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/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)

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, accompanies 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 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 became 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
۱۳۳۳۷۱۵۹۱۴
Phone
+98 21 5541 9151
Email
hosp_roozbeh@tums.ac.ir

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
Tehran
Province
Tehran
Postal code
15719-14911

Phone
+98 21 2222 3331
Email
amani_sadegh@yahoo.com
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
Street address
Kharazmi University, Daneshgah square, Shahid Beheshti street, Karaj
City
Karaj
Province
Alborz
Postal code
37551-31979
Phone
+98 26145796000
Email
amani_sadegh@yahoo.com

Person responsible for scientific 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
Sports Physiologist
Street address
Kharazmi University, Daneshgah square, Shahid Beheshti street, Karaj
City
Karaj
Province
Alborz
Postal code
37551-31979
Phone
+98 45796000261
Email
amani_sadegh@khu.ac.ir

Person responsible for updating data

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
Sports Physiologist
Street address
Kharazmi University, Daneshgah square, Shahid Beheshti street, Karaj
City
Karaj
Province
Alborz
Postal code
37551-31979
Phone
+98 26 1451 0006
Email
amani_sadegh@yahoo.com

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