

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effectiveness of telephone counseling based on mindfulness on relational concern of infertile women

Protocol summary

Study aim

Determining the effectiveness of telephone counseling based on mindfulness on relational concern of infertile women

Design

Clinical trial with control group, open label, random assignment in control group and intervention with random blocks of 4 by online randomizer, on 80 participants.

Settings and conduct

The first session will be held in person at the Fatima Al-Zahra Infertility Center. Demographic and midwifery and sexual anxiety questionnaires will be completed by the samples as a pre-test. Mindfulness counseling will be conducted in 8 sessions for 8 weeks by the researcher based on the standard Kabat-Zinn protocol, 7 sessions of which will be 30-minute phone calls to the participants. Daily mindfulness exercises are suggested and participants' questions will be answered in between sessions. No intervention will be done for the control group. After a period of 8 weeks, the women's sexual relational concern questionnaire will be completed virtually by all the participants in the two groups. To check the stability of the intervention, in the twelfth week after the start of the study, the samples are again requested to complete the sexual relational concern questionnaire virtually.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of infertility, ability to read and write, having personal mobile phone and age less than 50 Exclusion criteria: non-participation in two training sessions, attendance at other psychological interventions or training sessions, and known psychiatric illness.

Intervention groups

In the Intervention group, there will be 8 telephone counseling sessions based on mindfulness along with the pre-test and post-test of the sexual anxiety scale. The control group does not receive any counseling.

Main outcome variables

sexual relational concern

General information

Reason for update

Dear Recipient, Please implement the following changes to the research plan, as approved by the Babol University of Medical Sciences Research Council and Ethics Committee: * Replace "sexual anxiety" with "relational concern" in the title. * Remove "Babol city" from the title. * Increase the sample size per group from 30 to 40. Thank you.

Acronym

IRCT registration information

IRCT registration number: **IRCT20180218038783N8**

Registration date: **2024-01-20, 1402/10/30**

Registration timing: **prospective**

Last update: **2025-04-10, 1404/01/21**

Update count: **1**

Registration date

2024-01-20, 1402/10/30

Registrant information

Name

Fereshteh Behmanesh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01
Expected recruitment end date
 2027-01-21, 1405/11/01
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 Effectiveness of telephone counseling based on mindfulness on relational concern of infertile women

Public title
 Effectiveness of telephone counseling based on mindfulness on relational concern of infertile women

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Diagnosis of infertility Ability to read and write Having a personal cell phone Age less than 50 years Attending at least 6 mindfulness intervention sessions
Exclusion criteria:
 Attending other psychological interventions or training Having a known psychiatric illness

Age
 To 50 years old

Gender
 Female

Phase
 N/A

Groups that have been masked

- Data analyser

Sample size
 Target sample size: 80

Randomization (investigator's opinion)
 Randomized

Randomization description
 Participants (ratio 1:1) will be placed in two training and control groups (group A and B) using the randomization method with random blocks of 4 (produced by online randomizer). In such a way that the researcher cannot predict in which group the next person will be placed. The random allocation list will be solely at the discretion of the study administrator. The randomization list is taken from the following site: Sealed Envelope Ltd. 2022. Create a blocked randomization list. [Online] Available from: <https://www.sealedenvelope.com/simple-randomiser/v1/lists> [Accessed 31 Dec 2023].

Blinding (investigator's opinion)
 Single blinded

Blinding description
 In this study, due to the nature of the intervention, it will not be possible to blind the researcher in the first stage. Blinding will only be done for the data analyst

Placebo
 Not used

Assignment

Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Babol University of Medical Sciences

Street address

Babol University of Medical Sciences. Keshavarz St.

City

Babol

Province

Mazandaran

Postal code

4774547176

Approval date

2023-11-27, 1402/09/06

Ethics committee reference number

IR.MUBABOL.REC.1402.141

Health conditions studied

1

Description of health condition studied

infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

2

Description of health condition studied

sexual relational concern

ICD-10 code

F41

ICD-10 code description

Other anxiety disorders

Primary outcomes

1

Description

The score of relational concern dimension of sexual satisfaction questionnaire of Chesley et al

Timepoint

Before, after and one month after the end of study

Method of measurement

The 6-question relational concern questionnaire, which is one of the dimensions of the multidimensional sexual satisfaction questionnaire of Chesley et al

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Counseling based on mindfulness will be conducted in eight sessions for 8 weeks (one session per week) by the researcher with the help of a psychiatrist based on the standard Kabat-Zinn protocol, 7 sessions of which will be held by contacting the participants for 30 minutes. . The first meeting will be held in person at Fatemeh Al-Zahra Infertility Center in order to explain the objectives, stages of the study, a summary of the method of implementation of the work verbally, obtaining informed consent and also assuring the participants to keep their information confidential. In the first session and before the consultation, demographic and midwifery questionnaires and sexual relational concern questionnaires will be completed by the samples. Each session will have a goal and during that mindfulness exercises will be done. Also, mindfulness tasks are suggested for women to practice in everyday events. In the intervals between the sessions, the researcher will respond to the calls of the samples to clear their doubts and questions. After a period of 8 weeks, the women's sexual relational concern questionnaire will be completed virtually by the participants. To check the stability of the educational intervention of the present study, after a one-month follow-up period (twelfth week), the samples are again asked to complete the sexual relational concern questionnaire in virtual form.

Category

Treatment - Other

2

Description

Control group: At Fatemeh Al-Zahra Infertility Center, in order to express the goals, stages of the study, a summary of the method of performing the work verbally, obtaining informed consent, and also assuring the participants to keep their information confidential, we will talk to them and request them. to complete demographic, midwifery and sexual relational concern questionnaires. No intervention will be done for the control group. Again, 8 weeks later and 12 weeks later, the control group will complete the sexual relational concern questionnaire virtually. Routine care includes standard infertility treatments.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatima Al-Zahra Infertility Center

Full name of responsible person

Fereshteh Behmanesh

Street address

Babol University of Medical Sciences, Keshavarz Street

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4717647745

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Mehdi Rajab Nia

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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

Babol 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
Babol University of Medical Sciences
Full name of responsible person
Fereshteh Behmanesh
Position
Assistant Professor
Latest degree
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Reproductive Health
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Person responsible for updating data

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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