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## **RESEARCH ARTICLE**

# Comparative prospective randomized study of clinical effects of maintained versus nonmaintained non-surgical spinal decompression therapy in treatment of chronic lumber disc herniation

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# Manuscript Info

## Abstract

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Hamada Mohammad Ahmed **Introduction:** LBP (Low Back Pain) is a common musculoskeletal symptom that may be caused by a variety of diseases and disorders that affect the lumber spine as chronic lumber disc herniation (CLDH).

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**Aim:** To detect the differences between clinical effects of maintained Vis non-maintained non-surgical spinal decompression therapy (NSSDT) in patients with CLDH.

**Subjects and Methods:** 96 patients with CLDH were randomized into two matched groups. Both groups received 18 NSSDT sessions over a 5-week period (phase 1) followed by six months (phase 2) where only the maintained NSSDT group received one NSSDT session every two weeks

**Results:** By the end of the phase 2 a significantly higher difference in the disc height in the maintained NSSDT group (95% CI, 0.6; 2.48, p=0.002) while the disc herniation index is significantly lower when compared to the non-maintained NSSDT group (95% CI, 106.8; 30.8, p<0.001). Also, the Oswestry disability score was decreased significantly more in the maintained NSSDT group.

**Conclusions:** Patients with chronic LBP caused by CLDH are benefited from treatment with maintained NSSDT to sustain the improved post-treatment pain, disability scores and the gained spinal mobility.

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# **INTRODUCTION**

Low back pain (LBP) is quite common health problem and many of us will suffer from LBP at some point of our lives [1]. LBP pain in patients aged less than 45 years old leading to limitation of their physical activities, causing frequent doctor's visits, and the third most common cause for surgical procedures[2,3].Disc herniation comprise about 5% of patients with chronic LBP[4].

The management of persistent LBP remains debated. The traditional approach has been non-surgical treatment with analgesia and physiotherapy with limited efficacy of these modalities. A number of alternative interventions such as massage, spinal manipulation, exercises, acupuncture, back school and cognitive behavioral therapy have been also tried with limited efficacy.

Traction has often been utilized to treat patients with a herniated lumbar disc. Although data exist supporting the use of traction to widen the intervertebral space, reduce disc protrusion and intradiscal pressure, and improve motor evoked potentials and leg mobility [5, 6], systematic reviews of clinical trials of traction for lumbar disc herniation have found that traction is probably not effective in improving pain, compared to placebo, sham or

other treatments.[7, 8, 9] this can be explained by the fact that the pull force in traction is linear and may elicit the body's proprioceptive response that triggers paravertebral muscle contraction, which may reduce the distractive effect [10].

Currently, the most advanced type of traction therapy is non-surgical spinal decompression that has been developed to overcome traction drawbacks. DRX9000 spinal decompression system is an example of these systems that has been developed as a non-invasive potentially therapeutic approach to treatment of LBP. It works by applying computerized angulated traction causing distraction of the two vertebrae surrounding the affected disc leading to lowering of the elevated intradiscal pressure in the herniated disc into the negative range up to -150 mmHg [9].

This negative pressure creates central vacumm causing suction of herniated disc material and improve blood flow into the affected disc from adjacent bony endplates and epidural vessels to provide fluids, oxygen and nutrients to rehydrate the nucleus and perhaps repair of the annulus [11].

However, systematic reviews to date emerged conflicting results. While, some studies were unable to find sufficient evidence to support the use of this modality [6,7], another studies found that this modality may be effective in reducing chronic LBP [8,9]. However, the aforementioned studies evaluated the therapeutic of non-surgical spinal decompression therapy (NSSDT) only for short term but no attempt was made to evaluate the long term outcome of maintained NSSDT. To the authors best knowledge, no study was done prior to this study to assess the difference between maintained and non-maintained NSSDT on the improvement of symptoms and signs of CLDH.

The aim of this study is to detect the differences between the clinical effects of maintained Vis non maintained NSSDT in treatment of CLDH.

## **Patients and Methods**

This study is a randomized clinical trials that was performed in Kuwait, between August 2012 and January 2014.

Prior the study an informed verbal and / or written consent was taken from each patient explaining to them all procedure of the study and the benefits as well as the disadvantages for participation.

Also, we got all the necessary institutional and ethical approval to conduct this study.

This study involved 100 patients suffering from CLDH either L4-5 or L5 S1. These patients were 72 males and 28 females, their age range was between 23 - 48 years old. The mean duration of their lumber disc herniation is around 19 months, their mean height is around 162-164 cm and weight is around 78-81 Kg. Exclusion criteria included Patients with disc herniation of <3 months, red flags (motor weakness, bladder and bowel incontinence, sexual dysfunction, spinal infection and fractures), previous back surgery, or lumbar spine disease other than the disc herniation in addition to the exclusion criteria for MRI as metal implants, pacemakers and claustrophobia. Also, pregnant ladies or ladies who plan to conceive during the study period were not allowed to participate in the study.

The DRX9000 uses a split-table design to reduce friction between the patient and the device. The patient lays supine; a chest and shoulder support system are used to control the upper body and a knee rest is used to eliminate pelvic rotation. The angle of treatment force (pull angle) adjusted at 10° for L5-S1 disc herniation and at 15° for L4-L5 disc. In the first day the decompression force used =5 kg less than 1/2 body weight, =1/2 body weight in the second day and 5 kg higher than 1/2 body weight in the third day and thereafter. Treatment length was 45 minutes.

After selection of the patients and before the start of the 1st phase 4 patients were excluded according to exclusion criteria.

The study passed into 2 phases:

 $1^{st}$  phase: include interviewing all patients taking full history and physical examination. They were asked to describe their back pain (mode and date of onset), to list present symptoms suggesting specific spinal disease, past back therapy (including NSSDT or surgery), or longer use of corticosteroids. Local musculoskeletal examination and full neurologic examination were applied to them. Laboratory investigations included complete blood count, erythrocyte sedimentation rate, and C-reactive protein.

Confirming the diagnosis was done by doing radiological examinations (plain) then magnetic resonance imaging (MRI) of the lumbar spine.

We described to the patients the back instructions and they received 18 treatment sessions of NSDT over a five-week period using the DRX9000 device (treatment was administered five times per week for the first two weeks and three times per week for a further two weeks, then two sessions for the last week) followed by pelvic tilt range of motion (ROM) exercise to be performed in a pain-free range for 10 times after each manipulation and 10 times thrice / day on the days they did not attend the session.

After the completion of the  $1^{st}$  phase, patients were randomized into 2 equal group that were matched for age, gender, duration of the disease and back pain related symptoms and signs by the means of block randomization (block size =4).

<u>Phase 2</u> took place for subsequent 6 months in which one of the 2 groups (randomly selected) was given the maintained NSSDT while the other one not given NSSDT.

In the this 6-month period (phase 2) the patients in the maintained NSSDT received the same NSSDT as one session/2 weeks followed by the back exercise while the patients in the non-maintained NSSDT follow the same back exercises but with no NSSDT.

During this period one patient from the maintained group dropped out due to travelling abroad and 2 female patients from the non-maintained group were excluded due to occurrence of pregnancy.

The patients were randomized and managed in the NSSDT sessions by a physician and assessed throughout the follow-up intervals by another who was completely blind to patients being assessed. Patient's allocation and patient flowchart during the study is shown in Figure 1.

#### **Outcomes Measured:**

Measuring the outcomes in this study was done through either subjective, objective or disc measurements as follow:

1. Subjective measures:

- a. Assessment of Pain levels by a visual analogue scale (VAS). This numeric pain rating is considered a good tool for determining the current intensity of pain. We tried to adjust the use of analgesics and other medications for both group that were used by the same kind and dose. These medications were gradually withdrawn and stopped [12].
- b. Disease-specific: The Oswestry Disability Index (also known as the Oswestry Low Back Pain Disability Questionnaire) is an extremely important tool that researchers and disability evaluators use to measure a patient's permanent functional disability [13].
- 2. Objective measure:

A-For lumbar motion assessment, modified Schober test was done by asking the patient to stand up with the feet hip width apart and make a mark at the central point between the two posterior superior iliac spine and from this point two marks were made one 5 cm below and the other 10 cm above. then ask the patient to keep knee straight and bend forward to touch the toes and measure the distance between the top and the below marks and note the difference[14].

B-Lateral flexion tested by asking patient to stand with his heel against the wall and feet hip width a part. The patient back also must be against the wall and the fingers extended down to his side ,the distance from the tip of fingers to the floor is measured. The patient then asked to side flex keeping the back against the wall and then re-measure the distance from fingers to floor and note the difference. This is done also in the other side [14].

3. Disc measurements:

The third main outcomes were the change in average lumbar disc height and disc herniation index as measured by MRI. The average disc height and the disc herniation index were calculated two times; prior the first treatment session (at baseline) and a day after the last session (end of phase 2). For each patient the height of the lumbar intervertebral disc and the disc herniation index were measured. The disc measurements were done in the axial MRI slice, in which there was greatest encroachment of the disc

a. Estimation of disc herniation index (Figure2): It was performed in axial MRI plane, the distance of herniated material (maximum antero-posterior disc length, AB) and the sagittal length of the spinal canal (maximum antero-posterior canal length, EF) were measures. A line was drawn which divided the herniated material into anterior and posterior halves. The width of the herniated material (CD) and the width of the spinal canal (GH) were measured at the level of this line. The following formula was used for the calculation of the "herniation index": (AB x CD)/(EF x GH)x 1,000[15].

b. Estimation of disc height (Figure 3): Disc height = (A+M+P)/3 (mm) where A: anterior disc height, M: middle disc height, P: posterior disc height in the MRI sagittal view. The human stature has a circadian rhythm as follow taller in the morning after the discs decompress while the body is supine overnight and shorter in the night after the discs have borne weight during daily activity and it was estimated that 80% of the daily height loss was during the three hour of rising [16]. So, all MRI examinations were done at least two hour after the subject got out of bed.

All outcomes (except disc height) were evaluated at baseline and at the end of phase 1 and phase2.

#### Statistical analysis

All statistical analyses were performed using SPSS for windows version 17.0 (SPSS, Chicago, IL). Continuous data obtained at baseline and at end of phase 1 and phase 2 were expressed as mean  $\pm$ SD. The comparisons of the continuous data between the two groups were performed using independent Student's t test. The paired t test is used for the comparison of the continuous variables between pre- and post-treatment in each group. Categorical data (gender and level of disc herniation) were expressed in number and percent and compared between the two groups using the  $\chi^2$  test. The 95 % confidence intervals (CI) for the difference in means were calculated. Statistical significance was set at p<0.05.

## Results

Table 1 showed that the two groups were matched as regard to the some selected personal and medical criteria as age, gender, duration of LDH, Height, weight, BMI and Lumbosacral disc herniation.

The outcome measures did not differ significantly between the two groups at the end of the initial5-weeksof NSSDT (phase 1) (Table 2). However by the end of the second phase of NSSDT (after 6 months), patients who continued to take NSSDT had significantly lower pain, disability scores and better spinal mobility than those who did not maintain NSSDT.

## Change of the Oswestry disability score.

By the end of first phase, the NSSDT significantly reduced the disability score in maintained NSSDT group by 14.2 points (from 38.6 to 24.4) and non-maintained NSSDT by 14.3 points (from 38.3 to 24) when compared to the baseline scores. By the end of the 6-month period, while the disability score in the non-maintained NSSDT group elevated back toward the pre-treatment level, the score was further reduced (by of 16.6 points below the baseline level) in patients who received maintenance NSSDT. The average Oswestry disability score of the maintained and non-maintained NSSDT groups at the end of the second phase was  $22 \pm 1.3$  and  $35.7 \pm 3$  respectively. This difference was significant (95% CI, -15; -12.5, p<0.001) (Table 3 and 4).

#### Change of the VAS-pain during the treatment period.

A greater difference, however, was seen in VAS-pain scores over the duration of the study. The initial phase of treatment yielded a VAS-pain reduction of 22 and 20.6 mm (p<0.001) in the maintained and the non-maintained NSSDT groups respectively and the difference between the two groups was insignificant. However by the end of the phase 2 the VAS-pain score showed a reduction of 27.3 mm from baseline score whereas it is returned near to the pre-treatment level (a reduction of 22.3 mm) in the group of patients who discontinued there therapy intervention. The VAS-pain score in the maintained group was  $23.7 \pm 2.5$  versus  $47.4 \pm 3.1$  mm in the non-maintained group (95% CI, -24.9; -22.6, p<0.001) (Table 3).

#### Change of the spinal mobility during the treatment period.

There is an increase in the ROM of spine flexion and lateral bending in the maintained NSSDT group at the first phase and the increase is continued in the second phase, whereas in the non-maintained NSSDT group, there is increase in the spinal movement after the first phase only and decreased to reach near the pre-treatment level by the end of the second phase. By the end of phase 2, the Schober's test increased by 4.8 cm (from 17.7 to 22.5 cm) in the maintained NSSDT group while it is increased by only 0.6 cm in the non-maintained NSSDT group. The difference of the modified Schober's test between the two groups at the end of phase 2 was significant (95% CI, 3.49; 4.44, p<0.001). The spinal lateral bending was increased from 15 ±0.8 at baseline to 16.7 ±1.5 by the end of phase 1 and continued to improve to 18.9 ±0.8 by the end of phase 2 in the maintained NSSDT group while in the non-maintained NSSDT group, it returned to baseline value by the end of phase 2 after initial improvement at the end of phase 1 (Table 3).

#### Change of the disc height and disc herniation index during the treatment period.

MRI outcomes were measured only at baseline and at the end of phase 2. Disc height and disc herniation index were similar in the two groups at baseline (P>0.05). By the end of the phase 2 the disc height in the maintained NSSDT was  $8.9 \pm 2.5$  mm compared to  $7.4 \pm 2$  mm in the non-maintained NSSDT group. This difference was significant (95% CI, 0.6; 2.48, p=0.002) (Table 3). The average disc height in the maintained NSSDT group was increased from 7.1  $\pm 2.1$  to  $8.9 \pm 2.5$  mm (Figure 4). Similarly, by the end of the phase 2 the disc herniation index in the maintained NSSDT was 211.9  $\pm 98$ compared to 280.7  $\pm 86$ in the non-maintained NSSDT group. This difference was significant (95% CI, 106.8; 30.8, p<0.001) (figure 5) (Table 3).

## Tables

Table 1. Demographic characteristics and disease related outcome measures of the maintained and non-maintained NSSDT groups at baseline

	Maintained NSSDT group	Non-maintained NSSDT	Р
		group	
Patient characteristics			
n	47	46	
Age (years) (mean $\pm$ SD)	35.5 ±7.9	34.6 ±7.5	0.941
Males (n,%)	33 (70.2%)	35 (76.1%)	0.523
LDH Duration (months) (mean ±SD)	19.2 ±2.9	19.3 ±3.7	0.836
Height (cm)	$164.6 \pm 11$	$162.3 \pm 10.4$	0.313
Weight (kg)	81 ±14.6	$78.2 \pm 14.1$	0.352
BMI $(Kg/m^2)$	$29.6 \pm 1.9$	29.4 ±2	0.606
L4-5/L5-S1herniation (n, %)	16 (34%)/31 (66%)	16 (34.8%)/30 (65.2%)	1.000
Outcome measures			
Oswestry Disability Score (%)	38.6 ±3.5	38.3 ±3.6	0.677
VAS-pain (mm)	50.9 ±6	49.7 ±6	0.332
Modified Schober's test (cm)	17.7 ±0.7	17.9 ±0.7	0.125
Lateral bending test	15 ±0.8	14.9 ±0.8	0.603
Average disc height on MRI (mm)	7.1 ±2.1	7.3 ±2	0.698
Disc herniation index	275.6 ±81.8	271.2 ±87.6	0.802

Table 2. Comparison of the outcome measures between the maintained and non-maintained DT groups after 5-week NSSDT (at end of phase 1)

	Maintained NSSDT group	Non-maintained NSSDT	Р
		group	
Oswestry Disability Score (%)	24.4 ±2.7	24 ±2.4	0.382
VAS-pain (mm)	$28.9 \pm 1.3$	29.1 ±1.5	0.377
Modified Schober's test (cm)	$20.7 \pm 1.7$	$20.5 \pm 1.7$	0.534
Lateral bending test	16.7±1.5	17.1 ±1.5	0.142

	Maintained NSSDT	Non-maintained NSSDT	Р
	group	group	
Oswestry Disability Score (%)	22 ±3.1	36.7 ±3	< 0.001
VAS-pain (mm)	23.7 ±2.5	47.4 ±3.1	< 0.001
Modified Schober's test (cm)	$22.5 \pm 1.2$	$18.5 \pm 1.1$	< 0.001
lateral bending test	$18.9\pm0.8$	14.9 ±0.8	< 0.001
Average disc height on MRI	8.9 ±2.5	7.4 ±2	0.002
(mm)			
Disc herniation index	211.9 ±98	270.7 ±86	< 0.001

Table 3. Comparison of the outcome measures between the maintained and non-maintained DT groups after 6-month NSSDT (at end of phase 2)

## Table 4. Changes of the outcomes from the baseline at the end of phase 1 and phase 2

	At end of phase 1		At end of phase 2	
	Change from	Paired t test	Change from	Paired t test
	baseline	Р	baseline	Р
Maintained NSSDT				
Oswestry Disability Score (%)	-14.2	< 0.001	-16.6	< 0.001
VAS-pain (mm)	-22	< 0.001	-27.2	< 0.001
Modified Schober's test (cm)	3	< 0.001	4.8	< 0.001
Lateral bending test	1.7	< 0.001	3.9	< 0.001
Non-Maintained NSSDT				
Oswestry Disability Score (%)	-14.3	< 0.001	-2.6	0.033
VAS-pain (mm)	-20.6	< 0.001	-2.3	0.037
Modified Schober's test (cm)	2.6	< 0.001	0.6	0.082
Lateral bending test	2.2	< 0.001	0	0.900

# Figures

## Figure 1. Flow diagram of participants through the trial





**Figure 2.** line was drawn to divide the herniated material into anterior and posterior halves. The herniation index is calculated as: (AB x CD)/EF x GH) x 1,000. AB = maximum antero-posterior disc length, CD = width of the herniated material at the level of the mid AB distance, EF = maximum antero-posterior canal length, GH = width of the spinal canal at the level of the mid AB distance.



**Figure 3.** Measurement of the lumber disc height is schematically presented on the sagittal view of the magnetic resonance image. A: anterior disc height, M: middle disc height, P: posterior disc height. Disc height: (A + M + P)/3 (mm).

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Figure 4 a. Change in the disc height as measured with MRI before and 6-month after treatment in the maintained NSSDT group.

Figure 4 b.



<u>Figure 5 a</u>. Change in the disc herniation indexes measured with MRI before and 6-month after treatment in the maintained NSSDT group.

Figure 5 b.







Herniation index as measured A. Before treatment(7.3) and B. After treatment (5.4).



A. Before treatment



B. After treatment

Increased average disc height as measured in its anterior, middle and posterior parts and the sum is divided by 3, so it is 8 mm and 8.4 mm before A. and after B. treatment respectively.

# Discussion

This study aimed assessing the long term effects of maintained NSSDT on the improvement of symptoms and signs of CLDH. The current study resulted in that the disc height in the maintained NSSDT was  $8.9 \pm 2.5$  mm compared to  $7.4 \pm 2$  mm in the non-maintained NSSDT group.

Also, the disc herniation index in the maintained NSSDT was  $211.9 \pm 98$  compared to  $280.7 \pm 86$  in the nonmaintained NSSDT group, moreover, the Oswestry disability score was decreased significantly more in the NSSDT group more than the other group. This study confirms previous reports showing that NSSDT is an effective modality in CLDH for short-term effects at the end of the 1<sup>st</sup> phase. In the current study, 5-weeks NSSDT sessions have reduced pain from 50.9 to 28.9 in the maintained NSSDT group and from 49.7 to 29.1 in the non-maintained NSSDT group. This level of pain reduction is in agreement with many previous studies that used DXR9000 for the management of the chronic LBP [4,8].

The effects of maintained NSSDT in maintaining levels of pain and functional capacity gained after an initial phase of treatment was assessed and evaluated in this study. VAS-pain, Oswestry Disability Score, and spinal mobility were sustained at the better post-treatment levels only for maintained NSSDT group whereas these outcomes decreased to their levels before treatment began, for the non-maintained NSSDT group.

Subjective outcome measures are widely used to evaluate the outcome of LBP [17].Pain measurement depends on first and foremost on patient report. Farrar et al., [18] reported that on average a reduction in pain intensity of at least 2 points (=20 mm) on the numeric rating scale is a clinically significant change. This cut-off point is used to distinguish the responders from non-responders to analgesia. In our study, the pain reduction in the maintained and the non-maintained NSSDT groups was 22 and 20.6 mm (=2.2 and 2.06 points) respectively. However, by the end of the second phase, pain reduction in the maintained NSSDT group was 27.2 mm (=2.72 points) whereas the pain reduction in the non-maintained NSSDT group was only 2.3 mm (=0.23 points) which is less than the cut-off point. This indicates that while patients in the maintained group continue to improve, the patients in the non-maintained group returned to their baseline pain level after the initial improvement. Using this cut-off point, at the end of phase 2, the maintained NSSDT has decreased pain by 2 points or more in 72.3% (34 out of 47 patients) versus 15.2% (7 out of 46 patients).

Our results also concluded that the Oswestry disability score improved in the two groups at the end of phase 1. However, there is statistical significance and clinical importance of the disability score difference (13.7 points) observed at the end of second phase in our study between the maintained NSSDT group and non-maintained NSSDT group. Fritz and Irrgang [19] showed that a six-point difference in the Oswestry Questionnaire was the minimal clinically important difference. This six-point difference is the amount of change that distinguishes between patients who have improved and those who have not improved.

In the current study, we investigated the change in disc height and disc herniation index before and after the treatment. Disc herniation index was decreased from 275.6 ±81.8 at baseline to 211.9 ±98 at the end of phase 2 in the maintained NSSDT while remain at the baseline level in the non-maintained NSSDT. Disc herniation index was found to be significantly lower in the maintained NSSDT than in the non-maintained NSSDT. Our results showed that there is an increase of disc height from 7.1 to 8.9 mm in the maintained NSSDT while it is only increased from 7.3 to 7.4 mm in the non-maintained NSSDT which may explain the better outcomes in the former group of patients. Apfel and co-workers investigated the change in disc height before and after 6-week decompression treatment using CT scanning and found that disc height increased by 1.3 mm compared to 1.8 mm in our study in the maintained NSSDT group of patients. Besides the treatment duration, this discrepancy can be explained by the use of MRI for evaluation of disc height in our study. MRI scan is excellent in precise localization of the disc margins and appreciation of the herniated part especially in T2-FRFSE sequences that better delineate disc margins against vertebral end plates and fluid of the thecal sac, is more sensitive than CT scan in measuring of the disc height because of poor imaging of soft tissues and cannot examine internal disc morphology [4]. To our best knowledge, there is only one study done by Apfl and coworkers, who found a positive correlation between the increased in the disc height and the improvement of disco genic LBP, this might be explained by that the NSSDT reduces the elevated intradiscal pressure in the herniated disc into the range creating central vacuum causing suction of the herniated disc material. Regeneration of the compressed disc could be promoted by the relief of stress and the increased lumber disc height with a later reducing the load on the facet joint Ramos and Martin [5,9].

In CLDH, muscle spasm could directly cause pain [20]. Further reduction in disc height likely aggravates the pain-spasm-pain cycle and also simultaneously irritates the facet joint. Pain may also be induced within the disc

as nerve fibers grow into the inner part of the annulus fibrosus or nucleus pulpous [21]. In either case, the decrease of the pressure on the disc should assist the regeneration of the disc and diminish facet joint stress [4, 20].

The optimal frequency of the session and intervals between it needed future testing. Past studies that investigated the effect of continuous manipulation in chronic LBP support our thoughts that the un-satisfactory results during follow-up may be due to longer intervals between the sessions. The trials in which increased numbers of spinal manipulation treatment sessions were applied, obtained better outcome in short-term, and continued for some time after stoppage of treatment, than the trials used less numbers of sessions. For example, studies that applied 12 [22] or 10 [23] manipulation sessions during 6-week lead to improvement of pain relief and disability reduction than studies that offered lesser number of sessions over longer treatment period resulted in either mild [24] (eight sessions over 12 weeks) or no benefits over sham treatment (seven sessions over 5 months) [17].

## Conclusion and Recommendations:

Our study concluded that patients with chronic LBP caused by CLDH are benefited from treatment with maintained NSSDT after the starting with intensive course to sustain the improved post-treatment pain and disability scores and the gained spinal mobility.

There is a need for future studies to find out for how long the NSSDT should be maintained and when to stop it without relapse of pain. Larger further studies may be carried out to put answers and deduct this debate.

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