Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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Name of organization / entity
Mazandaran University of Medical Science

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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
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Email
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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
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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
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
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Position
Student (MSc)
Latest degree
Bachelor
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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