

# 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 over 120 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. Focusing on 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 Hospital

##### 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 Institute

#### Full name of responsible person

Samira Masumian

#### Position

Student Of Phd

#### Other areas of specialty/work

#### Street address

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samira.masumian@yahoo.com

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## Person responsible for scientific inquiries

### Contact

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#### Other areas of specialty/work

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#### 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*