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Protocol

Effectiveness of Craniosacral therapy, Bowen therapy, static touch, and standard exercise program on sleep quality in fibromyalgia syndrome: A protocol for a randomized controlled trial

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ABSTRACT

Introduction: Sleep disturbance is a common feature seen in fibromyalgia syndrome (FMS), negatively impacting quality of life. FMS participants often opt for complementary therapies for their symptoms. However, there is limited evidence on manual therapies aimed at influencing sleep quality in those with FMS in India. Thus, this study aims to determine the effectiveness of Craniosacral therapy, Bowen therapy, static touch, and standard exercise program on sleep quality in participants with FMS.

Methods: 132 participants diagnosed with FMS will be randomly allocated to one of four groups (Craniosacral therapy, Bowen therapy, static touch, or standard exercise program). The participants in all groups will receive once-a-week supervised sessions for 12 weeks, except those in the standard exercise group who will receive once-a-week supervised sessions on the 1st, 2nd, 3rd, 5th, 9th, and 12th week, and twice-weekly home exercises for those 6 weeks. Then, they will be asked to do thrice weekly home exercises for the remaining weeks up to 12 weeks. After 12 weeks, all the participants will be taught and asked to do the standard exercise program at home for another 12 weeks. A blinded assessor will take the outcomes at baseline, at the end of the 12th and 24th week of intervention. The study's primary outcome is the Pittsburgh sleep quality index. The secondary outcomes are pressure pain threshold, quality of life, physical function, fatigue, pain catastrophizing, kinesiophobia, and positive-negative affect. Repeated measures ANOVA and appropriate post hoc tests will be applied to analyze the between-group differences.

Conclusion: The current study will provide insights into the treatment options to manage sleep and fibromyalgia symptoms.

Trial registration: Clinical Trials Registry-India: CTRI/2020/04/024551 (April 9, 2020).

1. Introduction

Fibromyalgia syndrome (FMS) is a musculoskeletal disorder with widespread chronic pain, cognitive and sleep disturbances, anxiety, depression, and fatigue as the key features [1]. It accounts for 0.2–6.6% of the world's population [2], with a mean prevalence of 2.7% [3]. Sleep impairment is one of the core features of FMS, which impairs health-related quality of life [4,5]. Poor sleep is seen in 90% of FMS individuals [6,7]. Individuals with FMS 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 [6,8]. 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

Abbreviations: FMS, Fibromyalgia; CST, Craniosacral therapy; NREM, Non-Rapid Eye Movement; SWS, Slow-wave sleep; ANS, Autonomic nervous system; PSQI, Pittsburgh Sleep Quality Index.

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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 [4,9]. Thus, treatment strategies focusing on the identification and intervention of sleep problems can curtail the morbidity in FMS [6, 8–10].

The management of FMS comprises a multidisciplinary approach consisting of medications, participant education, and various non-pharmacological interventions [11]. The usage of complementary and alternative therapies is highly prevalent in FMS individuals [12,13]. These therapies' high acceptance rate and safety make their use recommendable in FMS management [14,15]. Nonetheless, extensive high-quality studies with active and manual comparator groups are recommended [15,16].

Craniosacral therapy (CST) is a gentle manual therapeutic procedure that applies light touch over the body (such as feet, back, and head) to evaluate the delicate craniosacral rhythm. The craniosacral (CS) system comprises the meningeal, fascial, and bony structures of the cranium and spinal column [17]. A meta-analysis by Haller et al. 2019 suggested that CST can have significant effects in chronic pain disorders such as neck pain, backache, migraine, fibromyalgia, and pelvic pain [18]. Presumably, the 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, visceral, endocrinal, and immunological systems via the autonomic pathways [17].

Bowen therapy is another hands-on treatment that uses a succession of hand moves over the musculotendinous structures and causes body arousal through central nervous system, endocrinal and fascial routes. This mechanism, in turn, aims to produce relaxation and enhance blood and lymphatic flow. It is assumed that the gentle rolling moves over the muscles cause the stimulation of muscle spindles bringing the tissue state to normal and stimulating healing and well-being. A systematic review by Hansen et al. 2011 demonstrated that Bowen therapy could produce improvements in chronic illnesses like frozen shoulder and migraine, with few case studies showing improvement in back pain, fibromyalgia, and sacroiliac pain [19].

Touch is found to have an influential role in several elements of human growth, including physical, emotional, intellectual, and behavioral attributes [20–22]. It may possess the potential to decrease stress among participants [23]. Consequently, static touch may serve as a placebo control group to compare the efficacy of manual therapies using touch.

Various professional organizations have strongly recommended exercises for FMS management [11]. Several studies have manifested the benefits of exercise on multiple FMS features such as pain, function, fatigue, anxiety, depression, sleep, and quality of life [24–29].

Autonomic dysfunction is a characteristic feature of FMS that correlates with FMS symptom severity [30]. Reportedly autonomic nervous system (ANS) holds a vital role in sleep physiology. It is found to modulate cardio-vascular functioning in the course of sleep induction and sleep phases [31]. Evidence shows that CST, Bowen therapy, and aerobic exercises might alter the ANS function by switching sympathetic to parasympathetic dominance, thus influencing sleep quality [18, 32–34].

The available evidence demonstrates the effects of CST and Bowen therapy in chronic conditions [18,19]. However, limited evidence exists on their effectiveness on sleep quality in individuals with FMS, fostering the need for more randomized controlled trials. Furthermore, these therapies need to be compared to a standard intervention, such as exercise, and a manual control group, such as static touch, as touch itself is found beneficial [23]. Therefore, this study intends to appraise the effectiveness of Craniosacral therapy, Bowen therapy, static touch, and standard exercise program on sleep quality in FMS using the Pittsburgh Sleep Quality Index. The study's secondary objectives are to determine the effectiveness of these therapies on other symptoms of FMS, such as pain threshold, fibromyalgia impact, physical function, fatigue, pain catastrophizing, kinesiophobia, and positive and negative affect.

2. Methods

2.1. Study design

The current protocol is for an "assessor-blinded randomized parallel-group placebo-controlled trial". The "Consolidated Standards of Reporting Trials (CONSORT) guidelines" will be used for performing the trial [35]. The outcomes will be taken at baseline, at the end of the 12th and 24th week of intervention by a physiotherapist blinded to the intervention. The illustration of the study flow is reported in Fig. 1. The authors followed the "Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines" [36] for protocol reporting. The study is approved by the institutional research and scientific committee (IRSC) and the ethics committee (EC) of Manipal Hospital, Bangalore. The study was registered in the clinical trials registry with trial registration number CTRI/2020/04/024551 in April 2020, version 1.0, after which no changes have been made.

2.2. Participant recruitment, sample size, and eligibility criteria

The participants diagnosed with fibromyalgia using the "2016 Revisions to the 2010/2011 American College of Rheumatology (ACR) fibromyalgia diagnostic criteria" [1] will be enrolled at the physiotherapy department of Manipal Hospital, Bangalore, after a reference from the consulting physician. The participant recruitment will take place from July 2020 to February 2023. The formula for "repeated measures ANOVA" [37] was used to compute the study's sample size. With 80% power, 5% level of significance (z value adjusted for four groups), three time points, 0.4 correlation among repeated observations, 4.03 as the standard deviation of Pittsburgh Sleep Quality Index (PSQI) [38] with clinically significant difference of 3 and 20% drop out rate, the minimum sample size required for the study is 132. To achieve an adequate sample size, the investigator will visit the physicians regularly and update them about the trial's recruitment. The study's eligibility criteria are mentioned in Table 1.

2.3. Randomization, allocation, and blinding

The process of randomization will be carried out by a blinded investigator (such as a statistician) uninvolved in the trial. The participants will be randomized into four groups using "computer-generated block randomization" using 1:1 allocation using sealedenvelope.com. The investigator will place the allocation sequence in "sequentially numbered opaque sealed envelopes" kept safely in a cabinet. The principal investigator will explain the trial process to the participants and obtain informed consent from the eligible candidates. After the blinded assessor collects the baseline and demographic data, the treatment therapist will open the sealed envelopes in sequence and deliver the treatment accordingly. The blinded assessor will take the outcomes at baseline, 12 weeks, and 24 weeks.

2.4. Intervention

The interventions will be delivered by an experienced physiotherapist certified and trained in CST and Bowen therapy. All the interventions will be administered at the physiotherapy department of Manipal Hospital, Bangalore. The participants in the manual intervention groups (CST, Bowen therapy, and static touch) will receive 45 min, once-weekly sessions for 12 weeks. The participants in the standard exercise group will receive once-a-week supervised sessions on the 1st, 2nd, 3rd, 5th, 9th, and 12th week and do twice-weekly home exercises for those 6 weeks. They will be asked to do thrice weekly home exercises for the remaining weeks until 12 weeks. At the end of 12 weeks, all the outcomes will be assessed; the participants in all the groups will be

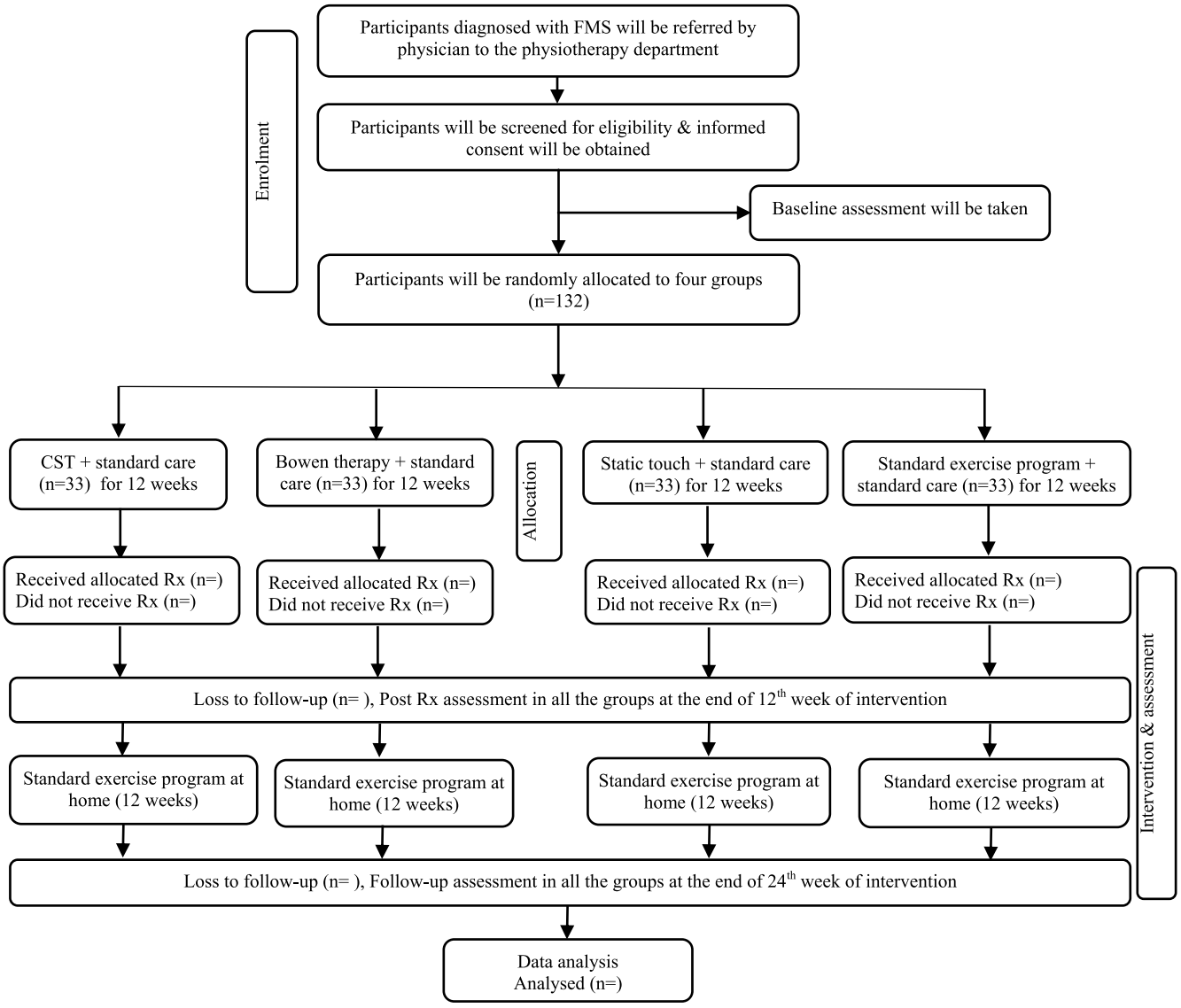

Fig. 1. Study CONSORT flowchart
Abbreviations: FMS-Fibromyalgia syndrome, CST-Craniosacral therapy, Rx-Treatment.
Note: Standard care consists of participant education, sleep hygiene, and physician medication.

Table 1
Selection criteria.

Included
Males and females
Aged 18–60 years
Diagnosed case of FMS according to "2016 Revisions to 2010/2011 American College of Rheumatology fibromyalgia diagnostic criteria" for ≥1 year
"Pittsburgh sleep quality index score" > 5
Excluded
"Spinal injuries, inflammatory rheumatic conditions, Obstructive sleep apnea, uncontrolled endocrine disorders
Participants involved in current/recent practice of therapies such as mindfulness meditation or cognitive behavioral therapy.
Diagnosed psychological, personality & neurological disorders such as dementia, alzheimer's disease, parkinsonism
Acute aneurysms, cerebral hemorrhage, bleeding disorders, pregnancy, systemic infection, dermatitis, healing fractures that may be contraindicated to the intervention.
Intolerance to or discomfort with physical touch".

Abbreviations: FMS-Fibromyalgia syndrome.

taught the standard exercise program (within 1–2 sessions) and asked to do them at home for another 12 weeks. They will be asked to note their exercises in their exercise logs. The participants will be followed up at the end of the 24th week, during which follow-up assessment will be taken, and adherence to exercise sessions will be recorded.

All the participants will receive standard care, consisting of education about fibromyalgia, sleep hygiene, and medications prescribed by the consulting physician. The participants will be called on separate days to avoid contamination of various interventions. The participant's physical activity level will be noted every time the participant comes for the treatment session. If the participants take any additional intervention during the study period, the investigators will report the same and analyze its effects on the outcomes.

2.4.1. Craniosacral therapy (CST)

CST consists of gentle touch over various body regions palpating the delicate craniosacral rhythm. The intervention will consist of the following ten steps: "still point (at feet), diaphragms release, sacral techniques, dural tube rock/glide, frontal lift, parietal lift, sphenobasilar compression-decompression, temporal bone techniques,

temporomandibular joint compression-decompression, still point at occiput (CV-4)" [39,40].

The participant will lie supine on a couch in comfortable, light clothing. The therapist will sit beside the participant on an adjustable seat height stool. The session will begin by applying light touch over the feet and assessing and manipulating the craniosacral rhythm. The transition from one step to the other will occur when the therapist feels the signs of release, such as "softening, warmth, deep breath by the participant, therapeutic pulse and energetic repelling". The treatment will end with a still point at the head. At the end of the session, the participant will lie on the couch for 5 min and gradually get up. The participant will be advised to drink plenty of water and refrain from strenuous activity for at least 24 h. The same advice will be given to Bowen therapy and static touch groups.

2.4.2. Bowen therapy

Bowen therapy consists of gentle thumb and/or finger moves over muscles, their insertion, or tendons with a two-minute gap between every move. The intervention will consist of the following muscle sequences: "Erector spinae (left, right), Gluteus medius (left, right), Biceps femoris (left, right), IT band (left, right), Longissimus thoracis (4 points), Lower Trapezius (left, right), Rhomboids Major (left, right) and Rhomboids Minor (left, right), Levator Scapulae (left, right), Latissimus dorsi (left, right), Erector Spinae (8 points), Posterior and middle scalene (left, right), Semispinalis capitis (left, right), Upper trapezius (left, right), Levator scapulae (left, right), the head procedure" [41].

The participant will be lying on a couch in comfortable, light clothing. The initial moves (till erector spinae 8 points) will be performed in prone and the remaining in supine. For each move, the therapist will roll the muscle laterally to take up the slack; hold the position for 15 s and then gently roll the muscle medially. Each muscle move will be performed first on the left side and then on the right side. After the moves on both sides, the therapist will provide a pause for 2 min. The same procedure will be repeated for all the Bowen moves and end with the head procedure.

2.4.3. Static touch (placebo group)

In this group, the therapist will place their hand over the body regions corresponding to craniosacral and Bowen therapies. The treatment will last for 45 min. The intervention will consist of the following sequence: "sacrum, lumbar paraspinal region (left, right), thoracic paraspinal region (left, right), neck, thigh (left, right), scapular region (left, right), posterolateral hip (left, right), forehead, lateral aspect of the head (left, right) and occiput".

The participant will be asked to lie supine in comfortable clothing on a couch. The therapist will place their hand at each position for 3 min without any movement or intention to treat. The session will start with sacrum and end with head procedure (9–10 min). The total time for treatment in this group will be the same as that in the CST and Bowen therapy groups (45 min).

2.4.4. Standard exercise program

This program will consist of aerobic exercise, stretching, and strengthening as per the "American College of Sports Medicine's FITT (Frequency, Intensity, Time, and Type) recommendations" for individuals with fibromyalgia. The exercise program will include a 5 min warm-up, 30–60 min of aerobic exercise training, 10 min each of stretching and strengthening exercises, and a 5 min cool-down. The frequency of the exercises will be thrice a week, progressing to 4- or 5-times as per the participants' ability. During home exercises, the participants will be asked to do resisted exercises on alternate days (other than those for stretching and aerobic exercises) to allow sufficient recovery time. The participants will be asked to begin exercising with light intensity, progressing to a moderate intensity using "Borg's rate of perceived exertion" scale of 6–20 [42].

The aerobic exercises may include brisk walking, swimming, or cycling as per the comfort/preference of the participant. Stretching exercises will consist of triceps, pectorals, calf, hamstring, quadriceps, erector spinae, trapezius, and levator scapulae. The participant will perform 3 repetitions of each muscle stretch with a hold of 10 s, progressing to 30 s. Strengthening exercises will start with static exercises of deep cervical flexors, scapular muscles, abdominals, back extensors, glutei, quadriceps, and hamstrings, followed by dynamic exercises of upper and lower limbs and trunk. The participants will be asked to initially perform one set of each of these exercises for 5 repetitions, progressing to two sets of 10 repetitions as tolerated.

The dynamic exercises will start with active exercises and then progress to resisted exercises. The exercises will begin supine and progress to sitting/ standing as per the participant's ability. The active exercises will include shoulder and elbow flexion and extension; back exercises (cat and camel, rotation); hip and knee flexion and extension. The resisted exercises will consist of elastic bands/weight cuffs and body weight. The resisted exercises will be added if the participant can do at least 3 repetitions of a movement without much pain and fatigue at 50% 1 RM or rate of perceived exertion of 5–6 on a 10-point scale. If the participant experiences pain at 50% 1 RM, the resistance will be reduced to a level where they do not experience any pain or fatigue. The resistance will progress by 2 to 10% when the participants can do 2 sets of 10 repetitions without pain and fatigue for 2 consecutive sessions [43].

The exercises will be modified, added, or removed according to the participant's needs and ability to perform them. The exercise program schedule is mentioned in Table 2.

2.5. Progression and adherence

The progression of exercises will follow the ACSM's progression guidelines. "The rate of progression of the exercises will depend entirely on the symptoms and response of the participant to the exercise on any particular day. The participants will be educated on modifying, reducing the intensity or avoiding certain exercises when their symptoms are exacerbated" [42].

Adherence to the exercise program in all the groups will be encouraged using telephone communication (every 2 weeks), videotapes demonstrating the exercise program, and exercise logs. There will be no follow-up exercise visits for the manual therapy groups. If the participants in these groups have difficulty performing exercises, this will be resolved during regular telephonic conversations (every 2 weeks).

2.6. Outcomes

The study's primary outcome is sleep quality which will be assessed using the "Pittsburgh Sleep Quality Index" which has 7 components: "subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbance, use of sleep medication, and daytime dysfunction". Each component is rated from 0 (no problem) to 3 (severe problem). The total score of the 7 components ranges from 0–21; higher scores indicate poor sleep quality. An individual with a total score > 5 is identified as a poor sleeper. "It has good internal consistency (Cronbach's alpha, α=0.83) and test-retest reliability (Pearson's correlation coefficient, $r = 0.85$) and validity" [44]. The secondary outcomes of the study are as follows:

Pressure pain threshold (PPT) will be measured using a pressure algometer at "9 paired points of the body as determined by American College of Rheumatology 1990 criteria (occiput, lower cervical, mid trapezius, supraspinatus, second rib, lateral epicondyle, gluteal, greater trochanter, medial knee)" [45]. The pressure will be gradually increased until the participant experiences a change in sensation from pressure to pain. At this point, the threshold value will be noted. The procedure will be repeated 3 times (with an interval of 10–15 s), and the average value will be used for analysis [46]. A point with a PPT value < 4 kg/cm^2 will be considered a tender point [45].

Table 2
Exercise program schedule.

	Week 1–3	Week 4–5	Week 6–9	Week 10–12
Exercise schedule	Once/week supervised sessions, 2 unsupervised sessions at home	One follow-up session at week 5, 2 unsupervised sessions at home	One follow-up session at week 9, 2 unsupervised sessions at home	One follow-up session at week 12, 2 unsupervised sessions at home
Exercise frequency	thrice/week	thrice/week, Progress to 4 or 5 days/week as tolerated		
Exercise intensity	RPE 9–11	RPE 9–11 Progress to RPE 12–14 as tolerated		
Aerobic exercise	Start with 5–10 mins to build up 20–30 mins/day (1st 2 weeks)	Exercise progressed by 5 mins every 2 weeks as tolerated. Goal- 50–60 mins		
Resisted exercise	Static and active exercises 5 repetitions → 10 repetitions, 1 set → 2 sets (1st 2–3 weeks)	Resistance added 50% 1RM (or RPE 5–6 out of 10) as tolerated (at least 3 repetitions without pain and much fatigue)	Resistance progressed by 2–10% as tolerated	Resistance progressed by 2–10% as tolerated. Goal: 80% 1RM
Stretching exercise	3 repetitions (10 s hold)	Progress the holding time to 30s		

Abbreviations: RPE-Rate of Perceived Exertion (Borg 6–20), RM-Repetition Maximum.

The "Revised Fibromyalgia Impact Questionnaire" will be used to evaluate the quality of life and fibromyalgia impact. It consists of 3 subdomains: function, overall impact, and symptoms. Each domain is rated from 0 (no difficulty) to 10 (great difficulty). The total score ranges from 0–100; the higher the score, the greater the FMS impact [47].

The physical function will be assessed using "Patient-Reported Outcomes Measurement Information System–Physical Function- Short-Form". It comprises 10 questions concerning physical activities, each rated from 1 (unable to do) to 5 (without any difficulty). The total score ranges from 10 to 50, with higher scores indicating better physical function [48].

Fatigue will be assessed using the "Multidimensional Assessment of Fatigue". It contains 16 items, each rated from 1 (no fatigue) to 10 (severe fatigue). The total score is calculated as the global fatigue index, ranging from 1–50. The higher the fatigue index, the greater the fatigue [49].

Pain catastrophizing will be evaluated using the "Pain Catastrophizing Scale". It consists of 13 thoughts or feelings experienced by people when in pain. The participants are required to rate the degree to which they experience each item from 0 (not at all) to 4 (always). The total score varies from 0–52, with higher scores denoting greater catastrophizing [50].

Kinesiophobia will be evaluated using the "Tampa Scale for Kinesiophobia". It assesses the fear of movement experienced by an individual. It is a 17-item Likert scale instrument rated from 1 (strongly disagree) to 4 (strongly agree). The total score varies from 17 to 68, with higher scores indicating greater kinesiophobia [51].

"Positive-negative affect" will be assessed using the "Positive and Negative Affect Schedule"). It has 10 items each for positive and negative feelings experienced by the individuals. Each item is rated from 1 (very slightly or not at all) to 5 (extremely). The total scores are calculated separately for positive and negative affect, ranging from 10 to 50. Higher scores imply a greater affect [52].

2.7. Data monitoring and management

The primary investigator will be accountable for the conduct and progress of the trial. A "data monitoring and safety committee" (DMSC) will monitor the integrity of the collected data and the safety of the participants. The investigator will update the trial's progress every 6 months to the DMSC, the IRSC, and EC via regular meetings. Any amendments required will be reported to the committees during the meeting. The investigators will ask the participants to report any untoward event they may experience after the intervention. Although serious adverse events are less likely in the trial, any significant event, such as aggravation of symptoms or soreness, will be noted and reported to the DMSC and concerned physician within 24 h. Based on the DMSC's recommendation, the event will be notified in detail to the ethics and institutional research committee within 14 days, and their recommendation will be implemented.

The data collected will be safely stored in a secure cabinet and only accessible to the trial investigators. The participant's data will be deidentified and entered in Microsoft Excel. The baseline data will include the participant's demographic data (age, gender, height, weight, diet, addiction, marital and employment status), fibromyalgia duration and medications, associated illness, and physical activity level. The investigator will also record the number of participants with non-adherence, withdrawals, loss to follow-up, and reasons for the same will be noted.

2.8. Statistical analysis

The deidentified data will be sent to a statistician for analysis. Descriptive statistics will be used to analyze the demographic data. "Repeated measures analysis of variance" and "Kruskal Wallis test" will be utilized to analyze the data, which follow normal and skewed distribution, respectively. The main effects for the time, group, and time-group interaction will be determined. The post hoc tests will be used to assess the pair-wise between-group differences. Statistical significance will be laid at $p < 0.05$. Intention to treat (ITT) analysis will be applied to compensate for the loss to follow-up or any missing outcome data affecting the power of the study. Thus, ITT analysis will be done if the power of the study is affected (when dropouts are more than expected, i.e.,>20%). If ITT will be required, the last observation carried forward method will be used to impute the follow-up measurement. Subgroup analysis will be performed using appropriate statistical tests as suggested by the statistician.

2.9. Ethics, confidentiality, and dissemination

The study procedure will be explained to the participants, informed consent will be obtained, and the investigators will keep the data confidential. The research will be performed following the "1964 Declaration of Helsinki ethical guidelines".

3. Discussion

Sleep is vital to restore the body's functions, thus contributing to good health [9]. Evidence shows a strong association between deprived sleep and impaired pain suppressive pathways among healthy people [9] and a higher risk of FMS in adult females [53]. An association exists between disturbed sleep, FMS symptoms, and quality of life [5,54,55]. Additionally, sleep disruptions in FMS individuals result in significant periods of daytime somnolence, which may adversely affect the performance of the individual [8].

The present study protocol is the first to compare therapies such as Craniosacral therapy and Bowen therapy with a manual placebo group, such as static touch, and a standard group, such as exercise in FMS participants. Limited evidence exists on the efficacy of these therapies in

FMS individuals [18,19,26]. Thus, the outcomes of our research will offer invaluable insights into the role of various treatments on sleep quality and quality of life.

The current protocol will provide information about these therapies' impact on somatic (fatigue, pain threshold, function) and psychosocial (pain catastrophizing, kinesiophobia, positive-negative affect) variables influencing FMS. Our study will also render an understanding of the feasibility of applying the therapies in clinical settings and their adherence among FMS individuals.

Craniosacral therapy is hypothesized to influence the CNS, which may influence the performance of the visceral, endocrinal, and immune systems [17]. Thus, we may hypothesize that it might be more effective than other manual therapies. However, since the manual interventions make use of touch, the effect of static touch needs to be differentiated from these touch interventions. Bowen therapy is thought to work directly on the muscles producing relaxation [56]. Thus, we expect that it might influence somatic symptoms more than psychological ones. Exercise is found to reduce FMS symptoms and improve the quality of life [57]. Thus, we also expect exercises to improve outcomes in the current study. In summary, the researchers hypothesized that each of the interventions might have an influence on FMS symptoms.

The study has certain limitations. PSQI is a valid and reliable subjective measure for assessing sleep quality. However, future studies may use polysomnograms as an objective method for studying sleep quality. Secondly, the study is localized to a region in India. Therefore, study results cannot be generalized, suggesting the need to conduct studies across different geographical locations in India.

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CRediT authorship contribution statement

RU and VP: Research design and concept; acquisition, analysis, and interpretation of the data; drafting of the work; revision and final approval of the manuscript to be published. **DG and YS:** Research design; analysis and interpretation of data; revision and final approval of the version to be published.

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.

Data availability

The deidentified participant data underlying the study results will be shared after publication for three years with researchers who provide a methodologically sound proposal.

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