Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of virtual mindfulness counseling on the level of pregnancy anxiety of women undergoing IVF treatment

Protocol summary

Study aim
Determining the effect of virtual mindfulness-based counseling on the level of anxiety during pregnancy of women treated with assisted reproductive methods

Design
The current study is a semi-experimental study of the clinical trial type with a parallel method and a control group on a sample size of 64 people (32 people in each group) using the random number table method using online software (www.Random .org/sequences) will be selected.

Settings and conduct
Referring to Yazd Reproductive Sciences Research Institute, 64 women were selected pregnant women with a history of infertility and treated with assisted reproductive methods based on the entry and exit criteria, and the patients were assigned to two intervention and control groups. The test group will receive eight training sessions in the form of 60 to 90-minute group counseling based on mindfulness.

Participants/Inclusion and exclusion criteria
Inclusion criteria: gestational age of 20 weeks or later, pregnant women with a history of infertility and being treated with assisted reproductive methods, using at least one or more assisted reproductive methods (IVF-IUI-ICSI, etc.), exclusion criteria: having a history Miscarriage, severe anxiety according to the Vandenberg questionnaire, having mental disorders and being treated for mental disorders

Intervention groups
After dividing into two groups, people will complete the study questionnaires .The Intervention group receives eight virtual training sessions in the form of 60 to 90-minute group counseling based on mindfulness once a week.At the end of the eighth session, Vandenberg pregnancy anxiety questionnaire is completed again by both groups.

Main outcome variables
Comparing the mean Score of Anxiety during Pregnancy of Women Treated with Assisted Reproductive Methods before, Immediately and one month after the Intervention in two Experimental and Control groups.

General information

Reason for update
Wrong registration of the scientific title of the trial

Acronym

IRCT registration information
IRCT registration number: **IRCT20221106056415N1**
Registration date: **2023-02-07, 1401/11/18**
Registration timing: **retrospective**

Last update: **2023-09-26, 1402/07/04**
Update count: **1**

Registration date
2023-02-07, 1401/11/18

Registrant information

Name
Fatemeh Solimany monfared

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 38 3333 5602

Email address
fsm171171@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-09, 1401/09/18

Expected recruitment end date
2023-01-08, 1401/10/18

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of virtual mindfulness counseling on the level of pregnancy anxiety of women undergoing IVF treatment

Public title
Counseling based on mindfulness on pregnancy anxiety of women undergoing in vitro fertilization (IVF) treatment
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
1- Pregnant women with a history of infertility and treated with assisted reproductive methods 2- Use at least one or more assisted reproductive methods (IVF-IUI-ICSI and...) 3- The ability to use online counseling and have an Android or iOS smart phone 4- Willingness to participate in the study 5- The ability to understand and speak Persian 6- Cooperation in doing homework 7- Having a minimum education at middle school level 8- Pregnancy age 20 weeks and later
Exclusion criteria:
Having mental disorders and being treated for mental disorders Simultaneous participation in another study Receiving psychological services at the beginning of the study Having pregnancy-related disorders such as threatened Abortion, Preeclampsia, Threatened premature birth, etc. Suffering from systemic diseases based on the pregnancy record (Chronic diabetes, Chronic hypertension, Thyroid disease, Cardiovascular disease, etc.) Abnormality in the fetus Experiencing a severe mental crisis during the past 6 months, such as the Death of Parents and... Drug and Alcohol addiction Having a disabled child or Having a disabled child in the family Having a history of abortion Existence of severe anxiety based on the Vandenberg questionnaire
Age
From **20 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
The current study is a semi-experimental study of the clinical trial type in a parallel method. In this study, 64 women from eligible mothers referring to the Reproductive Sciences Research Institute will be selected based on the entry and exit criteria using the random number table method using online software (www.Random.org/sequences) and the patients They are assigned to two intervention groups (mindfulness counseling) and control group. Again, each of the groups is divided into two subgroups by a simple random method (4 subgroups of 16 people in two groups). assisted reproductive method) will be investigated.
Blinding (investigator's opinion)
Single blinded
Blinding description
The participants are unaware of the allocation in the study groups
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Yazd University of Medical Sciences
Street address
No.8,alley 21,Shahid Mohammad Montazeri street,Shahrekord city
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8814666686
Approval date
2022-10-25, 1401/08/03
Ethics committee reference number
IR.SSU.REC.1401.055

Health conditions studied

1

Description of health condition studied
Anxiety during pregnancy of women treated with assisted reproductive methods
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pregnancy anxiety score of women treated with assisted reproductive methods before, immediately and one month after the intervention in two experimental and control groups
Timepoint

The effect of mindfulness counseling in a virtual way on the level of anxiety during pregnancy of women treated with assisted reproductive methods before, immediately and one month after the intervention in two experimental and control groups.

Method of measurement

The researcher will select 64 women among pregnant women with a history of infertility and treated with assisted reproductive methods based on the entry and exit criteria using the random number table method using online software (www.Random.org/sequences). And patients are assigned to two intervention groups (mindfulness counseling) and control group. Again, each group is divided into two subgroups by a simple random method (4 subgroups of 16 people in two groups). Informed and voluntary consent is obtained from the participants. Then, the demographic and gynecology and obstetrics questionnaire related to the current pregnancy of the participants, which includes: questions about age, infertility period, gestational age, education level, occupation, spouse's education level, spouse's occupation, adequacy of family income for living expenses, place of residence satisfaction with life, the type of treatment methods and the frequency of treatment failure. Also, Vandenberg Pregnancy Anxiety Questionnaire is completed by the participants of both groups through Prasline software before starting the intervention.Vandenberg pregnancy anxiety questionnaire is completed again by both groups. The follow-up period of this research is one month later, when the Vandenberg pregnancy anxiety questionnaire is completed again by both groups, and then the obtained data are entered and analyzed in the statistical software SPSS version 22.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The purpose of mindfulness is that a person who is facing the stress of motherhood can learn meditation based on mindfulness and this makes a person as a mother aware of her emotional reactions and deal with them more skillfully. Mothers receive eight sessions of virtual training on the virtual network in the form of 60 to 90-minute group counseling based on mindfulness once a week. All sessions include a meditation exercise and a three-minute breathing exercise. It begins and ends. The people of the experimental group should do these techniques 3 times a day for 10 minutes each time at home as homework. At the end of the eighth session, Vandenberg pregnancy anxiety questionnaire is completed again by both groups. The follow-up period of this research is one month later, when Vandenberg pregnancy anxiety questionnaire is completed again by both groups.

Category

Treatment - Other

2

Description

Control group: Informed and voluntary consent is obtained from the participants. Then, the questionnaire of demographic and gynecological and midwifery characteristics as well as the Vandenberg Pregnancy Anxiety Questionnaire is completed by the participants through Pursline software before the intervention. After the intervention in the intervention group and at the end of the study and if the intervention is effective, educational The control group will be placed.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Research Institute of Reproductive Sciences, Yazd

Full name of responsible person

Dr. Fateme Zare Mobini

Street address

Yazd, Safiyeh, Timsar Falahi St., Bu Ali St., Infertility Research Center

City

Yazd

Province

Yazd

Postal code

۸۹۱۶۸۷۷۳۹۱

Phone

+98 35 3824 8122

Email

Fatemehzaremobini@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Ali reza morady

Street address

Yazd, Safiyeh, Timsar Falahi St., Bu Ali St., Infertility Research Center

City

Yazd

Province

Yazd

Postal code

8814666686

Phone

+98 35 3824 1751

Email

Fatemehzaremobini@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Fatemeh Solimany Monfared

Position

Master's Student In Counseling In Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

No8, alley 21 ,Shahid Mohammad Montazeri St., Shahrekord Town

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8814666686

Phone

+98 38 3333 5602

Email

Fatemehzaremobini@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Fatemeh Zaremobini

Position

Assistant Professor, Faculty member of midwifery department, PhD in reproductive health

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Yazd, Safiyeh, Timsar Falahi St., Bu Ali St., Infertility Research Center

City

Yazd

Province

Yazd

Postal code

8814666686

Phone

+98 35 3824 1751

Email

Fatemehzaremobini@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Fatemeh Zaremobini

Position

Assistant Professor, Faculty member of midwifery department, PhD in reproductive health

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Yazd, Safiyeh, Timsar Falahi St., Bu Ali St., Infertility Research Center

City

Yazd

Province

Yazd

Postal code

8814666686

Phone

+98 35 3824 1751

Email

Fatemehzaremobini@yahoo.com

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

If the intervention is effective, by applying the information obtained from the research and the application of this method, a solution can be provided to

improve mental health and psychological support for pregnant women with a history of infertility and undergoing treatment with assisted reproductive methods.

When the data will become available and for how long

Access starts 6 months after results are published

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

If the intervention is effective, by applying the information obtained from the research and the application of this method, a solution can be provided to

improve mental health and psychological support for pregnant women with a history of infertility and undergoing treatment with assisted reproductive methods.

From where data/document is obtainable

By correspondence with e-mail fsm171171@gmail.com Fateme Soleimani Monfared

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

After requesting and sending the research and follow-up information, the documents will be sent

Comments