

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Feb 2026

Comparing The Effect Of Extended PLISSIT and Group Counseling On Sexual Function and Satisfaction Of Pregnant Women

Protocol summary

Summary

This aim of this study is to compare the effect of Extended PLISSIT (EX-PLISSIT) counseling and group counseling on sexual function and sexual satisfaction among pregnant women. This study is a randomized controlled trial. The study population will be pregnant women referred to health care centers in the Zanjan city. Participants will be assign to two intervention and one control groups and each group will consist of 37 pregnant women. After obtaining informed consent, the first intervention group will receive the EX-PLISSIT counselling and the second one will receive client-centered group counseling. The control group will receive routine care. Participants will be married women with normal pregnancy who are in the first or second trimester of pregnancy and have no medical contraindication to do sexual activity during pregnancy. The main outcomes of this study will be sexual Function and satisfaction.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021225477N2**

Registration date: **2017-03-31, 1396/01/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-03-31, 1396/01/11

Registrant information

Name

Elahe Ahmadnia

Name of organization / entity

Social determinants of health center

Country

Iran (Islamic Republic of)

Phone

+98 24 3344 9192

Email address

ahmad@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahroud University of Medical Sciences

Expected recruitment start date

2017-03-15, 1395/12/25

Expected recruitment end date

2017-07-15, 1396/04/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing The Effect Of Extended PLISSIT and Group Counseling On Sexual Function and Satisfaction Of Pregnant Women

Public title

Comparing The Effect Of Two Methods Of Counseling On Sexual Function and Satisfaction In Pregnant Women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Nulliparity; Monogamous; Non-specific and chronic diseases; absence of contraindication for sexual activity during pregnancy; absence of sexual dysfunction according to the physician diagnosis; not receiving formal education about sexual activity during past 6 months; No history of psychiatric disorders at least in the last year; not using drugs such as

imipramine, Diazpoxide, Opioid or Alcohol. Exclusion criteria: conditions that prohibit sexual intercourse, serious interpersonal problems between couples.

Age

From **12 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **111**

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 Shahroud University of Medical Sciences

Street address

Shahroud University of Medical Sciences, Hafte Tir Square, Shahroud

City

Shahroud

Postal code

Approval date

2016-07-22, 1395/05/01

Ethics committee reference number

IR.SHMU.REC.1395.80

Health conditions studied

1

Description of health condition studied

Sexual Function and Sexual Satisfaction

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sexual Satisfaction

Timepoint

Baseline and 4 Weeks after Intervention

Method of measurement

Hadson Sexual Satisfaction

2

Description

Sexual Function

Timepoint

Baseline and 4 Weeks after Intervention

Method of measurement

FSFI Standardized Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1 (Extended PLISSIT counselling): In this group, 2-4 Individual counseling sessions will be held weekly for each participant.

Category

Other

2

Description

Intervention group 2 (Client-centered group counseling): the participants will be divided into five 7-8 member groups and 4-5 group counseling sessions will be held for them. Each session will take about 1 to 1.5 hours.

Category

Other

3

Description

Control group: routine care

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Health care centers in Zanjan

Full name of responsible person

Street address

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahroud University of Medical Sciences

Full name of responsible person

Mohammad Hassan Emamian

Street address

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

Elahe Ahmadnia

Position

Ph.D candidate in Fertility health

Other areas of specialty/work**Street address**

Shahroud University of Medical Sciences, Hafte Tir Square, Shahroud

City

Shahroud

Postal code**Phone**

+98 23 3344 7195

Fax**Email**

ahmad@zums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Student Research Committee, School of Nursing and Midwifery, Shahroud University of Medical Sciences

Full name of responsible person

Elahe Ahmadnia

Position

Ph.D candidate in Fertility health

Other areas of specialty/work**Street address**

Shahroud University of Medical Sciences, Hafte Tir Square, Shahroud.

City

Shahroud

Postal code**Phone**

+98 23 3344 7195

Fax**Email**

ahmadnea52@yahoo.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Student Research Committee, School of Nursing and Midwifery, Shahroud University of Medical Sciences

Full name of responsible person

Elahe Ahmadnia

Position

Ph.D candidate in Fertility health

Other areas of specialty/work**Street address**

Shahroud University of Medical Sciences, Hafte Tir Square, Shahroud.

City

Shahroud

Postal code**Phone**

00

Fax**Email**

ahmadnea52@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