Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A study of efficacy of mindfulness-based cognitive therapy in reducing ruminating, improving mindfulness and self-compassion in patients with treatment-resistant depression

Protocol summary

Study aim
Determine the efficiency of efficacy of Mindfulness-based cognitive therapy in Reducing Ruminating, Improving Mindfulness and Self-Compassion in Patients with Treatment-resistant depression

Design
Randomised,with a sample size of 24,a clinical trial with a control group

Settings and conduct
Farabi Hospital

Participants/Inclusion and exclusion criteria
Lack of therapeutic response to enough doses of two antidepressants for an adequate period(after 18 weeks)؛Score 19 or higher in Beck depression inventory؛Having a diagnostic criterion for major depressive disorder؛Reading 9th grade education level to complete the questionnaire

Intervention groups
Patients are randomly divided into experimental and control groups, and the treatment program will be provided to the experimental group for eight sessions, and the control group will receive only medication.

Main outcome variables
Increase self-compassion, increase consciousness and reduce stomach cramps, and reduce symptoms of depression.

General information

Reason for update

Acronym
MBCT

IRCT registration information
IRCT registration number: **IRCT20180205038630N1**
Registration date: **2018-02-27, 1396/12/08**
Registration timing: **prospective**
Last update: **2018-02-27, 1396/12/08**
Update count: **0**

Registration date
2018-02-27, 1396/12/08

Registrant information

Name
Ali Akbar Foroughi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-21, 1397/01/01

Expected recruitment end date
2018-04-19, 1397/01/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A study of efficacy of mindfulness-based cognitive therapy in reducing ruminating, improving mindfulness and self-compassion in patients with treatment-resistant depression

Public title
A study of efficacy of mindfulness-based cognitive therapy in patients with treatment-resistant depression

Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Lack of therapeutic response to enough doses of two antidepressants for an adequate period(after 18 weeks) Score 19 or higher in Beck depression inventory Having a diagnostic criterion for major depressive disorder Reading 9th grade education level to complete the questionnaire Having a minimum age of 18 and a maximum of 45 years
Exclusion criteria:
Having intense suicidal thoughts Need to be Hospitalization Failure to do homework related to treatment Affected by seasonal depression
Age
From **18 years** old to **45 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
By simple random method individuals are assigned to the control and test groups using sealed envelope
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
Oil field, Facing Taleghani Hospital
City
Kermanshah
Province
Kermanshah
Postal code
56423-22222
Approval date
2018-01-17, 1396/10/27
Ethics committee reference number
IR.KUMS.REC.1396.586

Health conditions studied

1

Description of health condition studied
Resistant to depression
ICD-10 code
P91.4
ICD-10 code description
Neonatal cerebral depression

Primary outcomes

1

Description
Score in Self-Compassion Inventory (Short Form)
Timepoint
At the beginning of the study, after the study (after the end of the intervention) and two months after the study
Method of measurement
Self-Compassion Inventory

2

Description
Mindfulness Questionnaire Score
Timepoint
At the beginning of the study, after the study (after the end of the intervention) and two months after the study
Method of measurement
Southampton Mindfulness Questionnaire for Consciousness

3

Description
Score in the rumination questionnaire
Timepoint
At the beginning of the study, after the study (after the end of the intervention) and two months after the study
Method of measurement
Ruminative Response Questionnaire

4

Description
Depression Score in Beck Questionnaire and Hamilton Grading Scale
Timepoint
At the beginning of the study, after the study (after the end of the intervention) and two months after the study
Method of measurement
Beck Depression Inventory and Hamilton's Grading Scale for Depression

Secondary outcomes

1

Description
Quality of Life Score
Timepoint
Study beginning, after study, two months after study
Method of measurement
Beck Depression Inventory

2

Description
Life expectancy score
Timepoint
Study beginning, after study, two months after study
Method of measurement
Beck Depression Inventory

3

Description
Changing the cost of treatment
Timepoint
Study beginning, after study, two months after study
Method of measurement
Beck Depression Inventory

Intervention groups

1

Description
Intervention group: For eight weeks in addition to antidepressants they also receive cognitive therapy based on mind-awareness.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Farabi Hospital
Full name of responsible person
Dr. Vahid Farnia
Street address
Farabi Hospital, Dolat Abad Square
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Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Farid Najafi
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Taleghani Hospital, Oil Field
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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
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Position
Student
Latest degree
Master
Other areas of specialty/work
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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