Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effectiveness of augmented tele-rehabilitation based on mobile application to routine physical therapy on pain, range of motion, disability and quality of life in patients with adhesive capsulitis: Randomized controlled trial

Protocol summary

Study aim

Investigating the effect of adding telerehabilitation to routine physiotherapy on pain, range of motion, disability, and quality of life outcomes in frozen shoulder patients

Design

A clinical trial with a control group, with double-blind, randomized parallel groups, phase 3 was conducted on 24 patients.
https://www.sealedenvelope.com/simple-randomiser/v1/lists was used for randomization

Settings and conduct

Both groups receive 12 physiotherapy sessions over 4 weeks, including hot pack, TENS, low-level laser therapy, joint mobilization, and PNF techniques. The intervention group will also use a mobile app providing guided home exercises, which adjusts difficulty based on patient feedback. The app includes instructional videos, timers, and daily questionnaires. Sessions last approximately 60 minutes. The research location are at the The special clinic of Ghaem Hospital and Comprehensive Rehabilitation Center in Mashhad, on Parastar Street.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Limited active and passive shoulder range of motion, history of shoulder pain for at least 4 weeks, requirements to download and install the application Exclusion criteria: Bilateral involvement, history of trauma, surgery, or infection

Intervention groups

The intervention group will include patients who receive the mobile app in addition to conventional physiotherapy. The comparison group will include patients who receive conventional physiotherapy only.

Main outcome variables

Score of Shoulder Pain and Disability Index questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221030056342N7**
Registration date: **2025-12-06, 1404/09/15**
Registration timing: **registered_while_recruiting**

Last update: **2025-12-06, 1404/09/15**
Update count: **0**

Registration date

2025-12-06, 1404/09/15

Registrant information

Name

Afsaneh Zeinalzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3884 6710

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-20, 1404/06/29

Expected recruitment end date

2026-09-20, 1405/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effectiveness of augmented tele-rehabilitation based on mobile application to routine physical therapy on pain, range of motion, disability and quality of life in patients with adhesive capsulitis: Randomized controlled trial

Public title
Investigating the effect of remote rehabilitation in physiotherapy treatment of frozen shoulder patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Limitation in both active and passive range of motion shoulder pain for at least 4 weeks access to a mobile phone capable of installing the tele-rehabilitation app
Exclusion criteria:
Bilateral diagnosis of frozen shoulder Frozen shoulder may be secondary to trauma (fracture or dislocation) or secondary to systemic problems (rheumatoid arthritis) cervical radiculopathy history of shoulder surgery Not able to work with the application

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the unit block randomization method is used. For this method, the size of each block must first be determined (for example, a block of four). Then, a list of blocks is written and numbers are assigned to them (AABB(1)- ABAB(2)- ABBA(3)- BBAA(4)- BABA(5)- BAAB(6)), then random numbers between one and six are selected (for example, 1 4 5, etc.), and finally, the treatment allocation list is determined based on the previous random numbers (... AABB-BBAA-BABA-).} The randomization sequence will be prepared with the help of the website www.sealedenvelope.com. The steps for allocating individuals to the groups are as follows: Preparation of Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE): Each position in the allocation list (e.g., the first position, which is A; the second, which is A; the third, which is B; etc.) is placed inside an opaque, sealed envelope. Only a serial number (1, 2, 3, ...) is marked on the outside of each envelope. Randomization at the Time of Each Individual's Enrollment: After verifying the eligibility and obtaining informed consent from each participant, a researcher who is directly involved with the participant (and is typically unaware of the envelope's contents) opens the envelope with the lowest available serial number. Group Allocation: The content inside the envelope (the letter A for the intervention group or B for the control group) determines which group that specific participant is assigned to.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Patients will be divided into two groups, intervention and control, by the sample allocator from the set of envelopes and according to the order indicated by the number on the back of the envelopes. The sample allocator, who will be unaware of the coding method, will be blind to the outcome assessor before treatment and then in the fourth week of treatment. The therapist will also be blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences

Street address
Mashhad, at the end of Shahid Fakuri Blvd, between Shahid Al Shahidi Square and Shahid Javan Square of Mashhad Medical Sciences, Knowledge and Health Village, Central Organization of Knowledge

City
Mashhad

Province
Razavi Khorasan

Postal code
9177899191

Approval date
2025-04-26, 1404/02/06

Ethics committee reference number
IR.MUMS.REC.1404.052

Health conditions studied

1

Description of health condition studied
Frozen shoulder syndrome

ICD-10 code
M75.0

ICD-10 code description
Adhesive capsulitis of shoulder

Primary outcomes

1

Description
Score of Shoulder Pain and Disability Index Questionnaire
Timepoint
Immediately before and after treatment
Method of measurement
The SPADI questionnaire is used to assess pain and disability in patients with shoulder disorders. The questionnaire consists of 13 questions in two separate sections: pain (5 items) and disability (8 items). The total score ranges from 0 to 100, with higher scores indicating greater pain and disability.

Secondary outcomes

1

Description
Score of Visual Analogue Scale
Timepoint
Immediately before and after treatment
Method of measurement
In this scale, there is a 10 cm horizontal line segment, the left end of which corresponds to the absence of pain and the other end corresponds to the most severe pain that the person experiences. The distance between the left side and the marker is calculated in centimeters and is calculated as the intensity of the pain.

2

Description
Range of motion
Timepoint
Immediately before and after treatment
Method of measurement
To examine the range of motion of the shoulder joint, a goniometer will be used in the supine position based on Kelley guidelines.

3

Description
Score of 12 Item Short Form Survey Quality of Life Questionnaire
Timepoint
Immediately before and after treatment
Method of measurement
It is a 12-question questionnaire and a shorter version of the 36SF- which is divided into two main sections: physical and mental health. A higher score indicates a better quality of life and a lower score indicates a lower quality of life.

4

Description
Quick Disabilities of Arm, Shoulder, and Hand Questionnaire
Timepoint
Immediately before and after treatment
Method of measurement
It is an 11-question questionnaire that assesses the degree of disability in daily activities, limitations in work and recreational activities, the degree of pain, and the psychological impact of the condition. Scores on this questionnaire range from 0 to 100. Higher scores indicate greater disability, and lower scores indicate less disability.

5

Description
Score of Global Rating Scale
Timepoint
Immediately before and after treatment
Method of measurement
The scale is 11 points, ranging from -5 (much worse) to 0 (no change) and +5 (much better). The patient is asked to rate the change in the shoulder following the treatment plan.

Intervention groups

1

Description
Individuals in the control group will receive 12 one-hour sessions of treatment as follows: 1. Low-power laser will be applied for 30 seconds to 8 painful points of the shoulder joint capsule with an energy of 1.8 Joules per point. 2. After that, in the second stage, electrical skin stimulation with a frequency of 150 and a current intensity of 25 to 35 mA (at a level of comfort determined by the patient) will be applied for 15 minutes.3. Before performing mobilization and stretching exercises, a hot pack is applied for 15 minutes to increase the flexibility of collagen. 4. The second diagonal flexion pattern in the upper limb in the involved hand along with the Hold-Relax technique will be performed as a 10-second contraction of the antagonist muscle, 5 times per session.5. At the end of each session, individuals in both groups are taught the necessary exercises to exercise at home at least once a day, observing the precautions for each stage of the exercise.
Category
Treatment - Other

2

Description
Individuals in the Intervention group will receive 12 one-hour sessions of treatment as follows: 1. Low-power laser will be applied for 30 seconds to 8 painful points of the shoulder joint capsule with an energy of 1.8 Joules per point. 2. After that, in the second stage, electrical skin stimulation with a frequency of 150 and a current intensity of 25 to 35 mA (at a level of comfort determined by the patient) will be applied for 15 minutes.3. Before performing mobilization and stretching

exercises, a hot pack is applied for 15 minutes to increase the flexibility of collagen. 4. The second diagonal flexion pattern in the upper limb in the involved hand along with the Hold-Relax technique will be performed as a 10-second contraction of the antagonist muscle, 5 times per session.5. At the end of each session, individuals in both groups are taught the necessary exercises to exercise at home at least once a day, observing the precautions for each stage of the exercise. The intervention group receives the same exercises and care recommendations in the form of a mobile application.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Special Physiotherapy Clinic of Ghaem Hospital
Full name of responsible person
Mr Mohammad Javad Zarandi
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Narjes building, first floor, Physiotherapy Department, Qaem Hospital, Nurse Street
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Afsaneh Zeinalzadeh
Position
Associate Professor, Department of Physiotherapy, Mashhad University of Medical Sciences
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
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Azadi Square, East Gate of Ferdowsi University of Mashhad, University Campus, Kharazmi Building, Faculty of Paramedical and Rehabilitation Sciences, Department of Physiotherapy
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available