

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Comparing the effect of mindfulness-based cognitive behavioral therapy and hypiran on depression and quality of life of patients with major depressive disorder

Protocol summary

Study aim

The aim of this study is to comparing the effect of mindfulness-based cognitive behavioral therapy (MBCT) and hypiran on depression and quality of life of patients with major depressive disorder.

Design

Clinical trials with control group, community based and pragmatic with parallel groups, non-randomized

Settings and conduct

In this study, 55 patients suffering from moderate or severe underlying depression will enroll into the study, based on psychiatrist's diagnosis using the convenience sampling method, from the psychiatric department of Hajar Hospital and Hazrat Rasoul Clinic in Shahrekord.

Participants/Inclusion and exclusion criteria

Inclusion criteria: suffering from moderate or severe underlying depression, based on psychiatrist's diagnosis, education level of at least elementary school and age over 10 years old; and patients having organic brain disorders and mental retardation and having other underlying psychiatric disorders will not enrolled in the study.

Intervention groups

Patients will divide into four groups. All groups will receive fluoxetine, as a standard treatment, at a dose of 20-60 mg. In addition, Group 1, will receive 8 sessions of MBCT and second group, 60 drops of herbal Hypiran drop per day for 2 months based on the brochure will receive. Each ml of Hypiran drop (Poursina, Iran) contains 0.25 mg of hypericin (hydroalcoholic extract of the tea plant). The third group, in addition to standard medication will receive 8 sessions of MBCT treatment and 60 drops of Hypiran per day for 2 months and fourth group (control group) will underwent the standard medication alone.

Main outcome variables

Changes in the symptoms of depression; Changes in quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110514006480N17**

Registration date: **2018-10-13, 1397/07/21**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-13, 1397/07/21**

Update count: **0**

Registration date

2018-10-13, 1397/07/21

Registrant information

Name

Mohammad Taghi Moradi

Name of organization / entity

Shahrekord University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of mindfulness-based cognitive behavioral therapy and hypnotherapy on depression and quality of life of patients with major depressive disorder

Public title

Effect of mindfulness-based cognitive behavioral therapy on patients with major depressive disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Moderate or severe underlying depression, based on psychiatrist's diagnosis
Education level of at least elementary school
Age over 10 years old

Exclusion criteria:

Having organic brain disorders and mental retardation
Having other underlying psychiatric disorders

Age

From 10 years old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 55

Randomization (investigator's opinion)

Not randomized

Randomization description

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 Shahrekord University of Medical Sciences

Street address

Vice Chancellor for research, Shahrekord University of Medical Sciences, Kashani Street, Shahrekord

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

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Approval date

2017-04-24, 1396/02/04

Ethics committee reference number

IR.SKUMS.REC.1396.38

Health conditions studied

1

Description of health condition studied

Major depressive disorder (moderate)

ICD-10 code

F32.1

ICD-10 code description

Major depressive disorder, single episode, moderate

2

Description of health condition studied

Major depressive disorder (severe)

ICD-10 code

F32.2

ICD-10 code description

Major depressive disorder, single episode, severe without psychotic features

Primary outcomes

1

Description

Depression status

Timepoint

Before the intervention, two months after starting treatment

Method of measurement

The Beck questionnaire

2

Description

Quality of life status

Timepoint

Before the intervention, two months after starting treatment

Method of measurement

SF-36 quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: They will receive oral fluoxetine, as a standard treatment, at a dose of 20-60 mg, for 2 months.

Category

Treatment - Drugs

2

Description

Intervention group 1: They will receive 8 sessions of mindfulness-based cognitive behavioral therapy (MBCT) in addition to oral fluoxetine (20-60 mg, for 2 months). The overall structure of the MBCT program was 2- to 2.5-hour sessions over an eight week period. A structured program of homework including 45 minutes of daily practice, formal exercises, and in some days unofficial mind-boggling exercises was also used, and sometimes the individual recorded his/her observations of his/her own daily experiences.

Category

Treatment - Other

3

Description

Intervention group 2: In addition to fluoxetine (20-60 mg, for 2 months), they will receive 60 drops of herbal Hypiran drop per day for 2 months based on the brochure. Each ml of Hypiran drop (Poursina, Iran) contains 0.25 mg of hypericin (hydroalcoholic extract of the tea plant).

Category

Treatment - Drugs

4

Description

Intervention group 3: In addition to fluoxetine (20-60 mg, for 2 months), they will receive 8 sessions of MBCT treatment and 60 drops of Hypiran per day for 2 months. The overall structure of the MBCT program was 2- to 2.5-hour sessions over an eight week period. A structured program of homework including 45 minutes of daily practice, formal exercises, and in some days unofficial mind-boggling exercises was also used, and sometimes the individual recorded his/her observations of his/her own daily experiences.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hajar hospital

Full name of responsible person

Doctor Seyed-Kamal Solati

Street address

Psychiatry Department, Hajar Hospital, Parastar Street

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2

Recruitment center

Name of recruitment center

Shahrekord specialized clinic of Hazrate Rasoul (SA)

Full name of responsible person

Seyed Kamal Solati

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Specialized clinic of Hazrate Rasoul (SA), Molavi four-way, Shahrekord

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<https://skums.ac.ir/Index.aspx?tempname=rasolclinic&lang=1&sub=60&epageld=13739>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr. Seyed Kamal Solati

Street address

Deputy of Research and Technology, Shahrekord University of Medical Sciences, Ayatollah kashani Blvd., Shaharekord

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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

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Seyed Kamal Solati

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

Shahre-kord University of Medical Sciences

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Position

Associate Professor

Latest degree

Ph.D.

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