

Does Improvement Towards A normal Cervical Configuration Aid in the Management of Fibromyalgia 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 ($P<0.0005$), Multidimensional Fatigue Inventory ($P<0.0005$), General Health Questionnaire ($P<0.0005$), Beck Anxiety Inventory ($P<0.0005$), Beck Depression Inventory ($P<0.0005$), and VAS ($P<0.0005$). **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, Traction.

INTRODUCTION

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

Despite the high prevalence of the condition⁸, its conservative treatment has remained a challenge for the available treatments directed towards fibromyalgia (FM) (e.g. physical aerobic exercise, biofeedback, physical therapies, and multidisciplinary treatments) as variable and long-term observational studies have found that outcomes are typically poor^{9,41,42}. 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 patients with FM and other medically unexplained symptoms²².

Although the exact cause of FM has not been discovered, various research theories in nutrition, stress factors, altered pattern of sleep and changes in neurotransmitters¹ there is growing evidence that central nervous system dysfunction is hypothesized that FMS is a coexisting condition that appears to involve altered afferent processing and which is associated with abnormal integration⁴⁶.

Many of our postural reflexes are mediated by the vestibulocollic reflex, cervical

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 Ju 12-week treatment investigation follow-up.

Patients were enrolled, if the American College of criteria53 for FMS, experienced at least 48 months with no recent symptoms to any degree, report on the pain intensity, age reported a score ≥ 59 on the FM",⁴⁴ and able to read and English.

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

The patients were random means of a balanced stratified either the experimental group control group (n=40). The balanced for type of medication age by using a stratification generates a sequence of letters (correlatively ordered permutations category and combination of sequences assigned to patients envelopes containing the allocation to the study groups. An independent p to the research protocol and involved in the trial, operated assignment.

Interventions

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

Educative program

It consisted of twelve 2-delivered over the treatment period per week). This educative part included information about typical course, medical conditi

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 relaxation 50 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 Ost 42 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 (Deneroll Industries (www.deneroll.com) of Sydney, Australia). Here, the patient lies flat on their

back on the ground with their legs bent and arms by their sides. They are encouraged to relax whilst wearing the Deneroll. The Deneroll was placed on the ground and positioned in the position of the neck depending on the side addressed. The traction session was three times per week for 12 weeks. It began with 3 minutes per session and progressed to a maximum of 2 minutes per session in incremental fashion. The Deneroll orthotic was placed in the following regions based on lateral radiographic displacements:

1. In the upper cervical region. This position allows bending of the upper cervical segments while causing slight anterior head tilt (AHT). One subject had this placement location.
2. In the mid-cervical region (C3-C6). This position allows extension of the mid-upper cervical segments creating a slight posterior head tilt. Twenty five subjects had 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 had this placement location.

We did not ask participants to start any new regular physical exercise programs (that were used in this study) or other non-pharmacological interventions for FM during their involvement.

Outcome Measures

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

Fibromyalgia Impact Questionnaire

The primary outcome measure determining the treatment as effective was the Fibromyalgia Impact Questionnaire (FIQ), which is a valid self-report questionnaire developed to assess participant status, progress, and improvement. 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 lateral bending) were selected to cover the postures in three planes. A representative example of the Formetric system's print output is graphically for a study group patient.

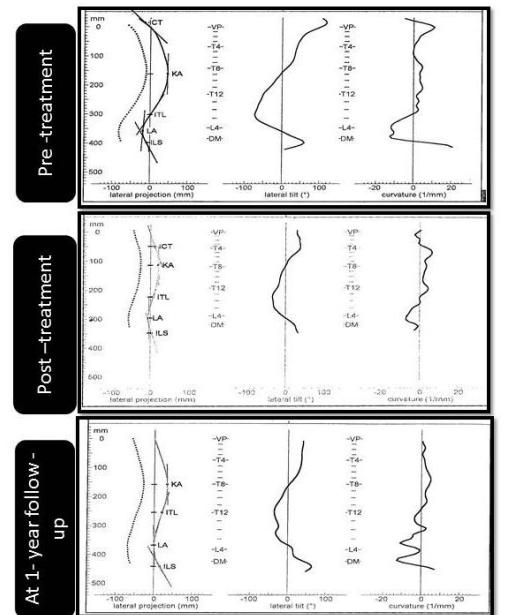


Fig. (1): Example of the Formetric output.

The Pain Catastrophizing Scale

The PCS was used to measure factors: rumination, magnification, and helplessness associated to pain. Items measured on a 5-point Likert scale ranging from 0 (not at all) to 4 (all the time). Higher scores indicate a greater tendency to catastrophize pain symptoms.¹¹

Algometric score

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

Sleep quality

The PSQI¹⁰ was used to measure sleep quality and disturbances over a 1-month interval. Nineteen individual items were grouped into seven "component" scores: sleep 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, previous research,⁶ a clinically relevant change is a 15-20% reduction in FIQ score (which equals to a ~1 point reduction). We can detect differences 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 15 points. Assuming a maximum loss to follow-up of 30%, we recruited a total of 35 participants 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 the missing data, we constructed multiple imputation models including variables potential predictors. Due to the fact that data were missing at random and variables correlated with that, we used the multivariate normal distribution of the data. Levene's test and Smirnov's test allowed for parametric methods for significance testing. To examine the comparative effectiveness of alternative treatments over the course of a 1-year follow-up, a 2-way repeated measures analysis of covariance (using the linear model) was conducted. The independent variables included one independent factor (group), one repeated measure (time), and one interaction factor (group × time). (The baseline value was used as covariates to adjust for the between group differences in the outcome in the model = baseline value - mean baseline value). The independent samples t-test was used to determine the difference between forward head correction treatment and 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. All of them completed the entire study at the 1-year follow up. The characteristics of the patients are shown in Table 1.

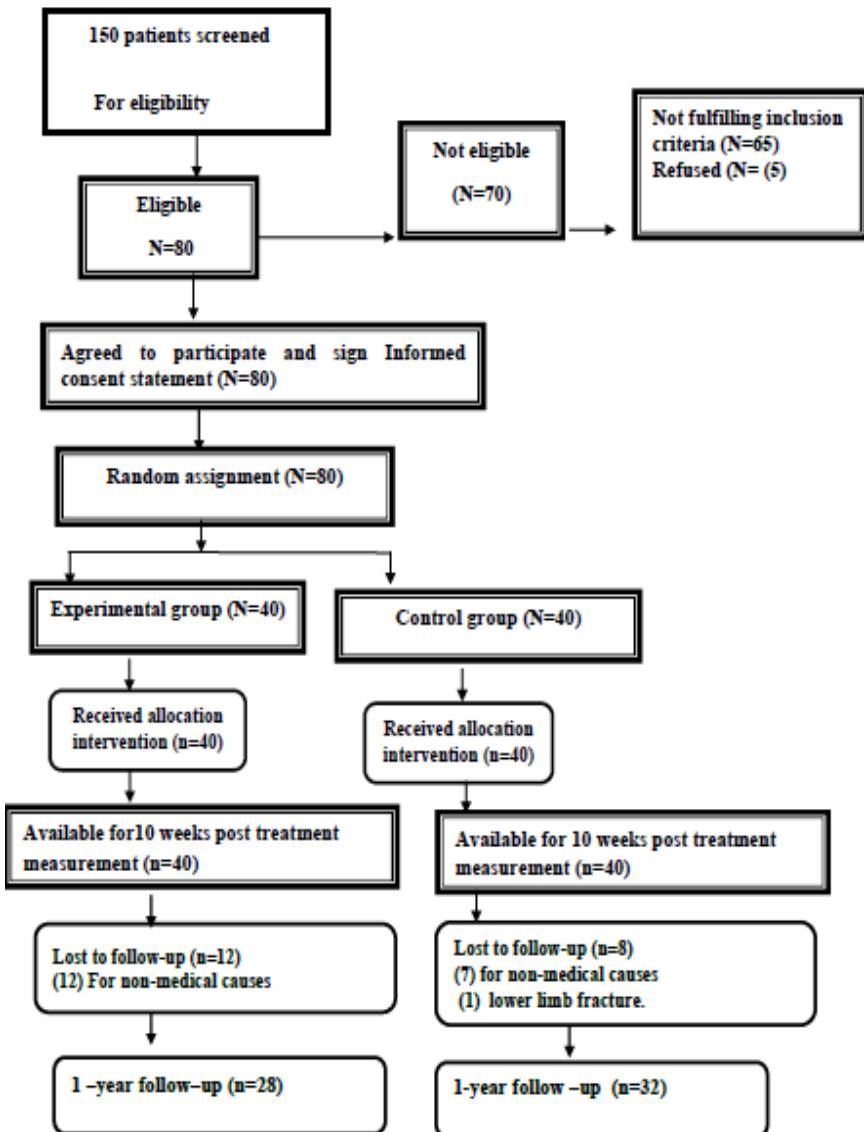


Fig. (2): Flow chart.

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/m ²		
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 insignificant difference b experimental and control groups 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 term of trunk inclination, lumbar lordosis, thoracic kyphosis, trunk imbalance, pelvic inclination, and surface rotation ($P<.0005$). At follow-up, the analysis showed significant differences b experimental and control groups measured variables including the AHT, ARA, all the FM outcomes; FIQ, PCS, Algometric score, Fatigue, GHQ ($F=72$ $P<0.0005$), VAS, and 3D posture parameters.

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•Table (2): The changes in postural parameters in experimental and control groups over time.

	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*
	C	6.4±1	6.3±1.1	6.7±1.3		
++		<0.0005[-1.3 - .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
	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
	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
	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
	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
	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
	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; F

++: scores of 10 weeks post-treatment and of 2-year follow-up were compared between two groups with independent [P value (95% confidence interval)]; E: experimental group; C: control group.

Table (3): The changes in fibromyalgia management outcomes in experimental and control groups over time.

	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
	C	71.3±5.8	43.6±7.4	47.9±7.7		
++		.4 [-1.2 -2.9]		<0.0005*[-40.6 -36.4]		
PCS	E	43.8±3.6	24.5±3.1	9.4±2.8	.000	.012
	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
	C	2.1±.1	19.9±4.2	29.3±3.9		
++		.1 [-1.8 -.19]		<0.0005*[-25.4 -23.9]		
Algometric score	E	140.1±11.3	166.8±12	189.2±9.6	<.0005*	.000
	C	141.3±14.2	167.6±11.7	146.1±16.3		
++		.09 [-.5 -.044]		<0.0005*[-2.9 -2.1]		
PSQI	E	14±3.1	9.5±2	5.5±2.9	.000	.000
	C	16.1±2.8	9.6±2.1	14.2±2.8		
++		.8 [-.8 -.66]		<0.0005*[-9.779 -7.721]		
MFI	E	77.7±8.4	50.9±6.4	24.4±9.4	<.0005*	.000
	C	74.8±5.7	52.6±6.4	61.5±6.2		
++		.14[-4.01 -.61]		<0.0005*[-39.9 -34.2]		
BAI	E	32.1±6	21.2500±4.30067	7.2500±3.34778	.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
	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
	C	4.6±1	3.1±1.3	4.7±1.5		
++		.3[-.57 -.17]		<0.0005*[-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 Deneroll 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 Deneroll 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 1 a neurological regulation of human posture that is largely head posture^{30,25}, and consequent afferentation process. Static posture is compromised by dysafferation region which results from lack of muscle tone and muscle fatigue in response to strain placed upon various sp such as the splenius capitatus, sternocleidomastoid, and levator scapulae forward head posture^{25,51}.

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

The application of a multi-component intervention program alone or in combination with Deneroll cervical extension traction appears to be approximately equally effective in successfully improving the management outcomes after 12 weeks of treatment. Following 12 weeks of treatment, the marked improvement in the management outcomes may be attributed to the positive effects of the multi-component intervention program. This finding is supported by a recent meta-analysis that showed that multi-component interventions are effective in the short term for reducing symptoms of FM including pain, depression and quality of life²⁶. However, the effect was disappointing without a continued effect other than maintaining physical fitness. The significant improvement in the control group may be attributed to the placebo effect of the multi-component intervention. Indeed, there is strong evidence for the positive effects of multi-component interventions on the key symptoms of FMS over time^{33,34,27,29}.

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

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 reversible 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 st structures, including bones, discs, facet joints, musculotend 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 is dependent upon cervical mechanoreceptors and afferent ligament and musculotendinous fibers. Correcting the postural distortion is a possible explanation for the improvement of FMS. This explanation has been confirmed by the final studies that have reported that correction is paramount to restore afferent input to the CNS, and 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. We did not inform participants regarding the values assigned to the different treatment arms and informed them that they have a realistic potential for improvement. We informed them of the existing evidence to suggest that our approach is superior to the other. The nature of radiological assessments is a major limitation in this study. Radiologists and x-ray technologists used high-frequency equipment to minimize the risk factor of x-ray exposure times. Shielding and lead block or reduce the x-ray beam to sensitive tissues and areas of interest, rare earth (intensifying) materials decrease x-ray exposure by collimation to narrow the x-ray beam. These include areas of interest only, kilo voltage and minimized milliamperage to further reduce the x-ray dosage.

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

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 العنقى الطبيعي يساعد في علاج حالات الألم العضلى الليفي : دراسة عشوائية

لأثار قصيرة وطويلة المدى لإضافة شد الذئب رول العنقى إلى برنامج متعدد الوسائل على نتائج علاج الألم العضلى قياسات القوام ثلاثة الأبعاد والقوام العنقى الجانبي. تم تقسيم 80 مريضاً بين 40 ، 65 سنة من الذين عانوا من متلازمة مع وجود الرأس في الوضع الأمامي ونقص في تغير الفقرات العنقية عشوائياً إلى المجموعة الضابطة أو المجموعة من المجموعتين عن طريق ذلك تألف المجموعة التجريبية شد الذئب رول العنقى ، وتم قياس متلازمة الألم العضلى الليفي ، قياس كارثية الألم البصري ، مقياس بيك لللقالق ، مقياس بيك للإكتاب ، قياسات القوام ثلاثة الأبعاد المخزون متعددة الأبعاد ، استبيان الصحة العامة ، مقياس بيك للإكتاب ، قياسات القوام ثلاثة الأبعاد في (تغير 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 ، لفقة (عند مستوى دلالة 0.05) ، قياسات القوام ثلاثة الأبعاد (عند مستوى دلالة أقل من 0.05) ، استبيان تأثير متلازمة (عند مستوى دلالة أقل من 0.0005) ، قياس الألم البصري (عند مستوى دلالة أقل من 0.0005) ، مقياس كارثية الألم أقل من 0.0005) ، مجموع نقاط الألم نتيجة الضغط (عند مستوى دلالة أقل من 0.0005) ، مؤشر نوعية النوم (عند 0.0005) ، التعب المفخزنون متعددة الأبعاد (عند مستوى دلالة أقل من 0.0005) ، استبيان الصحة العامة (عند 0.0005) ، مقياس بيك لللقالق وقياس بيك للأكتاب (عند مستوى دلالة أقل من 0.0005) ، استبيان الصحة العامة (عند 0.0005) ، العنقى إلى برنامج متعدد الوسائل مفيد في علاج المرضى الذين يعانون من متلازمة الألم العضلى الليفي . زمة الألم العضلى الليفي ، العنق ، وضع الرأس ، الشد .