

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Effects of sexual counseling based on the PLISSIT (Permission, Limited Information, Specific Suggestions, Intensive Therapy) model on the sexual quality of life, sexual function Index and sexual satisfaction of postpartum women

Protocol summary

Study aim

Determining the effect of sexual counseling based on the PLISSIT on postpartum women's sexual problems.

Design

Clinical trial with control group, with parallel groups,

Settings and conduct

First, the list of all women aged 18 to 45 from the Sib system of health centers in Babol city who had a delivery two months to one year ago. It will be telephone calls to each of them. Eligible women will enter the study after obtaining written informed consent. First, they complete the sexual life quality, sexual function and sexual satisfaction, and then they are randomly assigned to intervention and control groups.

Participants/Inclusion and exclusion criteria

Women aged 18 to 45 who had a delivery two months to a year ago, at least elementary literacy, have stable sexual activity with their partner for at least the last 4 weeks. Exclusion criteria consist of severe psychiatric disorders, history of drug abuse (herself or her husband), chronic medical diseases and using drugs that cause sexual dysfunction, experiencing a stressful event in the last three months, having a premature baby or a baby with one of the known abnormalities, the death of the baby for any reason.

Intervention groups

The intervention group receives the PLISSIT model online during 4 sessions of 25 to 30 minutes, once a week consecutively. This model, which includes: 1) Permission. This means that the client should talk freely about their sexual concerns. 2) limited information, the therapist gives limited information about the patient's concerns. 3) specific suggestions, the patient is given special suggestions so that he can manage his sexual problems. 4) intensive therapy, Psychosexual therapy is performed by the researcher and the psychiatrist of the team. The

control group will not receive any type of intervention and they will be under routine care of pregnancy and postpartum.

Main outcome variables

Quality of sexual life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200122046228N3**

Registration date: **2023-04-24, 1402/02/04**

Registration timing: **prospective**

Last update: **2023-04-24, 1402/02/04**

Update count: **0**

Registration date

2023-04-24, 1402/02/04

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-25, 1402/02/05

Expected recruitment end date

2023-10-27, 1402/08/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of sexual counseling based on the PLISSIT (Permission, Limited Information, Specific Suggestions, Intensive Therapy) model on the sexual quality of life, sexual function Index and sexual satisfaction of postpartum women

Public title

Effects of sexual counseling based on the PLISSIT model on the sexual quality of life, sexual function Index and sexual satisfaction of postpartum women

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Postpartum women between 18 and 45 years old who had a vaginal delivery or cesarean delivery two months to one year before. Women who can at least read and write. Have consistent sexual activity with their husband for at least the last four weeks.

Exclusion criteria:

Severe psychiatric disorders, Psychotic disorder and bipolar disorder History of addiction of the mother or her husband Chronic medical diseases that affect sexual issues Using drugs that cause sexual dysfunction such as barbiturates, benzodiazepines, antidepressants, antihypertensive Experiencing a stressful event in the last three months (death or acute illness of a close relative, major change in living situation such as the imprisonment of the husband and..) Undesirable consequences of a newborn such as premature birth, birth with one of the known abnormalities or infant death,

AgeFrom **18 years** old to **45 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **72****Randomization (investigator's opinion)**

Randomized

Randomization description

Random assignment to one of the two study groups the block randomization method with a block size of 6 will be used. Then, according to the block randomization protocol (Randomization list using the statistical program in R software environment version 3.6.1), the participants will be divided into one of the two groups: PLISSIT, and the control group; They will be allocated a

ratio of 1:1 so that the researcher cannot predict which group the next person will be placed in the intervention or control groups in each center. The participants are allocated to two groups of 36 people.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Randomization will be done using a block of six

Secondary Ids

empty

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

Research Ethics Committee of Health Research Institute, Babol University of Medical Sciences

Street address

Vice Chancellor for Research, Babol University of Medical Sciences, Ganj Afrooz Ave.

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Approval date

2022-10-17, 1401/07/25

Ethics committee reference number

IR.MUBABOL.REC.1401.089

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

Female Sexual dysfunction after childbirth

ICD-10 code

F52

ICD-10 code description

Sexual dysfunction not due to a substance or known physiological condition

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

Postpartum Sexual Quality of Life

Timepoint

Before the start of the intervention and two months after the end of the intervention

Method of measurement

To evaluate postpartum sexual quality of life, the 22-question scale of PSQOL-F, Rahmani et al. will be used.

Secondary outcomes

1

Description

Female Sexual Function Index

Timepoint

Before the start of the intervention and two months after the end of the intervention

Method of measurement

The 19-question scale of the Female Sexual Performance Index (FSFI) is used to evaluate sexual performance

2

Description

Sexual satisfaction

Timepoint

Before the start of the intervention and two months after the end of the intervention

Method of measurement

Larson's 25-question sexual satisfaction scale will be used to evaluate sexual satisfaction.

Intervention groups

1

Description

Intervention group: Intervention group: In the intervention group, psychosexual counseling will be done virtually in the sky room based on the PLLISIT model individually during 4 sessions of 25 to 30 minutes once a week for consecutive weeks depending on the needs of the research subjects.

Category

Treatment - Other

2

Description

Control group: The control group does not receive any intervention, and they will be under routine care according to the integrated care of pregnancy and postpartum, and finally, after the end of the intervention and evaluations, due to ethical considerations, the contents of the consultation will be provided to the control group in the form of a compact CD file.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sultan Mohammad Taher

Full name of responsible person

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2

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

No

Title of funding source

Babol University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

University of Medical Sciences, Ganj Afrooz St., Babol, Iran

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable