

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Feb 2026

### The effect of aquatic exercise program on pain, dryness, motor function, happiness, body composition and hip circumference of elderly men with osteoarthritis of the knee

#### Protocol summary

##### Study aim

Evaluation of the effects of aquatic exercise program on pain, dryness, motor function, happiness, body composition and hip circumference in elderly men with knee osteoarthritis

##### Design

The sample size in this study was 40 people who were randomly divided into 2 experimental groups (aquatic exercise) and control group. 48 hours before and after the aquatic exercise, the WOMAC and Happiness questionnaires were filled out by both groups, and measurements of body composition and hip circumference were completed and analyzed by all subjects.

##### Settings and conduct

The participants of the experimental group start the aquatic exercise training program for 6 weeks under the supervision of the researcher (in the Kosar pool in Rasht). The water aquatic program was performed three times a week for 50 minutes.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Age over 65 years 2) Gender (Man) 3) Have a history of at least 6 months of knee osteoarthritis Exclusion criteria: 1) Inability to perform aquatic exercises 2) Taking supplements and medications to reduce knee pain during the month before the study

##### Intervention groups

Aquatic exercise training group (20 people), control group (20 people)

##### Main outcome variables

WOMAC Questionnaire Indices (including pain, dryness, motor function) and Happiness Questionnaire, body mass index and hip circumference

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180503039517N10**

Registration date: **2021-04-07, 1400/01/18**

Registration timing: **prospective**

Last update: **2021-04-07, 1400/01/18**

Update count: **0**

##### Registration date

2021-04-07, 1400/01/18

##### Registrant information

##### Name

Soleyman Ansari Kolachahi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 3375 2906

##### Email address

solomonansari@phd.iaurasht.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-04-14, 1400/01/25

##### Expected recruitment end date

2021-04-25, 1400/02/05

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effect of aquatic exercise program on pain, dryness, motor function, happiness, body composition and hip circumference of elderly men with osteoarthritis of the knee

## Public title

The effect of aquatic exercise program on pain, dryness, motor function, happiness, body composition and hip circumference of elderly men with osteoarthritis of the knee

## Purpose

Education/Guidance

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age over 65 years Gender (Man) Have a history of at least 6 months of knee osteoarthritis

### Exclusion criteria:

Inability to perform aquatic exercises Taking supplements and medications to reduce knee pain during the month before the study

## Age

From **65 years** old

## Gender

Male

## Phase

N/A

## Groups that have been masked

- Outcome assessor
- Data analyser

## Sample size

Target sample size: **40**

## Randomization (investigator's opinion)

Randomized

## Randomization description

40 males with osteoarthritis of the knee will be selected by available sampling method. Through a lottery (participants' names were written on paper and will be divided into experimental and control groups through random lottery)

## Blinding (investigator's opinion)

Double blinded

## Blinding description

In this research, responsible for collecting and processing the data, the type of intervention, and the participants in the research groups are unaware.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

Ethics committee

## Name of ethics committee

The ethics committee of Islamic Azad University, Rasht Branch

## Street address

Islamic Azad University, Rasht Branch, Lakan Blv

## City

Rasht

## Province

Guilan

## Postal code

۴۱۳۷۶۵۴۹۱۹

## Approval date

2020-08-17, 1399/05/27

## Ethics committee reference number

IR.IAU.RASHT.REC.1399.036

## Health conditions studied

### 1

#### Description of health condition studied

knee osteoarthritis

#### ICD-10 code

M17

#### ICD-10 code description

Osteoarthritis of knee

## Primary outcomes

### 1

#### Description

Womak Questionnaire Indicators (including pain, dryness, motor function)

#### Timepoint

48 hours before and after the exercise intervention

#### Method of measurement

WOMAC Questionnaire

### 2

#### Description

Happiness and satisfaction of life

#### Timepoint

48 hours before and after the exercise intervention

#### Method of measurement

Oxford Happiness Questionnaire - Short Form

### 3

#### Description

Body composition (body mass index, fat percentage and hip circumference)

#### Timepoint

48 hours before and after the exercise intervention

#### Method of measurement

Measure height and weight, subcutaneous fat and hip circumference with scales, tape measure and caliper

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Intervention group: The experimental group starts the aquatic exercise training program for 6 weeks under the supervision of the researcher (in the Kosar pool in Rasht). The aquatic exercise program is done three times a week for 50 minutes. At the end of the sixth week, the final evaluation is performed and the participants complete the Womak questionnaire again and their weight, height, fat percentage and thigh circumference are measured again.

#### Category

Rehabilitation

### 2

#### Description

Control group: At the beginning and end of the study, they complete the Womak questionnaire and their weight, height, fat percentage and thigh circumference are measured again.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Zibaknar Sports Club

##### Full name of responsible person

Jamshid Ansari

##### Street address

Rasht - Zibaknar - Seyed Al-Shohada Street

##### City

Rasht

##### Province

Guilan

##### Postal code

4419865615

##### Phone

+98 13 3375 2906

##### Email

solomonansari@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Alireza Seidavi

##### Street address

Islamic Azad University of Rasht Branch, Lakan Blv

##### City

Rasht

##### Province

Guilan

##### Postal code

۴۱۳۷۶۵۴۹۱۹

##### Phone

+98 13 3375 2906

##### Email

solomonansari@yahoo.com

#### 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

Private

#### 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

Soleyman Ansari Kolachahi

##### Position

Non faculty doctor

##### Latest degree

Specialist

##### Other areas of specialty/work

Sport Medicine

##### Street address

second floor, Adibsaber Apartment, next to Esparo restaurant, Prof. Samei Blv.

##### City

Rasht

##### Province

Guilan

##### Postal code

4193193933

##### Phone

+98 13 3375 2906

##### Email

solomonansari@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Soleyman Ansari Kolachahi

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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 further 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**

Yes - There is 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

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

Raw and processed data

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

Start of access period from 1401

**To whom data/document is available**

Academic researchers, research colleagues and participants

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

Use research results and data in future meta-analysis research

**From where data/document is obtainable**

Corresponding Author

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

Request the researcher via email

**Comments**