# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Investigating the effect of combined aqua-exercise on complete blood count, physical performance, body composition and quality of life of elderly men

## Protocol summary

**Study aim**

The purpose of this study is to investigate the effect of combined exercise in water on blood cell count, physical performance, body composition and quality of life of elderly men.

**Design**

A randomized clinical trial with an intervention group and control group with parallel groups on 40 elderly people aged 60 to 75 years, which writing the names on papers and lottery will be used for randomization.

**Settings and conduct**

This study will be conducted with the approach of improving immune function, physical function, body composition and quality of life of elderly men in Shahrekord city. After checking and being eligible to enter the study, 40 people will be selected and trained for 8 weeks (according to the sports protocol designed by the researcher) in the Martyrs' Pool of Shahrekord city.

**Participants/Inclusion and exclusion criteria**

Elderly people without special diseases and capable of doing exercise, confirmed by a general physician, not suffering from any known cardiovascular diseases and blood pressure disorders, as well as not having movement problems or any clinical conditions that can limit doing exercise will be selected. Criteria for not entering the study is inflecting cardiovascular and hematological disorders, as well as motor and cognitive problems.

**Intervention groups**

The first group is the water training group that will implement the set protocol and the second group is the control group.

**Main outcome variables**

Complete blood count, physical performance, body composition and quality of life

## General information

**Reason for update**

**Acronym**

-

**IRCT registration information**

IRCT registration number: **IRCT20200408046997N2**
Registration date: **2024-01-17, 1402/10/27**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-17, 1402/10/27**
Update count: **0**

**Registration date**

2024-01-17, 1402/10/27

**Registrant information**

**Name**
Ali Samadi
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
**Phone**
+98 21 5121 2456
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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2024-01-13, 1402/10/23

**Expected recruitment end date**

2024-02-03, 1402/11/14

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**
Investigating the effect of combined aqua-exercise on complete blood count, physical performance, body composition and quality of life of elderly men

**Public title**
Investigating the effect of combined aqua-exercise on health and physical performance of elderly men
**Purpose**
Other
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Males aged 60 to 75 Not having contraindication to do exercise Not doing regular exercise in past 6 month
**Exclusion criteria:**
Having known cardiovascular disease having cognitive and metabolic disorder, such as diabetes Not being able to do exercise because of musculoskeletal limitations
**Age**
From **60 years** old to **75 years** old
**Gender**
Male

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **40**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
The samples will be assigned to the study groups, i.e., combined Aqua exercise group (A) and control group (B) using the block randomization method. First the size of each block and the number of blocks will be determined. Considering that the total sample size is 40, 10 blocks of 4 will be used and each block will be used for 4 subjects. Using Random Allocate Software random blocks of 4 with (A) and (B) letters will be created, and then the block number will be selected by lottery, and subjects 1 to 4 will be assigned to the combined aqua exercise group (A) or control group (B) based on the order of letters of the block. Rest of the subjects will be assigned to the combined aqua exercise group (A) or control group (B) in a similar manner.
**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 Shahed University
**Street address**
Shahed University, opposite to the Holy shrine of Imam Khomeini, Khalij Fars Expressway, Tehran, Iran
**City**
Tehran
**Province**
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**Postal code**
3319118651
**Approval date**
2023-09-26, 1402/07/04
**Ethics committee reference number**
IR.SHAHED.REC.1402.071

## Health conditions studied

### 1

**Description of health condition studied**
Elderly people
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

### 1

**Description**
Complete blood count
**Timepoint**
Before and after
**Method of measurement**
Photometric method

### 2

**Description**
Physical performance
**Timepoint**
Before and after
**Method of measurement**
senior fitness test

### 3

**Description**
body composition
**Timepoint**
Before and after
**Method of measurement**
Body composition Analyzer

### 4

**Description**

Quality of life
**Timepoint**
Before and after
**Method of measurement**
Using SF-36 questionnaire

## Secondary outcomes

### 1

**Description**
Blood pressure
**Timepoint**
Before and after
**Method of measurement**
Sphygmomanometer

### 2

**Description**
blood oxygen
**Timepoint**
Before and after
**Method of measurement**
Oximeter

### 3

**Description**
Lipid profile
**Timepoint**
Before and after
**Method of measurement**
Photometric method

### 4

**Description**
weight
**Timepoint**
Before and after
**Method of measurement**
Scale

### 5

**Description**
Body mass index
**Timepoint**
Before and after
**Method of measurement**
Scale and stadiometer

## Intervention groups

### 1

**Description**
After performing the pretests for both the combined aquatic exercise and control groups, the exercise group will complete the exercise program for 8 weeks (3 sessions pre week/ 60 minutes each session). All exercises will be done in water with the presence a researcher and an aqua exercise specialist. Each training session includes a 10-minute warm-up in the water (stretching movements and various types of walking in the water and a number of combined stretching and jumping exercises), 20 minutes of resistance exercises in the water for large and main muscle groups (strengthening the chest, thighs and arms) using traction and bouncy forces, along with stretching and aerobics exercises in water for 20 minutes (fast walking, jumping and performed combined with stretching movements and jumping to increase the heart rate) and 10 minutes of cooling down (including, light stretching movements and gentle walking in water).
**Category**
Rehabilitation

### 2

**Description**
During the study, the control group will have the usual daily physical activities and go through the normal daily lives and will not participate in any regular and purposeful exercise training program.
**Category**
Rehabilitation

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Shohada pool
**Full name of responsible person**
Ebrahim Shafeghat
**Street address**
North Hafez street
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## Sponsors / Funding sources

### 1

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info@shahed.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Shahed 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**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to

make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Not applicable