Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of counseling based on PLISSIT model on sexual function and satisfaction in pregnant women

Protocol summary

Summary

This clinical trial will be carried out on70 pregnant women with 16-20 weeks of gestational age. After explaining the research objectives, and obtaining the written consent from persons who have the inclusion criteria, they will fill sexual performance questionnaire. The sampling will be down by using four and six block randomization among the participants who receive sexual performance scores less than 28. Then we will have two groups. (35 in sexual counseling and 35 in control groups). Then sexual satisfaction and individual-social questionnaire will be filled by the participants. In the intervention group, sex counseling will be given on the basis of the PLISSIT model (Permission, Limited Information, Specific Suggestion, intensive Treatment) and the control group will also receive routine prenatal care. Four weeks after the last counseling session and after coordination with pregnant women by phone calls, post-test questionnaires will be filled by them.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201505246582N14**
Registration date: **2017-06-26, 1396/04/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-06-26, 1396/04/05

Registrant information

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Mahin Kamalifard
Name of organization / entity
Tabriz University of Medical Sciences and Health Services
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, university of Tabriz medical sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-11-21, 1396/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of counseling based on PLISSIT model on sexual function and satisfaction in pregnant women

Public title

Effect of counseling based on PLISSIT model on sexual function and satisfaction in pregnant women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Married women between 18 to 35 years old; Nulliparous pregnant women with gestational age of 16-20 weeks; Having documents in health-care centers in Ardabil city; Sexual performance score below 28; Literacy of reading and writing; Being monogamy - Exclusion Criteria: Prohibiting sexual activity for medical reasons (multiple pregnancy; threatened abortion;

history of recurrent miscarriage; preterm delivery; severe and prolonged contractions of orgasm; incompetent cervix; the existence of placenta prevail; vaginal bleeding; premature rupture of membranes); Having known physical and mental illnesses according to self-reported (deafness or hearing impairment; mental retardation; diabetes; pre-eclampsia); Consumption of drugs affecting sexual relationships (sildenafil; antidepressants; antihistamines; diazepam's; barbiturates; amphetamines; antihypertensive drugs, cocaine, etc.);Consumption of plant foods for increasing libido in women or men (Ginseng; cinnamon; ginger; etc.); Addiction or habitual consumption of alcohol by women; Participate in other similar studies; Occurrence of unpleasant event during the 3 months before the study (death or serious illness of close relatives).

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
The randomization will be down by using both four and six blocks.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
ethics committee of Tabriz University of Medical Sciences

Street address
Research Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street,

City
Tabriz

Postal code
5165665931

Approval date
2017-03-06, 1395/12/16

Ethics committee reference number
IR.TBZMED.REC.1395.1311

Health conditions studied

1

Description of health condition studied
Pregnancy-related condition, unspecified

ICD-10 code
O26.9

ICD-10 code description
Pregnancy-related condition, unspecified

Primary outcomes

1

Description
Sexual Performance

Timepoint
Before intervention and 4 weeks after intervention

Method of measurement
Sexual performance questionnaire (FSFI)

Secondary outcomes

1

Description
Sexual satisfaction

Timepoint
Before intervention and 4 weeks after intervention

Method of measurement
Sexual satisfaction questionnaire (LSSQ)

Intervention groups

1

Description
In the intervention group, sex counseling based on PLISSIT model will be given singularly during meetings with 45-60 min duration, once a week for consecutive weeks according to participants needs.

Category
Behavior

2

Description
control group: will receive routine prenatal care.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Health-care centers in Ardabil city

Full name of responsible person
Jila Shahbazi
Street address
Nursing & Midwifery Faculty
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, university of Tabriz medical sciences
Full name of responsible person
Mohammad Reza Rashidi
Street address
Research Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street
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Tabriz
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, university of Tabriz 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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mahin kamalifard
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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