

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Comparison the Effectiveness of Cognitive Behavioral Therapy and Mindfulness-Based Stress Reduction on Anxiety, Psychological Well-being, Marital Satisfaction and Maternal Neonatal Outcomes of Nuliparous women

#### Protocol summary

##### Study aim

Comparison the Effectiveness of Cognitive Behavioral Therapy and Mindfulness-Based Stress Reduction on Anxiety, Psychological Well-being, Marital Satisfaction and Maternal Neonatal Outcomes of Nuliparous women

##### Design

A randomized controlled clinical trial with parallel groups, Randomized block, sample size 45 (15 persons per group)

##### Settings and conduct

Prior to the start of the sessions and obtaining a license, all three groups completed the Anxiety Questionnaire, Psychological Welfare, and Marital Satisfaction. Then, the experimental group A (mindfulness-based stress reduction) and experimental group B (cognitive-behavioral therapy) were grouped weekly among women in the Tehran Health Center. The control group did not intervene. The study is being held at the Tehran Health Center.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria were being Iranian, age 35-20 years, being primitive, literacy, no history of miscarriage or intrauterine death and infertility, no pregnancy problems (blood pressure, bleeding, diabetes, thyroid disease, Congenital anomalies, fetal anomalies), no adverse events over the past 6 months, no addiction, and no treatment for psychiatric disorders. Exclusion Criteria were lack of cooperation of the sample group in each stage of research and having physical and physical problems and a history of psychiatric problems.

##### Intervention groups

For the first Mindfulness-based stress reduction, for the second group cognitive behavior therapy, and in the third group, no intervention will be performed.

##### Main outcome variables

Anxiety, psychological well-being, marital satisfaction

and maternal consequences

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200514047449N1**

Registration date: **2020-06-28, 1399/04/08**

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

Last update: **2020-06-28, 1399/04/08**

Update count: **0**

##### Registration date

2020-06-28, 1399/04/08

##### Registrant information

##### Name

Elahe Shahtaheri

##### Name of organization / entity

Islamic azad university kish,iran

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2243 5703

##### Email address

e.shahtaheri@iaukishint.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-12-11, 1398/09/20

##### Expected recruitment end date

2020-07-15, 1399/04/25

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Comparison the Effectiveness of Cognitive Behavioral Therapy and Mindfulness-Based Stress Reduction on Anxiety, Psychological Well-being, Marital Satisfaction and Maternal Neonatal Outcomes of Nuliparous women

**Public title**  
Comparison the Effectiveness of Cognitive Behavioral Therapy and Mindfulness-Based Stress Reduction on Anxiety, Psychological Well-being, Marital Satisfaction and Maternal Neonatal Outcomes of Nuliparous women

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Being Iranian Age range 20 to 35 years Being primitive Have literacy No history of miscarriage or intrauterine death and infertility Absence of pregnancy problems (blood pressure, bleeding, diabetes, thyroid disease, placenta previa, fetal anomalies) No accidents during the last 6 months Not addicted and not being treated for psychiatric disorders  
**Exclusion criteria:**  
No cooperation of the sample group at each stage of the study Having physical and physical problems and a history of psychiatric problems

**Age**  
From **20 years** old to **35 years** old

**Gender**  
Female

**Phase**  
N/A

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

**Sample size**  
Target sample size: **45**

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

**Randomization description**  
Using the block randomization method by the statistical consultant, the following randomization is done in 3 groups of cognitive behavior therapy (CBT), Mindfulness-based stress reduction (MBSR) and control: First, the list of names of qualified people is provided and coded. In block randomization, the number of participants in all groups will be very close, this is done by building blocks of sequences and intersections so that the same number of participants are allocated to study groups within each group. First, we encode the groups based on the Latin letters as follows: A =cognitive behavior therapy, B = Mindfulness-based stress reduction and C control group In this study, with three groups A, B and C, we create the following six groups and assign the numbers 1 to 6 to each: ABC-ACB-BAC-BCA-CAB-CBA Then, using the table of random numbers, we contract that if the numbers 1, 2, 3, 4, 5, 6, and 6 appear in order, one of these blocks

will be selected, and if another number appears, we will assume it to be null and void and move on to the next selection. In fact, we have obtained a random sequence of numbers with a table of random numbers, which we consider the order of the assigned allocation for each number. In this way, the number of people in the groups will be almost equal.

**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 Hormozgan University of Medical Sciences

**Street address**

No. 64, Janbazan Ave., North Karegar Street

**City**

Kish

**Province**

Hormozgan

**Postal code**

1437697419

**Approval date**

2019-12-07, 1398/09/16

**Ethics committee reference number**

IR.HUMS.REC.1398.337

**Health conditions studied**

1

**Description of health condition studied**

Pregnancy

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

1

**Description**

Anxiety

**Timepoint**

Measurement will be done in pre-test, post-test and follow-up three months after post-test

**Method of measurement**

Beck Anxiety Inventory

## 2

### **Description**

Psychological well-being

### **Timepoint**

Measurement will be done in pre-test, post-test and follow-up three months after post-test

### **Method of measurement**

Psychological well-being Questionnaire

## 3

### **Description**

Marital satisfaction

### **Timepoint**

Measurement will be done in pre-test, post-test and follow-up three months after post-test

### **Method of measurement**

Marital satisfaction Questionnaire

## 4

### **Description**

Infant Maternal Consequences

### **Timepoint**

Measurement will be done in pre-test, post-test and follow-up three months after post-test

### **Method of measurement**

Checklist of Infant Maternal Consequences

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

First Intervention Group: MBSR-based stress reduction training was conducted for 8 weekly sessions (120 minutes each session) for the experimental group. The regular routine of each session included reviewing the homework of the previous session, feedback on existing questions and problems, teaching the intended materials and techniques, meditation skills, discussing stress and coping techniques, and presenting homework.

#### **Category**

Treatment - Other

### 2

#### **Description**

Second Intervention Group: Cognitive Behavioral Therapy refers to the training that is performed once a week for 10 sessions and for 45 minutes each session for mothers. Familiarity with the process of childbirth is marital satisfaction.

#### **Category**

Treatment - Other

## 3

### **Description**

Control group: No Intervention

### **Category**

N/A

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Tehran Health Center

##### **Full name of responsible person**

Elahe Shahtaheri

##### **Street address**

No. 11, West Azerbaijan Ave., Valiasr Blvd.

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

2578695784

##### **Phone**

+98 21 8457 9643

##### **Email**

elishah1348@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Islamic Azad University

##### **Full name of responsible person**

Alireza Roosta

##### **Street address**

Kish Island, Sana'i Boulevard, Free Zone Organization Square, Islamic Azad University of Kish International Branch.

##### **City**

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##### **Province**

Hormozgan

##### **Postal code**

7941775883

##### **Phone**

+98 76 4442 2720

##### **Email**

Info@laukishint.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**  
Elahe Shahtaheri  
**Position**  
Student  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Psychology  
**Street address**  
Nombr 26, #4 Alley Ali hosseini ST, Niazzadeh ST,  
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**City**  
Tehran  
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**Postal code**  
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e.shahtaheri@iaukishint.ac.ir

## Person responsible for scientific inquiries

### Contact

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e.shahtaheri@iaukishint.ac.ir

## Person responsible for updating data

### Contact

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**Full name of responsible person**  
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**Position**  
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**Latest degree**  
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**Street address**  
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e.shahtaheri@iaukishint.ac.ir

## 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

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

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

Only part of the data, such as information about the main outcome or the like, can be shared.

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

Start of access period 6 months after printing results

### To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

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

Any type of analysis on the data delivered is permitted

### From where data/document is obtainable

Elahe Shahtaheri Adress: No. 11, West Azerbaijan Ave.,  
Valiasr Blvd. Tel: +98 21 8457 9643

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

elishah1348@gmail.com  
**Comments**

The request will be sent by email to: