

# 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

###### Name

Jamileh Malakouti

###### Name of organization / entity

Nursing Faculty

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1477 2699

###### Email address

malakoutij@tbzmed.ac.ir

##### 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

MSC Midwifery

#### Other areas of specialty/work

#### Street address

School of Nursing and Midwifery, South Shariat St

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## Person responsible for scientific inquiries

### Contact

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## **Person responsible for updating data**

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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*