Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 affliated 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
Age
From **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
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 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@gmai.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