Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Oct 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 the1.5 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
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Iran (Islamic Republic of)
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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 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

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 satisfacation 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 Questionnare

Secondary outcomes

1

Description

Sexual satisfacation

Timepoint

Before; immediately and one month after intervention

Method of measurement

Larson sexual satisfacation standard questionnare

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