Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effectiveness of Mindfulness-Based Stress Reduction on decreasing depression and Anxiety levels, and improving Quality of Life of the women with generalized anxiety disorder

Protocol summary

Summary

This study has been conducted to investigate the effectiveness of Mindfulness-Based Stress Reduction on Quality of Life, stress, anxiety in Patients with generalized anxiety disorder. This research was conducted by using semi- experimental study with pretest-posttest design, using control group. So, from females with generalized anxiety disorder who appointed in Imam Hossein hospital in Tehran in 2013, 34 participants were selected and randomly assigned in two equal experimental and control groups. Experimental group experienced 8 weeks over120 minutes of Mindfulness-Based Stress Reduction therapy. data will gather by BDI, BAI, PWI-A, GAD-7 at pre interventoin phase and from treatment initiation to eight week after that. both groups will compare on Quality of Life, stress, anxiety at the end of eight week.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014110819855N1**
Registration date: **2014-12-30, 1393/10/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-12-30, 1393/10/09

Registrant information

Name

Samira Masumian

Name of organization / entity

Tehran Psychiatry Institue

Country

Iran (Islamic Republic of)

Phone

+98 21 3349 6990

Email address

samira.masumian@yahoo.com

Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2014-11-26, 1393/09/05

Expected recruitment end date

2015-03-22, 1394/01/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of Mindfulness-Based Stress Reduction on decreasing depression and Anxiety levels, and improving Quality of Life of the women with generalized anxiety disorder

Public title

Effectiveness of Mindfulness-Based Stress Reduction therapy on patient with generalized anxiety disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Informed consent; age range of 18 - 40 years; being female Exclusion criteria: Underlying medical diseases and psychological disorders(Psychosis, demantia, cancer); receiving any other treatment (including psychotherapy)

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

N/A

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

Iran University of Medical Sciences

Street address

Hemat Highway, Iran University of Medical Sciences, Tehran, Iran

City

Tehran

Postal code

Approval date

2014-08-25, 1393/06/03

Ethics committee reference number

24477

Health conditions studied

1

Description of health condition studied

Generalized anxiety disorder

ICD-10 code

F41.1

ICD-10 code description

Anxiety that is generalized and persistent but not restricted to, or even strongly predominating in, any particular environmental circumstances (i.e. it is "free-floating"). The dominant symptoms are variable but include complaints of persistent nervousne

Primary outcomes

1

Description

Depression

Timepoint

pretest.posttest (at the end of 8 session)

Method of measurement

Beck inventory

2

Description

Anxiety

Timepoint

pretest.posttest (at the end of 8 session)

Method of measurement

Beck anxiety

3

Description

Generalized anxiety

Timepoint

pretest.posttest (at the end of 8 session)

Method of measurement

Generalized anxiety inventory

4

Description

Quality of life

Timepoint

pretest.posttest (at the end of 8 session)

Method of measurement

Quality of life inventory

Secondary outcomes

empty

Intervention groups

1

Description

WEEKS 1 and 2) Raisin exercise Body scans meditation, 6 days per week, 45 minutes a day. Sitting with awareness of breathing, 10 minutes per day. Mindfulness of breathing meditation. WEEKS 3 and 4) Alternate body scan with yoga (45 minutes) if possible, 6 days per week. Continue sitting with awareness of breathing, 15-20 minutes per day. Focusingon one unpleasant event each day and completing an unpleasant – events diary. Three-step breathing space. WEEKS 5 and 6) Full sitting meditation practice. Sit 30-45 minutes per day, alternating with yoga. Begin. walking meditation. Three-step breathing space, Three times a day and as needed. WEEK 7) Longer sitting meditation Practice 45 minutes per day using your own choice of methods, either alone or in combination. WEEK 8) Go back to using tapes. Do body scan at least twice this week. Reviewing the course as a whole. Continue the sitting and the yoga.

Category

Other

2

Description
They had no treatment and were in waiting list
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Hosein Haspital
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mental Health Research Center
Full name of responsible person
Seyed Vahid Shariat
Street address
Iran University of Medical Sciences, Hemat Highway, Tehran, Iran
City
Iran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mental Health Research Center
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
Tehran Psychiatry Institue
Full name of responsible person
Samira Masumian
Position
Student Of Phd
Other areas of specialty/work
Street address
Satarkhan, Tehran Psychiatry Institue, Tehran, Iran
City
Tehran
Postal code
Phone
+98 21 3349 6990
Fax
Email
samira.masumian@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran Psychiatry Institue
Full name of responsible person
Samira Masumian
Position
Student Of Phd
Other areas of specialty/work
Street address
Satarkhan, Tehran Psychiatry Institue
City
Tehran
Postal code
Phone
+98 21 3349 6990
Fax
Email
samira.masumian@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran Psychiatry Institue
Full name of responsible person
Samira Masumian
Position
Student Of Phd
Other areas of specialty/work
Street address
City
Tehran
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