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 Shahroud University of Medical Sciences

Street address

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

City

Shahroud

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahroud University of Medical Sciences

Full name of responsible person
Dr.Mohammad Hassan Emamian

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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
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Other areas of specialty/work
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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