

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 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

Email address

faribamohamadyarii@gmail.com

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 participate 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 worrying 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/li> sts 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

Shahrood University of Medical Sciences

Full name of responsible person

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

Shahrood 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

Shahrood 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