Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Oct 2026

Comparing the effectiveness of smartphone-based mindfulness intervention, face-to-face and combined, on sleep disorders, suicidal thoughts, psychological flexibility, fusion of thought and action, and intensity of manic and mixed phases in patients with bipolar disorder.

Protocol summary

Study aim

Comparison of the effectiveness of mindfulness intervention based on smart mobile phone face-to-face and integrated on sleep disorders, suicidal thoughts, psychological flexibility, thought-action fusion and intensity of manic and mixed phases of patients with bipolar disorder

Design

The clinical trial includes three experimental groups and one control group of bipolar disorder patients who meet the entry criteria, 60 bipolar disorder patients were selected according to the available method and non-randomly assigned to one of the 4 research groups. was, that the participants did not know which experimental group they were participating in.

Settings and conduct

First, an introduction letter will be obtained from the education department of Shahrood Islamic Azad University, and then it will be referred to the welfare organization and psychiatric clinics of Gorgan city. The introduced sample is trained by well-being rehabilitation centers and psychiatric clinics after obtaining consent from the individuals and being placed in experimental and control groups.

Participants/Inclusion and exclusion criteria

Age range from 15 to 50 years, at least diploma education, diagnosis of bipolar disorder based on the psychiatrist's opinion, at least six months have passed since the diagnosis of the disease, not receiving an electrical shock, not receiving other psychological treatments during the intervention, access to a smartphone, unwillingness to participate in research.

Intervention groups

Mindfulness test group based on smart mobile phone, face-to-face mindfulness test group, combined test group, and control group

Main outcome variables

Sleep disorders; suicidal thoughts; psychological flexibility; fusion of thought and action; intensity of manic and mixed phases

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170719035180N4**
Registration date: **2023-03-29, 1402/01/09**
Registration timing: **prospective**

Last update: **2023-03-29, 1402/01/09**
Update count: **0**

Registration date

2023-03-29, 1402/01/09

Registrant information

Name

Seyed Mosa Tabatabaee

Name of organization / entity

Semnan University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-03, 1402/01/14

Expected recruitment end date
2023-09-05, 1402/06/14
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effectiveness of smartphone-based mindfulness intervention, face-to-face and combined, on sleep disorders, suicidal thoughts, psychological flexibility, fusion of thought and action, and intensity of manic and mixed phases in patients with bipolar disorder.

Public title
Effectiveness of mindfulness intervention on patients with bipolar disorder
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of bipolar disorder according to the opinion of a psychiatrist. At least a diploma education. At least 6 months have passed since the diagnosis of the disease. Not receiving electronic shock. Not pregnant. Not receiving other psychological interventions during the intervention. Access to a smart mobile phone.
Exclusion criteria:
Unwillingness to participate in research.
Age
From **15 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahrood Azad University
Street address
University Blvd., Shahrood, SemnanTown
City
Shahrood
Province
Semnan
Postal code
36199-43189
Approval date
2023-02-15, 1401/11/26
Ethics committee reference number
IR.IAU.SHAHROOD.REC.1401.076

Health conditions studied

1

Description of health condition studied
Bipolar Disorder
ICD-10 code
F31
ICD-10 code description
Bipolar disorder

Primary outcomes

1

Description
sleep disorders. In this study, sleep disorders mean the score that the participants receive from answering questions 1 to 18.
Timepoint
before the start of intervention (pre-test), immediately after the end of the intervention(post - test) and one month after that(follow up)
Method of measurement
Sleep quality questionnaire of Petersburg et al

2

Description
Suicidal thoughts: In the present study, suicidal thoughts mean the score that participants get from answering questions 1 to 19 of Beck et al.'s suicide thoughts questionnaire.
Timepoint
Before the start of the intervention (pre-test), immediately after the end of the intervention (post-test) and one month after that (follow-up)
Method of measurement
Beck et al.'s suicidal ideation questionnaire

3

Description
Psychological flexibility: Psychological flexibility in the present study is the score that the participants get from

answering questions 1 to 20 of the psychological flexibility questionnaire of Dennis et al. (2010).

Timepoint

Before the start of the intervention (pre-test), immediately after the end of the intervention (post-test) and one month after that (follow-up)

Method of measurement

Psychological flexibility questionnaire of Dennis et al

4

Description

Fusion of thought-action: The meaning of fusion of thought-action in the present study is the score that the participants get from answering questions 1 to 19 of the questionnaire of fusion of thought-action by Rachman et al. (1988).

Timepoint

before the start of intervention (pre-test), immediately after the end of the intervention(post - test) and one month after that(follow up)

Method of measurement

Thought-action fusion questionnaire Rachman et al

5

Description

Bipolar disorder: Bipolar disorder in the present study is the score that the participants get from answering questions 1 to 11 of the Maniai Yang et al. questionnaire (1978).

Timepoint

Before the start of the intervention (pre-test), immediately after the end of the intervention (post-test) and one month after that (follow-up)

Method of measurement

Yang et al.'s mania questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: face-to-face intervention of mindfulness: first introduction and familiarization and explanation of the concept of automatic guidance: introduction of the program and a brief description of 8 sessions, familiarization of the group members with each other and the consultant, determination of group goals and rules, familiarization with the concepts of mindfulness training and the need for training Mindfulness, explanation about automatic guidance and raisin eating meditation, and then for 30 minutes, body check meditation and conscious breathing, assignment. Second, facing obstacles: reviewing the tasks of the previous session (doing body check meditation and discussing this experience), practice obstacles and Mindfulness program solutions for it and breathing mindfulness meditation practice, discussing the difference between thoughts and feelings, doing sitting meditationAssignment. Third, awareness of breathing or conscious breathing: practicing seeing and hearing, sitting meditation and breathing with attention to bodily senses, discussing homework, three-minute breathing space practice, doing yoga exercises, assignment. Fourth, staying in the present. : Sitting meditation with attention to breathing, body sounds and thoughts (which is also called four-dimensional sitting meditation). Teaching how to stay in the present, assigning assignments. Fifth, permission/permission to attend (accepting thoughts and feelings): reviewing the assignment of the previous session, explaining the concept of acceptance, doing sitting meditation (awareness and presence of the mind from breathing, sounds, thoughts and feelings), presenting and performing yoga movements,Assignment. Sixth, thoughts are not facts: practice of three-minute breathing space, discussion of homework in pairs, presentation of an exercise entitled "creating thoughts, separate views" with this theme: the content of thoughts are mostly not real, use of poetry and metaphor and Its connection with the quality of mindfulness, assignment. Seventh, how can I take care of myself in the best way? Sitting meditation and awareness of everything that comes into awareness in the moment. Presenting an exercise for making a list of pleasant and unpleasant life events, experiencing awareness and non-judgmental (non-selective) acceptance, assignment. 8. Acceptance and change (using what you have learned so far): body check meditation, three-minute breathing space exercise, discussion of Methods of coping with obstaclesMeditation, getting feedback from the participants and taking the post-test, preparing for the end of the sessions and the end of the intervention

Category

Treatment - Other

2

Description

Intervention group: Mindfulness based on a smart phone. 1st body scan in 5 minutes, restful sleep on the first day, self-love training. 2nd body scan in 10 minutes, restful sleep on the second day, letting go of comparison and perfectionism. 3rd body scan in 20 minutes, restful sleep on the day Third, getting rid of stress and fear. Fourth, body scan in 30 minutes, easy sleep on the fourth day, self-acceptance and challenging the main beliefs. Fifth, easy sleep on the fifth day, source of inner happiness, correct breathing training, breathing according to the time of exhalation. Exhalation and breath holding, (simple breathing exercise for relief) 6th day, restful sleep, sixth day, order and law in relationships, breathing according to the time of inhalation, exhalation and breath holding (attention breathing exercise), 7th day, restful sleep, balance, breathing according to time Inhale, exhale and hold your breath (square breathing exercise)8th day, comfortable sleep, empathy, breathing according to the time of inhalation, exhalation and breath holding (heart breathing exercise)

Category

Treatment - Other

3

Description

Intervention group: Combining the intervention of face-to-face mindfulness training and training through the first training application of the meditation technique with the sound of fire. Automatic guidance and meditation of eating raisins. 2. Teaching meditation technique with the sound of the forest. Practicing seeing and hearing. The third training of meditation technique with the sound of rain. Sitting meditation, teaching how to stay in the present moment. Fourth, teaching the technique of meditation with the sound of flight. The use of poetry and metaphor and its relationship with the quality of mindfulness.Fifth, correct breathing training, breathing based on the time of inhalation, exhalation and breath holding, (simple breathing exercise for relief). Preparation of a list of pleasant and unpleasant events in life. Sixth breathing based on the time of inhaling, exhaling and holding the breath (attention breathing exercise). Experience awareness and acceptance without judgment (non-selective). 7th breathing based on the time of inhaling, exhaling and holding the breath (square breathing exercise). Methods of dealing with the obstacles of doing meditation. Eighth breathing based on the time of inhaling, exhaling and holding the breath (heart breathing exercise). Summarizing the content and conducting the post-exam.

Category

Treatment - Other

4

Description

Control group: no intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Rehabilitation centers for neuropsychiatric patients under the supervision of welfare and psychiatri

Full name of responsible person
Zahra Mohamadzamani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Azad University

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Grant name
0

Grant code / Reference number
0

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Islamic Azad University

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
Semnan University

Full name of responsible person
Seyed Mosa Tabatabaee

Position
Faculty member of cognitive sciences

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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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
Undecided - It is not yet known if there will be 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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
after de-identification ,All data is shared.

When the data will become available and for how long
Access starts after the articles are published

To whom data/document is available
Psychology students and researchers

Under which criteria data/document could be used
En The results of the research are done without sending the statistics, if the statistics are requested, they will cooperate according to the needs of the researcher.

From where data/document is obtainable
mzamani.zahra@gmail.com

What processes are involved for a request to access data/document
En A request for documentation is made and the documentation is provided to the researcher within a week

Comments