

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Efficacy of mindfulness based emotional balance self-help program on psychopathology indicators, mindfulness and self-compassion in students

#### Protocol summary

##### Summary

This study aimed to evaluate the efficacy of mindfulness based emotional balance self-help program on reduction of depression, anxiety and stress. The main inclusion criterion is being student in Kermanshah University of Medical Sciences at the time of study conduction and main inclusion criteria is doing mindfulness exercises regularly or study of workbook before participating in the study. 80 students were randomly assigned to the experimental group (n = 40) or control group (n = 40). Intervention is mindfulness based emotional balance workbook (Colen and Brito Pons, 2015) that deliver to experimental group after translation to Persian. The primary outcome variables are stress, anxiety and depression. Emotion dysregulation and self-compassion had been selected as secondary outcome variables.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017022010063N6**

Registration date: **2017-03-06, 1395/12/16**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-03-06, 1395/12/16

##### Registrant information

###### Name

Kheirollah Sadeghi

###### Name of organization / entity

Kermanshah University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 1826 0700

###### Email address

khsadeghi@kums.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Kermanshah University of Medical Sciences

###### Expected recruitment start date

2017-02-19, 1395/12/01

###### Expected recruitment end date

2017-04-04, 1396/01/15

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Efficacy of mindfulness based emotional balance self-help program on psychopathology indicators, mindfulness and self-compassion in students

###### Public title

Efficacy of mindfulness based emotional balance self-help program on psychopathology indicators, mindfulness and self-compassion in students

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion criteria: Studying in Kermanshah University of Medical Sciences At the time of study; at least 18 years old; Currently do not get any type of psychotherapy; Do not suffer from a serious mental disorder (eg, psychotic or mood disorders) Exclusion criteria: Not having tools to listen to audio files related to meditation; regular practice of mindfulness exercises before participating in the study (once a week or more); Study of workbook before participating in the study

###### Age

No age limit  
**Gender**  
Both  
**Phase**  
N/A  
**Groups that have been masked**  
*No information*  
**Sample size**  
Target sample size: **80**  
**Randomization (investigator's opinion)**  
Randomized  
**Randomization description**  
**Blinding (investigator's opinion)**  
Single blinded  
**Blinding description**  
**Placebo**  
Not used  
**Assignment**  
Parallel  
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

**Name of ethics committee**

Kermanshah University of Medical Sciences

**Street address**

Headquarter, Shahid Beheshti Blvd, Kermanshah

**City**

Kermanshah

**Postal code****Approval date**

2017-02-20, 1395/12/02

**Ethics committee reference number**

KUMS.REC.1395.657

## Health conditions studied

### 1

**Description of health condition studied**

Depression

**ICD-10 code**

F32.9

**ICD-10 code description**

Depressive episode, unspecified

### 2

**Description of health condition studied**

Anxiety

**ICD-10 code**

F41.9

**ICD-10 code description**

Anxiety disorder, unspecified

### 3

**Description of health condition studied**

Stress

**ICD-10 code**

Z73.3

**ICD-10 code description**

Stress, not elsewhere classified

## Primary outcomes

### 1

**Description**

Depression

**Timepoint**

pre-test, post-test, two months follow up

**Method of measurement**

depression, anxiety and stress scale

### 2

**Description**

Anxiety

**Timepoint**

pre-test, post-test, two months follow up

**Method of measurement**

depression, anxiety and stress scale

### 3

**Description**

stress

**Timepoint**

pre-test, post-test, two months follow up

**Method of measurement**

depression, anxiety and stress scale

## Secondary outcomes

### 1

**Description**

emotion dysregulation

**Timepoint**

pre-test, post-test, two months follow up

**Method of measurement**

difficulties in emotion regulation scale

### 2

**Description**

Self-compassion

**Timepoint**

pre-test, post-test, two months follow up

**Method of measurement**

Self-compassion Scale

## Intervention groups

**1**

**Description**

Interventional group: eight-week self-help program using mindfulness based emotion balance workbook (Colen and Pons, 2015). This book include 195 pages and conduct in 8 weeks.

**Category**

Behavior

**2**

**Description**

Control group: no intervention (wait-list)

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Meysam Bazani

**Street address**

-medical school, next to Emam Reza hospital, Shahid Shiroudi Avld, Kermanshah

**City**

Kermanshah

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Behruz Hamzeh

**Street address**

Headquarte, Shahid Beheshti Blvd, Kermanshah

**City**

Kermanshah

**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**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Meysam Bazani

**Position**

MSc

**Other areas of specialty/work**

**Street address**

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**Web page address**

**Person responsible for scientific inquiries**

**Contact**

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**Full name of responsible person**

Meysam Bazani

**Position**

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**Other areas of specialty/work**

**Street address**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Kheirollah Sadeghi

**Position**

Assistant Professor

**Other areas of specialty/work**

**Street address**

**City**

**Postal code**

**Phone**

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**Fax**

**Email**

**Web page address**

## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*