

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of sexual health counseling with a problem-solving approach Online and face-to-face on the sexual satisfaction of women with polycystic ovary syndrome

Protocol summary

Study aim

Comparing the effectiveness of sexual health counseling with problem solving approaches with online and face-to-face on sexual satisfaction of women with polycystic ovary syndrome

Design

This intervention research (consultation with a problem solving approach), in a randomized semi-experimental way without blinding, on 56 women with polycystic ovary syndrome, who were divided into two groups in person (28 people) and online (28 people) will be divided. Sampling in the centers will be targeted non-random sampling.

Settings and conduct

Diabetes Research Center and Baqaei Pour Clinic of Yazd, sampling, random allocation, counseling intervention by the researcher

Participants/Inclusion and exclusion criteria

Inclusion Women with polycystic ovary syndrome according to the Rotterdam criteria and doctor's diagnosis Iranian and resident of Yazd city At least literate in reading and writing and speaking Persian language Completion of informed consent to participate in the research Ages 18-45 years Having Smart mobile phone Desire to install the messenger program Married To cross At least one year from the start of marriage Exclusion Using drugs that affect sexual performance (for example: blood lipid-lowering drugs, cimetidine, digoxin, progesterone, antidepressants, etc.) Consumption of alcohol and psychoactive substances according to the patient Simultaneous participation in similar studies People with known mental problems under medical treatment (such as depression, etc.) pregnancy Women who have recently given birth and have children less than 6 months old The occurrence of major stress in the last 6 months, including the loss of loved ones

Intervention groups

Counseling with a problem-solving approach is held in six two-hour sessions in one group in person and the other online (in Messenger program) once a week.

Main outcome variables

Change in mean sexual satisfaction scores

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230302057590N1**

Registration date: **2023-03-25, 1402/01/05**

Registration timing: **prospective**

Last update: **2023-03-25, 1402/01/05**

Update count: **0**

Registration date

2023-03-25, 1402/01/05

Registrant information

Name

Fatemeh Dehghanimohammadabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3836 3583

Email address

f.dehghanimohammadabadi@stu.ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of sexual health counseling with a problem-solving approach Online and face-to-face on the sexual satisfaction of women with polycystic ovary syndrome

Public title

Investigating sexual health counseling with a problem-solving approach with online and face-to-face on sexual satisfaction of women with polycystic ovary syndrome

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Women with polycystic ovary syndrome according to the Rotterdam criteria and doctor's diagnosis Iranian and resident of Yazd city At least literate in reading and writing and speaking Persian language Completion of informed consent to participate in the research Ages 18-45 years Having Smart mobile phone Desire to install the messenger program Married To cross At least one year from the start of marriage

Exclusion criteria:

Using drugs that affect sexual performance (for example: blood lipid-lowering drugs, cimetidine, digoxin, progesterone, antidepressants, etc.) Consumption of alcohol and psychoactive substances according to the patient Simultaneous participation in similar studies People with known mental problems under medical treatment (such as depression, etc.) pregnancy Women who have recently given birth and have children less than 6 months old The occurrence of major stress in the last 6 months, including the loss of loved ones

AgeFrom **18 years** old to **45 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **56****Randomization (investigator's opinion)**

Randomized

Randomization description

Eligible women are selected by purposive sampling and each woman is assigned a code from 1 to 56 for random assignment. According to the output of the software, the random numbers prepared by the statistician with the online software by randomization method on the web using the site <http://www.graphpad.com/quickcalcs/index.cfm> are 28 numbers in group A and 28 numbers In group B, they are randomly assigned, and neither the women nor the

researcher knows the name of the group to which each woman will be assigned. The numbers of each group are written on a piece of paper and placed inside a sealed envelope, then a collaboration outside the research team is asked to use a simple randomization method to determine which groups are face-to-face and which are online.

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 Committee of Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Bahonar Square, Yazd

City

Yazd

Province

Yazd

Postal code

8916189165

Approval date

2023-01-24, 1401/11/04

Ethics committee reference number

IR.SSU.REC.1401.084

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

Counseling on sexual satisfaction

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Sexual satisfaction score in Larson's sexual satisfaction questionnaire

Timepoint

Before the start of the intervention, immediately after the end of the intervention and one month after the end of the intervention

Method of measurement

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first intervention in the face-to-face group is held in the form of 6 2-hour sessions at the diabetes clinic once a week by a senior student of counseling in midwifery, under the supervision of the research team. Larson's sexual satisfaction questionnaire will be completed three times before, immediately after and one month after the end of the intervention. A reminder SMS will be sent to all people the day before the sessions. will be The content of the sessions includes the undeniable fact of the problem in life, talking about polycystic ovary syndrome, teaching the anatomy and physiology of the reproductive system, creating creative solutions, evaluating options and choosing the best solution, implementing and reviewing solutions, evaluating the implemented method, Summarizing and reviewing meetings. At the end of each session, the important topics are summarized and the women are asked to do their homework until the next session. In each meeting, the contents of the previous meetings will be reviewed and homework will be checked.

Category

Behavior

2

Description

The second intervention group: intervention in the online group in the form of 6 sessions of 2 hours in the space of the messenger program in the form of PowerPoint and Voice in a group once a week by a senior student of counseling in midwifery, under the supervision of the research team. Larson's sexual satisfaction questionnaire will be completed three times before, immediately after and one month after the end of the intervention. A reminder SMS will be sent to all people the day before the meeting. The content of the sessions includes the undeniable fact of the problem in life, talking about polycystic ovary syndrome, teaching the anatomy and physiology of the reproductive system, creating creative solutions, evaluating options and choosing the best solution, implementing and reviewing solutions, evaluating the implemented method, Summarizing and reviewing meetings. At the end of each session, the important topics are summarized and the women are asked to do their homework until the next session. In each meeting, the contents of the previous meetings will be reviewed and homework will be checked.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqaipour Clinic, Shahid Sadoughi Hospital, Yazd

Full name of responsible person

Behnaz Enjezab

Street address

Next To The Main Door Of Shahid Sadoughi Hospital, Math Square, Safaiye

City

Yazd

Province

Yazd

Postal code

8915887857

Phone

+98 35 3822 9105

Email

enjezabbehnaz@yahoo.com

2

Recruitment center

Name of recruitment center

Diabetes clinic

Full name of responsible person

Behnaz Enjezab

Street address

Art Hall Alley, Bahnar Square, Shahid Sadoughi Blvd

City

Yazd

Province

Yazd

Postal code

8917693571

Phone

+98 35 3728 0228

Fax

+98 35 3728 0216

Email

enjezabbehnaz@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Amirhoshang Mehrparvar

Street address

Yazd, Bahnar Square, Central Organization of Yazd University of Medical Sciences

City

Yazd

Province

Yazd

Postal code

8916978477

Phone

+98 35 3726 3733

Fax

Email

ah.mehrparvar@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Behnaz Enjezab

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Bouali Ave, Safaiyeh

City

Yazd

Province

Yazd

Postal code

8916877443

Phone

009838241751

Email

enjezabbehnaz@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Behnaz Enjezab

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Bouali Ave, Safaiyeh

City

Yazd

Province

Yazd

Postal code

8916877443

Phone

009838241751

Email

enjezabbehnaz@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Behnaz Enjezab

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Bouali Ave, Safaiyeh

City

Yazd

Province

Yazd

Postal code

8916877443

Phone

009838241751

Email

enjezabbehnaz@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Individual data of study participants can be shared after un identifying.

When the data will become available and for how

long

After printing the results.

To whom data/document is available

The data will be accessible to researchers working in scientific and academic institutions.

Under which criteria data/document could be used

Scientific use.

From where data/document is obtainable

enjezabbehnaz@yahoo.com

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

At least one week after receiving the requester's email.

Comments