

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 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

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Email address

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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	
<u>1</u>	
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	Tehran
Postal code	3319118651
Approval date	2023-09-26, 1402/07/04
Ethics committee reference number	IR.SHAHED.REC.1402.071
Health conditions studied	
<u>1</u>	
Description of health condition studied	Elderly people
ICD-10 code	
ICD-10 code description	
Primary outcomes	
<u>1</u>	
Description	Complete blood count
Timepoint	Before and after
Method of measurement	Photometric method
<u>2</u>	
Description	Physical performance
Timepoint	Before and after
Method of measurement	senior fitness test
<u>3</u>	
Description	body composition
Timepoint	Before and after
Method of measurement	Body composition Analyzer
<u>4</u>	
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

Sponsor
Name of organization / entity
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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
 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
Name of organization / entity
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Full name of responsible person
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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