scapular muscles, abdominals, back extensors, glutei, quadriceps and hamstrings, followed by dynamic upper and lower limbs and trunk exercises. The resistance exercises were performed using elastic bands/weight cuffs and body weight. The exercises were customized according to each participant's comfort and capacity to perform. The progression rate of the exercises depended on the symptoms and response of the participant. The participants were advised to modify, reduce the intensity, or avoid

a particular exercise when their symptoms worsened. The details of the exercise program can be found in the study protocol [56].

### 2.5. Outcomes

The primary outcome was PSQI and was used to evaluate sleep quality. PSQI has 7 components: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbance, use of sleep medication and daytime dysfunction. Each domain is scored from 0 to 3 with 0 = no difficulty and 3 = severe difficulty. All the domain scores are then totalled to get a global score from 0 to 21, with higher scores indicating worse sleep quality. A PSQI score > 5 can differentiate good and poor sleepers with a sensitivity of 89.60% and specificity of 86.50%. It has good internal consistency (Cronbach's $\alpha = 0.83$) and test–retest reliability (Pearson's correlation coefficient, $r = 0.85$) and validity [55].

The secondary outcome of the study was pressure pain threshold (PPT). PPT was evaluated utilizing a pressure algometer at 9 paired points on the body as determined by the American College of Rheumatology's 1990 criteria (occiput, lower cervical, mid trapezius, supraspinatus, second rib, lateral epicondyle, gluteal, greater trochanter and medial knee) [63]. A PPT value < 4 kg/cm$^2$ was counted as a tender point [63]; accordingly, the total number of tender points was calculated. The average PPT of all 18 points (PPT total) was calculated and noted.

The other outcomes related to general and specific quality of life issues were evaluated on separate scales: quality of life and fibromyalgia impact were evaluated using the Revised Fibromyalgia Impact Questionnaire (FIQR) [64]; physical function was tested using the Patient-Reported Outcomes Measurement Information System–Physical Function-Short-Form (PROMIS-PF) [65]; fatigue was tested using the Multidimensional Assessment of Fatigue

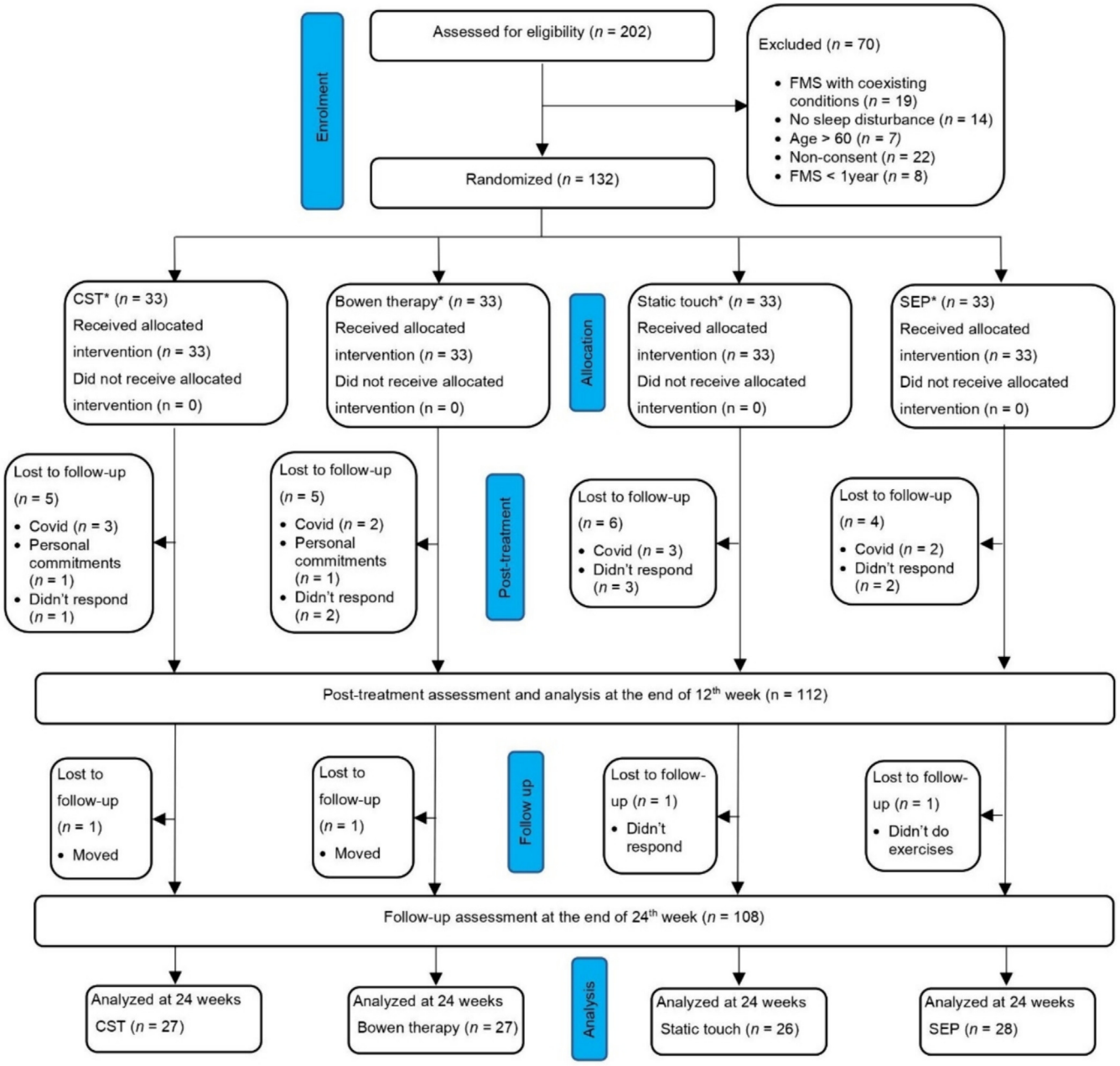


**Fig. 1.** CONSORT flow chart. FMS: fibromyalgia syndrome; CST: craniosacral therapy; SEP: standard exercise program; COVID: corona virus disease. *Standard care was given along with the intervention.

(MAF) [66]; pain catastrophizing was scored on the Pain Catastrophizing Scale (PCS) [67]; kinesiophobia was tested using the Tampa Scale for Kinesiophobia (TSK) [68]; and positive–negative affect was quantified using the Positive and Negative Affect Schedule (PANAS) [69].

### 2.6. Sample size

The sample size computation utilized the repeated measures analysis of variance (ANOVA) [70] formula, and used 80% power, 5% significance level, 3 time points, 0.4 correlation among repeated measures, 4.03 standard deviation of PSQI [71], a minimal clinically important difference (MCID) of 3 [72], and a 20% drop-out rate. A sample size of 132 participants was required in total.

### 2.7. Statistical analysis

The data were analyzed using Jamovi software (version 2.3, Australia). The demographic variables were reported using descriptive statistics. The Shapiro-Wilk test was used to analyze the data's normality. One-way ANOVA and chi-square tests were used to determine the baseline differences between the groups for continuous and categorical variables, respectively. Repeated measures ANOVA was used to analyze the main effects for the time, group, and time-group interaction for all outcomes. The

**Table 1**
Demographic data of the study participants.

| Variable | CST ($n$ = 33) | Bowen ($n$ = 33) | Static touch ($n$ = 33) | SEP ($n$ = 33) | $P$ value |
|---|---|---|---|---|---|
| Age (year, mean ± SD) | 37.15 ± 10.80 | 37.15 ± 9.55 | 42.36 ± 11.14 | 37.42 ± 11.65 | 0.140 |
| BMI (kg/m$^2$, mean ± SD) | 25.44 ± 4.32 | 26.18 ± 4.59 | 28.04 ± 4.30 | 27.37 ± 5.73 | 0.120 |
| Gender ($n$ [%]) | | | | | 0.738 |
| Female | 30 (90.91%) | 30 (90.91%) | 31 (93.94%) | 28 (84.85%) | |
| Male | 3 (9.09%) | 3 (9.09%) | 2 (6.06%) | 5 (15.15%) | |
| Employed ($n$ [%]) | | | | | 0.015 |
| Yes | 20 (60.61%) | 21 (63.64%) | 13 (39.39%) | 10 (30.30%) | |
| No | 13 (39.39%) | 12 (36.36%) | 20 (60.61%) | 23 (69.70%) | |
| Education ($n$ [%]) | | | | | 0.002 |
| School | 1 (3.03%) | 2 (6.06%) | 8 (24.24%) | 7 (21.21%) | |
| Bachelors | 18 (54.55%) | 14 (42.42%) | 21 (63.64%) | 12 (36.36%) | |
| Masters | 14 (42.42%) | 17 (51.52%) | 4 (12.12%) | 14 (42.42%) | |
| Marital status ($n$ [%]) | | | | | 0.296 |
| Married | 23 (69.70%) | 24 (72.73%) | 29 (87.88%) | 24 (72.73%) | |
| Unmarried | 10 (30.30%) | 9 (27.27%) | 4 (12.12%) | 9 (27.27%) | |
| Socioeconomic status ($n$ [%]) | | | | | 0.529 |
| Upper middle | 31 (93.94%) | 30 (90.91%) | 29 (87.88%) | 27 (81.82%) | |
| Lower middle | 2 (6.06%) | 3 (9.09%) | 4 (12.12%) | 6 (18.18%) | |
| Physical activity level ($n$ [%]) | | | | | 0.265 |
| Low | 25 (75.76%) | 20 (60.61%) | 18 (54.55%) | 18 (54.55%) | |
| Moderate | 8 (24.24%) | 13 (39.39%) | 15 (45.45%) | 14 (42.42%) | |
| High | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 1 (3.03%) | |
| Diet ($n$ [%]) | | | | | 0.690 |
| Vegetarian | 16 (48.48%) | 15 (45.45%) | 17 (51.52%) | 10 (30.30%) | |
| Non-vegetarian | 6 (18.18%) | 7 (21.21%) | 6 (18.18%) | 10 (30.30%) | |
| Mixed | 11 (33.33%) | 11 (33.33%) | 10 (30.30%) | 13 (39.39%) | |
| Comorbidities ($n$ [%]) | | | | | |
| Diabetes mellitus | 1 (3.03%) | 1 (3.03%) | 3 (9.09%) | 6 (18.18%) | 0.120 |
| Hypertension | 4 (12.12%) | 3 (9.09%) | 4 (12.12%) | 3 (9.09%) | 0.999 |
| Thyroid disorder | 9 (27.27%) | 13 (39.39%) | 6 (18.18%) | 7 (21.21%) | 0.215 |
| PCOD | 3 (9.09%) | 3 (9.09%) | 2 (6.06%) | 3 (9.09%) | 0.999 |
| Dyslipidemia | 1 (3.03%) | 3 (9.09%) | 2 (6.06%) | 4 (12.12%) | 0.695 |
| Vitamin deficiency | 24 (72.73%) | 24 (72.73%) | 18 (54.55%) | 23 (69.70%) | 0.332 |

BMI: body mass index; CST: craniosacral therapy; PCOD: polycystic ovarian disease; SD: standard deviation; SEP: standard exercise program.

**Table 2**
Baseline clinical characteristics of the included participants.

| Variable | CST ($n$ = 33) | Bowen ($n$ = 33) | Static touch ($n$ = 33) | SEP ($n$ = 33) | $P$ value |
|---|---|---|---|---|---|
| FMS duration (year) | 4.27 ± 3.58 | 4.57 ± 3.60 | 5.55 ± 4.02 | 4.45 ± 6.36 | 0.107 |
| FMS severity score | 22.24 ± 4.39 | 21.82 ± 4.22 | 21.06 ± 4.95 | 20.18 ± 4.93 | 0.291 |
| PSQI global score | 13.36 ± 3.05 | 12.30 ± 3.00 | 12.82 ± 4.02 | 12.12 ± 3.49 | 0.451 |
| PPT total score | 1.73 ± 0.66 | 1.81 ± 0.76 | 1.69 ± 0.79 | 2.09 ± 0.72 | 0.118 |
| FIQR total score | 64.53 ± 16.30 | 60.13 ± 16.85 | 56.49 ± 20.97 | 58.96 ± 15.42 | 0.306 |
| PROMIS-PF score | 30.09 ± 7.60 | 34.45 ± 7.07 | 31.9 ± 8.04 | 32.49 ± 6.31 | 0.129 |
| MAF score | 37.51 ± 6.85 | 35.56 ± 7.90 | 34.17 ± 9.68 | 32.81 ± 8.77 | 0.139 |
| PCS score | 33.81 ± 13.49 | 33.36 ± 11.27 | 27.59 ± 12.82 | 27.42 ± 12.40 | 0.065 |
| TSK score | 43.56 ± 9.62 | 41.19 ± 7.31 | 41.21 ± 8.69 | 39.73 ± 7.58 | 0.324 |
| PANASp | 24.66 ± 8.16 | 27.81 ± 6.58 | 27.38 ± 8.59 | 29.58 ± 9.54 | 0.126 |
| PANASn | 32.69 ± 9.29 | 28.03 ± 8.82 | 24.79 ± 8.34 | 25.91 ± 8.63 | 0.003 |

Data are represented as mean ± standard deviation. CST: craniosacral therapy; FIQR: Revised Fibromyalgia Impact Questionnaire; FMS: fibromyalgia syndrome; MAF: Multidimensional Assessment of Fatigue; PANASp: Positive and Negative Affect Schedule positive affect score; PANASn: Positive and Negative Affect Schedule negative affect score; PCS: Pain Catastrophizing Scale; PPT total: average pressure pain threshold of 18 tender points; PROMIS-PF: Patient-Reported Outcomes Measurement Information System–Physical Function–Short-Form; PSQI: Pittsburgh Sleep Quality Index; SEP: standard exercise program; TSK: Tampa Scale for Kinesiophobia.

Levene's test was used to test the homogeneity of variances. Partial eta squared values were used as the measure of effect size from the repeated measures ANOVA analysis. Tukey's post hoc test was used to compare the effects between groups post-treatment and at follow-up, if there was a statistically significant finding in the interactions. The effect sizes for between-group comparisons were calculated using the formula, *Cohen's* $d = t\sqrt{(\frac{1}{n1} + \frac{1}{n2})}$, where $t$ is the t-statistic and $n_1$ and $n_2$ are the sample sizes of the two groups being compared. The variables that did not follow normal distribution were analyzed using the non-parametric measures (Kruskal-Wallis test for baseline differences and Friedman ANOVA for between group interactions).

## 3. Results

In this study, 132 participants were enrolled and allocated to four groups: CST group, Bowen therapy group, Static touch group and SEP group (Fig. 1). There was significant difference in education and employment status among groups at baseline (Tables 1 and 2). To check if this could affect the result, we performed one-way ANOVA to analyze the difference in the PSQI scores across the levels of education and employment status and found no significant difference. The medication history did not vary significantly across the groups (Table S1).

### 3.1. Sleep quality

The results demonstrated significant interactions for PSQI global (overall sleep quality) ($P < 0.001$), subjective sleep quality ($P = 0.002$), sleep duration ($P = 0.003$) and habitual sleep efficiency ($P < 0.001$) between baseline and the 12th and 24th weeks of the intervention (Table 3).

Tukey's post hoc test showed that significant differences in the mean PSQI global scores were present in the CST group *vs* static touch ($P = 0.037$, Cohen's $d = 0.95$) and Bowen therapy *vs* static touch ($P = 0.023$, Cohen's $d = 0.99$) at 12 weeks. However, there were no differences between the groups at 24 weeks (Table 4). The post hoc test for PSQI subdomains showed no significant difference across the groups.

### 3.2. PPT

Table 5 reports the results of repeated measures ANOVA (group interactions) for PPT and post hoc comparisons for group interactions. The results demonstrated significant group interactions for PPT total (average PPT of all the 18 tender points) ($P < 0.001$) and the number of tender points ($P = 0.033$).

Tukey's post hoc comparisons (Table 5) showed a significant difference in the mean PPT total scores in Bowen therapy group *vs* static touch group ($P = 0.002$, Cohen's $d = 1.42$) and SEP group

**Table 3**
Repeated measures analysis of variance for sleep quality: time × group interactions.

| PSQI score | Time point | CST ($n$ = 27) | Bowen ($n$ = 27) | Static touch ($n$ = 26) | SEP ($n$ = 28) | Time × group interaction | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Mean square | $F$ | $P$ value | Partial eta squared |
| PSQI global | Baseline | 13.63 ± 3.18 | 12.41 ± 2.82 | 12.58 ± 3.87 | 11.68 ± 3.28 | 38.60 | 11.50 | < 0.001 | 0.25 |
| | 12 weeks | 8.19 ± 3.16 | 8.04 ± 3.52 | 11.38 ± 3.76 | 9.82 ± 3.03 | | | | |
| | 24 weeks | 8.11 ± 2.23 | 8.04 ± 4.08 | 11.04 ± 3.91 | 7.96 ± 3.13 | | | | |
| Subjective sleep quality | Baseline | 1.93 ± 0.83 | 1.63 ± 0.69 | 1.65 ± 0.80 | 1.75 ± 0.70 | 1.08 | 4.13 | 0.002 | 0.11 |
| | 12 weeks | 0.78 ± 0.42 | 0.85 ± 0.53 | 1.27 ± 0.78 | 1.11 ± 0.42 | | | | |
| | 24 weeks | 0.93 ± 0.27 | 0.85 ± 0.66 | 1.31 ± 0.79 | 0.93 ± 0.60 | | | | |
| Sleep latency | Baseline | 2.37 ± 0.84 | 2.26 ± 1.02 | 2.42 ± 0.95 | 2.29 ± 0.94 | 0.76 | 1.64 | 0.144 | 0.05 |
| | 12 weeks | 1.67 ± 1.11 | 1.19 ± 0.88 | 1.88 ± 0.95 | 1.82 ± 0.95 | | | | |
| | 24 weeks | 1.44 ± 0.75 | 1.37 ± 0.93 | 1.92 ± 0.89 | 1.75 ± 0.80 | | | | |
| Sleep duration | Baseline | 2.04 ± 1.06 | 1.96 ± 0.81 | 2.00 ± 0.94 | 1.71 ± 0.98 | 1.57 | 3.83 | < 0.001 | 0.10 |
| | 12 weeks | 1.00 ± 0.78 | 1.11 ± 1.16 | 1.77 ± 0.91 | 1.46 ± 0.79 | | | | |
| | 24 weeks | 1.04 ± 0.71 | 1.07 ± 0.92 | 1.65 ± 0.94 | 1.07 ± 0.60 | | | | |
| Habitual sleep efficiency | Baseline | 2.15 ± 1.06 | 1.85 ± 1.13 | 1.65 ± 1.23 | 1.46 ± 1.23 | 2.75 | 4.40 | < 0.001 | 0.11 |
| | 12 weeks | 0.96 ± 0.90 | 0.85 ± 1.1 | 1.50 ± 1.21 | 0.93 ± 1.15 | | | | |
| | 24 weeks | 0.89 ± 0.89 | 0.74 ± 0.98 | 1.58 ± 1.17 | 0.64 ± 0.95 | | | | |
| Sleep disturbances | Baseline | 1.48 ± 0.58 | 1.70 ± 0.61 | 1.58 ± 0.58 | 1.32 ± 0.48 | 0.21 | 1.09 | 0.367 | 0.03 |
| | 12 weeks | 1.00 ± 0.56 | 1.07 ± 0.62 | 1.23 ± 0.59 | 1.04 ± 0.33 | | | | |
| | 24 weeks | 1.15 ± 0.53 | 1.15 ± 0.53 | 1.23 ± 0.51 | 1.07 ± 0.38 | | | | |
| Sleep medication use | Baseline | 1.41 ± 1.45 | 0.93 ± 1.39 | 1.15 ± 1.38 | 1.29 ± 1.51 | 1.64 | 1.34 | 0.248 | 0.04 |
| | 12 weeks | 1.70 ± 1.46 | 1.89 ± 1.34 | 2.19 ± 1.20 | 2.25 ± 1.32 | | | | |
| | 24 weeks | 1.56 ± 1.42 | 1.74 ± 1.40 | 1.96 ± 1.25 | 1.54 ± 1.50 | | | | |
| Daytime dysfunction | Baseline | 2.22 ± 0.75 | 2.04 ± 0.85 | 2.12 ± 0.91 | 1.86 ± 0.89 | 0.61 | 1.45 | 0.209 | 0.04 |
| | 12 weeks | 1.07 ± 0.62 | 1.11 ± 0.75 | 1.54 ± 0.65 | 1.21 ± 0.83 | | | | |
| | 24 weeks | 1.11 ± 0.70 | 1.11 ± 0.89 | 1.38 ± 0.70 | 0.96 ± 0.74 | | | | |

Data are presented as mean ± standard deviation. CST: craniosacral therapy; PSQI: Pittsburgh Sleep Quality Index; SEP: standard exercise program.

**Table 4**
Tukey's post hoc comparisons for sleep quality: between-groups differences.

| Treatment | PSQI global at 12 weeks (MD [$P$ value]) | | | PSQI global at 24 weeks (MD [$P$ value]) | | |
|---|---|---|---|---|---|---|
| | Bowen | Static touch | SEP | Bowen | Static touch | SEP |
| CST | −0.15 (0.999) | 3.20 (0.037) | 1.64 (0.816) | −0.07 (0.999) | 2.93 (0.091) | −0.15 (0.999) |
| Bowen | – | 3.35 (0.023) | 1.78 (0.719) | – | 3.00 (0.074) | −0.07 (0.999) |
| Static touch | – | – | −1.56 (0.864) | – | – | −3.07 (0.055) |

CST: craniosacral therapy; MD: mean difference; PSQI: Pittsburgh Sleep Quality Index; SEP: standard exercise program. –: no value.

**Table 5**
Repeated measures analysis of variance for PPT: group interactions and post hoc comparisons for group interactions.

| Variable | Group interactions | | | | Post hoc comparisons for group interactions | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Mean square | *F* | *P* value | Partial eta squared | CST *vs* static touch | | Bowen *vs* static touch | | SEP *vs* static touch | |
| | | | | | MD ± SE | *P* value | MD ± SE | *P* value | MD ± SE | *P* value |
| PPT total | 7.28 | 6.83 | < 0. 001 | 0.26 | 0.57 ± 0.23 | 0.067 | 0.84 ± 0.23 | 0. 002 | 1.01 ± 0.24 | < 0.001 |
| TEP | 38.30 | 3.12 | 0.033 | 0.14 | −0.94 ± 0.77 | 0.640 | −1.77 ± 0.77 | 0.123 | −2.27 ± 0.81 | 0.043 |

CST: craniosacral therapy; MD: mean difference; PPT: pressure pain threshold; SE: standard error; SEP: standard exercise program; TEP: number of tender points.

**Table 6**
Repeated measures analysis of variance for quality of life: time × group interactions.

| FIQR | Time point | CST (*n* = 27) | Bowen (*n* = 27) | Static touch (*n* = 26) | SEP (*n* = 28) | Time × group interaction | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Mean square | *F* | *P* value | Partial eta squared |
| Total score | Baseline | 65.33 ± 17.28 | 61.07 ± 16.50 | 59.65 ± 20.93 | 60.18 ± 13.56 | 626.00 | 5.79 | < 0.001 | 0.14 |
| | 12 weeks | 42.59 ± 17.97 | 34.59 ± 19.29 | 50.38 ± 22.58 | 45.75 ± 18.51 | | | | |
| | 24 weeks | 35.70 ± 16.88 | 33.48 ± 19.99 | 45.88 ± 20.74 | 34.21 ± 16.72 | | | | |
| Function score | Baseline | 52.74 ± 17.13 | 49.56 ± 21.29 | 48.96 ± 23.72 | 49.32 ± 16.88 | 446.00 | 3.71 | 0.003 | 0.10 |
| | 12 weeks | 35.70 ± 16.98 | 28.22 ± 20.61 | 42.38 ± 23.33 | 38.71 ± 19.12 | | | | |
| | 24 weeks | 29.81 ± 16.79 | 26.74 ± 20.43 | 37.65 ± 21.85 | 28.25 ± 17.62 | | | | |
| Overall impact score | Baseline | 15.00 ± 4.60 | 13.33 ± 4.32 | 13.08 ± 5.75 | 13.86 ± 3.54 | 43.50 | 3.88 | 0.001 | 0.10 |
| | 12 weeks | 9.15 ± 4.48 | 6.89 ± 5.40 | 10.81 ± 5.58 | 9.11 ± 4.85 | | | | |
| | 24 weeks | 6.70 ± 4.23 | 7.33 ± 5.52 | 9.54 ± 4.69 | 6.39 ± 4.82 | | | | |
| Symptoms total score | Baseline | 65.56 ± 18.12 | 62.48 ± 14.13 | 60.50 ± 19.19 | 59.71 ± 13.45 | 512.70 | 5.19 | < 0.001 | 0.13 |
| | 12 weeks | 43.19 ± 19.54 | 38.26 ± 19.52 | 51.38 ± 22.30 | 47.57 ± 17.68 | | | | |
| | 24 weeks | 38.07 ± 16.81 | 35.19 ± 17.69 | 47.62 ± 20.44 | 36.61 ± 15.00 | | | | |

Data are presented as mean ± standard deviation. CST: craniosacral therapy; FIQR: Revised Fibromyalgia Impact Questionnaire; SEP: standard exercise program.

**Table 7**
Repeated measures analysis of variance for other outcomes: time × group interactions.

| Outcome | Time point | CST (*n* = 27) | Bowen (*n* = 27) | Static touch (*n* = 26) | SEP (*n* = 28) | Time × group interaction | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Mean square | *F* | *P* value | Partial eta squared |
| PROMIS-PF score | Baseline | 29.19 ± 7.18 | 34.37 ± 6.63 | 31.81 ± 7.99 | 33.04 ± 6.25 | 45.70 | 3.28 | 0.007 | 0.09 |
| | 12 weeks | 33.07 ± 7.27 | 38.11 ± 7.81 | 32.38 ± 8.29 | 35.86 ± 6.11 | | | | |
| | 24 weeks | 36.19 ± 7.34 | 39.11 ± 8.47 | 33.38 ± 8.09 | 38.46 ± 5.52 | | | | |
| MAF score | Baseline | 37.30 ± 7.00 | 35.81 ± 7.54 | 33.88 ± 9.91 | 33.86 ± 7.49 | 211.20 | 5.38 | < 0.001 | 0.13 |
| | 12 weeks | 25.93 ± 9.15 | 22.15 ± 9.16 | 30.08 ± 8.60 | 26.57 ± 9.09 | | | | |
| | 24 weeks | 19.52 ± 9.72 | 20.74 ± 9.71 | 26.27 ± 7.58 | 21.36 ± 9.74 | | | | |
| PCS score | Baseline | 33.44 ± 13.86 | 33.37 ± 10.90 | 28.77 ± 12.33 | 28.14 ± 12.30 | 144.00 | 3.00 | 0.009 | 0.08 |
| | 12 weeks | 21.00 ± 10.94 | 21.22 ± 10.97 | 23.65 ± 11.54 | 20.54 ± 9.56 | | | | |
| | 24 weeks | 16.37 ± 8.60 | 19.07 ± 11.75 | 20.88 ± 11.03 | 14.79 ± 12.15 | | | | |
| TSK score | Baseline | 44.00 ± 10.00 | 42.37 ± 6.97 | 41.85 ± 8.85 | 39.96 ± 7.59 | 11.40 | 0.68 | 0.648 | 0.02 |
| | 12 weeks | 38.56 ± 6.48 | 38.74 ± 8.13 | 38.08 ± 6.59 | 37.07 ± 6.63 | | | | |
| | 24 weeks | 36.59 ± 7.00 | 36.78 ± 7.70 | 35.92 ± 7.01 | 34.96 ± 7.53 | | | | |
| PANAS-positive affect score | Baseline | 25.78 ± 7.99 | 27.48 ± 6.76 | 27.08 ± 8.55 | 28.86 ± 8.55 | 56.80 | 2.18 | 0.055 | 0.06 |
| | 12 weeks | 29.48 ± 8.16 | 32.48 ± 6.52 | 29.50 ± 6.31 | 29.07 ± 8.05 | | | | |
| | 24 weeks | 29.67 ± 7.91 | 32.52 ± 7.34 | 30.77 ± 6.73 | 34.32 ± 6.86 | | | | |
| PANAS-negative affect score | Baseline | 33.15 ± 9.15 | 28.15 ± 9.07 | 24.96 ± 8.19 | 26.96 ± 8.45 | 69.60 | 2.76 | 0.017 | 0.07 |
| | 12 weeks | 26.56 ± 8.64 | 21.81 ± 9.25 | 22.00 ± 7.75 | 22.54 ± 6.57 | | | | |
| | 24 weeks | 23.63 ± 7.44 | 21.59 ± 8.20 | 22.69 ± 6.60 | 21.68 ± 8.22 | | | | |

Data are presented as mean ± standard deviation. CST: craniosacral therapy; MAF: Multidimensional Assessment of Fatigue; PCS: Pain Catastrophizing Scale; PROMIS-PF: Patient-Reported Outcomes Measurement Information System–Physical Function- Short-Form; PANAS: Positive and Negative Affect Schedule. SEP: standard exercise program; TSK: Tampa Scale for Kinesiophobia;

*vs* static touch group ($P < 0.001$, Cohen's $d = 1.69$), with no significant change between CST group and the static touch group ($P = 0.067$). These findings were evident at 12 weeks but not at 24 weeks in between-group post hoc comparisons. The SEP showed significant group interaction in the number of tender points compared to static touch group ($P = 0.043$, Cohen's $d = 1.12$).

### 3.3. Quality of life and fibromyalgia impact

The repeated measures ANOVA demonstrated a statistically significant difference in the mean scores of FIQR total ($P < 0.001$) and its subdomains across the time-group interaction (Table 6). The post hoc comparison for the time-group interaction denoted no significant difference in mean FIQR scores between the groups at the 12th and 24th weeks.

### 3.4. Other outcomes

The repeated measures ANOVA demonstrated statistically significant time-group interactions in the mean scores of PROMIS-PF ($P = 0.007$), MAF ($P < 0.001$), PCS ($P = 0.009$) and PANAS negative affect ($P = 0.017$) (Table 7). However, in post hoc comparisons, no significant difference was detected in mean scores of any outcome between the groups at the 12th and 24th weeks.

### 3.5. Adverse events and exercise adherence

No serious adverse events were noted in any treatment group throughout the study. However, 2 participants from the CST group and 2 from the Bowen therapy group experienced a mild increase in pain and tiredness for one day after the therapy. One participant from the static touch group felt mild disorientation after the treatment. Ten participants from the SEP group experienced soreness after doing the exercises.

The participants in all 4 groups had an exercise adherence of more than 70% (86.90% in CST, 81.90% in Bowen therapy, 72.50% in static touch and 83.40% in SEP).

## 4. Discussion

The current study aimed to determine the effectiveness of CST, Bowen therapy, static touch and SEP on sleep quality in FMS participants with disturbed sleep.

At the end of 12 weeks of intervention, the CST and Bowen therapy groups demonstrated significant improvement in global sleep quality compared to static touch. The amount of improvement was 3.20 points in the CST group and 3.35 points in the Bowen therapy group. This change of three or more has been established as the MCID in previous studies involving participants with insomnia [72] and chronic low back pain [73].

The improvement in sleep quality in both groups compared to static touch may be due to the alteration of the craniosacral rhythm [29] in the CST group and muscle tension [33] in the Bowen therapy group. Notably, the static touch control did not involve any intention to modify or alter the structures beneath the contact points. In addition, CST and Bowen therapy used a C-tactile touch compared to the non-C-tactile touch in the static touch group. C-tactile touch stimulates the slow unmyelinated C-tactile fibers, which respond to low force, slow velocity (1–10 cm/s), and skin temperature touch [74]. This C-tactile (affective) touch is supposed to influence the limbic system, mainly the insular cortex, which modulates sensory, emotional, motivational and cognitive functions, thus influencing sleep in FMS [75,76]. C-tactile touch is found to be superior in producing positive affect and reducing stress than a static touch (non-C-tactile touch) [77]. This suggests that a structured, educated touch is required to distinguish its effects from the effects of human touch.

Twenty-three participants in the CST group volunteered to report findings such as frequency of feelings of negativity, frequency of panic attacks, and perceived confidence level, as opposed to 20 in the Bowen group, 15 in the SEP, and 9 in the static touch group. The PANAS negative affect scores at baseline were higher in the CST (33.15) and Bowen therapy (28.15) groups than those in the static touch (24.96) and SEP (26.96) groups (Table 7). This could also have resulted in a greater reduction in the PANAS negative affect in the CST and Bowen therapy participants, thus influencing sleep. The within-group changes for the other psychological domains (PCS and TSK) were greater in the CST group compared to the Bowen therapy and SEP groups (Table 7). This suggests that CST may be preferred over Bowen therapy when the participants have associated psychological symptoms.

CST improved the mean sleep latency by 21.20 min, duration by 93.60 min and efficiency by 19.39%. Also, 14.81% of the CST participants reduced the medicine dosage by half, and 40.74% stopped using the medicines by the end of the 24-week study. Bowen therapy improved the mean sleep latency by 23.72 min, duration by 70.20 min and efficiency by 14.85%. Moreover, 11.11% of the participants reduced their medicine dosage by half, and 44.44% stopped using medicines by the end of the 24-week study. Both groups achieved the MCID for sleep duration ($\geq$ 40 min) and efficiency ($\geq$ 5%) [78] at 12 and 24 weeks from baseline, with CST demonstrating superior effects to Bowen therapy.

The current study's findings on the effectiveness of CST and Bowen therapy align with previous studies [79,80]. In the present study, therapy was given once a week for 12 weeks. Moreover, our study had a manual placebo group. This suggests that the beneficial effects of CST and Bowen therapy on sleep quality in FMS sufferers can be obtained within only 12 weeks.

The SEP group did not demonstrate any between-group improvement in sleep and did not achieve MCID at 12 weeks. The reason could be the protocol's semi-supervised (6 supervised sessions) nature and short duration of time (12 weeks). This finding is supported by a study in 2015 that concluded that supervised aerobic exercises performed twice a week for 24 weeks resulted in autonomic modulation [81]. In the current study, MCID was reached at 24 weeks. This suggests that exercises need to be performed regularly over a long period (at least 24 weeks) to achieve clinical improvement.

At the end of 24 weeks, the groups had no significant differences in the mean PSQI global scores. This could be because, after 12 weeks, all group participants performed the same exercises. Adding the exercises might have resulted in a similar improvement in sleep quality, reducing the variation across treatment groups. Though the sleep quality did not vary significantly across groups at 24 weeks (Table 4), the improved mean PSQI global scores at 12 weeks (8.19 in the CST group, and 8.04 in the Bowen therapy group) persisted through week 24 (8.11 in the CST group, and 8.04 in the Bowen therapy group) (Table 3). This showed that the improvements obtained from the manual therapy intervention could be retained by performing the SEP.

The present study showed significant differences in the mean PPT total score between Bowen therapy and static touch and SEP and static touch at 12 weeks. The between-group difference in PPT total score in both the groups (1.10 in the Bowen therapy group, and 1.20 in the SEP group) at 12 weeks reached the minimal detectable change of 0.45–1.13 [82]. There were no between-group differences in the total number of tender points at a specific time point. These findings indicate that the number of tender points may not be as sensitive to change following the interventions as the PPT (pain threshold) values at these points [83].

There were no significant between-group differences in the mean scores of the FIQR total and its subdomains. The reason could be that, according to Bennet et al. [84], FIQR is sensitive to change in symptomatology of FMS and has been shown to be a more responsive measure of participant-perceived improvement than changes in pain intensity, tender point count, and total tender point pain. All the manual intervention groups, including the placebo group, made use of touch. Evidence has shown that touch influences the physical, emotional, intellectual and behavioral attributes of individuals [35–37]. It is also believed to lower stress [38]. Moreover, participants in all the groups received standard medical care. Thus, the interventions' effects and standard care might have contributed to an improvement in the FIQR scores in all the groups.

The study demonstrated significant time-group interaction for physical function (PROMIS-PF), fatigue (MAF), pain catastrophizing (PCS) and negative affect (PANAS negative). However, no between-group differences were evident. FMS participants also have emotional dysfunction in addition to physical symptoms such as pain, fatigue and sleep problems [85,86]. A possible reason for the insignificant differences between the groups could be that the same therapist treated the participants in all the groups. Therefore, the therapist-participant interaction [87] and motivational concordance [88] might have affected the treatment outcomes and adherence. In addition, all the participants received standard medical care, which also might have influenced the outcomes.

The exercise adherence in all the groups was good (> 70%). This could be due to our combined exercise protocol, which focused on participant-dependent initiation and progression of the exercises along with exercise videos and regular follow-ups. These factors could have led to better tolerance of the exercises among all the participants. These findings are supported by a recent review in 2022 which suggested that exercises should begin and progress at an intensity based on the participants' symptoms and capacity [89].

This is the first study to determine the effectiveness of CST, Bowen therapy and exercises against a touch-based placebo group on sleep quality in FMS. Participants in all groups demonstrated good adherence to the exercises. This indicated better tolerance to our exercise protocol. This is the first study to evaluate the effects of interventions on the physical and psychological components of FMS. The study protocol was designed to implement manual therapy procedures in the short term and exercises in the long term, thus decreasing therapist dependency and encouraging self-efficacy. The limitations of the study were that the study was localized to a single geographic location involving an urban population. The blinding of the assessor, therapist and the participants was not possible.

The current study suggests that manual therapies such as CST and Bowen therapy are safe and can be readily implemented in clinical settings along with standard care. Educated touch involving a standard protocol is more effective in influencing FMS symptoms than touch. CST may be preferable over Bowen therapy when participants have associated psychological symptoms. These therapies can be utilized to improve sleep and several features of FMS in the short term. They can be integrated with different exercise types for further medium- and long-term improvements. For those who prefer to not use these manual therapy techniques, exercises can be used to achieve similar effects, but they require a longer time-scale to attain beneficial effects (~24 weeks). Combined exercises with participant-tailored exercise protocols are better tolerated by FMS participants.

Future studies can be conducted to determine the effect of therapies on outcomes such as polysomnography, heart rate variability, and markers such as melatonin, serotonin, endorphins and oxidative stress enzymes. The use of "booster doses" of CST/Bowen therapy can be evaluated to understand strategies for maintaining the beneficial effects of these therapies over the long-term. The cost-effectiveness of these therapies versus exercises can be evaluated in future trials. Future studies can also use standard medical care as a control group.

## 5. Conclusion

Twelve weeks of CST and Bowen therapy improved sleep quality, and Bowen therapy and an SEP improved pain threshold in FMS participants. These improvements were retained for an additional 12 weeks by adding exercises. CST and Bowen therapy are treatment options that can improve sleep and reduce pain. Exercises can be used as an independent intervention and maintenance program following manual therapies along with standard medical care.

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## Credit authorship contribution statement

**Reepa Avichal Ughreja:** Conceptualization, Methodology, Data curation, Investigation, Formal analysis. **Prem Venkatesan:** Conceptualization, Methodology, Validation, Supervision, Writing – review & editing. **Dharmanand Balebail Gopalakrishna:** Conceptualization, Methodology, Investigation, Writing – review & editing. **Yogesh Preet Singh:** Conceptualization, Methodology, Validation, Supervision, Writing – review & editing. **Vani Lakshmi R:** Methodology, Formal analysis, Writing – review & editing.

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## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

## Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.joim.2024.06.003.

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