

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The study of the effect of mindfulness-based counseling on the pregnancy anxiety and delivery satisfaction in primiparous women

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Determining the effect of mindfulness-based counseling on pregnancy anxiety and delivery satisfaction in primiparous women

Last update: **2019-02-24, 1397/12/05**

Update count: **0**

Registration date

2019-02-24, 1397/12/05

Design

A randomized controlled clinical trial with a parallel group design of 60 participants and without blindness

Registrant information

Name

Sousan Heydarpour

Name of organization / entity

Kermanshah University of Medical Sciences

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Settings and conduct

This study, which will be done in health centers and hospitals in Kermanshah, is not blinded one. Sixty people will be randomly assigned to the intervention group and the control group. At the beginning of the study, anxiety and satisfaction questionnaire will be provided to the patients. After the intervention, the anxiety and satisfaction questionnaire is again provided to the patients and the two groups will be compared.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women with 14 to 24 weeks gestational age; primiparous; wanted pregnancy; without medical and obstetrics complications based on the medical records; singleton; Having literacy. Exclusion criteria: having history of severe neuropsychiatric or psychiatric medications; Having history of addiction and use of psychoactive drugs; History of suicide or psychosis

Expected recruitment start date

2018-12-06, 1397/09/15

Expected recruitment end date

2019-06-05, 1398/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

For the intervention group, eight group intervention sessions will be conducted by the researcher twice a week on Mindfulness counseling. The control group receive routine care.

Scientific title

The study of the effect of mindfulness-based counseling on the pregnancy anxiety and delivery satisfaction in primiparous women

Main outcome variables

Pregnancy Anxiety; delivery Satisfaction

Public title

The study of the effect of mindfulness-based counseling

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170305032900N3**

Registration date: **2019-02-24, 1397/12/05**

on pregnancy anxiety and delivery satisfaction

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women with 14 to 24 weeks gestational age- primiparous- wanted pregnancy- singleton- literacy

Exclusion criteria:

Unwillingness to participate in the study- medical and obstetrics complications based on the medical records- history of severe neuro-psychiatric or psychiatric medications- history of addiction and use of psychoactive drugs- suicidal thoughts, history of suicide or psychosis

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

In this study simple randomization method was used to implement random assignment. In this way, 60 cards matched in appearance were prepared and on the 30 of cards the number or code of 1 was written that specifies the intervention group or mindfulness-based counseling and on the other 30 cards the number or code of 2 was written that identifies the control group means routine care. Then, each eligible person randomly selected one of these cards which the codes were written on it and in this way random allocation of groups was determined.

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 Kermanshah University of Medical Sciences

Street address

Shahid Beheshti Boulevard, Kermanshah

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2018-11-19, 1397/08/28

Ethics committee reference number

IR.KUMS.REC.1397.606

Health conditions studied

1

Description of health condition studied

pregnancy anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

Anxiety

Timepoint

before, immediately after and one month after intervention

Method of measurement

The Wendenberg Pregnancy anxiety Questionnaire has 17 items and five factors. The final score of this questionnaire is obtained by collecting the score of each statement. The score of each statement is ranged from one to seven; therefore, the pregnancy anxiety score can range from 17 to 119.

2

Description

Delivery satisfaction

Timepoint

24 hours after delivery

Method of measurement

Completing the Ganjir women's satisfaction questionnaire by participants

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: eight sessions of group mindfulness counseling twice a week by the researcher in addition to the routine care of clinics for pregnant women

Category

Prevention

2

Description

Control group: receive of routine care during pregnancy

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers in Kermanshah and hospitals of Kermanshah city

Full name of responsible person

dr sousan heydarpour

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میدان فردوسی

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

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Shahid Beheshti Blvd., Building No. 2, Deputy Director of Research and Technology

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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

Dr. Sousan Heydarpour

Position

Faculty Member of Kermanshah University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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