

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Effect of counseling on sexual knowledge, attitude and function in women with sexual dysfunction: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of counseling on sexual knowledge, attitude and function in women with sexual dysfunction

Design

This is a randomized clinical trial, in which 80 eligible patients will be randomly assigned to the intervention or control groups

Settings and conduct

The eligible women with sexual dysfunction referring to the Comprehensive Health Centers in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention or control groups through the drawing lots.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 30 years; Score less than 28 based on the Female Sexual Function Index (FSFI) questionnaire; Ability to speak, read and write in Persian; Married (first marriage). Exclusion criteria: Pregnancy or breastfeeding; Bigamy; Having a child; Separation from a spouse; Suffering from chronic physical or mental illness; Patient or spouse addiction to drugs or alcohol; Use of chemical or herbal medicines that affect sexual function.

Intervention groups

Intervention group: Routine treatment plus counseling sessions (including: the importance of sexual relations, the quality of the couple's relations, family health, anatomy and physiology of the reproductive system, sexual needs and problems, factors affecting sexual dysfunction, physical and mental differences between men and women, exercise, strategies enhancing sexual desire, improving sexual arousal skills, improving sexual diversity skills, teaching various sexual positions, correcting misconceptions about sex relationship) for 60 to 90 minute weekly for 4 weeks. Control group: Just routine treatment.

Main outcome variables

Sexual function, sexual knowledge, attitude

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N404**

Registration date: **2021-10-04, 1400/07/12**

Registration timing: **prospective**

Last update: **2021-10-04, 1400/07/12**

Update count: **0**

Registration date

2021-10-04, 1400/07/12

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

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-05, 1400/10/15

Expected recruitment end date

2022-08-06, 1401/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of counseling on sexual knowledge, attitude and function in women with sexual dysfunction: a randomized clinical trial

Public title

Effect of counseling on sexual knowledge, attitude and function in women with sexual dysfunction

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 18 to 30 years; Score less than 28 based on the Female Sexual Function Index (FSFI) questionnaire Ability to speak, read and write in Persian Married (first marriage)

Exclusion criteria:

Pregnancy or breastfeeding Bigamy; Having a child; Separation from spouse; Suffering from chronic physical or mental illness; Patient or spouse addiction to drugs or alcohol; Use of chemical or herbal medicines that affect sexual function

Age

From **18 years** old to **30 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

For random assignment of the patients to the intervention and control groups through random cluster sampling, the researcher will select eight centers among the Hamadan comprehensive health centers through drawing lots. Then, ten patients will be chosen randomly by drawing lots from referees of each center. For this, the researcher will prepare two sheets with "intervention" or "control" written on them. Then, when each patient refers, they will randomly take one of the sheets, and based on the selected sheet, the patient will be assigned to the intervention or control group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids****1****Registry name****Secondary trial Id****Registration date**

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

2021-09-25, 1400/07/03

Ethics committee reference number

IR.UMSHA.REC.1400.501

Health conditions studied**1****Description of health condition studied**

Sexual dysfunction

ICD-10 code

F52.8

ICD-10 code description

Other 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 knowledge and attitude

Timepoint

Before the intervention and 4 weeks after that

Method of measurement

Using the "Sexual Knowledge and Attitude Scale" (SKAS) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment plus counseling sessions (including: the importance of sexual relations, the quality of the couple's relations, family health, anatomy and physiology of the reproductive system, sexual needs and problems, factors affecting sexual dysfunction, physical and mental differences between men and women, exercise, strategies enhancing sexual desire, improving sexual arousal skills, improving sexual diversity skills, teaching various sexual positions, correcting misconceptions about sex relationship) for 60 to 90 minute weekly for 4 weeks

Category

Treatment - Other

2

Description

Control group: Just routine treatment

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Health Centers in Hamadan city

Full name of responsible person

Zahra Karami

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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. Saeid Bashirian

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Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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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

Zahra Karami

Position

MSc in Midwifery

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. Sudabeh Aghababaii

Position

Reproductive Health Specialist

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Other areas of specialty/work

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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

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.