

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

The effect of 8 weeks of selected hand strength training and cinnamon and honey supplementation on inflammatory biomarkers, function, and quality of life of women with hand osteoarthritis

Protocol summary

Study aim

The effect of 8 weeks of selected hand strength training and cinnamon and honey supplementation on inflammatory biomarkers, function and quality of life in women with osteoarthritis of the hand

Design

This clinical trial design was randomized as a parallel design, with the control group, and is non-blinded one. In this randomized study, phases 2-3 will be performed on 48 patients with hand osteoarthritis. A random number table is used for randomization and participants are assigned to four intervention and control groups (three intervention groups and one control group).

Settings and conduct

This study, which will be conducted in Imam Reza Hospital of Kermanshah, is a non-blinded one. At the beginning of the study, a quality of life questionnaire will be provided for patients. At the end of the study, the quality of life questionnaire is given to patients again.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent; women with hand osteoarthritis Women over 60 years Exclusion criteria: Women with cancer; Women with mental disorders

Intervention groups

The first intervention group will undergo selected strength training for 8 weeks. The second intervention group will use the honey supplement and cinnamon powder twice a day for 8 weeks. The third intervention group will undergo simultaneous hand exercises (8 weeks) and use of the honey supplement and cinnamon powder (8 weeks twice a day). The control group will not receive any intervention.

Main outcome variables

Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N173**

Registration date: **2021-08-07, 1400/05/16**

Registration timing: **retrospective**

Last update: **2021-08-07, 1400/05/16**

Update count: **0**

Registration date

2021-08-07, 1400/05/16

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-02, 1398/02/12

Expected recruitment end date

2019-07-03, 1398/04/12

Actual recruitment start date

2019-05-02, 1398/02/12

Actual recruitment end date

2019-07-03, 1398/04/12

Trial completion date

2019-07-06, 1398/04/15

Scientific title

The effect of 8 weeks of selected hand strength training and cinnamon and honey supplementation on inflammatory biomarkers, function, and quality of life of women with hand osteoarthritis

Public title

The effect of 8 weeks of selected hand strength training and cinnamon and honey supplementation on inflammatory biomarkers, function, and quality of life of women with hand osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent women with hand osteoarthritis
Women over 60 years

Exclusion criteria:

Women with cancer
Women with mental disorders

Age

From **60 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **48**

Actual sample size reached: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple random method. 48 cards with numbers from 1 to 48 are placed in the envelope. 12 cards that are randomly selected in the first stage are assigned to the first group. 12 cards that are randomly selected in the second stage are assigned to the second group, 12 cards that are randomly selected in the third stage are assigned to the the third group, the remaining 12 cards are assigned to the fourth group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2019-08-06, 1398/05/15

Ethics committee reference number

IR.KUMS.REC.1398.548

Health conditions studied

1

Description of health condition studied

Hand Osteoarthritis

ICD-10 code

M19.049

ICD-10 code description

Primary osteoarthritis, unspecified hand

Primary outcomes

1

Description

Quality of Life

Timepoint

Start of study and end of study (8 weeks later)

Method of measurement

Using Quality of Life Questionnaire (SF36)

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group will undergo selected strength training for 8 weeks every day (Daily with 10 repetitions during weeks one to two, 12 repetitions in weeks three to four and 15 repetitions in weeks five to eight)

Category

Treatment - Other

2

Description

The second intervention group will use the honey supplement and cinnamon powder once a day for 8 weeks

Category

Treatment - Other

3**Description**

The third intervention group will undergo simultaneous hand exercises for 8 weeks every day (Daily with 10 repetitions during weeks one to two, 12 repetitions in weeks three to four, and 15 repetitions in weeks five to eight) and use the honey supplement and cinnamon powder (8 weeks once a day).

Category

Treatment - Other

4**Description**

The control group will not receive any intervention

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam Reza Hospital

Full name of responsible person

Shayesteh Hasani

Street address

Emam Reza Hospital, Parastar Boulevard

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Dr. Arash Bochani

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Vice Chancellor for Research and Technology, Islamic Azad University, Kasra St

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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

Islamic Azad University

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**

Islamic Azad University

Full name of responsible person

Dr. Sedigheh Hosainpoor Delavar

Position

Faculty member of Kermanshah Azad University

Latest degree

Ph.D.

Other areas of specialty/work

Sport physiology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available