Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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

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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

Dr Zahra Massomi

Position

Health Fertility Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Department of Epidemiology

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Associate Professor

Other areas of specialty/work

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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*