Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

The effect of Bacopa monnieri extract on cognitive function and sleep quality in patients with mild cognitive impairment: a triple-blind clinical trial study

Protocol summary

Study aim

Determining the effect of Bacopa monnieri extract on cognitive function and sleep quality in patients with mild cognitive impairment (MCI).

Design

The study is a three-blind clinical trial (randomized control). The number of samples is 62. Using stratified random blocking method to identify groups in terms of gender (female / male),literacy level (diploma /undergraduate) and age (50-65 65<) are divided into two groups (intervention and control) Will take. Medications will be placed separately in A-B packages.

Settings and conduct

The present study is a triple-blind clinical trial (randomized controlled trial) (blind patient, blind physician and data analyzer). According to the mentioned inclusion criteria, patients with MCI referred to the office of the project partner who score < 26 in the MOCA Test will enter the study after obtaining the informed consent of the patients.

Participants/Inclusion and exclusion criteria

1. Conscious written consent 2. No psychiatric, gastrointestinal and kidney diseases 3. Have a minimum literacy 4. Score less than 26 on the MOCA 5. Not participating in another clinical trial during the past 2 months prior to the start of this study and other complementary medicine and cognitive rehabilitation programs 6. Do not take antidepressants, anticonvulsants, hypnotics and muscle relaxants according to self-declaration 7- Have at least two vascular risk factors such as: hypertension, diabetes, Hyperlipidemia, obesity and consumption have tobacco 8. Age: 50 years<

Intervention groups

The intervention group was given 160 mg capsules of Bacopa dry extract orally twice a day for two months .The control group is given a placebo (containing the same starch as the main drug).

Main outcome variables

In this study, the primary outcome of the study of cognitive function and the secondary outcome is the study of sleep quality.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210620051641N1**
Registration date: **2021-07-24, 1400/05/02**
Registration timing: **prospective**

Last update: **2021-07-24, 1400/05/02**
Update count: **0**

Registration date

2021-07-24, 1400/05/02

Registrant information

Name

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Name of organization / entity

Lorestan University Medical of science

Country

Iran (Islamic Republic of)

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+98 66 3322 7555

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-06, 1400/05/15

Expected recruitment end date

2022-05-05, 1401/02/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Bacopa monnieri extract on cognitive function and sleep quality in patients with mild cognitive impairment: a triple-blind clinical trial study

Public title
The effect of Bacopa monnieri extract on cognitive function and sleep quality in patients with mild cognitive impairment

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Conscious written consent Have a minimum literacy rate Score less than 26 on the Montreal Cognitive Assessment Test Having at least two vascular risk factors such as: hypertension, diabetes, hyperlipidemia, obesity and consumption have tobacco Being 50 years old or older

Exclusion criteria:
No psychiatric, gastrointestinal diseases (such as irritable bowel syndrome, celiac disease, peptic ulcer) and kidneys Failure to participate in another clinical during the past 2 months prior to the start of this study and other complementary medicine and cognitive rehabilitation programs Do not take antidepressants, anticonvulsants, hypnotics and muscle relaxants on their own declarative

Age
From **50 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **62**

Randomization (investigator's opinion)
Randomized

Randomization description
The present study is a triple-blind clinical trial (randomized controlled trial) (blind patient, blind physician and blind data analyzer). The randomization method is Stratified Random allocation. Its randomization unit is random blocks. Random layers including: gender, literacy and class age based on these variables as described by men / women, literacy level: diploma / undergraduate, age: 50 to 65.65 and above (50 to 65.65 and above) in two group (intervention and control) will be located. Randomization tool and how to create a random sequence: R software is a "blockrand" package.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The drugs will be placed separately in A-B packages. Participants and the whole research group are unaware of the final stage of extracting the final information from the contents of the envelopes (A-B), so the present study will be done in triple-blind.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Lorestan University of Medical Sciences

Street address
5 km of Boroujerd, Khorramabad road, campus of Lorestan University of Medical Sciences

City
khorramabad

Province
Lorestan

Postal code
6813833946

Approval date
2021-06-14, 1400/03/24

Ethics committee reference number
IR.LUMS.REC.1400.063

Health conditions studied

1

Description of health condition studied
mild cognitive impairment

ICD-10 code
F06.7

ICD-10 code description
F00-F09

Primary outcomes

1

Description
Evaluation of cognitive function using Montreal Cognitive Assessment questionnaire

Timepoint
Evaluation of cognitive function during the study in the pre-intervention, end of the first month and end of the second month of patients in person in the physician's

office.

Method of measurement

Evaluation of cognitive function using the Montreal Cognitive Assessment Questionnaire

Secondary outcomes

1

Description

Assess the quality of sleep

Timepoint

Evaluation of patients' sleep quality during the study in the pre-intervention, end of the first month and end of the second month in person at the physician's office

Method of measurement

Assessing patients' sleep quality using the Pittsburgh Sleep Quality Questionnaire

Intervention groups

1

Description

Intervention group: Participants were randomly assigned to take Bacopa Monnieri 160 mg standard extract orally twice daily for two months (1 with breakfast, 1 with dinner at 9 am and 9 pm 12 hours apart). It will be given.

Category

Treatment - Drugs

2

Description

Control group: Participants were randomized to placebo (containing starch equal to the main drug) orally twice a day for two months (1 with breakfast, 1 with dinner at 9 am and 9 pm). 12 hours apart) is given.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

clinic

Full name of responsible person

Maryam Delfan

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Sponsors / Funding sources

1

Sponsor

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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?

Yes

Title of funding source

Khoram-Abad University of Medical Sciences

Proportion provided by this source

30

Public or private sector

Private

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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Maryam Delfan

Position

Master student of internal medicine and nursing surgery

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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