

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 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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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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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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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