

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluating the impact of a multi media mental health self-care program based on cyber Space on the mental health of infertile women

Protocol summary

Study aim

Evaluating the effect of Multimedia mental health selfcare program in infertile women based on cyberspace on users mental health

Design

A clinical trial with a control group, randomized on 90 patients (45 patients in intervention group and 45 patients in control group), was used to randomize the order (RAND) in Excel software.

Settings and conduct

Place of Research: Fatemeh Al-Zahra Infertility Training and Treatment Center, Babol city. The participants are placed in the intervention and control groups with easy and continuous sampling and random allocation. Before and one month after the intervention, both groups will complete electronic questionnaires.

Participants/Inclusion and exclusion criteria

All infertile women eligible to enter the study, referred to Fatemeh Al-Zahra Infertility Center in Babol

Intervention groups

The intervention group is infertile women who refer to Fatemeh Al-Zahra Infertility Center in Babol city. In addition to receiving routine infertility care, they will have access to the content of their multimedia mental health care program through the link sent . The control group is infertile women who refer to Fatemeh Al-Zahra Infertility Center in Babol, who will receive only routine infertility care.

Main outcome variables

Mental health (anxiety, depression, infertility-related stress, perceived stress, psychological well-being), satisfaction

General information

Reason for update

Updating information related to the person responsible for scientific accountability of the study, Updating information related to the name of the responsible

person at the sampling site, Changing the sampling start date due to limited access to some messengers.

Modifying some entry criteria due to limited access to some messengers.

Acronym

IRCT registration information

IRCT registration number: **IRCT20210526051410N1**

Registration date: **2022-11-06, 1401/08/15**

Registration timing: **prospective**

Last update: **2023-01-28, 1401/11/08**

Update count: **1**

Registration date

2022-11-06, 1401/08/15

Registrant information

Name

FATEMEH YAHYAVI KOOCHAKSARAEI

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 4229 9150

Email address

fatemeh.yahyavi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-07-22, 1402/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the impact of a multi media mental health self-care program based on cyber Space on the mental health of infertile women

Public title

The impact of a multi media mental health self-care program based on cyber Space on the mental health of infertile women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Having personal satisfaction Primary infertility diagnosed in the case Primary infertility diagnosed in first marriage In infertility treatment Age group 20 years and older Having an Android smartphone Installation of persian messengers on mobile phone Adequate knowledge in the use of social networks (persian messengers) Internet access Iranian nationality Infertility duration one year and above Being literate in reading and writing

Exclusion criteria:

History or current history of severe psychological disorders based on the participant's report such as major depression, bipolar depression and suicidal ideation Substance abuse or psychotropic drugs History of first-degree relatives dying or losing a job in the past 6 months Having an adopted child

Age

From **20 years** old to **48 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

In this research, randomization into two intervention groups (45 people) and control (45 people) will be done by simple randomization method. For randomization, the function of random numbers in Excel software will be used.

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

Valiasr St., Tehran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2021-04-27, 1400/02/07

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1400.011

Health conditions studied

1

Description of health condition studied

Mental health

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Mental health of infertile women

Timepoint

Before and one month after the intervention

Method of measurement

Psychological Well-Being, Beck Depression, Spielberger Anxiety, Perceived Stress and Infertility Stress Questionnaires

Secondary outcomes

1

Description

Satisfaction with using a multimedia mental health self-care program

Timepoint

After the intervention

Method of measurement

Researcher-made questionnaire of satisfaction with education

Intervention groups

1

Description

Intervention group: Infertile women are referred to Fatemeh Al-Zahra Infertility Center in Babol. In addition to receiving routine infertility care, through the link sent

by the researcher to the content of the multimedia mental health self-care program uploaded on the Fatemeh Infertility Center website Al-Zahra will have access to the city of Babel and will use their mental health self-care behaviors for a specified period of time.

Category

Prevention

2

Description

Control group: Infertile women referred to Fatemeh Al-Zahra Infertility Center in Babol city will receive only routine infertility care during the intervention and are the same as the intervention group in terms of inclusion and exclusion criteria.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemeh Al-Zahra Fertility and Infertility Specialized Treatment Center

Full name of responsible person

Mahbobeh Faramarzi

Street address

Babol, Mazandaran

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Web page address

https://fz.mubabol.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Yemen St., Tehran

City

Tehran

Province

Tehran

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Email

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Web page address

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fatemeh Yahyavi

Position

Ph.D Student

Latest degree

Master

Other areas of specialty/work

Reproductive Health

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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

Masoumeh Simbar

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fatemeh Yahyavi

Position

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Latest degree

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Other areas of specialty/work

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