Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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Person responsible for updating data

Contact
Name of organization / entity
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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