

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### The Effectiveness of Cognitive-Behavioral Therapy on the Job Stress of Midwives in the Labor Department

#### Protocol summary

##### Study aim

The Effectiveness of Cognitive-Behavioral Therapy on the Job Stress of Midwives in the Labor Department

##### Design

Clinical trial with control group, randomized with quadruple blocks, the sample size was considered as 40.

##### Settings and conduct

The sampling sites are the obstetrics departments of Haji Narges moarafe and Tamin Ejtemaee hospitals. The researcher visits these sections and invites people to participate in the research. A briefing is to be held and after obtaining written consent and ensuring confidentiality of Information, the job stress questionnaire is completed by people who have the criteria for entering the study. Meetings are held in the classroom located in the Department obstetrics Haji Narges moarafe and tamin ejtemaee Hospital.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1 - Informed consent to participate in the study. 2 - Earning a score above 117 from the job stress questionnaire. 3 - Having at least a midwifery diploma. Exit criteria: 1 - Cognitive-behavioral therapy and any psychological intervention with in the last 12 weeks. 2 - A history of chronic medical and psychological illnesses. 3 - The use of psychoactive drugs. 4 - The experience of an unfortunate incident, such as the death of a first-degree relative, in the past six months.

##### Intervention groups

For the intervention group, 8 group counseling sessions will be held using the cognitive- behavioral therapy method. After the research, the control group will receive 2 intensive counseling sessions.

##### Main outcome variables

Job stress

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20190212042682N1**

Registration date: **2019-03-08, 1397/12/17**

Registration timing: **prospective**

Last update: **2019-03-08, 1397/12/17**

Update count: **0**

##### Registration date

2019-03-08, 1397/12/17

#### Registrant information

##### Name

Fatemeh Karaminejad

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3312 3251

##### Email address

karaminejad.f@ajums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2019-04-03, 1398/01/14

#### Expected recruitment end date

2019-05-04, 1398/02/14

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The Effectiveness of Cognitive-Behavioral Therapy on the Job Stress of Midwives in the Labor Department

#### Public title

The Effectiveness of Cognitive Behavioral Therapy on Midwives' Job Stress

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

Informed consent to participate in the study. Earning a score above 117 from the job stress questionnaire.

Having at least a midwifery diploma.

#### **Exclusion criteria:**

Cognitive-behavioral therapy and any psychological intervention within the last 12 weeks. A history of chronic medical and psychological illnesses. The use of psychoactive drugs. The experience of an unfortunate incident, such as the death of a first-degree relative, in the past six months.

### **Age**

No age limit

### **Gender**

Female

### **Phase**

N/A

### **Groups that have been masked**

No information

### **Sample size**

Target sample size: 40

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

Randomized

### **Randomization description**

The method of assigning people to the control and test groups is randomized and quadruple blocks (Using the table for random permutations). After determining the block size in this study, the block list is provided and the number assigned to them, then random numbers will be chosen between 1 and 6. AABB(1), ABAB(2), ABBA(3), BBAA(4), BABA(5), BAAB(6)

### **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 Ahvaz Jundishapur University of Medical Sciences

##### **Street address**

Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.

##### **City**

Ahvaz

### **Province**

Khuzestan

### **Postal code**

61357-15794

### **Approval date**

2019-01-25, 1397/11/05

### **Ethics committee reference number**

IR.AJUMS.REC.1397.803

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Job stress

#### **ICD-10 code**

#### **ICD-10 code description**

## **Primary outcomes**

### 1

#### **Description**

Job stress score based on Rice questionnaire

#### **Timepoint**

Job stress measurement before and after the intervention immediately after the end of the study (8 sessions) and one month after the completion of the study.

#### **Method of measurement**

Rice Job Stress Questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: For the intervention group, 8 group meeting sessions of 10 persons are conducted on a weekly 90-minute basis by consulting a Cognitive-behavioral therapy methodology researcher and supervised by an advisor in the classroom located in the obstetrics Departments of Haji Narges moarafe and tamin ejtemaee hospitals.

#### **Category**

Treatment - Other

### 2

#### **Description**

Control group: After the research, the control group will receive 2 intensive counseling sessions.

#### **Category**

Other

## **Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Haji Narges moarafe Hospital and tamin ejtemae hospitals.

**Full name of responsible person**

Khadija Hekmat

**Street address**

Shahid Motahari Street.,Hajia Narges Hospital ., tamin ejtemae hospital.

**City**

Mahshahr Port

**Province**

Khouzestan

**Postal code**

6353141319

**Phone**

+98 61 5233 5025

**Fax****Email**

hekmat1346@Gmail.com

### Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mohammad Badawi

**Street address**

Ahvaz Jundishapur University of Medical Science., Golestan Ave

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

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**Phone****Fax****Email**

itc@ajums.ac.ir

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

Yes

**Title of funding source**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Khadija Hekmat

**Position**

Faculty member

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

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### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Khadija Hekmat

**Position**

Faculty member

**Latest degree**

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**Other areas of specialty/work**

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### Person responsible for updating data

**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Fatemeh Karaminejad

**Position**

Master student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

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**Postal code**

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**Phone**

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**Email**

karaminejad.f1357@jmail.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**

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**

The whole potential data is unpublished after being unidentifiable

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

Data will be available after publication and available for a one-year period.

**To whom data/document is available**

Only for scholars working in scientific institutions.

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

The data are available with reference to the name of the investigator and clinical trials and research.

**From where data/document is obtainable**

Ms. Khadijeh Hekmat, Faculty Member of Ahvaz Jundishapur University of Medical Sciences Email address: hekmat1346@Gmail.com

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

Send the request via email will be answered as soon as possible.

**Comments**