Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Omidi

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 Omidi

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

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+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 Omidi

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

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

Street address

Isar Square, Dolatabad Blvd, Faculty of Nursing and Midwifery

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3826 6429

Email

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 Omidi

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