

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### Compare the effectiveness of Midwifery counseling based on cognitive behavioral counseling approach and conseling based on Extended Permission; Limited information; Specific Suggestion; Referral for intensive therapy( EX PLISSIT) model on sexual function and sexual satisfaction in women during lactation

#### Protocol summary

##### Summary

This study aimed to compare two methods of cognitive-behavioral and Extended Permission; Limited information; Specific Suggestion; Referral for intensive therapy( EX PLISSIT) counseling on function and sexual satisfaction in lactating women up to one year after delivery. Design: A randomized clinical trial without placebo how to do: In this study after obtaining informed consent from lactating women were randomly assigned into two intervention cognitive-behavioral and EX PLISSIT groups and a control group based on six blocks. 34 people will be in every group. Members of the three groups at the first meeting fill up the standard questionnaire female sexual function index (FSFI) and sexual satisfaction Larson. The members of the first intervention group participate on 4 group sessions of counseling based on cognitive behavioral approach that includes the 1.5 hour and second intervention group participate on 3 counseling sessions based EX Plissit-approach that includes 1 hour. The control group did not receive any intervention. Immediately and one month after the end of the sessions three groups will respond to post-test. Function and sexual satisfaction scores will be compared between the two intervention groups and between control and intervention groups. Inclusion criteria: living on Neyshabur city; having at least primary education; life with spouse ; having sexual relationship; maximum one year after of delivery; nulliparous; breastfeeding; having psychosomatic healthy; Before entering the study has not been treated sexual problems. Exclusion criteria: happening the stressful event in the past month; taking drugs that affect on sexual function.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016040827280N1**

Registration date: **2016-06-18, 1395/03/29**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-06-18, 1395/03/29

##### Registrant information

##### Name

Mahdieh Eshghi

##### Name of organization / entity

Shahroud university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3239 7213

##### Email address

eshghi@shmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for research; Shahroud University of Medical Sciences

##### Expected recruitment start date

2016-05-21, 1395/03/01

##### Expected recruitment end date

2016-09-22, 1395/07/01

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Compare the effectiveness of Midwifery counseling based on cognitive behavioral counseling approach and counseling based on Extended Permission; Limited information; Specific Suggestion; Referral for intensive therapy( EX PLISSIT) model on sexual function and sexual satisfaction in women during lactation

**Public title**  
The effect of cognitive behavioral counseling and Extended Permission; Limited information; Specific Suggestion; Referral for intensive therapy (EX PLISSIT) model on sexual function and sexual satisfaction in women during lactation

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
Inclusion criteria: living on Neyshabur city; having at least primary education; life with spouse ; having sexual relation; maximum one year after of delivery; nulliparous ; breastfeeding; having psychosomatic healthy; Before entering the study has not been treated sexual problems. Exclusion criteria: happening the stressful event in the past month; taking drugs that affect sexual function; in the EX PLISSIT group if you need a referral; the referral is given and the excluded .

**Age**  
No age limit

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **102**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
**Placebo**

Not used  
**Assignment**  
Parallel

**Other design features**  
Random allocation is done as a block of four. After obtaining informed consent based on cognitive behavioral table assigned to intervention and control groups allocated

**Secondary Ids**  
empty

## Ethics committees

1

### Ethics committee

#### Name of ethics committee

Ethics committee of Shahroud University of Medical Sciences

#### Street address

Central building of Shahroud University of Medical Sciences; Tir Square; Shahroud

#### City

shahroud

#### Postal code

3614773955

#### Approval date

2016-02-25, 1394/12/06

#### Ethics committee reference number

ir.shmu.iec.1394.192

## Health conditions studied

1

### Description of health condition studied

Sexual function and satisfaction of lactation period

#### ICD-10 code

f52.0

#### ICD-10 code description

Lack or loss of sexual desire

## Primary outcomes

1

### Description

Sexual function

### Timepoint

Before; immediately and one month after intervention

### Method of measurement

Female sexual function standard Questionnaire

## Secondary outcomes

1

### Description

Sexual satisfaction

### Timepoint

Before; immediately and one month after intervention

### Method of measurement

Larson sexual satisfaction standard questionnaire

## Intervention groups

1

### Description

Intervention2:3 sessions counseling based on EX PLISSIT.

### Category

Prevention

**2**

**Description**

Intervention group1: 4 group sessions based on cognitive behavioral counseling for 1.5 hours.

**Category**

Prevention

**3**

**Description**

control group: Do not receive any intervention.

**Category**

Prevention

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

urban health center

**Full name of responsible person**

Mahdieh Eshghi

**Street address**

Central building of Shahroud University of Medical Sciences;Hafte Tir Square;Shahroud

**City**

Shahroud

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice Chancellor for research; Shahroud University of Medical Sciences

**Full name of responsible person**

Dr Mohammadhasan Emamian

**Street address**

Central building of Shahroud University of Medical Sciences; Hafte Tir Square; Shahroud

**City**

Shahroud

**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; Shahroud 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**

Shahroud university of medical sciences

**Full name of responsible person**

Mahdieh Eshghi

**Position**

Master science of student counseling midwifery

**Other areas of specialty/work**

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Faculty member

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**Other areas of specialty/work**

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**Web page address****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*