

# 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)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

##### 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.

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6517838695

##### Phone

+98 81 3838 0572

##### Email

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

##### Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

##### City

Hamadan

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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

Mahsa Fatahi

##### Position

Midwifery Student

##### Latest degree

Master

##### Other areas of specialty/work

Midwifery

##### Street address

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

##### City

Hamadan

##### Province

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##### Postal code

6517838695

##### Phone

+98 81 3838 0572

##### Email

mahsa.ff1996@gmail.com

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

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zahramid2001@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

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School of Public Health, Hamadan University of

Medical Sciences, Shahid Fahmideh Ave

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**Province**

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**Postal code**

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**Phone**

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**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