

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 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

AgeFrom **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**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

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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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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

Ghazaleh Azar

Position

Student

Latest degree

Master

Other areas of specialty/work

Psychology

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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