

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the effect of adding blue light blocking glasses to the treatment in patients with type 1 bipolar disorder

Protocol summary

Study aim

Evaluation of the effect of adding blue light blocking glasses to the treatment of patients with mania period bipolar disorder type 1

Design

A controlled clinical trial with parallel, double-blind, randomized groups of 48 patients. Excel software rand function was used for randomization.

Settings and conduct

Patients aged 18 to 60 years who have been diagnosed with type 1 bipolar disorder (DSM-V) (Diagnostic and Statistical Manual of Mental Disorders, 5th edition) have referred to Ibn Sina Hospital with symptoms of bipolar mania type 1 since February 1, 2008. Of quality. Randomization was divided into control and intervention groups

Participants/Inclusion and exclusion criteria

Patients aged 18 to 60 years with definite diagnosis of bipolar disorder type 1 with symptoms of bipolar disorder have referred to Ibn Sina Hospital Satisfaction with inclusion in the study No entry conditions: Prior knowledge of blue block glasses History of migraine Symptoms of quitting or abusing alcohol or any other medication

Intervention groups

For patients with bipolar disorder, glasses that specifically block blue light are used for 7 consecutive days from 6 pm until bedtime. The control group will also use the same glasses that pass through all spectrums of light.

Main outcome variables

Changing the symptoms of bipolar mania through the standard questionnaire and YMRS scoring

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101130005280N52**

Registration date: **2022-04-26, 1401/02/06**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-26, 1401/02/06**

Update count: **0**

Registration date

2022-04-26, 1401/02/06

Registrant information

Name

Raheleh Nejati

Name of organization / entity

Mashhad University of Medical Sciences, Ibn-e- Sina Psychiatric Hospital

Country

Iran (Islamic Republic of)

Phone

+98 51 3711 2540

Email address

nejatir2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-20, 1401/01/31

Expected recruitment end date

2022-07-22, 1401/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of adding blue light blocking glasses to the treatment in patients with type 1 bipolar disorder

Public title

The effect of using blue light blocking glasses

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients aged 18 to 60 years who have been diagnosed with type 1 bipolar disorder according to DSM-V criteria (Diagnostic and Statistical Manual of Mental Disorders, 5th edition) have referred to Ibn Sina Hospital with symptoms of mania since February 1, 2022. Satisfaction with inclusion in the study

Exclusion criteria:

Prior knowledge of blue block glasses History of migraine Symptoms of quitting or abusing alcohol or any other medication

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

This is how random numbers are prepared with the help of Randomaize.com. According to the number of research samples, a number of envelopes with wrappers Aluminum (in order to avoid the clarity of the contents of the envelopes), is prepared and each of the random sequences created is registered on a card and the cards are placed inside the envelopes. In order to protect the random sequence, also on the outer surface of the envelopes Numbering is done in the same way. Finally, the lids of the letter envelopes are glued and placed in a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, they take one of the envelopes of the order, respectively, and the envelopes contain the odd number of the control group and the envelopes contain the even number.

Blinding (investigator's opinion)

Double blinded

Blinding description

The studied subjects and outcome evaluators are fully aware of the research subject and the purpose and process of the study, and will enter the study after filling out the consent, according to the entry conditions. Although, They will be unaware of the contents of the envelope and the group which they are assigned (control and intervention) (so they do not predict the outcome). The envelope is prepared with aluminum foil (in order to avoid the clarity of envelope contents), and each random sequences is recorded on a card.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2022-03-08, 1400/12/17

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.845

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

bipolar disorder

ICD-10 code

F30.3

ICD-10 code description

Manic episode in partial remission

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

Relative satisfaction

Timepoint

At the beginning of the intervention and 2, 4, 6 days after the intervention

Method of measurement

YMRS standard questionnaire and scoring

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For patients with bipolar disorder mania, glasses that specifically block blue light are used for 7 consecutive days from 6 pm until bedtime. And every day the progress of improvement will be measured through a standard questionnaire

Category

Treatment - Other

2

Description

Control group: In the control group, the same glasses will be used that pass all the light spectrum.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ibn Sina Psychiatric Hospital

Full name of responsible person

Ali Saghebi

Street address

Ibn-e-Sina psychiatric Hospital, Horre ameli avenue, Boo Ali square

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saghebial@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour

Street address

Mashhad University Street Qureshi Building

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Ali Saghebi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

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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