

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 38 1334 9509

##### Email address

mtmoradi@skums.ac.ir

##### 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

۸۸۱۵۷۱۳۴۷۱

### 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

##### **City**

Shahrekord

##### **Province**

Chahar-Mahal-va-Bakhtiari

##### **Postal code**

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##### **Phone**

+98 38 3222 5505

##### **Fax**

+98 38 3224 3715

##### **Email**

kamal\_solati@yahoo.com

## 2

#### **Recruitment center**

##### **Name of recruitment center**

Shahrekord specialized clinic of Hazrate Rasoul (SA)

##### **Full name of responsible person**

Seyed Kamal Solati

##### **Street address**

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

##### **City**

Shahrekord

##### **Province**

Chahar-Mahal-va-Bakhtiari

##### **Postal code**

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##### **Phone**

+98 38 3226 4833

##### **Fax**

##### **Email**

kamal\_solati@yahoo.com

##### **Web page address**

<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

##### **City**

Shahrekord

##### **Province**

Chahar-Mahal-va-Bakhtiari

##### **Postal code**

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##### **Phone**

+98 38 3334 2414

##### **Email**

kamal\_solati@yahoo.com

##### **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

**Street address**

Department of Psychiatry, Ayatollah Kashani hospital,  
Parastar Ave

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**Province**

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**Person responsible for scientific 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.

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**Person responsible for updating data**

**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.

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kamal\_solati@yahoo.com

**Web page address**

**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