

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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+98 936 371 3287

Email address

nafeerasouli@gmail.com

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

AgeFrom **55 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample sizeTarget 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

City

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 questionnaire

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 concentration

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

دکتر بهنام شریعتی

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

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?

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

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Nafee Rasouli

Position

PhD Condidate

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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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