

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Feb 2023

### The effect of mindfulness-based stress reduction counseling on perceived stress and emotion regulation of midwives

#### Protocol summary

##### Study aim

Determining the Effect of mindfulness-based stress reduction counseling on perceived stress and emotion regulation of midwives working in Hospitals in Zanjan

##### Design

In this research, 60 midwives who received over-28 at cohen perceived stress questionnaire were enrolled in the study and randomly divided into intervention and control groups and assigned to each participant a code.

##### Settings and conduct

The research population includes all midwives working in the delivery wards of hospitals in Zanjan. By co-ordinating with the director of nursing services and the departments of maternity wards of Ayatollah Mousavi and Imam Hossein hospitals, they will be involved in the research. Sampling is a census and allocation of individuals as a random block. Before the intervention, the researcher will insist on the satisfaction of the research samples to participate in the research and emphasize the confidentiality of information by introducing and explaining the subject of the research and its purpose. Intervention takes place in eight sessions of one and a half hours in the form of group counseling as a one-week session provided by the researcher.

##### Participants/Inclusion and exclusion criteria

Criteria for entering the study: 1) Having a expert degree in midwifery and higher. 2) Gaining a score of 28 from Cohen's Perceived Stress Questionnaire. 3) Having one year of work experience in obstetrics and gynecology. 4) Written consent for participation in the study. 5) The desire to participate regularly in group meetings. 6) No Smoking and Drug Abuse 7) Accommodation in Zanjan City  
Exit criteria: 1) Unwillingness to continue study 2) Absence more than two sessions in counseling sessions 3) Flawed completion of the questionnaire (so that more than 20 percent of the questions remain unanswered). 4) Getting out of the study if you diagnose mental disorders in each the level

##### Intervention groups

Intervention takes place in eight sessions of one and a half hours in the form of group counseling as a one-week session provided by the researcher. Control group members will not receive any advice.

##### Main outcome variables

Reducing stress

#### General information

##### Reason for update

##### Acronym

MBSR

##### IRCT registration information

IRCT registration number: **IRCT20160608028352N6**

Registration date: **2018-01-08, 1396/10/18**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-01-08, 1396/10/18**

Update count: **0**

##### Registration date

2018-01-08, 1396/10/18

##### Registrant information

##### Name

Roghieh Kharaghani

##### Name of organization / entity

Zanjan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 24 3314 8144

##### Email address

r.kharaghani@zums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Zanjan University of Medical Sciences

##### Expected recruitment start date

2018-01-05, 1396/10/15  
**Expected recruitment end date**  
2018-03-06, 1396/12/15  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
The effect of mindfulness-based stress reduction counseling on perceived stress and emotion regulation of midwives

**Public title**  
The effect of mindfulness-based stress reduction counseling on perceived stress and emotion regulation of midwives

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Having a expert degree in midwifery and higher Gaining a score of 28 from Cohen's Perceived Stress Questionnaire Having one year of work experience in obstetrics and gynecology. Female sex Interested in attending counseling sessions No smoking and drug abuse Accommodation in Zanjan city Not attending other counseling sessions in the last two months The lack of other stressful situations in life, such as the divorce or death of one of the loved ones  
**Exclusion criteria:**  
Getting out of the study if you diagnose mental disorders in each the level Unwillingness to participate in the study Completion of the incomplete questionnaire in such a way that more than 20% of the questions are unanswered

**Age**  
No age limit

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The census sampling method includes midwives working in two hospitals, Ayatollah Mousavi and Imam Hossein, whose score in the perceived stress questionnaire above the cutting line is 28, and other features of the study entry. The subjects were selected by simple sampling method and assigned as random block in two groups of intervention and control

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**  
**Placebo**

Not used  
**Assignment**  
Parallel  
**Other design features**

**Secondary Ids**

**1**

**Registry name**  
مرکز ثبت کارآزمایی بالینی ایران  
**Secondary trial Id**  
A-11-980-11  
**Registration date**  
2017-11-21, 1396/08/30

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**  
Ethics committee of Zanjan University of Medical Sciences  
**Street address**  
North Side Azadi Boulevard  
**City**  
Zanjan  
**Province**  
Zanjan  
**Postal code**  
4515613191  
**Approval date**  
2017-12-13, 1396/09/22  
**Ethics committee reference number**  
ZUMS.REC.1396.237

## Health conditions studied

**1**

**Description of health condition studied**  
STRESS  
**ICD-10 code**  
F43.2  
**ICD-10 code description**  
Adjustment disorders

## Primary outcomes

**1**

**Description**  
Perceived Stress  
**Timepoint**  
Before intervention , after intervention, and three months after intervention  
**Method of measurement**  
Cohen Perceived Stress Questionnaire

## Secondary outcomes

### 1

#### Description

Emotion regulation

#### Timepoint

Before intervention, after intervention, and three months after intervention

#### Method of measurement

Garretz and Roemer's Thrilling Setting Questionnaire

## Intervention groups

### 1

#### Description

30 Control group and 30 control group intervention groups will not receive any counseling

#### Category

Behavior

### 2

#### Description

Intervention group: Individuals in the intervention group will be given eight sessions of one and a half hours of group counseling for the reduction of consciousness-minded stress, all of which will be provided by the researcher. The number of sessions was determined according to the studies that were conducted using a similar counseling approach to the intervention of the researcher. Consultation sessions will be held at the Ayatollah Mousavi Hospital Preparatory Classes and will be held under the supervision of a Compliance Professor (Cognitive-Behavioral Mindfulness-Based Stress Management).

#### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Department of Maternity Hospitals Ayatollah Mousavi

##### Full name of responsible person

Fatemeh Aghamohammadi

##### Street address

Zanjan road gavazang of Ayatollah Mousavi Hospital

##### City

zanjan

##### Province

Zanjan

##### Postal code

4515613191

##### Phone

+98 24 3313 1000

##### Email

fateme\_am@yahoo.com

### 2

#### Recruitment center

##### Name of recruitment center

Department of Maternity Hospitals Imam hosin

##### Full name of responsible person

Fatemeh Aghamohammadi

##### Street address

Emam Hossein Hospital, Amjadiyeh Three Way, Early Culture Center

##### City

Zanjan

##### Province

Zanjan

##### Postal code

4519786911

##### Phone

+98 24 3301 1000

##### Email

fateme\_am@yahoo.com

### 3

#### Recruitment center

##### Name of recruitment center

Maternity wards of Ayatollah Mousavi and Imam Hossein hospitals

##### Full name of responsible person

Fatemeh Aghamohammadi

##### Street address

Zanjan road gavazang of Ayatollah Mousavi Hospital

##### City

zanjan

##### Province

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##### Postal code

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##### Phone

+98 24 3342 0651

##### Email

fateme\_am@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Zanjan University of Medical Sciences

##### Full name of responsible person

Dr Alireza Shoghli

##### Street address

Chancellor for Research and Technology of Zanjan University of Medical Sciences, First floor, North Side Azadi Boulevard, Zanjan

##### City

zanjan

##### Province

Zanjan

##### Postal code

4515613191

##### Phone

+98 24 3342 0651

**Email**

r.kharaghani@yahoo.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Zanjan University of Medical Sciences

**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**

Zanjan University of Medical Sciences

**Full name of responsible person**

Fatemeh Aghamohammadi

**Position**

Midwife

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

Zanjan . shahrak karmandan, Faculty of Nursing

Midwifery

**City**

zanjan

**Province**

Zanjan

**Postal code**

4515613191

**Phone**

+98 912 742 9115

**Fax****Email**

fateme\_am@yahoo.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Dr Roghieh Kharaghani

**Position**

Ph.D of Reproductive Health

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Health

**Street address**

Zanjan.shahrak karmandan, Faculty of Nursing

Midwifer

**City**

zanjan

**Province**

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**Postal code**

4515613191

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**Fax****Email**

r.kharaghani@zums.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Dr Roghieh Kharaghani

**Position**

Ph.D of Reproductive Health

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Health

**Street address**

chool of Nursing and Midwifery, Karmandan town,

zanjan

**City**

zanjan

**Province**

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**Postal code**

4515613191

**Phone**

+98 912 562 5984

**Fax****Email**

r.kharaghani@zums.ac.ir

**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to

make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

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

A portion of the data associated with the original outcome will be shared.

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

Start the access period from 1398

**To whom data/document is available**

Information will be available for scholars working in

academic and academic institutions

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

Apply this type of advice to another target group

**From where data/document is obtainable**

By e-mail address

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

It will be answered by email and immediately after ensuring the plan is used.

**Comments**

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