

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

Street address

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

City

Shahroud

Postal code

3614773955

Phone

+98 23 3239 7213

Fax

Email

MAHD_MOHAMAD@YAHOO.COM

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahroud university of medical sciences

Full name of responsible person

Mahbobeh Poorheidary

Position

Faculty member

Other areas of specialty/work

Street address

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

City

Shahroud

Postal code

3614773955

Phone

+98 23 3239 1850

Fax

Email

mah_poorheidary@yahoo.com

Web page address

Person responsible for updating data

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

Street address

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

City

Shahroud

Postal code

3614773955

Phone

+98 23 3239 7213

Fax**Email**

mahd_mohamad@yahoo.com

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