

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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)

Phone

+98 43347684

Email address

zanim931@mums.ac.ir

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, Ghoraihy 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, Ghoraisly Building, Daneshgah St

City

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 Counseling in Midwifery

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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PhD Reproductive Health

Other areas of specialty/work

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Person responsible for updating data

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Position

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Other areas of specialty/work

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zanim931@mums.ac.ir

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