Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

The effect of counseling based on the EX-PLISSIT model on the quality of sexual life and sexual function of pregnant women: A randomized controlled trial

Protocol summary

Study aim
Determining the effect of sexual counseling based on the EX-PLISSIT model on the quality of sexual life and sexual performance of women

Design
It is a randomized controlled trial with two parallel intervention and control arms.

Settings and conduct
In this study, the research population is pregnant women who meet the inclusion criteria and refer to Behshahr health centers (6 urban centers) for prenatal care. The evaluator and statistical consultant are blind.

Participants/Inclusion and exclusion criteria
In this study, the research population is pregnant women who refer to the health centers of Behshahr for prenatal care (6 urban centers). 1- The age of the pregnant mother is 18-35 2-Having a minimum high school education 3- Willingness to participate in the study 4- Iranian nationality 5- Cohabitation with spouse 6-weeks 12-16 7- Continuation of cohabitation during pregnancy 8- The score of sexual function based on the Female Sexual Function Index (FSFI) questionnaire should be below 28.

Intervention groups
In the intervention group, people will receive 4, 45-minute counseling sessions, one week apart, face-to-face and individually. Counseling according to the Ex-PLISSIT model takes place at 4 levels of permission (P), limited information (LI), specific suggestions (SS)) and intensive treatment (IT).

Main outcome variables
The primary outcome in the present study is sexual Function and the secondary outcome is quality of life.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161126031117N15**
Registration date: **2023-09-24, 1402/07/02**
Registration timing: **prospective**

Last update: **2023-09-24, 1402/07/02**
Update count: **0**

Registration date
2023-09-24, 1402/07/02

Registrant information

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Name of organization / entity
Mazandaran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-23, 1402/08/01

Expected recruitment end date
2023-12-22, 1402/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of counseling based on the EX-PLISSIT model on the quality of sexual life and sexual function of pregnant women: A randomized controlled trial

Public title

The effect of counseling on the quality of sexual life and sexual performance of pregnant women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

The age of the pregnant woman is 18-35 Have at least a high school education Willingness to participate in the study Iranian nationality Cohabitation with spouse 12-16 weeks of pregnancy

Exclusion criteria:

Having a history of chronic and special disease (diabetes, blood pressure, thyroid, neurological disease) Having pregnancy and childbirth complications in the current pregnancy and previous pregnancies (threat of miscarriage, abortion, stillbirth, premature birth, preeclampsia, gestational diabetes) Having mental and social problems, diagnosed with psychiatric problems or taking psychiatric drugs Having a severe family dispute, based on the pregnant mother's own statement Use of special drugs History of alcohol, cigarette and drug use High-risk pregnancy

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked random allocation method will be used to randomly assign samples to two intervention groups (consultation based on Ex-PLISSIT model) and control group. This method is usually used to balance the number of samples allocated to each of the studied groups. This feature helps the researcher to have the same number of samples assigned to the intervention and control groups of the study in cases where intermediate analyzes are needed during the sampling process. 15 blocks of 4 will be used for allocation, in each block two samples will be considered for the control group and two samples for the intervention group. Random Allocation software 2 will be used to allocate samples to each block after numbering the samples.

Blinding (investigator's opinion)

Single blinded

Blinding description

The Investigator and statistical consultant are blinded, and the pregnant women who meet the inclusion criteria are divided into two groups of 30 people, intervention and control, by random block assignment. By using computer software and choosing a block of four, we randomly assign 60 people into two groups A (intervention group) and B (control group). Based on the list extracted from the software, 60 envelopes are prepared and numbers 1 to 60 are written on them, and group A and group B are written inside them based on the list. According to the order of the pregnant mother, one envelope is considered for each mother. If the letter A is written inside the paper, it will be the intervention group and if the word B is written inside the paper, it will be the control group. The mother is not informed about the codes, and the people who are placed in the groups will be given to the evaluator by the liaison, and for data analysis, the code will be handed over to the professor of statistics.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

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4839795198

Approval date

2023-08-22, 1402/05/31

Ethics committee reference number

IR.MAZUMS.REC.1402.328

Health conditions studied

1

Description of health condition studied

Sexual Function and quality of life of pregnant women

ICD-10 code

Z70

ICD-10 code description

Counselling related to sexual attitude, behaviour and orientation

Primary outcomes

1

Description
Sexual Function of pregnant women
Timepoint
Before the intervention, immediately after the intervention, 12 weeks after the intervention
Method of measurement
FSFI Female (Sexual Function Index) Questionnaire

Secondary outcomes

1

Description
Quality of sexual life
Timepoint
Before the intervention, immediately after the intervention, 12 weeks after the intervention
Method of measurement
Questionnaire of the quality of women's sexual life by Simond et al. (2005)

Intervention groups

1

Description
Intervention group: In the intervention group, people will receive 4, 45-minute counseling sessions at an interval of one week, face-to-face and individually. Counseling according to the Ex-PLISSIT model takes place at 4 levels of permission (P), limited information (LI), specific suggestions (SS)) and intensive treatment (IT). The first level of the permission level (P) of the counselor by normalizing and creating a safe and private environment and a suitable therapeutic atmosphere, the client is given permission and opportunity to talk about the problem, feelings and sexual desires. By actively listening and communicating effectively and respecting the client's values and beliefs and away from any judgmental behavior, the counselor hears the client's problems and sexual disorders and communicates with the client using understandable words and language. The second level of limited information (LI) is limited and non-specialized information provided to clients. Providing information, knowledge and awareness about sexual relations and sexual health is one of the important aspects of health care. Giving information about sexual relations during pregnancy in the form of a brochure is given to all pregnant women in the intervention group, but at this stage, the first stage continues, and pregnant mothers are told that a brochure has been prepared by the research team and contains information. It is given to you about sex during pregnancy. Would you like to read it? After reading, you can ask any questions you have and we will be happy to answer them. Do you have any other questions about this? The third stage of special suggestions (SS)) In this stage, the consultant has identified the problems and expectations of the clients and based on the problem solving approach, information is given to deal with the specific problem of each person, for example giving sexual position Suitable for a mother who complains of back or abdominal pain during sexual intercourse or a mother who does not want to have intercourse due to infection. The fourth stage of intensive treatment (IT) may be pregnant mothers with complex physical or mental problems and It is interpersonal where there is a need for specialized intervention to deal with individual issues, for example referral to a gynecologist or a psychiatrist. People who need more specific counseling are referred to a sexologist or will receive more specific counseling based on their needs, and follow-up is done immediately after the intervention and 12 weeks after the intervention.
Category
Behavior

Recruitment centers

1

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1

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Grant name
The effect of sexual counseling based on the EX-PLISSIT model on the quality of sexual life of pregnant women: a randomized controlled trial

Grant code / Reference number
14990

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

Title of funding source
Mazandaran 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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The information related to the research is shared with the aim of keeping the names of the people and keeping their identities confidential and complying with the 31

codes of ethics

When the data will become available and for how long

2024

To whom data/document is available

All researchers and those interested in research

Under which criteria data/document could be used

To conduct review and supplementary research and prenatal care centers

From where data/document is obtainable

In order to receive data or documents, the responsible author can be reached by email at khanisog343@gmail.com and the midwifery counseling student at habibi71.farangis@gmail.com. If the article is published, you can refer to it according to the journal's address.

What processes are involved for a request to access data/document

First, you should send an email to the responsible author of the article and make your request, and if the responsible author and the research team deem it appropriate, the documents and files will be provided in a short period of time.

Comments