

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### The Effect of Leisure-time Physical Activity Program on Activity Daily Living and Hope in the Elderly men

#### Protocol summary

##### Study aim

The Effect of Leisure Time Physical Activity Program on Activity Daily Living and Hope in Elderly Men

##### Design

A clinical trial with control and intervention groups, with parallel groups, double-blind, randomized on 60 elderly samples. Statistical software was used for randomization.

##### Settings and conduct

Selected park or parks with ease of access for samples

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age 60 to 80 years old; absence of acute underlying disease; absence of debilitating motor problems and defects. Exclusion criteria: acute illness and hospitalization during the study; inability to tolerate research interventions.

##### Intervention groups

Before starting the intervention, Barthel and Adult Hope Scale (AHS) demographic information questionnaires are completed by the researcher through a face-to-face interview with the elderly. Leisure time physical activities are performed in 8 sessions, once a week (8 weeks) and each session lasts at least 45 minutes in groups and in three groups of ten people. So that all three groups receive interventions on three different days every week. The intervention items include walking for thirty minutes, balance exercise for the elderly for fifteen minutes (including exercises: standing on one leg - standing on the toe - walking on the heel and toes - moving by sticking the heel to the big toe - walking in the figure of eight in English. Each for three minutes). The control group will receive the usual physical activities performed by themselves and the contingency plans of the respective health center. Two weeks after the end of the intervention, the mentioned questionnaires will be completed again.

##### Main outcome variables

Activity Daily Living; hope

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230224057518N1**

Registration date: **2023-07-10, 1402/04/19**

Registration timing: **retrospective**

Last update: **2023-07-10, 1402/04/19**

Update count: **0**

##### Registration date

2023-07-10, 1402/04/19

##### Registrant information

##### Name

Mahdi Azizi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3662 8015

##### Email address

azizim982@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-04-21, 1402/02/01

##### Expected recruitment end date

2023-05-05, 1402/02/15

##### Actual recruitment start date

2023-04-21, 1402/02/01

##### Actual recruitment end date

2023-05-05, 1402/02/15

##### Trial completion date

empty

##### Scientific title

The Effect of Leisure-time Physical Activity Program on Activity Daily Living and Hope in the Elderly men

#### Public title

The Effect of Leisure-time Physical Activity Program on Activity Daily Living and Hope in the Elderly men

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Age 60 to 80 years Living at home Absence of acute underlying disease Ability to communicate verbally Not participating in similar programs No use of drugs and alcohol The absence of a stressful event within the last 6 months Informed consent Absence of disabling motor problems and defects Absence of sensory disorders (such as vision and hearing disorders)

##### Exclusion criteria:

Acute illness and hospitalization during the study Absence of more than one session Inability to tolerate research interventions

#### Age

From **60 years** old to **80 years** old

#### Gender

Male

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **60**

Actual sample size reached: **60**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Random allocation of samples into two intervention and control groups using SPSS statistical software and concealment of random allocation using two sealed envelopes, which specify the control and intervention groups, and the researcher is not aware of its content before random allocation. .

#### 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 Mashhad University of Medical Sciences, Mashhad College of Nursing and Midwifery

#### Street address

Faculty of Nursing and Midwifery, Doctora Crossroad, Ibn Sina St., Mashhad, Khorasan Razavi

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9137913199

#### Approval date

2023-02-27, 1401/12/08

#### Ethics committee reference number

IR.MUMS.NURSE.REC.1401.103

## Health conditions studied

### 1

#### Description of health condition studied

Elderly

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

The degree of dependency in Activity Daily Living

#### Timepoint

Before the start of the intervention and two weeks after the end of the intervention

#### Method of measurement

Barthel Activity Daily Living Scale

### 2

#### Description

Degree of hope

#### Timepoint

Before the start of the intervention and two weeks after the end of the intervention

#### Method of measurement

Snyder Hope Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Intervention items include walking for thirty minutes, balance training for the elderly for fifteen minutes (including exercises: standing on one leg - standing on the toe - walking on the heel and toes - moving by attaching the heel to the big toe- walking in the form of eight in English. each for three minutes). In order to facilitate the intervention, the intervention group is divided into three groups of ten people, and the

mentioned interventions are performed equally for all three groups, and there is no special difference between the members of the intervention groups, nor in the interventions performed.

### Category

Lifestyle

## 2

### Description

Control group: They will receive the usual physical activities performed by themselves and the possible plans of the relevant health center. No other specific intervention in the study will be done for them.

### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Safari comprehensive Health Center

##### Full name of responsible person

Mahdi Azizi

##### Street address

8th Taban Avenue, 23d Hashemyie Boulevard,  
Mashhad

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9137913199

##### Phone

+98 51 3884 8643

##### Email

AziziM982@mums.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Abobargh Health Center

##### Full name of responsible person

Mahdi Azizi

##### Street address

Villa Ave, Facouri Boulevard, Mashhad City

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9137913199

##### Phone

+98 51 3866 6046

##### Email

AziziM982@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Majid Ghayour Mobarhan

##### Street address

Gharashi Building, Next to Hoveyze Cinema,  
Daneshgah Ave, Mashhad City

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9138813944

##### Phone

+98 51 3841 1538

##### Email

vcresraech@mums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

##### Full name of responsible person

Mahdi Azizi

##### Position

Student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nursery

##### Street address

Faculty of Nursing and Midwifery, Doctora Crossroad,  
Ibn Sina St., Mashhad, Khorasan Razavi

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9137913199

**Phone**

+98 51 38591511-3

**Fax**

+98 51 3859 7313

**Email**

AziziM982@mums.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mahdi Azizi

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Faculty of Nursing and Midwifery, Doctora Crossroad,  
Ibn Sina St., Mashhad, Khorasan Razavi

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913199

**Phone**

+98 51 38591511-3

**Fax**

+98 51 3859 7313

**Email**

AziziM982@mums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mahdi Azizi

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Faculty of Nursing and Midwifery, Doctora Crossroad,

Ibn Sina St., Mashhad, Khorasan Razavi

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913199

**Phone**

0098 51 38591511-3

**Fax**

+98 51 3859 7313

**Email**

AziziM982@mums.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**

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

**Informed Consent Form**

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

**Clinical Study Report**

Yes - There is 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**

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

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

Part of the individual data of the participants, such as information about the main outcome or the same information

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

The access period starts 6 months after the results are published

**To whom data/document is available**

Academic and scientific researchers

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

A practical program for applying the results in society

**From where data/document is obtainable**

Correspondence by email to: AziziM982@mums.ac.ir

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

Providing the reason for the request and data usage and, if approved, providing documentation

**Comments**