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

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Name of organization / entity
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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

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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

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Sponsors / Funding sources

1

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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
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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