

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The efficacy of sexual health counseling (group and telephone counseling) on sexual satisfaction and function in lactating women

Protocol summary

Study aim

assess the effectiveness of group sex and sexual health counseling on the satisfaction and sexual function of lactating women.

Design

Randomised, A randomized, sham controlled clinical trial with a parallel group design of 90 patients, enrolled between and

Settings and conduct

Randomized clinical trial, Health centers in Yazd

Participants/Inclusion and exclusion criteria

Entry requirements: Women who are nulliparous 18 years of age Married Iranian Muslims whose first marriage is the sole wife of a person living side by side Child is healthy, monogamous, terminated, is the result of natural birth and has exclusive breastfeeding At least reading and writing skills Have phones Non-arrival conditions: Rebirth Unwanted pregnancy in the present delivery Instrumental vaginal delivery Grade 4 rupture during labor Macrosomal neonate Infant death, abnormalities and postpartum health problems Presence of signs of postpartum depression All diseases and Or drugs that affect the sexual function of couples Drug addiction to each spouse Their growth in a single parent A history of any abnormal functioning and sexual abuse during pre-pregnancy Genital surgery, hormonal dysfunction Using hormonal contraceptive methods Severe family disagreement Lady is lactating.

Intervention groups

Groups counseling Telephone counseling

Main outcome variables

sexual satisfaction, sexual function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170809035592N2**

Registration date: **2018-11-10, 1397/08/19**

Registration timing: **retrospective**

Last update: **2018-11-10, 1397/08/19**

Update count: **0**

Registration date

2018-11-10, 1397/08/19

Registrant information

Name

samira haji maghsoudy

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 3262 6921

Email address

samira.hm@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2017-12-21, 1396/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of sexual health counseling (group and telephone counseling) on sexual satisfaction and function in lactating women

Public title

The efficacy of sexual health counseling (group and telephone counseling) on sexual satisfaction and function in lactating women

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Women who are nulliparous 18 years of age Married Iranian Muslims whose first marriage is the sole wife of a person living side by side Child is healthy, monogamous, terminated, is the result of natural birth and has exclusive breastfeeding At least reading and writing skills Have phones

Exclusion criteria:

Rebirth Unwanted pregnancy in the present delivery Instrumental vaginal delivery Grade 4 rupture during labor Macrosomal neonate Infant death, abnormalities and postpartum health problems Presence of signs of postpartum depression All diseases and Or drugs that affect the sexual function of couples Drug addiction to each spouse Their growth in a single parent A history of any abnormal functioning and sexual abuse during pre-pregnancy Genital surgery, hormonal dysfunction Using hormonal contraceptive methods Severe family disagreement Lady is lactating.

Age

From **18 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Using a random number table, simple randomization was done individually.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Factorial

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Sadoughi University of Medical Sciences

Street address

Shahid Sadoughi University of Medical Sciences, Alem Sq., Safaieh Yazd Yazd Iran, Islamic Republic Of Yazd

City

Yazd

Province

Yazd

Postal code

8991768547

Approval date

2017-08-02, 1396/05/11

Ethics committee reference number

IR.SSU.REC.1396-95

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

Sexual satisfaction sexual function

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

sexual satisfaction

Timepoint

Before the intervention, immediately and one month after the end of the intervention

Method of measurement

Larsson Sexual Satisfaction Questionnaire

Secondary outcomes**1****Description**

sexual function

Timepoint

Before the intervention, immediately and one month after the end of the intervention

Method of measurement

Sexual Function Questionnaire (FSFI)

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

"Intervention group 1:" Five weekly counseling sessions

Category

Treatment - Other

2**Description**

"Intervention group 2:" Five weekly phone calls

Category

Treatment - Other

3

Description

"Control group:" without intervention.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers in Yazd

Full name of responsible person

Samira Haji Maghsoudy

Street address

Azad Shahr

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Phone

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Email

samira_hajimaghsoudy@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzaie

Street address

Shahid Sadoughi University of Medical Sciences, Alem
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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

Yazd 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

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Samira Haji Maghsoudy

Position

A graduate student in midwifery advice

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Mahshid Bokaie

Position

PhD in Reproductive Health

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for updating data

Contact

Name of organization / entity
Shahid Sadoughi University of Medical Sciences
Full name of responsible person
Samira Haji Maghsoudy
Position
A graduate student in midwifery advice
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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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

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

Title and more details about the data/document

We will show all of the data.

When the data will become available and for how long

Get started 9 months after printing results

To whom data/document is available

All people are allowed.

Under which criteria data/document could be used

The data will be available for scientific research with reference to the research. In order to access the data, they can reply to the person's email address.

From where data/document is obtainable

Samira Hajimaghsoudy
samira_hajimaghsoudy@yahoo.com 00989132738876

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

Applicants can respond to the email of the respondent and receive a response within a week.

Comments