Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of sex consultation on sexual function and the quality of sexual life based on “Women's Postpartum Sexual Health Program”

Protocol summary

Summary

Objective: The effect of sex consultation on sexual function and the quality of sexual life based on Women's Postpartum Sexual Health Program. Implementation: It is a single blind randomized clinical trial with two groups of intervention and control. Two groups of 40 women, who have inclusion criteria and 3 months to one year is passed from their delivery, will be investigated. Subjects are divided into intervention and control groups randomly and we use demographic characteristics questionnaire, Depression, Anxiety and Stress Scales (DASS-21), the Female Sexual Function Index (FSFI) and also the Sexual Quality of Life-Female (SQOL-F) questionnaire. Multistage sampling will be utilized in this study. First, two Health Centers will be selected randomly among five Health Centers in Mashhad. Then two centers which are served by the chosen Health Centers will be selected at random. After that, a control group and an intervention group will be selected from each center. Convenience sampling will be used to choose women who take their babies to Health Center for vaccination or other services and 3 months to one year is passed from their delivery. Inclusion criteria: Be Iranian and lives in Mashhad; 18 to 35 years old; Literacy; Be in the period of three months to one year after her delivery. Exclusion criteria: Addiction to drugs or alcohol in any of couple; Takes medications that affect sexual function; Occur stressful event during the last 6 months. Intervention: It lasts 5-7 weeks, and with 1-3 weeks gap between sessions. The researcher holds the first three sessions, composed of 6-8 person groups. In the last session, each subject and her spouse receive a 60-90 minutes consultation in the presence of a psychologist. The first session is about female sexual response and postpartum period. After one week, the second session is held about biological, psychological and social factors to avoid sexual issue in postpartum period. The third session is held after two weeks with the subject of intimate and effective communication. The aim of fourth session is supporting each subject and her spouse. Sexual function and the quality of sexual life will be measured before and 8 weeks after the intervention, so both groups can be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062228575N1**
Registration date: **2017-05-02, 1396/02/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-05-02, 1396/02/12

Registrant information

Name

Maryam Zamani

Name of organization / entity

School of Nursing and Midwifery

Country

Iran (Islamic Republic of)

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+98 43347684

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences, Vice chancellor for research

Expected recruitment start date

2016-06-25, 1395/04/05

Expected recruitment end date

2016-08-26, 1395/06/05

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

Scientific title
The effect of sex consultation on sexual function and the quality of sexual life based on “Women's Postpartum Sexual Health Program”

Public title
Sexual counseling in women's postpartum
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Be Iranian and lives in Mashhad; 18 to 35 years old; Literacy; Be in the period of three months to one year after her delivery; Has a healthy full-term baby from a singleton pregnancy; Be married and the only wife of her spouse; Lives with her spouse at the moment; Starts having sex again after her delivery; Has reported at least one sexual dysfunction in the last two months; The scores of DASS-21 are less than 25 in the scale of stress, less than 14 in the scale of anxiety and less than 20 in the scale of depression; The score of Dyadic Adjustment Scale (DAS) is more than 38.
Exclusion criteria: Addiction to drugs or alcohol in any of couple; Takes medications that affect sexual function; Occur stressful event during the last 6 months; Medical history in any of couple; Mental problems in any of couple; Suffers from complication after her last delivery; Has experienced pelvic surgery (repair colporrhaphy) or genital irradiation. Exclusion criteria during the study: Lack of tendency to continue her cooperation; Pregnancy during the study; Has not sexual relationship during the study; Occur stressful event during the intervention; Receive sexual training during the study; Attends in less than three sessions.
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single 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 Mashhad University of Medical Sciences
Street address
Mashhad University of Medical Sciences, Vice chancellor for research, Ghoraishy Building, Daneshgah St
City
Mashhad
Postal code
Approval date
2016-06-20, 1395/03/31
Ethics committee reference number
IR.MUMS.REC.1395.161

Health conditions studied

1

Description of health condition studied
Sexual counseling in women's postpartum
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 the intervention and 8 weeks after ending of treatment
Method of measurement
sexual function questionnaire (FSFI)

Secondary outcomes

1

Description
Women's quality of sexual life
Timepoint
Before the intervention and 8 weeks after ending of treatment
Method of measurement
Sexual Quality of Life-Female (SQOL-F) questionnaire

Intervention groups

1

Description
. It lasts 5-7 weeks, and with 1-3 weeks gap between sessions. The researcher holds the first three sessions, composed of 6-8 person groups. In the last session, each subject and her spouse receive a 60-90 minutes consultation in the presence of a psychologist . The first session is about female sexual response and postpartum period. After one week, the second session is held about biological, psychological and social factors to avoid sexual issue in postpartum period. The third session is held after two weeks with the subject of intimate and effective communication. The aim of fourth session is supporting each subject and her spouse. Sexual function and the quality of sexual life will be measured before and 8 weeks after the intervention, so both groups can be compared.
Category
Behavior

2

Description
There was no intervention in the control group
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hasan health center
Full name of responsible person
Zamani
Street address
Mofateh 24 St, Mofateh Blvd
City
Mashhad

2

Recruitment center
Name of recruitment center
Ghand Abkooh health center
Full name of responsible person
Zamani
Street address
Talash 11 st
City
Mashhad

3

Recruitment center
Name of recruitment center
Imam Reza health center
Full name of responsible person
Zamani
Street address
Resalat45 st
City
Mashhad

4

Recruitment center
Name of recruitment center
Chahardah Masoom health center
Full name of responsible person
Zamani
Street address
Tabarsi 17 St, Tabarsi Blvd
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences, Vice chancellor for research
Full name of responsible person
Mohsen Tafaghodi
Street address
Mashhad University of Medical Sciences, Vice chancellor for research, Ghoraishy Building, Daneshgah St
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Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences, Vice chancellor for research
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
School of Nursing and Midwifery
Full name of responsible person
Maryam Zamani
Position

Master of Cunseling in Midwifery
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Person responsible for scientific inquiries

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Person responsible for updating data

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Web page address

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
Data Dictionary
empty