Physiotherapy Section

Effect of Transdermal Magnesium and Moderate Intensity Theraband Training on Pressure Pain Threshold, Disability and Quality of Life among Adults with Sciatic Pain: A Research Protocol

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ABSTRACT

Introduction: Sciatic pain, commonly known as sciatica, is a prevalent condition characterised by radiating pain along the sciatic nerve pathway, significantly affecting an individual's quality of life due to discomfort, numbness, and muscle weakness.

Need of the study: Cost-effective, non-invasive methods of treating sciatic pain are increasingly necessary. Investigating the synergistic effects of TM and MIT training may provide an innovative approach to promoting integrative pain management techniques by enhancing quality of life, reducing disability, and improving pressure pain threshold in affected individuals.

Aim: To study the effect of Transdermal Magnesium (TM) and moderate-intensity Theraband (MIT) training on quality of life among adults with sciatic pain.

Materials and Methods: A two-group, randomised, pretest-post-test clinical trial will be conducted in recognised hospitals in Delhi, India using simple random sampling from February 2025 to February 2026. Two groups will be formed, each consisting of 56 participants. Group A will be the experimental group and will receive a TM spray and MIT training using Theraband exercises. Group B, the control group, will receive sham TM spray and MIT training with Theraband exercises. Both groups will undergo the intervention three days per week for eight weeks. The paired t-test will be employed to assess within-group changes, while the unpaired t-test will be used for intergroup comparisons, with a significance level of p<0.05. This integrated approach addresses both biochemical and functional aspects, offering comprehensive rehabilitation benefits.

Keywords: Magnesium, Muscle weakness, Sciatic nerve

INTRODUCTION

Sciatic pain, often known as sciatica, is a severe condition characterised by pain radiating along the course of the sciatic nerve, which runs from the lower back through the hips and buttocks and down the legs [1]. It significantly reduces an individual's quality of life due to discomfort, numbness, and muscle weakness. Traditional treatment methods include pharmacotherapy, physical therapy, and, in severe cases, surgery [2]. However, adjunctive therapies such as Transdermal Magnesium (TM) and Moderate-Intensity Theraband (MIT) training have attracted recognition for their potential to effectively manage sciatic pain. TM involves the topical administration of magnesium to the skin, usually in the form of creams or oils. Magnesium is required for neuromuscular conduction and nerve transmission and helps reduce inflammation and muscle tension, both of which are significant contributors to sciatic pain. Recent research indicates that magnesium supplementation can relieve nerve pain by inhibiting N-methyl-D-aspartate (NMDA) receptors, a key pain mechanism. This may relieve pain and exert an anti-inflammatory effect, potentially increasing muscle function and improving overall pain management [3].

Meanwhile, MIT training uses elastic resistance bands to perform movements that strengthen muscles, increase flexibility, and promote overall neuromuscular health. These exercises can help relieve sciatic pain by increasing blood flow, promoting the release of endorphins, and improving range of motion, thereby reducing muscular tension and pain. Research suggests that MIT exercises

effectively target muscles that support the spine, such as the core, glutes, and lower back, helping stabilise the spine and alleviate strain on the sciatic nerve. This can reduce the frequency and intensity of sciatic pain episodes and support long-term rehabilitation.

Combining TM and MIT provides a synergistic approach to addressing sciatic pain. TM offers anti-inflammatory and muscle-relaxing benefits at the biochemical level, while MIT strengthens and mobilises the affected muscles, improving functional recovery and overall quality of life. The integrated approach addresses both the underlying physiological challenges and the functional limitations associated with sciatic pain, offering a comprehensive rehabilitation strategy. The present study will be aimed to evaluate the effects of magnesium supplementation and MIT training on pressure pain threshold, disability, and quality of life among adults with sciatic pain.

Objectives:

- To assess the impact of magnesium supplementation on the pressure pain threshold among adults with sciatic pain.
- To determine the effectiveness of MIT training in reducing disability levels in individuals with sciatic pain.
- To evaluate the combined effect of magnesium supplementation and Theraband training on improving the quality of life in adults with sciatic pain.

Alternate Hypothesis (H_a): Magnesium supplementation and MIT training significantly improve pressure pain threshold, reduce disability, and enhance quality of life among adults with sciatic pain.

Null Hypothesis (H_a): Magnesium supplementation and MIT training have no significant effect on pressure pain threshold, disability, or quality of life among adults with sciatic pain.

REVIEW OF LITERATURE

The MIT training has emerged as a viable treatment for sciatic pain, defined by radiating pain along the sciatic nerve pathway. Recent research has shown that it is effective in increasing pressure pain threshold, reducing disability, and improving quality of life in persons with sciatic pain [4]. TherBand training sessions use elastic resistance bands to strengthen muscles, enhance flexibility, and promote neuromuscular health. According to research, these exercises effectively target the muscles that support the spine, such as the core, glutes, and lower back, stabilising the spine and relieving strain on the sciatic nerve. This stabilisation decreases the frequency and intensity of sciatic pain episodes, promoting long-term healing [5].

A study on chronic musculoskeletal pain found that combination exercise programs, such as TherBand training, significantly improved local pressure pain thresholds and reduced pain severity [6]. Another study on mechanical low back pain discovered associations between physical activity, quality of life, and disability, underscoring the importance of focused exercises in improving general well-being [5]. The combination of TherBand training and additional interventions, such as psychological treatments, has also shown promise. Systematic evaluations reveal that integrated therapies improve pain management and quality of life more than solitary treatments [7]. These findings emphasise the significance of treating the psychological as well as physical elements of pain [8].

MATERIALS AND METHODS

The proposed study is a randomised parallel-group, active-controlled trial will be conducted in recognised hospitals in Delhi using simple random sampling from February 2025 to February 2026. The study has ethical clearance from the Institutional Ethical Committee (IEC) number SEC/SAHS/PHD/24/02. The trial will be conducted in the Physiotherapy Outpatient Department at Amar Jyoti Research Centre (CTRI/2025/06/088574) [Table/Fig-1]

Patient with Sciatic pain assessed for eligibility (n=112) Provision of study information to eligible patients Approval to participants by signing the consent form Baseline assessment Randomized allocation (n=112) Control Group (n=56) Intervention group (n=56) Sham Treatment + TheraBand Transdermal Magnesium Spray + TheraBand Exercise Follow Up Follow Up 8 Weeks after completed treatment 8 Weeks after completed treatment Individual Interview about Individual Interview about experience of participatory care experience of participatory care [Table/Fig-1]: Flow Chart for study Protocol

provides an overview of the protocol. Informed consent will be obtained from voluntary participants before treatment. Participants will be assured that there will be no harmful effects on their health and that their privacy will be maintained. The primary outcomes will be the Numeric Pain Rating Scale (NPRS) and the Roland-Morris Disability Questionnaire (RMDQ) to assess pain and disability due to low back pain, and serum magnesium to assess magnesium levels [9,10]. The secondary outcomes will be 36-Item Short-Form Survey (SF-36) [11] and an algometer measurement (Biotronix Solution Forever, Delhi, India; Model: Digital Dolorimeter Algometer) [4].

Sample size calculation: The sample size was calculated using G Power for sample size estimation. With an effect size of 0.6, power of 0.80, alpha of 0.05 (two-tailed), and a dropout rate of 10%, the calculated sample size is 112 participants [12].

Recruitment of participants: One hundred twelve patients with sciatic pain will be recruited for the study according to the selection criteria using purposive sampling. Demographic data such as name, age, gender, occupation, address, and contact number will be collected on a pre-designed case record form.

Inclusion criteria:

- 18-65 years
- Low back pain with radiculopathy (L4-L5 and L5-S1)
- Unilateral
- Positive Straight Leg Raise (SLR) test [13]
- Chronic pain for 3 to 6 months [14]

Exclusion criteria:

- Surgical intervention
- Spinal infection
- Spinal tumour
- Spinal fracture

Randomisation: Participants will be randomly allocated to either the experimental group or the conventional physiotherapy group using concealed opaque envelope allocation and block randomisation to attain similar group sizes. The random block size will be 7, with 20 blocks in total. The allocation sequence will be generated by a staff member who is not involved in enrolment or assignment of participants to groups [15].

Study Procedure

Participants will be assessed for lumbar radiculopathy (sciatic nerve pain) using the SLR test. A written informed consent form will be obtained from the patient for voluntary participation. Participants will be recruited based on the selection criteria and randomly allocated into two groups: Group A (experimental) will receive TM spray plus TherBand exercises, and Group B (control) will receive sham TM spray plus TherBand exercises. They will receive 24 treatment sessions of 30-45 minutes each, over eight weeks (three days per week). Outcome measures NPRS, RMDQ, SF-36, and serum magnesium levels will be measured at baseline and on the last day, i.e., after the 24th session. The principal investigator will deliver the intervention in person.

Group-A (TM spray + Theraband exercises)

Transdermal Magnesium (TM) spray: The patient will be in the prone position; the therapist will apply the magnesium spray (Dr Mg+ Speed Recovery, located in Dehradun) over the course of the sciatic nerve. A total of ten sprays will be applied along the nerve route.

Theraband exercises:

 Hamstring stretching: The patient will be in a supine position with the band around the sole of the foot, holding both ends of the TherBand. The patient will lift the leg by gently pulling on the TherBand to increase the stretch while keeping

- the leg straight. Hold the stretch for 30-45 seconds, 15-20 repetitions [16].
- 2. Hip abduction: The patient will be in a standing position. The therapist will attach the band to a stable anchor point, such as a door handle. The patient will stand with feet shoulderwidth apart and wrap the band around the ankle. With the feet together, the patient will move the leg out to the side and then back to the midline. Repeat this movement for 15-20 repetitions with a hold of 30-45 seconds [17].
- 3. Hip flexion: The patient will be in a standing position. The therapist will attach one end of the band to the patient's ankle and the other end to an anchor behind the patient. The patient will move the leg forward to create hip flexion. The patient will perform the exercise for 15-20 repetitions in a set, for three sets [18].
- 4. Lumbar extension: The patient will sit on the floor with knees straight and one end of the band looped around the feet. Grasp the other end of the band at chest level. Keeping the back straight and upright, lean backward away from the feet without arching the back; hold the position, then slowly return to the starting position. Repeat the exercise for 15-20 repetitions in a set for three sets [19].
- 5. Trunk rotation: Anchor the band at chest height, grasp it with both hands, and step away from the anchor sideways. The patient will extend the arms in front and twist the torso until the arms are straight out to the side (away from the anchor). Reverse the motion and perform on both sides. This motion will be repeated for 15-20 times on each side for three sets [20].

Group-B (Theraband exercises + sham treatment)

Participants in the control group will receive TherBand exercises along with placebo TM spray. Each exercise consists of 15-20 repetitions×three sets, with three sessions per week for eight weeks.

Numeric Pain Rating Scale (NPRS): A widely used tool in clinical settings to quantify a patient's pain intensity. It asks patients to rate their pain on a scale from 0 to 10, with 0 representing "no pain" and 10 the "worst pain imaginable" [21].

Roland Morris Disability Questionnaire (RMDQ): A self-administered instrument used to measure the degree of disability due to low back pain. Higher scores indicate greater disability; the score ranges from 0 to 24 [22].

SF-36: The short form (36) health survey, commonly known as the SF-36, is a 36-item, patient-reported survey designed to measure health status and quality of life. Developed from the medical outcomes study, the SF-36 assesses eight health domains: physical functioning, role limitations due to physical health, bodily pain, general health perceptions, vitality, social functioning, role limitations due to emotional health, and mental health. It provides insights into how patients perceive their overall health and the impact of illness on their daily lives. The SF-36 produces two summary scores: the Physical Component Score (PCS) and the Mental Component Score (MCS), which reflect the physical and mental health dimensions. Widely used in clinical trials, health policy evaluations, and general population surveys, the SF-36 is a valuable tool for comparing the burden of different diseases, assessing the benefit of treatments, and monitoring the health of populations [23].

Serum electrolyte (Magnesium): Magnesium is an essential mineral involved in numerous physiological processes, including muscle and nerve function. Normal serum magnesium levels typically range from 1.7 to 2.2 mg/dL [24].

Data monitoring: An independent researcher will perform all statistical analyses on the datasets. Participants' names will be kept confidential. A treating physiotherapist will monitor the treatment sessions in each group.

Follow-up: The therapist will encourage participants to follow up by phone or email on specific days, with follow-ups conducted after one week.

STATISTICAL ANALYSIS

All data will be analysed using IBM Statistical Package for the Social Sciences (SPSS) Statistics 20 (Chicago, IL). The independent researcher will conduct the analyses and manage the datasets. The Shapiro-Wilk test will be used to assess normality of the data distribution. Based on normality, descriptive statistics will be expressed as mean and Standard Deviation (SD), or Median And Interquartile Range (IQR). Within-group comparisons will use a paired t-test or Wilcoxon signed-rank test. Between-group comparisons will use an independent t-test or Mann-Whitney U test. For all analyses, a p-value ≤0.05 will be considered significant [25].

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