

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of counseling with cognitive behavioral therapy approach versus no counseling on sexual satisfaction and marital quality 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 satisfaction and marital quality 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 without counseling. Primary outcome: (a) Assessing sexual satisfaction before and 8 weeks after intervention using Hudson standard sexual satisfaction questionnaire: (b) assessing marital quality before and 8 weeks after intervention using Busby standard marital quality questionnaire Randomization: The patients will be randomly assigned to intervention and control groups using stratified randomization. Blinding: Not possible.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201610209014N125**  
Registration date: **2016-10-22, 1395/08/01**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-10-22, 1395/08/01

#### 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

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

#### Expected recruitment start date

2016-05-24, 1395/03/04

#### Expected recruitment end date

2017-04-24, 1396/02/04

#### 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 satisfaction and marital quality in women with sexual malfunction: a randomized clinical trial

#### Public title

Effect of counseling with cognitive behavioral therapy approach versus no counseling on sexual satisfaction and marital quality 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 stratified randomization. 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

2016-05-23, 1395/03/03

#### Ethics committee reference number

IR.UMSHA.REC.1395.573

## 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

Assessing sexual satisfaction

#### Timepoint

before and 8 weeks after intervention

#### Method of measurement

using Hudson standard sexual satisfaction questionnaire

### 2

#### Description

assessing marital quality

#### Timepoint

before and 2 and 4 weeks after intervention

#### Method of measurement

using Busby standard marital quality 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 without counseling.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

School of Nursing and Midwifery

##### Full name of responsible person

Dr Zahra Massomi

##### 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  
Fahmideh Ave

**City**  
Hamadan

#### 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**  
Dr Zahra Massomi

**Position**  
Health Fertility Specialist

#### Other areas of specialty/work

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School of Nursing and Midwifery, Hamadan University  
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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Department of Epidemiology

**Full name of responsible person**  
Dr Jalal Poorolajal

**Position**  
Associate Professor

#### Other areas of specialty/work

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## 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*

