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Optimizing therapeutic exercise for shoulder overuse syndrome: effects on edema reduction, range of motion, and pain relief using data-driven approaches

Submission date
31/08/2025

Recruitment status
No longer recruiting

Registration date
18/09/2025

Overall study status
Completed

Last Edited
12/09/2025

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Shoulder pain is a common problem in older adults, affecting their ability to perform daily tasks like lifting, reaching, and carrying. This study will provide valuable information about whether exercise therapy is more effective than standard physiotherapy in improving both pain and function in elderly patients. Understanding the impact of these interventions will help to find better treatments that can help older adults live more comfortably. This study aims to investigate the effects of exercise therapy on pain reduction, shoulder range of motion, and pectoralis minor muscle length in elderly patients with chronic shoulder pain. Participants will be assessed for their pain levels, shoulder mobility, and muscle length at the beginning of the study and after completing the 6-week treatment program.

Who can participate?
The study involves elderly patients (aged 60 and above) who have chronic shoulder pain (lasting for at least 3 months).

What does the study involve?
The study compares two treatments:
Exercise therapy: A structured program of stretching and strengthening exercises designed to improve shoulder movement and reduce pain.
Physiotherapy (Placebo): A common physiotherapy treatment using methods like infrared therapy, ultrasound, and TENS (transcutaneous electrical nerve stimulation), but without the specific therapeutic exercises targeted at improving shoulder function.

Participants will be randomly assigned to one of two groups: one group will receive exercise therapy and the other will receive physiotherapy (placebo). Both groups will receive treatments for 18 sessions over the course of 6 weeks. Pain reduction will be measured using the Visual Analog Scale (VAS), a simple scale where patients rate their pain from 0 (no pain) to 10 (worst possible pain). Shoulder mobility will be assessed through measuring the range of motion in

shoulder abduction and external rotation. Pectoralis minor muscle length will be measured using ultrasound to evaluate any changes in muscle flexibility.

At the end of the 6 weeks, participants will be reassessed, and their improvements in pain levels, shoulder movement, and muscle flexibility will be compared between the two groups. This will allow us to determine whether exercise therapy offers significant benefits over traditional physiotherapy.

What are the possible benefits and risks of participating?
The results of this study could potentially lead to improved treatment protocols for elderly patients suffering from chronic shoulder pain, helping them to regain mobility and reduce pain more effectively.

The risks involve temporary muscle soreness or discomfort following exercise sessions, and a potential for minor musculoskeletal strain if exercises are performed incorrectly.

All interventions were supervised by qualified professionals to ensure safety and correct technique.

Where is the study run from?
Tri-Chandra Multiple Campus, Tribhuvan University, Nepal

When is the study starting and how long is it expected to run for?
May 2025 to July 2025

Who is funding the study?
Ultimate Medical Technology Co., China

Who is the main contact?
Dr Bhishma Karki, bhishma.karki@trc.tu.edu.np

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Effects of exercise therapy on pain reduction, range of motion, and pectoralis minor muscle length in elderly patients with shoulder pain: A randomized controlled trial comparing exercise therapy to a placebo intervention

Acronym
E-PRIME

Study objectives
Primary Objective:
To assess the effects of exercise therapy (stretching and strengthening exercises) on pain reduction, range of motion (ROM), and pectoralis minor muscle length in elderly patients with chronic shoulder pain.

Secondary Objectives:
To compare the effectiveness of exercise therapy with a placebo intervention on reducing shoulder pain intensity (measured by the Visual Analog Scale).

To evaluate the improvement in range of motion (abduction and external rotation) in patients undergoing exercise therapy versus those receiving a placebo.

To examine the changes in pectoralis minor muscle length after a period of exercise therapy compared to placebo treatment.

Ethics approval required
Ethics approval not required

Ethics approval(s)
An Ethical Review Waiver on 25/05/2025 confirms that the Institutional Ethics Committee of Tribhuvan University reviewed the study and determined that it did not require formal ethical approval under the university’s guidelines.

Study design
Single-blind parallel-group randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Chronic shoulder pain in elderly patients

Interventions
This study is a single-blind, parallel-group, randomized controlled trial (RCT) conducted at a tertiary care rehabilitation center. Randomization was achieved using a computer-generated sequence, with block randomization (block size of 4) to ensure balanced allocation between two groups. Participants were randomly assigned in a 1:1 ratio to one of two intervention arms:

Exercise Therapy (ET): A structured program involving stretching and strengthening exercises aimed at improving shoulder mobility, reducing pain, and enhancing muscle length. The program includes exercises targeting the scapular stabilization and shoulder strengthening.

Physiotherapy (Placebo): A control intervention consisting of standard physiotherapy modalities including infrared therapy, ultrasound therapy, and transcutaneous electrical nerve stimulation (TENS), with no active therapeutic benefit to the shoulder's functional capacity.

Both groups received their allocated intervention for 18 sessions across the 6-week period, with all sessions supervised. There were no changes to the trial design after commencement, and the study followed the pre-defined methods throughout.

Outcomes were assessed at baseline and post-intervention (immediately after the 6-week program). The single-blind aspect refers to the outcome assessment, where the evaluator measuring outcomes was blinded to group allocation. Participants were also unaware of the existence of the other treatment arm to minimize bias.

Intervention Type
Mixed

Primary outcome(s)
Pain reduction as measured by the Visual Analog Scale (VAS) for shoulder pain intensity at baseline and post-intervention (immediately after the 6-week program)

Key secondary outcome(s))
The secondary outcome measures were assessed at baseline and post-intervention (immediately after the 6-week program):
1. Range of Motion (ROM): Improvement in shoulder abduction and external rotation range of motion, measured using a goniometer
2. Pectoralis Minor Muscle Length: Changes in the pectoralis minor muscle length, measured using ultrasound or muscle length measurement techniques

Completion date
16/06/2023

Eligibility

Key inclusion criteria

1. Age: Participants aged 60 years or older.
2. Chronic Shoulder Pain: Participants with chronic shoulder pain lasting at least 3 months.
3. Diagnosis: Participants with a diagnosis of shoulder impingement syndrome, rotator cuff tendinopathy, or other musculoskeletal disorders causing shoulder pain.
4. Range of Motion: Participants with limited shoulder range of motion (abduction or external rotation).
5. Pain Level: Participants with a Visual Analog Scale (VAS) pain score of at least 4 (moderate pain) at baseline.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
60 years

Sex
All

Total final enrolment
66

Key exclusion criteria
1. Acute Shoulder Injury: Participants with recent shoulder injuries (less than 3 months) or acute trauma to the shoulder.
2. Surgical History: Participants who have had shoulder surgery in the past 6 months.
3. Severe Shoulder Dysfunction: Participants with severe loss of shoulder function or contraindications to physical activity.
4. Other Medical Conditions: Participants with neurological, cardiovascular, or musculoskeletal conditions that affect the shoulder or prevent participation in the intervention.
5. Pregnancy: Female participants who are pregnant or planning to become pregnant during the study period.
6. Uncontrolled Health Conditions: Participants with uncontrolled diabetes, rheumatoid arthritis, or any other systemic illness that could interfere with participation.
7. Non-compliance: Participants who are unable or unwilling to comply with the study protocol or follow-up visits.

Date of first enrolment
15/01/2023

Date of final enrolment
05/05/2023

Locations

Countries of recruitment
Nepal

Study participating centre
Tribhuvan University Teaching Hospital
Maharajgunj
Kathmandu, Bagmati Pradesh
Nepal
44613

Sponsor information

Organisation
Ultimate Medical Technology Co

Funder(s)

Funder type
Industry

Funder Name
Ultimate Medical Technology Co

Results and Publications

Individual participant data (IPD) sharing plan
This study is committed to making the individual participant data (IPD) available to the research community to promote transparency and allow for further analysis.

1. Data Storage and Repository:
The datasets generated during this study will be stored in a publicly available repository such as: Open Science Framework (OSF) or Zenodo, ensuring the data is accessible to researchers globally.
Link to be provided after study publication.

2. Type of Data to be Shared:
The following data will be shared:
Demographic information (age, gender, etc.)

Pain scores (measured by the Visual Analog Scale, VAS)
Range of motion measurements (abduction and external rotation)
Pectoralis minor muscle length measurements (using ultrasound)

3. Data Availability Timeline:
The IPD will be made publicly available 12 months after the study's publication.
The data will be stored in a publicly accessible repository (OSF/Zenodo), and links to the data will be shared in the publication's supplementary materials.

4. Access Criteria:
The data will be available to researchers upon request for non-commercial academic research purposes only.
Requests for data will be submitted via a formal contact (e.g., study PI or designated team member) and will require a research proposal that meets ethical and scientific criteria.
Contact for Data Requests: Dr Bhishma Karki, bhishma.karki@trc.tu.edu.np

5. Mechanism of Data Sharing:
Data will be shared via a secure online repository (e.g., OSF or Zenodo) where datasets will be anonymized and made available through a public link.
Data will be made available with appropriate anonymization to ensure participant confidentiality and comply with GDPR or relevant data protection laws.

6. Consent from Participants:
Informed consent was obtained from all study participants prior to enrollment. The consent forms include clauses about the use of anonymized data for research purposes.

7. Ethical and Legal Restrictions:
Ethical approval was obtained from the Ethics Committee of Tribhuvan University (Kathmandu, Nepal).
The shared data will be anonymized and will not include any personally identifiable information (PII).
Data will not be shared with any commercial entities unless participants' explicit consent is obtained.

8. Comments on Data Anonymization:
All shared data will be fully anonymized by removing participant identifiers such as names, addresses, or any direct identifiers.
Only aggregated, de-identified data will be available to ensure that participants' privacy is maintained.

9. Exceptions:
In case of unforeseen circumstances or legal restrictions (e.g., specific local laws or data protection issues), access to data may be restricted, but we will provide a clear rationale for any such limitations.

10. Long-term Availability:
The dataset will remain accessible for at least 5 years after the publication date, allowing researchers to explore the data for further studies or meta-analyses.

IPD sharing plan summary

Stored in publicly available repository