

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

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Zanjan

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4519786911

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3

Recruitment center

Name of recruitment center

Maternity wards of Ayatollah Mousavi and Imam Hossein hospitals

Full name of responsible person

Fatemeh Aghamohammadi

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Zanjan road gavazang of Ayatollah Mousavi Hospital

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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

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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

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Province

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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

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Midwifer

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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

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chool of Nursing and Midwifery, Karmandan town,

zanjan

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Phone

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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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