

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The impact of an educational package on genital self-image and sexual function in women: a randomized controlled trial

Protocol summary

Summary

Objective: Determining the effect of training package on mental image of reproductive system appearance and sexual function. Design: The controlled randomized clinical trial. Method: It will be conducted in health centers of Qazvin. The qualified individuals will randomly be allocated to two groups of 62 persons with blocks of 4 and 6. One of the members of research team who is not involved in sample selection, will determine random allocation sequence using the computer program. The closed opaque envelopes will be scored respectively and used to hide the allocation. Inclusion criteria: The women who have not given birth (nullipara women) and the women with parity 1 and 2 with normal (natural) and cesarean childbirth, living with permanent husband (during recent four weeks). The exclusion criteria consists of the women with multiple sex partners and divorce record. Interventions: In the intervention group, three training sessions will be held every day for an hour. The contents of training sessions in the intervention group are as follows: the first session is about the anatomy and physiology of reproductive system along with the images of natural external organ of reproductive (genital) system, the second session about the familiarity with female sex hormones and sensitive sexual organs (clitoris, labia major and minor and vaginal entrance), the third session is about the causes of negative mental image of doing unnecessary surgery and the implications of unnecessary surgeries of genital system. In the control group, the training package will be given them after completing the questionnaire. The variables of main outcome: mental image and sexual function will be measured before intervention and four weeks after intervention

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201506148170N8**

Registration date: **2015-09-24, 1394/07/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-09-24, 1394/07/02

Registrant information

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Name of organization / entity

Nursing Faculty

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

women's Reproductive Health Research Center

Expected recruitment start date

2015-09-06, 1394/06/15

Expected recruitment end date

2015-12-06, 1394/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of an educational package on genital self-image and sexual function in women: a randomized controlled trial

Public title

The impact of an educational package on genital self-image and sexual function in women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Having tendency to participate in the research, Iranian nationality, literacy level at the extent of elementary and above, the women who have not given birth (nullipara women) and the women with parity 1 and 2 with normal (natural) and cesarean childbirth, the age of 18-40 years, not having mental disease and mental obsession according to the patient's statement and not using the psychotropic drugs, lack of reproductive system diseases (vaginitis, herpes, genital warts, scarring caused by surgery or trauma, burn) according to the individual's statement, the first marriage and being monogamous couples, living with permanent husband (during recent four weeks), lack of pregnancy and breastfeeding, being sexually active (having sex during recent four weeks based on sexual function questionnaire). Exclusion criteria: Not having tendency to continue the participation in the study, the women with multiple sex partners (prostitutes), divorce record, pelvic surgeries and the other genital organs surgeries, radiotherapy and chemotherapy

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **124**

Randomization (investigator's opinion)

Randomized

Randomization description**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 Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences Research &

Technology, Golgasht Street

City

Tabriz

Postal code**Approval date**

2015-06-13, 1394/03/23

Ethics committee reference number

tbzmed.rec.1394.253

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

33: Management, directors and family health programs

ICD-10 code

Z41,Z41.1,

ICD-10 code description

Procedures for purposes other than remedying health state, Other plastic surgery for unacceptable cosmetic appearance, Counselling related to sexual attitude, behaviour and orientation, Sex counselling, unspecified

Primary outcomes**1****Description**

Genital self-image

Timepoint

Before and four weeks after training

Method of measurement

Inventory image of genitalia

2**Description**

Sexual Function

Timepoint

Before and four weeks after training

Method of measurement

Female Sexual Function Index questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

In the control group, after completing the mental image self-made questionnaire and the female sexual function questionnaire, they were asked to refer again in the fourth week. In the fourth week, the control group will also be given the training package, after completing the female sexual function index questionnaires and the questionnaire of women's mental image of their reproductive (genital) system

Category

Prevention

2

Description

In the intervention group, three training sessions will be held every day for an hour. If the training time does not agree with the participants, the time and date of holding the class will be coordinated with them. Considering the sample size of 62 persons, the number of participants in each group will be between 10 persons in each training session for intervention group during three weeks. At the beginning of session, the participants will be given the training package. The contents of training sessions in the intervention group are as follows: the first session is about the anatomy and physiology of reproductive system along with the images of natural external organ of reproductive (genital) system, the second session about the familiarity with female sex hormones and sensitive sexual organs (clitoris, labia major and minor and vaginal entrance), the third session about the causes of negative mental image of doing unnecessary surgery and the implications of unnecessary surgeries of genital system and after training, the individuals are participated in the group discussion and their questions are answered. They will refer for re completing the female sexual function index and the questionnaire of women's mental image of their reproductive (genital) system four weeks after finishing the training sessions

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Centers in Qazvin

Full name of responsible person

Mina Sabbaghan

Street address

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Tabriz University of Medical Sciences

Full name of responsible person

Doctor Mohammad Reza Rashidi

Street address

Research department, Third floor, Central Construction Number 2, Tabriz Medical Science University, Golgasht Street, Azadi Avenue, Tabriz

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Vice Chancellor for Research, Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

School of Nursing and Midwifery, Tabriz

Full name of responsible person

Mina Sabbaghan

Position

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty