

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The Effectiveness of Consultation Based on PLISSIT model On sexual function of women during First six month after delivery

Protocol summary

Summary

This study is to determine the effect of counseling based on PLISSIT model on sexual function of women after delivery in Bandarabbas. This study population comprised Lactating women during First six month after delivery. This is a quasi experimental-controlled study and The participants will be divided into two groups by using Permutation block randomization. The sample size concludes of 45 patients in the intervention group and 45 patients in the control group. Inclusion criteria: having sexual problem; primiparous women. Exclusion criteria: happening any problem during study (such as pregnancy). In intervention group counseling will be done in one session which last for one hour. In this study primary outcome is sexual function.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062522921N1**

Registration date: **2015-11-06, 1394/08/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-06, 1394/08/15

Registrant information

Name

Mojdeh Banaei

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research and Technology, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-11-01, 1394/08/10

Expected recruitment end date

2016-02-29, 1394/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Consultation Based on PLISSIT model On sexual function of women during First six month after delivery

Public title

The Effectiveness of Consultation Based on PLISSIT model On sexual function of women during First six month after delivery

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: primiparous and lactating women after a term singleton delivery; during 6 months after delivery; having at least one sexual problem (FSFI score<28; lack of stressful events during pregnancy and after childbirth; lack of complications in pregnancy and after childbirth; lack of mental and chronic physical illness. Exclusion criteria: becomes pregnant; lack of access to participation; the loss of the baby; away from his wife.

Age

From **20 years** old to **39 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 90

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 Shahid Beheshti University of Medical Science

Street address

Shahid Beheshti University of Medical Sciences,Velenjak St. Shahid Chamran Highway, Tehran, Iran

City

Tehran

Postal code

1985717443

Approval date

2015-09-29, 1394/07/07

Ethics committee reference number

SBMU2.REC.1394.96

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

sexual problem

ICD-10 code

F52

ICD-10 code description

Sexual dysfunction,not caused by organic disorder or disease

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

Sexual Function

Timepoint

Before intervention; 4 weeks after intervention

Method of measurement

FSFI Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

just Routine consultation is done in control group.

Category

Other

2**Description**

In the interventional group, a meeting is done in an hour; that will talk about the problems of the patient and her sexual function although it may be opposite of therapist's beliefs. In the next step the therapist gives a brief information about patient's worries which is directly about sexual problems and concerns of patients ; Specific suggestions will be presented at the next step of the patient to enable her to manage her sexual problems. finally focused consultation is done by team psychiatrist.

Category

Early detection

Recruitment centers**1****Recruitment center****Name of recruitment center**

An urban Health center (Imam Hossein) affiliated to Bandarabbas University of Medical Sciences

Full name of responsible person

maryam sharifinasab

Street address

No.69, Niyayesh Ave, Imam Hossein Street, Bandarabbas, Iran

City

Banddar abbas

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research and Technology, Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Afshin Rezghi

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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, Shahid
Beheshti 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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Full name of responsible person
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Position
Midwifery master student

Other areas of specialty/work

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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

