

# Effectiveness of a simple and graded Home Exercise Programme on pain, functional abilities and Quality of Life among adults with Chronic Non-specific Low Back Pain in Rural Community – A Study Protocol

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## ABSTRACT:

### Background:

Chronic Non-specific Low Back Pain (CNLBP) is a leading cause of disability and sickness absenteeism among the working population. The individuals suffering from CNLBP have difficulty in attending Physiotherapy regularly in rural areas could overcome by a Home Exercise Programme (HEP). However, evidence for effectiveness of HEP is inconclusive, and the complexity and burden of exercises were found to be important barriers related to adherence to HEP. This study aims to find out the effectiveness of a simple and graded HEP on CNLBP.

### Methods:

A prospective controlled trial with 140 CNLBP patients will be conducted. The participants will be allocated to either HEP or conventional physiotherapy based on the participant's preference. The participants in the HEP will perform six exercises each day, for five days in a week, for six weeks. The participants in conventional physiotherapy will perform flexibility and strengthening exercises for low back for the same duration. Assessment will be done at the baseline, at the end of III and VI weeks. The outcome measures are pain intensity (Numeric Pain Rating Scale), functional abilities (Patient-Specific Functional Scale), Quality of Life (WHOQOL-BREF) and adherence to HEP. Within the group analysis will be done by Kruskal Wallis ANOVA test and between-group analysis by Friedman's two-way ANOVA.

### Discussion:

This article describes the protocol of a controlled trial to find out the effectiveness of a simple and graded HEP in treating CNLBP. The result of this study will provide an alternative and possibly cost-effective method of management for adults with CNLBP.

**Key Words:**

Quality of Life, Functional Abilities, Chronic Non-specific Low Back Pain, Home Exercise Programme.

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**1. Introduction:**

Low Back Pain (LBP) is a major global public health burden and it remains the leading cause of Years Lived with Disability (YLD) worldwide (GBD, 2018). The number of prevalent cases increased with age and peaked at 45–54 years for both sexes. (Chen S *et al.*, 2021). The pooled point, annual and lifetime prevalence of LBP in India was 48%, 51% and 66% respectively. Moreover, the pooled prevalence rates were highest among females, rural population, and elementary workers. (Shetty GM *et al.*, 2022). LBP can seriously affect the quality of life when compared with other chronic diseases or disorders (Maher C *et al.*, 2017). About 90% of LBP cases are presenting as non-specific LBP, and it is associated often with work productivity loss (WHO, 2023) and this could be due to sickness absenteeism (Kuijer, W. *et al.*, 2006, Macías-Toronjo I *et al.*, 2020).

Exercise has a positive impact on managing chronic LBP. Exercise therapy reduces pain and improves function in people with Chronic Non-specific Low Back Pain (CNLBP) if it entails specially created programmes, such as stretching or strengthening, and administered under supervision. Long-term supervised combined exercise and motivational program had significant improvements in disability, pain intensity, and working ability (Twomey L, *et al.*, 1995, Friedrich M *et al.*, 2005, Hayden JA *et al.*, 2005). Individuals with CNLBP have difficulty in attending Physiotherapy clinics regularly, for time-consuming sessions and prolonged treatment period, though it plays an important role in the treatment of CNLBP. This difficulty could be overcome by a Home Exercise Programme (HEP). However, evidence for effectiveness of HEP is inconclusive (Quentin *et al.*, 2021) and it has been found that the complexity and burden of exercises was found to be important barriers related to adherence of HEP (Palazzo C, *et al.*, 2016). Hence, a simple and graded exercise programme was developed for individuals with CNLBP.

The aim of this article is to introduce a study protocol to evaluate the effect of a simple and graded Home Exercise Programme (HEP) on Pain intensity, Functional Abilities, and Quality of Life among adults with CNLBP.

**2. Methods and design:****2.1 Study Design:**

This study is a two arm, prospective, non-randomized controlled trial of patients with CNLBP and will be conducted in the rural community setting of Puducherry Union Territory, India.

**2.2 Sample selection:**

LBP patients attending the Physiotherapy department of the selected Community Health Centres and Primary Health Centres of the rural areas of Puducherry. They will be evaluated thoroughly by complete medical examination, physical assessment and laboratory investigations to rule out the definite pathological causes of low back pain and confirm the diagnosis of CNLBP. Screened patients who fulfil the inclusion criteria will be explained about

the study procedures verbally, in addition to the printed information sheets, and who give consent will be recruited by convenient sampling method.

### **2.3 Selection Criteria:**

Inclusion Criteria: 1) Male and female adults, aged between 25 and 55 years, residing in rural areas with persistent low back pain for about 12 weeks and less than 1 year duration, 2) Back Pain localised anywhere between the costal margin and the gluteal folds with no radiating pain, and able to perform the Activities of Daily Living (ADL) and occupational activities with the pain intensity ranging between 4 and 7 in the Numeric Pain Rating Scale in the last 2 weeks, 3) 25 cms. or greater in the *Functional Reach Test* among the study population.

Exclusion Criteria: 1) Red Flag symptoms including, a history of major trauma/ potential spinal fracture, inflammatory disease, infection, malignancy, persistent night pain, bladder or bowel dysfunction, and/or lower extremity neurological deficit, 2) Previous history of surgery to the lumbar spine, abdomen, pelvis or hip, 3) Congenital malformations like Severe spinal stenosis, and cauda equina syndrome, 4) Acquired ailments like spondylolisthesis, spinal nerve root compression, Sacro-iliac pathology and fibromyalgia, 5) Therapeutic radiological interventions or injections in the past 3 months, 6) Any contraindication for exercise therapy (e.g. uncontrolled hypertension, previous myocardial infarction, cardiovascular disease, peripheral vascular disease, respiratory disorders), 7) Study participants unable to perform isometric contraction and hold it for 30 seconds while testing, 8) Pregnancy.

### **2.4 Group Allocation of participants:**

Baseline assessment will be taken for the enrolled participants and will be allocated into control and experimental group based on preference of the participants.

### **2.5 Intervention:**

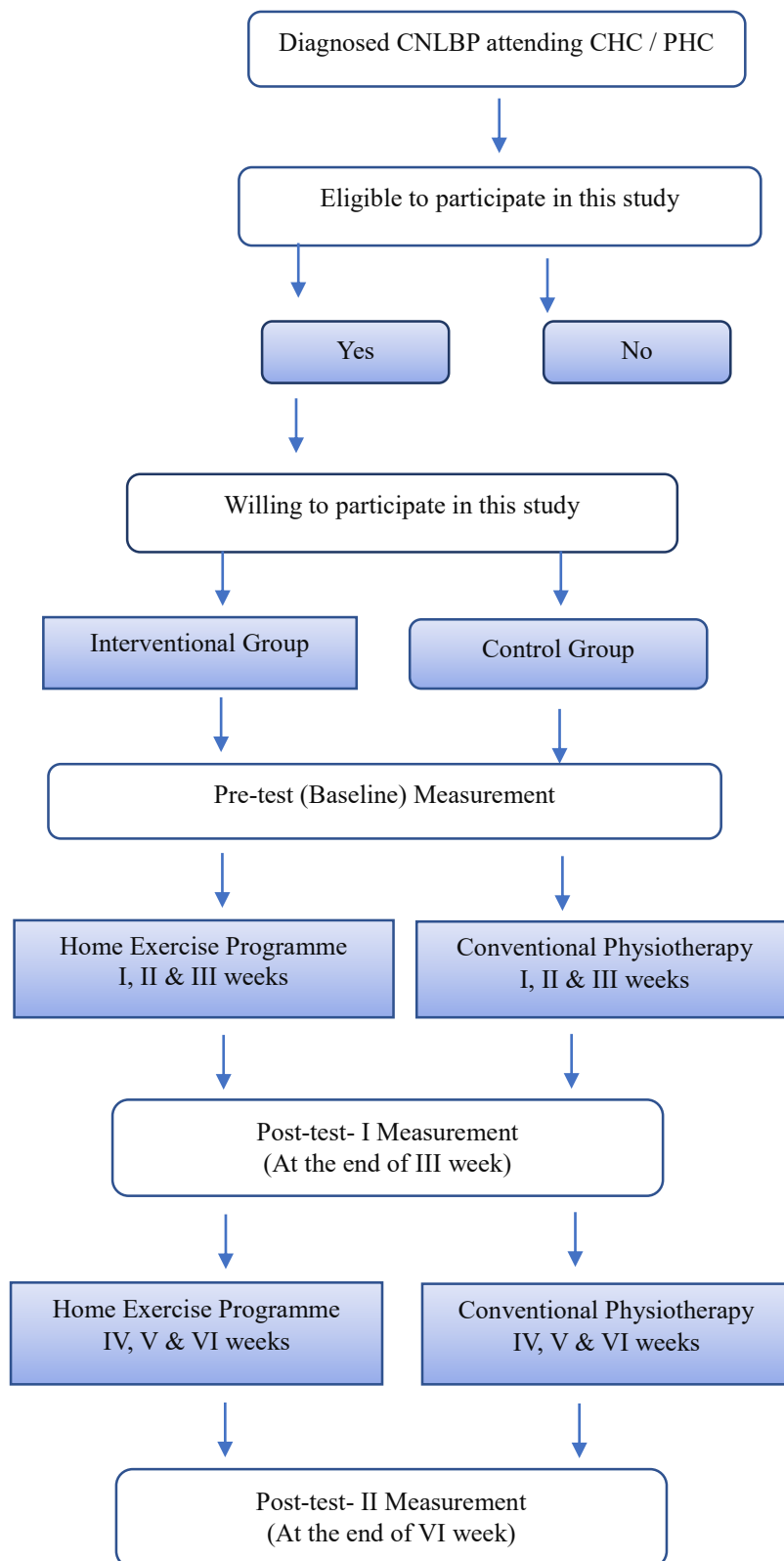
As the aim of this study is to compare the effect of Home Exercise Programme developed by the principal investigator with conventional physiotherapy for chronic low back pain, each one of the selected participants will receive anyone of the above intervention strategy only.

2.5.1 Control Group: Participants in the control group were given short wave diathermy for pain reduction, followed by that, were undergone spinal extensor & flexor muscles strengthening exercises and spinal extensors flexibility exercises. Each exercise was practiced for 10 times with the rest period of 2 to 3 minutes in between the exercise, under the supervision of a Physiotherapist, 5 days a week, for 6 weeks.

2.5.2 Experimental Group: Participants in the experimental group will be instructed to carry out the home exercise protocol developed for this study. These exercises are developed to improve the spinal and pelvic mobility and flexibility of muscles around this region, strength of the spinal muscles and core stability. The participants in the HEP will perform six exercises each day, for five days in a week, for six weeks.

Each participant will be given the week-wise exercise chart, one after the other for the respective weeks, as they complete. To improve the flexibility, self-stretching exercises for the spinal extensors and side flexors, hip flexors and extensors, hip adductors and rotators will be done by the participants. Each muscle group will be stretched 10 times with the hold time of 15 to 20 seconds. Each mobility exercise for the spinal column and the pelvis will be repeated 10 times. The core stability exercises and the strengthening exercises for the abdominals, spinal extensors and rotators, hip flexors and extensors will be done for 10 times, with hold time of 5 to 10 seconds for the isometric exercises.







**Fig.1 Consort Flowchart of the study participants.**




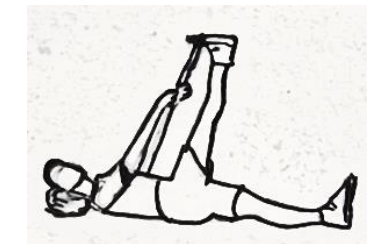

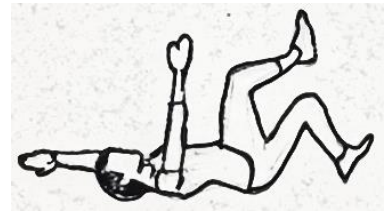


**HOME EXERCISE PROGRAMME FOR CHRONIC NON-SPECIFIC LOW BACK PAIN**

[ 6 Exercises x 10 repetitions each x 5 sessions/week x 6 weeks]

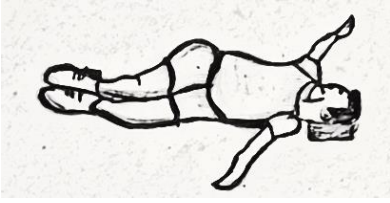
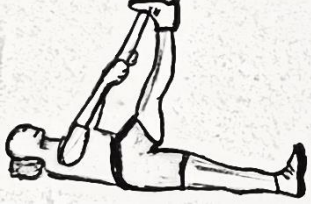




**Home Exercise Programme: I - WEEK**

No.	Exercise	Instructions
1.1		<p><b>Hamstring stretch:</b> Lying on the floor, place your left thigh perpendicular to the ground (at about 90°) against the wall and straighten the knee. Hold it for 15 secs. and return back. Repeat the same with the right limb.</p>
1.2		<p><b>Pelvic Tilt:</b> Lying on the floor, with a folded towel under the pelvis, pull the navel towards the spine by flattening the back, tightening stomach and buttock muscles, hold for 5 secs and relax.</p>
1.3		<p><b>Clam Shell:</b> Lying on the left side, lift the knee up and down without twisting the body, and not moving the foot. Repeat the same on right side.</p>
1.4		<p><b>Cat and Camel:</b> In quadruped position, make a hump by arching the back up. Hold for 5 seconds and then slowly lower the back into a sagging position. Hold for 5 seconds and relax.</p>
1.5		<p><b>Cobra:</b> Lying on the abdomen with hips and legs relaxed, lift your head and upper chest up, resting on the forearm, elbows close to the body. Hold it for 10 Seconds. Return back to flat lying and relax.</p>
1.6		<p><b>Seated side bending:</b> Sitting on a chair, with hands at the sides, gently bend on the left side with the left fingers reaching the ground. Return back to the starting position. Repeat on the same on right side.</p>







**Home Exercise Programme: II - WEEK**

No.	Exercise	Instructions
2.1		<p><b>Knee to Chest:</b> Lying on the floor, bring left knee in to the chest and hug it by wrapping the hands over the leg. Hold it for 15 seconds and back to the position. Repeat on the same on right side.</p>
2.2		<p><b>Hamstring stretch with strap:</b> Lying on the floor, bring the left thigh to about 90°. Using a strap over the foot straighten the knee. Hold it for 15 seconds and bring the limb down, relax. Repeat the same on right side.</p>
2.3		<p><b>Pelvic Bridging:</b> Lying on the back with knees bent at 90°, feet flat on floor, lift the hips off the floor, hold for 10 seconds, and drop. Relax for 10 seconds and repeat the same.</p>
2.4		<p><b>Inverted Bug:</b> Lying on the back with hips and knees bent (like tabletop position), arms to a position in front of thigh, lower right leg to ground simultaneously extend left arm back over the head. Repeat the same with left leg and right arm.</p>
2.5		<p><b>Piriformis Stretch:</b> Lying on the back, with left ankle crossed over the right knee, press gently the left knee with the hand. Hold for 15 seconds. Repeat the same with right ankle over the left knee.</p>
2.6		<p><b>Quadriceps Stretch:</b> Lying on the stomach, pull the left ankle of the flexed leg towards the hip and hold it for 15 seconds. Relax down. Repeat the same with the right side.</p>

### Home Exercise Programme: III - WEEK

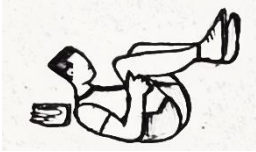
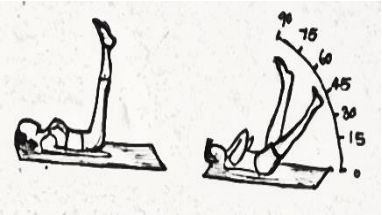



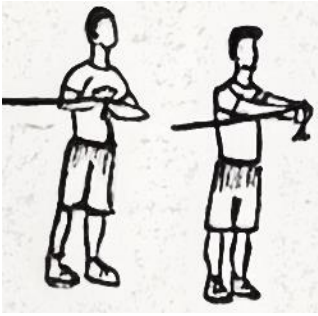
No.	Exercise	Instructions
3.1		<p><b>Upper Trunk Rotation:</b> Lying on the left side with both hips and knees bent to 90° and arms together, take away the right arm off the shoulder with trunk rotation to create “T” shape with arms and shoulder. Return back. Repeat the same on right side.</p>
3.2		<p><b>Hamstring stretch with strap:</b> Lying on the floor, bring the left thigh to about 90°. Using a strap over the foot straighten the knee. Hold it for 20 seconds and bring the limb down, relax. Repeat the same on right side.</p>
3.3		<p><b>Thigh Wide Stretch:</b> Sitting on the floor with legs apart in V shape, spread the legs as wide as possible, keeping the chest high and lean forward with the hands over the knees. Hold it for 15 seconds and relax.</p>
3.4		<p><b>Boat:</b> Lying on the abdomen, pull both the legs of flexed knees towards the spine by holding the feet and lift both the thighs together. Hold for 15 seconds. Relax back to lying.</p>
3.5		<p><b>Cross Leg Stretch:</b> Sitting on the chair, with right ankle crossed over the left knee, sit up tall and press the right knee gently downwards. Hold it for 15 seconds and relax. Repeat the same with the left ankle over the right knee.</p>
3.6		<p><b>Quadriceps Stretch with wall support:</b> Standing up with the right hand supporting on the wall, bring the left foot towards the hip, grasp it with the hand and gently push the thigh backwards, without bending the trunk, until the stretch is felt over the front thigh. Hold it for 15 seconds. Repeat the same with right leg.</p>

**Home Exercise Programme: IV - WEEK**

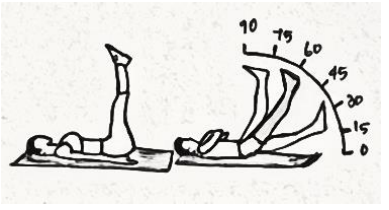

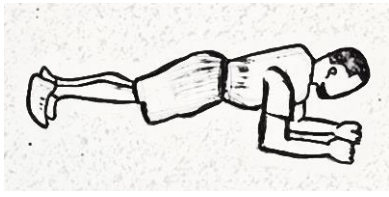
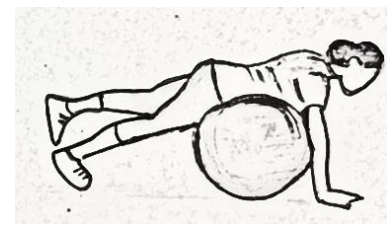
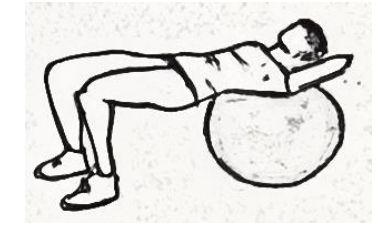
No.	Exercise	Instructions
4.1		<p><b>Both Knees to Chest:</b> Lying on the back, lift the head and bring both the knees in to the chest. Hold it for 5 seconds and relax.</p>
4.2		<p><b>Both Legs Raise:</b> Lying on the floor, lift both the legs up with knee straight, feet facing the ceiling. Hold it for 10 seconds and bring down.</p>
4.3		<p><b>Opposite Shoulder Tap:</b> In quadruped position, take the right hand and tap the left shoulder, and return back. Repeat it on the left side.</p>
4.4		<p><b>Leg back lift:</b> In quadruped position, lift the left leg straight out behind the body, hold it for 5 seconds and return back. Repeat the same on right side.</p>
4.5		<p><b>Cross leg forward lean stretch:</b> Sitting on the chair, with right ankle crossed over the left knee, sit up tall and press the right knee gently downwards and lean forward. Hold it for 15 seconds and relax. Repeat the same with the left ankle over the right knee.</p>
4.6		<p><b>Quadriceps stretch in standing:</b> Standing up straight, bring the left foot towards the hip, grasp it with the hand and gently push the thigh backwards, without bending the trunk, until the stretch is felt over the front thigh. Hold it for 15 seconds. Repeat the same with right side.</p>

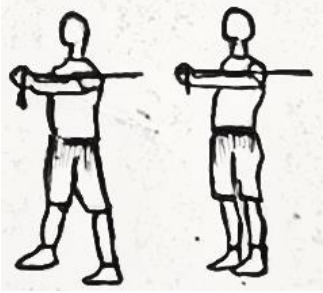


### Home Exercise Programme: V - WEEK

No.	Exercise	Instructions
5.1		<p><b>Both Knees to Chest:</b> Lying on the back, lift the head and upper chest, and bring both the knees in to the chest. Hold it for 10 seconds and relax.</p>
5.2		<p><b>Both Legs Raise:</b> Lying on the floor, lift both the legs up with knees straight, feet facing the ceiling at about 90°. Hold it for 5 seconds and bring down and stop at midway around 45°. Hold it for 5 seconds and then drop down to relax.</p>
5.3		<p><b>Full Plank:</b> Lying on the abdomen, come to “push-up” position (hips and knees are raised) with forearms on the ground, hold for 5 seconds and then relax.</p>
5.4		<p><b>Chicken Wing:</b> In quadruped position, keeping the left hand behind the head, lift the left elbow up and down with trunk rotation. Repeat the same with the right side.</p>
5.5		<p><b>Standing Telescope Arm:</b> Standing up with both arms straight at side, creating a ‘T’. Keeping the right foot behind the left, rotate the trunk towards the left. Return back to the position. Repeat the same with the left foot behind and rotate to the right.</p>
5.6		<p><b>Tube stretch-out:</b> Standing sideways to the elastic tube at a distance with slight resistance on the tube, extend the arms out in front of body from the chest, engaging the core region (abdomen). Hold it for 5 seconds, and relax.</p>

**Home Exercise Programme: VI – WEEK**

No.	Exercise	Instructions
6.1		<p><b>Both Legs Raise:</b> Lying on the floor, lift both the legs up to 90° with knees straight. Hold it for 5 seconds. Bring down and stop at around 60°, hold it for 5 seconds; and further down to 30°, hold for 5 seconds and then drop down to relax.</p>
6.2		<p><b>Crawl Lifts:</b> In quadruped position with hips and knees bent and elbows straight, lift the left arm forward while straighten the right leg backwards. Hold it for 10 seconds and relax. Repeat the same with the right arm and left leg.</p>
6.3		<p><b>Full Plank:</b> Lying on the abdomen, come to “push-up” position (hips and knees are raised) with forearms on the ground, hold for 10 seconds and then relax.</p>
6.4		<p><b>Stability Ball Leg-lift:</b> Lying on the abdomen over the stability ball with the hands and feet on the ground, press the ball with the trunk and then lift the left leg up. Hold it for 5 seconds. Repeat the same with the right leg.</p>
6.5		<p><b>Stability Ball Rolling:</b> Lying on the upper back over the stability ball, with both the hands behind the head and the feet on the ground, roll the ball up and down using the knees and stabilising the trunk.</p>

6.6		<p><b>Tube Walk-out:</b> Stand with the elastic tube tied at the left side, at a distance, to have slight resistance. Stabilising the trunk, keep the elbows straight in front of the chest and take a step right side away from the anchor point. Hold it for 5 seconds and return back and relax. Repeat the same with the tube at right side and step towards left.</p>
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## 2.6 Outcome Measures:

At the baseline, the information of the participants' including age, gender, educational level, occupation (nature of job), body-mass index, time since onset of symptoms, sickness absenteeism in the previous month will be collected.

The primary outcome measures are Pain intensity, functional ability and quality of life and the secondary outcome of this study is adherence to the intervention. Pain will be measured by using Numeric Pain Rating Scale (NPRS), Functional Abilities by the Patient-Specific Functional Scale (PSFS) and the Quality of Life by using the WHOQOL–BREF. The adherence to the exercise will be monitored by a week-wise exercise diary. The participants will be asked to record the details of date and time of exercise performed, ability to do and the number of repetitions for each exercise. The primary and secondary outcome measures will be measured at the baseline, and at the end of III and VI weeks of the intervention period.

**2.6.1 Numeric Pain Rating Scale (NPRS):** This scale is used to quantify the pain intensity in adults on a 11-point ordinal scale ranging from 0 to 10, higher the score severe the intensity of pain. This is highly correlated with Visual analogue Scale with correlation co-efficient ranges between 0.86 to 0.95 and the test-retest reliability co-efficient is 0.95. A reduction of 1.5 points on the NPRS score during 4 weeks follow-up is reported as Minimal Clinically Important Difference (Childs, JD, *et al.*, 2005).

**2.6.2 Patient-Specific Functional Scale (PSFS):** This scale is used to measure the functional outcome and to quantify the activity limitation for patients with orthopedic conditions, including CNLBP. In this, the inability or the difficulty in performing the important activities, identified by the patients, due to the low back pain are subjectively quantified by the patients on a 11-point ordinal scale ranging from 0 to 10. The intra-class correlation co-efficient is 0.82, and the Minimal Detectable Change is 2.8 (Mathis, RA, *et al.*, 2019).

**2.6.3 WHOQOL-BREF:** This scale consisting of 26 questions, in which 2 are about general quality of life (QOL) and general health and the remaining 24 covering the 4 domains, namely, physical health, psychological health, social relations and environmental health. The internal consistency is high and Cronbach's alpha co-efficient is 0.896. (Ilić, I, *et al.*, 2019). Higher the total score indicates better QOL.

## 2.7 Sample Size Estimation:

Based on the findings of Muhammad Arca *et al.*, (2020) on pain reduction by Physiotherapist prescribed home exercise program, to observe a difference of 1.06 on pain intensity measured by VAS between the groups, with the power of 80% and alpha error of 5%, 62 participants are required in each group.

Accounting for the non-response rate and loss to follow-up 70 participants per group will be recruited. The sample size was calculated using Open Epi, Version 3, open-source calculator-SSMEAN.

### **2.8 Statistical Analysis:**

All the data will be analyzed using - Descriptive statistics will be used to describe the characteristics of the study sample, and will be summarized based on the demographic variables. Since the primary and secondary outcome variables of this study are non-parametric, the Shapiro-Wilk test will be carried out to test the normality of the data. If the data are normally distributed, within the group analysis will be done by one-way ANOVA and between the group analysis by two-way ANOVA. Otherwise, equivalent non-parametric Kruskal Wallis ANOVA test and Friedman's two-way ANOVA will be used respectively. Two-sided test will be carried out with the 'level of significance' of 0.05.

### **3. Discussion:**

A recent meta-analysis conducted to find the effect of Home Exercise Training in patients with non-specific low back pain reported that Home-based Exercise training is equally effective in reducing pain and decreasing the functional limitation on comparing with the training given at other settings. However, Palazzo *et al.*, (2016) conducted a study to find out the barriers to adherence for home-based exercise program among patients with chronic low back pain and found that the number, effectiveness, complexity and burden of exercises are the factors related to exercises affecting the adherence. Hence, the aim of this home exercise programme is to overcome these factors and improve the adherence. This protocol is developed with simple and graded exercises to target the musculoskeletal factors contributing to chronic non-specific low back pain.

The aim of this study is to present a protocol of a controlled trial to compare the effectiveness of the simple and graded home-based exercise programme with the conventional physiotherapy intervention. This study will investigate the effectiveness of this 6-week home exercise programme on pain intensity, functional abilities and quality of life of those individuals. This home exercise programme is assumed to be superior in increasing the adherence, thereby, will improve the above outcome components. The result of this study could give an affordable, accessible and sustainable exercise intervention for adults with chronic non-specific low back pain. The result of this study also will contribute to an evidence-based home exercise programme for the clinical practice.

### **Authors' contribution**

TMDJ, VS and AG conceived the initial idea of the study. All authors contributed in developing the study design and TM and VS developed the exercise programme. TM wrote the first draft and coordinated the write-up of the article. All authors critically reviewed the manuscript, and approved the article.

**ORCID iD: (TM)** 0009-0008-9524-4919.

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## Conflict of Interest:

None declared.

## Ethical approval:

The study was approved by the Institute Ethics Committee (Human Studies) of Indira Gandhi Medical College and Research Institute, Government of Puducherry Institution (No.425/IEC-35/IGMC&RI/PP-30/2022, and registered in the Clinical Trials Registry-India, Indian Council of Medical Research (ICMR)- National Institute of Medical Statistics (No. CTRI/2022/10/046841).

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