Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effects of attention and working memory-based cognitive intervention on behavioral and neurological evidences of cognitive functions in older adults with mild cognitive impairment

Protocol summary

Study aim

The aim of this study was to investigate the effect of cognitive intervention based on strengthening attention and working memory on behavioral and neurological evidences of cognitive functions in the elderly with mild cognitive impairment.

Design

A randomized controlled clinical trial with balanced blocked randomization was conducted on 30 elderly people between August 2018 and March 2019.

Settings and conduct

Elderly people with MCI who were recruited from Rofideh rehabilitation hospital and Memory and Cognition Clinic (BCC), were divided into intervention and control groups by the secretary of the laboratory using balanced blocked randomization method after confirming their disorder according to the inclusion and exclusion criteria, performing neuropsychological tests and recording event-related potentials in the cognitive science laboratory of Shahid Beheshti University.

Participants/Inclusion and exclusion criteria

Elderly people over 60 years old with subjective memory complaint and objective memory impairment participated in this study; Individuals were excluded from the study based on the history of mental, neurological, and medical disorders, substance abuse, as well as unmodified sensory Impairment and hand mobility impairment.

Intervention groups

The intervention group attended 12 sessions of a cognitive intervention program scheduled twice a week. The 45-minute sessions were implemented using the Attentive Rehabilitation of Attention and Memory (ARAM) software. The ARAM is a computerized cognitive rehabilitation program with 10 graded progressive tasks for training attention and working memory. Participants assigned to the control group were on the waiting list and could receive cognitive intervention after a 3-month follow-up period.

Main outcome variables

selective attention; working memory; amplitude and latency of N100 and P300 brain potentials

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161204031227N1**
Registration date: **2021-08-09, 1400/05/18**
Registration timing: **retrospective**

Last update: **2021-08-09, 1400/05/18**
Update count: **0**

Registration date

2021-08-09, 1400/05/18

Registrant information

Name

Mahdieh Esmaeili Tarzi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8876 1695

Email address

mahdiye.esmaili@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-05, 1396/06/14

Expected recruitment end date

2018-03-05, 1396/12/14

Actual recruitment start date
2017-09-19, 1396/06/28
Actual recruitment end date
2018-05-11, 1397/02/21
Trial completion date
2018-05-19, 1397/02/29

Scientific title
The effects of attention and working memory-based cognitive intervention on behavioral and neurological evidences of cognitive functions in older adults with mild cognitive impairment

Public title
The efficacy of cognitive training intervention on cognitive functions of the older adults with mild cognitive impairment
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Monolingual Persian-speaking elderly people over 60 years old with education higher than elementary level Memory complaint by the patient or a close relative Objective Memory impairment in Rey Auditory Verbal Learning Test (1.5 SDs below the age-matched and education-matched norms) Independence in activities of daily living and complex activities of life Normal global cognitive function (Mini-Mental Status Examination score > 22) No evidence of dementia No depression (Geriatric Depression Scale score < 5)
Exclusion criteria:
History of a variety of neurological, medical and psychiatric disease including a history of stroke in the last 12 months, cardiovascular disease, schizophrenia, personality disorder, and bipolar disorder History of substance abuse Unmodified sensory impairment and hand mobility impairment History of participating in cognitive intervention programs in the last 6 months
Age
From **60 years** old to **100 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Actual sample size reached: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the patients were allocated to the intervention and control groups using balanced blocked randomization method. 4 blocks of size 8 with equal proportion of patients assigned to each group (intervention group A, and control group B) were used (i.e., 16 patients in each group). Assignment of individuals to these two groups was done by the laboratory secretary who was unaware of the selected codes.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of University of Social Welfare and Rehabilitation Sciences
Street address
Koodakyar Ave, Daneshjou Blvd, Velenjak
City
Tehran
Province
Tehran
Postal code
1985713834
Approval date
2016-10-09, 1395/07/18
Ethics committee reference number
IR.USWR.REC.1395.355

Health conditions studied

1

Description of health condition studied
Mild cognitive impairment
ICD-10 code
G31.84
ICD-10 code description
Mild cognitive impairment, so stated

Primary outcomes

1

Description
Selective attention
Timepoint
Before intervention, immediately after 12 sessions of intervention and 3 months later
Method of measurement
Attention Network Test (ANT)

2

Description
Working memory
Timepoint

Before intervention, immediately after 12 sessions of intervention and 3 months later

Method of measurement

N-back test

3

Description

Amplitude of N100 component of event-related potentials

Timepoint

Before intervention and immediately after 12 sessions of intervention

Method of measurement

Event-related potentials were recorded using Mitsar amplifier from 32 scalp electrodes during the attention network test

4

Description

Latency of N100 component of event-related potentials

Timepoint

Before intervention and immediately after 12 sessions of intervention

Method of measurement

Event-related potentials were recorded using Mitsar amplifier from 32 scalp electrodes during the attention network test

5

Description

Amplitude of P300 component of event-related potentials

Timepoint

Before intervention and immediately after 12 sessions of intervention

Method of measurement

Event-related potentials were recorded using Mitsar amplifier from 32 scalp electrodes during the attention network test

6

Description

Latency of P300 component of event-related potentials

Timepoint

Before intervention and immediately after 12 sessions of intervention

Method of measurement

Event-related potentials were recorded using Mitsar amplifier from 32 scalp electrodes during the attention network test

Secondary outcomes

1

Description

episodic memory score

Timepoint

Before intervention, Immediately after 12 sessions of intervention and 3 months later

Method of measurement

Rey Auditory Verbal Learning Test (RAVLT)

Intervention groups

1

Description

Intervention group: In the Intervention group, After the evaluation session (using cognitive function evaluation tests) and recording of Event-Related Potentials (ERPs) participants were trained using Attentive Rehabilitation of Attention and Memory app (ARAM) in 10 sessions of 45 minutes twice a week and then re-evaluated in the twelfth session. The ARAM is a computerized cognitive rehabilitation program with different tasks for training attention and working memory. The program consisted of 10 graded progressive tasks. All tasks had 10 levels and participants could shift to the higher level after gaining 80 percent of score in each level.

Category

Rehabilitation

2

Description

Control group: Participants assigned to the control group did not receive any intervention and were on the waiting list and could receive cognitive intervention after a 3-month follow-up period

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Brain and cognition clinic

Full name of responsible person

Dr Mohammad Reza Shalbafan

Street address

No. 33, East Zartosht Ave., Valiasr Street

City

Tehran

Province

Tehran

Postal code

1594834111

Phone

+98 21 8880 2063

Fax

+98 21 8880 2063

Email

info@bacogc.com

Web page address

https://bcclinic.ir/

2

Recruitment center

Name of recruitment center
Rofeideh Rehabilitation Hospital
Full name of responsible person
Dr Elham Looni
Street address
No. 9, Nemati Alley, South Salimi Ave., Andarzgoo Blvd., Gheitarieh
City
Tehran
Province
Tehran
Postal code
1935073476
Phone
+98 21 2220 5326
Fax
+98 21 2223 2741
Email
rofeideh.hospital@uswr.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Dr. Hamid Reza Khorram Khorshid
Street address
Koodakyar Ave., Daneshjou Blvd., Velenjak
City
Tehran
Province
Tehran
Postal code
1985713871
Phone
+98 21 2218 0083
Email
hrkhkh@yahoo.com
Web page address
https://www.uswr.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
University of social welfare and rehabilitation sciences
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
University of social welfare and rehabilitation sciences
Full name of responsible person
Mahdieh Esmaeili Tarzi
Position
PhD Candidate
Latest degree
Master
Other areas of specialty/work
Geriatrics
Street address
Koodakyar Ave., Danshjou Blvd., Velenjak
City
Tehran
Province
Tehran
Postal code
1985713871
Phone
+98 21 8876 1695
Email
mah.esmaeili@uswr.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Mahdieh Esmaeili Tarzi
Position
PhD Candidate
Latest degree
Master
Other areas of specialty/work
Geriatrics
Street address
Koodakyar ave., Daneshjou Blvd., Velenjak
City
Tehran
Province
Tehran
Postal code
۱۹۸۵۷۱۳۸۷۱
Phone
+98 21 8876 1695
Email
mah.esmaeili@uswr.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Mahdieh Esmaeili Tarzi
Position
PhD Candidate

Latest degree
Master
Other areas of specialty/work
Geriatrics
Street address
Koodakyar Ave., Daneshjou Blvd., Velenjak
City
Tehran
Province
Tehran
Postal code
1985713871
Phone
+98 21 8876 1695
Email
mah.esmaeili@uswr.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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