

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Effect of counseling with cognitive behavioral therapy approach versus no counseling on sexual function in women with sexual malfunction: a randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of counseling with cognitive behavioral therapy approach versus no counseling on sexual function in women with sexual malfunction. Design: a randomized clinical trial. Setting and conduct: The eligible women sexual malfunction who will refer to Health Centers of Hamadan City during the study period will be enrolled into the trial. Inclusion criteria: age of 18 to 45 years; married; literate; passing at least 6 months of married life; Hamadan resident. Exclusion criteria: pregnancy; physical or mental disease; drug or alcohol addiction. Intervention group: Routine care plus counseling with cognitive behavioral therapy approach 2 hours a week for 8 weeks. Control group: Just routine care. Primary outcome: sexual function before and 8 weeks after intervention using standard sexual function questionnaire. Randomization: The patients will be randomly assigned to intervention and control groups using random number table. Blinding: Not possible.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201610209014N124**

Registration date: **2016-11-05, 1395/08/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-05, 1395/08/15

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2016-08-02, 1395/05/12

Expected recruitment end date

2017-07-02, 1396/04/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of counseling with cognitive behavioral therapy approach versus no counseling on sexual function in women with sexual malfunction: a randomized clinical trial

Public title

Effect of cognitive behavioral therapy on sexual function in women with sexual malfunction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age of 18 to 45 years; married; literate; passing at least 6 months of married life; Hamadan

resident. Exclusion criteria: pregnancy; physical or mental disease; drug or alcohol addiction.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **198**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: The patients will be randomly assigned to intervention and control groups using random number table. Blinding: Not possible.

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 the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2016-08-02, 1395/05/12

Ethics committee reference number

IR.UMSHA.REC.1395.50

Health conditions studied

1

Description of health condition studied

sexual malfunction

ICD-10 code

F52

ICD-10 code description

Sexual dysfunction, not caused by organic disorder or disease

Primary outcomes

1

Description

sexual function

Timepoint

before and 8 weeks after intervention

Method of measurement

using standard sexual function questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine care plus counseling with cognitive behavioral therapy approach 2 hours a week for 8 weeks.

Category

Treatment - Other

2

Description

Control group: Just routine care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Nursing and Midwifery

Full name of responsible person

Arezoo Shayan

Street address

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

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
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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

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

School of Nursing and Midwifery

Full name of responsible person

Arezoo Shayan

Position

Midwife

Other areas of specialty/work

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Person responsible for updating data

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty