

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

The effect of online brief mindfulness-based counseling on infertility related distress in infertile women under treatment: A randomized controlled clinical trial

Protocol summary

Study aim

Determining the effect of abbreviated mindfulness-based counseling on the level of infertility distress in infertile women undergoing treatment: an online intervention.

Design

A clinical trial with a control group, double-blind, randomized, on 70 infertile women under treatment. The rand function of Excel software will be used for randomization.

Settings and conduct

Infertile women will be invited to participate in the research by attending and presenting a written letter of introduction to health centers, clinics, etc. in Mazandaran province. An invitation will also be given on social networks. The possibility of blinding the participants and There is no researcher conducting the intervention during the intervention process, the blinding process will be done by the people who are responsible for collecting information and analyzing data.

Participants/Inclusion and exclusion criteria

Inclusion criteria Iranian nationality, proficiency in the Persian language, having smartphones; And.. Exclusion criteria: intends to use donated embryos, eggs, or surrogates

Intervention groups

The abbreviated awareness course will be held for four group training sessions, each session lasting 2 hours and once a week for 4 weeks. The course will include all the techniques taught in the 8-week course. Less time will be provided to practice each technique in class. After each session, assignments will be given to the participants to practice mindfulness techniques outside the classroom. The supporting materials of the main intervention include a mindfulness manual and forms for exercises. who have noticed and talked about how to find this experience. Each session ends with 3 minutes of breathing exercises

Main outcome variables

Infertility distress, perceived stress, Infertile women's quality of life, laboratory pregnancy testing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160619028528N7**

Registration date: **2023-02-01, 1401/11/12**

Registration timing: **prospective**

Last update: **2023-02-01, 1401/11/12**

Update count: **0**

Registration date

2023-02-01, 1401/11/12

Registrant information

Name

Zeinab Hamzehgardeshi

Name of organization / entity

Mazandaran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 7342

Email address

z.hamzehgardeshi@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-14, 1401/11/25

Expected recruitment end date

2023-03-01, 1401/12/10

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of online brief mindfulness-based counseling on infertility related distress in infertile women under treatment: A randomized controlled clinical trial

Public title
The effect of online brief mindfulness-based counseling on infertility related distress in infertile women under treatment

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Iranian nationality Proficiency in Persian language Having smartphones and being able to use them Women less than 45 years old Diagnosed infertility Women treated with assisted reproductive methods (IVF.IUI) (Anti Mullerian Hormone (AMH)more than 5/ng/mL

Exclusion criteria:
- Intention to use donated embryos, eggs or surrogates Cancellation of the treatment plan for any reason by the doctor People who are under the advice of a psychologist or psychiatrist at the time of the study or at least one month before the start of the study People with major psychiatric disorders at the time of study Suffering from systemic diseases such as diabetes, high blood pressure, hyperlipidemia, and thyroid gland disease; Based on treatment history, file information, and research unit report. Based on the treatment history, file information, and research unit report. Death of a relative or an unfortunate accident at least 3 months before the start of the intervention Occurrence of pregnancy detected by blood test during the study Psychiatric drug use (self-report) Stepchild Use of cigarettes, hookahs and alcoholic beverages People with a history of previous marriages - people who were eligible to receive or needed to be prescribed any psychotropic medication or psychotherapy counseling during the study.

Age
To **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
The blocked random allocation methods will randomly assign the samples to two intervention groups (awareness attention) and a control group (routine care).

This method is usually used in order to balance the number of samples allocated to each of the studied groups. This feature helps the researcher to have the same number of samples allocated to the intervention and control groups of the study in cases where intermediate analysis is needed during the implementation of the sampling process. For this purpose, blocks of four will be considered. The six blocks may be TTCC, CTTC, CTCT, CCTT, TCTC, and TCCT, where T is for the intervention group and C is for the control group. The rand between functions in Excel will be used to select the blocks randomly. The production numbers will be between 1 and 6 and based on the production number of the desired block, all 4 samples will be assigned to the intervention and control groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Due to the nature of the intervention, it will not be possible to blind the participants and the researcher responsible for the intervention during the intervention process, therefore, in order to control the bias of blinding at the level of the evaluator (evaluator bias), the process of blinding will be carried out in the people who are responsible for collecting information and analyzing data.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Vice chancellor for research, Mazandaran University of Medical Sciences ,Moalem Square, Sari, Mazandaran, Iran

City

Sari

Province

Mazandaran

Postal code

48178-57344

Approval date

2022-10-11, 1401/07/19

Ethics committee reference number

IR.MAZUMS.REC.1401.332

Health conditions studied

1

Description of health condition studied

Distress of infertile women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Secondary outcome: Improving quality of life

Timepoint

Before intervention ,immediately after the intervention ,one month after the completion of the intervention in the intervention groups (recipient of online counseling and control)

Method of measurement

Infertile women's quality of life questionnaire.

2

Description

perceived stress

Timepoint

Before intervention ,immediately after the intervention ,one month after the completion of the intervention in the intervention groups (recipient of online counseling and control)

Method of measurement

Newton's infertility stress questionnaire

3

Description

laboratory pregnancy testing

Timepoint

Before intervention ,immediately after the intervention ,one month after the completion of the intervention in the intervention groups (recipient of online counseling and control)

Method of measurement

blood test

Secondary outcomes

1

Description

perceived stress of infertile women

Timepoint

Before, immediately after the intervention, and one month after the completion of the intervention in the intervention groups (recipient of online counseling and control)

Method of measurement

Newton's infertility stress questionnaire,

2

Description

quality of life score of infertile women

Timepoint

Before, immediately after the intervention, and one month after the completion of the intervention in the intervention groups (recipient of online counseling and control)

Method of measurement

Infertile women's quality of life questionnaire.

3

Description

laboratory pregnancy testing

Timepoint

Before intervention ,immediately after the intervention ,one month after the completion of the intervention in the intervention groups (recipient of online counseling and control)

Method of measurement

blood test

Intervention groups

1

Description

The abbreviated awareness course for four group training sessions, each group of seven people will hold 2 hours each session and once a week for 4 weeks. This course will include all the techniques taught in the 8-week course including: mindful breathing, body scanning, guided imagery, kindness, mindful eating, mindful walking or other movements, mindful conversations, and observing one's emotions. Mindful walking or other movements will be used in place of the yoga used during the 8-week course to vary the movements for each person depending on their physical ability (such as sitting in a chair). In order to adapt the content of the required sessions that is shortened in this intervention, the researcher will change the regular education by introducing more than one topic in each class, and also a shorter period of time will be allocated for each topic (about 45 minutes) and less time for Practice of each technique will be provided in class. After each session, participants will be given assignments to practice mindfulness techniques for 20 to 30 minutes outside of class. It is believed that home practice less than 2 days per week is not sufficient and that participants who are more engaged in the session spend more time practicing home skills and are therefore likely to experience better outcomes. Supportive items of the main intervention include a mindfulness manual. Various topics include mindfulness meditation instructions, definition of mindfulness, the importance of being present in the present moment, progress notes and forms for exercises. The first half hour is dedicated to formal mindfulness exercises. Then the participants talk about their feelings, what they noticed and how they found this experience. Each session ends with 3 minutes of breathing exercises.

Category

Behavior

2

Description

Control group: The control group receives routine care

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

After obtaining the approval of the Ethics Committee of Mazandaran University of Medical Sciences, r

Full name of responsible person

Zeinab Hamzehgardeshi

Street address

Vesal street

City

Sari

Province

Mazandaran

Postal code

4816715793

Phone

+98 11 3336 7342

Fax

+98 11 3336 8915

Email

Z.hamzehgardeshi@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

دکتر مجید سعیدی

Street address

Vice chancellor for research, Mazandaran University of Medical Sciences, Moalem Square, Sari, Mazandaran, Iran.

City

Sari

Province

Mazandaran

Postal code

48431-63181

Phone

+98 11 4443 4210

Email

Majsaeedi@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Negin Salarian

Position

Student (MSc)

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Royan.Shohada Street.Kalej 5

City

Noor

Province

Mazandaran

Postal code

4656184933

Phone

+98 11 4451 7185

Email

N.Salarian@mazums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Zeinab Hamzehgardeshi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Nasibeh Nursing and Midwifery Faculty, Amir Mazandarani Street

City

Sari

Province

Mazandaran

Postal code

48431-63181

Phone

009833367342

Fax

+98 11 3337 8915

Email

z.hamzehgardeshi@mazums.ac.ir

+98 11 4451 7185

Email

N.salarian@mazums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Negin Salarian

Position

Student (MSc)

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Royan.shohada street,kalej 5

City

Noor

Province

Mazandaran

Postal code

4656184933

Phone

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