

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jul 2026

### Study of the effect of self-compassion training on the anxiety of primiparous women in the first stage of labor with control of the patient companion: Clinical trial with factorial design

#### Protocol summary

##### Study aim

Study of the effect of self-compassion training on the anxiety of primiparous women in the first stage of labor with control of the patient companion: Clinical trial with factorial design

##### Design

This study is a non-blinded clinical trial. The study population will be all primiparous women referring to Motazadi hospital of Kermanshah. 88 eligible women will be selected conveniently and randomly assigned to 4 groups.

##### Settings and conduct

This study that will be conducted in Motazadi hospital of Kermanshah is non-blinded. At the beginning of the study, Spielberger Anxiety Inventory will be provided for them. At the end of the study, the anxiety questionnaire will be provided for the study participants again.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: nulliparous women; Pregnancy age 20-29 weeks at the start of self-compassion training; Pregnancy age 42-38 weeks at delivery  
Exclusion criteria: Use of psychotropic drugs or neurology drugs; History of infertility; Fetal anomaly diagnosis

##### Intervention groups

The first intervention group will receive 8 self-compassion training sessions of 90 min (Based on Gilbert's compassion-focused therapy book) and researcher companionship with the pregnant mother during labor for 8 weeks. The second intervention group will receive 8 self-compassion training sessions of 90 min (Based on Gilbert's compassion-focused therapy book) and no researcher accompanying the pregnant mother during labor. The third intervention group will not receive compassion training, but there is a researcher accompanying the pregnant mother during labor for 8 weeks. The control group will not receive compassion training and there is no researcher accompanying the

pregnant mother during labor for 8 weeks.

##### Main outcome variables

Anxiety

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200227046627N1**

Registration date: **2020-03-19, 1398/12/29**

Registration timing: **prospective**

Last update: **2020-03-19, 1398/12/29**

Update count: **0**

##### Registration date

2020-03-19, 1398/12/29

##### Registrant information

##### Name

Sahar Omid

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 3725 6816

##### Email address

omidisahar1375@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-08, 1399/01/20

##### Expected recruitment end date

2020-09-10, 1399/06/20

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Study of the effect of self-compassion training on the anxiety of primiparous women in the first stage of labor with control of the patient companion: Clinical trial with factorial design

**Public title**

Study of the effect of self-compassion training on the anxiety of primiparous women in the first stage of labor with control of the patient companion

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Nulliparous women Pregnancy age 20-29 weeks at the start of self-compassion training Pregnancy age 42-38 weeks at delivery

**Exclusion criteria:**

Use of psychotropic or neurology drugs History of infertility Fetal anomaly diagnosis

**Age**From **18 years** old**Gender**

Female

**Phase**

N/A

**Groups that have been masked***No information***Sample size**Target sample size: **88****Randomization (investigator's opinion)**

Randomized

**Randomization description**

Using the random number table, participants are divided into four groups of 22 . Those with a code number 1 to 22 will be in group A, those with numbers 23 to 44 in group B, numbers 45 to 66 in group C and numbers 67 to 88 in group D.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Factorial

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Kermanshah University of

Medical Sciences

**Street address**

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Approval date**

2017-02-03, 1395/11/15

**Ethics committee reference number**

ir.kums.rec.1398.1151

**Health conditions studied****1****Description of health condition studied**

Anxiety

**ICD-10 code**

F41.1

**ICD-10 code description**

Generalized anxiety disorder

**Primary outcomes****1****Description**

Anxiety

**Timepoint**

Beginning and end of study

**Method of measurement**

Using Spielberger Anxiety Inventory

**Secondary outcomes**

empty

**Intervention groups****1****Description**

The first intervention group will receive 8 self-compassion training session of 90 min ( Based on Gilbert's compassion-focused therapy book )and researcher companionship with the pregnant mother during labor for 8 weeks

**Category**

Lifestyle

**2****Description**

The second intervention group will receive 8 self-compassion training session of 90 min ( Based on Gilbert's compassion-focused therapy book) and no

researcher accompanying the pregnant mother during labor  
**Category**  
Lifestyle

### 3

#### **Description**

The third intervention group will not receive compassion training, but there is a researcher accompanying the pregnant mother during labor for 8 weeks

#### **Category**

Other

### 4

#### **Description**

The control group will not receive compassion training and there is no researcher accompanying the pregnant mother during labor for 8 weeks.

#### **Category**

Other

## **Recruitment centers**

### 1

#### **Recruitment center**

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

Motazadi Hospital

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

Sahar Omid

##### **Street address**

Ferdowsi Square, Motazadi Hospital

##### **City**

Kermanshah

##### **Province**

Kermanshah

##### **Postal code**

6715847141

##### **Phone**

+98 83 3826 6429

##### **Email**

omidisahar1375@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

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

Kermanshah University of Medical Sciences

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

Dr. Farid Najafi

##### **Street address**

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

##### **City**

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+98 83 3836 0014

##### **Email**

fnajafi@kums.ac.ir

##### **Grant name**

##### **Grant code / Reference number**

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

Yes

##### **Title of funding source**

Kermanshah 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**

Kermanshah University of Medical Sciences

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

Sahar Omid

##### **Position**

Master of Counseling in Midwifery

##### **Latest degree**

Bachelor

##### **Other areas of specialty/work**

Counseling in Midwifery

##### **Street address**

Isar Square, Dolatabad Blvd, Faculty of Nursing and Midwifery

##### **City**

Kermanshah

##### **Province**

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##### **Postal code**

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##### **Email**

omidisahar1375@gmail.com

## **Person responsible for scientific inquiries**

#### **Contact**

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

Kermanshah University of Medical Sciences

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

Dr. Marziyeh Kaboudi

##### **Position**

Member of Kermanshah University of Medical

Sciences  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Reproductive Health  
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fkaboudi@kums.ac.ir:

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Kermanshah University of Medical Sciences  
**Full name of responsible person**  
Sahar Omid  
**Position**  
Master of Counseling in Midwifery  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Counseling in Midwifery  
**Street address**  
Isar Square, Dolatabad Blvd, Faculty of Nursing and Midwifery  
**City**  
Kermanshah  
**Province**  
Kermanshah  
**Postal code**  
6715847141

**Phone**  
+98 83 3826 6429  
**Email**  
omidisahar1375@gmail.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

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

### Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Not applicable

### Data Dictionary

Not applicable

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

The main outcomes of the study will be shared.

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

3 months

### To whom data/document is available

If requested, results will be made available to other academic researchers

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

Collected data is confidential and will not be shared with anyone else

### From where data/document is obtainable

To receive the documentation, email send for update manager

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

In a 15-day period, the documents will be sent e-mail

### Comments