

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of virtual reality based training and motor-cognitive dual task training effects on the linear and nonlinear features of center of pressure in older adults

Protocol summary

Summary

The main purpose of this study is to find which type of treatment (cognitive-motor intervention or virtual reality method) is more effective to improve the postural control of older adults. It is estimated 27 healthy older adults are sufficient for this study. The inclusion criteria for healthy older adults are the following: Age \geq 65 years old, be free from any severe cardiopulmonary disease, neurological disorder, musculoskeletal impairment or any history of falls in the prior 6 months. Subjects are excluded from either group if had any dizziness, fatigue, vigorous physical activity or stress before testing. After baseline evaluation, subjects are randomly allocated to one of the two groups: (1) cognitive-motor dual-task training, (2) virtual reality based training. Cognitive-motor dual-task training is balance training while simultaneously engaging in a secondary cognitive task. Virtual reality based training is balance training in a virtual environment using programs of Wii fit. Participants in these groups are attended 12-16 sessions, 3 sessions per week, and 60 minutes per session. The outcome measurements take place at 3 time points: (1) before initiation of intervention (baseline), (2) after completion of training, (3) 8 weeks after completion of training. The outcome measurements are linear and nonlinear parameters of center of pressure under different dual task conditions and parameters related to clinical and neurocognitive tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016122626779N2**

Registration date: **2016-12-30, 1395/10/10**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-12-30, 1395/10/10

Registrant information

Name

Hossein Bagheri

Name of organization / entity

Tehran University of Medical Sciences, Faculty of Rehabilitation

Country

Iran (Islamic Republic of)

Phone

+98 21 7753 3939

Email address

hbagheri@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of virtual reality based training and motor-cognitive dual task training effects on the linear and nonlinear features of center of pressure in older adults

Public title

Comparison of virtual reality based training and motor-cognitive dual task training effects on the linear and nonlinear features of center of pressure in older adults

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age \geq 65 years old; BBS score $>$ 40; TUG score \leq 20; ABC score \geq 50%; MMSE score \geq 24; HADS- depress subscale score \leq 7; Have no severe cardiopulmonary disease, neurological disorder and musculoskeletal impairment; Have no history of falls in the prior 6 months. Exclusion criteria: had vigorous physical activity before testing; had dizziness, fatigue, and stress during testing

Age

From **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **27**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Tehran University of Medical Sciences

Street address

Central Organization of Tehran University of Medical Sciences, Qods St., Keshavarz Blvd.

City

Tehran

Postal code

Approval date

2016-12-24, 1395/10/04

Ethics committee reference number

REC-1395-1294

Health conditions studied

1

Description of health condition studied

elderly

ICD-10 code

G31.1

ICD-10 code description

Senile degeneration of brain, not elsewhere classified

Primary outcomes

1

Description

Verbal reaction accuracy

Timepoint

before training, after completion of training, 8 weeks
after completion of training

Method of measurement

Recorder - Sound Forge Pro

2

Description

Correlation dimension

Timepoint

before training, after completion of training, 8 weeks
after completion of training

Method of measurement

force plate

3

Description

Verbal reaction time

Timepoint

before training, after completion of training, 8 weeks
after completion of training

Method of measurement

Recorder - Sound Forge Pro

4

Description

Lyapunov exponent

Timepoint

before training, after completion of training, 8 weeks
after completion of training

Method of measurement

force plate

5

Description

approximate entropy

Timepoint

before training, after completion of training, 8 weeks
after completion of training

Method of measurement

force plate

6

Description

Postural sway area

Timepoint

before training, after completion of training, 8 weeks
after completion of training

Method of measurement

force plate

7

Description

Phase plane

Timepoint

before training, after completion of training, 8 weeks
after completion of training

Method of measurement

force plate

8

Description

Velocity of center of pressure displacement

Timepoint

before training, after completion of training, 8 weeks
after completion of training

Method of measurement

force plate

9

Description

Standard deviation of center of pressure displacement

Timepoint

before training, after completion of training, 8 weeks
after completion of training

Method of measurement

force plate

Secondary outcomes

1

Description

BBC score

Timepoint

before training, after completion of training, 8 weeks
after completion of training

Method of measurement

Questionnaire

2

Description

TUG time

Timepoint

before training, after completion of training, 8 weeks
after completion of training

Method of measurement

Timmer

3

Description

ABC score

Timepoint

before training, after completion of training, 8 weeks
after completion of training

Method of measurement

Questionnaire

4

Description

TMT (A,B) score

Timepoint

before training, after completion of training, 8 weeks
after completion of training

Method of measurement

Questionnaire and timer

Intervention groups

1

Description

Balance training in a virtual environment using programs of Wii fit. Participants in this group are attended 12-16 sessions, 3 sessions per week, and 60 minutes per session.

Category

Behavior

2

Description

Balance training while simultaneously engaging in a secondary cognitive task. Participants in this group are attended 12-16 sessions, 3 sessions per week, and 60 minutes per session.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Rehabilitation Faculty

Full name of responsible person

Dr. Roya Khanmohammadi

Street address

Tehran-enghelab street- piche shemiran- Physical
Therapy Department

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences Vice chancellor for research

Full name of responsible person

Dr. Masud Yunesian (Research Deputy of Tehran University of Medical Sciences)

Street address

Central Organization of Tehran University of Medical Sciences, Qods St., Keshavarz Blvd.

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran University of Medical Sciences Vice chancellor for research

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Rehabilitation Faculty- Tehran University of Medical Sciences

Full name of responsible person

Dr. Roya Khanmohammadi

Position

PhD of physiotherapy

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Professor

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty