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Research Article

EFFICACY OF NEUROMUSCULAR THERAPY IN PATIENTS WITH CHRONIC LOW BACK PAIN

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ABSTRACT

Low back pain (LBP) is a common musculoskeletal problem that is often chronic or recurrent. Myofascial trigger points (MTrPs) cause low back pain and are prevalent in patients with LBP. The aim of this study was to assess the effectiveness of multimodal treatment of MTrPs in patients with chronic low back pain. A single-assessor, blinded, randomized, controlled trial was conducted at Mannam Ayurveda Medical College, Pandalam. The intervention group received comprehensive treatment on alternate days consisting of trigger point releasing by manual compression of the MTrPs, stretching of the muscles and *Dhanyamla dhara*. Patients were instructed to perform muscle-stretching and relaxation exercises and maintain good posture. The control group was received only *Dhanyamla dhara*. The Oswestry Low Back Pain Disability questionnaire score (OLBPD) (primary outcome), Visual Analogue Scale for Pain (VAS-P), and the number of muscles with MTrPs were assessed at base line, 3 and 6 weeks in the intervention group and compared with those of a control group. As compared to the control group, the intervention group showed significant improvement ($P < 0.05$) on the OLBPD after 6 weeks. The results of this study show that 6-week comprehensive treatment of MTrPs in lower back muscles such as Piriformis, Quadratus lumborum, and iliopsoas muscles reduces the number of muscles with active MTrPs and is effective in reducing symptoms and improving Sciatica. IVDP can be prevented by early detection and deactivation of Myofascial trigger points. Combination therapy of trigger point releasing with Ayurvedic therapies shows highly beneficial in LBP.

KEYWORDS: *Gridhrasi*, Myofascial trigger points, Pressure release, Piriformis syndrome, *Dhanyamla dhara*, muscle stretching, pain scale.

INTRODUCTION

Trigger points are defined as discrete, focal, hyperirritable spots located in taught band of skeletal muscle, which are painful on compression and can produce local and referred pain, which can perplex medical professionals who are not familiar with trigger points. The aim of this study was to assess the effectiveness of multimodal treatment of Myofascial Trigger points (MTrPs) in patients with chronic low back pain. However, several case studies have suggested that the treatment of MTrPs in patients with low back pain may be beneficial; although well-designed controlled studies are still lacking. Modern medicine tends to overlook the muscles as a source of pain, preferring to concentrate on the nerve and disc problems. [1]

The misdiagnosis of pain is the most important issue taken by Travell and Simons. Referred pain from trigger points mimics the symptoms of a very long list of common maladies, but physicians, in weighing all the possible causes for a given condition, rarely consider a myofascial source. The study of trigger points has not historically been part of medical education. Travell & Simons hold that most of the common everyday pain is caused by myofacial trigger points and that ignorance of the basic concept could inevitably lead to false diagnosis and ultimate failure to deal effectively with pain.

The common cause of muscle pain is myofascial pain caused by myofascial trigger points. A trigger point is caused by certain malfunction of the junction between the nerve fibers and the muscle fibers. This malfunction causes the group of muscle fibers to stay contracted, even when the muscle is relaxed. These groups of contracted muscle fibers resemble a knot in a rope, and affect the muscle in the following ways, such as Increased Muscle tension: The contracted group of muscle fibers prevents the muscle from completely relaxing, causing the muscle to be tense and stiff. Muscle weakness The presence of the contracted fibers prevents the muscle from contracting fully and smoothly, and thus impairing the strength of the muscle. Muscle Fatigue: The constantly contracted group of muscle fibers utilizes an incredible amount of energy, exhausting the supply of oxygen for the rest of the muscle fibers. This causes the muscle to feel lethargic and fatigued. Muscle spasm: A trigger point is actually like a tiny spasm in a muscle. Over a period of time, as the muscle become exhausted, more and more groups of muscle fibers become involved, leading to a fully fledged muscle contraction. [2-6]

Once a trigger point is activated, waste products will begin to accumulate. These waste products are nerve irritants, and perpetuate pain. Due to the accumulation of waste product, blood supply to the area is interrupted; resulting in a contracture (tight band) of muscle fibers and ischemia, and results in pain are felt by the patient. In addition to affecting the proper functioning of muscles,

trigger points affects the nervous system by producing referred pain and other symptoms.

Other symptoms related to trigger points

Tingling or Numbness in various regions of the body, Visual disturbance. Vertigo and Balance problems, Excessive tearing of eye or redness, Soreness of throat, Dry cough, Sinus head ache and discharge, Abdominal bloating and heart burn, Pelvic cramps etc.

Sciatica: piriformis syndrome is one of the many causes of sciatica. Piriformis muscle spasms compress the sciatic nerve, results in the radiating leg pain. The pain is worse with prolonged sitting or standing. The pain is initially minimal when walking, but increases after a certain distance, but increases after a certain distance.

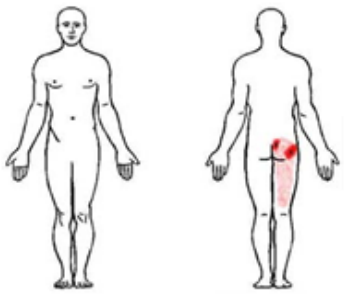
Pain, weakness, numbness and other discomforts along the path of the sciatic nerve-often accompanies low back pain, which afflicts every adult from time to time, costing billions of dollars in healthcare and more lost days work than anything of. In Ayurveda, this condition is termed as *Gridhrasi* and most of the doctors believed this as a result of herniated disc.[7] But in our opinion, the IVDP is not the cause in all cases. *Gridhrasi* is a neuromuscular disorder that occurs when the sciatic nerve is compressed or otherwise irritated by the piriformis muscle causing pain, tingling and numbness in the buttock and along the path of the sciatic nerve.

The tendons (*Kandaras*) originating from calcanium goes to the phalanges, get vitiated by *Vatha* due to over use or mal alignment, exerts over strain on the muscles and tendon, the foot become unstable on walking and as a result the external rotators (piriformis muscle) gets over strained. Because of the overstrain exerted on the piriformis muscle (muscles of buttocks), myofascial trigger points will develop on these muscles- (Charaka described this pain distribution in such a way that "*spik poorve kadee prishtooru janu jangha padam kramat*")[8] means – the pain starts at the buttocks and then spreads to lumbar and descending down the thigh and in to the leg. The muscular strain causes inflammation, shortening of the muscle and increase the bulk (due to the accumulation of waste products) that causes compression on the sciatic nerve. Generally this condition is known as piriformis[9] syndrome refers to sciatica symptoms, not originating from disc herniation. There are various other activities such as prolonged sitting, poor posture for extended time, long distance driving, trauma, twisting of pelvis etc. may cause over load to the piriformis muscle and results in sciatica symptoms. An unresolved piriformis syndrome can contribute trigger points to other muscles such as Quadratus lumborum, Iliopsoas, gluteus muscles etc. results in severe type of low back pain.

There can be as many as ten muscle groups involved in a low back disorder. A simple case of low back pain may involve only two or three muscle group, but if left untreated, up to ten additional muscle groups may be involved. The trigger points in these additional muscle can produce sciatica like pain or numbness that down the leg. The following muscle groups are primarily involved in most of the low back pain disorders.

- The Piriformis muscle
- The Quadratus lumborum muscle
- The Gluteus medius & minus
- The Iliopsoas muscles

Piriformis Syndrome: It is a neuromuscular disorder that occurs when the sciatic nerve is compressed or irritated by piriformis muscle causing pain, tingling and numbness in the buttocks and along the path of the sciatic nerve descending down the thigh and in to the leg. Diagnosis is often difficult due to few standardized diagnostic tests, but one of the most important criteria is to exclude sciatica resulting from compression/irritation of spinal nerve roots, as by a herniated disc. The syndrome may be due to certain anatomical variations in the muscle- nerve relationship, or from overuse or strain. When the piriformis muscle shortens or spasms due to trauma or over use, trigger points develops in it, and it can compress the sciatic nerve beneath the muscle. This particular condition known as piriformis syndrome refers to sciatica symptoms not originating from spinal roots and /or spinal disc herniation, but involving the overlying piriformis muscle. More than 16% of all adult work disability evaluations and examinations are performed to rate the patient's partial or total disability associated with chronic low back pain. It is estimated that at least 6% of patients who are diagnosed as having low back pain actually have piriformis syndrome.[9] There are two trigger points in the piriformis muscle, which is deep inside the buttock. Generally, the medial trigger point refers pain to the sacroiliac joint area, while the lateral trigger point has referral pain mainly in the posterior hip area. However, both trigger points are known to cause pain to affect all three regions (posterior hip, sacroiliac joint, and the general area of the buttock).



Delay in diagnosing piriformis syndrome may lead to pathologic conditions of the sciatic nerve, chronic somatic dysfunction, and compensatory changes resulting in pain, paresthesia, hyperesthesia, and muscle weakness.

Neuromuscular therapy: (Trigger point therapy) is a very specific form of body work, the goal of which is to re-establishes a balance between the nervous system and muscular systems thereby balancing the body. Therapeutic treatments for addressing soft tissue injuries involve massage therapy, manual therapy; trigger point therapy, or Active Release Technique. These treatments increase blood flow, decrease muscle spasms, enhance flexibility, speed healing, and promote proper tissue repair.

A Neuromuscular therapy session is based on a thorough posture and movement analysis to spot the imbalance and break the dysfunctional cycle. [16] Clinical

trigger point therapy is a systematic, comprehensive approach to relieving physical pain. The system is based on the research of Drs.Janet Travell M.D. and David Simons M.D. and was developed by Dr.Laura Perry in 2001. Trigger point therapy can reduce pain, increase movement, and allows the muscle to lengthen and become stronger again. To treat trigger points, heavy pressure must be applied to the trigger point. Light pressure is not effective for treating trigger points, and in fact may increase spasms as the muscle tries to protect itself leading to increased and more constant pain. In contrast, moderate to heavy pressure applied to a trigger point causes the pain to initially increase, but then as the muscle relaxes, the pain will fade. Pressure should be applied slowly and released slowly for best result. The pressure should be maintained until there is a change in pain. If there is no decrease in pain after one minute, stop the pressure- this is probably not a trigger point. After applying pressure to trigger points, the relaxed muscles should be stretched. If the muscles are not returned to normal length, there is a greater likelihood the trigger point will reoccur. Stretching is safer and less painful after the trigger points have been released. When pressure is applied to the trigger point, the chemical/ pressure cycle is interrupted, which helps to stop the contraction and the pain in the muscle. Additionally, the muscle is heated and kneaded during treatment, which helps to increase circulation and to remove the metabolic waste products. *Dhanyamla dhara* is a sudation procedure described in Ayurveda especially in Kerala *Panchakarma* therapies. *Dhanyamlam* is a specially prepared liquid medicament. As per this procedure, moderately heated *Dhanyamla* will be poured all over the body except head after covering the body with a cotton cloth. The duration of treatment will be 40 to 50 minutes to generate sweating. This will dilate the blood vessels and enhance blood circulation, by which eliminate the metabolic waste products through the sweat. According to Ayurvedic principles, the sudation process will liquefy the waste products from all over the body and carry it to the *Koshta* (intestine). From there, it can be eliminated by *Virechana* or *Vasthi*. While stretching the muscle, the muscle fibers become lengthened which decreases the pressure component of the pain cycle. It is important to understand that trigger points are not the same as acupressure points or *Marma* points. For treatment to be effective, the specific trigger points or contracted portion of the muscle must be released.

The aim of the current study was to assess the effectiveness of a comprehensive treatment program of MTrPs in lower back and buttock muscles on symptoms and the functioning of the lower back in patients with chronic non traumatic, non specific low back pain compared with a control group.

MATERIALS AND METHODS

A single-blinded RCT was conducted, which was approved by the Medical Ethics Committee of the Mannam Ayurveda Medical College, Pandalam, and the study protocol was accepted and financed by Kerala State Council For Science, Technology And Environment, Thiruvananthapuram.

Patients in the study sample

The patients were recruited by conducting medical camps after publicity through news papers/local channels; or referred by other doctors of nearby hospitals. A total number of 90 patients were selected on the basis of below inclusion and exclusion criteria. The suitable patients who consented for participation in the trial were randomly divided into two Groups of 45, namely Intervention Group & Control Group. Three patients from intervention group and One patient from control group were dropped out from the trial due to their personal inconvenience.

The inclusion criteria

Patients being in the age between 18 years and 65 years, LBP with sciatica of duration of more than 6 weeks and less than 6 months for the current episode, agreement for randomization and willingness to sign an informed consent form.

The Exclusion criteria

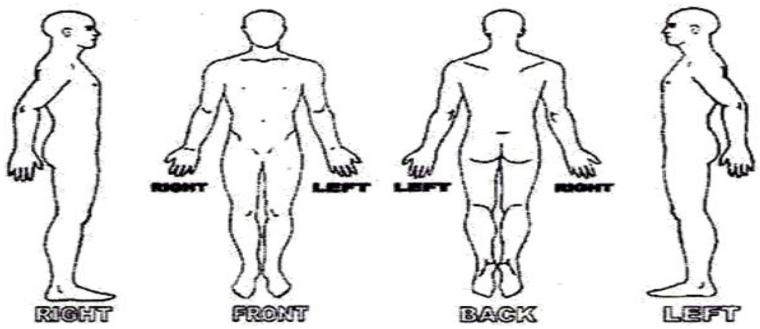
Specified pregnancy, serious medical problems (e.g. peripheral neuropathy, multiple sclerosis, hemiplegic, myelopathy etc.) urinary incontinence, spine disorders with boney lesions (e.g. osteoporosis, fracture, unstable spondylolysthesis, multiple myeloma), with radiographs taken as clinically indicated, significant mental disorders (e.g. psychosis, mania, major depression), litigation, automobile injuries, work injuries and history of lumbar surgery.

I. Subjective parameters

1. Pain

Please describe your current pain complaint:

Please indicate (by shading in) where you are experiencing your pain (or other symptoms):



Please indicate (by circling) which term(s) best describe your symptoms:

Aching	Burning	Stabbing	Tender to Touch
Sharp, well defined	Tingling	Shooting	Radiating
Diffuse, poorly defined	Numbness	Cramping	Throbbing

Severity of Pain:

Please indicate (circle) the severity of your pain:

(No Pain) 0….1….2….3….4….5….6….7….8….9….10 (Severe Pain)

Treatment Area/Body Part Pain

1 = No pain
2 = Tolerable discomfort
3 = Minimal pain, when in certain positions or situations, can be ignored
4 = Pain cannot be ignored, but can be tolerated, minimal concentration interference
5 = Pain occasionally interferes with concentration, minimal pain compensation behaviors, performance difficulties with one or two tasks
6 = Pain interferes with concentration and/or performance difficulties 25% of the time, pain compensation behaviors displayed
7 = Pain interferes with concentration and performance difficulties 50% of the time, pain compensation behaviors displayed
8 = Pain interferes with concentration and performance difficulties 75% of the time, pain compensation behaviors displayed
9 = Pain continuously interferes with concentration and performance is limited, pain compensation behaviors displayed
10 = Intolerable pain, concentration and performance interference except basic needs of eating, toileting

1.2 After treatment

Please circle the percentage of your improvement since beginning therapy:

0 10 20 30 40 50 60 70 80 90 100

No improvement **Complete recovery**

2. Low back Pain Disability Score

Scoring the Modified Oswestry Low Back Pain Index

- The first statement in each section has a value of 0, the second a value of 1, the third 2, the fourth 3, the fifth 4, and the last statement 5. If a patient marks 2 boxes, score the highest value box.
- Add the scores. If the patient didn't complete all sections, the final score is divided by the total possible score (5 for each section answered), and then multiplied by 100 to determine a disability percentage. Example: If only 9 sections were answered for a total of 24, then 24/45 = 0.53. Multiplied by 100 = 53%.
- All values should be rounded to the nearest whole number, i.e. 26.5 is 27% and 33.33 is 33%.
- Put the actual disability percentage in the functional assessment score section of the EMR.

Objective parameters

1. Number of trigger points (tender spots) in lower back and buttock muscles

Identification of Trigger points by palpation of the following muscles

a. Piriformis Muscle
b. Quadratus Lumborum Muscle
c. Iliopsoas Muscle
d. Gluteus Medius Muscle

The identified trigger points were marked in the above picture used for the pain description. Number of trigger points was assessed before and after treatment.

2. Presence of taut band

3. Presence of nodule

4. Local Twitch response

5. Local or referred pain

Sample size

The planned sample size was determined on the basis of an assumed mean improvement of the primary outcome, a Oswestry Low Back Pain Disability questionnaire score of 10 points (SD ± 22), which implies an effect size of 0.68 To test the null hypothesis at α = 0.05 with 90% power and assuming a uniform dropout rate of 5%, it was calculated that 45 patients in each group would be required.

Randomization

After collection of patients' data at baseline, the included patients were randomly assigned to either the intervention group or the control group. A research assistant performed the randomization by generating random numbers using Research Randomizer software (http://www.randomizer.org/) These numbers were stored on a computer and were accessible only by the research assistant. No stratification or blocking strategies were used.

Blinding, Outcome Assessment- Blinding of the patients and the treating therapists was impossible because of the treatment characteristics. Hence a blinded independent assessor from our institution with no previous contact with the patient performed the assessment. The assessments were made at intake, prior to randomization and at 3, and 6 weeks. The total number of back and buttock muscles with active and latent MTrPs was counted. For every patient, only one observer was active. A detailed medical history were taken, which include demographic variables and potential prognostic factors and a set of self administered questionnaires regarding outcome measurements, including the Oswestry Disability Index questionnaire, and the Visual Analogue Scale for Pain (VAS-P). Subsequently, upon completion of 14

treatment sessions within 3 weeks, the patient was asked once again to fill out all questionnaires and forms, and follow-up physical examinations were performed. A third assessment was carried out after six weeks.

Interventions

The treatment started with inactivation of active, pain-producing MTrPs by manual compression by the principal investigator. The PI applied gentle, gradually increasing pressure on the MTrP until the finger encountered a definite increase in tissue resistance. At that point, the patient commonly would feel a certain degree of discomfort or pain. The pressure was maintained until the therapist sensed relief of tension under the palpating finger or the patient experienced a considerable decline in pain. At that point, the PI could repeat this procedure several times until pressure on the MTrP would provoke only a little discomfort without pain. This technique was combined with other manual techniques, such as deep stroking (pressure directed along the length of the taut band) or strumming (pressure applied perpendicularly across the muscle fibers). Both techniques can manually stretch the trigger point area and the taut band. These manual techniques could be preceded or followed by "*Dhanyamladhara*". The effectiveness of muscle-stretching exercises was enhanced by including short isometric contractions and relaxation (hold-relax). Patients were instructed to perform simple gentle static stretching and relaxation exercises at home several times during the day. All patients received ergonomic advice and instructions to assume and maintain good posture.

According to Travell, ischemic compression decreases the sensitivity of painful nodules in muscles. Simons proposed that local pressure may equalize the length of sarcomeres in the involved Trp and consequently decrease the pain. Additionally, the subsequent tissue relaxation created by attaining a position of TrP ease has been proposed as a mechanism of facilitating unopposed arterial filling which allows for a reduction of tone in the tissues involved. This reduction in local tone further results in the improvement of local circulation and decreased pain.

The patients in the control group were given mild massage and *Dhanyamladhara* only for a treatment session of 14 days within 3 weeks. All individual treatments, however, were consistent with the limits of the treatment protocol.

Data assessment

Two Doctors each from Kayachikitsa and Salyathantra department performed the physical examination, of the lumbar spine and the MTrP palpation of the back and buttock muscles. The total number of muscles with active and latent MTrPs was counted. The observing doctors were blinded to the patient treatment allocations during the entire study period. The assessments were made at intake, prior to randomization and at 3, and 6 weeks. For every patient, only one observer was active. A detailed medical history was completed, which included demographic variables and potential prognostic factors and a set of self-administered questionnaires regarding outcome measurements, including the OLBPD questionnaire, the Visual Analogue Scale for Pain (VAS-P). After the data from the worksheet were transferred into the statistical software packages SPSS for windows Version 10. The analyses were based on an intent-to-treat methodology such that all data's were analyzed regardless of patient compliance. The analyses were performed using one-way- variance (ANOVA) on the two groups, with contrasts for comparisons of individual groups.

Stop rule

Treatments were discontinued when patients were completely free of symptoms or when the patient and physical therapist agreed that treatment would not further benefit the patient. Participation in the study continued unless patients decided to stop participation in the study. Patients were free to withdraw from the study at any time without consequences for their treatment.

Outcome measures

Primary outcome measure

The Oswestry Low Back Pain Disability questionnaire is an internationally widely used multidimensional 10-item self-report measure focusing on physical function, pain and emotional and social parameters The score ranges from 0 to 50 whereby a higher score indicates greater disability. The Minimal Clinically Important Difference (MCID) is approximately a 10-point difference between pre- and post treatment.

Secondary outcome measures

The Visual Analogue Scale for Pain (VAS-P) is a self-report scale consisting of a horizontal line 10 cm in length that is anchored by the ratings "no pain" at the left side (score 0) and "worst pain imaginable" at the right side (score 10), The VAS-P1 was used to measure pain at the current moment or at the base line before treatment., average pain after treatment of 21 days was measured as VAS-P2 and the most severe pain after 42 days was measured as VAS-P3. A 4-cm change is considered to be a MCID in patients with Low back pain.

The total number of back and buttock muscles with MTrPs was counted using the same methods as at baseline and then compared with the baseline measurements. While the patient was in a supine or prone position, depending on the muscle that was examined, 17 muscles were palpated bilaterally for the presence of a taut band, spot tenderness, the presence of a nodule, local twitch response and local and referred pain. When the patient recognized the pain from compression on the tender spot, the MTrPs were considered to be active. When the pain was only local and not familiar, MTrPs were considered to be latent. At base, 3, and 6 weeks, participants were asked to complete a self-assessment form, which included questions regarding whether they had changed their self-management or had received any medical treatment that could have influenced.

Statistical analysis

Both groups were compared for baseline characteristics using a t-test and a $\chi 2$ test for binominal variables. For the OLBPD, VAS-P and the number of muscles with MTrPs, the repeated measures test was used to assess the significance of treatment between the two

groups at week 3rd, and 6th week. We considered a mean difference of more than 10 points on the OLBPD as a MCID. Effect sizes measured using Cohen's d was calculated to examine the average impact of the intervention. According to the method of Cohen, d ≈ 0.2 indicates small effect and negligible clinical importance, d ≈ 0.5 indicates medium effect and moderate clinical importance and d ≈ 0.8 indicates a large effect and crucial clinical importance. To compare patients who improved by more than 10 points with patients who improved by less than 10 points on the OLBPD questionnaire, we calculated the relative risk (RR) and the 95% confidence interval (95% CI). The proportions of patients who had clinically improved between groups were compared by calculating the RR and the 95% CI at 6 weeks and 12 weeks. Pearson's correlation coefficients were used to relate the variables of number of muscles with active MTrPs and the OLBPD questionnaire score.

In addition, the effect of the intervention was evaluated by using regression analysis. Covariates in this multiple linear regression model were the OLBPD questionnaire score at 6th week as the dependent variable, the group variable as the OLBPD questionnaire score at baseline, and the number of muscles with active MTrPs at intake.

To evaluate the success of the blinding procedure, both observers were asked to identify the treatment allocation. A goodness-of-fit $\chi 2$ test was used to determine whether the number of correctly and incorrectly identified cases fitted a probability of 50%. For all comparisons, $P < 0.05$ was considered statistically significant (two-tailed). If the 95% CI of the difference did not include the value 0, the difference was statistically significant at $\alpha = 0.05$.

OBSERVATIONS AND RESULTS

Between September 2014 and September 2016, 104 patients were randomly assigned to either the intervention group or the control group. At baseline, both groups were comparable with regard to all variables and had no statistically or clinically relevant differences, except for the number of muscles with latent MTrPs.

The observations and results in signs and symptoms in control and the intervention groups have been made in the following headings.

(1) Symptom wise observations

(2) Oswestry low back pain disability score (OLBPD)

(3) Visual analogue scale for pain(VASP) and

(4) The Number of trigger points present.

Table 1: Comparative assessment of symptomatic relief in control group

SNO	Symptoms	Mean BT	Mean AT	Mean diff	SD	SE	T value	P value	result
1	Presence of taut band	2.295	1.5227	0.7727	0.642	0.0968	7.98	<0.01	Significant
2	Tender spots	3.4545	2.4545	1	0.482	0.0727	13.76	<0.01	Significant
3	Presence of nodules	3	2.2272	0.7727	0.604	0.091	8.49	<0.01	Significant
4	Local twitch points	2.0681	1.3181	0.75	0.575	0.0867	8.65	<0.01	Significant
5	Referred pain	1.8636	0.5454	0.5454	0.503	0.0758	7.195	<0.01	Significant

Table 2: Comparative assessment of symptomatic relief in intervention group

S.NO	Symptoms	Mean BT	Mean AT	Mean diff	SD	SE	T value	P value	result
1	Presence of taut band	2.1428	0.1904	1.9523	0.6228	0.0961	20.315	<0.01	H. significant
2	Tender spots	3.4047	0.238	3.1667	0.8239	0.1271	24.91	<0.01	H. significant
3	Presence of nodules	3.0476	0.333	2.7142	0.8050	0.1242	21.85	<0.01	H. significant
4	Local twitch points	2.1428	0.1904	1.9523	0.6608	0.1019	19.16	<0.01	H. significant
5	Referred pain	1.8095	0.1667	1.6428	0.6176	0.0953	17.24	<0.01	H. significant

Table 3: Comparative assessment of control group and intervention group

S.NO	Symptoms	Mean control	Mean intervention	Mean diff	SE	T value	P value	result
1	Presence of taut band	1.5227	0.1904	1.3323	0.1277	10.429	< 0.01	Significant
2	Tender spots	2.4545	0.238	2.2165	0.1383	16.626	< 0.01	Significant
3	Presence of nodules	2.2272	0.333	1.8942	0.1394	13.589	< 0.01	Significant
4	Local twitch points	1.3181	0.1904	1.1277	0.1289	8.744	< 0.01	Significant
5	Referred pain	1.3181	0.1667	1.1514	0.1186	9.711	< 0.01	Significant

Primary outcome measure

I. OLBPD questionnaire –(Subjective parameters)

The difference between the intervention group and the control group was significant after 6 weeks. The difference of the mean value before treatment and after six weeks for the control group and intervention group are 14.13 and 33.09 respectively. The multivariate test for repeated measures shows there is significant difference in OLBPD scores at 1% level of significance. There is a significant difference between level 1 and level 2.But level 2 and level 3 do not show a significant difference.

Table 4: Showing effect of therapy in low back pain disability score

Descriptive Statistics				
	Group	**Mean**	**Std. Deviation**	**N**
OLBP1	Control	62.33	10.67	44
	Intervention	48.46	12.92	42
	Total	55.56	13.67	86
OLBP2	Control	53.09	9.58	44
	Intervention	10.14	7.09	42
	Total	32.11	23.18	86
OLBP3	Control	48.20	9.10	44
	Intervention	14.37	32.83	42
	Total	31.68	29.17	86

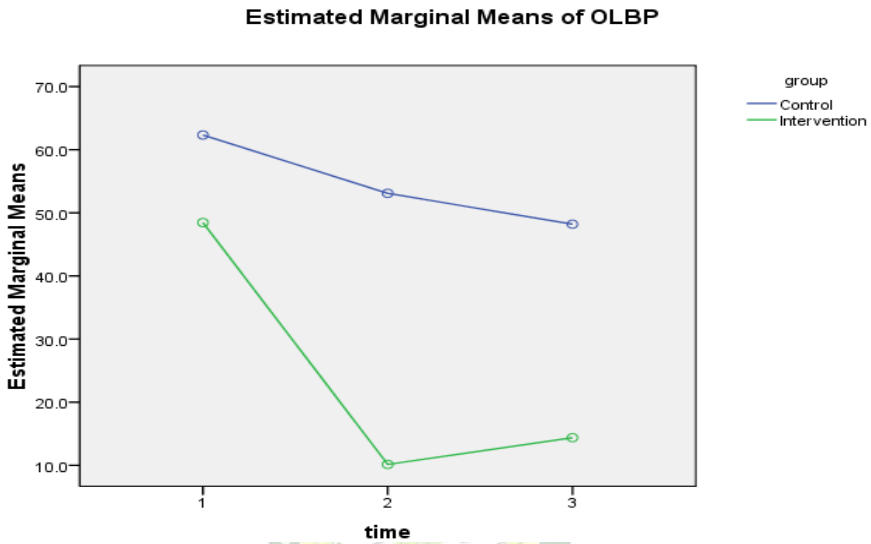


Fig.1: Showing effect of therapy in low back pain disability score

Table 5: The following test shows there is significant difference in OLBP scores among 3 levels in between control and intervention at 1% level of significance.

Measure: OLBP

Transformed Variable: Average

Source	**Type III Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**
Intercept	133640.912	1	133640.912	1147.84	.000
group	19619.026	1	19619.026	168.508	.000
Error	9779.964	84	116.428		

CONTROL

Table 6: Multivariate Tests

Effect		**Value**	**F**	**Hypothesis df**	**Error df**	**Sig.**
Time	Pillai's Trace	0.837	107.85	2.000	42.000	.000
	Wilks' Lambda	0.163	107.85	2.000	42.000	.000
	Hotelling's Trace	5.136	107.85	2.000	42.000	.000
	Roy's Largest Root	5.136	107.85	2.000	42.000	.000

Table 7: Tests of Within-Subjects Contrasts [a]

Measure: OLBP

Source	**Time**	**Type III Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**
Time	Level 1 vs. Level 2	3754.582	1	3754.582	151.432	.000
	Level 2 vs. Level 3	1053.502	1	1053.502	38.753	.000

The multivariate test for repeated measures shows there is significant difference in OLBP scores in between 3 repeated measures at 1% level of significance (F=107.85, P-value <.01)

The above test shows there is significant difference in between first and second sets at 1% level of significance. Also, there is significant difference in between second and third sets at 1% level of significance.

Intervention

Table 8: Multivariate Tests

Effect		Value	F	Hypothesis df	Error df	Sig.
Time	Pillai's Trace	0.898	176.18	2.000	40.000	.000
	Wilks' Lambda	0.102	176.18	2.000	40.000	.000
	Hotelling's Trace	8.809	176.18	2.000	40.000	.000
	Roy's Largest Root	8.809	176.18	2.000	40.000	.000

The multivariate test for repeated measures shows there is significant difference in OLBP scores in between 3 repeated measures at 1% level of significance (F=176.18, P-value <.01).

Table 9: Tests of Within-Subjects Contrasts [a]

Measure: OLBP

Source	Time	Type III Sum of Squares	df	Mean Square	F	Sig.
Time	Level1 vs. Level2	61678.339	1	61678.339	359.831	.000
	Level 2 vs. Level 3	752.687	1	752.687	.656	.423

a. group = Intervention

The above test shows there is significant difference in between first and second sets at 1% level of significance. But, there is no significant difference in between second and third sets.

Secondary outcomes –(Subjective parameters)

II. VASP- showing effect of therapy in pain index

Table 10: 1VASP- showing effect of therapy in pain index

Descriptive Statistics

	Group	Mean	Std. Deviation	N
VASP1	Control	6.68	0.674	44
	Intervention	6.21	0.871	42
	Total	6.45	0.807	86
VASP2	Control	5.23	0.677	44
	Intervention	2.45	0.633	42
	Total	3.87	1.540	86
VASP3	Control	4.91	0.640	44
	Intervention	2.05	0.731	42
	Total	3.51	1.592	86

VAS-P1, VAS-P2 and VAS-P3

The intervention group showed, on average, significantly lower scores on all VAS-P scales compared with the control group after 6 weeks: The difference of the mean value at the baseline and after six weeks for the control group was 1.97 and that for intervention group was 4.16. The graphical representation of estimated marginal means of VASP is shown in Fig.2. For the control group, the test shows, there is a significant difference in between first and second levels at 1% level of significance. Also there is significant difference between second and third level. For the intervention group, the P- value <0.01 shows that there is significant difference between each levels.

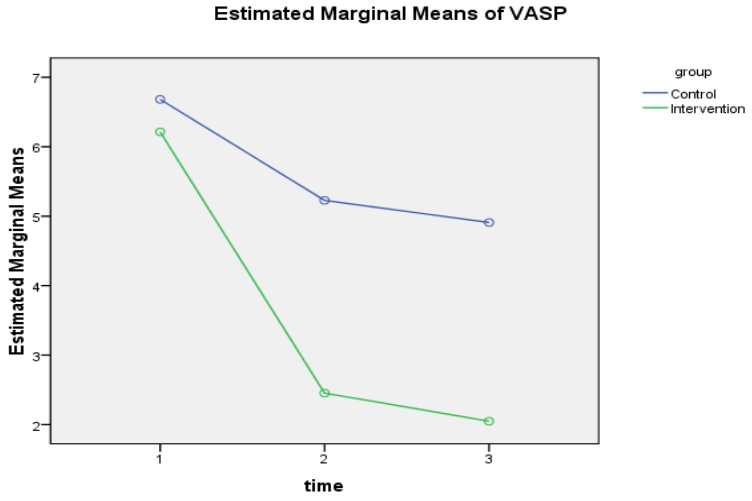


Fig.2 VASP-showing effect of therapy in pain index

Table 11: The following test shows there is significant difference in VASP scores among 3 levels in between control and intervention at 1% level of significance

Measure: VASP

Transformed Variable: Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	1809.886	1	1809.886	5363.3	.000
Group	88.956	1	88.956	263.608	.000
Error	28.346	84	.337		

1. Control

Table 12: Multivariate Tests [b]

Effect		Value	F	Hypothesis df	Error df	Sig.
Time	Pillai's Trace	.855	124.30	2.000	42.000	.000
	Wilks' Lambda	.145	124.30	2.000	42.000	.000
	Hotelling's Trace	5.919	124.30	2.000	42.000	.000
	Roy's Largest Root	5.919	124.30	2.000	42.000	.000

The multivariate test for repeated measures shows there is significant difference in VASP scores in between 3 repeated measures at 1% level of significance (F=124.30, P-value <.01).

Table 13: Tests of Within-Subjects Contrasts [a]

Measure: VASP

	Source Time	Type III Sum of Squares	df	Mean Square	F	Sig.
Time	Level 1 vs. Level 2	93.091	1	93.091	174.730	0.000
	Level 2 vs. Level 3	4.455	1	4.455	16.591	0.000

a group = Control

The above test shows there is significant difference in between first and second sets at 1% level of significance. Also, there is significant difference in between second and third sets at 1% level of significance.

2. Intervention

Table 14: Multivariate Tests [b]

Effect		Value	F	Hypothesis df	Error df	Sig.
Time	Pillai's Trace	0.970	639.785	2.000	40.000	.000
	Wilks' Lambda	0.030	639.785	2.000	40.000	.000
	Hotelling's Trace	31.989	639.785	2.000	40.000	.000
	Roy's Largest Root	31.989	639.785	2.000	40.000	.000

b. group = Intervention

The multivariate test for repeated measures shows there is significant difference in VASP scores in between 3 repeated measures at 1% level of significance (F=639.785, P-value <.01).

Table 15: Tests of Within-Subjects Contrasts [a]

Measure: VASP

	Source time	Type III Sum of Squares	df	Mean Square	F	Sig.
Time	Level 1 vs. Level 2	594.381	1	594.381	1031.77	.000
	Level 2 vs. Level 3	6.881	1	6.881	17.502	.000

a. group = Intervention

The above test shows there is significant difference in between first and second sets at 1% level of significance. Also, there is significant difference in between second and third sets at 1% level of significance.

Table 16: Assessment of OLBP and VASP for control group

SNO	symptoms	Mean Bt	Mean AT	Mean diff	SD	SE	P value	result
1	OLBP	62.328	48.197	14.1306	6.6	0.9949	<0.01	significant
2	VASP	6.6818	4.909	1.7727	0.742	0.1118	<0.01	significant

Table 17: Assessment of OLBP and VASP for intervention group

SNO	Symptoms	Mean Bt	Mean AT	Mean diff	SD	SE	P value	Result
1	OLBP	48.4595	9.1875	39.273	12.342	1.904	<0.01	H.Significant
2	VASP	6.2142	2.0476	2.0476	0.7937	0.122	<0.01	H.Significant

III. Number of trigger points (Objective parameters)

The number of active MTrPs was significantly lower in the intervention group than in the control group after 6 weeks. The control group's mean value varies from 6.05 (at the base line) to 4.59 (after six weeks). The mean of intervention group varies from 5.71 to 1.95. The graphical presentation of the mean of TrP is given by Fig.3. The multivariate test for repeated measures shows there is significant difference in TrP scores in between 3 repeated measures at 1% level of significance for the control group as well as the intervention group.

When we tested the significance within each level, the control group showed in between first and second levels at 1% level of significance. But there is no significant difference between level 2 and 3 at 1% level of significance. (P value >01)

For the intervention group, there is significant difference between level 1 and level 2, and also between level 2 and level 3 at 1% level of significance.

Table 18: Shows the effect of therapy in the number of trigger points in lower back muscles

Descriptive Statistics

	Group	Mean	Std. Deviation	N
TrP1	Control	6.05	1.275	44
	Intervention	5.71	1.066	42
	Total	5.88	1.182	86
TrP2	Control	4.86	0.979	44
	Intervention	2.48	0.671	42
	Total	3.70	1.464	86
TrP3	Control	4.59	0.996	44
	Intervention	1.95	0.731	42
	Total	3.30	1.587	86

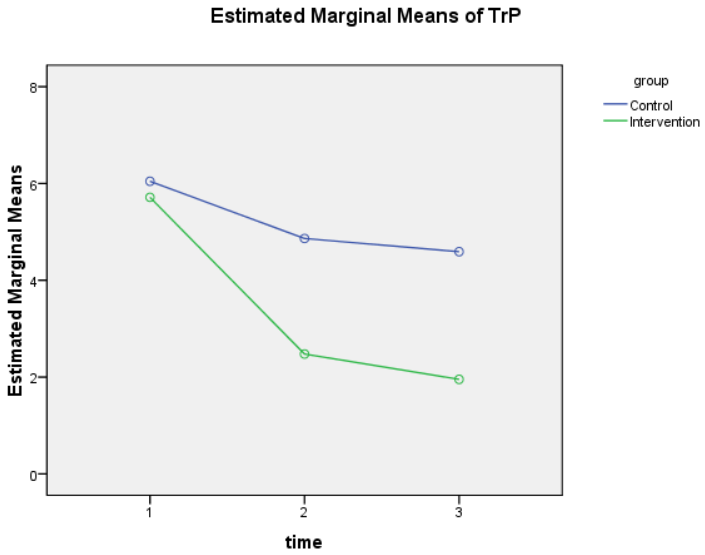


Fig 3: The effect of therapy in the number of trigger points in lower back muscles

Table 19: The following test shows there is significant difference in TrP scores among 3 levels in between control and intervention at 1% level of significance.

Measure: TrP

Transformed Variable: Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	1569.979	1	1569.979	2173.2	.000
group	68.522	1	68.522	94.851	.000
Error	60.683	84	.722		

1. CONTROL

Table 20: Multivariate Tests [b]

Effect		Value	F	Hypothesis df	Error df	Sig.
Time	Pillai's Trace	0.812	90.747	2.000	42.000	.000
	Wilks' Lambda	0.188	90.747	2.000	42.000	.000
	Hotelling's Trace	4.321	90.747	2.000	42.000	.000
	Roy's Largest Root	4.321	90.747	2.000	42.000	.000

b. group = Control

The multivariate test for repeated measures shows there is significant difference in TrP scores in between 3 repeated measures at 1% level of significance (F=90.747, P-value <.01).

Table 21: Tests of Within-Subjects Contrasts [a]

Measure: TrP

	Source Time	Type III Sum of Squares	df	Mean Square	F	Sig.
Time	Level 1 vs. Level 2	61.455	1	61.455	159.714	.000
	Level 2 vs. Level 3	3.273	1	3.273	5.691	.022

The above test shows there is significant difference in between first and second sets at 1% level of significance. Also, there is significant difference in between second and third sets at 5% level of significance.

2. INTERVENTION

Table 22: Multivariate Tests [b]

Effect		Value	F	Hypothesis df	Error df	Sig.
Time	Pillai's Trace	.933	278.200	2.000	40.000	.000
	Wilks' Lambda	.067	278.200	2.000	40.000	.000
	Hotelling's Trace	13.910	278.200	2.000	40.000	.000
	Roy's Largest Root	13.910	278.200	2.000	40.000	.000

The multivariate test for repeated measures shows there is significant difference in TrP scores in between 3 repeated measures at 1% level of significance (F=278.2, P-value <.01).

Table 23: Tests of Within-Subjects Contrasts [a]

Measure: TrP

Source	time	Type III Sum of Squares	df	Mean Square	F	Sig.
Time	Level 1 vs. Level 2	440.381	1	440.381	506.909	.000
	Level 2 vs. Level 3	11.524	1	11.524	25.572	.000

a. group = Intervention

The above test shows there is significant difference in between first and second sets at 1% level of significance. Also, there is significant difference in between second and third sets at 1% level of significance.

DISCUSSION

Summary of main findings

This single-blinded RCT evaluated the effectiveness of a 6-week comprehensive neuro muscular therapy (NMT) program in patients with chronic, non traumatic, low back pain when compared with a control group. After 6 weeks, the intervention group showed statistically as well as clinically significant differences compared with the control group on the primary and secondary outcome measures. The NMT consists of ischemic compression by means of applying direct sustained digital pressure to the TrP with sufficient force over 10 to 16 seconds, The pressure is gradually applied, maintained and gradually released. The area is then massaged, stretched manually and apply *Dhanyamla dhara* as to reduce the tension in the affected muscle and subsequently reduce the pain. The combination of NMT and *Dhanyamla dhara* showed more effective in the targeted approach to releasing the TrPs. While the control group was received only *Dhanyamla dhara*. The sudation procedures like *Dhanyamla dhara, Pathrapotala sweda* etc. are commonly utilized for achieving pain reduction in musculo skeletal disorders. That is why both groups demonstrated significant levels of improvement in pain intensity ($p<0.01$) and low back pain disability index ($p<0.01$). The between-group analysis indicated that there was significantly greater improvement in pain and OLBPD favoring the group receiving the NMT with *Dhanyamla dhara*. The effect sizes were considered to be medium and consistent with the hypothesized effect size. The number of back and buttock muscles with active MTrPs was significantly lower in the intervention group than in the control group, supporting the assumed biomedical mechanism underlying MTrP therapy. In the present study, the NMT with sudation procedures (*Dhanyamla dhara*) was found superior versus *Dhanyamla dhara* only in its ability to improve pain, low back pain disability index, number of trigger points and the symptomatic parameters.

In the present study most of the participants were diagnosed previously as IVDP and were treated with NSAIDs. On keen observation and history taking, it was revealed that there was strong evidence of the presence of Trps in the back and buttock muscles. Hence we can assume that the MTrPs are the main causative factor for IVDP.

CONCLUSION

Participants in the intervention group had better outcomes on all outcome measures after 6 weeks of a comprehensive MTrP treatment program than did those on the control group. Clinically relevant improvements were achieved in 85% of the patients with low back pain, and the number of muscles with active MTrPs was significantly decreased.

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