

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Comparison of the effect of two educational methods of the mindfulness and cognitive emotion regulation strategies on psychological well-being and anxiety of graduate students of midwifery before the final clinical examination

#### Protocol summary

##### Study aim

Determining and comparing the effect of two educational methods of mindfulness and cognitive emotion regulation strategies on psychological well-being and anxiety of mid-term midwifery students before the final clinical exam

##### Design

A clinical field trial with two intervention and one control groups, parallel groups, randomized, on 27 final year midwifery students, a random number table will be used for randomization

##### Settings and conduct

This study will be performed in Isfahan University of Medical Sciences, School of Nursing and Midwifery. Eligible individuals with written consent to participate in the study, after explaining the objectives and methods of study and completing the questionnaires, will be divided into three groups using a table of random numbers. Then, the intended interventions will be performed on two intervention groups. At the end, all participants will complete the questionnaires again.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Having written consent to participate in the study 2. Being in the last semester of midwifery 3. Do not take drugs that affect the psychological status 4. Lack of experience of an unfortunate, anxious or stressful events during the last 6 months 5. No medical disease (diabetes, hypertension, thyroid disease, cardiovascular disease, kidney disease, nervous disease, etc.) Exclusion criteria: 1. Failure to participate in more than 25% of educational programs 2. Reluctance to continue participating in the study

##### Intervention groups

Intervention group 1 = Education based on mindfulness  
Intervention group 2 = Education based on cognitive emotion regulation strategies  
Control group= No

intervention

##### Main outcome variables

Psychological well-being, anxiety

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160224026756N7**

Registration date: **2020-08-26, 1399/06/05**

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

Last update: **2020-08-26, 1399/06/05**

Update count: **0**

##### Registration date

2020-08-26, 1399/06/05

##### Registrant information

##### Name

Mahnaz Noroozi

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3441 1421

##### Email address

noroozi@nm.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-08-22, 1399/06/01

##### Expected recruitment end date

2020-10-22, 1399/08/01  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**

Comparison of the effect of two educational methods of the mindfulness and cognitive emotion regulation strategies on psychological well-being and anxiety of graduate students of midwifery before the final clinical examination

**Public title**

Comparison of the effect of two educational methods on psychological well-being and anxiety of graduate students of midwifery before the final clinical examination

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Being in the last semester of midwifery Having written consent to participate in the study

**Exclusion criteria:**

taking drugs that affect the psychological status Having experience of unfortunate, anxious or stressful events during the last 6 months Having Medical disease (diabetes, hypertension, thyroid disease, cardiovascular disease, kidney disease, nervous disease, etc.)

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 27

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

For sampling random numbers table will be used. In this way, the samples included in the research will be numbered from 1 to n. Then, to select the samples from the table, we will randomly start from a table point (with closed eyes put fingers in a point) into direction of row and select the people in order for control, intervention 1 and intervention 2 groups.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Isfahan University of Medical Sciences

**Street address**

Hezar Jarib street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

81746-73461

**Approval date**

2020-03-13, 1398/12/23

**Ethics committee reference number**

IR.MUI.RESEARCH.REC.1398.823

**Health conditions studied**

1

**Description of health condition studied**

Psychological well-being

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

1

**Description**

Anxiety

**Timepoint**

At the beginning of the study, after the intervention

**Method of measurement**

Friedman Exam Anxiety Questionnaire

2

**Description**

Psychological well-being

**Timepoint**

At the beginning of the study, after the intervention

**Method of measurement**

Psychological Welfare Scale Questionnaire

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

Intervention 1 group: Education based on mindfulness. This educational program will be held in 8 sessions (twice a week) for 2 hours.

### Category

Other

## 2

### Description

Intervention 2 group : Education based on cognitive emotion regulation strategies. This educational program will be held in 8 sessions (twice a week) for 2 hours.

### Category

Other

## 3

### Description

Control group: No intervention

### Category

Other

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Faculty of Nursing and Midwifery, Isfahan University of Medical Sciences

#### Full name of responsible person

Dr Fariba Taleghani

#### Street address

Hezar Jarib Street

#### City

Isfahan

#### Province

Isfahan

#### Postal code

84746-73461

#### Phone

+98 31 3792 7500

#### Email

taleghani@nm.mui.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Esfahan University of Medical Sciences

#### Full name of responsible person

Dr Shaghayegh Haghjoui Javanmard

#### Street address

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#### Phone

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#### Email

research@mui.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

#### Full name of responsible person

Dr Mahnaz Noroozi

#### Position

Associate Professor, Isfahan University of Medical Sciences

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Reproductive Health

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Esfahan University of Medical Sciences

#### Full name of responsible person

Dr Mahnaz Noroozi

#### Position

Associate Professor, Isfahan University of Medical

Sciences  
**Latest degree**  
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**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

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Esfahan University of Medical Sciences  
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Dr Mahnaz Noroozi  
**Position**  
Associate Professor, Isfahan University of Medical Sciences  
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**Email**  
noroozi@nm.mui.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

Data of participants are privacy

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

Not applicable

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

No - There is not a plan to make this available

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

The results of clinical study will be published as an article.

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

Immediately after publishing the results.

### To whom data/document is available

Everyone

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

Scientific using with citation to article.

### From where data/document is obtainable

noroozi@nm.mui.ac.ir

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

Request to receive the published file of the article containing research information

### Comments