Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

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+98 35 3262 6921

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Masoud Mirzaie
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Samira_hajimaghsoudy@yahoo.com
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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Person responsible for updating data

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Other areas of specialty/work
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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