

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effectiveness of counseling pregnant women on the PLISSIT model on quality of sexual life and sexual satisfaction couples in pregnancy

Protocol summary

Summary

Design: The study was a randomized clinical trial with two groups of experimental and control. It was conducted without blind. Implementation: Pregnant women and their spouses, who were served by Daneshamooz and Kargaran health centers, will be investigated. Convenience sampling will be used based on the day of visit to health centers randomly. Then subjects will be divided into control and intervention groups after giving informed written consent and satisfying inclusion criteria. Inclusion criteria Pregnant woman: Being 18 to 35 years old; Be a planned pregnancy. Inclusion criteria husband: Be a planned pregnancy for her spouse; Does not have medical history; Has'nt sexual dissatisfaction during her pregnancy. Exclusion criteria at the beginning of the study Pregnant woman: Current Pregnancy is after infertility treatment; Tobacco smoking, drug user, alcohol consumption or psychoactive drug. Exclusion criteria during the study Pregnant woman: Lack of tendency of pregnant woman to continue her cooperation; Incomplete questionnaires. Exclusion criteria at the beginning of the study Husband: Tobacco smoking, drug user, alcohol consumption or psychoactive drug; Mental problem history. Exclusion criteria during the study Husband: Lack of tendency to continue his cooperation; Incomplete questionnaires; Occur stressful event during the study. Intervention: Quality of sexual life and sexual satisfaction questionnaire will be filled in by both groups. Routine care consultation will be provided for control group. In intervention group, two sessions (60 to 90 minutes) will be held by a midwife researcher based on PLISSIT model with one week gap. The time of each session depends on mother's problem and educational booklet will be given to the spouses of intervention group. Quality of sexual life and sexual satisfaction will be evaluated two and four weeks after intervention in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021324469N3**

Registration date: **2017-03-08, 1395/12/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-08, 1395/12/18

Registrant information

Name

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Name of organization / entity

Mashhad University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences, Vice chancellor for research

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2016-11-20, 1395/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of counseling pregnant women on the PLISSIT model on quality of sexual life and sexual satisfaction couples in pregnancy

Public title

Effectiveness of counseling pregnant women on quality of sexual life and sexual satisfaction couples in pregnancy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria Pregnant woman: giving a written consent; having literacy; Being Iranian and living in Mashhad; Being 18 to 35 years old; Be a planned pregnancy; Has an alive singleton pregnancy; Be the first, second, third or fourth pregnancy; Does not have medical history; Does not have obstetric complications during her pregnancy or high risk pregnancy; Has'nt sexual dissatisfaction during her pregnancy. Inclusion criteria husband giving a written consent; having literacy; Being Iranian and living in Mashhad; Be a planned pregnancy for her spouse; Does not have medical history; Has'nt sexual dissatisfaction during her pregnancy. Exclusion criteria at the beginning of the study Pregnant woman: Current Pregnancy is after infertility treatment; Tobacco smoking, drug user, alcohol consumption or psychoactive drug; Mental problem history; happening stressful events during the past 6 months; Has experienced abortion; Takes medicine affecting on mental health; Has sexually transmitted disease; Does have vaginal intercourse due to hit in pelvic area or penis deformity. Exclusion criteria during the study Pregnant woman: Lack of tendency of pregnant woman to continue her cooperation; Incomplete questionnaires; Be admitted to the hospital due to problems related to pregnancy during the study; Occur stressful event during the study; Be inaccessible in the second and the fourth week after consultation; Questionnaire is not filled in by the spouse of the pregnant woman. Exclusion criteria at the beginning of the study Husband Tobacco smoking, drug user, alcohol consumption or psychoactive drug; Mental problem history; happening stressful events during the past 6 months; Takes medicine affecting on mental health; Has sexually transmitted disease; Taking medications effecting sexual function; Does have vaginal intercourse due to hit in pelvic area or penis deformity. Exclusion criteria during the study Husband Lack of tendency to continue his cooperation; Incomplete questionnaires; Occur stressful event during the study.

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **256**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

subjects were allocated to each group of intervention and control randomly by Table of random numbers.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences, Vice chancellor for research, Ghoraihy Building, University St

City

Mashhad

Postal code**Approval date**

2016-05-17, 1395/02/28

Ethics committee reference number

IR.MUMS.REC.1395.64

Health conditions studied**1****Description of health condition studied**

Effectiveness of counseling pregnant women on quality of sexual life and sexual satisfaction couples in pregnancy

ICD-10 code

F52

ICD-10 code description

sexual dysfunction, not caused by organic disorder or disease

Primary outcomes**1****Description**

sexual satisfaction

Timepoint

Before the intervention and 2 and 4 weeks after begining of intervention

Method of measurement

Larson sexual satisfaction questionnaire (LSSQ)

2

Description

Quality of sexual life

Timepoint

Before the intervention and 2 and 4 weeks after beginning of intervention

Method of measurement

Quality of sexual life questionnaire (SQOL)

Secondary outcomes

empty

Intervention groups

1

Description

Before intervention, Quality of sexual life (SQOL-F) and sexual satisfaction questionnaire (LSSQ) will be filled in by intervention group. two sessions (60 to 90 minutes) will be held by a midwife researcher based on PLISSIT model with one week gap. A Consultant starts her speech by asking some open question about sexual satisfaction. Then pregnant woman begins to speak. Therefore, consultant will be aware of her mistake thought, false belief, incomplete information and worries. In addition, using a few pictures will be helpful to explain anatomy and physiology of the reproductive system. A midwife provides consultation for all members of intervention group. Educational booklet will be given to the spouses of intervention group including anatomy and physiology of the reproductive system, and information and recommendation about pregnancy sex issues. Quality of sexual life and sexual satisfaction will be evaluated two and four weeks after intervention.

Category

Behavior

2

Description

Routine care consultation will be provided for control group

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Daneshamooz health center

Full name of responsible person

Zamani

Street address

Daneshamooz10 St, Vakil Abad Blvd

City

Mashhad

2

Recruitment center

Name of recruitment center

Kargaran health center

Full name of responsible person

Najmeh Dehlari

Street address

Chaman Blvd, Nakhresi St

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences, Vice chancellor for research

Full name of responsible person

Mohsen Tafaghodi

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Mashhad University of Medical Sciences, Vice chancellor for research, Ghoraihy Building, Daneshgah St

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Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad University of Medical Sciences, Vice chancellor for research

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

School of Nursing and Midwifery

Full name of responsible person

Najmeh Dehlari

Position

Master of counseling in Midwifery

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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School of Health Public

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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