

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effectiveness of Mindfulness-Based Stress Reduction (MBSR) on the rate of depression, anxiety, stress, and the perception of low back pain after childbirth

#### Protocol summary

##### Study aim

The purpose of this study was to investigate the effectiveness of mindfulness on the rate of depression, anxiety, stress, and the perception of low back pain in women after their childbirth.

##### Design

This study was a semi-experimental design with control group, community-based, with a sample size of 40 patients and randomized.

##### Settings and conduct

The location of the study was sa'adat abad health center in Tehran and the study was done on women with low back pain after childbirth. for sampling and randomization, the women were divided into two groups, namely experimental and control. Eight sessions of the mindfulness program were conducted for the experimental group.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria Having back pain after three months from the childbirth Having chronic back pain due to childbirth - Exclusion criteria Having mental disorders Receiving simultaneous psychotherapy or medical treatment for low back pain

##### Intervention groups

The mindfulness training program was carried out in 8 sessions once every week. Each session took 120 minutes for the experimental group. The control group did not receive intervention.

##### Main outcome variables

Depression, Anxiety, Stress, Perception of Low Back Pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181011041308N1**

Registration date: **2018-11-26, 1397/09/05**

Registration timing: **retrospective**

Last update: **2018-11-26, 1397/09/05**

Update count: **0**

##### Registration date

2018-11-26, 1397/09/05

##### Registrant information

###### Name

Mahmoud Reza Alebouyeh

###### Name of organization / entity

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Iran (Islamic Republic of)

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-12-22, 1396/10/01

##### Expected recruitment end date

2018-01-04, 1396/10/14

##### Actual recruitment start date

2018-01-06, 1396/10/16

##### Actual recruitment end date

2018-01-11, 1396/10/21

##### Trial completion date

2018-02-16, 1396/11/27

##### Scientific title

The effectiveness of Mindfulness-Based Stress Reduction (MBSR) on the rate of depression, anxiety, stress, and the perception of low back pain after childbirth

##### Public title

The effectiveness of Mindfulness therapy on the perception of pain

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Having back pain after three months from the childbirth  
Having chronic back pain due to childbirth

**Exclusion criteria:**

Having mental illness Using other treatments related to back pain including psychological or physical Use of pain killer medications

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **40**

Actual sample size reached: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

For randomization, random allocation rule which is a limited randomization method was used. Thus, after determining a sample size of 40 people, their names were put in a lottery vase randomly. Then, the first 20 names which were taken out randomly were dedicated to the experimental group. The remaining names were dedicated to the control group.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Scientific Committee on Ethics in Biomedical Research, Tehran Azad University of Medical Sciences

**Street address**

Tehran-Ghods Town (West), Iran's Sims Street-Headquarters of the Ministry of Health, Medical Education and Training, Block A, Thirteenth Class

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**Province**

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**Postal code**

1916893813

**Approval date**

2017-12-19, 1396/09/28

**Ethics committee reference number**

IR.IAU.TMU.REC.1396.217

**Health conditions studied****1****Description of health condition studied**

Chronic low back pain

**ICD-10 code**

M54.5

**ICD-10 code description**

Low back pain

**Primary outcomes****1****Description**

Perception of pain

**Timepoint**

Before intervention, after intervention, and one month after intervention

**Method of measurement**

Oswestry Disability Index (ODI)

**2****Description**

Depression, Anxiety, Stress

**Timepoint**

Before intervention, after intervention, and one month after intervention

**Method of measurement**

Depression, Anxiety, Stress Scale (DASS)

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Experimental group: This group received the mindfulness program during eight weeks, one 120-minute session each week. A brief explanation of the sessions is given as follows. First session: defining the general guideline considering the privacy and confidentiality of the private life of the people, asking people to introduce themselves to each other, training the body verification, homework, discussion and scheduling weekly meetings, distribution of notes, handouts and CDs. Second session: Training body relaxation for the 14 group of muscles including forearm, arm, calf, thighs, abdomen, chest, shoulders, neck, lips, eyes, and forehead. Third session: Training body relaxation for the 6 group of muscles including

hands and arms, legs and thighs, abdomen and chest, forehead and lips, and the homework for the body relaxation. Fourth session: Introduction to the method for the breath mindfulness, training the technique of inhale and exhale with relaxation and without thinking about other issues, training the technique for watching the breath, and the homework for the breath mindfulness before the sleep. Fifth session: Training the technique for the attention to the body movements during breath, concentration on the body parts and their movements and the search for physical senses, and homework for the eating mindfulness. Sixth session: Training to concentrate on the mind, positive and negative thoughts, pleasant and unpleasant thoughts, letting the positive and negative thoughts to enter the mind and easily moving them out of the mind without making judgment and paying deep attention to them. Seventh session: a 40-minute sitting meditation, review of the homeworks, exercising the observation of the relation between activity and the behavior. Eighth session: review of the past sessions, conclusion, and questions and answers.

**Category**

Other

**2**

**Description**

Control group: This group did not receive the mindfulness program and they were monitored to avoid using psychological and physical treatments or pain killers during the eight weeks.

**Category**

Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Sa'adat Abad Community Health Center

**Full name of responsible person**

Farzaneh Farahmand

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Near the prison shop, the front of Evin prison, Street martyr Kachuei, Saadat Abad,

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Narges Babakhani

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**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Islamic Azad University

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Academic

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Narges Babakhani

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Only pre-test, post-test and follow-up data are available.

**When the data will become available and for how long**

The time of access is 6 months after the publication of the article.

**To whom data/document is available**

Data is only available for academic researchers.

**Under which criteria data/document could be used**

It can be submitted to the reviewers or critics of the article. Applicants must be academic members of a university.

**From where data/document is obtainable**

Islamic Azad University of Roodehen, Tehran, Dr. Narges babakhani, Address Email: babakhani@riau.ac.ir

**What processes are involved for a request to access data/document**

By sending an email to Dr Babakhani and then confirming it, you can receive the data and it takes less than two weeks.

**Comments**