Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

The effect of single and dual task balance training on balance, cognitive function and fear of falling retired recovered from COVID-19

Protocol summary

Study aim

Investigate the effect of single and dual task balance training on, fear of falling, cognitive function and balance of older adults who recovers from COVID 19

Design

A semi-experimental clinical trial with a control group with parallel groups, two-way blind randomized on 45 patients. Rand function of Excel software was used for randomization.

Settings and conduct

After achieving the entry criteria, people were divided into three groups of single and dual task balance training and control based on the score inTime up and go test. The experimental groups perform exercises for 4 weeks and a total of 12 sessions. The dual task training group performed cognitive tasks at the same time as balancing tasks. All groups in the pre-test and post-test stage only performed balance tasks without cognitive tasks at the same time.

Participants/Inclusion and exclusion criteria

The criteria for entering the research are at least 60 years old, being able to read and write, living in Kerman, and being able to walk a distance of 10 meters without aids. The severity of COVID 19 in these people is at level 1 whose symptoms include headache, loss of sense of smell, cough, fever, chest pain and fatigue. And those who were severely affected by this disease were not selected in this research. Exclusion criteria include: psychosis and acute psychiatric conditions, progressive psychiatric diseases such as MS and Parkinson's, scoring less than 24 on the MMSE, visual and auditory impairment

Intervention groups

The experimental groups performed the exercises under conditions with and without dual task, while the participants in the control group only participate in the pre-test and post-test

Main outcome variables

Fall prevention; Improve balance; Reduce age-related cognitive disorders; Improvement of the psychological factor associated with falling; Reducing the side effect of Covid 19.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221207056741N1**
Registration date: **2023-05-01, 1402/02/11**
Registration timing: **retrospective**

Last update: **2023-05-01, 1402/02/11**
Update count: **0**

Registration date

2023-05-01, 1402/02/11

Registrant information

Name

Hesam Iranmanesh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3281 4885

Email address

hesam.iranmanesh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-25, 1401/11/05

Expected recruitment end date

2023-03-06, 1401/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of single and dual task balance training on balance, cognitive function and fear of falling retired recovered from COVID-19

Public title

The effect of single and dual task balance training on balance dependent factors of older adults recovered from COVID-19

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Aging between 60-80 Ability to stand for a minute and walk for 10 for 10 minutes without and aids and stick Normal vision Being able to read and write Being healthy or not having used any balance affecting medicine Having tested positive in COVID19 and being hospitalized in a recent year Living in Kerman city Scoring more than 24 points at Standardized Mini-Mental State Examination

Exclusion criteria:

Progressive neurological condition such as Parkinson disease, or Alzheimer Existence of cardiovascular disease (myocardial infarction, congestive heart disease, uncontrolled blood pressure, hypotension, decreased heart rate) Significant visual and auditory impairments History of depression, anxiety or other mental disorders Having a history of rheumatic and metabolic diseases such as rheumatoid arthritis, diabetes Existence of severe deformities of the joints of the lower limbs or trunk, such as severe Kyphosis or scoliosis, severe osteoarthritis of the hip and knee joints. Having a history of balance disorder and frequent positional dizziness Having a history of joint replacement in the lower limb Consuming alcohol, sedatives or any type of special medicine that affects balance or cognitive status. High inflammation of lungs up to 40% due to COVID 19

Age

From **60 years** old to **75 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

All of the participants in this investigation are divided in tow experimental groups and a control group. they will be participated in a per-test, training and post-test in separate days and they will not be in communication with each other. Therefor there would be a one-way blinding

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Baqiyatullah University of Medical Sciences

Street address

MollaSadra street, Vanak Square, Tehran

City

Tehran

Province

Tehran

Postal code

1435915371

Approval date

2023-02-25, 1401/12/06

Ethics committee reference number

IR.BMSU.BAQ.REC.1401.126

Health conditions studied

1

Description of health condition studied

COVID 19

ICD-10 code

U09.9

ICD-10 code description

Post Covid 19 Condition

Primary outcomes

1

Description

Berg Balance scale to measure functional balance status in elderly people.

Timepoint

In this research, this variable will be taken from people 24 hours before the training phase and 24 hours after the end of the last training session.

Method of measurement

This test consists of 14 sub-tests that will be administered by the examiner and higher scores in this test indicate higher functional balance. To perform this test, very simple devices such as a timer, a ruler, and a step with a height of 18 to 20 cm will be used.

2

Description
People's reaction time in serial reaction time software to measure cognitive performance in elderly people.
Timepoint
In this research, this variable will be taken from people 24 hours before the training phase and 24 hours after the end of the last training session.
Method of measurement
In this test, the person must respond to the stimuli that are presented in a specific and predetermined pattern on the monitor screen as quickly as possible. For the answer, the person must press the desired key of each stimulus on the keyboard. Reaction time refers to the duration of the presentation of the stimulus until the response to it. Obviously, the faster a person responds, it shows the learning of the sequence and the better functioning of the central nervous and cognitive system of the person.

3

Description
Gait speed in Timed Up And Go Test.
Timepoint
In this research, this variable will be taken from people 24 hours before the training phase and 24 hours after the end of the last training session.
Method of measurement
Timed Up And Go test will be used to measure gait speed. In this test, the person has to get up from a chair with a handle with a height of approximately 46 cm and a handle height of 65 cm, walk 3 meters, go around an obstacle, turn around and sit down. The person performs this test in two conditions with and without the cognitive task at the same time.

4

Description
Measuring the psychological variable of fear of falling by Yardley et al.'s (2005) fear of falling scale.
Timepoint
In this research, this variable will be taken from people 24 hours before the training phase and 24 hours after the end of the last training session.
Method of measurement
This questionnaire contains 16 questions that people fill in two stages at the beginning and at the end of the training protocol. Higher scores in this test indicate greater fear of falling and lower self-efficacy.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 1- Single task balance exercise 2- Dual task balance training group 3- Control group, In this research, the single task exercise group only practices balance exercises, while the dual task exercise group simultaneously performs cognitive activity at the same time as balance exercise. The control group in this research only participates in the pre-test and post-test.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Fateme Zahra Hospital
Full name of responsible person
Hossain Shirvani
Street address
Parvin Eetesami St,
City
Kerman
Province
Kerman
Postal code
76139 77895
Phone
+98 34 3246 6116
Email
Info@bmsu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Hossain Shirvani
Street address
Vanak Square, Molla Sadra street
City
Tehran
Province
Tehran
Postal code
1435916471
Phone
+98 21 8804 0060
Email
Info@bmsu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bagheiat-allah University of Medical Sciences
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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

hossain shirvani

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

Street address

MollaSadra street,Vanak Square

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

021880400600912

Email

shirvani.h2006@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Hesam Iranmanesh

Position

Phd candidate

Latest degree

Master

Other areas of specialty/work

Motor behaviour

Street address

No. 9 Rezvan alley, Rezvan blvd, Kerman, Iran

City

kerman

Province

Kerman

Postal code

7618973741

Phone

+98 34 3281 4885

Email

hesam.iranmanesh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

hesam iranmanesh

Position

Phd

Latest degree

Master

Other areas of specialty/work

Motor behaviour

Street address

No. 9, Rezvan blvd, Kerman, Iran

City

kerman

Province

Kerman

Postal code

7618973741

Phone

+98 34 3281 4885

Email

hesam.iranmanesh@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The data will be presented as results of the articles

When the data will become available and for how long

One year after publication

To whom data/document is available

The users of the data will be determined according to the opinion of the project officials and Baqiyatullah University of Medical Sciences

Under which criteria data/document could be used

Only under the supervision of Baqiyatullah University of Medical Sciences

From where data/document is obtainable

Baqiyatullah University of Medical Sciences

What processes are involved for a request to access data/document

After the completion of the testing process and a month has passed since its end, the applicant can receive the required information by sending an email to the address of Baqiyatullah University. It is obvious that the

information will be provided to them at the discretion of Baqiyatullah University.

Comments