

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Investigate the effect of group psycho educational counseling on the sexual intimacy of lactating women who refer to health centers in Rafsanjan

Protocol summary

Study aim

To determine the impact of Psychological counseling on the sexual intimacy of lactating women.

Design

Clinical trial with control group, intervention, simple randomization, 32 persons under consultation and 32 persons in control group

Settings and conduct

Of the eight Rafsanjan urban clinics, four health centers will be selected randomly and then will be divided into two centers intervention and two centers control. From both intervention and control groups the pre-test questionnaire will be taken. Subsequently, Psychological counseling will be given to the intervention group. Four weeks after the last counseling session, both groups will receive post-test.

Participants/Inclusion and exclusion criteria

Entry requirements: women with first childbearing, 3-6 months after childbirth. Conditions of non-arrival: postpartum depression, chronic mental and physical disease history, couples' addiction and smoking, previous presence in sex education classes, pregnancy, losing a baby, being away from marriage, severe marital conflicts and adverse events.

Intervention groups

The intervention group receive several Psychological counseling. The control group does not receive any counseling.

Main outcome variables

Sexual intimacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151103024866N12**

Registration date: **2018-11-09, 1397/08/18**

Registration timing: **retrospective**

Last update: **2018-11-09, 1397/08/18**

Update count: **0**

Registration date

2018-11-09, 1397/08/18

Registrant information

Name

Katayoun Alidousti

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-23, 1397/02/03

Expected recruitment end date

2018-07-21, 1397/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigate the effect of group psycho educational counseling on the sexual intimacy of lactating women who refer to health centers in Rafsanjan

Public title

Investigate the effect of group psycho educational counseling on the sexual intimacy of lactating women who refer to health centers in Rafsanjan

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Period of 3 to 6 months after childbirth Primiparous women

Exclusion criteria:

Not having postpartum depression Not having history of mental and physical illness (diabetes, kidney problems, heart problems ..) Use breast milk Non-addicted couples Lack of previous sex education classes The desire to attend all meetings

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization

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**

Kerman University of Medical Sciences Ethics committee

Street address

campus University beginning around sevsn gardens alavi: kerman

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kerman

Province

Kerman

Postal code

7616913555

Approval date

2017-12-27, 1396/10/06

Ethics committee reference number

ir.kmu.rec.96000195

Health conditions studied**1****Description of health condition studied**

The sexual intimacy

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Sexual intimacy score in the Bagarozzi questionnaire

Timepoint

Before the consultation and Four weeks after intervention

Method of measurement

Sexual intimacy Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

This interventional study was carried out in the statistical society of lactating women referring to health centers in Rafsanjan in 1397. In this study, firstly, after obtaining informed written consent from women, 70 women with first delivery and lactating will be selected in an easy sampling. Of the eight Rafsanjan urban clinics, four health centers will be selected randomly and then divided into two centers intervention and two centers control. The intervention consists of 6 sessions of one-hour counseling with a sequence of one week each session for intervention group in groups of five to ten people. Initially, from both groups intervention and control the pre-test questionnaire were taken. Subsequently, psychiatric counseling was given to the intervention group. Four weeks after the last counseling session, both groups received post-test. In order to prevent the control group from learning the contents and distort the results, the control and intervention groups are selected from separate health centers. Also, in order to be more confident, the intervention group is asked to not talk with other people during the training course on the educational content, except with their spouse.

Category

Behavior

2**Description**

Control group: No intervention will be received and only

completes the questionnaire.

Category

Behavior

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Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Health center

Full name of responsible person

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Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vice chancellor for research kerman university of medical sciences

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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

vice chancellor for research kerman 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

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available