

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Investigating the effect of midwife-led counseling by smartphone on sexual self- concept of Infertile women

Protocol summary

Study aim

To determine the effect of midwife counseling through cell-phone on sexual self- concept among infertile women in the selected center affiliated by Alborz medical university.

Design

In this study, 80 infertile women aged 25 to 35 years old and eligible for inclusion in the study who are referred to the selected infertility centers of the Alborz University of Medical Sciences are selected. They then complete Snell (1995) questionnaire. The score of the questionnaire is compared before and after the intervention. This intervention will be through social consultation software on the smartphone.

Settings and conduct

It is a randomized controlled clinical trial without blinding. setting and conduct: selected Infertility Centers affiliated by Alborz University of Medical Sciences

Participants/Inclusion and exclusion criteria

Inclusion criteria: being Iranian; Women aged 25 to 35 years old; primary infertility and being on treatment with IVF method; access to smartphone and Internet and ability to use social media software like Telegram; Reading and writing ability; written consent; Infertility due to a female factor such as tuberculosis, ovary and fallopian tube pathology, endometriosis, adhesions, etc.; spouse consent; Having regular sex with a spouse
Non inclusion criteria: Secondary infertility and infertility treatments other than IVF; Having physical illnesses such as multiple sclerosis, lupus, strokes and ... that affects sexual function, according to the patient's report; mental disorders such as depression and anxiety; Taking antidepressants; Women working in medical care units; unwanted marriage

Intervention groups

In this group, counseling related to sexual self- concept along with routine consultation related to infertility will be provided twice a week via a Telegram channel. The Telegram channel (for a period of two months training

consisting of 8 counseling sessions twice a week) will be directed by the Admin and the relevant contents will be posted. Participants won't be allowed to discuss with each other about their opinions. They can just contact with the researcher through privacy. To ensure that the participants read the topics presented in the telegram in each session, several questions will be developed by the researcher related to the subject of each session and will be asked after each session.

Main outcome variables

sexual self_ concept

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160503027728N9**

Registration date: **2018-02-11, 1396/11/22**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-11, 1396/11/22**

Update count: **0**

Registration date

2018-02-11, 1396/11/22

Registrant information

Name

Zohreh Mahmoodi

Name of organization / entity

Nursing&Midwifery faculty

Country

Iran (Islamic Republic of)

Phone

+98 26 3430 4433

Email address

zohrehmahmoodi@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of midwife-led counseling by smartphone on sexual self- concept of Infertile women

Public title

The effect of midwife counseling on sexual self- concept of Infertile women

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Being Iranian. 25-35 years old women. primary infertility and being on treatment with IVF method access to smartphone and Internet and ability to use social media software like Telegram Reading and writing ability Written consent Infertility due to a female factor such as tuberculosis, ovary and fallopian tube pathology, endometriosis, adhesions, etc.) Spouse consent Having regular sex with the spouse

Exclusion criteria:

Secondary infertility and infertility treatments other than IVF Having physical illnesses such as multiple sclerosis, lupus, strokes and ... that affects sexual function, according to the patient's report; mental disorders such as depression and anxiety Taking antidepressants Women working in medical care units unwanted marriage

AgeFrom **25 years** old to **35 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **80****Randomization (investigator's opinion)**

Randomized

Randomization description

Available sampling and block randomization method

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**

Ethics committee of Alborz University of Medical Sciences

Street address

Alborz University of Medical Sciences, Shahrake Edari, North Taleghai square, Karaj, Iran

City

Karaj

Province

Alborz

Postal code

3149779453

Approval date

2017-12-30, 1396/10/09

Ethics committee reference number

ABZUMS.REC.1396.146

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

sexual self-concept of infertile women

ICD-10 code

N97

ICD-10 code description

Female infertility

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

sexual self concept score in Snell questionnaire

Timepoint

befor intervention and at the end of the consultation session and one month after finishing the conseling

Method of measurement

sexual self concept questionnaire

Secondary outcomes

empty

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

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consisting of 8 counseling sessions twice a week) will be directed by the Admin and the relevant contents will be posted. Participants won't be allowed to discuss with each other about their opinions. They can just contact with the researcher through privacy. To ensure that the participants read the topics presented in the telegram in each session, several questions will be developed by the researcher related to the subject of each session and will be asked after each session through the Telegram.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kamali hospital

Full name of responsible person

Dr.Zohreh Mahmoodi

Street address

Karaj Kamali Hospital, Kamali Allay, Tallegani street ,Karaj

City

Karaj

Province

Alborz

Postal code

3149779453

Phone

+98 26 3255 5000

Email

zohrehmahmoodi2011@gmail.com

2

Recruitment center

Name of recruitment center

Rouyesh Infertility Treatment Center

Full name of responsible person

Dr Zohreh Mahmoodi

Street address

No.151, Golestan 18 Ave , Taleghani Blvd

City

Karaj

Province

Alborz

Postal code

3149779453

Phone

+98 26 3250 6243

Email

zohrehmahmoodi2011@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Dr.Mohammad Nori Sepeher

Street address

Noor street, Taleghani Square, Karaj

City

karaj

Province

Alborz

Postal code

3149779453

Phone

+98 26 3255 5000

Email

zohrehmahmoodi2011@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Alborz 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

Alborz University of Medical Sciences

Full name of responsible person

Dr.Zoreh Mahmoodi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Department of Nursing., Alborz University of Medical Sciences, Golestan 1, Eshteraki Street, Baghestan, Karaj ,Iran.

City

Karaj

Province

Alborz

Postal code

561-31452

Phone

+98 26 3455 4103

Email

zohrehmahmoodi2011@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Dr. Zohreh Mahmoodi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Golestan 1, Eshteraki Street, Baghestan, Karaj ,Iran.

City

Karaj

Province

Alborz

Postal code

561-31452

Phone

+98 26 3455 1034

Email

zohrehmahmoodi2011@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Dr .Zohreh Mahmoodi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Eshteraki Street, Baghestan, Karaj ,Iran.

City

Karaj

Province

Alborz

Postal code

56131452

Phone

+98 26 3430 4433

Email

zohrehmahmoodi2011@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document**When the data will become available and for how long**

10 mounts after the beginning of the study

To whom data/document is available

Alborz Nursing and Midwifery school

Under which criteria data/document could be used

Improvement of sexual self-concept

From where data/document is obtainable

Alborz Nursing and Midwifery school

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

Alborz University of Medical Sciences

Comments