

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

The effect of psycho-sexual counseling based on the cognitive-behavioral approach to improving women's genital self-image and reinforcing their reproductive health: a randomized clinical trial study

Protocol summary

Study aim

Determine the effects of psycho-sexual counseling based on the cognitive-behavioral approach to improving women's genital self-image and reinforcing their reproductive health

Design

Two arms parallel-group randomized trial. the sample size determine 54 for each group and a total of 108. In this study, the randomization method will be a randomized block design with a block size of 4.

Settings and conduct

The list of eligible women aged 15-49 years has been prepared by a researcher from Amol health centers and women will be randomly assigned to two test or control groups. The first intervention session will be held at the health care center and the rest of the intervention sessions due to the Corona pandemic will be provided online and offline through Skyroom and WhatsApp software.

Participants/Inclusion and exclusion criteria

Having Iranian nationality reading and writing literacy
Being married Sexuality active not being pregnant not being Menopause not being in the first six months after childbirth Having a mobile phone with an Android system and internet access Satisfaction and voluntary participation Healthy women in terms of genital anatomy based on self-report Absence of major psychiatric disorders based on self-report (such as depression, anxiety, obsession) No history of genital surgeries such as hysterectomy, oophorectomy No cancer in the genital area (like vagina cancer, cervix cancer)

Intervention groups

The intervention group will spend 8 weeks, one session per week and each session for 90 minutes in the Skyroom space, and will receive the content of the intervention provided by the researcher. The provided content will also be placed in the WhatsApp group space.

Standard questionnaires will be completed before, immediately, and 2 months after the intervention in the control group

Main outcome variables

Promoting women's genital image and their reproductive health

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220302054166N1**

Registration date: **2022-05-11, 1401/02/21**

Registration timing: **prospective**

Last update: **2022-05-11, 1401/02/21**

Update count: **0**

Registration date

2022-05-11, 1401/02/21

Registrant information

Name

Mina Malary

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 5054

Email address

malary@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-28, 1401/03/07

Expected recruitment end date

2022-06-28, 1401/04/07

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of psycho-sexual counseling based on the cognitive-behavioral approach to improving women's genital self-image and reinforcing their reproductive health: a randomized clinical trial study

Public title
The effect of psycho-sexual counseling based on the cognitive-behavioral approach to improving women's genital self-image and reinforcing their reproductive health

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Having Iranian nationality reading and writing literacy
Being married Sexuality active not being pregnant not being Menopause not being in the first six months after childbirth Having a mobile phone with Android system and internet access Satisfaction and voluntary participation Healthy women in terms of genital anatomy based on self-report Absence of major psychiatric disorders based on self-report (such as depression, anxiety, obsession) No history of genital surgeries such as hysterectomy, oophorectomy No cancer in the genital area (like vagina cancer, cervix cancer)
Exclusion criteria:
Unwillingness of the women to continue participating in the study

Age
From **15 years** old to **49 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **108**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the randomization method will be a randomized block design with a block size of 4. The block randomization method is designed to randomize participants into groups that result in equal sample sizes. This method is used to ensure a balance in sample size across groups over time. in this clinical trial with control and treatment groups, a randomized block procedure would be as follows: (1) block size of 4 will be chosen, (2) possible balanced combinations with 2 T (intervention) and 2 C (control) subjects will be calculated as 6 (CCTT, CTCT, CTTC, TCCT, TCTC, TTCC) and (3) blocks will be randomly chosen to determine the assignment of all

participants.

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 Shahrood University of Medical Sciences

Street address

Shahrood University of Medical Sciences and Health Services, Hafte Tir Square, Shahrood, Iran

City

Shahrood

Province

Semnan

Postal code

3614773955

Approval date

2020-02-03, 1398/11/14

Ethics committee reference number

IR.SHMU.REC.1398.127

Health conditions studied

1

Description of health condition studied

genital self-image in women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

genital self-image

Timepoint

Before the intervention, immediately and 2 months after the intervention

Method of measurement

d Female Genital Self-Image Scale(FGSIS)

Secondary outcomes

1

Description

Reproductive health (Intention of Reproductive Health Promoting Behaviors and sexual health (such as sexual function, sexual distress, sexual self-esteem, and sexual satisfaction))

Timepoint

Before the intervention, immediately and 2 months after the intervention

Method of measurement

The intention of Reproductive Health Promoting Behaviors, (Female Sexual Distress Scale-Revised(FSDS-R)), (Female Sexual dysfunction index(FSFI-6)), Sexual self-esteem, sexual satisfaction

Intervention groups

1

Description

The intervention group will spend 8 weeks, one session per week (8 sessions in total) and each session for 90 minutes in the Skyroom space, the link of which has been sent to them via WhatsApp, and will receive the content of the intervention provided by the researcher. On the other hand, the content provided will be placed in the WhatsApp group space so that participants can refer to it again and use it if they wish. In addition, if you have any questions, mention them in the group so that the researcher can review and answer them.

Category

N/A

2

Description

Control group: The control group will receive the mobile application but they did not access the intervention content until the end of the research. Then, based on the ethics of the research and their willingness can use the content of Intervention. Standard questionnaires will be completed before, immediately after 6 sessions of intervention, and 2 months after the intervention in the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Amol healthcare centers, Mazandaran province

Full name of responsible person

Mina Malary

Street address

Talib Amoli Street

City

Amol

Province

Mazandaran

Postal code

4615746173

Phone

+98 11 4425 3237

Email

Minamalary@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr.Mohammad Hassan Emamian

Street address

Shahroud University of Medical Sciences and Health Services, Hafte Tir Sq. Shahroud, Iran.

City

Shahroud

Province

Semnan

Postal code

36147-73947

Phone

+98 23 3239 4499

Email

pishgiri@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Maryam Farjamfar

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

7tir street

City

Shahroud

Province

Semnan

Postal code

3614773947

Phone

+98 23 3239 5054

Email

viraa.academy@yahoo.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shahroud University of Medical Sciences

Full name of responsible person

Maryam Farjamfar

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

Street address

7tir street

City

Shahroud

Province

Semnan

Postal code

3614773947

Phone

+98 23 3239 5054

Email

viraa.academy@yahoo.com

Person responsible for updating data

Contact**Name of organization / entity**

Shahroud University of Medical Sciences

Full name of responsible person

Mina Malarly

Position

Student

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

7tir street

City

Shahroud

Province

Semnan

Postal code

3614773947

Phone

009832935054

Email

Minamalarly@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