Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of couple-centered counseling based on EX-PLISSIT model versus control group on sexual function and satisfaction of couples in pregnant women with sexual dysfunction: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of couple-centered counseling based on EX-PLISSIT model versus control group on sexual function and satisfaction of couples in pregnant women with sexual dysfunction

Design

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

Settings and conduct

This study will be performed in the Comprehensive Health Centers in Hamadan city on 80 eligible pregnant women with sexual dysfunction. The patients will be randomly assigned to the intervention and control groups through the block randomization. Blinding is not possible in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 45 years Singleton pregnancy Gestation age 24 to 28 weeks Sexual dysfunction Secondary education and more Exclusion criteria: Depressive disorder Pregnancy complications such as gestational diabetes, preeclampsia, bleeding, premature rupture of the amnion sac

Intervention groups

Intervention group: Routine care during pregnancy plus couple-oriented counseling based on the IX-PLISSIT model, one session per week for 45 to 60 minutes for 4 weeks including: false thoughts and beliefs about sexual contact during pregnancy, anatomy and physiology of the reproductive system, cycle sexual response in men and women, sexual desire changes during pregnancy, optimal position of intimacy during pregnancy, factors that reduce sexual desire Control group: Just routine care during pregnancy

Main outcome variables

Primary outcome: Sexual function Sexual satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N442**
Registration date: **2022-09-11, 1401/06/20**
Registration timing: **prospective**

Last update: **2022-09-11, 1401/06/20**
Update count: **0**

Registration date

2022-09-11, 1401/06/20

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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+98 81 1838 0090

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-21, 1401/06/30

Expected recruitment end date

2023-02-19, 1401/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of couple-centered counseling based on EX-PLISSIT model versus control group on sexual function and satisfaction of couples in pregnant women with sexual dysfunction: a randomized clinical trial

Public title
Effect of couple-centered counseling based on EX-PLISSIT model versus control group on sexual function and satisfaction of couples in pregnant women with sexual dysfunction

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18 to 45 years Singleton pregnancy Gestation age 24 to 28 weeks Sexual dysfunction Secondary education and more

Exclusion criteria:
Depressive disorder Pregnancy complications such as gestational diabetes, preeclampsia, bleeding, premature rupture of the amnion sac

Age
From **18 years** old to **45 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 care during pregnancy plus couple-oriented counseling based on the IX-PLISSIT model, one session per week for 45 to 60 minutes for 4 weeks including: false thoughts and beliefs about sexual contact during pregnancy, anatomy and physiology of the reproductive system, cycle sexual response in men and women, sexual desire changes during pregnancy, optimal position of intimacy during pregnancy, factors that reduce sexual desire

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
2020-10-03, 1399/07/12

Ethics committee reference number
IR.UMSHA.REC.1399.549

Health conditions studied

1

Description of health condition studied
Sexual dysfunction

ICD-10 code
F52

ICD-10 code description
Sexual dysfunction not due to a substance or known physiological condition

Primary outcomes

1

Description
Sexual function

Timepoint
Before the intervention and 4 weeks after that

Method of measurement
Using the Female Sexual Function Index (FSFI) questionnaire

2

Description
Sexual satisfaction

Timepoint
Before the intervention and 4 weeks after that

Method of measurement
Using the Lindaberg Sexual Satisfaction questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Routine care during pregnancy plus couple-oriented counseling based on the IX-PLISSIT model, one session per week for 45 to 60 minutes for 4 weeks including: false thoughts and beliefs about sexual contact during pregnancy, anatomy and physiology of the reproductive system, cycle sexual response in men and women, sexual desire changes during pregnancy, optimal position of intimacy during pregnancy, factors that reduce sexual desire

Category
Treatment - Other

2

Description
Control group: Just routine care during pregnancy

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Comprehensive Health Centers in Hamadan city

Full name of responsible person
Mahsa Fatahi

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

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6517838695

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mahsa.ff1996@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Dr. Reza Shokoohi

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Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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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
Mahsa Fatahi

Position
Midwifery Student

Latest degree
Master

Other areas of specialty/work
Midwifery

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Dr. Zahra Masoomi

Position

Reproductive Health Specialist

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

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