Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation and comparison of the effectiveness of cognitive-behavioral therapy of insomnia (CBT-I) and mindfulness therapy (MBSR) on sleep quality, insomnia severity, emotional regulation and sleep dysfunctional beliefs in people with insomnia

Protocol summary

Study aim

effectiveness of cognitive-behavioral therapy of insomnia (CBT-I) and mindfulness therapy (MBSR) on sleep quality, insomnia severity, emotional regulation and sleep dysfunctional beliefs in people with insomnia.

Design

The clinical trial consisted of three groups (including two intervention groups and a control group). The sample size of each group was 10 patients. This study is a pre-test and post-test clinical trial. The sampling method was random allocation assigned by lot by selecting a paper lot from the bag. Out of 68 patients with insomnia, one number was assigned randomly to each group (group 1: CBT-I, group 2: mindfulness, and group 3: control) and these numbers were recorded on paper lotteries and each patient has randomly selected a lottery.

Settings and conduct

The intervention was performed in the sleep clinic of Hazrat Rasool Akram Hospital and blinding has not been performed in this study.

Participants/Inclusion and exclusion criteria

Entry requirements: - Getting a score lower than average in the questionnaires of sleep quality and emotional regulation and a score higher than the average in the questionnaires of insomnia severity and dysfunctional sleep beliefs Age between 20 and 50 years Do not take any other medicine at the same time Exit conditions: - Consumption of psychiatric and hypnotic drugs - Addiction and alcohol consumption Lack of cognitive-behavioral insomnia exercises and mindfulness exercises

Intervention groups

Cognitive-behavioral insomnia treatment intervention group Insomnia Mindfulness Treatment Intervention Group Control group: Routine measure

Main outcome variables

The first variable: the severity of insomnia، The second variable: sleep quality، Third variable: emotional regulation، Fourth variable: sleep dysfunctional thoughts

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210714051894N1**
Registration date: **2021-09-15, 1400/06/24**
Registration timing: **retrospective**

Last update: **2021-09-15, 1400/06/24**
Update count: **0**

Registration date

2021-09-15, 1400/06/24

Registrant information

Name

Masoomeh Yarahmadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6347 1269

Email address

yarahmady.1980@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-23, 1398/12/04

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

2020-02-23, 1398/12/04

Actual recruitment end date

2021-02-19, 1399/12/01

Trial completion date

2021-02-19, 1399/12/01

Scientific title

Evaluation and comparison of the effectiveness of cognitive-behavioral therapy of insomnia (CBT-I) and mindfulness therapy (MBSR) on sleep quality, insomnia severity, emotional regulation and sleep dysfunctional beliefs in people with insomnia

Public title

Comparison of the effectiveness of cognitive-behavioral therapy of insomnia and mindfulness treatment in insomnia

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent to participate in a clinical trial Receiving a lower than average score in the Sleep Quality and Emotional Regulation Questionnaire and a higher than average score in the Insomnia Intensity Questionnaire and dysfunctional sleep beliefs Age between 20 to 50 years Minimum literacy, primary education Lack of sleep drug during the study

Exclusion criteria:

Use of psychiatric and hypnotic drugs Taking traditional medicines such as sleeping pills Addiction and alcohol consumption Failure to perform cognitive-behavioral exercises for insomnia and mindfulness exercises

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method was random allocation assigned by lot by selecting a paper lot from the bag. Among the patients referred to the Sleep Disorders Clinic of Hazrat Rasool Akram Hospital (PBUH) and private clinics, patients who were diagnosed with insomnia disorder by a psychiatrist and sleep fellowship based on the characteristics mentioned in DSM-5 were selected. Then, out of 68 patients with insomnia, one number was assigned randomly to each group (group 1: CBT-I, group 2: mindfulness, and group 3: control) and these numbers were recorded on paper lotteries and each patient has randomly selected a lottery.

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

Islamic Azad University, Ahvaz Research Sciences Branch

Street address

Kianpars

City

Ahvaz

Province

Khouzestan

Postal code

6887561349

Approval date

2020-11-18, 1399/08/28

Ethics committee reference number

IR.IAU.AHVAZ.REC.1399.051

Health conditions studied

1

Description of health condition studied

Insomnia

ICD-10 code

G47.0

ICD-10 code description

Insomnia

Primary outcomes

1

Description

Severe insomnia

Timepoint

At the beginning of the intervention and 8 weeks after the intervention

Method of measurement

Questionnaire Insomnia Severity Index (ISI)

2

Description

Sleep Quality

Timepoint

At the beginning of the intervention and 8 weeks after the intervention

Method of measurement

Pittsburgh Questionnaire

3

Description
Emotional Regulation
Timepoint
At the beginning of the intervention and 8 weeks after the intervention
Method of measurement
Gross Questionnaire (ERQ)

4

Description
Dysfunctional Sleep Thoughts
Timepoint
At the beginning of the intervention and 8 weeks after the intervention
Method of measurement
Maureen Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: CBT-I: Session 1 (Insomnia assessment) Complete assessment of the nature of insomnia, teaching the patient how to monitor the baseline of sleep through a table of sleep reports for two weeks by the patient (before treatment). Session 2 (Introduction of the components of primary behavioral therapy) A: Introduction of therapeutic logic and criteria of sleep education: Introduction of sleep rules. Insomnia Behavioral Regime: Calculating the Time Allowed to Stay in Bed: Providing Basic Health Training's Sleep: Managing Patient Expectations and Adherence to Treatment G: Homework Session 3 (Introducing Cognitive Therapy Strategies) A: Reviewing and Commenting on Sleep Notes Patient and Demonstration Progress: The Basis and Logic of Cognitive Therapy for the Patient: A discussion of constructive concern techniques. Session 4 (Continuation of cognitive therapy) Review the pre-treatment session, review the findings of the sleep report form and the process of progress and follow the treatment instructions, how to record thoughts related to insomnia, review common cognitive errors in people with insomnia such as all or Nothing, catastrophic, mind-reading. Session 5 (follow-up / problem solving) A: Review and comment on the work of the constructive concern and record the patient's thoughts and show progress B: Adjust the recommendations regarding the time allowed to stay in bed: Review and encourage adherence to the treatment plan: Solve Problem - Behavioral part: Problem solving - Cognitive part. Session 6 (reviewing the end of the treatment period) Reviewing previous assignments, troubleshooting in the areas of cognitive components of treatment, patient homework is reviewed in each session and the necessary instructions are provided. The patient's completed sleep schedule is reviewed weekly and the patient's average sleep efficiency is completed in the previous week.
Category
Treatment - Other

2

Description
Intervention group: Mindfulness: 1- Initiating mind: Remember that every night is a new night. Be open and try something different! What you have done so far probably does not work well. 2- Working on changing the patient's mental perspective Lack of effort: Sleep is a process that can not be forced. But instead of letting it be seen, more effort to sleep longer or better will not work. Awareness of the patient of the importance of accepting existing conditions to make a change. This is counterproductive and contradicts the natural process of daily letting go that allows you to fall asleep. Trying to reduce the anxiety caused by the consequences of insomnia 4. Lack of judgment: You can easily judge that waking state is negative and pessimistic, especially if you do not sleep well for a few nights. However, this negative energy can disrupt the sleep process. A clear relationship with sleep can be a useful relaxation topic. Trying to Make a Better Relationship With Sleep 5. Acceptance: Recognizing and accepting your current situation is the first important step in choosing how to respond. If you can accept that you are not drowsy and will probably not fall asleep soon, why not get out of bed? Many people who have trouble sleeping avoid getting out of bed. Unfortunately, spending too much time waking up in bed can keep you awake. Trying to accept the existing conditions in order to start the change process. 6. Trust: Trust your sleep system and let it work for you! Make sure your mind and body can adjust to losing sleep. Knowing that short naps often make you feel more satisfied with fragmented sleep can help you build confidence in your sleep system. Also, sleep deprivation can cause good sleep as long as it is not accompanied by increased effort to sleep well. Confidence in your current sleep state 7. Patience: Be patient! It is unlikely that both the quality and quantity of your sleep will improve immediately.
Category
Treatment - Other

3

Description
Control group: In the control group, no intervention was performed simultaneously with the experimental group, but at the end of the intervention in the experimental group, the same treatment was performed for the control group.
Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Sleep Clinic of Hazrat Rasool Akram Hospital

Full name of responsible person
Dr Mir Farhad GhalehBandi

Street address
Sattar Khan St. - Niayesh St.

City
Tehran

Province
Tehran

Postal code
1445613131

Phone
+98 21 6655 1616

Email
Yarahmady.1980@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Fariba Hafezi

Street address
Sattar Khan

City
Tehran

Province
Khouzestan

Postal code
1445613131

Phone
+98 21 6347 1369

Fax

Email
hrmc@iums.ac.ir

Grant name

Grant code / Reference number

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
Islamic Azad University

Full name of responsible person
Masoomeh Yarahmady

Position
Psychologist

Latest degree
Master

Other areas of specialty/work
Psychology

Street address
Sattar Khan St. - Niayesh St.

City
Tehran

Province
Tehran

Postal code
1445613131

Phone
+98 21 6347 1269

Email
Yarahmady.1980@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Fariba Hafezi

Position
Science Committee

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
Ahvaz- Kianpars

City
Ahvaz

Province
Khouzestan

Postal code
163-61555

Phone
+98 61 1443 5288

Email
Febram315@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Masoomeh Yarahmadi

Position
Psychology

Latest degree
Master
Other areas of specialty/work
Psychology
Street address
Sattar Khan - Niayesh Street
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6347 1269
Email
Yarahmady.1980@yahoo.com

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
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
In this study, none of the patients' personal studies will be shared and only data related to the main outcome of the intervention will be shared.
When the data will become available and for how long
March 2020 to March 2021
To whom data/document is available
Researchers and researchers
Under which criteria data/document could be used
For further analysis (meta-analysis)
From where data/document is obtainable
Masoomeh yarahmadi 09123197245
Yarahmady.1980@yahoo.com
What processes are involved for a request to access data/document
Data on the variables of insomnia severity, sleep quality, emotional regulation and sleep dysfunctional thoughts were collected and analyzed separately.
Comments