

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Therapeutic effects of low-level laser therapy in reducing obsessive compulsive disorder symptoms in bipolar patient treatment Compared with the control group

Protocol summary

Study aim

Therapeutic effects of LLLT in reducing ocd symptoms compared with the control group

Design

A clinical trial with a control group, 30 patients with OCD and definitive diagnosis of the level of OCD by questionnaire (YBOCS) and the method of randomization is also done as block randomization.

Settings and conduct

This study will be conducted in the psychiatry department of SBMU. One group will be treated with low level laser for 4 weeks and 9 sessions. The control group is also treated with a device with zero intensity in 4 weeks. The patients and I were blinded in the study, and the third person, who is a colleague of the psychologist, acted as an intermediary between the patients based on age, sex, dosage of drugs consumed and equivalent, duration of obsession. The level of education, marital status, duration of disease onset, previous hospitalization rate, type of drug and their equivalent dose are divided in such a way that there is almost a similar sample in the other group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: outpatients under treatment for OCD, over 18 years old without claustrophobia and psychosis with 2 month medication stabilization. Exclusion criteria: unwillingness to cooperate, complications in patients, patients with a history of neurological diseases, pregnancy or acute and chronic physical illness and receive ECT.

Intervention groups

Two homogeneous groups of 30 patients in a treatment group and a control group. The first group will be formed by patients who will receive laser therapy in the first 4 weeks of outpatient visits, and the second group will be selected as a control group similar to the first group.

Main outcome variables

Average score of obsessive thoughts and behaviors
Average score of anxiety Obsessive compulsive disorder symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230815059151N1**

Registration date: **2023-10-14, 1402/07/22**

Registration timing: **prospective**

Last update: **2023-10-14, 1402/07/22**

Update count: **0**

Registration date

2023-10-14, 1402/07/22

Registrant information

Name

Ali Faghfour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8846 9459

Email address

ali_md07@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-03-20, 1403/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Therapeutic effects of low-level laser therapy in reducing obsessive compulsive disorder symptoms in bipolar patient treatment Compared with the control group

Public title

Investigating the effect of low-level laser in reducing obsessive-compulsive symptoms

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients undergoing OCD treatment are referred to a psychiatric clinic as outpatients Age above 18 years No claustrophobia Patients should be in drug stabilization for at least 2 months The patient is not psychotic

Exclusion criteria:

Patients with a history of neurological disease such as epilepsy Having other neurological disorders such as parkinsonism Traumatic brain injury Brain stroke pregnancy Acute and chronic physical illness Cases receiving antidepressant treatment or ECT (convulsive therapy with electroshock).

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

The patients and the researcher are blinded in the study and the third party arranges the samples in two groups in such a way that in terms of age and sex, level of education, marital status, duration of the onset of the disease, the amount of previous hospitalization, the type of drug and the equivalent dose, they are almost identical. There is a similar one in another group. This third party will also place the laser device on the patient's head.

Placebo

Not 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

6th floor, Building No. 2, Shahid Beheshti University of Medical Science, Shahid Arabi, Yemen St, Shahid Chamran Highway, Tehran

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Postal code

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Approval date

2023-06-27, 1402/04/06

Ethics committee reference number

lr.sbm.u.msp.rec.1402.155

Health conditions studied**1****Description of health condition studied**

Obsessive compulsive disorder

ICD-10 code

F42

ICD-10 code description

Obsessive-compulsive disorder

Primary outcomes**1****Description**

OCD severity based on the Yale-Brown Obsessive Compulsive Scale (Y-BOCS)

Timepoint

Measuring the level of obsessive compulsive disorder before the start of treatment and then at the end of treatment and one month after the last treatment in an outpatient visit to a psychiatric clinic.

Method of measurement

Yale-Brown Obsessive Compulsive Scale Questionnaire (Y-BOCS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will be formed by patients who receive laser therapy as an adjuvant treatment in the first four weeks of outpatient visits. This group is treated with low-power laser for 9 sessions over a period of 4 weeks. 24 semi-conductor lasers with a power of 100 mW are used for laser treatment of patients, which are placed on a helmet. 12 of the lasers have a visible wavelength of 630 nm and the other 12 have a wavelength of 810 nm. The laser beam is pulsed with a frequency of 75 Hz and a duty cycle of 20 percent for 10 to 20 minutes to the scalp area of the patients. According to the diameter of the laser beam on the skull surface of the patients, which is 0.21 cm², the power density and energy density applied to the patients in each session are 0.9 W/cm² and 56.5 J/cm², respectively.

Category

Treatment - Other

2

Description

Control group: The control group is treated with a silent laser device with zero intensity in the first 4 weeks of outpatient visits for 9 sessions.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Ali Faghfouri

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Shahid Arabi St., next to Shahid Beheshti University of Medical Science, Shahid Arabi St., Yemen St, Shahid Chamran Highway, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

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5th floor, Building No. 2, Shahid Beheshti University of Medical Science, Shahid Arabi, Yemen St, Shahid Chamran Highway, Tehran

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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

Ali Faghfouri

Position

Psychiatry resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Position

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Person responsible for updating data

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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

Main outcome information and aggregate data can be shared after de-identifying individuals.

When the data will become available and for how long

Immediately after printing the results

To whom data/document is available

All researchers working in academic and scientific institutions and people working in the industry and all those interested

Under which criteria data/document could be used

By observing the ethical principles, it is possible to use the data for future research or other purposes.

From where data/document is obtainable

By phone or e-mail address (Ali_md07@yahoo.com) with the person responsible for the study

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

Providing explanations for where and how to use data by explaining ethical protocols

Comments