

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the efficacy of mindfulness-based stress reduction on reduction on pathological worry in Non-clinical population

Protocol summary

Summary

The aim of this study is to examine the Effectiveness of Mindfulness-based stress reduction on pathological worry in non-clinical population. Design: General plan of this study is consisted of experimental pre-test and post-test with follow-up period. Setting and conduct: The study population were female undergraduate students in Shahed University that have not any psychological disorder and they did not receive any treatment in the last year. Then these people were randomly divided into two groups: experimental (Mindfulness-based stress reduction) and control group. Each group were completed scales considered; as a pre-test, post-test, one month and three months after the completion of their intervention. The main conditions of inclusion and exclusion criteria of participants: Inclusion criteria: gender of female, Engagement with education in undergraduate and Lack of psychological disorders. Exclusion criteria: Absence of the inclusion criteria. Interventions: Mindfulness-based stress reduction is designed at 8 weekly 2-hour session. Control group do not receive any psychotherapy. Main outcome measures: In this study the main variables are pathological worry and meta worry.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016090329648N1**

Registration date: **2016-11-26, 1395/09/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-11-26, 1395/09/06

Registrant information

Name

Elham Mirzaei

Name of organization / entity

Shahed University

Country

Iran (Islamic Republic of)

Phone

+98 51 3622 6484

Email address

mirzaeie2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahed University

Expected recruitment start date

2012-09-15, 1391/06/25

Expected recruitment end date

2012-12-19, 1391/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of mindfulness-based stress reduction on reduction on pathological worry in Non-clinical population

Public title

The efficacy of mindfulness on worry

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Engagement with education in undergraduate, gender of female, Being in the age range of 18 to 24, Obtain a score of above Cut-off point in PSWQ (Cut-off point: 50), Do not receive drug or psychological

treatment and or consulting in last year, Lack of generalized anxiety disorder or other psychological disorder. Exclusion criteria: Absence of the above conditions.

Age

From **18 years** old to **24 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

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

Shahed University

Street address

Shahed University, In front of Shrine, Persian Gulf Freeway, shahed university

City

Tehran

Postal code

3319118651

Approval date

2012-09-10, 1391/06/20

Ethics committee reference number

130/23417

Health conditions studied

1

Description of health condition studied

Pathological worry

ICD-10 code

F54

ICD-10 code description

Psychological and behavioural factors associated with disorders or diseases classified elsewhere

2

Description of health condition studied

Pathological worry

ICD-10 code

F43.2

ICD-10 code description

Adjustment disorders

3

Description of health condition studied

Pathological worry

ICD-10 code

F48.0

ICD-10 code description

Neurasthenia

Primary outcomes

1

Description

Pathological worry

Timepoint

Pre - post test, follow up

Method of measurement

Penn State Worry Questionnaire (PSWQ), GAD-7

2

Description

Meta worry

Timepoint

Pre- post worry, follow up

Method of measurement

Wells Anxiety Thoughts Inventory

Secondary outcomes

1

Description

positive and negative affect

Timepoint

Pre - post test, follow up

Method of measurement

Positive and Negative Affect scale (PANAS)

2

Description

Symptoms of depression

Timepoint

Pre - post test, follow up

Method of measurement

Beck Depression Inventory (II)

Intervention groups

1

Description

The control group in the study do not receive intervention (no action).

Category

N/A

2

Description

The experimental group received 8 sessions of mindfulness-based stress reduction model (in two months, each week one session, 2-2.5 hours).

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

All colleges of Shahed University

Full name of responsible person

Elham Mirzaee, MA of Clinical psychology

Street address

Tehran, Shahed University, Persian Gulf Freeway, In front of Shrine

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Mohammadhadi Shoaee

Street address

In front of Shrine, Persian Gulf Freeway

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahed University

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

Shahed University

Full name of responsible person

Dr.Mohammadreza Shairi

Position

PhD in Clinical Psychology, Associate Professor of Clinical psychology

Other areas of specialty/work

Street address

Tehran, Shahed University, Persian Gulf Freeway, In front of Shrine

City

Tehran

Postal code

Phone

+98 21 5121 2470

Fax

Email

Shairigm@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Elham Mirzaee

Position

MA of Clinical psychology

Other areas of specialty/work

Street address

Tehran, Shahed University, Persian Gulf Freeway, In front of Shrine

City

Tehran

Postal code

Phone

+98 21 5121 2470

Fax

Email

mirzaeelham88@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Elham Mirzaee

Full name of responsible person

Position

MA of Clinical psychology

Other areas of specialty/work

Street address

City

Postal code

Phone
Fax
Email
mirzaeeelham88@gmail.com
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