

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

medical Schoo, Next to Imam Reza hospital, Shahid Shirudi Avld, Kermanshah

City

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Phone

+98 83 4622 0118

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bazani.misam@yahoo.com

Web page address

Person responsible for scientific 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

medical school, next to Emam Reza hospital, Shahid Shirudi Avld, Kermanshah

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Web page address

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

00

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