

# 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, Shahrood 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

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**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

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## 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**

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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*