Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 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
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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
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Ph.D candidate in Fertility health
Other areas of specialty/work
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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