Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of consultation versus no consultation on sexual function of lactating women with decreased libido: a randomized clinical trial

Protocol summary

Study aim
To assess the effect of consultation versus no consultation on sexual function of lactating women with decreased libido

Design
This is a randomized clinical trial, in which 104 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct
The eligible lactating women with decreased libido who will refer to Health Centers of Songhor City during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 18 to 35 years; Lactating women; Decreased libido; Term singleton labor; Exclusive breastfeeding; Living with husband; Ability to speech Persian; Literate Exclusion criteria: Pregnancy; Stressful accidents; Pregnancy complications; Mental or physical disease; Using opioid or alcohol; Death or disease of the newborn

Intervention groups
Intervention group: Routine pregnancy care and a face-to-face consultation one hour a week for 4 weeks Control group: Just pregnancy care

Main outcome variables
Primary outcome: Assessing sexual function before intervention and 4 weeks after that using a standard questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N247**
Registration date: **2018-10-27, 1397/08/05**
Registration timing: **prospective**
Last update: **2018-10-27, 1397/08/05**
Update count: **0**

Registration date
2018-10-27, 1397/08/05

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-11-16, 1397/08/25

Expected recruitment end date
2019-10-17, 1398/07/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of consultation versus no consultation on sexual function of lactating women with decreased libido: a randomized clinical trial

Public title
The effect of consultation versus no consultation on sexual function of lactating women with decreased libido

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 35 years; Lactating women; Decreased libido; Term singleton labor; Exclusive breastfeeding; Living with husband; Ability to speech Persian; Literate

Exclusion criteria:

Pregnancy; Stressful accidents; Pregnancy complications; Mental or physical disease; Using opioid or alcohol; Death or disease of the newborn

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: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block 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

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2018-10-13, 1397/07/21

Ethics committee reference number

IR.UMSHA.REC.1397.482

Health conditions studied

1

Description of health condition studied

Decreased libido

ICD-10 code

R68.82

ICD-10 code description

Decreased libido

Primary outcomes

1

Description

Assessing sexual function

Timepoint

Before intervention and 4 weeks after that

Method of measurement

Using a standard questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine pregnancy care and a face-to-face consultation one hour a week for 4 weeks

Category

Treatment - Other

2

Description

Control group: Just pregnancy care

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Centers of Songhor City

Full name of responsible person

Tahereh Heshmatian

Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Tahereh Heshmatian

Position

Midwifery Student

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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Position

Fertility Health Specialist

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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