

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Comparing the effect of exergame and balance training on knee proprioception, balance and quality of life among older adults. Randomized control trial

Protocol summary

Study aim

The purpose of the study is to compare effect of exergame, strength training and mixed of them on knee proprioception, balance and quality of life among elderly

Design

A randomized clinical trial study, single-blind, Factorial, 56 elderly randomized to 3 intervention groups and a control group through web-based randomization

Settings and conduct

Participants are divided into four groups: Balance training, exergame, the combination of balance, and exergame, and control groups. This study is single-blind that the outcome assessor is blind to interventions. This study will be conducted in the neighborhood of Tehran Municipality, District 7, and the participants will be explained the importance of protocol. The protocols are 8 weeks and three 40-minute sessions per week.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 65 years of age and older with the ability and mobility to join the group training sessions. Able to walk without an Assistive Device. Exclusion Criteria: Have acute or chronic disease with influence on balance control (e.g., Parkinson's disease; diabetes or peripheral neuropathy). Who participated in regular exercise programs in the last 6th month.

Intervention groups

Balance training (intervention 1): Balance training is done for 8 weeks and three days a week 2. Video game training (intervention 2): Participants play Xbox Kinect games for 8 weeks and three days in the week. 3 combinations of both (intervention 3): the combination of Xbox games and balance training for 8 weeks and three days a week. 4. Control group: There is no activity during the 8 weeks of the training program.

Main outcome variables

Knee proprioception, Balance, Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180627040251N4**

Registration date: **2021-09-14, 1400/06/23**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-14, 1400/06/23**

Update count: **0**

Registration date

2021-09-14, 1400/06/23

Registrant information

Name

Hassan Sadeghi

Name of organization / entity

Kharazmi University

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 8001

Email address

hassan.sadeghi81@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-01, 1400/05/10

Expected recruitment end date

2021-10-04, 1400/07/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of exergame and balance training on knee proprioception, balance and quality of life among older adults. Randomized control trial

Public title

Comparison of exergame and balance exercises on balance and knee proprioception of the elderly

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

65 years of age and older with the ability and mobility to join the group training sessions. Able to walk without an Assistive Device.

Exclusion criteria:

Have acute or chronic disease with influence on balance control (e.g., Parkinson's disease; diabetes or peripheral neuropathy). Who participated in regular exercise programs in the last 6th month.

Age

From **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomized into one of four groups (Three intervention and one control) using an online randomization system (randomizer.org). A member of the research team who is not involved in the selection of samples will determine the randomization sequence using a computer program. Participants will be notified of their group allocation with a sealed envelope.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the outcome assessor is blind to the groups' randomization and interventions receiving by participants. In this way, during the evaluation before and after the intervention protocol, they do not make mistakes in their judgments in favor of a specific therapeutic intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Sport Sciences Research Institute (SSRI)

Street address

No. 3, 5th Alley, Miremad Street, Motahhari Street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1587958711

Approval date

2021-07-20, 1400/04/29

Ethics committee reference number

IR.SSRC.REC.1400.076

Health conditions studied

1

Description of health condition studied

Fall

ICD-10 code

R29.6

ICD-10 code description

Repeated falls

2

Description of health condition studied

Gait

ICD-10 code

R26

ICD-10 code description

Abnormalities of gait and mobility

3

Description of health condition studied

posture

ICD-10 code

R29.3

ICD-10 code description

Abnormal posture

4

Description of health condition studied

Balance exercises

ICD-10 code

Y93.B9

ICD-10 code description

Activity, other involving muscle strengthening exercises

5

Description of health condition studied

Quality of Life

ICD-10 code

Z73

ICD-10 code description

Problems related to life management difficulty

Primary outcomes

1

Description

Knee Proprioception test

Timepoint

immediately before intervention; immediately after intervention and 3 month after intervention

Method of measurement

Biodex Isokinetic Dynamometer

Secondary outcomes

1

Description

Static Balance

Timepoint

immediately before intervention; immediately after intervention and 3 month after intervention

Method of measurement

Single leg Stance test

2

Description

Quality of Life

Timepoint

immediately before intervention; immediately after intervention and 3 month after intervention

Method of measurement

Quality of Life questioner

Intervention groups

1

Description

Intervention group1: In this group, the Exergaming training sessions are done by the Xbox Kinect, which uses Console and Kinect Sensors. The sensor is an infrared camera that diagnoses the position and movements of the player automatically and records the various activities of the participants. By selecting the games, the person is placed in front of the infrared camera and performs the movements based on the movements performed by the console. The experiment is carried out three times per week and continues for eight weeks. Each session will be 40 minutes, which includes warming up and cooling down before and after the exercise.

Category

Rehabilitation

2

Description

Intervention group 2: Three times per week in eight weeks of balance exercises. These exercises' programs are including activities to improve balance and lower limb muscle proprioception. Such exercises are the single leg stance with eyes open and closed, then standing on the unstable surface. The duration of each session is 40 minutes, including warming up and cooling down before and after the exercise sessions.

Category

Rehabilitation

3

Description

Intervention group 3: Participants of this group perform two types of exercises including exergame and balance in each session three times per week in eight weeks. Half of the training session time is assigned to exergame (intervention one) and the other half is devoted to balance exercises (intervention two). Each session, which includes warming up and cooling down before and after the exercise, lasts for 40 minutes.

Category

Rehabilitation

4

Description

Control group 1: without any intervention. During this period, the control group asked to perform routine daily activities and not participate in specific exercises.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Department of Municipality District 7

Full name of responsible person

Miss Maryam Priyaie

Street address

Gorgan Neighborhood House, Tavakoli Park, Shahid Madani St,

City

Tehran

Province

Tehran

Postal code

1615786614

Phone

+98 21 7754 0432

Email

info.region7@tehran.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kharazmi University

Full name of responsible person

Dr Jamshid Shanbehzadeh

Street address

Vice-Chancellor for Research and Technology. No. 43.
South Mofatteh Ave., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

15719-14911

Phone

+98 21 2222 8001

Fax**Email**

Jamshids@khu.ac.ir

Web page address

<https://research.khu.ac.ir/en>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kharazmi University

Proportion provided by this source

50

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**

Kharazmi University

Full name of responsible person

Dr. Hassan Sadeghi

Position

Postdoctoral Research

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

Street address

3th floor. Faculty of sport science and Physical
Education, Shahid Keshvari Sports Complex, Razan
Jonobi, Mirdamad,

City

Tehran

Province

Tehran

Postal code

33111-15447

Phone

+98 21 2222 8001

Email

Hassan.sadeghi81@yahoo.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Kharazmi University

Full name of responsible person

Dr. Hassan Sadeghi

Position

Postdoctoral Research

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

Street address

3th floor. Faculty of sport science and Physical
Education, Shahid Keshvari Sports Complex, Razan
Jonobi, Mirdamad,

City

Tehran

Province

Tehran

Postal code

33111-15447

Phone

+98 21 2222 8001

Email

Hassan.sadeghi81@yahoo.com

Person responsible for updating data

Contact**Name of organization / entity**

Kharazmi University

Full name of responsible person

Dr. Hassan Sadeghi

Position

Postdoctoral Research

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

Street address

3th floor. Faculty of sport science and Physical
Education, Shahid Keshvari Sports Complex, Razan
Jonobi, Mirdamad,

City

Tehran

Province

Tehran

Postal code

33111-15447

Phone

+98 21 2222 8001

Email

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

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

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

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