

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

Country

Iran (Islamic Republic of)

Phone

+98 21 2213 6136

Email address

alebuieh.mr@iums.ac.ir

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

City

Tehran

Province

Tehran

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

Street address

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

City

Tehran

Province

Tehran

Postal code

1558738816

Phone

+98 21 2211 5750

Email

sghc@iums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Narges Babakhani

Street address

Rudehen shahrake pona

City

Roudehen

Province

Tehran

Postal code

3973188981

Phone

+98 21 7650 5015

Email

info@riau.ac.ir

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

Street address

Roudehen, Academic Complex

City

Roudehen

Province

Tehran

Postal code

397318898

Phone

+98 21 2291 5385

Email

babakhani@riau.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Research Committee of Islamic Azad University of
Roudehen

Full name of responsible person

Narges Babakhani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Roudehen, Academic Complex

City

Roudehen

Province

Tehran

Postal code

3973188981

Phone

+98 21 2291 5385

Email

babakhani@riau.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Research Committee of Islamic Azad University of
Roudehen

Full name of responsible person

Elaheh Sobhani

Position

student

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Roudehen, Academic Complex

City

Roudehen

Province

Tehran

Postal code

3793188981

Phone

+98 21 2282 2976

Email

Elahe_so61@yahoo.com

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