

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 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 on 70 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 done 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

Name

Mahin Kamalifard

Name of organization / entity

Tabriz University of Medical Sciences and Health

Services

Country

Iran (Islamic Republic of)

Phone

+98 414796770

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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 previa; 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**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

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kamalifardm@tbzmed.ac.ir

Web page address**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

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University of Medical Sciences, University Street**City**

Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding sourceVice 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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Full name of responsible person

mahin kamalifard

PositionMS of Midwifery, Academic member of Nursing and
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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