# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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**

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**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
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## Sponsors / Funding sources

**1**

**Sponsor**
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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**
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**

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**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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**Other areas of specialty/work**

Motor behaviour

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## Person responsible for updating data

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**Latest degree**

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## 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**