Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of audio biofeedback device with tracking patterns device for home-based rehabilitation of the osteoarthritis shoulder: A Feasibility and User Acceptance Study

Protocol summary

Study aim

Comparison of the effect of the auditory biofeedback device with the device of following treatment patterns in the rehabilitation at home of patients with shoulder arthritis.

Design

The clinical trial is in two groups, with parallel groups, one-blinded and randomized. 22 participants in two groups of 11 people participated in the study. 22 therapists will also be present to perform the exercises to rate the tools. The rand function of Excel software will be used for randomization.

Settings and conduct

This study will be single blind. Each participant will randomly receive one of the two treatment tools first, and after the evaluation of the first tool, will spend a one-week period without shoulder-related treatment. Then he receives another tool. The study will be done in Tehran and the evaluations will be done in the rehabilitation center in Tehran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People with arthritis of one or both shoulders according to the physician's diagnosis • Aged 40 to 60 years • Without a history of surgery and burns in the shoulder • Absence of contracture and adhesion in the shoulder • The ability to perform exercises without causing any health risks Exclusion criteria: unwillingness to continue • Pain during exercises

Intervention groups

Eligible subjects will be randomly assigned by sealed envelopes to group A (will receive the biofeedback tool first) or group B (will receive the laser pattern tool first). Both groups will be treatment-free for one week after completing the three-day period, and then receive the other tool. In this way, group A will use laser movement therapy tools for three days and group B will use biofiber tools for three days.

Main outcome variables

Pain level of users Acceptance and satisfaction of users Therapists' satisfaction score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210607051511N1**
Registration date: **2023-11-25, 1402/09/04**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-25, 1402/09/04**
Update count: **0**

Registration date

2023-11-25, 1402/09/04

Registrant information

Name

zahra jiryaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3425 5716

Email address

jiryaei.z@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-07, 1402/07/15

Expected recruitment end date

2024-03-05, 1402/12/15

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of audio biofeedback device with tracking patterns device for home-based rehabilitation of the osteoarthritis shoulder: A Feasibility and User Acceptance Study

Public title
Comparison of audio biofeedback device with tracking patterns device for home-based rehabilitation of the osteoarthritis shoulde
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
People with osteoarthritis in one or both shoulders People without surgery or burn in shoulder People without any scar or spastic in shoulder Ability to do exercise without any dangerous
Exclusion criteria:
No interest to keep on studying Feel pain and complain during exercises and washout period
Age
From **40 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible subjects will be randomly assigned by sealed envelopes to group A (will receive the biofeedback tool first) or group B (will receive the laser pattern tool first). The randomization process will be done by someone unaware of the study protocol.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study will be single blind. Each participant will randomly receive one of the two treatment tools using the sealed envelope method, and after the evaluation of the first tool, they will spend a one-week period without treatment related to the shoulder. Then he receives another tool. The participants will not know how the other tool works until the end of the intervention with the first tool.
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran university medicine science
Street address
Shahnazari alley- Madar squre- Mirdamad avenue
City
Tehran
Province
Tehran
Postal code
1545913487
Approval date
2023-07-03, 1402/04/12
Ethics committee reference number
IR.IUMS.REC.1402.348

Health conditions studied

1

Description of health condition studied
Shoulder Osteoarthritis
ICD-10 code
M19.9
ICD-10 code description
Osteoarthritis, unspecified site

Primary outcomes

1

Description
Pain is an unpleasant sensation and experience related to real or potential tissue damage that has physiological and psychological components.
Timepoint
In beginning study- after intervention A- after intervention B
Method of measurement
Visual scale of pain intensity

2

Description
Acceptance and satisfaction of users
Timepoint
In beginning study- after intervention A- after intervention B
Method of measurement
Likert scale

3

Description

Satisfaction of therapists

Timepoint

In beginning study- after intervention A- after intervention B

Method of measurement

Likert scale

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: The auditory biofeedback device, for three days each participant uses the device and performs five specified exercises.

Category

Rehabilitation

2

Description

The second intervention group: Tracking Patterns device, for three days each participant uses the tool and performs five specified exercises.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Nahal clinic

Full name of responsible person

Zahra Jiryaei

Street address

24 unit, 2 flat, Tehranpars building, Taheri alley, 196 west street, 3rd square of tehranpars

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Zahra Jiryaei

Position

Ph.D Student

Latest degree

Ph.D.

Other areas of specialty/work

Orthopedics

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inquiries

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Rehabilitation management

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Person responsible for updating data

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Position
Therapist

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Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The data obtained from the evaluation results of the participants will be placed in the statistical analysis software and their results will be published.

When the data will become available and for how long
After study will finish and submit it to a journal

To whom data/document is available
For researcher will be available.

Under which criteria data/document could be used
final results will be available for everyone that is interested in it.

From where data/document is obtainable
To Zahra Jiryaei: Jiryaei.z@gmail.com

What processes are involved for a request to access data/document
The applicant must first introduce him/herself by email and continue for what purpose he needs the results. After sending the email and confirming it, he/she will have access to the final data after ten days.

Comments