

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The effect of training through the application on improving the quality of life of infertile women

Protocol summary

Study aim

Investigating the effect of training through the application on improving the quality of life of infertile women

Design

This research is an experimental study - first by the quality of life of infertile women questionnaire-25 with 7 factors (psychological effects, sexual life with infertility, family and social effects, concerns related to infertility, physical effects, adaptive approaches, and factors preventing compromise) The quality of life is checked and if they get a score of 50% or less in each item, they will receive training related to the problem. The evaluation will be done one month and two months after the intervention, and the evaluations will be done with the same quality of life of infertile women questionnaire.

Settings and conduct

Sampling will be done by simple random sampling in Taleghani Hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran.

Participants/Inclusion and exclusion criteria

Infertile women (one year after unprotected intercourse pregnancy has not occurred in them) No underlying disease No psychiatric disorders official contract Living with a spouse in the present No movement of grief in the last 6 months

Intervention groups

For the intervention group, the application for improving the quality of life of infertile women contains 57 educational clips of 5 to 25 minutes in 7 areas of improving physical, mental, sexual, family-social health, adaptation and removing barriers to adaptation and addressing related concerns, the content of which is by reproductive health experts and the psychologist has been prepared and validated, installed and will be used by the research samples for two months. Then, in order to determine the effectiveness of the intervention, it will be completed twice, once after one month after use and again two months after use.

Main outcome variables

Quality of life of infertile women

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120122008801N24**

Registration date: **2022-07-24, 1401/05/02**

Registration timing: **prospective**

Last update: **2022-07-24, 1401/05/02**

Update count: **0**

Registration date

2022-07-24, 1401/05/02

Registrant information

Name

Masoumeh Simbar

Name of organization / entity

Shahid Beheshti University for Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 8820 2517

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msimbar@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-19, 1401/11/30

Expected recruitment end date

2023-06-20, 1402/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of training through the application on improving the quality of life of infertile women

Public title
The effect of training through the application on improving the quality of life of infertile women

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of infertility with the opinion of a gynecologist
Diagnosis of infertility with the opinion of a gynecologist
official marriage No bereavement experience in the last 6 months
Exclusion criteria:
Lack of informed consent

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
After obtaining informed consent and explaining the research objectives, all eligible women will be invited to the study and if they are willing and interested in participating in the study, they will be included in the research and will be randomly assigned to one of the control groups (n=50) and intervention (n=50) will be included. In this research, randomization into two groups will be done by the block randomization method. This way, 50 binary blocks will be considered in such a way that 25 blocks with order A and dimension B and another 25 blocks with order B and dimension A will be considered. Then, using the RAND() command in Excel software, 50 random numbers will be generated, and using these numbers, these 50 blocks will be sorted randomly. Then, the participants in the intervention group (A) and the control group (B) according to the order of visiting and in the order of A and B in each block. In this way, two groups of 50 people will be randomly assigned to intervention and control groups.

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

Research Ethics Committees of School of Pharmacy and Nursing & Midwifery- Shahid Beheshti University

Street address

Midwifery and Reproductive Health Research Center, Shahid Beheshti University of Medical Sciences, Cross of Vali-Asr and Hashemi Rafsanjani Highway, Opposite to Rajae Heart Hospital, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

۱۹۹۶۸۳۵۱۱۹

Approval date

2022-06-21, 1401/03/31

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1401.063

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Quality of life of infertile women

Timepoint

Measuring the quality of life of infertile women at the beginning of the study (before the start of the intervention), one month and two months after using the application

Method of measurement

Questionnaire of quality of life of infertile women

Secondary outcomes

empty

Intervention groups

1

Description

In the "intervention group", before the intervention, the demographic information questionnaire and the questionnaire for the quality of life of infertile women will be completed by the participants. For the "intervention group", the application for improving the quality of life of infertile women contains 57 educational clips of 5 to 25 minutes in 7 areas of improving physical, mental, sexual, family-social health, adaptation, and overcoming obstacles of the adaptation and also the related concerns. The content will be prepared and validated by the experts of reproductive health and psychologist and designed as an application. This application will be installed and used by the participants of the intervention group for one month. The application will be designed by the computer department of Tarbiat Modares University, Tehran, Iran. Then, in order to determine the effectiveness of the intervention, the questionnaire for the quality of life of infertile women will be completed twice, once one month after use and again two months later.

Category

Other

2**Description**

In the "control group", the participants will receive the routine education and counseling services of the clinic and will not install the application. The participants of the "control group" will also complete the demographic questionnaire and as well as the questionnaire for the quality of life of infertile women at the beginning of the study. In order to determine the effectiveness of the intervention, this group will also complete the questionnaire for the quality of life of infertile women twice, once after one month and once again after two months of routine interventions. The "control group" will receive the application for quality of life improvement after completing the study. In order to prevent the transfer of information between the intervention and control groups, the researcher will emphasize to the participants of the intervention group not to transfer information to the control group and reassure them about providing the content of the application to the "control group" after the completion of the study.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Taleghani Hospital

Full name of responsible person

Masoumeh Simbar

Street address

Midwifery and Reproductive Health Research Center, Shahid Beheshti University of Medical Sciences, Cross of Vali-Asr and Hashemi Rafsanjani Highway, Opposite to Rajaei Heart Hospital, Tehran, Iran

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Presidential Scientific and Technological Vice President

Full name of responsible person

Dr. Sorena Sattari

Street address

No. 20, Laden St., Sheikh Bahai North Street, Mollasadra Street, Vanak Square

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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

Presidential Scientific and Technological Vice President

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**

Other

Person responsible for general inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Masoumeh Simbar

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Masoumeh Simbar

Position

Professor/ PhD of reproductive health

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Full name of responsible person

Dr. Masoumeh Simbar

Position

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Latest degree

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Other areas of specialty/work**Street address**

Department of Reproductive Health and Midwifery,
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Web page address**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

All data is potentially shareable after de-identifying
individuals

When the data will become available and for how long

The access period starts 6 months after the results are
published

To whom data/document is available

Researchers working in academic and scientific
institutions

Under which criteria data/document could be used

The data can be obtained by requesting from the main
researcher and obtaining permission from Shahid
Beheshti University of Medical Sciences with the
confidentiality of the names of the individuals.

From where data/document is obtainable

Dr. Masoumeh Simbar Midwifery and Reproductive
Health Research Center, Shahid Beheshti University of
Medical Sciences, Cross of Vali-Asr and Hashemi
Rafsanjani Highway, Opposite to Rajae Heart Hospital,

Tehran, Iran Tel: ۰۲۱۸۸۲۰۲۵۱۲ Postal Code: ۱۹۹۶۸۳۵۱۱۹ Fax:
۰۰۹۸۲۱ ۸۸۶۵۵۳۷۶

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

Request from the principal investigator, obtaining permission from Shahid Beheshti University of Medical Sciences

Comments