

Efficacy of Mobilisation with Movement and Class IV LASER in Non Diabetic Adults with Adhesive Capsulitis: A Research Protocol

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ABSTRACT

Introduction: Adhesive Capsulitis (AC) is a common idiopathic and self-limiting condition, characterised by painful shoulder stiffness and progressive limitations of both active and passive shoulder motion following rigidity and fibrosis of the joint capsule. Exercise therapy intervention with electrotherapy is performed as part of the conventional and ongoing rehabilitation.

Need of the study: Mobilisation With Movement (MWM) and Class IV Light Amplification by Stimulated Emission of Radiation (LASER) therapy are commonly used physiotherapy interventions, but comparative evidence on their effects on Pressure Pain Threshold (PPT), disability, and quality of life is lacking. Evaluating PPT offers an objective assessment of pain sensitivity, disability, and quality of life, which reflect functional outcomes.

Aim: The proposed study aims to evaluate the comparative effect of MWM and Class IV LASER therapy among patients with AC on reducing pain, decreasing disability, and improving quality of life.

Materials and Methods: The present study is a three-arm randomised clinical trial that will be conducted at Physiogenix Rehabilitation, Jyoti Hospital, Gurugram, Haryana, India, from February 2025 to February 2026. Total 84 individuals (male and female), between 45-75 years, will be recruited based on the designed inclusion and exclusion criteria. Patients will be randomly allocated into three groups. Group A will receive MWM along with conventional physiotherapy, Group B will receive Class IV LASER Therapy along with conventional physiotherapy, and Group C will receive only Conventional Physiotherapy. All three groups will receive the intervention for five times a week for four weeks. Primary outcome measure to be used will be the Numeric Pain Rating Scale (NPRS) for assessment of pain, and the secondary outcome measure will be Shoulder Pain and Disability Index (SPADI), Range of Motion (ROM) and PPT. Analysis of Variance (ANOVA) test will be used for the between-group comparisons, and a p-value <0.05 will be considered significant.

Keywords: Exercise therapy, Joint capsule, Light amplification by stimulated emission of radiation, Quality of life, Range of motion

INTRODUCTION

The AC is an idiopathic, painful, and disabling disorder that leads to restricted range and pain in and around the shoulder joint. AC is also known as frozen shoulder, which is a fibrosing and inflammatory condition characterised by progressive pain and a decrease in volume of the glenoid capsule [1]. The incidence ranges from 2-5% in the general population, whereas 20% in people with diabetes and the incidence is higher in males than in females [2]. The AC is classified into two major categories, primary or secondary, when its aetiology is unknown. Secondary AC can result from conditions such as upper extremity fractures, cardiopulmonary disorders, diabetes mellitus, stroke, neurological disorders, biceps tendinitis, acromioclavicular joint arthritis, rotator cuff pathologies, and calcific tendinitis, among others [3].

According to Neviaser AS and Hannafin JA, AC is divided into four overlapping but distinct clinical stages, beginning with shoulder pain and limited movement. In Stage 1, symptoms last from zero to three months. Patients experience pain during both the active and passive ROM. The underlying pathology includes hypertrophic and hypervascular synovitis, while the joint capsule remains relatively normal. In Stage 2, symptoms persist for three to nine months, characterised by chronic pain that worsens with movement. During this stage, the pathology is characterised by synovial hypervascularity and the formation of scar tissue within the capsule. Stage 3 typically lasts from nine to 15 months and is associated

with minimal pain but a restricted ROM. The joint capsule becomes thickened and fibrotic, resulting in a reduction in articular volume. Finally, Stage 4 spans approximately 15 to 24 months, during which patients experience minimal pain along with gradual improvement in ROM. This phase involves capsular remodelling, which may take six months or longer to complete [4].

There are various surgical and non surgical approaches to treat AC. Among them, surgical approaches include manipulation under anaesthesia, arthroscopic capsular release and synovectomy, and this surgical intervention can lead to several complications such as glenoid and labral injuries, neuropraxia, fractures, rotator cuff pathology, etc., Non surgical interventions include pharmacological treatments and intra-articular injections, while non pharmacological approaches comprise physical therapies such as Class IV laser therapy, transcutaneous electrical nerve stimulation, and therapeutic ultrasound [5]. Among non surgical approaches, Class IV laser therapy is a non invasive modality with deeper penetration into muscles and joints, used to promote healing, relieve pain, and reduce inflammation. Also, known as High-Intensity Laser Therapy (HILT), it delivers greater power output compared to conventional low-level lasers. Through the mechanism of photobiomodulation, it has been shown to decrease inflammation, alleviate pain, enhance microcirculation, and facilitate tissue healing. Consequently, it creates a favourable environment for rehabilitation, enabling patients to participate more effectively in exercise and fitness programs [6,7].

Various exercise therapy programmes have been described in the literature for the management of AC. These include active-assisted ROM exercises, passive stretching, and Codman's pendular exercises. In addition, MWM is a technique used to address joint dysfunction, reduce pain, and improve ROM. In this approach, the therapist applies a mobilisation at the peripheral joint while the patient actively performs the physiological movement [8]. Manual therapy is employed to alleviate joint stiffness and restriction of movement in AC. Of these, MWM is gaining popularity because of its focus on combining a sustained manual glide with active, pain-free movement. This method can correct minor joint posture errors and reestablish normal arthrokinematics, decreasing discomfort. MWM is considered particularly beneficial, as it encourages active patient participation and facilitates rapid functional improvement without increasing discomfort [9].

Therefore, understanding the effectiveness of commonly used physiotherapy interventions such as MWM and Class IV laser therapy is essential. By analysing their impact on pain threshold, disability, and health-related quality of life, this study aims to generate evidence that can inform and guide physiotherapy practice. This research provides the basis for the present research and highlights the clinical significance of a more comparative, experimental treatment for AC.

Primary objectives:

1. To evaluate the effect of MWM on PPT and quality of life in non diabetic adults with AC.
2. To evaluate the effect Class IV LASER Therapy on PPT and quality of life in non diabetic adults with AC.

Secondary objective:

1. To compare the effect of MWM and Class IV LASER Therapy on PPT and quality of life in non diabetic adults with AC.

Null hypothesis (H_0): MWM and Class IV LASER may have no significant effect in combating pain, increasing ROM, and improving the overall quality of life among non diabetic adults with AC.

Alternate hypothesis (H_1): MWM and Class IV LASER may have a significant effect in combating pain, increasing ROM, and improving the overall quality of life among non diabetic adults with AC.

REVIEW OF LITERATURE

The AC (frozen shoulder) is a disabling and painful condition that is characterised by increasing stiffness of the shoulder as well as a diminished ROM and functional limitations. In clinical practice, it is well recognised that pain and stiffness are interrelated, forming a cycle in which pain limits movement, reduced mobility leads to capsular tightness, and increased stiffness further aggravates pain during exercise. Recent research indicates that structured physiotherapy programmes can improve ROM, reduce pain, and enhance functional performance; however, the effectiveness of specific manual therapy techniques and modality-based interventions requires further investigation [10].

The MWM has gained attention due to its combined neurological and mechanical effects. Among manual therapy techniques, Mulligan-based approaches particularly MWM are increasingly being evaluated for their effectiveness in managing shoulder pain and mobility deficits. Dias D et al., conducted a systematic review examining the effects of MWM on pain, disability, and ROM, and reported that MWM was effective in reducing shoulder pain and improving ROM and functional outcomes [11].

Amjad F et al., conducted a randomised clinical trial comparing MWM to Gong's mobilisation technique. The findings demonstrated improvements in pain, ROM, and functional status, as measured using the SPADI [12]. Similarly, Shahzad A et al., performed a systematic review on various mobilisation techniques, reporting consistent positive outcomes in reducing pain and enhancing mobility. These

findings further highlight the significance of mobilisation within comprehensive physiotherapy management [13].

Another study performed by Sayed El Sawabey MF, et al., evaluated the comparative effect of MWM versus diclofenac phonophoresis and conventional physiotherapy and found that both MWM and diclofenac phonophoresis, along with conventional physiotherapy, were found to be effective in decreasing pain; MWM was found to be superior in improving the shoulder ROM [14].

Atan T et al., conducted a prospective double-blinded, sham-controlled, randomised study to evaluate HILT for AC. This study evaluates the effects of HILT on pain, disability, and quality of life in patients with AC. Thirty-six patients was randomised into three groups: HILT plus therapeutic exercises, sham-laser plus therapeutic exercises, and therapeutic exercises only. All participants completed 25 minutes of supervised shoulder exercises per session. Fifteen sessions of HILT significantly improved pain and quality of life, but did not show greater benefits for disability or function compared to the other groups [1].

Anwer Z et al., evaluated the effect of laser therapy and GD Maitland mobilisation in AC and found that both treatments were effective in reducing pain and improving the shoulder range and function. GD Maitland is more effective than Laser Therapy when measured at 30 days [2].

The combination of manual therapy and exercise remains among the most suggested physiotherapy methods for ailments, primarily because it targets the capsular restriction and aids in the restoration of functional movement.

Thus, the present study aims to evaluate the comparative effect of MWM and Class IV LASER on reducing pain, decreasing disability, and improving quality of life among patients with AC.

MATERIALS AND METHODS

The present study is a three-arm randomised clinical trial that will be conducted at Physiogenix Rehabilitation (Jyoti Hospital), Gurugram, Haryana, India, from February 2025 to February 2026. The ethical clearance is obtained from the Institutional Ethical Committee (IEC) under number SEC/SAHS/PHD/24/06. The trial is registered with Clinical Trials Registry India (CTRI/2025/05/086918). Informed consent will be obtained from participants before treatment, and assurance will be given to the participants that there will be no harmful effects on their health, and their privacy will be protected.

Inclusion criteria:

- 45-75 years;
- Non diabetic adults;
- Unilateral Grade I and Grade II AC;
- Diagnosed with Magnetic Resonance Imaging (MRI);
- Shoulder pain for at least three months;
- Severity of pain is higher than three out of ten on Numeric Pain Rating Scale (NPRS);
- Patients with a restricted range of passive shoulder flexion, abduction, external rotation, and extension of the shoulder to less than 50% of the contralateral shoulder.

Exclusion criteria:

- History of Shoulder Trauma;
- Glenohumeral Osteoarthritis;
- History of recent lungs, breast, or bypass surgery;
- Skin allergy;
- Use of opioid medication.

Sample size calculation:

Formula for sample size: $N = 2(Z_{1-\alpha} + Z_{1-\beta})^2 / 3F^2$

Where,

N =total sample size

k =number of groups (3)

α =Type I error (usually 0.05)

β =Type II error (1 – power)

$Z_{1-\alpha}$ =Z-value for significance level

$Z_{1-\beta}$ =Z-value for desired power

f =Cohen's effect size

$f=0.64$ [14]

$Z_{1-\alpha}=1.96$

$Z_{1-\beta}=1.64$

$\alpha=0.05$

Power=95%

Now Put the values in the formula:

$$n=2 (1.96+1.64)^2/3 \times (0.64)^2$$

$$=2 \times 12.96/1.2288$$

$$=25.92/1.2288$$

$$n=21.09$$

With 30% dropout

$$30\% \text{ of } 21.09=6.327$$

$$\text{By adding } 6.327+21.09=27.417=28 \text{ (samples in each group)}$$

$$28 \times 3=84 \text{ participants}$$

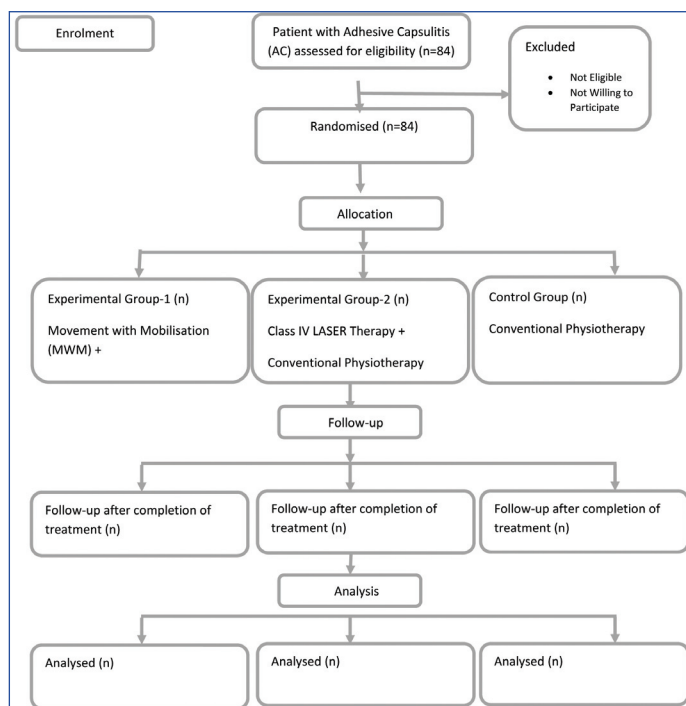
$$\text{Total sample size}=84$$

Eighty-four participants diagnosed with AC will be recruited from the Jyoti Hospital Physiotherapy Outpatient Department (OPD) based on the eligibility criteria. Participants will be randomly assigned to three groups: the MWM group (28 patients), the Class IV LASER Therapy group (28 patients), and the conventional physiotherapy group (28 patients) using convenience sampling. Following enrolment and baseline assessment, participants will be randomly assigned in a 1:1:1 ratio to Group A, Group B, or Group C using block randomization. Allocation will be concealed using Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE), which will be opened only after completion of baseline measurements. The generation of the allocation sequence and the enrollment of participants will be conducted by a staff member who is not involved in the enrollment process or in assigning participants to their groups. The patient will receive a total of twenty treatment sessions, 30-40 minutes per day for four weeks, i.e., five days a week for four weeks. The intervention will be administered by the principal investigator [Table/Fig-1].

Study Procedure

Group A: Mobilisation With Movement (MWM): Group A will receive the MWM technique based on Mulligan's concept of manual therapy. The intervention will be administered in 3-5 sets of 6-10 repetitions [9]. Mid-range mobilisation in the sitting position using postero-lateral glides will be applied for shoulder flexion, abduction, and elevation, while inferior glide MWM will be used to restore internal rotation. For end-range shoulder elevation, inferior glide and supine posterior glide techniques will be applied, and posterior joint mobilisation will be used to improve external rotation [15]. In addition, participants will receive conventional physiotherapy. Treatment will be provided five times per week for a duration of four weeks, with assessments conducted before and after the intervention.

Group B: Class IV LASER therapy: Group B will receive the Class IV LASER with continuous mode at a power output of 8 W, 808 nm and energy dosage of 48.0 J/cm² along with a total energy of 4800 J. The patient will be in a supine position with the shoulder joint relaxed. Marks were made on the skin on the four different aspects of the shoulder at the tender, painful arc. In this contact method, the



[Table/Fig-1]: CONSORT flow chart of study protocol.

position of the beam will lie directly over the marked points on the shoulder joint [2]. They will also receive conventional physiotherapy as described above for five days a week for four weeks. Pre- and post-treatment assessments will also be taken.

Group C: Conventional therapy: Group C will receive conventional physiotherapy. Gentle progressive stretching exercise till the limit of pain will be applied for 30 seconds, in the directions of shoulder flexion, external rotation, and internal rotation. Each movement will be held for 30 seconds, followed by 15 seconds of relaxation. Shoulder mobilisation exercises aimed at improving ROM, such as the shoulder wheel, wall climbing (finger ladder), and Codman's pendular exercises, will be performed for five repetitions in three sets, with a 3-minute rest interval between sets. A moist heat pack will also be applied for 20 minutes. The above treatment protocol will be administered five times per week for four weeks [16].

Study Outcomes

Primary outcomes:

NPRS: The NPRS is a reliable and valid tool. Its reliability is 0.95. It is used to assess the intensity of the pain. In this, the patient will be asked to mark a number between 0-10, where 0 indicates no pain, 1-3 indicates mild pain, 4-6 indicates moderate pain, and 7-10 indicates severe pain. The MCID value for the NPRS is 2 [17].

Secondary outcomes:

1) SPADI: The SPADI is a self-administered questionnaire used to assess two primary domains: pain and functional ability. The pain subscale consists of five items that evaluate the severity of pain, and the functional subscale includes eight items that measure the level of difficulty experienced during daily activities involving the upper extremities. The questionnaire typically takes 5-10 minutes to complete and is widely recognised as a reliable and valid tool for the assessment of shoulder-related conditions [18].

2) ROM: The ROM of the shoulder joint- flexion, abduction, external rotation, and internal rotation- will be assessed in both active and passive modes using a goniometer in the supine position. The goniometer (SG Medical) will be calibrated by aligning its arms to 0° on a flat surface and verifying its accuracy against a known angle (e.g., 90°), ensuring that any deviation remains within ±1-2°.

3) PPT: The PPT will be assessed using an algometer on various muscles in the shoulder, specifically the levator scapulae, subscapularis, and pectoralis minor. These three muscles will be

evaluated on the affected side of the body in patients with AC. The algometer (Biotronix Solution Forever, Delhi, India; Model: Digital Dolorimeter Algometer) will be positioned with the probe against the muscle belly, and pressure will be applied at a rate of 30 kPa per second [19].

The outcome measures will be assessed at baseline and at the last day of the treatment.

STATISTICAL ANALYSIS

Statistical analyses will be conducted using version 20 of the statistical software (Statistical Package for the Social Sciences (SPSS) Inc., Chicago, IL). The normality of the collected data will be assessed using the Shapiro-Wilk test. A between-group comparison will be done by using ANOVA. If the data is not normally distributed, then the Kruskal-Wallis Test will be used. Depending on the results of this test, descriptive statistics will be presented either as mean \pm Standard Deviation (SD) or as median with interquartile range. A significance level of $p < 0.05$ will be used for all analyses and will be considered statistically significant.

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