

Does Improvement Towards A normal Cervical Configuration Aid in the Management of Fibromy randomized controlled trial

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ABSTRACT

Objective: To investigate the short and long term effects of adding Deneroll cervical extension traction to a multi-modal program on fibromyalgia management outcomes in addition to three-dimensional postural measures, and cervical sagittal alignment. **Methods:** In this study, 80 patients between 40 and 65 years who experienced fibromyalgia syndrome with definite forward head posture and cervical hypo-lordosis were randomly assigned to the control or experimental group. Both groups received a multi-modal program. Additionally, the experimental group received Deneroll cervical traction. The Fibromyalgia Impact Questionnaire was administered, and the Visual analogic scale, Pain Catastrophizing Scale, algometric score, Pittsburgh Sleep Quality Index, Multidimensional Fatigue Inventory, General Health Questionnaire, Beck Anxiety Inventory, Beck Depression Inventory, three-dimensional postural measures, and cervical sagittal alignment in terms of anterior head translation distance and absolute rotatory angle were measured in all of the patients at three intervals. **Results:** The general linear model with repeated measures indicated a significant group \times time effect in favor of the experimental group on the measures of anterior head translation ($P < .0005$), absolute rotatory angle ($P = .05$), the three-dimensional postural parameters ($P < .05$), Fibromyalgia Impact Questionnaire ($P < .0005$), Pain Catastrophizing Scale ($P < .0005$), Algometric score ($F = P < .0005$), Pittsburgh Sleep Quality Index ($P < .0005$), Multidimensional Fatigue Inventory ($P < .0005$), General Health Questionnaire ($P < .0005$), Beck Anxiety Inventory ($P < .0005$), Beck Depression Inventory ($P < .0005$), and VAS ($P < .0005$). **Conclusions:** The results suggest that the addition of Deneroll cervical extension traction to a multi-modal treatment program is beneficial in treating patients with fibromyalgia syndrome. **Key words:** Fibromyalgia syndrome, Cervical, Head posture, Trtion.

INTRODUCTION

Fibromyalgia syndrome is a common and chronic disorder of pain regulation, as it involves increased sensitivity to pain (hyperalgesia) and lowered pain threshold (allodynia)³⁷, patients may also have a number of other symptoms such as fatigue, non-restorative sleep patterns, cognitive difficulties^{7,52} along with decreased quality of life³⁵.

Despite the high prevalence of this condition⁸, its conservative treatment remained a challenge for the available treatments directed at fibromyalgia (FM) (e.g. pharmacological, aerobic exercise, biofeedback, physical therapies, and multidisciplinary treatments). The outcome of these treatments is variable and long-term observational studies have four outcomes are typically poor^{9,41,4}. In a survey of 1,200 primary care physicians in the United States (33% response rate) found that 14% of respondents indicated excellent satisfaction with management of FM and other medically unexplained symptoms²².

Although the exact cause of FM has apparently not been discovered, various research theories in nutrition, stress factors, altered pattern of sleep and changes in neurotransmitters, there is growing evidence that central nervous system dysfunction is hypothesized that FM is a condition that appears to involve afferent processing and which is associated with abnormal sensory integration⁴⁶.

Many of our postural reflexes, the vestibulocollic reflex, cervic

pelvo-ocular reflex, vestibuloocular reflex, cervico-ocular reflex, and cervical somatosensory input, are housed, or occur, within the head and neck region³⁸. A correction of altered cervical sagittal configuration therefore, could be required to achieve optimal full spine postural correction, where the rest of the spine orients itself in a top-down fashion¹³. More important, this posture correction is essentially required to normalize aberrant afferent input to the CNS, which is considered as an essential component of normal sensorimotor integration⁴⁶.

Despite the fact that there is some evidence of a link between cervical posture and fibromyalgia^{36,39}, to the best of our knowledge, no published randomized controlled trial has addressed the issue of head and cervical posture correction and its impact on the FMS management outcomes. Accordingly, the primary hypothesis of this study was that cervical curve restoration and forward head posture correction will have short and long term effects on the three dimensional (3D) spinal posture parameters as well as FMS management outcomes such as Fibromyalgia Impact Questionnaire (FIQ), Pain Catastrophizing Scale (PCS), Algometric score, Pittsburgh Sleep Quality Index (PSQI), Multidimensional Fatigue Inventory (MFI), General Health Questionnaire (GHQ), Beck Anxiety Inventory (BAI), Beck Depression Inventory (BDI), and Visual Analogue Scale (VAS). In the current study we used a new orthotic cervical traction termed the Denneroll to help restore normal sagittal spinal configuration based on principles of 3-point bending traction methods²¹.

METHODS

Methods

A prospective, randomized, controlled study was conducted at a research laboratory of our university. All the patients were conveniently selected from our institution's outpatient clinic. The patients participated in the study after signing an informed consent form prior to data collection. Recruitment began after approval was obtained from our local institutional review board. Patients were

recruited from May 2011 to June 2012 for a 12-week treatment investigation follow-up.

Patients were enrolled, if they met the American College of Rheumatology criteria⁵³ for FMS, experienced at least 48 months with no recent improvement in symptoms to any degree, reported on the pain intensity, age reported a score ≥ 59 on the FM⁴⁴, and able to read and understand English.

Exclusion criteria include current medical disease, unstable hypertension, cardiovascular problems, current infection, and history of any medical conditions such as hepatitis, lupus, multiple sclerosis, rheumatoid arthritis, polio, epilepsy, rheumatic fever, history of neck or back surgery, psychiatric disorder affecting compliance.

The patients were randomized using means of a balanced stratified randomization into either the experimental group or control group (n=40). The randomization was balanced for type of medication and age by using a stratification method that generates a sequence of letters (1 to 10) correlatively ordered permutated into two categories and combination of categories assigned to patients in sealed envelopes containing the allocation sequence for the study groups. An independent person not involved in the research protocol and not involved in the trial, operated the randomization assignment.

Interventions

The patients in both groups received a 12-week multi-modal intervention supervised by a physical therapist, including an educational program, cognitive behavioral therapy, and exercise program.

Educative program

It consisted of twelve 2-hour sessions delivered over the treatment period (one session per week). This educative part included information about the typical course of the condition, medical conditions

causes of the illness, the influence of psychosocial factors on pain, current pharmacologic and non-pharmacologic treatments, the benefits of regular exercise, and the typical barriers to behavior change. The patients were encouraged to be active, to ask questions and to discuss issues with the speakers or with other participants. It was important that they shared their daily experience of the syndrome because it helps to illustrate the theoretical concepts addressed in the sessions. A summary of the contents of each educative session was provided earlier.¹⁷

Cognitive behavior therapy (CBT)

The CBT (12 weekly, 2-hour sessions), especially focused on the patients' thinking and involved problem-solving, stress and pain coping strategies, and relaxation⁵⁰ was led by a clinical psychologist. Patients were taught the meaning of the stress-tension-pain circle as a cognitive pain model and learned coping strategies and the reduction of catastrophising thoughts. Patients received weekly homework tasks, and encouraged to engage in physical activities. The patients participated in relaxation exercises during and between the sessions. The psychologist emphasized the need to practice the relaxation techniques at home daily. The therapists identified instances of maladaptive thinking and encouraged the group to challenge these instances and to provide more appropriate interpretations and alternatives.

Exercise program

The program conducted for 1 hour 3 times a week for 12 weeks. This exercise program consisted of relaxation techniques based on the published regimen by Ost⁴² dynamic (slow, controlled leg and arm swings), active stretching (i.e., bringing the leg up high and holding it there without anything to keep it in that extended position), and passive stretching (i.e., reaching out to the feet while sitting up).¹

Those in the control group received only a 12-week multimodal intervention program. The experimental group additionally received Deneroll cervical extension traction (Denneroll Industries (www.denneroll.com) of Sydney, Australia). Here, the patient lies flat on their

back on the ground with their arms and legs by their sides. They were encouraged to relax whilst on the Denneroll. The Denneroll was placed on the ground and positioned in the posterior of the neck depending on the problem addressed. The traction session was performed three times per week for 12 weeks. It began with 3 minutes per session and progressed to a maximum of 20 minutes per session in incremental fashion. The Denneroll orthotic was placed in the following regions based on the radiographic displacements:

1. In the upper cervical region. This position allows extension bending of the upper cervical while causing slight anterior head tilt (AHT). One subject required this placement location.
2. In the mid-cervical region (C2-C5). This position allows extension bending of the mid-upper cervical segments creating a slight posterior head tilt. Twenty five subjects required this placement location.
3. In the upper thoracic lower-cervical (C6-T1) region. This position allows extension bending of the lower cervical segments while causing significant posterior head tilt. Thirty four subjects required this placement location.

We did ask participants to start any new regular physical exercise programs (that were unrelated to the study) or other non-pharmacological interventions for FM during the study period.

Outcome Measures

Patients were assessed at baseline (pre-treatment), 10 weeks post-treatment, and at the 1-year follow-up).

Fibromyalgia Impact Questionnaire

The primary outcome was the Fibromyalgia Impact Questionnaire (FIQ), which is a valid self-report questionnaire developed to assess participant status, progress, and quality of life. The FIQ is composed of 10 subscales

and symptoms (physical function, work missed day, job ability, feel good, pain, fatigue, sleep, stiffness, anxiety and depression).²⁴ The total scores range from 0 to 100, higher the FIQ score, the greater is the impact of FMS on the participant.

Other outcome measures used to compare effectiveness of the treatment between the study and control groups included the 3D spinal posture parameters, VAS, PCS, algometric score, PSQI, MFI, GHQ, BAI, BDI, and cervical sagittal alignment in terms of AHT distance and absolute rotatory angle (ARA).

Cervical radiographs

A repeatable and reliable method⁴⁷ was used to quantify the main outcome measurement represented in cervical lordosis (ARA C2-C7) and any amount of anterior head translation distance AHT (C2-C7).

Rasterstereographic posture analysis

Rasterstereography (Formetric 2, Diers International GmbH, Schlangenbad, Germany) was used to examine posture and back shape characters. All testing procedures were done following Lippold et al's protocol.³² The Formetric scans were taken in a relaxed standing position. The patient was positioned in front of the black background screen at a distance of two meters from the measurement system. The column height was aligned to move the relevant parts of the patient's back into the center of the control monitor by using the column up/down button of the control unit; to ensure the best lateral and longitudinal position of the patient a permanent mark on the floor was used. The patient's back surface (including upper buttocks) was completely bare in order to avoid image disturbing structures.

After the patient and the system were correctly positioned, the system was ready for image recording. The image processing consists of automatic back surface reconstruction and shape analysis. The sagittal plane parameters (lumbar angles, thoracic angles, and trunk inclination), the frontal plane parameters (trunk imbalance and lateral deviation) and the transversal plane parameters

(vertebral surface rotation and) were selected to cover the pos three planes. A representative e Formetric system's print o graphically for a study group pat

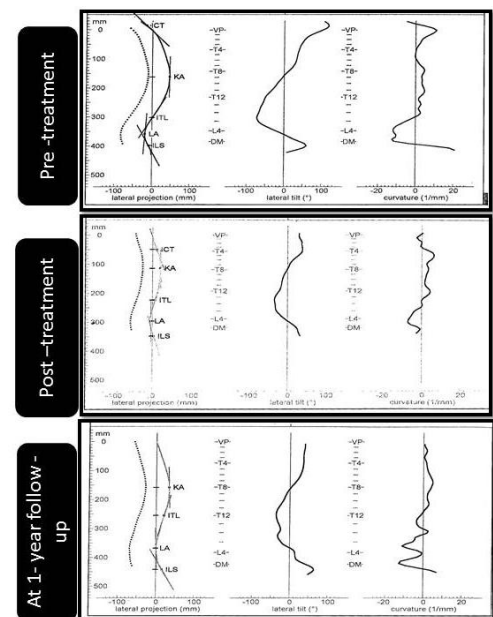


Fig. (1): Example of the Formetric out.

The Pain Catastrophizing Scal

The PCS was used to factors: rumination, magni helplessness associated to pain. items measured on a 5-point ranging from 0 (not at all) to 4 Higher scores indicate a greater catastrophize pain symptoms.¹¹

Algometric score

Algometric score (k, calculated as the average of pain-generating pressure values 18 points.⁴⁸

Sleep quality

The PSQI¹⁰ was used to quality and disturbances over a interval. Nineteen individual i seven "component" scores: su quality, sleep latency, sleep dur

sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. The sum of scores for these seven components yields one global score.

Fatigue

The MFI was used to measure fatigue severity. It covers the following dimensions: general fatigue, physical fatigue, mental fatigue, reduced motivation and reduced activity. Scores on each subscale range from 4 to 20, with higher scores indicating greater fatigue.¹⁶

General Health Questionnaire

The (GHQ-20) is a 20-item instrument for measuring psychological distress in chronic diseases. The 20-items use a four-point Likert scale ranging from "no distress at all" to "much more distress than usual" and are summated to give a total score from 0 to 60 where 0 is the best possible score indicating no distress. A score of 24 or more is defined as pathological psychological distress.⁴³

Beck Anxiety Inventory

The BAI instrument measures anxiety severity while discriminating anxiety from depression. It contains 21 items with a total score of 0–63, where higher scores indicate more anxiety.⁴

Beck Depression Inventory

The BDI is a questionnaire developed and validated for patients with depression. It contains 21 items that assess the cognitive and affective factors associated with depression. The range of score is 0–63, where values above 13 indicate presence of depression, and values above 21 indicate major depression.⁵

Pain intensity

Evaluation was done according to the VAS, the patients were presented with a 10cm line and asked to mark an X on the line indicating the intensity of their pain over the past week. The line was labeled "no pain" at point zero at one end and "the worst pain you can imagine" at point 10 at the other end. The distance from point 0 was measured with a metric ruler and was scored between 0 and 10.

Sample size determination

The required sample determined for the primary outcome i.e. overall score of FIQ. In previous research,⁶ a clinically significant change is a 15-20% reduction in score (which equals to a ~1 reduction). We can detect difference of at least 15% with a power of 95% with two groups (intervention and control group) of 25 participants, with FIQ of ~70 and a standard deviation of 10. Assuming a maximum drop of 30%, we recruited a total of 50 patients with FM for each group.

Data analysis

To compare the experimental group with the control group, the statistical analysis was based on the intention-to-treat principle. *P* values less than 0.05 were considered significant. We used multiple imputation to handle the missing data. To impute missing data, we constructed multiple imputation models including variables potentially related to the fact that data were missing. To examine the comparative effectiveness of alternative treatments over the 6-month follow-up, a 2-way repeated measures analysis of covariance (using the linear model) was conducted. The independent variables were patients who entered the study (group), time (time), and their interaction (group × time). The primary outcome as covariates was the difference in the mean baseline value. The independent variable was used to determine the difference between the traditional treatment at different time points.

RESULTS

A diagram of the patients' retention and randomization throughout the study is shown in Figure 2. A total of 150 patients were initially screened. After the screening process, 80 patients were eligible to participate in the

study. In total, 80 (100%) completed follow-up after 10 weeks of treatment; of them completed the entire study at the 1-year follow up. The characteristics of the patients are shown in Table 1.

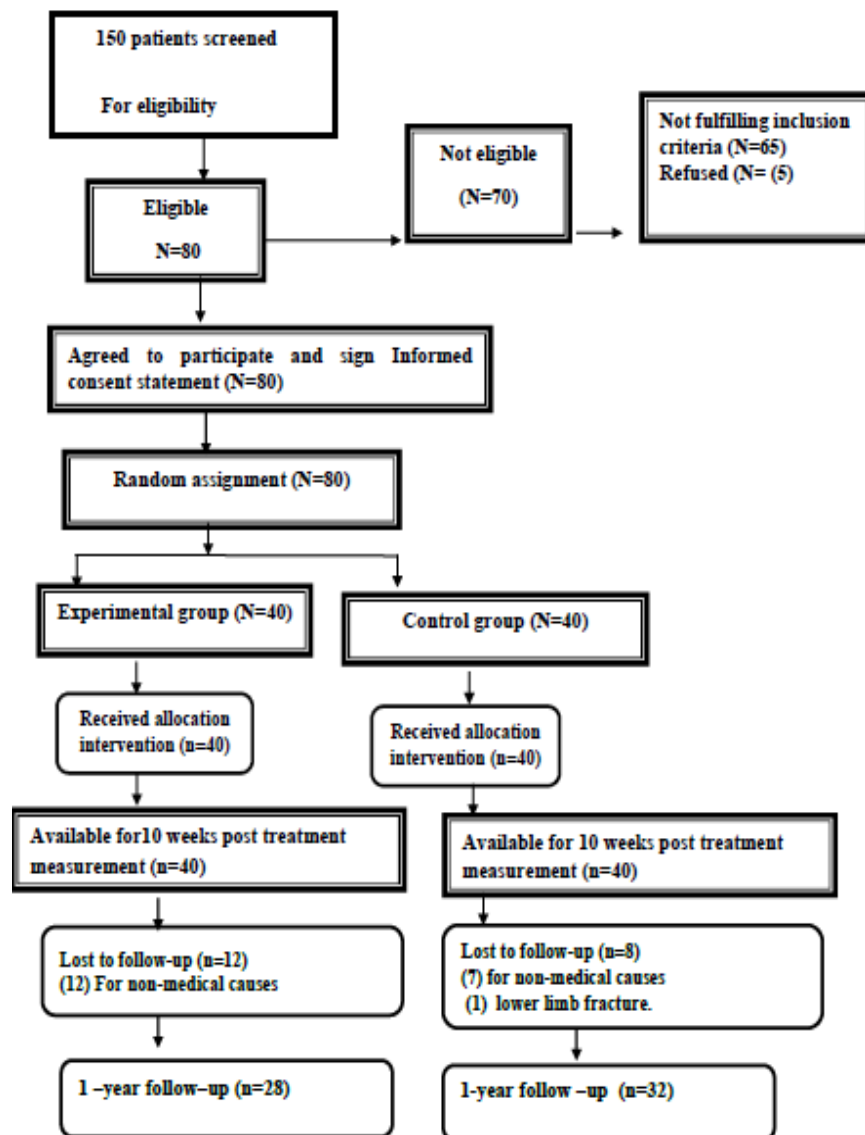


Fig. (2): Flow chart.

Table (1): Baseline participant demographics.

	Study group (n=40)	Control group (n=40)
Age(y)	54.3±7 Range 47–65	52.2±6 Range 45–64
Weight(kg)	75 ± 9	80 ± 10
Gender (%)		
Male	30	28
Female	10	12
Body mass index mean (SD),Kg\m2		
graduation		
Primary school	7(17.5%)	9(22.5%)
Secondary school	14(35%)	12(30%)
Advanced technical colleague certificate	10(25%)	8(20%)
University diploma	7(17.5%)	9(22.5%)
Others	2 (5%)	2(5%)
Marital status (%)		
Single	5(12.5%)	4(10%)
Married	33(82.5%)	35(87.5%)
Separated, divorced, or widowed	2(5%)	1(2.5%)
Pain duration		
1-5 y	12(30%)	9(22.5%)
>5 y	28(70%)	31(77.5%)

The results are summarized and presented as the mean (SD) in Tables 2 and 3. The general linear model with repeated measures indicated significant group × time effects in favor of the experimental group on the measures of anterior head translation ($F=17.1$ $P<.0005$), ARA ($F= 3.6$ $P=.05$), the three-dimensional postural parameters in terms of the trunk inclination ($F= P=.01$), lumbar lordosis ($F=8.4$ $P=.005$), thoracic kyphosis ($F=11.6$ $P<.001$), trunk imbalance ($F=17.1$ $P<.0005$), pelvic inclination ($F=17.1$ $P<.0005$), and surface rotation ($F=18.1$ $P<.0005$) ($P<.0005$), FIQ ($F=1092.6$ $P<.0005$), PCS ($F=1340.8$ $P<.0005$), Algometric score ($F=575.8$ $P<.0005$), PSQI ($F=168.9$ $P<.0005$), MFI ($F=474.9$ $P<.0005$), GHQ ($F=1779.8$ $P<.0005$), BAI ($F=2560.6$ $P<.0005$), BDI ($F=872.964$ $P<.0005$), and VAS ($F=140.3$ $P<.0005$).

After 12 weeks of treatment, the two arms of treatment appeared to be approximately equal in successfully improving

the fibromyalgia management (unpaired t-test analysis b insignificant difference b experimental and control groups on previous variables including PCS($P=0.2$), Algometric score ($P=0.8$), MFI ($P=0.1$), BAI($P=0.09$), BDI($P= 0.07$) ($P=0.3$).

There were significant differences between the groups for the AHT 3D postural parameters in terms of inclination, lumbar lordosis, thoracic kyphosis, trunk imbalance, pelvic inclination, and surface rotation ($P<.0005$). At follow-up, the analysis showed no significant differences between the experimental and control groups for the measured variables including the translation, ARA, all the FM outcomes; FIQ, PCS, Algometric score, Fatigue, GHQ ($F=72$ $P<.0005$), VAS, and 3D posture parameters.

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Table (2): The changes in postural parameters in experimental and control groups over ti

		Pre treatment	Post treatment	1-year follow up	P		
					Group	Time	Group Vs time
SR	E	5.8±.8	4.8±.9	4.8±1	<0.0005*	<0.0005*	<0.0005*
	C	6.4±1	6.3±1.1	6.7±1.3			
++			<0.0005[-1.3 -1.82]	<0.0005[-1.98 -1.3]			
L.L	E	51.6±5.4	42.5±3.7	44.4±3.4	<0.0005*	.032	.005
	C	49.4±3.4	48.1±3.2	52.4±5.1			
++			<0.0005[-7.5 -5.13]	<0.0005*[-10.1 -6.9]			
T.K	E	66.5±3.8	56.1±4.3	57.2±4.1	<.0005*	.6	.001
	C	64.2±5.7	61.7±4.5	65.3±5.4			
++			<0.0005[-7.7 -4.5]	<0.0005[-10.5 -7.11]			
T.In	E	6.1±1.1	4.1±1.1	4.3±1.4	<.0005*	.001	.013
	C	6.7±1.2	6.5±1.2	7.2±1.4			
++			<0.0005*[-2.5 -1.8]	<0.0005*[-3.1 -2.1]			
T.Im	E	20.4±2.8	14.5±3.4	14.9±3.4	.000	.016	.000
	C	20.1±2.8	19.1±2.3	21.1±2.8			
++			<0.0005*[-5.9 -4.06]	<0.0005*[-7.5 -5.5]			
AHT	E	27.9±4.1	14.5±3.4	14.9±3.4	.000	.016	.000
	C	27±2.9	19.1±2.3	21.1±2.8			
++			.000[-5.9 -4.1]	.000[-7.6 -5.4]			
ARA	E	6.6±5.1	19.4±2.9	18.3±2.9	.000	.04	.05
	C	7.5±4.9	7.15±4.8	5.5±3.6			
++			.000[12.4 13.4]	.00[12.8 13.8]			

SR: surface rotation; L.L: lumbar lordosis; T.K: trunk kyphosis; T.In: trunk inclination; T.Im: trunk imbalance; P ++: scores of 10 weeks post-treatment and of 2-year follow-up were compared between two groups with indepen [P value (95% convedince interval)]; E: experimental group; C: control group.

Table (3): The changes in fibromyalgia management outcomes in experimental and contimec.

		Pre treatment	Post treatment	1-year follow up	P		
					Group	Time	Group Vs time
FIQ	E	70.9±4.4	44.1±7.2	9.3±3.4	.000	.002	.000
	C	71.3±5.8	43.6±7.4	47.9±7.7			
++			.4 [-1.2 2.9]	<.0005* [-40.6 -36.4]			
PCS	E	43.8±3.6	24.5±3.1	9.4±2.8	.000	.012	.000
	C	42.5±3	24.9±3.4	36.3±3.1			
++			.2[-1.851 .412]	.000[-27.9 -25.8]			
GHQ	E	2.2±.3	18.3±3.6	4.4±1.2	<.0005*	.0000	<.0005*
	C	2.1±.1	19.9±4.2	29.3±3.9			
++			.1 [-1.8 .19]	<.0005*[-25.4 -23.9]			
Algometric score	E	140.1±11.3	166.8±12	189.2±9.6	<.0005*	.000	<.0005*
	C	141.3±14.2	167.6±11.7	146.1±16.3			
++			.09 [-.5 .044]	<.0005*[-2.9 -2.1]			
PSQI	E	14±3.1	9.5±2	5.5±2.9	.000	.000	.000
	C	16.1±2.8	9.6±2.1	14.2±2.8			
++			.8 [-.8 .66]	<.0005*[-9.779 -7.721]			
MFI	E	77.7±8.4	50.9±6.4	24.4±9.4	<.0005*	.000	<.0005*
	C	74.8±5.7	52.6±6.4	61.5±6.2			
++			.14[-4.01 .61]	<.0005* [-39.9 -34.2]			
BAI	E	32.1±6	21.2500±4.30067	7.2500±3.34778	.000	.000	.000
	C	33.4±4.9	22.5833±3.64665	29.8333±2.24867			
++			.098[-.949 .081]	.000[-23.169 -21.338]			
BDI	E	19.3 ±3.7	11.5833±1.86213	4.5000±1.26892	.000	.635	.000
	C	20.1± 3.4	12.4167±2.34551	19.0000±2.21704			
++			.074[-1.2 .06]	.000[-14.8 -13.7]			
VAS	E	5.2±.8	3.2±1.2	2.9±1.6	<.0005*	.3	<.0005*
	C	4.6±1	3.1±1.3	4.7±1.5			
++			.3[-.57 .17]	<.0005*[-2.6 1.6]			

DISCUSSION

This randomized controlled trial compared the cervical sagittal alignment in terms of AHT distance and ARA, three-dimensional postural measures, and outcomes of FIQ, PCS, algometric score, PSQI, MFI, GHQ, BAI, BDI, VAS in a group receiving a Denneroll traction and a multi-component intervention program to a group receiving only a multi-component intervention program. The comparison between the experimental and control groups in the AHT, ARA and the three-dimensional posture parameters revealed significant differences at the two follow-up points. The results of the FM management outcomes such as FIQ, PCS, algometric score, PSQI, MFI, GHQ, BAI, BDI, and VAS after 12 weeks indicated that the positive changes are equally successful in both groups. At the 1-year follow-up, the statistically significant changes favoring the outcomes of the experimental group provide objective evidence that biomechanical dysfunction in terms of abnormal cervical sagittal configuration, influences the long-term outcome measures of FM.

The improvement in the forward head posture and cervical lordotic curve recorded by the study group is similar to that reported in a pilot study that showed the effectiveness of this type of traction on restoring sagittal spinal configuration¹⁸. Stretching of the viscous and plastic elements of the longitudinal ligament and intervertebral disc, in addition to an effective soft tissue stretch through the entire neck area in the direction of the normal head and neck posture, may be the possible explanation for restoring the normal cervical lordosis and reduction of AHT¹⁹.

In the current study we found that the experimental group receiving the Denneroll cervical extension traction experienced significant changes in posture parameters occurring in sagittal, transverse, and coronal planes. These significant changes may suggest the important role of the cervical spine on global spinal posture. These results are conceptually in agreement with

neurophysiological studies that link a neurological regulation of human posture that is largely head posture^{30,25}, and consequent afferentation process. Static posture is compromised by dysafferentation region which results from lack of muscle fatigue in response to strain placed upon various segments such as the splenius capitis, sternocleidomastoid, and levator scapulae forward head posture^{25,51}.

These results are further supported by those reported by Diab¹³, who showed the role of head posture on the three-dimensional spinal posture parameters and "forward head correction was improving the scoliotic posture in coronal, and sagittal planes".

The application of a multi-component intervention program alone or in combination with Denneroll cervical extension traction appears to be approximately equivalent to successfully improving the management outcomes after treatment. Following 12 weeks of treatment, the marked improvement in management outcomes may be attributed to the positive effects of the multi-component intervention program. This is supported by a recent meta-analysis which showed that multi-component intervention is effective in the short term for improving symptoms of FM including depression and quality of life, but disappointingly without a sustained continued effect other than in terms of physical fitness. The significant differences in the control group may be attributed to the short-term effects of multi-component intervention. Indeed, there is strong evidence of the positive effects of multi-component intervention on the key symptoms of FMS over time^{33,34,27,29}.

After 10 weeks of treatment, it was surprising that the addition of rehabilitation to a multi-component programme did not produce a statistically better effect than

component programme across all FM management outcomes, given the preliminary evidence of significant role of normal posture in normalizing the afferentation process. There is no clear explanation for these findings, but we can speculate that a sustained postural imbalance can result in establishment of a state of continuous asymmetric loading. Once it is established and maintained beyond a critical threshold for weight and time, there will be increases in the degenerative changes in the muscles, ligaments, bony structures and neural elements^{20,26}. Most important, when the asymmetry is reversed and the unbalanced loading is thereby corrected by restoring normal posture, the reversibility of these degenerative changes or even its improvement will need some time. Although direct empirical support to this explanation is lacking, the delayed recovery after posture correction is in agreement with Diab and Moustafa who reported more decrease in pain intensity scale after 6 months follow up compared to 10-weeks post treatment¹⁴. Also of interest, Diab identified more decrease in functional index scale after 3 months follow up compared to 10-weeks post treatment¹³.

At the 1-year follow-up, the significant changes favoring the outcomes of the experimental group for all FM management outcomes, suggest that addressing posture impairments may be essentially required for the long-term management. In general, these findings are highly supported by other studies that highlighted the role of abnormal, asymmetrical posture, which is considered by some to be an important etiological factor and/or associated with FMS^{36,39}. These findings concurred with those of Dolphens et al.,¹⁵ who concluded that global spinal posture, especially of gross body segments, is required to achieve significant clinical improvement.

Normalizing the abnormal mechanical stresses and restoring the normal afferentation process are the possible explanations for the positive role of normal posture in management of FMS. More specifically, the continuous asymmetrical loading and muscle imbalance from biomechanical dysfunction represented by cervical sagittal configuration and sagittal, transverse and coronal abnormal spinal posture

elicits abnormal stress and strain on the structures, including bones, discs, facet joints, musculotendons and neural elements that are predisposing factors for pain^{20,26}.

Neurophysiologically, abnormal posture causing a barrage of nociceptive input⁴⁹, resulting in dysafferentation that sensorimotor integration dependent upon cervicocollic mechanoreceptors and afferent input from ligament and musculotendons, correcting the postural distortion for this pathophysiologic process is a possible explanation for the improvement of FMS. This explanation has been confirmed by the findings of studies that have reported that posture correction is paramount to restoring afferent input to the CNS, and enabling the body to correctly perceive its environment^{3,28}.

Our analysis has potential limitations, each of which indicates directions for future study. The primary limitation was investigator blinding. With respect to participants regarding the value of the treatment arms and informed consent, they have a realistic potential for bias. We informed them of the existing evidence to suggest that the proposed approach is superior to the other approaches. The nature of radiological assessment is one of the major limitations in this study. Radiologists and x-ray technologists can minimize the risk factor of x-ray exposure by using high-frequency equipment to minimize exposure times. Shielding and collimation can block or reduce the x-ray beam to sensitive tissues and areas of interest, rare earth intensifying screens can decrease x-ray exposure by collimation to narrow the x-ray beam to include areas of interest only, and high kilovoltage and minimized milliamperage can further reduce the x-ray dosage.

Within these limitations, the contribution of our study is that it shows the independent effect of cervical rehabilitation in form of cervical posture restoration and forward head posture

on long term global spinal posture in the transverse, coronal, and sagittal planes, in addition to other outcome measures related to FM including FIQ, PCS, Algometric score, PSQI, MFI, GHQ,BAI, BDI, and VAS which, to the best of our knowledge, has not been previously reported. We hypothesized that the results of this study introduce new guidelines in the treatment of FMS.

Conclusions

Adding Deneroll cervical extension traction to a multi-modal program has a short- and long-term positive effect on three-dimensional spinal posture in patients with FMS. After 12 weeks of treatment, the two treatment arms appear to be equally successful in improving the FM management outcomes including FIQ, PCS, Algometric score, PSQI, MFI, GHQ,BAI, BDI, and VAS. The long-term analysis, at the 1-year follow-up, revealed statistically significant changes favoring the FM management outcomes of the experimental group.

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Competing interests

None.

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الملخص العربي

هل التحسن نحو القوام العنقي الطبيعي يساعد في علاج حالات الألم العضلي الليفي : دراسة عشوائية

لأثار قصيرة وطويلة المدى لإضافة شد الدنى رول العنقي إلى برنامج متعدد الوسائط على نتائج علاج الألم العضلي قياسات القوام ثلاثية الأبعاد والقوام العنقي الجانبي . تم تقسيم 80 مريضاً بين 40 ، 65 سنة من الذين عانوا من متلازمة مع وجود الرأس في الوضع الأمامي ونقص في تقعر الفقرات العنقية عشوائياً إلى المجموعة الضابطة أو المجموعة من المجموعتين برنامج متعدد الوسائط . بالإضافة إلى ذلك تلقت المجموعة التجريبية شد دنى رول العنقي ، وتم قياس متلازمة الألم العضلي الليفي ، قياس الألم البصري ، مقياس كارتية الألم ومجموع نقاط الألم نتيجة الضغط ، مؤشر المخزون متعددة الأبعاد ، استنبيا الصحة العامة ، مقياس بيك للقلق ، مقياس بيك للإكتئاب ، قياسات القوام ثلاثية الأبعاد (ي تقعر الفقرات العنقية ومدى الإزاحة الأمامية للرأس) لكل المرضى في ثلاث فترات . وأظهرت النتائج وجود تأثير في صالح المجموعة التجريبية للقياسات التالية : مدى الإزاحة الأمامية للرأس (عند مستوى دلالة أقل من 0.0005) ، لقة (عند مستوى دلالة 0.05) ، قياسات القوام ثلاثية الأبعاد (عند مستوى دلالة أقل من 0.05) ، استنبيا تأثير متلازمة (عند مستوى دلالة أقل من 0.0005) ، قياس الألم البصري (عند مستوى دلالة أقل من 0.0005) ، مقياس كارتية الألم (عند مستوى دلالة أقل من 0.0005) ، مجموع نقاط الألم نتيجة الضغط (عند مستوى دلالة أقل من 0.0005) ، مؤشر نوعية النوم (عند 0.0005) ، التعب المخزون متعددة الأبعاد (عند مستوى دلالة أقل من 0.0005) ، استنبيا الصحة العامة (عند 0.0005) ، مقياس بيك للقلق ومقياس بيك للإكتئاب (عند مستوى دلالة أقل من 0.0005) . وقد دلت النتائج على أن العنقي إلى برنامج متعدد الوسائط مفيد في علاج المرضى الذين يعانون من متلازمة الألم العضلي الليفي . زمة الألم العضلي الليفي ، العنق ، وضع الرأس ، الشد .