Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

Acceptance and commitment therapy and psychological factors, in patients with insomnia

Protocol summary

Study aim
A study of effect of acceptance and commitment therapy on psychological indicators in patients with insomnia
Design
Randomized Controlled Clinical trial, with parallel groups
Settings and conduct
This experimental study will be done with control group and pretest/post test at the Center for Sleep Disorders in Farabi Hospital in Kermanshah.
Participants/Inclusion and exclusion criteria
Getting sick of insomnia; having ages 18-60; not having a chronic medical illnesses
Intervention groups
The experimental group includes patients who receive psychological therapy. The control group includes patients who receive drug treatment.
Main outcome variables
sleep quality; Experiential avoidance; Emotional Dysregulation; dysfunctional beliefs and attitudes about sleep; acceptance of sleep difficulties

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20150822023705N11**
Registration date: **2018-11-02, 1397/08/11**
Registration timing: **registered_while_recruiting**

Last update: **2018-11-02, 1397/08/11**
Update count: **0**
Registration date
2018-11-02, 1397/08/11

Registrant information
Name
Mostafa Alikhani
Name of organization / entity
Kermanshah University of Medical Sciences - Substance Abuse Prevention Research Center
Country
Iran (Islamic Republic of)
Phone
+98 838264513
Email address
mo.alikhani@kums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-08-23, 1397/06/01
Expected recruitment end date
2019-01-30, 1397/11/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Acceptance and commitment therapy and psychological factors, in patients with insomnia

Public title
Acceptance and commitment therapy and psychological factors in patients with insomnia
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Having complete patient satisfaction to participate in research Individuals should be between the ages of 18 and 60 The minimum qualification is grade 9. There are no chronic diseases, such as diabetes, cardiovascular diseases, respiratory diseases
Exclusion criteria:

Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple random
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 Kermanshah University of Medical Sciences
Street address
Building No.2, Shahid Beheshti Blvd, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
City
Kermanshah
Province
Kermanshah
Postal code
6719851115
Approval date
2017-11-26, 1396/09/05
Ethics committee reference number
IR.KUMS.REC.1396.478

Health conditions studied

1

Description of health condition studied
Insomnia
ICD-10 code
G47.0
ICD-10 code description
Insomnia

Primary outcomes

1

Description
Sleep quality
Timepoint
Comparison of sleep quality score in pre-test and post-test intervals of 60 days.
Method of measurement
For measuring the sleep quality variable, the individual score in Pittsburgh sleep quality questionnaire is calculated.

2

Description
Emotional dysregulation
Timepoint
Comparison of emotional dysregulation score in pre-test and post-test intervals of 60 days.
Method of measurement
the individual score in Gratz & Roamer's emotional dysregulation scale

3

Description
dysfunctional beliefs and attitudes about sleep
Timepoint
Comparison of dysfunctional beliefs and attitudes about sleep score in pre-test and post-test intervals of 60 days.
Method of measurement
For measuring the dysfunctional beliefs and attitudes about sleep variable, the individual score in Morin dysfunctional beliefs and attitudes about sleep questionnaire is calculated.

4

Description
acceptance of Sleep Problems
Timepoint
Comparison of acceptance of Sleep Problems score in pre-test and post-test intervals of 60 days.
Method of measurement
For measuring the acceptance of Sleep Problems of score in acceptance of Sleep Problems questionnaire is calculated.

5

Description
experiential avoidance
Timepoint
Comparison of experiential avoidance score in pre-test and post-test intervals of 60 days.
Method of measurement
For measuring the experiential avoidance of score in experiential avoidance questionnaire is calculated.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients who participate in Acceptance and Commitment Therapy. This course is for 8 sessions and each session is an hour.
Category
Behavior

2

Description
Control group: Patients who receive zolpidem for treatment. In the first week, the dose is 5ml but my be increase until 10ml. It is consumed overnight for two months.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
sleep center disorders
Full name of responsible person
Ali Zakiei
Street address
Isar square, Farabi Hospital
City
Kermanshah
Province
Kermanshah
Postal code
6719851115
Phone
+98 83 3826 5255
Email
zakieiali@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Koroush Hamzehee
Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences Kermanshah
City
Ker,amnshah
Province
Kermanshah
Postal code
6719851115
Phone
+98 83 3836 0014
Email
khamzehee@kums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Ali Zakiei
Position
Researcher
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Isar square, Farabi Hospital
City
Kermanshah
Province
Kermanshah
Postal code
6719851115
Phone
+98 83 3826 5255
Email
zakieiali@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Habibillah Khazaei
Position

Faculty member

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

Street address
Isar square, Farabi Hospital

City
Kermanshah

Province
Kermanshah

Postal code
6719851115

Phone
+98 83 3826 5255

Email
hakhazaie@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Ali Zakiei

Position
Researcher

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
Isar square, Farabi Hospital

City
Kermanshah

Province
Kermanshah

Postal code
6719851115

Phone
+98 83 3826 5255

Email
zakieiali@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not 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
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
The overall results of the study are published without mentioning the patients' names.

When the data will become available and for how long
Start the access period from September 2019

To whom data/document is available
Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used
For people who want scientific research.

From where data/document is obtainable
Kermanshah University of Medical Sciences

What processes are involved for a request to access data/document
The applicant must submit his application to the university.

Comments