# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Effect of PLISSIT-based Counseling on Sexual Function of Pregnant Women

## Protocol summary

**Summary**

This study determine the effect of counseling based on PLISSIT model on sexual function of pregnant women in Razan. study population is pregnant women of 8-10 weeks of gestation. The participants will be divided into two groups by using Permutation block randomization. The sample size concludes of 43 patients in the intervention group and 43 patients control group. Inclusion criteria: gestational age between 8-10 weeks; First pregnancy and living in the city of Razan. Exclusion criteria: any problem during study. In intervention group counseling will be done in four sessions which each session last for 40-70 minutes. In this study primary outcome is sexual function

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2015100324325N1**
Registration date: **2016-01-22, 1394/11/02**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2016-01-22, 1394/11/02

**Registrant information**

**Name**

Farzaneh Khezrian

**Name of organization / entity**

Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 81 3622 7664

**Email address**

fkhezrian@kums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Kermanshah University of Medical Sciences

**Expected recruitment start date**

2015-09-23, 1394/07/01

**Expected recruitment end date**

2015-12-21, 1394/09/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of PLISSIT-based Counseling on Sexual Function of Pregnant Women

**Public title**

Effect of counseling on sexual function of pregnant women

**Purpose**

Health service research

**Inclusion/Exclusion criteria**

Inclusion criteria: consent to participate in the study; gestational age between 8-10 weeks; First pregnancy and living in the city of Razan. Exclusion criteria: any problem during study

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **86**

**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 Kermanshah University of Medical Sciences

**Street address**
Opposite Taleghani hospital,Taleghani Blvd,

**City**
Kermanshah

**Postal code**

**Approval date**
2015-06-23, 1394/04/02

**Ethics committee reference number**
kums.rec.1394.41

## Health conditions studied

### 1

**Description of health condition studied**
sexual function

**ICD-10 code**
F52.9

**ICD-10 code description**
Unspecified sexual dysfunction, not caused by organic disorder or diseas

## Primary outcomes

### 1

**Description**
Sexual function

**Timepoint**
Before and one month after intervention

**Method of measurement**
Female sexual function index questionnaire

### 2

**Description**
Desire

**Timepoint**
Before and one month after intervention

**Method of measurement**
Female sexual function index questionnaire

### 3

**Description**
Orgasm

**Timepoint**
Before and one month after intervention

**Method of measurement**
Female sexual function index questionnaire

### 4

**Description**
Lubrication

**Timepoint**
Before and one month after intervention

**Method of measurement**
Female sexual function index questionnaire

### 5

**Description**
Pain

**Timepoint**
Before and one month after intervention

**Method of measurement**
Female sexual function index questionnaire

### 6

**Description**
Satisfaction

**Timepoint**
Before and one month after intervention

**Method of measurement**
Female sexual function index questionnaire

### 7

**Description**
Arousal)

**Timepoint**
Before and one month after intervention

**Method of measurement**
Female sexual function index questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
control group, at first The FSFI questionnaire was completed by patients and measured level of sexual function in people. In this group the subjects not given counseling and special training and just receiving

prenatal care. Finally, a month after the last session of the counseling groups FSFI questionnaire was completed by subjects and level of sexual function is measured and compared

**Category**

Other

**2**

**Description**

intervention group, at first the FSFI questionnaire in order to assess the sexual function completed with intervention group. Then participate in counseling sessions. For individual counseling are using PLISSIT model. unit of the research groups in terms case are participating in consultation meetings that 4 sessions of individual counseling with intervals of 7 days. the time of sessions are 40 to 70 minutes . Finally, a month after the last counseling session sexual function of subjects are assessed and compared.

**Category**

Other

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Number 1 Health Center

**Full name of responsible person**

Farzaneh Khezrian

**Street address**

Khanverdiloo Street

**City**

Razan

**2**

**Recruitment center**

**Name of recruitment center**

Number 2 Health Center

**Full name of responsible person**

Farzaneh Khezrian

**Street address**

Farhangian Street

**City**

Razan

**3**

**Recruitment center**

**Name of recruitment center**

Ghorve Health Center

**Full name of responsible person**

Farzaneh Khezrian

**Street address**

Motahari Street

**City**

Razan

**4**

**Recruitment center**

**Name of recruitment center**

Damagh Health Center

**Full name of responsible person**

Farzaneh Khezrian

**Street address**

Imam Street

**City**

Razan

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Vice Chancellor for research Kermanshah University of Medical Sciences

**Full name of responsible person**

Cyrus hamzehi

**Street address**

Number 2 Building ,Shahid beheshti Blvd

**City**

Kermanshah

**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 Kermanshah 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**

Kermanshah University of Medical Sciences, School of Nursing and Midwifery

**Full name of responsible person**

Marzieh Kaboudi

**Position**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*