

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effect of Motivational Interview on Self-care(health promotional behaviors) and Quality of Life among infertile women with Polycystic Ovary Syndrome

Protocol summary

Study aim

Determining the effect of motivational interview on self-care (health-promoting behaviors) and quality of life of infertile women with polycystic ovary syndrome

Design

The present study is a clinical trial study of the pragmatic randomized clinical trial type. It consists of an Intervention group of 30 people and a control group of 30 people that will be sampled according to the checklist of the entry criteria. random allocation of samples will be done using random blocking.

Settings and conduct

Sampling being treated at the infertility clinic of imam khomeini hospital . To control the detection bias, the evaluator-blinded method will be used for the evaluators of the outcomes. In order to control the attrition bias, a statistical analysis approach with two separate methods of analysis will be used Intention to treat and pre-protocol and for comparing them with each other. based on the design of the study, the pragmatic clinical trial of client satisfaction will also be measured.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Infertile women 15-40 years old with polycystic ovary syndrome of Iranian nationality,Being literate ,agreement to participate Exclusion Criteria : Any linguistic or cognitive problems, under the care of a psychiatrist,any history of major depression or major family disputes and grief in the week leading up to the beginning of the study, other chronic illnesses have not occurred,Participation in another study

Intervention groups

Both the intervention group and the control group will receive the standard treatments for women with polycystic ovary syndrome, and the intervention group will receive an additional motivational interview. At the end of the intervention process, a set of training files of the sessions will be given to the members of the control

group.

Main outcome variables

The grade of HPLP-II questionnaire score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160619028528N4**

Registration date: **2020-08-11, 1399/05/21**

Registration timing: **retrospective**

Last update: **2020-08-11, 1399/05/21**

Update count: **0**

Registration date

2020-08-11, 1399/05/21

Registrant information

Name

Zeinab Hamzehgardeshi

Name of organization / entity

Mazandaran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 7342

Email address

z.hamzehgardeshi@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Motivational Interview on Self-care(health promotional behaviors) and Quality of Life among infertile women with Polycystic Ovary Syndrome

Public title
Effect of motivational interview on self-care and quality of life among infertile women with polycystic ovary syndrome

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Infertile women with polycystic ovary syndrome based on rotterdam criteria according to the diagnosis of an experienced physician Age (15-40) Nationality: iranian Being literate Agreement to participate in this research
Exclusion criteria:
Having suffered from other chronic diseases during the last 3 months A consumer of cigarettes, hookah, or alcoholic drinks Any history of major depression or major family disputes and grief (death of close relatives)in the week leading up to the beginning of the study Under the care of a psychologist or a psychiatrist at least one month before the start of the study and taking psychiatric medication Any linguistic or cognitive problems that would prevent the completion of the questionnaire of the research unit Participation in another study

Age
From **15 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling in this study the first stage of sampling carried out in order to identify the eligible women with polycystic ovary syndrome will be done through convenience sampling method. Then in the next stage, 60 eligible patients will be assigned to an intervention group (motivational interview recipient) and a control group (routine care) using a computer software and the randomized blocking method with quadruple and hexagonal blocks. To hide the allocation, 60 envelopes in a translucent package with consecutive numbers were used. The packages were then opened in the order in which the participants entered the open study and then the type of the groups of every participant was determined.

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 Mazandaran University of Medical science

Street address

Moalem square, Vice chancellor for research

City

Sari

Province

Mazandaran

Postal code

4843163181

Approval date

2020-05-12, 1399/02/23

Ethics committee reference number

IR.MAZUMS.REC.1399.191

Health conditions studied

1

Description of health condition studied

Polycystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

Health-promoting behaviors

Timepoint

Before the intervention, immediately after the intervention and 8 weeks after the intervention

Method of measurement

Health-promoting lifestyle profile II questionnaire

Secondary outcomes

1

Description

Quality of life

Timepoint

Before the intervention, immediately after the intervention and 8 weeks after the intervention

Method of measurement

Modified polycystic ovary syndrome health-related quality of life questionnaire

Intervention groups

1

Description

Intervention group: The intervention group consists of 5 group counseling sessions using the social networking application, Whatsapp, for 60-90 minutes. The first part of the session will be the motivational interview section and the second part will be the self-care education program. With regard to the subject of "the quality of life" the following concepts will be discussed: informing the participates about polycystic ovary syndrome, complications, teaching self-care behaviors including diet And exercise. In a motivational interview, exercises such as decision-making balance, readiness cycle for change, increased conflict between self-care behaviors and values, behavior in different situations, and having a vision will be utilized.

Category

Rehabilitation

2

Description

Control group: The control group receives only the center's usual medical which includes periodic visits, tests, and a one-time educational recommendations for weight loss, exercise, and a healthy diet.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility clinic of Imam Khomeini Hospital in Sari

Full name of responsible person

Dr. Sepide Peyvandi

Street address

Imam Square .Razi Street

City

Sari

Province

Mazandaran

Postal code

33131 48166

Phone

+98 11 3335 0670

Fax

Email

dr_peyvandi@yahoo.com

Web page address

<https://imamhospital.mazums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Majid Saeedi

Street address

Moalem Street, Vice chancellor for research

City

Sari

Province

Mazandaran

Postal code

48431-63181

Phone

+98 11 4443 4210

Email

majsaeedi @ gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Fatemeh Ansari

Position

Student (MSc)

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Caspian Square. Justice street, 6th Golestan street

City

Sari
Province
Mazandaran
Postal code
4817944693
Phone
+98 11 3320 3800
Fax
Email
Ansari5664@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr. Zeinab Hamzehgardesh
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Nasibeh Nursing and Midwifery Faculty, Vesal Street,
Amir Mazandarani Street
City
Sari
Province
Mazandaran
Postal code
48431-63181
Phone
+98 11 3336 7342
Fax
+98 11 3337 8915
Email
z.hamzehgardeshi@mazums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences
Full name of responsible person
Fatemeh Ansari
Position
student (MSc)
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Caspian Square. Justice Street, 6th Golestan Street
City
Sari
Province
Mazandaran
Postal code
4817944693
Phone
+98 11 3323800
Fax
Email
Ansari5664@yahoo.com

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