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 psychiatrics 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

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Name of organization / entity

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Iran (Islamic Republic of)

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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,
Age
From **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
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Sponsors / Funding sources

1

Sponsor
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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

Person responsible for general inquiries

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Fatemeh Nasiri Amiri
Position
University associate professor
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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