# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

25 Jun 2026

## Comparing the effects of Xbox Kinect and aerobic exercise on blood pressure, quality of sleep, and quality life among elderly

## Protocol summary

**Study aim**
Comparison of the effect of aerobic exercise and Xbox Kinect on blood pressure and quality of sleep and life in elderly people with hypertension

**Design**
This study is the double-blind randomized trial. Participants randomly divided into three groups of aerobic(15), Xbox(15), and control(15).

**Settings and conduct**
Participants divided into three groups of aerobic, XBox and control. In this single-blind study, the outcome assessors are blind to the details of protocols. This study was done in the Jahandidegan retirement community center. duration of exercise is 8 weeks and three times per week and 40 min for each session.

**Participants/Inclusion and exclusion criteria**
Inclusion Criteria: the age of participants be 50 years and above; Willing to participate in the study; At least one year has passed since the diagnosis of primary hypertension by a specialist physician; No underlying diseases like diabetes, congestive heart failure, nephropathy; They have not participated in any other exercise program in the past six months;.. Have systolic and diastolic blood pressure; The participants are authorized to participate in the exercise program with the permission of a specialist physician; Having no physical limitation to attend exercise; Exclusion Criteria: Acute or chronic disease with documented influence on balance and gait Control (e.g., Parkinson's disease; diabetes or peripheral neuropathy); Joint replacement and fracture; Use of assertive gait devices (e.g., walking canes and frames; Missing exercise protocol more than two sessions;

**Intervention groups**
1. Aerobic Exercise Group: Perform aerobic exercises for 8 weeks and three days a week 2. Video Game Training Group: The players play Xbox Kinect games for 8 weeks and three days a week. Control group: without exercise

**Main outcome variables**
Blood Pressure; Quality of Life; Quality of Sleep

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20180627040251N1**
Registration date: **2020-03-30, 1399/01/11**
Registration timing: **retrospective**

Last update: **2020-03-30, 1399/01/11**
Update count: **0**

**Registration date**
2020-03-30, 1399/01/11

**Registrant information**

**Name**
Hassan Sadeghi

**Name of organization / entity**
Kharazmi University

**Country**
Iran (Islamic Republic of)

**Phone**
+98 21 2222 8001

**Email address**
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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2019-10-22, 1398/07/30

**Expected recruitment end date**
2020-02-19, 1398/11/30

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Comparing the effects of Xbox Kinect and aerobic exercise on blood pressure, quality of sleep, and quality life among elderly

**Public title**
Effects of aerobic exercises and Xbox Kinect on blood pressure, quality of sleep and life of older adults

**Purpose**
Health service research

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Age 50 years and above Willing to participate in the study At least one year has passed since the diagnosis of primary hypertension by a specialist physician No underlying diseases like diabetes, congestive heart failure, nephropathy They have not participated in any other exercise program in the past six months With a systolic blood pressure of 120-140 mmHg and diastolic blood pressure of 90-80 mmHg The participants are authorized to participate in the exercise program with the permission of a specialist physician Having no physical limitation to attend exercise Having a sense of hearing and vision

**Exclusion criteria:**
acute or chronic disease with documented influence on balance and gait control (e.g., Parkinson’s disease; diabetes or peripheral neuropathy Joint replacement and fracture use of assertive gait devices (e.g., walking canes and frames Missing exercise protocol more than two session

**Age**
From **50 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**
Target sample size: **45**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Simple randomization

**Blinding (investigator's opinion)**
Single blinded

**Blinding description**
In this study, the outcome assessor is blind to interventions during the pre-test and post-test.

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethical Committee of Shiraz University of Medical Science

**Street address**
5th Floor, Central building of Shiraz University of Medical Sciences, Zand St., Shiraz, Iran

**City**
Shiraz

**Province**
Fars

**Postal code**
71348-14336

**Approval date**
2019-07-20, 1398/04/29

**Ethics committee reference number**
IR.SUMS.REC.1398.669

## Health conditions studied

### 1

**Description of health condition studied**
Blood Pressure

**ICD-10 code**
R03

**ICD-10 code description**
Abnormal blood-pressure reading, without diagnosis

### 2

**Description of health condition studied**
Quality of Life

**ICD-10 code**
Z73

**ICD-10 code description**
Problems related to life management difficulty

### 3

**Description of health condition studied**
Quality of Sleep

**ICD-10 code**
G47

**ICD-10 code description**
Sleep disorders

### 4

**Description of health condition studied**
Aerobic Exercise

**ICD-10 code**
Y93.A3

**ICD-10 code description**
Activity, aerobic and step exercise

## Primary outcomes

### 1

**Description**
Blood Pressure
**Timepoint**
Before and after intervention
**Method of measurement**
Aneroid Sphygmomanometer Measure

## Secondary outcomes

### 1

**Description**
Quality of Life
**Timepoint**
Before and after intervention
**Method of measurement**
Quality of Life questioner

### 2

**Description**
Quality of Sleep
**Timepoint**
Before and after intervention
**Method of measurement**
Quality of sleep Questioner

## Intervention groups

### 1

**Description**
Exergame Intervention group: Participants play video games with Xbox Kinect for 8 weeks and three days a week. The duration of each session is 40 minutes, including pre-workout warm-up, a video game program, and post-workout cooling.
**Category**
Rehabilitation

### 2

**Description**
Intervention group Aerobic Exercise: Participants do aerobic exercise for 8 weeks and three days a week. The duration of each session is 40 minutes, including pre-workout warm-up, aerobic exercise program, and post-workout cooling.
**Category**
Rehabilitation

### 3

**Description**
Control group without exercise or Intervention: Participants in this group will have no exercise during the study
**Category**
N/A

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Jahandidegan Community Center in Shiraz
**Full name of responsible person**
Dr Mosavi
**Street address**
Khold Barin Park, Besaat St., Shiraz. Iran
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Jahandidegandaycare@yahoo.com

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Shiraz University of Medical Sciences
**Full name of responsible person**
Dr. Younes Ghasemi
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7th floor, Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd., Shiraz,
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**Email**
vcrdep@sums.ac.ir
**Web page address**
http://research.sums.ac.ir/fa/index.html
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Shiraz University of Medical Sciences
**Proportion provided by this source**
60
**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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Mohammadali Nazarinia

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Dermatology

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## Person responsible for scientific inquiries

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**Full name of responsible person**

Hassan Sadeghi

**Position**

Researcher

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Sport Medicine

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## Person responsible for updating data

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**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Hassan Sadeghi

**Position**

Researcher

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Sport Medicine

**Street address**

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**Web page address**

http://sgrc.sums.ac.ir/fa/contact_us/index.html

## 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**

Yes - There is 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**

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**

The data can publish for publishing paper

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

The study protocol will be available after publishing the paper

**To whom data/document is available**

everyone

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

For future studies

**From where data/document is obtainable**

Via email

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

The applicant needs to introduce his/her and need to explain the purpose of request as well. The information will send you as soon as possible.

**Comments**