

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Assessment of the effect of hand exercise on functional indexes of hand in patients with hand osteoarthritis

#### Protocol summary

##### Study aim

The effect of hand exercise on hand functional indexes in patients with osteoarthritis

##### Design

Clinical trial with intervention and control group, Double blind, randomized with sample size of 40 Patients. Forty packed envelopes are prepared for the patients. Rheumatologist will randomly give the patient an envelope after the diagnosis and refer him to the therapist ,who will exercise the patient or place him on the waiting list according to the envelope type. Therefore, the researcher, patient, and rheumatologist do not know the intervention type.

##### Settings and conduct

The place of study will be Rheumatology Clinic of Zanjan Vali-e-asr Hospital.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: People over the age of 40 who have clinical symptoms of hand osteoarthritis; the presence of bouchard nodule, or heberden nodule in the interdigital joints, of hand fingers ; Symptoms of osteoarthritis in hand x-rays. Non-inclusion criteria: Participate in exercise therapy for hands in the last 6 months; Hand Intra-articular injection in the last 3 months; History of hand joint replacement or joint prosthesis; patients who candidate undergoing surgery during the study; Participate in other interventional studies; Use of cane and walker and armpit; recent use of therapeutic creams.

##### Intervention groups

Intervention group: A group of 20 patients will be treated at home for 4 weeks. Control group: The second group includes 20 patients will be in a waiting list. After 4 weeks, this group will also do home exercise.

##### Main outcome variables

Hand function; Hand power; Hand pain; Hand fatigue

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190715044220N1**

Registration date: **2020-01-24, 1398/11/04**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-01-24, 1398/11/04**

Update count: **0**

##### Registration date

2020-01-24, 1398/11/04

##### Registrant information

##### Name

Iraj Alibiglou

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 24 3302 3236

##### Email address

iraj-ab@zums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-07-11, 1398/04/20

##### Expected recruitment end date

2020-02-19, 1398/11/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Assessment of the effect of hand exercise on functional indexes of hand in patients with hand osteoarthritis

### Public title

The effect of exercise on patients with osteoarthritis of hand

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

People over the age of 40 who have clinical symptoms of hand osteoarthritis The presence of bouchard nodule, in the interdigital joints of the hand fingers The presence of heberden nodule in the interdigital joints of the hand fingers Osteoarthritis symptoms on hand X-ray

#### Exclusion criteria:

Participate in hands-on exercises in the last 6 months Hand Intra-articular injection in the last 3 months History of hand joint replacement or hand joint prosthesis Participate in other interventional studies Use of cane and walker and armpit Rheumatologic disease or other hand diseases, such as CTS or tendinitis History of hand major trauma Patients with systemic diseases, such as diabetes and ..., who have neuropathy patients who candidate undergoing surgery during the study recent use of therapeutic creams

### Age

From **40 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Participant
- Investigator

### Sample size

Target sample size: **40**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Samples will be selected using simple random allocation method, taking into account entry and exit criteria and the randomization tool is the sealed envelope.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

40 packed envelopes are prepared for the patients. Rheumatologist will randomly give the patient an envelope after the diagnosis and refer him to the therapist ,who will exercise the patient according to the envelope type, or place him on the waiting list. Therefore, the researcher, patient, and rheumatologist do not know the intervention type.

### Placebo

Not used

### Assignment

Crossover

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Zanzan University of Medical Sciences

##### Street address

Zanzan university of medical sciences, Azadi Sq. zanzan

##### City

Zanzan

##### Province

Zanzan

##### Postal code

4515613191

#### Approval date

2019-07-13, 1398/04/22

#### Ethics committee reference number

IR.ZUMS.REC.1398.155

## Health conditions studied

### 1

#### Description of health condition studied

Hand Osteoarthritis

#### ICD-10 code

M19.049

#### ICD-10 code description

osteoarthritis of hand

## Primary outcomes

### 1

#### Description

Improved hand function

#### Timepoint

4 weeks after intervention

#### Method of measurement

FIHOA questionnaire

### 2

#### Description

Improved hand strength

#### Timepoint

4 weeks after intervention

#### Method of measurement

FIHOA questionnaire

### 3

#### Description

Improved hand pain

#### Timepoint

4 weeks after intervention  
**Method of measurement**  
FIHOA questionnaire

#### 4

**Description**  
Improved hand fatigue  
**Timepoint**  
4 weeks after intervention  
**Method of measurement**  
FIHOA questionnaire

### Secondary outcomes

empty

### Intervention groups

#### 1

**Description**  
Intervention group: A group of 20 patients are treated with home exercise for 4 weeks. Special Exercise for Hand Fingers Osteoarthritis (includes Finger Stretch, Make a Fist, Finger Lift and Thumb Touch which are done 10 times each exercise) will be done 3 times daily.

**Category**  
Rehabilitation

#### 2

**Description**  
Control group: A group of 20 patients will be on the waiting list for home exercise after 4 weeks

**Category**  
Rehabilitation

### Recruitment centers

#### 1

**Recruitment center**  
**Name of recruitment center**  
Rheumatology Clinic - Zanjan Valiasr Hospital  
**Full name of responsible person**  
Alireza Sadeghi  
**Street address**  
Shariati St., Valiasr Hospital  
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**Province**  
Zanjan  
**Postal code**  
4515776978  
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Sadeghialireza@yahoo.com

### Sponsors / Funding sources

#### 1

**Sponsor**  
**Name of organization / entity**  
Zanjan University of Medical Sciences  
**Full name of responsible person**  
Dr.Alireza Shoghli  
**Street address**  
Zanjan University of Medical Sciences ,Azadi square,  
Zanjan  
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Zanjan  
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4515613191  
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**Email**  
shoghli@zums.ac.ir  
**Web page address**  
http://zums.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Zanjan 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**  
Zanjan University of Medical Sciences  
**Full name of responsible person**  
Alireaz Sadeghi  
**Position**  
Associate professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Rheumatologist  
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Valiasr Hospital, Shariati street  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Zanjan University of Medical Sciences  
**Full name of responsible person**  
Iraj Alibiglou  
**Position**  
Resident  
**Latest degree**  
Medical doctor

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Internal Medicine  
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4515776978  
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iraj-ab@zums.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

Not applicable

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Not applicable

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

All data is shareable

### When the data will become available and for how long

Since the end of 1398

### To whom data/document is available

public

### Under which criteria data/document could be used

There is no specific requirement

### From where data/document is obtainable

Responsive person email address

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

One month after the written request to Responsive person

### Comments