

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

effect of laser therapy in reducing of cognitive symptoms, anxiety and depression in patients with mild and moderate dementia

Protocol summary

Study aim

Therapeutic effects of low-level laser therapy in reducing of cognitive symptoms, anxiety and depression in patients with mild and moderate dementia

Design

A clinical trial with a control group with two-way randomized parallel groups on 24 patients. Block randomization is used for randomization.

Settings and conduct

In the Memory Clinic of Taleghani Hospital, patients will enter the study after obtaining consent from both the patient and the family, and the psychologist (non-blind) will collect their information based on age, gender, level of education, marital status, and the duration of the onset of the disease, presenting symptoms and the level of depression and anxiety through a questionnaire. He takes notes and divides them homogenously into two treatment and control groups and finally gives the information obtained from the questionnaires to the (blind) researcher to be analyzed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Dementia patients aged 65 years or older who have been diagnosed with dementia for at least 2 years and are under treatment. exclusion criteria: patients with other major psychiatric disorders, history of severe head trauma, claustrophobia, drug use, benzodiazepines use, and those who have significant changes in symptoms and medication regimen in the last 6 months.

Intervention groups

The group is treated with low power laser for 2 weeks and 3 sessions of 20 minutes each week, the control group has the device on their head but it is turned off. The level of anxiety and depression and cognitive symptoms in the first and sixth session and one month later are compared between the groups using the evaluation questionnaire and the results before and after.

Main outcome variables

Anxiety(Hamilton's questionnaire); depression (GDS questionnaire);Cognitive symptom(MMSE questionnaire)

General information

Reason for update

lack of patient

Acronym

IRCT registration information

IRCT registration number: **IRCT20220614055175N1**

Registration date: **2022-12-12, 1401/09/21**

Registration timing: **registered_while_recruiting**

Last update: **2023-09-30, 1402/07/08**

Update count: **1**

Registration date

2022-12-12, 1401/09/21

Registrant information

Name

Somayeh Jarrahi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8888 7176

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jarrahi1364@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2024-03-18, 1402/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
effect of laser therapy in reducing of cognitive symptoms, anxiety and depression in patients with mild and moderate dementia

Public title
Therapeutic effects of low-level laser therapy in reducing of cognitive symptoms, anxiety and depression in patients with mild and moderate dementia Compared with the control group

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with with mild and moderate dementia who have been diagnosed for at least two years Age over 65 years. Both genders
Exclusion criteria:
 Patients with a history of major psychiatric disorder clastrophobia substance use benzodiazepin use People who have significant changes in symptoms and drug regimen in the last 6 months history of sever traumatic brain injury

Age
From **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of randomization is done as block randomization for 24 people. If A is for treatment and B is for control, first we define 6 combinations with equal allocation as follows: 1=(ABBA) 2=(ABAB) 3=(AABB) 4=(BABA) 5=(BBAA) 6=(BAAB) Then, using the table of random numbers from 1 to 6, six numbers are selected and based on the numbers selected from the list above, we determine the order of the patient or the control.

Blinding (investigator's opinion)
Double blinded

Blinding description
Each patient is assigned a code at the beginning of the study, which will be known by that code until the end of the study. This study was conducted in a double-blind manner, so that the patients, doctors, and clinical caregivers and the data analyzer are not aware of the groupings and only the third party, who is the psychologist of the department It will group people and

evaluate relevant questionnaires before and after treatment.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
 Taleghani Hospital,kodakyar Street , Student Blvd ,Valenjak
City
 Tehran
Province
 Tehran
Postal code
 1985711151

Approval date
2022-10-23, 1401/08/01

Ethics committee reference number
IR.SBMU.MSP.REC.1401.349

Health conditions studied

1

Description of health condition studied
Dementia

ICD-10 code
F03

ICD-10 code description
Unspecified dementia

Primary outcomes

1

Description
Depression

Timepoint
Before and after treatment

Method of measurement
Geriatric depression Scale questionnaire

2

Description
Anxiety

Timepoint
Before and after treatment

Method of measurement

Hamilton anxiety questionnaire

3

Description

Cognitive symptom

Timepoint

Before and after treatment

Method of measurement

minimal mental status examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group will be formed by patients who receive PBM (photobiomodulation) as an auxiliary treatment for two weeks and their information is based on age, sex, level of education, marital status and duration of disease onset, cognitive symptoms and depression and anxiety level are noted by the relevant questionnaires and they are treated with low power laser for 2 weeks and 3 sessions every week. The level of depression, anxiety and cognitive symptoms are evaluated again by questionnaire at the end of the treatment and one month after the last treatment when visiting the clinic and the before and after results are compared between the 2 groups.

Category

Treatment - Devices

2

Description

Control group: The people of the second group will be selected as the same control group as the first group. Cognitive symptoms, level of depression and anxiety are evaluated by a questionnaire at the beginning of the treatment, at the last session of the treatment and one month after the last treatment at the clinic and the before and after results are compared between the 2 groups.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Ali Kheradmand

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Taleghani Hospital, kodakhyar Street , Student Blvd

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Student Blvd ,Valenjak

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Email

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Web page address

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Somayeh Jarrahi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

Sarshar dormitory number 12,sarshar dead end alley,Valiasr street

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

علی خردمند

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Province

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Postal code

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can potentially be shared after de-identifying individuals

When the data will become available and for how long

Access starts 6 months after the results are published

To whom data/document is available

All researchers working in academic and scientific institutions, doctors and pharmaceutical companies will be allowed to access the information

Under which criteria data/document could be used

The applicant can access the information after providing proof of identity

From where data/document is obtainable

Applicants can contact Dr. Somayeh Jarrahi by email to receive the desired documents or data.jarrahi1364@gmail.com

What processes are involved for a request to access data/document

The applicant can communicate with the researcher through email and receive the basic data after presenting the identity documents

Comments