Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the effect of 8 weeks Xbox Kinect and strength training on balance and Biomechanical parameters of gait among elderly fallers

Protocol summary

Study aim
The purpose of the study is to compare effect of exergame, strength training and mixed of them on balance and walking ability of elderly fallers

Design
A randomized clinical trial study, single-blind, Factorial, 52 elderly randomized to 3 intervention groups and a control group through web-based randomization.

Settings and conduct
Participants are divided into four groups: strength training, exergame, the combination of strength, 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 to join the study. had a history of falls in the previous year. No history of syncope falls. Able to walk without an Assistive Device. Obtain the score of less than 24 for a Mini-mental state examination (MMSE). Obtain a score of less than 26 on the Montreal Cognitive Assessment. Exclusion Criteria: Have acute or chronic disease with an 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
Strength training (intervention 1): Strength 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 strength 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
Gait analysis, Static Balance, Dynamic Balance, Cognitive assessment score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180627040251N2**
Registration date: **2020-06-29, 1399/04/09**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-29, 1399/04/09**
Update count: **0**

Registration date
2020-06-29, 1399/04/09

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
2020-06-17, 1399/03/28

Expected recruitment end date
2020-08-18, 1399/05/28

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of 8 weeks Xbox Kinect and strength training on balance and Biomechanical parameters of gait among elderly fallers

Public title

Exergame and strength training on gait and balance among elderly fallers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

65 years of age and older with the ability and mobility to join the group training sessions. Had a history of falls in the previous year. Able to walk without an Assistive Device. Obtain score less than 24 on the Mini-mental state examination (MMSE) . Obtain score less than 26 on the Montreal Cognitive Assessment. No history of syncope falls.

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: **52**

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

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Kharazmi University-Iran

Street address

Enghlab- Mofateh St. Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۹۱۱-۱۵۷۱۹

Approval date

2020-01-12, 1398/10/22

Ethics committee reference number

IR.KHU.REC.1398.038

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

Mild cognitive impairment

ICD-10 code

G31.84

ICD-10 code description

Mild cognitive impairment, so stated

5

Description of health condition studied
Ṡtrength Exercises
ICD-10 code
Y93.B9
ICD-10 code description
Activity, other involving muscle strengthening exercises

Primary outcomes

1

Description
Gait Analysis
Timepoint
Before and after Exercise Protocol
Method of measurement
Motion analysis systems

Secondary outcomes

1

Description
Static Balance
Timepoint
Before the exercise program and after exercise program
Method of measurement
Biodex Balance System SD

2

Description
Functional Mobility
Timepoint
Before the exercise program and after exercise program
Method of measurement
Timed Up and Go test (TUG)

3

Description
Cognitive Assessment
Timepoint
Before the exercise program and after exercise program
Method of measurement
Montreal Cognitive Assessment

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 strength exercises. These exercises' programs are including activities to improve lower limb muscle strength. Such exercises are the Theraband exercises and sit to stand exercises with chair depending on the ability of the participants. 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 strength 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 strength 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 Priyaie
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Gorgan Neighborhood House, Tavakoli Park, Shahid Madani St,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran's National Elites Foundation
Full name of responsible person
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Fax
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran's National Elites Foundation
Proportion provided by this source
90
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

2

Sponsor
Name of organization / entity
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Full name of responsible person
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Web page address
https://pess.khu.ac.ir/index.php?sid=42&slc_lang=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
10
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
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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
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