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 toopen their case. The number of meetings, timings andinstructions 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 Sceince

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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 participant 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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Sponsors / Funding sources

1

Sponsor
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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
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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