

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 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

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Shahnazari alley- Madar squire- Mirdamad avenue

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Tehran

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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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Full name of responsible person

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Position

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Latest degree

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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