

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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