

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of twelve weeks of low intensity combined exercise with visual stimulation on cognitive and physical performance and brain wave changes of Alzheimer's patients

#### Protocol summary

##### Study aim

Effect of 12 weeks of combined training with visual stimulation on brain wave changes and physical status of Alzheimer's patients

##### Design

A clinical trial with control group, with parallel groups, single-blind, randomized, phase two on 32 patients with Alzheimer's disease. Randomization will be done through block randomization method (blocks of size 4) using the website <https://www.sealedenvelope.com/simple-randomiser/v1/lits>.

##### Settings and conduct

How to do the study: field research. Place of study: Roozbeh Hospital in Tehran.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients age (60-75 years); minimal ability to do exercise; mild cognitive impairment. Non-inclusion criteria: Patients who are unable to walk or stand; vascular cognitive impairment; Dementia depression.

##### Intervention groups

Intervention group: The participants in the intervention group executed 24 workouts; twice a week for 12 weeks. Each session lasted about 40- 60 minutes in which 10 minute for warm-up, 20-40 minutes for main exercises and 10 minutes for cool down. The participants performed a combined protocol included brain activity (with closed eyes and cognitive activities) and physical activity (muscle endurance, balance, aerobic capacity). Control group: without any intervention and training as a comparison of the disease process with the first intervention group.

##### Main outcome variables

Primary outcome variables: Cognitive and physical performance. Secondary outcome variables: Changes in brain waves in EEG

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190504043468N1**

Registration date: **2020-08-05, 1399/05/15**

Registration timing: **retrospective**

Last update: **2020-08-05, 1399/05/15**

Update count: **0**

##### Registration date

2020-08-05, 1399/05/15

##### Registrant information

##### Name

Elnaz Parvin

##### Name of organization / entity

Kharazmi University Of Tehran

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4490 2497

##### Email address

eparvin94@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-12-21, 1398/09/30

##### Expected recruitment end date

2020-01-29, 1398/11/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

The effect of twelve weeks of low intensity combined exercise with visual stimulation on cognitive and physical performance and brain wave changes of Alzheimer's patients

### Public title

Effects of low-intensity training on patients with Alzheimer's disease

### Purpose

Prevention

### Inclusion/Exclusion criteria

#### Inclusion criteria:

age range (50 -70 yr) ability to do exercise stage 1 and 2 Alzheimer's disease

#### Exclusion criteria:

Patients who are unable to walk or stand Patients suffering from Alzheimer's disease due to severe depression Alzheimer's patients who have this disease because of a heart attack Alzheimer's patients who develop Alzheimer's due to obstruction of the cerebrovascular system Patients with cardiovascular problems who are not allowed to exercise by their doctor

### Age

From **50 years** old to **75 years** old

### Gender

Both

### Phase

2

### Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

### Sample size

Target sample size: **32**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Allocating subjects to the study groups (intervention and control) was done through block randomization using blocks of size 4. This was done by the website (<https://www.sealedenvelope.com/simple-randomiser/v1/lists>). In each block, two subjects were from the intervention group and two subjects were from the control group, which was arranged randomly. Finally, eight blocks were used.

### Blinding (investigator's opinion)

Single blinded

### Blinding description

Practitioners, assessor, and analysts are not in the research team.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee for Research in Sport Science Research Institute

##### Street address

No 3; Fifth Alley; Miramad avenue; Motahari avenue

##### City

Tehran

##### Province

Tehran

##### Postal code

1587958711

#### Approval date

2019-03-11, 1397/12/20

#### Ethics committee reference number

IR.SSRC.REC.1398.037

## Health conditions studied

### 1

#### Description of health condition studied

Alzheimer's disease

#### ICD-10 code

G30.0

#### ICD-10 code description

Alzheimer disease with early onset

## Primary outcomes

### 1

#### Description

Cognitive changes

#### Timepoint

Once before practicing and once again at the end of twelve weeks of practice

#### Method of measurement

The questionnaire was based on the diagnosis of a physician and SPMSQ, cognitive status questionnaire MMSE; mental status brief examination ; Knowledgeable cognitive decline questionnaire on IQCDE ; The European dimension of the five dimensional quality of life D-EuroQol; Depression Scale of the Elderly GDS;

### 2

#### Description

Memory

#### Timepoint

Once before practicing and once again at the end of twelve weeks of practice

#### Method of measurement

ROLAND RUDAS global demographics scale

### 3

#### **Description**

Physical performance

#### **Timepoint**

Once before practicing and once again at the end of twelve weeks of practice

#### **Method of measurement**

The chair sit and reach test; Maximal isometric handgrip strength test; The timed up and go; The six minute walk test;

## **Secondary outcomes**

### 1

#### **Description**

Brain waves changes

#### **Timepoint**

Once before practicing and once again at the end of twelve weeks

#### **Method of measurement**

electroencephalogram

## **Intervention groups**

### 1

#### **Description**

Intervention group: Low-intensity compound exercises. The participants in the intervention group will perform 24 workouts twice a week for 12 weeks. Each session lasts about 40-60 minutes, including ten minutes of warm-up, 20-40 minutes of main exercises, and ten minutes of cool down. The participants adhered to a combined protocol, including brain activities (eyes-closed training and cognitive activities) and physical activities (muscle endurance, balance, and aerobic capacity). The main training protocol consisted of five parts. The first part of the training protocol includes sitting and standing on an armchair, accompanied by shoulder girdle strengthening (three sets with 5-15 reps, followed by a gradual increase in resistance and repetition, using dumbbells and Pilates bands). The second part includes crossing over five sponge obstacles (height: 15-20 cm) with eyes closed (two repetitions in the first three sessions, gradually increasing to two reps every three sessions); the distance between the obstacles is variable. In the third part, the participants cross over a safe balance beam board (2 m) with eyes closed (two repetitions in the first three sessions, gradually increasing to two reps every three sessions). In the fourth part, six-vowel stations are placed in a semicircular arrangement at a four-meter distance in front of the subject with eyes closed. The subjects would be asked to identify the sound of each station, move toward it, perform the predetermined exercises for 15 seconds (e.g., butterfly curls, Hercules curls, knee raises, hand raises, and biceps curls), and return. There are only two stations in the first session, which increases by one station every three sessions to reach a total of six stations. In the last part, there are four colored lights in front of the participants, each

indicating a predetermined exercise. As long as the light is on (10-15 seconds), the subject is required to perform the relevant exercise (e.g., red light: side-right lunge; blue light: side-left lunge; green light: backward right lunge; and yellow light: backward left lunge). This part will last for two minutes in the first session, which increases by one minute every three sessions to reach five minutes by the end. The exercises will change every three sessions and become more intense. The workouts are performed individually, and each individual will attend the center at a certain time. To monitor the workout intensity, heart rate (HR) is monitored by a smart watch. In this study, no specific drug is used.

#### **Category**

Rehabilitation

### 2

#### **Description**

Control group: without any intervention and training

#### **Category**

Rehabilitation

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Roozbeh Hospital

##### **Full name of responsible person**

Dr. Fatemeh Mohammadian

##### **Street address**

No.606; Karegar street; District 11

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

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##### **Phone**

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##### **Email**

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## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Kharazmi University

##### **Full name of responsible person**

Sadegh Amani-Shalamzari

##### **Street address**

No.43. South Mofatteh Ave.,

##### **City**

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##### **Province**

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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**

Kharazmi 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**

Kharazmi University

**Full name of responsible person**

Sadegh Amani-Shalamzari

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Exercise Physiologist

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

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**Full name of responsible person**

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**Position**

Assistant Professor

**Latest degree**

Ph.D.

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Sports Physiologist

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**Position**

Assistant Professor

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**Email**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Because of ethic issues

**Study Protocol**

No - There is not 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**

Undecided - It is not yet known if there will be a plan to

make this available  
**Data Dictionary**

Undecided - It is not yet known if there will be a plan to  
make this available