Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 Scinces, Ibn-e- Sina Psychiatric Hospital

Country
Iran (Islamic Republic of)

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+98 51 3711 2540

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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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ghayourm@mums.ac.ir
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
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Person responsible for updating data

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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