Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of home-based exercise in older adults

Protocol summary

Study aim
The aim of the present study is to help the elderly adult during the corona pandemic to perform home-based exercise to improve postural control, physical self-efficacy and improve their quality of life.

Design
Double-blind randomized clinical trial with control group (n=36).

Settings and conduct
The present quasi-experimental study is performed in the rehabilitation laboratory of Arak University. The experimental groups performs Otago and Fit and fall proof home-based exercise for 8 weeks, 3 sessions per week. Static and dynamic balance, quality of life, fear of falling, physical and cognitive self-efficacy measure with 4 stage static balance test, timed up and go test, OPQOL-35, FES-I questionnaire, SSEA and MMSE quesionnaire respectively. Data analyzer and evaluators do not know how to allocate and group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age range 60-80 years, no history of spine surgery and hip replacement. Exclusion criteria: history of cardio-respiratory disorders in the last two years, visual impairment, severe musculoskeletal disorders such as severe osteoarthritis.

Intervention groups
Intervention groups: The participants in the intervention group 1,2 perform Otago and fit and fall proof exercises respectively for eight weeks, three sessions per week. Control group: They will have the usual routine of their lives.

Main outcome variables
Static and dynamic balance, quality of life, fear of falling, physical and cognitive self-efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200204046368N6**
Registration date: **2021-08-14, 1400/05/23**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-14, 1400/05/23**
Update count: **0**

Registration date
2021-08-14, 1400/05/23

Registrant information

Name
Zahra Raeisi
Name of organization / entity
Arak University
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-12, 1400/05/21

Expected recruitment end date
2021-08-20, 1400/05/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of home-based exercise in older adults

Public title
Home based exercise and older adults

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age 60 to 80 years No neurological disorders such as Alzheimer's, MS, Parkinson's No musculoskeletal disorders such as rheumatoid arthritis and muscular dystrophy

Exclusion criteria:

History of spine or hip surgery Visual impairment Any illness that can affect the research variables

Age

From **60 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is parallel. The randomization unit is individual. The Randlist software is used to randomly assign subjects to study groups. At , the number of subjects and groups is given to the software. Then, with this software, each subject is assigned a code. A group is then randomly assigned to each code by the software.

Blinding (investigator's opinion)

Double blinded

Blinding description

The researcher that do laboratory tests were not aware of the allocation of study groups. The data analyzer will not be aware of the groups classification. The information of the groups will be provided to the data analyzer in the form of numbers 1, 2, 3 and for each participant with a code.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Bu Ali Sina university ethics committee in research

Street address

Shahid Mostafa Ahmadi Roshan Street

City

Hamedan

Province

Hamadan

Postal code

6517838695

Approval date

2021-07-10, 1400/04/19

Ethics committee reference number

IR.BASU.REC.1400.022

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Static and dynamic balance

Timepoint

Before and after 8 week intervention

Method of measurement

4 stage static balance test and timed up and go test

2

Description

Quality of life

Timepoint

Before and after 8 week intervention

Method of measurement

Older People’s Quality of Life Questionnaire (OPQOL-35)

3

Description

Fear of falling

Timepoint

Before and after 8 week intervention

Method of measurement

Falls Efficacy Scale - International Questionnaire (FES-I)

4

Description

physical and cognitive self-efficiency

Timepoint

Before and after 8 week intervention

Method of measurement

self-efficacy scale (SSES) questionnaire and Mini-Mental State Exam (MMSE) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: The intervention group 1 performs Otago exercises for 8 weeks, 3 sessions per week. Subjects are monitored by researchers every week. They write down their activity level in a notebook.Exercise booklet including complete guide and video including explanations and how to perform the exercises correctly will be provided to the participants.
Category
Rehabilitation

2

Description
Intervention group 2: The intervention group 2 performs Fit and fall proof exercises for 8 weeks, 3 sessions per week. Subjects are monitored by researchers every week. They write down their activity level in a notebook.Exercise booklet including complete guide and video including explanations and how to perform the exercises correctly will be provided to the participants.
Category
Rehabilitation

3

Description
Control group: The control group performs their normal activities for 8 weeks.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Arak university
Full name of responsible person
Zahra Raeisi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Arak university
Proportion provided by this source
100
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
Arak University
Full name of responsible person
Zahra Raeisi
Position
Assistant professor
Latest degree
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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
Not applicable

Data Dictionary
Not applicable