Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jul 2026

Comparing the effectiveness of Cognitive Rehabilitation and Cognitive Behavioral Therapy (CBT) on reducing depressive symptoms and improving the quality of life in the elderly with Major Depressive Disorder (MDD)

Protocol summary

Study aim

Comparing the effectiveness of cognitive behavioral therapy and cognitive rehabilitation intervention on reducing depressive symptoms and the quality of life in the elderly with major depressive disorder

Design

The clinical trial consists of two treatment groups. A randomization table with balanced blocks will be used. To ensure blinding, the coordinator and evaluator will not be aware of the intervention given to each patient. Patients will be evaluated on three occasions. The sample size for each group is 17 individuals.

Settings and conduct

The research environment is the clinic of the Iran University of Medical Sciences. To ensure the double-blind process, cards with codes are given to eligible participants. The main researcher will receive the assigned card for each patient. A: cognitive rehabilitation intervention, B: cognitive behavioral therapy. A trained individual, who is unaware of the treatment type, will evaluate the effectiveness of the treatment.

Participants/Inclusion and exclusion criteria

Entry criteria: Obtaining a diagnosis of major depression, scoring higher than 6 on the Geriatric Depression Scale, Receiving antidepressants, age over 55 years, education above seventh grade. Non-entry criteria: Suffering from cognitive disorders, scoring higher than 26 on the Montreal Cognitive Assessment Test, Suffering from psychotic disorders or brain damage

Intervention groups

In the cognitive-behavioral intervention group (gold standard treatment), we will be using the treatment protocol for elderly depression. This protocol consists of 7 main modules. We have specifically 4 modules in cognitive rehabilitation group. Both groups of patients will receive 16 intervention sessions, twice a week.

Main outcome variables

The main outcome: depression symptoms and quality of life. Secondary outcomes: executive function, attention and concentration, processing speed, and verbal memory.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240110060672N1**
Registration date: **2024-02-17, 1402/11/28**
Registration timing: **registered_while_recruiting**

Last update: **2024-02-17, 1402/11/28**
Update count: **0**

Registration date

2024-02-17, 1402/11/28

Registrant information

Name

Nafee Rasouli

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date
2025-02-19, 1403/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effectiveness of Cognitive Rehabilitation and Cognitive Behavioral Therapy (CBT) on reducing depressive symptoms and improving the quality of life in the elderly with Major Depressive Disorder (MDD)

Public title
Comparing the effectiveness of Cognitive Rehabilitation and Cognitive Behavioral Therapy (CBT) on reducing depressive symptoms and improving the quality of life in the elderly with Major Depressive Disorder (MDD)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of major depression by semi-structured SCID interview A score higher than 6 in the Geriatric Depression Scale (GDS) Receiving antidepressants (SSRI) At least 3 weeks have passed since the start of drug treatment At least 55 years old Education above seventh grade
Exclusion criteria:
Major and minor cognitive impairment based on DSM-5 A score lower than 26 in the MoCA Having psychotic disorders or brain damage
Age
From **55 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **34**
Randomization (investigator's opinion)
Randomized
Randomization description
This study is conducted as a double-blind study. The person responsible for assessing the elderly individuals based on the inclusion criteria and referring them to the main researcher will be unaware of the treatment assigned to each patient. Similarly, the trained person evaluating the effectiveness of the treatment will also be unaware of the type of treatment provided to the elderly. This process will be further explained in order to ensure double-blinding. To achieve double-blinding, cards with codes written on them are used. These codes are based on a randomization table with balanced blocks that were designed in advance. The coordinator will have access to these cards and will distribute them to individuals who meet the entry criteria and have completed the informed consent. The cards will then be provided to the main researcher for future reference. The main researcher or therapist will observe the letter written in front of each patient's code on the randomization table. If the letter A is written, cognitive rehabilitation intervention will be performed. If the letter B is written, cognitive behavioral therapy will be administered. Before the intervention begins, the effectiveness of the treatment will be evaluated by a trained person who is unaware of the treatment assigned to each patient. This person will enter the results of each test, along with the corresponding number and name of each elderly individual, into Excel.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study is conducted as a double-blind study. The person responsible for assessing the elderly individuals based on the inclusion criteria and referring them to the main researcher will be unaware of the treatment assigned to each patient. Similarly, the trained person evaluating the effectiveness of the treatment will also be unaware of the type of treatment provided to the elderly. This process will be further explained in order to ensure double-blinding.
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences (IUMS), Shahid Hemmat Highway
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Tehran
Province
Tehran
Postal code
14496-14535
Approval date
2023-07-23, 1402/05/01
Ethics committee reference number
IR.IUMS.REC.1402.355

Health conditions studied

1

Description of health condition studied

Major Depressive Disorder (MDD)

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Depression symptoms

Timepoint

In three stages including: the beginning of the study (before the start of the intervention), immediately after the end of the intervention, 3 months after the end of the intervention.

Method of measurement

Depression criteria of DSM-5 (SCID), Geriatric Depression Scale (GDS)

2

Description

Quality of life

Timepoint

In three stages including: the beginning of the study (before the start of the intervention), immediately after the end of the intervention, 3 months after the end of the intervention.

Method of measurement

The World Health Organization Quality of Life Persian questioner

Secondary outcomes

1

Description

executive function

Timepoint

In three stages including: the beginning of the study (before the start of the intervention), immediately after the end of the intervention, 3 months after the end of the intervention.

Method of measurement

Trial making test, Verbal fluency

2

Description

attention and consentration

Timepoint

In three stages including: the beginning of the study (before the start of the intervention), immediately after the end of the intervention, 3 months after the end of the intervention.

Method of measurement

Digit span (DS)

3

Description

Information processing speed

Timepoint

In three stages including: the beginning of the study (before the start of the intervention), immediately after the end of the intervention, 3 months after the end of the intervention.

Method of measurement

Symbol Digit Modality Test (SDMT)

4

Description

Verbal memory

Timepoint

In three stages including: the beginning of the study (before the start of the intervention), immediately after the end of the intervention, 3 months after the end of the intervention.

Method of measurement

Logical Memory (LM)

Intervention groups

1

Description

Intervention group 1: Cognitive rehabilitation

Category

Rehabilitation

2

Description

Intervention group 2: Cognitive Behavioral Therapy (CBT)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان رسول

Full name of responsible person

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Sponsors / Funding sources

1

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Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
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Web page address
https://en.iums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
grant
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
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Nafee Rasouli
Position
PhD Condidate
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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
-
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available