

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 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 timmer

## **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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**Web page address****Person responsible for scientific  
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Rehabilitation Faculty- Tehran University of Medical  
Sciences

**Full name of responsible person**

Dr. Hossein Bagheri

**Position**

Professor

**Other areas of specialty/work****Street address**

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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*