

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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/lists>.

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)

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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/ists>). 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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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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