Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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, metacarpopharngeal 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

Niloofar 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, metacarpopharngeal 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 ≥ 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

City
Tehran

Province
Tehran

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
Niloofar 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
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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
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Medical doctor
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Person responsible for updating data

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Medical doctor
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https://ehms.sbmu.ac.ir

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, Tehamtan - 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