Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

The effectiveness of the implementation of Rehacom Cognitive Rehabilitation Therapy on cognitive function of the elderly with normal cognition, MCI, and mild Alzheimer: A pilot study

Protocol summary

Study aim

The effectiveness of the implementation of Rehacom Cognitive Rehabilitation Therapy on cognitive function of the elderly with normal cognition, MCI, and mild Alzheimer: A pilot study

Design

72 elderly people will be entered into the study based on the inclusion criteria. The elderly will be divided into two groups based on their cognitive status and educational status based on random allocation. This study is a single blinded study and the study subjects will not be aware of the study groups. At first, all the elderly will be evaluated using the initial evaluation of Rehacom software. The control group will not receive any program. The elderly in the intervention group will undergo cognitive rehabilitation for 8 weeks, two 45-minute sessions per week with Rehacom software.

Settings and conduct

The statistical population of the study will be the elderly who refer to the daycare centers of Gorgan City. Informed consent will be obtained at the beginning of the research. The primary assessment of the elderly will be done by using the MoCA form and the GDS-15 form. The elderly will be entered into the study if they meet other inclusion criteria.

Participants/Inclusion and exclusion criteria

Being older than 65 years Literate person (having at least a diploma) Obtaining a score of 11 and greater on the MoCA Obtaining a score of less than 8 on the GDS-15 (Geriatric Depression Scale-15) Ability to speak Persian Having a personal desire to participate in the study Having no epilepsy, vision problems, hearing, or severe disabilities Having a formal or informal caregiver

Intervention groups

The intervention group will receive the cognitive rehabilitation program. The control group is evaluated only at the beginning and end of the study.

Main outcome variables

The processing speed and the difficulty of the test during 2 months (16 sessions) before and after the intervention in two groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180213038710N2**
Registration date: **2023-09-10, 1402/06/19**
Registration timing: **prospective**

Last update: **2023-09-10, 1402/06/19**
Update count: **0**

Registration date

2023-09-10, 1402/06/19

Registrant information

Name

Maryam Chehrehgosha

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2218 0004

Email address

chehrehgosha@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-06-20, 1403/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of the implementation of Rehacom Cognitive Rehabilitation Therapy on cognitive function of the elderly with normal cognition, MCI, and mild Alzheimer: A pilot study

Public title

The effectiveness of implementation of Rehacom Cognitive Rehabilitation Therapy on cognitive function of the elderly with normal cognition, MCI and mild Alzheimer: A pilot study

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Being older than 65 years Literate person (having at least diploma) Obtaining a score of 11 and greater on the MoCA Obtaining a score of less than 8 on the GDS-15 (Geriatric Depression Scale-15) Ability to speak Persian Having a personal desire to participate in the study Having no epilepsy, vision problems, hearing, or severe disabilities Having aformal or informal caregiver

Exclusion criteria:

Inability to continue participating for any reason Failure to attend two consecutive or alternating sessions

Age

From **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to evenly distribute people based on their cognitive status into two intervention and control groups; the participants will be divided into three groups based on the scores obtained from the MoCA form, the elderly with normal cognitive status and the elderly with mild cognitive impairment (MCI) and elderly with mild Alzheimer's will be randomly assigned in two intervention and control groups. The random assignment of the elderly will be done based on the cognitive and educational status of the elderly. The Stratified random block method will be done based on education level (diploma, Associate/Bachelor degree, Master's degree or higher) and cognitive status (normal, MCI, mild Alzheimer's) and participants allocated to intervention and control groups. Based on education level and cognitive status, 6 stratifications will be formed. Within each stratify; the method of random blocks of 6 will be used to assign participants to two groups A (intervention) and group B (control). For this, the list of blocks is first written and numbers are assigned to them AABB(1)-ABAB(2)-ABBA(3)-BBAA(4) and the order of these blocks will be determined randomly by Excell software.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study will be a single-blinded randomized clinical trial. Therefore, the participants of the study will not be informed from the study groups (intervention-control). For this purpose, sampling of the participants in the intervention and control groups will be done from different centers in the city. The possibility of blinding the researcher is not possible due to the mastery of Rehacom evaluation software.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Central Building of Tabriz University of Medical Sciences, Golgasht Street, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2023-08-28, 1402/06/06

Ethics committee reference number

IR.TBZMED.REC.1402.404

Health conditions studied

1

Description of health condition studied

Alzheimer

ICD-10 code

G30.1

ICD-10 code description

Alzheimer's disease with late onset

Primary outcomes

1

Description
Processing speed of cognitive tests based on Rehacom
Timepoint
In the intervention group at the beginning of the study, in each treatment session, at the end of the intervention/in the control group at the beginning of the study and at the end of the study
Method of measurement
Rehacom software measures these variables.

2

Description
The difficulty level of the test
Timepoint
In the intervention group at the beginning of the study, in each treatment session, at the end of the intervention/in the control group at the beginning of the study and at the end of the study
Method of measurement
Rehacom software measures these variables.

Secondary outcomes

1

Description
Cognitive status based on MoCA score
Timepoint
In the intervention group at the beginning of the study, in each treatment session, at the end of the intervention/in the control group at the beginning of the study and at the end of the study
Method of measurement
Rehacom software measures these variables

Intervention groups

1

Description
"Intervention group" (recipient of cognitive rehabilitation based on Rehacom software): In the intervention group, the rehabilitation program for the intervention group will be implemented individually for 16 sessions of 45 minutes twice a week. Based on the Rehacom platform, the areas of self-awareness, orientation, attention, visual processing, motor vision, motor planning, memory, organization, and problem-solving can be trained. However, each session focuses on the cognitive deficit of different domains. The method of performing each of these tasks will be explained by the researcher for better comprehension of instruction for the elderly. The program of each session will be different from the previous session, which will motivate the subjects to continue the treatment.
Category
Rehabilitation

2

Description
"Control group": In the control group, The Rehacom evaluation will be performed before the intervention (at the beginning of the study) and after the intervention period, will be done in the elderly in the control group. These people will carry out their normal life routines and will not receive any rehabilitation intervention.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Day care centers for the elderly in Gorgan
Full name of responsible person
Maryam Chehrehgoosha
Street address
No 18, Edalat 37Ave, Gorgan, Golestan/No 24, Alley 7,Imam Reza Ave, Sarkhajeh Square, Gorgan, Golestan
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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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Web page address
https://aria.tbzmed.ac.ir/
Grant name
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University of Medical 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
Gorgan University of Medical Sciences
Full name of responsible person
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Person responsible for updating data

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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
Considering that part of the information is related to the elderly with mild Alzheimer's and MCI, the research team prefers that the information is not available to other people except the research team.
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
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable