

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Design, implementation, and evaluation of an electronic support intervention versus usual care on improving the reproductive health of couples undergoing infertility treatment and investigating the effect of this intervention on the response to treatment: a randomized clinical trial

Protocol summary

Study aim

Evaluating the effect of electronic intervention on the reproductive health of infertile couples and the response to treatment

Design

Random and controlled clinical trial, one-blind with 100 samples

Settings and conduct

The study will be place at the infertility department of Bahar Hospital, in Shahroud, Semnan Province. The participants will be infertile couples who seek treatment at this center. Blinding will be conducted by statistician who will provide a block list to an individual not involved in the study. This person will then prepare envelopes that contain the names of either the intervention or control group following the order of the list and number them accordingly. The envelopes will be handed over to the person in charge of the infertility department. Once informed consent is obtained from the infertile couple, the first envelope sealed from the numbered box which is provided by the infertility department official will be given to the principal investigator.

Participants/Inclusion and exclusion criteria

Entry criteria: Couples with primary or secondary infertility, Non-entry criteria: Participation in other educational classes and having a mental illness .

Intervention groups

The participants of the intervention group are invited to attend training classes during their first visit to the infertility center to open their case. The number of meetings, timings and instructions on how to participate in the classes are explained both verbally and in writing. Educational videos are uploaded on the infertility center's website and couples are provided with these videos according to predetermined schedule. The control group only receives routine care provided by the center..

Main outcome variables

Reproductive health, response to treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100701004281N4**

Registration date: **2023-11-11, 1402/08/20**

Registration timing: **registered_while_recruiting**

Last update: **2023-11-11, 1402/08/20**

Update count: **0**

Registration date

2023-11-11, 1402/08/20

Registrant information

Name

Azam Hamidzadeh

Name of organization / entity

Shahroud University of Medical Science

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-01, 1402/08/10

Expected recruitment end date

2024-04-29, 1403/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design, implementation, and evaluation of an electronic support intervention versus usual care on improving the reproductive health of couples undergoing infertility treatment and investigating the effect of this intervention on the response to treatment: a randomized clinical trial

Public title

The effect of an electronic intervention on the reproductive health and response to treatment in infertile couples

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

A Diagnosis of infertility or a history of unsuccessful attempts to conceive for twelve months or more, primary or secondary infertility, absence of living children in secondary infertility, absence of adopted children, ability to read and write, residents of Shahroud city, couples receiving assisted reproductive methods For the first time, the agreement of both couples to participate in the study, having a smart phone or computer that receives the educational program or text messages and mastering its use at home, work, etc., having informed consent to participate in the study, lack of Any physical or mental illness in the couple, willing to participate in the research

Exclusion criteria:

Having psychological diseases, a history of psychological diseases, taking psychiatric drugs or participating in other psychological interventions during the treatment stages such as (IVF...), experiencing a stressful or unfortunate event in the last 6 months and engaging in smoking, alcohol or consumption, or drugs use in couples.

Age

From **21 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation of couples is conducted using a

block of four and by a computer randomization administered by a statistician. A table is generated from this allocation and envelopes are prepared by an individual who is not involved in this research. These envelopes are numbered sequentially and contain either the intervention or control type. The thick envelopes, arranged in the specified order, are then placed in a box. The responsibility for admitting participants to the infertility section, which is not involved in the research, lies with someone else. Once participants provide their consent to participate in the study, the admission officer of the infertility center will open the envelope and allocate participant to the designated group. Participants will remain unaware of the group allocation.

Blinding (investigator's opinion)

Single blinded

Blinding description

All participants (infertile couples) in the control and intervention groups will receive routine care, however the intervention group will also receive electronic counseling through educational videos posted on the infertility center website. These videos will have their educational content reviewed and approved by professors in this field. Participants in the control group will only receive usual care. Both groups will be unaware of this allocation. Clinical caregivers will perform all routine tasks for both groups without being notified. The person responsible for data collection is a research assistant who will complete the questionnaires over the phone or in person for both groups. The research assistant who analyzes the data from the questionnaires will also be unaware of the assigned groups.

Placebo

Not used

Assignment

Parallel

Other design features

A single-blind clinical trial, with a parallel control group. The randomization process will be carried out using computer program resulting 100 participants with 50 assigned to the intervention group and 50 to the control group.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahroud University of Medical Sciences

Street address

Shahroud University of Medical Sciences and Health Services, Hafte Tir Square, Taheri Ave

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Shahroud

Province

Semnan

Postal code

3614773955

Approval date

2023-11-06, 1402/08/15

Ethics committee reference number

IR.SHE.REC.1400.087

Health conditions studied**1****Description of health condition studied**

Infertility

ICD-10 code

Male and F

ICD-10 code description

N97.4

Primary outcomes**1****Description**

Improving Reproductive Health

Timepoint

Before intervention, after completion of counseling sessions

Method of measurement

Reproductive Health Questionnaire

2**Description**

Infertility stressB

Timepoint

Before the intervention - after the counseling sessions

Method of measurement

Using the Infertility Stress Questionnaire

3**Description**

life Style

Timepoint

Before the intervention - after the counseling sessions

Method of measurement

Using the Walker's Health Promotion Lifestyle Questionnaire

4**Description**

The scores of the dimensions of the sexual self-concept

Timepoint

Before the intervention - after the counseling sessions

Method of measurement

Using the Snell Sexual Self-Concept Questionnaire

5**Description**

Drug Compliance (MARS's 10-item questionnaire) was

conducted to measure drug compliance, the grading rate was never = 5, rarely = 4, sometimes = 3, most often = 2, always = 1. The scores obtained from this The questionnaire is divided into 10, and thus the range of scores to be obtained in a questionnaire is from 1 to 5. A score of more than 4.5 indicates good drug compliance and a score of less than 4.5 indicates poor drug compliance.)

Timepoint

Before the intervention - after the counseling sessions

Method of measurement

Using questionnaire Medication Adherence (MARS)

Secondary outcomes**1****Description**

Ovarian follicle size

Timepoint

Before the intervention and during 10th to 12th of menstrual cycle (in case of lack of proper size of the ultrasound follicle on days 14-16 and finally 20-22 cycles) after the intervention

Method of measurement

vaginal ultrasound

2**Description**

Numbers of dominant follicles

Timepoint

Before the intervention and during 10th to 12th of menstrual cycle (in case of lack of proper size of the ultrasound follicle on days 14-16 and finally 20-22 cycles) after the intervention

Method of measurement

vaginal ultrasound

3**Description**

Implantation Rate

Timepoint

Two weeks after the assisted reproductive procedure

Method of measurement

Serum BhCG level

Intervention groups**1****Description**

Control group: usual care provided infertility ward

Category

N/A

Recruitment centers**1****Recruitment center**

Name of recruitment center

infertility ward at Bahar hospital in Shahroud

Full name of responsible person

Azam Hamidzadeh

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Bahar Hospital, 22 Bahman street

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

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Full name of responsible person

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Web page address<https://shmu.ac.ir/research/fa>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Shahroud University of Medical Sciences

Proportion provided by this source

20

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**

Shahroud University of Medical Sciences

Full name of responsible person

Azam Hamidzadeh

Position

faculty member

Latest degree

Master

Other areas of specialty/work

Reproductive Health

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

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Person responsible for updating data**Contact****Name of organization / entity**

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Faculty member

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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

After publishing the article and anonymizing the participants, the data file can be sent via email as requested

When the data will become available and for how long

After publishing the research paper of the project for 6 months

To whom data/document is available

For all Academic Researcher

Under which criteria data/document could be used

An approved proposal whose goals indicate the need for this information

From where data/document is obtainable

By Email

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

After the approval of the project partners, the information will be sent within three weeks

Comments