Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The study of the effectiveness of midwifery counseling on pregnancy anxiety and over-anxiety with the "mindfulness approach" among women who have become pregnant through assisted reproductive technologies.

Protocol summary

Study aim

This study aims to determine the effectiveness of midwifery counseling with a mindfulness approach on pregnancy anxiety and over-anxiety of pregnant women with a history of infertility (conceived through assisted reproductive methods).

Design

Clinical trial including control group, parallel groups, randomized will be conducted on 70 cases without blinding. A randomizer will be employed for randomization.

Settings and conduct

This trial will be conducted on two groups of eligible pregnant women. Women with an anxiety score of 60 or more and an over-anxiety score of 14 or more will be allocated to two groups "the intervention" and "the control" by random block method. For the intervention group, mindfulness group counseling will be done during 8 sessions at the Comprehensive Cealth Center in Tehran in 2023. The control group will receive routine prenatal care. Vandenberg's pregnancy anxiety and over-anxiety questionnaire will be completed by interview before, immediately and four weeks after the intervention for both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient's willingness to particioate. Pregnant women aged 20-490. History of primary or secondary infertility. Pregnancy through assisted reproductive methods. Gestational age of 24 to 14 weeks. Pregnancy anxiety score 60, or more. Research score of 14 and more Non-inclusion criteria: Pregnant women with any history of psychiatric diseases or psychological treatment. Diseases such as diabetes. Need for special care. Severe mental crisis during the last 3 months.

Intervention groups

For the intervention group, mindfulness counseling will be done during 8 face-to-face sessions in Tehran in 2023. The control group will receive routine prenatal care.

Main outcome variables

Pregnancy anxiety and over-anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230912059414N1**
Registration date: **2023-10-17, 1402/07/25**
Registration timing: **prospective**

Last update: **2023-10-17, 1402/07/25**
Update count: **0**

Registration date

2023-10-17, 1402/07/25

Registrant information

Name

Fariba Mohamadyari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7727 2164

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of the effectiveness of midwifery counseling on pregnancy anxiety and over-anxiety with the "mindfulness approach" among women who have become pregnant through assisted reproductive technologies.

Public title

The study of the effectiveness of midwifery counseling on pregnancy anxiety and excessive worrying with the "mindfulness approach" among women who have become pregnant through assisted reproductive technologies.

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Patient's willingness to paticipate Pregnant women aged 20-49 Women with a history of primary or secondary infertility Having at least reading and writing ability Having conceived with assisted reproductive methods Gestational age of 14 to 24 weeks Getting pregnancy anxiety score of 60, or more Getting an excessive worring score of 14, or more

Exclusion criteria:

Women with any history of psychiatric disorder and psychological treatment Developing certain medical diseases such as diabetes, cardiovascular problems The need for special care such as absolute rest due to pregnancy complications Fatal abnormalities Having experienced a severe emotional crisis over the last 3 months, such as bereavement, according to the person's statement

Age

From **20 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Quadruple blocks. In this study, we will use the Restricted randomization method of block randomization. The size of all blocks is equal and we in this two-group experiment of 4 blocks (including 2 participants in We will have an intervention group and 2 participants in the control group). The method of hiding the sequence of allocating white envelopes is used. Using the website https://www.sealedenvelope.com/simple-randomiser/v1/lists and with the help of the methodology consultant, the allocation sequence was generated.

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 Shahrood University of Medical Sciences

Street address

Shahrood University of Medical Sciences and Health Care Services, 7th Tir Square, Shahrood, Iran

City

Shahrood

Province

Semnan

Postal code

۳۶۱۴۷-۷۳۹۴۳

Approval date

2023-09-11, 1402/06/20

Ethics committee reference number

IR.SHMU.REC.1402.090

Health conditions studied

1

Description of health condition studied

Pregnancy anxiety and Meta worry of pregnant women with assisted reproduction methods

ICD-10 code

F53

ICD-10 code description

Puerperal psychosis

Primary outcomes

1

Description

Pregnancy anxiety of women who have become pregnant through assisted reproduction methods

Timepoint

Completing the Vandenberg pregnancy anxiety questionnaire by the pregnant woman before the start of counseling sessions and then immediately after the end of the counseling sessions and 4 weeks after the sessions.

Method of measurement

Vandenberg pregnancy anxiety questionnaire

2

Description
Meta worry of pregnant women with assisted reproduction methods
Timepoint
Filling out the meta worry questionnaire by the pregnant woman before the start of counseling sessions and then immediately after the end of the counseling sessions and 4 weeks after the sessions.
Method of measurement
Meta worry questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: eight midwifery consultation sessions with the approach of mindfulness
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Infertility treatment centers in Tehran
Full name of responsible person
Fariba Mohamadyari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahroud University of Medical Sciences
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Vice President 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
Shahroud 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
Shahroud University of Medical Sciences
Full name of responsible person
Fariba Mohamadyari
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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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
It can be shared after making participants unidentified

When the data will become available and for how long
After defending and passing the master's thesis

To whom data/document is available
It will be available for researchers working in academic and scientific institutions

Under which criteria data/document could be used
Clinical research

From where data/document is obtainable
Administrator's email

What processes are involved for a request to access data/document
After authentication of the person, who have requested and in what field it will be applied will be sent as soon as possible

Comments