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A randomized controlled trial investigating the effects of craniosacral therapy on pain and heart rate variability in fibromyalgia patients

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Context: Fibromyalgia is a prevalent musculoskeletal disorder associated with widespread mechanical tenderness, fatigue, non-refreshing sleep, depressed mood and pervasive dysfunction of the autonomic nervous system: tachycardia, postural intolerance, Raynaud's phenomenon and diarrhoea.
Objective: To determine the effects of craniosacral therapy on sensitive tender points and heart rate variability in patients with fibromyalgia.
Design: A randomized controlled trial.
Subjects: Ninety-two patients with fibromyalgia were randomly assigned to an intervention group or placebo group.
Interventions: Patients received treatments for 20 weeks. The intervention group underwent a craniosacral therapy protocol and the placebo group received sham treatment with disconnected magnetotherapy equipment.
Main measures: Pain intensity levels were determined by evaluating tender points, and heart rate variability was recorded by 24-hour Holter monitoring.
Results: After 20 weeks of treatment, the intervention group showed significant reduction in pain at 13 of the 18 tender points ($P<0.05$). Significant differences in temporal standard deviation of RR segments, root mean square deviation of temporal standard deviation of RR segments and clinical global impression of improvement versus baseline values were observed in the intervention group but not in the placebo group. At two months and one year post therapy, the intervention group showed significant differences versus baseline in tender points at left occiput, left-side lower cervical, left epicondyle and left greater trochanter and significant differences in temporal standard deviation of RR segments, root mean square deviation of temporal standard deviation of RR segments and clinical global impression of improvement.
Conclusion: Craniosacral therapy improved medium-term pain symptoms in patients with fibromyalgia.

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Introduction

In fibromyalgia, the perception of pain is known to be related to modifications in the central nervous system that result in the amplification of nociceptive impulses.[1–3] This phenomenon, known as 'central sensitization', has been attributed to neuronal synaptic plasticity in response to previous pain episodes. Differences in the degree of central sensitization would explain the variations in pain intensity experienced by fibromyalgia patients.[1–3] The four main sites in the pain system that are potentially susceptible to modification are peripheral tissue, brain, descending modulation system and spinal cord.[2]

It has not been scientifically demonstrated that pain is generated solely by upper areas of cortical activity.[4] In fibromyalgia, abnormal levels of substance P and serotonin in brain and in spinal cord at nerve root level produce abnormalities in neuroendocrine and nociceptive functions that can cause sleep disruption, enhanced pain perception and symptoms of intestinal dysfunction.[5]

Both fibromyalgia and chronic fatigue syndrome appear to be associated with alterations in autonomic function.[6,7] The most common forms of dysautonomia, observed in one-third of fibromyalgia patients, are neuromediated hypotension and orthostatic tachycardia syndrome. Patients have an exaggerated increase in heart rate in response to exercise.[8] Dysautonomia is often associated with intense fatigue. A study using heart rate variability analysis and head-upright tilt table test demonstrated that autonomic nervous system dysfunction is frequent in patients with fibromyalgia and that dysautonomia may play a central role in the pathogenesis of this disease. Hence, fibromyalgia may be a pain syndrome that is maintained by the sympathetic nervous system.[9,10] Researchers using 24-hour Holter monitoring to study the circadian behaviour of the autonomic nervous system reported sympathetic hyperactivity in fibromyalgia patients throughout the 24-hour period.[11] Dysautonomia, used here to describe a sympathetic nervous system that is persistently hyperactive but at the same time hyporeactive to stress, is detected in fibromyalgia patients by means of heart rate variability analysis and/or the head-upright tilt table test.[3,12] Thus, Vaeroy *et al.*[13] and Elam *et al.*[14] reported a lower peripheral sympathetic response to acoustic stimulation, cooling and muscle contraction in fibromyalgia patients than in healthy controls.

Manual therapeutic techniques have been reported to produce significant improvements in pain intensity and range of movement in fibromyalgia patients.[15–19] The technique known as craniosacral therapy is based on a study by Hack *et al.*,[20] who reported that the rectus capitis posterior minor muscle of the head was bound to the dura mater at the atlanto-occipital joint, with a large amount of connective tissue (fasciae) between the two structures. It was subsequently reported that lesions or stress affecting this connection may be a potentially important factor in the onset of chronic pain, among other symptoms. Thus, a dysfunction in the rectus capitis posterior minor muscle triggers a central sensitization phenomenon that promotes hypertonia in paravertebral muscles.[20–26]

Various studies have demonstrated the efficacy of alternatives and complementary therapies to reduce pain symptoms in fibromyalgia.[15–19] However, we could find no studies that address the effects of craniosacral therapy in tender points and heart rate variability. The purpose of this investigation, therefore, was to assess the therapeutic effects of craniosacral therapy on tender points and heart rate variability in these patients. We hypothesized that craniosacral therapy would decrease disease symptoms.

Methods

The present investigation was a randomized controlled trial. A sample of 135 patients was selected by non-probabilistic accidental sampling from among all patients with fibromyalgia ($n = 250$) with computerized hospital records at Torrecardenas Hospital (Almeria, Spain) who were receiving protocolized pharmacological treatment. Figure 1 depicts the recruitment process. Study inclusion criteria were diagnosis of fibromyalgia, age of 16–65 years, and signing of informed consent to study participation. Exclusion criteria were impaired skin integrity, the practice of any type of regular physical exercise or receipt of any

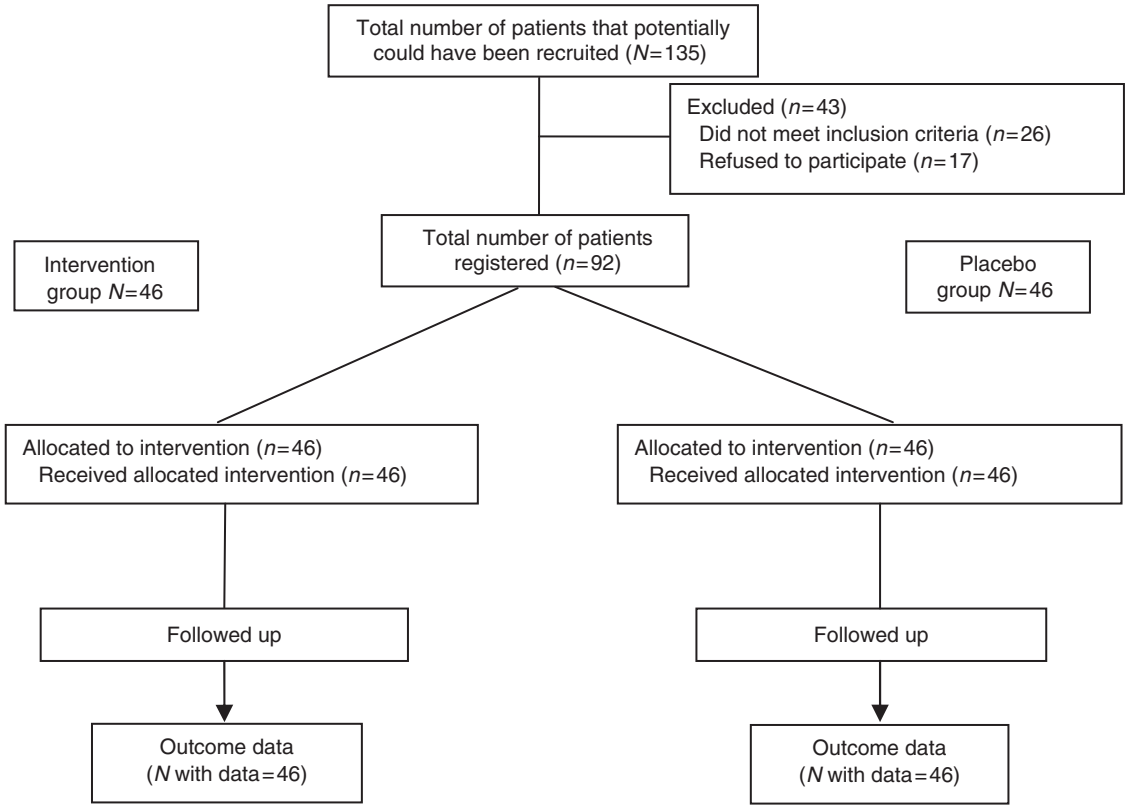

Figure 1 Flow of patients who participated in the study. None of the 92 randomized patients withdrew because of adverse events.

other non-pharmacological therapies. The study was approved by the University of Almeria Ethics Committee.

The final study group of 92 patients (aged 16–65 years) were assigned by a balanced stratified random assignment method to an intervention group for craniosacral therapy ($n = 46$ females) or a placebo group for sham treatment with disconnected magnetotherapy equipment ($n = 46$ females). Stratified balanced randomization was performed to guarantee balance between the groups in the type of medication they were receiving. The groups were balanced for type of medication received, using a stratification system that generates a sequence of letters for each combination of categories. Sequences were derived from a table of correlatively ordered permutations of the letters A and B in groups of six, with each letter appearing three times (AAABBB, ABABAB, etc.). The sequences assigned to patients were placed in envelopes containing the allocation to each study group.

Before application of therapeutic protocol, baseline data were gathered on pain intensity and heart rate variability. Twice a week for 20 weeks, the intervention group received a 1-hour session of craniosacral therapy and the placebo group received a sham treatment protocol with disconnected magnetotherapy equipment on cervical dorsal and lumbar regions (10 minutes per region). A second assessment of the seven variables was performed immediately after the final treatment session. A third and fourth assessment was performed at two months and 1 year. Craniosacral and magnetotherapy therapists and patients were not blinded to the therapy

allocation, although the patients were not aware that one was a sham treatment. Pain intensity and heart rate variability were evaluated by a blinded assessor, who did not know whether patients belonged to the intervention or placebo group.

Room temperature was always maintained at 29.8–34.5°C and relative humidity at 39–42% (Oregon Scientific Model pe 299N; Oregon Scientific Ltd, Maidenhead, UK). In order to control for any seasonal bias, interventions were carried out in all seasons from 15 April 2006 to 15 March 2008.

Outcome measures

Body composition by bioelectrical impedance analysis

Percentage of body fat was determined by attaching electrodes to hands and feet and measuring the resistance of body tissues to an electrical signal by means of a Tanita BF-350 Body Composition Analyser (Tanita Corporation, Tokyo).

Tender point evaluation (pressure algometry)

Pain was assessed at 18 tender point sites in accordance with American College of Rheumatology recommendations[27] by using a Wagner FPI 10 pressure algometer (pressures from 0.5 to 5 kg at 10 0.5-kg intervals). Sites were as follows: (1) right occiput, posteroinferior region of head at insertion of right occipital musculature; (2) left occiput, posteroinferior region of head at insertion of left occipital musculature; (3) right-side lower cervical at anterior aspects of intertransversal spaces between fifth (C5) and seventh (C7) cervical vertebrae; (4) left-side lower cervical at same localizations; (5) right trapezius muscle at midpoint of upper border; (6) left trapezius muscle at same localization; (7) right supraspinatus muscle at its origin in the upper region of the scapula near internal border; (8) left supraspinatus muscle at same localization; (9) second right rib at closest point to the sternum; (10) second left rib at same localization; (11) right lateral epicondyle at the humeral bone bridge where forearm extensor muscles begin; (12) left lateral epicondyle at same localization; (13) right gluteal muscle, in upper outer quadrant at anterior fold of muscle; (14) left gluteal muscle at same localization; (15) right greater trochanter of the femur, a bony prominence in which piriformis muscles are inserted; (16) left greater trochanter at the same localization; (17) right knee at subcutaneous tissue of internal portion above the knee joint line; (18) left knee at same localization.

Electrocardiogram recordings

These were obtained with two recording channels and five Red Dot monitoring electrodes. A Holter device (Rozinn Digital Holter Model RZ153) was used to record the analogue signal (10 bits) over 24 hours. Sampling range was 128 samples and the frequency response filter was estimated to be between 0.05 and 60 Hz. Electrodes were attached as follows: channel 1 (−), at right border of the sternal manubrium; channel 1 (+), at axillary anterior line of sixth left rib; channel 2 (−), at left border of sternal manubrium; channel 2 (+), approximately 1 cm to right of the xyphoid apophysis; and earth channel, at right floating ribs on the bony part.

QRS complexes and deviations from RR intervals

These were determined by using the Holter computer application. Spectral analysis of RR interval variability was carried out to identify dominating frequencies in the heart rate variability analysis.

Clinical global impression of severity

The severity of the patient's physical condition was evaluated by a single researcher (GMP) on a Likert scale ranging from level 1 (absence of illness) to level 7 (extremely ill).[28]

Clinical global impression of improvement

The improvement perceived by the patient was assessed on a Likert scale ranging from level 1 (very much improved) to level 7 (extremely ill).[28]

Treatment intervention

Craniosacral therapy protocol

Craniosacral therapy is a manual therapeutic method to assess and treat problems affecting the craniosacral system.[22,24,25] The rhythm of the craniosacral system can be considered similar to that of the cardiovascular and respiratory systems, among other rhythmic systems. Palpation methods can be used for functional observations and for the treatment of dysfunctions. The most accessible areas of this system are the cranial bones, sacrum and coccyx, since these are associated with membranes containing cerebrospinal fluid. This liquid is generated and reabsorbed within the system, producing a palpable rhythm with a frequency of 6–12 cycles/min and providing a dynamic communication cycle within a semi-closed hydraulic system. Information on the state of the craniosacral system can be obtained by palpitating the frequency, fullness, symmetry and quality of the craniosacral rhythm. Evaluation and treatment of the craniosacral system is achieved by means of very light lifting or traction force techniques, using <5 g of pressure. Treatment is aimed at removing the restrictive obstacle and returning the system to its natural state.[22] The craniosacral therapy protocol in this study established the following sequence of manipulative therapy[24,25]: still point (in feet), pelvic diaphragm release, scapular girdle release, frontal lift, parietal lift, compression–decompression of sphenobasilar fascia, decompression of temporal fascia, compression–decompression of temporomandibular joint and evaluation of dural tube (balance of dura mater).

Statistical considerations

Variance homogeneity was tested with the Levene test, obtaining a 95% confidence level and P-value >0.05 and confirming variance equality. After performing descriptive statistics of variables at baseline, the normal distribution of variables was determined using the Kolmogorov–Smirnov test, expressing continuous data as means with standard deviation (SD) in the text and tables.

Temporal changes in the scores were examined by using a two-way repeated measures ANOVA. Three experimental factors were considered: group factor, with two components (craniosacral therapy group and sham therapy group); time factor, with four components (baseline time, immediate post-therapy, two months post therapy and one year post therapy) and individual factor (46 in placebo group and 46 in intervention group). The group and time factors had fixed crossed effects, while the individual factor had randomized effects nested within each study group.

Treatment efficacy was analysed by using a t-test for paired samples. Independent t-tests were applied to baseline scores to determine whether the random assignment to groups adequately controlled for baseline demographic differences. Changes in variables within each group were measured using the paired t-test for independent samples. The Pearson correlation coefficient was applied to establish correlations among variables. Data were stored in a database constructed with SPSS for Windows version 17.0 (SPSS Inc., Chicago, IL, USA).

Results

Patients

Out of 135 candidate patients, 109 were selected for the study (105 women, 4 men), aged 38–64 (mean age: 52.532 ± 11.658 years old). Seventeen patients withdrew from the study before randomized assignation, yielding a final study sample of 92 patients (Figure 1). Demographic characteristics are shown in Table 1. Baseline characteristics were similar between the intervention and placebo groups except in the temporal standard deviation of RR segments ($P<0.024$) and root mean square deviation of temporal standard deviation of RR segments ($P<0.049$) (Table 2). The number of tender points did not significantly differ ($P<0.178$) between the intervention (650) and placebo (641) groups. No significant intragroup differences in body composition were detected in any of the four analyses performed during the study, and no significant differences in body composition were found between the study groups at any time point (baseline: cellular mass $P<0.889$, extracellular mass $P<0.840$, lean mass $P<0.424$; 20 weeks: cellular mass $P<0.938$, extracellular mass $P<0.816$, lean mass $P<0.416$; 2 months: cellular

Table 1 Demographic characteristics of the groups

Characteristics	Intervention ($n=46$)	Placebo ($n=46$)	*P*-value
Mean age (SD)	53.85 (10.12)	51.34 (13.07)	0.096
Female (%)	46 (50)	46 (50)	1.000
Educational level (%)			
Grade school	20 (43.5)	15 (32.6)	0.056
High school	15 (32.6)	18 (39.1)	0.088
University	11 (23.9)	13 (28.3)	0.102
Employment status (%)			
Full-time	23 (50)	20 (43.5)	0.082
Part-time	10 (21.7)	11 (23.9)	0.356
Unemployed	13 (28.3)	15 (32.6)	0.134
Marital status (%)			
Married	30 (65.2)	27 (58.7)	0.091
Divorced	11 (23.9)	16 (34.8)	0.061
Never married	5 (10.9)	3 (6.5)	0.177

P-value <0.05 (95% confidence interval).

mass $P<0.885$, extracellular mass $P<0.833$, lean mass $P<0.427$; 1 year: cellular mass $P<0.732$, extracellular mass $P<0.829$, lean mass $P<0.532$) (Table 2).

At baseline, significant correlations were found (Pearson correlation coefficient) in the presence of tender points between right and left supraspinatus muscles ($r=0.381$; $P=0.015$), right and left trapezius muscles ($r=0.625$; $P=0.006$), right and left second ribs ($r=0.537$; $P=0.010$), and right and left lower cervicals ($r=0.512$; $P=0.008$).

Results immediately after 20 weeks of therapy

Pressure algometry analyses showed significant reductions in the number of tender points in the intervention group versus placebo group in the right occiput ($P<0.044$), left occiput ($P<0.035$), right-side lower cervical ($P<0.035$), left-side lower cervical ($P<0.048$), right trapezius muscle ($P<0.018$), left trapezius muscle ($P<0.040$), right supraspinatus muscle ($P<0.031$), left second rib ($P<0.040$), right lateral epicondyle ($P<0.017$), left lateral epicondyle ($P<0.023$), left gluteal muscle ($P<0.033$), right greater trochanter ($P<0.044$) and left greater trochanter ($P<0.031$). No reduction in the number of tender points was observed in the placebo group (Tables 3 and 4). The intervention group showed a significant

Table 2 Differences between groups in quantification of pain intensity, risk of relapse, and heart rate variability

Variable	Baseline Mean (SD)		*P*-value Pre T	20 weeks Mean (SD)		*P*-value 1st PT	2 months Mean (SD)		*P*-value 2nd PT	1 year Mean (SD)		*P*-value 3rd PT
	IG ($n=46$)	PG ($n=46$)		IG ($n=46$)	PG ($n=46$)		IG ($n=46$)	PG ($n=46$)		IG ($n=46$)	PG ($n=46$)	
Heart rate	80.36 (12.13)	83.23 (13.23)	0.089	83.32 (14.29)	81.43 (15.34)	0.099	79.12 (15.26)	84.34 (17.23)	0.071	80.78 (16.78)	86.65 (17.98)	0.065
HRV	2.45 (0.32)	2.97 (0.56)	0.024*	2.35 (0.54)	2.65 (0.34)	0.043*	2.54 (0.61)	2.79 (0.41)	0.047*	2.63 (0.98)	2.92 (1.03)	0.035*
RMSD	160.45 (60.43)	176.34 (85.45)	0.049*	163.45 (62.41)	173.13 (87.56)	0.046*	158.33 (61.37)	171.23 (56.67)	0.031*	170.43 (64.58)	177.76 (77.89)	0.047*
CGI-I				5.02 (0.76)	6.20 (0.89)	0.039*	5.99 (0.88)	6.30 (0.65)	0.046*	6.14 (0.80)	6.43 (0.72)	0.048*
CGI-S	6.25 (0.92)	5.92 (1.07)	0.151	5.68 (0.89)	6.00 (1.04)	0.047*	5.79 (3.31)	5.98 (5.80)	0.059	5.96 (2.15)	6.12 (3.97)	0.072
Body composition												
CM	22.84 (2.86)	22.75 (2.55)	0.889	22.78 (2.87)	22.66 (2.33)	0.938	22.81 (2.84)	22.72 (2.75)	0.885	22.69 (1.36)	22.49 (3.47)	0.734
EM	37.06 (3.23)	37.20 (3.06)	0.840	37.12 (3.19)	37.23 (3.01)	0.816	37.25 (3.25)	37.20 (3.07)	0.833	37.12 (4.23)	38.14 (4.07)	0.943
LM	59.05 (5.68)	58.01 (5.08)	0.424	59.16 (5.67)	57.99 (5.78)	0.416	59.22 (5.67)	58.20 (5.80)	0.427	59.32 (6.72)	59.76 (5.81)	0.678

**P*-value <0.05 (95% confidence interval).
IG, intervention group; PG, placebo group; Pre T, pre therapy; 1st PT, post therapy (immediately after 20 weeks of treatment); 2nd PT, post therapy (two months after treatment); 3rd PT, post therapy (1 year after treatment); HRV, temporal standard deviation of RR segments; RMSD, root mean square deviation of HRV index; CGI-I, clinical global impression of improvement; CGIs, clinical global impression of severity; CM, cellular mass; EM, extracellular mass; LM, lean mass.

Table 3 Differences between groups in numbers of patients with painful tender points (nine tender points I)

Tender points	Baseline PTP		*P*-value Pre T	20 weeks PTP		*P*-value 1st PT	2 months PTP		*P*-value 2nd PT	1 year PTP		*P*-value 3rd PT
	IG ($n=46$)	PG ($n=46$)		IG ($n=46$)	PG ($n=46$)		IG ($n=46$)	PG ($n=46$)		IG ($n=46$)	PG ($n=46$)	
RO	37	34	0.462	27	36	0.044*	29	38	0.035*	33	35	0.639
LO	39	36	0.426	29	38	0.035*	29	38	0.035*	31	40	0.025*
LCR	38	37	0.791	29	38	0.035*	33	38	0.219	35	39	0.298
LCL	37	36	0.799	26	35	0.048*	27	36	0.044*	30	39	0.030*
RTM	36	37	0.799	23	34	0.018*	31	37	0.158	35	39	0.298
LTM	37	39	0.587	28	37	0.040*	32	40	0.044*	36	42	0.083
RSM	40	36	0.276	24	34	0.031*	30	39	0.030*	36	38	0.604
LSM	34	34	1.000	35	36	0.806	31	37	0.158	34	37	0.462
2nd RR	36	34	0.626	31	33	0.655	33	37	0.334	34	34	1.000

*P-value <0.05 (95% confidence interval).
Values are presented as numbers of patients with painful tender points.
PTP, painful tender points; IG, intervention group; PG, sham group; Pre T, pre therapy; 1st PT, post therapy (immediately after 20 weeks of treatment); 2nd PT, post therapy (two months after treatment); 3rd PT, post therapy (1 year after treatment); RO, right occiput; LO, left occiput; LCR, lower cervicals (righ-side); LCL, lower cerivicals (left-side); RTM, right trapezius muscle; LTM, left trapezius muscle; RSM, right supraspinatus muscle; LSM, left supraspinatus muscle; 2nd RR, second right rib.

Table 4 Differences between groups in numbers of patients with painful tender points (nine tender points II)

Tender points	Baseline PTP		*P*-value Pre T	20 weeks PTP		*P*-value 1st PT	2 months PTP		*P*-value 2nd PT	1 year PTP		*P*-value 3rd PT
	IG ($n=46$)	PG ($n=46$)		IG ($n=46$)	PG ($n=46$)		IG ($n=46$)	PG ($n=46$)		IG ($n=46$)	PG ($n=46$)	
2nd LR	35	36	0.806	28	37	0.040*	32	36	0.348	34	37	0.462
RLE	36	37	0.799	29	38	0.017*	31	40	0.025*	35	38	0.445
LLE	37	36	0.799	27	37	0.023*	29	38	0.035*	29	38	0.035*
RG	37	37	1.000	26	33	0.131	27	36	0.044*	36	39	0.426
LG	32	34	0.648	23	33	0.033*	26	32	0.199	30	33	0.506
RGT	37	35	0.618	27	36	0.044*	31	36	0.246	34	36	0.629
LGT	34	34	1.000	24	34	0.031*	26	35	0.048*	28	37	0.040*
RK	36	35	0.806	35	35	1.000	32	36	0.348	34	35	0.812
LK	32	34	0.648	32	33	0.821	33	32	0.821	34	32	0.648

*P-value <0.05 (95% confidence interval).
Values are presented as numbers of patients with painful tender points.
PTP, painful tender points; IG, intervention group; PG, sham group; Pre T, pre therapy; 1st PT, post therapy (immediately after 20 weeks of treatment); 2nd PT, post therapy (two months after treatment); 3rd PT, post therapy (1 year after treatment); 2nd LR second left rib; RLE, right lateral epicondyle; LLE, left lateral epicondyle; RG, right gluteal muscle; LG, left gluteal muscle; RGT, right greater trochanter, LGT, left greater trochanter; RK, right knee; LK, left knee.

reduction in pain at 13 of the 18 tender points in comparison with baseline values: right occiput, $P<0.028$); left occiput, $P<0.026$); right-side lower cervical, $P<0.033$); left-side lower cervical, $P<0.042$); right trapezius muscle, $P<0.026$); left trapezius muscle, $P<0.042$); right supraspinatus muscle, $P<0.042$); left second rib, $P<0.042$); right lateral epicondyle, $P<0.026$); left lateral epicondyle, $P<0.033$); left gluteal muscle, $P<0.026$); right greater trochanter, $P<0.042$); and left greater trochanter, $P<0.023$). Repeated-measures ANOVA showed a significant time × groups interaction for right occiput ($F=8.326$; $P<0.023$); left occiput ($F=7.543$; $P<0.029$); right-side lower

cervical ($F=5.722$; $P<0.035$); left-side lower cervical ($F=4.123$; $P<0.019$); right trapezius muscle ($F=7.015$; $P<0.012$); left trapezius muscle ($F=3.756$; $P<0.040$); right supraspinatus muscle ($F=5.045$; $P<0.009$); left lateral epicondyle ($F=7.945$; $P<0.031$); right gluteal muscle ($F=7.836$; $P<0.035$); left gluteal muscle ($F=7.836$; $P<0.034$); right greater trochanter ($F=8.276$; $P<0.023$) and left greater trochanter ($F=8.034$; $P<0.031$).

No significant differences in heart rate variability versus baseline were observed in either group. However, the intervention and placebo groups significantly differed in temporal standard deviation of RR segments ($P<0.043$) and in root mean square deviation of temporal standard deviation of RR segments ($P<0.046$) (Table 2). Clinical global impression of improvement ($P<0.033$) and clinical global impression of severity ($P<0.042$) values were significantly improved in the intervention group versus baseline but not in the placebo group (clinical global impression of improvement, $P<0.064$ and clinical global impression of severity, $P<0.081$ versus baseline) (Table 2). Repeated-measures ANOVA showed a significant time × groups interaction for clinical global impression of improvement ($F=6.329$; $P<0.043$) and clinical global impression of severity ($F=5.124$; $P<0.048$).

Results at two months post therapy

The groups significantly differed in number of tender points at the right occiput ($P<0.035$), left occiput ($P<0.035$), left-side lower cervical ($P<0.044$), left trapezius muscle ($P<0.044$), right lateral epicondyle ($P<0.025$), left lateral epicondyle ($P<0.035$), right gluteal muscle ($P<0.044$) and left greater trochanter ($P<0.048$). At two months, significant differences in temporal standard deviation of RR segments ($P<0.047$) and root mean square deviation of temporal standard deviation of RR segments ($P<0.031$) versus baseline values were observed in the intervention group but not in the placebo group. Clinical global impression of improvement values were significantly higher in the intervention group than in the placebo group ($P<0.046$), but the groups did not significantly differ in clinical global impression of severity values ($P<0.059$). Repeated-measures ANOVA showed a significant time × groups interaction for tender points [right occiput ($F=6.745$; $P<0.044$), left occiput ($F=7.522$; $P<0.029$), left-side lower cervical ($F=8.326$; $P<0.023$), right supraspinatus muscle ($F=8.784$; $P<0.022$), left lateral epicondyle ($F=6.378$; $P<0.044$), right gluteal muscle ($F=7.631$; $P<0.030$), left greater trochanter ($F=10.489$; $P<0.047$), clinical global impression of improvement ($F=9.629$; $P<0.043$) and clinical global impression of severity ($F=11.368$; $P<0.048$)].

Results at one year post therapy

At one year after therapy, the intervention group showed significant differences versus baseline at left occiput ($P<0.019$), left-side lower cervical ($P<0.026$), left epicondyle ($P<0.035$) and left greater trochanter ($P<0.044$) and significant differences versus baseline in temporal standard deviation of RR segments ($P<0.026$), root mean square deviation of temporal standard deviation of RR segments ($P<0.035$) and clinical global impression of improvement ($P<0.040$). The groups significantly differed in tender points at left occiput ($P<0.025$), left-side lower cervical ($P<0.030$), left lateral epicondyle ($P<0.035$) and left greater trochanter ($P<0.040$) and in temporal standard deviation of RR segments ($P<0.035$), root mean square deviation of temporal standard deviation of RR segments ($P<0.047$), and clinical global impression of improvement ($P<0.048$). Repeated-measures ANOVA showed a significant time × groups interaction for tender points (left occiput ($F=8.932$; $P<0.046$), left lateral epicondyle ($F=5.923$; $P<0.048$), and clinical global impression of improvement ($F=6.956$; $P<0.040$).

Discussion

After a twice-weekly programme of craniosacral therapy for 20 weeks, pressure algometry measurements demonstrated a significant reduction in tender points in this series of patients with fibromyalgia. Pain reduction was recorded at all

studied sites with the exception of the right gluteal muscle and both knees.

Ziljstra *et al.*[29] found a significantly lower number of tender points in fibromyalgia patients at two and three months after a six-month programme of talasotherapy combined with exercise, education and recreational activities. Multimodal treatment programmes have produced significant reductions in painful tender points, which persisted up to six months after the treatment.[30] Significant reductions in tender points were reported after a combined six-week programme of aerobic exercise, biofeedback assisted group relaxation training and biofeedback-assisted exercise.[31]

Manual therapies appear to be widely used by fibromyalgia patients[32,33] and to offer them pain relief and an enhanced quality of life. Craniosacral therapy was found to contribute to a better quality of life in fibromyalgia patients, improving their mood, nocturnal rest, and physical function.[34] Baranowsky *et al.*[35] and Singh *et al.*[17] reported that manual therapy and acupuncture significantly improved the quality of life of these patients, probably because osteomuscular pain is a cardinal symptom of this disease.[36] Younger patients with a background of anxiety and depression are also increasingly turning towards alternative and complementary therapies for a solution to their health problems.[36]

Another manual therapy technique used in these patients is ischaemic compression therapy, developed by Travell and Simons.[37] Its application to sensitive zones followed by spinal manipulations in alternate sessions reduced the number of tender points determined by applying 4 kg of pressure with a pressure algometer.[38] These beneficial effects persisted for one month after one month without treatment, improving the health of patients and supporting the use of the two techniques. The effectiveness of ischaemic compression therapy and craniosacral therapy can be understood in terms of the physiopathological processes of the fascia.[37] Traditional medicine limits its assessment of muscular function to contractile capacity. However, there are no specific parameters to indicate its dysfunction, since muscle biopsies do not reveal differential alterations with regard to muscular function in sedentary persons with no muscle training or clinical symptoms of fibromyalgia.

Physical therapeutic techniques can be considered as complementary to drug therapies and may be used in combination with other non-drug therapies in a multidisciplinary approach. Thus, cognitive therapy can make a major contribution[39] and meditation and hypnosis achieve important reductions in the sensory perception of pain via indirect effects on areas of the brain that deal with sensations and reactions to pain.[40,41] A multidisciplinary therapeutic approach has been shown to improve the levels of pain intensity perceived by fibromyalgia patients.[42,43]

We found no significant differences between mean heart rate variability values before and after the therapy, as also reported by previous studies on manual therapy.[44] Fibromyalgia patients have lower than average cardiovascular and aerobic capacity, and their muscular system makes inefficient use of oxygen. Their consequently reduced functional capacity can have a negative effect on cardiovascular and peripheral circulation.[44]

Our findings indicate that craniosacral therapy improves medium-term pain symptomatology in fibromyalgia patients. The improvement observed at two months dissipated over the one-year follow-up, underscoring the need for this manual therapy treatment to be sustained in order to remain effective. We cannot report on its effects on the autonomic nervous system, since no significant changes in heart rate variability were detected. According to these results, craniosacral therapy can be considered a complementary therapeutic approach to fibromyalgia that diminishes the patient's perception of pain. This therapy should be included as part of the multimodal therapeutic approach to these patients.

Although the examiners who measured the outcome variables were blinded to the group assignment of the patients, the therapists were not. The patients themselves were evidently aware of the type of therapy received but were not aware that one was a sham treatment. A further study limitation is that the patients were recruited from a single hospital and the receipt of any other type of alternative or complementary therapy was an exclusion criterion (to enhance the homogeneity

of the sample), restricting extrapolation of our findings to patients with these characteristics.

As reported by some authors, manual therapy may be even more effective if integrated into a more holistic wellness intervention that includes other health-promoting behaviours such as exercise.[31] Future studies are warranted to study the effects on these patients of craniosacral therapy in combination with other alternative approaches

Clinical messages

- A 20-week programme of craniosacral therapy offers clinical benefit to fibromyalgia patients.
- It reduces the number of painful tender points.
- It increases the clinical global impression of improvement.
- It reduces the clinical global impression of severity.

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