Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of consuling with EXPLISSIT approach on sexual function and marital satisfaction in newly delivered women: A Randomized Controlled Trial

Protocol summary

Study aim

Determine the effectiveness of consuling with EXPLISSIT approach on sexual function and marital satisfaction in newly delivered women: A Randomized Controlled Trial

Design

The selected individuals will be assigned by random blocking with blocks 4 and 6 with a ratio of 1: 1 to two groups (Consultation recipient and control, 34 people for each group), the type allocation will be written on the paper and placed in the opaque packets numbered down, the pockets will be opened in the order of the individuals entering the study and the type of group will be specified.

Settings and conduct

The study will be in the health centers of Ardabil city and in the intervention group, sexual counseling will be given by the trained midwife during a 60-90 minute or more session in accordance with the EXPLISSIT model and participants in control group get routine care.

Participants/Inclusion and exclusion criteria

Having at least a literacy guide; score less than 28 from the FSFI questionnaire; single lactating women being between 3 and 6 months after childbirth; having a call number to follow up; husband's monogamous. Exclution criteria: exposure to a stressful event or any complication of pregnancy; having a history of depression; having a history of chronic physical and mental illness; use of any drug that is effective on sexual response; child with known anomalies or preterm; marriage separation; the death of the baby after delivery for any cause; addiction to a person or his wife; the history of sexual dysfunction in couples before pregnancy.

Intervention groups

Intervention group: in the intervention group, sexual counseling will be given by the trained midwife during a 60-90 minute or more session in accordance with the EXPLISSIT model and will be based on the concerns and needs of the participants. Control group: get routine care

Main outcome variables

Sexual function; marital satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111122008170N12**
Registration date: **2018-05-02, 1397/02/12**
Registration timing: **prospective**

Last update: **2018-05-02, 1397/02/12**
Update count: **0**

Registration date

2018-05-02, 1397/02/12

Registrant information

Name
Jamileh Malakouti
Name of organization / entity
Nursing Faculty
Country
Iran (Islamic Republic of)
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malakoutij@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-05, 1397/03/15

Expected recruitment end date

2018-09-06, 1397/06/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effectiveness of consuling with EXPLISSIT approach on sexual function and marital satisfaction in newly delivered women: A Randomized Controlled Trial

Public title
The effectiveness of consuling with EXPLISSIT approach on sexual function and marital satisfaction in newly delivered women
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Having at least a literacy guide according to the person herself Score less than 28 from the Female Sexual Function Index questionnaire (FSFI) Single lactating women Being between 3 and 6 months after childbirth Having a call number to follow up Husband's monogamous
Exclusion criteria:
Exposure to a stressful event or any complication of pregnancy during pregnancy and postpartum (for example: death of a family members) according to the person herself Having a history of depression pre-pregnancy, during pregnancy and postpartum according to the person herself Having a history of chronic physical and mental illness such as cardiovascular disease, diabetes, severe depression and high blood pressure that consumes the drug according to the person herself Use of any effective medicines on person's sexual response, (antihypertensive drugs, thiazide diuretics, antidepressants, antihistamines, Barbiturates, narcotics, diazepins, amphetamines and cocaine) according to the person herself Child with known anomalies or preterm (less than 37 weeks) Marriage separation (emotional divorce or full divorce) The death of the baby after delivery for any cause Addiction to a person or his wife according to the person herself The history of sexual dysfunction before pregnancy in couples (including disorders of sexual desire or orgasm in women, early and late ejaculation, erectile dysfunction and male orgasm) according to the person herself
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **68**
Randomization (investigator's opinion)
Randomized
Randomization description
The selected individuals will be assigned by random blocking using the RAS software with blocks 4 and 6 with a ratio of 1: 1 to two groups (Consultation recipient and control, 34 people for each group), the type allocation will be written on the paper and placed in the opaque packets numbered down, the pockets will be opened in the order of the individuals entering the study and the type of group will be specified. The allocation sequence will be performed by the person not involved in the sampling and collecting of data.
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 Tabriz University of Medical Sciences
Street address
Tabriz University of Medical Sciences Research & Technology, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
51665118
Approval date
2018-03-05, 1396/12/14
Ethics committee reference number
IR.TBZMED.REC.1396.1131

Health conditions studied

1

Description of health condition studied
Sexual dysfunction in women newly delivered
ICD-10 code
F52.9
ICD-10 code description
Unspecified sexual dysfunction, not caused by organic disorder or disease

Primary outcomes

1

Description

Sexual function score

Timepoint

Before the intervention, 4 and 8 weeks after the intervention

Method of measurement

Female Sexual Function Index questionnaire

2

Description

Marital satisfaction score

Timepoint

Before the intervention, 4 and 8 weeks after the intervention

Method of measurement

Enrich Marital Satisfaction questionnaire

Secondary outcomes

1

Description

Quality of sexual life score

Timepoint

Before the intervention, 4 and 8 weeks after the intervention

Method of measurement

Female sexual quality of life questionnaire

Intervention groups

1

Description

Intervention group: In the intervention group, sexual counseling will be given by the trained midwife during a 60-90 minute or more session in accordance with the EXPLISSIT model and will be based on the concerns and needs of the participants

Category

Prevention

2

Description

Control group: Get routine care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers in Ardebil

Full name of responsible person

Robab Gholizadeh

Street address

Ardebil, Ayatollah Moghadas Ardebili St., Shahid Moadi St., Alawi Medical Education Center

City

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Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Robab Gholizadeh

Position

Student of Master in Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery
Street address
Ardebil, Ayatollah Moghadas Ardebili St., Shahid Moadi St., Alawi Medical Education Center
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
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Master of Midwifery
Latest degree
Master
Other areas of specialty/work
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Postal code
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Email
205rgh@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The results of the clinical study will be published as a paper.
When the data will become available and for how long
Immediately after printing the results
To whom data/document is available
All researchers
Under which criteria data/document could be used
Scientific use with reference to article
From where data/document is obtainable
E-mail: malakoutij@tbzmed.ac.ir
What processes are involved for a request to access data/document
Up to a week after correspondence by email
Comments