

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The Effect of Home Hand Exercise on joint pain and range of motion in patients with Rheumatoid Arthritis: A Randomized Clinical Trial

Protocol summary

Study aim

Determining the effect of therapeutic exercise at home on pain and range of motion of hand joints in patients with rheumatoid arthritis

Design

A RCT with a control group, without blinding, randomly with a ratio of 1:1, using the "Ralloc" package, in parallel on two groups of 77 (total population = 154) for four weeks (the duration of the study). They will be visited by a rheumatologist and sports medicine specialist who receive pharmaceutical and sports interventions.

Settings and conduct

This is a RCT will be conducted at Imam Hussein Hospital in Tehran, from 2023 to 2024. Two groups of 77 patients each, diagnosed with RA, will participate in this study. Both groups will receive standard drug therapy. Additionally, the case group will perform specialized exercises prescribed by a sports medicine specialist for their hands, three times a day at home for a maximum of one month.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients over 18 years of age with rheumatoid arthritis based on the ACR/EULAR 2010 The absence of joint pain in the wrist, metacarpopharngal or proximal interphalangeal joint A stable history of medication in at least the past 3 months Inability to perform daily activities Exclusion criteria: Diabetes and BMI ≥ 30 k/m2 Significant OA in the hands Hand surgery in the past 6 months Active disease (acute phase of the disease)

Intervention groups

Intervention group: undergoing standard drug treatment and performing sports exercises three times a day (3 sets of 10 for range of motion and pain and one set of 10 twice a day for hand grip)) at home for a maximum of one month Control group: they recieve standard drug treatment without doing exersice (follow-up period = one month from the start of the study).

Main outcome variables

Primary outcome: checking the amount of pain

Secondary outcome: range of motion and hand grip

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240619062183N1**

Registration date: **2024-10-05, 1403/07/14**

Registration timing: **prospective**

Last update: **2024-10-05, 1403/07/14**

Update count: **0**

Registration date

2024-10-05, 1403/07/14

Registrant information

Name

Nilloofar Abozarzadeh Tahamtan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7343 3000

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-10-11, 1403/07/20

Expected recruitment end date

2025-03-20, 1403/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Home Hand Exercise on joint pain and range of motion in patients with Rheumatoid Arthritis: A Randomized Clinical Trial

Public title

The Effect of Home Hand Exercise in patients with Rheumatoid Arthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients over 18 years of age with rheumatoid arthritis, in whom the diagnosis of rheumatoid arthritis is definite based on the criteria of ACR/EULAR 2010 The absence of joint pain in the wrist, metacarpopharangeal or proximal inter-phalanx History of stable medication in the last 3 months Personal expression is the inability to perform daily activities

Exclusion criteria:

Patients with diabetes and Body Mass Index above 30 kg/m2 (BMI $\geq$ 30 k/m2), Patients who have significant Osteoarthritis in the hands, Hand surgery in the last 6 months Patients who have active disease (in phase are acute)

Age

From 18 years old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 154

Randomization (investigator's opinion)

Randomized

Randomization description

All people eligible to enter the study will be randomly placed in one of the two intervention or control groups with a ratio of 1:1. The randomization method will be permuted block randomization, the blocks will be based on the sample size in 25 blocks in sizes 2, 4, 6, 8, 10 using the "Ralloc" package in STATA software. Patients will be included in each group based on the determined sample size and based on the list of randomized individuals (along with a specific research code for each individual).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of School of Medicine, Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Arabi St., Student Blvd., Valenjak, Tehran

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Province

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Postal code

1983969411

Approval date

2024-04-09, 1403/01/21

Ethics committee reference number

IR.SBMU.MSP.REC.1403.048

Health conditions studied

1

Description of health condition studied

Rheumatoid Arthritis

ICD-10 code

M05

ICD-10 code description

Rheumatoid arthritis with rheumatoid factor

Primary outcomes

1

Description

Examining the pain level is a scale to measure the intensity of the patient's pain at rest, which is numbered from zero to ten. The number zero indicates the absence of pain and the number ten indicates the maximum amount of pain in the state of rest.

Timepoint

The duration of the study is one month, and all the mentioned outcomes are measured twice, once at zero time (start of the study and before the intervention) and the second time on the 30th day after the intervention.

Method of measurement

Visual pain measurement system (VAS) will be used to measure the pain level of the subjects. This method is a scale to measure the patient's pain intensity at rest, which is numbered from zero to ten. The number zero indicates the absence of pain and the number ten indicates the maximum amount of pain in the state of rest

Secondary outcomes

1

Description

Range of motion

Timepoint

The duration of the study is one month, and all the mentioned outcomes are measured twice, once at zero time (the beginning of the study and before the intervention) and the second time on the 30th day after the intervention.

Method of measurement

The patient's range of motion in hand flexion and extension is measured by goniometer

2

Description

Hand grip

Timepoint

The duration of the study is one month, and all the mentioned outcomes are measured twice, once at zero time (the beginning of the study and before the intervention) and the second time on the 30th day after the intervention.

Method of measurement

Hand Grip is measured by dynamometer

Intervention groups

1

Description

Intervention group: under standard medical treatment and performing sports exercises according to specialized training by a sports medicine specialist in the hand three times a day (3 sets of 10 for range of motion and pain and one set of 10 for hand grip twice a day) in home for a maximum of one month

Category

Rehabilitation

2

Description

Control group: they are only subjected to standard drug treatment without doing sports (follow-up period = one month from the start of the study).

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital Complex

Full name of responsible person

Niloofer Abozarzadeh Tahamtan

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Shahid Madani Street, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti 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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Niloofar Abozarzadeh Tahamtan

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Parisa Delkash

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Niloofar Abozarzadeh Tahamtan

Position

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

All patient information will be entered into the database (Excel file) after collecting it in a paper checklist, and after checking the range of data in terms of the presence of outliers and cleaning it (data cleaning), it will be prepared for statistical analysis. The final data file will be provided to the research assistant of internal diseases department to conduct further studies.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

If there is a positive conclusion from the plan and the need for further studies in this field

From where data/document is obtainable

Dr. Niloofar Abozarzadeh, Tahamtan - Imam Hossein Hospital - Rheumatology Clinic

What processes are involved for a request to access data/document

Through the written request of the applicant to the research department of the hospital

Comments