Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of counseling based on BETTER model versus control group on sexual function and satisfaction of breastfeeding women: a randomized clinical trial

Protocol summary

Study aim
To assess the effect of counseling based on BETTER model versus control group on sexual function and satisfaction of breastfeeding women

Design
This is a randomized clinical trial with a control group, in which eligible patients will be randomly assigned to the intervention and control groups using block randomization.

Settings and conduct
This study will be conducted at the Comprehensive Health Centers in Hamadan city, involving 80 eligible breastfeeding women. The patients will be randomly assigned to the intervention and control groups through the block randomization. However, it should be noted that blinding is not feasible in this trial.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 18 to 35 years Sexual dysfunction Primiparous with term and singleton delivery Having sex in the last 4 weeks Exclusive breastfeeding Exclusion criteria: Drug or alcohol addiction Stop breastfeeding

Intervention groups
Intervention group: Routine breastfeeding care plus counseling sessions based on the BETTER model for 60 to 90 minutes once a week for four weeks Control group: Routine breastfeeding care

Main outcome variables
Primary outcome: Sexual function score, sexual satisfaction score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N492**
Registration date: **2023-12-10, 1402/09/19**
Registration timing: **prospective**

Last update: **2023-12-10, 1402/09/19**
Update count: **0**

Registration date
2023-12-10, 1402/09/19

Registrant information

Name
Jalal Poorolajal

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

Country
Iran (Islamic Republic of)

Phone
+98 81 1838 0090

Email address
poorolajal@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-28, 1402/10/07

Expected recruitment end date
2024-07-10, 1403/04/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of counseling based on BETTER model versus control group on sexual function and satisfaction of

breastfeeding women: a randomized clinical trial

Public title
Effect of counseling based on BETTER model versus control group on sexual function and satisfaction of breastfeeding women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18 to 35 years Sexual dysfunction Primiparous with term and singleton delivery Having sex in the last 4 weeks Exclusive breastfeeding
Exclusion criteria:
Drug or alcohol addiction Stop breastfeeding
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: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Routine breastfeeding care plus counseling sessions based on the BETTER model for 60 to 90 minutes once a week for four weeks (including discussion about the areas of sexual function and its changes, anatomy and physiology of the female reproductive system, factors affecting sexual response, the effect of breastfeeding on sexual performance, the four cycle of sexual response and the difference between men and women in each of the stages of the sexual response cycle, techniques to enhance sexual performance)
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, Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Approval date
2023-11-25, 1402/09/04
Ethics committee reference number
IR.UMSHA.REC.1402.554

Health conditions studied

1

Description of health condition studied
Sexual disfunction
ICD-10 code
F66
ICD-10 code description
Other sexual disorders

Primary outcomes

1

Description
Sexual function score
Timepoint
Before the intervention and four weeks after the intervention
Method of measurement
using the Women's Sexual Function Index (FSFI)

2

Description
Sexual satisfaction score
Timepoint
Before the intervention and four weeks after the intervention
Method of measurement
Using the Larson Sexual Satisfaction Questionnaire (LSSQ)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Routine breastfeeding care plus counseling sessions based on the BETTER model for 60 to 90 minutes once a week for four weeks (including discussion about the areas of sexual function and its changes, anatomy and physiology of the female reproductive system, factors affecting sexual response, the effect of breastfeeding on sexual performance, the

four cycle of sexual response and the difference between men and women in each of the stages of the sexual response cycle, techniques to enhance sexual performance)

Category

Treatment - Other

2

Description

Control group: Routine breastfeeding care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Health Centers in Hamadan city

Full name of responsible person

Maryam Kiani Aliabadi

Street address

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

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

maryamkiani6783@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

Street address

Hamadan University of Medical Sciences, Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

Email

info.research@umsha.ac.ir

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

Maryam Kiani Aliabadi

Position

Midwifery Student

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

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

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

maryamkiani6783@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Soudabeh Aghababaii

Position

Reproductive health specialist

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

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

City

Hamadan

Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0572
Email
aghababaii@Yahoo.com

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
Street address
School of Public Health, Hamadan University of Medical Sciences, Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0090
Email
poorolajal@umsha.ac.ir

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