

# 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, 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  $\geq 30$  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

nilloofar.abozarzadeh@gmail.com

##### 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, metacarpopharngal 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/m<sup>2</sup> (BMI  $\geq$  30 k/m<sup>2</sup>), 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

##### Street address

Shahid Madani Street, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1617763141

##### Phone

+98 21 7343 3000

##### Fax

+98 21 7343 3000

##### Email

niloofar.abozarzadeh@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Afshin Zarghi

##### Street address

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

##### City

Tehran

##### Province

Tehran

##### Postal code

1983969411

##### Phone

+98 21 23871

##### Fax

+98 21 23871

##### Email

sci@sbmu.ac.ir

#### 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

**Street address**

Shahid Madani St, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1617763141

**Phone**

+98 21 7343 3000

**Fax**

+98 21 7343 3000

**Email**

niloofar.abozarzadeh@gmail.com

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Internal Medicine

**Street address**

Shahid Madani St, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1617763141

**Phone**

+98 21 7343 3000

**Fax**

+98 21 7343 3000

**Email**

niloofar.abozarzadeh@gmail.com

**Web page address**

<https://ehms.sbmu.ac.ir>

**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**

Internal Medicine

**Street address**

Shahid Madani St, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1617763141

**Phone**

+98 21 7343 3000

**Fax**

+98 21 7343 3000

**Email**

parisa.delkash@yahoo.com

**Web page address**

<https://ehms.sbmu.ac.ir>

**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, 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