Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Effects of consulting based on PLISSIT model on sexual function and satisfaction of pregnant women attending to Health Care Centres

Protocol summary

Summary

Objective: This study is to determine the effect of counseling based on PLISSIT model on sexual satisfaction and sexual function of pregnant women in Malayer. This study population comprised pregnant women of 24-26 weeks of gestation. The participants will be divided into two groups by using Permutation block randomization. The sample size concludes of 40 patients in the intervention group and 40 patients control group. Inclusion criteria: having any disorder dysfunction confirmed by a psychiatrist; not having any disorder during pregnancy. Exclusion criteria: happening any problem during study. In intervention group counseling will be done in four sessions which each session last for one hour. In this study primary outcome is sexual satisfaction and secondary outcome is sexual function.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015070713405N11**
Registration date: **2015-10-15, 1394/07/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-10-15, 1394/07/23

Registrant information

Name

Seyyedeh Zahra Masoumi

Name of organization / entity

Hamedan University of Medical Sciences, School of Nursing and Midwifery

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research and Technology, Hamedan University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of consulting based on PLISSIT model on sexual function and satisfaction of pregnant women attending to Health Care Centres

Public title

The impact of consulting on satisfaction and sexual function of pregnant women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria include: The age range 18-35 years; single fetus and gestational age 24-26 weeks; lack of mental disorders according to psychiatrist ; not having gestational diabetes melitus, preeclampcia, bleeding, premature rupture of membranes; not taking sedative drugs; having sexual dysfunction confirmed by a psychiatrist; not having a history of having sexual dysfunction before pregnancy; exclusively female sexual dysfunction confirmed by psychiatrist. Exclusion criteria

includes: occuring any problem in pregnancy during study (abruption, fetal abnormal situation, cord prolapse, bleeding, diabetes, hypertension, preterm labor); abnormal pattern of fetal heart rate or decrease of fetal movements that require medical intervention.

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **80**

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 Hamedan University of Medical Sciences

Street address
Hamedan University of Medical Sciences, Fahmideh Ave, Hamedan,Iran

City
Hamedan

Postal code
6516645977

Approval date
2015-07-25, 1394/05/03

Ethics committee reference number
IR.UMSHA.REC.1394.225

Health conditions studied

1

Description of health condition studied
Consulting relationship to satisfaction and sexual function

ICD-10 code
F52

ICD-10 code description
Lack or loss of sexual desire

Primary outcomes

1

Description
sexual satisfaction

Timepoint
Before intervention; 2 weeks after intervention; 4 weeks after intervention

Method of measurement
Lindaberg Questionnaire

Secondary outcomes

1

Description
Sextual function

Timepoint
Before intervention; 2 weeks after intervention; 4 weeks after intervention

Method of measurement
FSFI Questionnaire

Intervention groups

1

Description
In the interventional group, meetings once a week over 4 weeks is done in an hour; The first session will talk about the problems of the patient and her sexual function although it may be opposite of therapist’s beliefs. In the second session the therapist gives a brief information about patient’s worries which is educational and directly about sexual problems and concerns of patients ; Specific proposals will be presented at the third session of the patient to enable her to manage her sex problems. In the fourth session focused consultation is done by team psychiatrist.

Category
Early detection

2

Description
just Routine prenatal care is done in control group.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Number one

Full name of responsible person
Behnaz Nejati

Street address
Valiasr street;Thirty-two yards
City
Malayer

2

Recruitment center
Name of recruitment center
Number tree
Full name of responsible person
Behnaz Nejati
Street address
Tahery street; Brujerd street
City
Malayer

3

Recruitment center
Name of recruitment center
Number four
Full name of responsible person
Behnaz Nejati
Street address
next Baghe gole; Arak street
City
Malayer

4

Recruitment center
Name of recruitment center
Number five
Full name of responsible person
Behnaz Nejati
Street address
GHaem maghami street; alley Mohammadi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for Research and Technology, Hamedan University of Medical Sciences
Full name of responsible person
Dr Saeed Bashiriyan
Street address
Hamedan University of Medical Sciences, Fahmideh Ave, Hamedan,Iran
City
Hamedan
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 and Technology, Hamedan 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
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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