Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

Hassan.sadeghi81@yahoo.com

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