

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

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

Protocol summary

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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

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

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

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 disease

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

Ph.D, Scientific Advisory Board

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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