Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Iran (Islamic Republic of)

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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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Younes Ghasemi
Street address
7th floor, Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd., Shiraz,
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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

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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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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Other areas of specialty/work

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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

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