

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The Effect of Sexual Counseling with Cognitive-Behavioral Therapy approach on Sexual Function of Menopausal women

Protocol summary

Study aim

The effect of cognitive-behavioral counseling on sexual function of postmenopausal women

Design

Random assignment to intervention and control groups

Settings and conduct

The first stage is selected by random cluster from the triple zones of the city of Kashan. Six centers (from each region of the two centers) are selected by lot. In the next stage, between the two centers, a center will be selected as the intervention group and the center will be the control group based on the draw. Was .

Participants/Inclusion and exclusion criteria

Marital status, lack of addiction in couples, lack of couples with diabetes, lack of sensory and motor skills in couples, having reading and writing skills, normal menopause, age 45-60 years old, in the first 5 years after menopause Being, amenorrhea for more than a year, monogamy, lack of menopause at the age of less than 40 years, lack of stressful experiences in the last three months, natural sexuality of the spouse According to the person himself and not taking herbal remedies containing phytoestrogens or sexual supplements Exit criteria: Missing more than two sessions at CBT sessions. Wife's death or separation from her during study.

Intervention groups

Of eligible eligible menopausal women who are willing to participate in the research, they will be continuously sampled, followed by a completed questionnaire, and screening will be performed, and those who have a score of HNS performance less than 28 will be included in the research project. . Sampling will last as long as the prescribed sample size reaches the quintile. Consultative councils will be formed in the presence of clinical psychologists in groups of 10 persons twice a week in 8 sessions for the intervention group.

Main outcome variables

The effect of cognitive-behavioral counseling on desire, psychological stimulation, humidity, orgasm, satisfaction

and sexual pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160709028847N5**

Registration date: **2019-02-09, 1397/11/20**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-09, 1397/11/20**

Update count: **0**

Registration date

2019-02-09, 1397/11/20

Registrant information

Name

leila Neisani

Name of organization / entity

Iran University Medical of Science

Country

Iran (Islamic Republic of)

Phone

+98 88006990

Email address

neisani89@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Sexual Counseling with Cognitive-Behavioral Therapy approach on Sexual Function of Menopausal women

Public title

The Effect of Sexual Counseling with Cognitive-Behavioral Therapy approach on Sexual Function of Menopausal women

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Iranian nationality Marital status Being Muslim Not being in the profession of psychology and psychiatry No addiction in couples Not having couples to have diabetes Not having sensory and motor disturbances in couples Have reading and writing skills Do not use sedative medications Menopause The age of a woman is 45 to 60 years old In the first 5 years after menopause Amenorrhea for more than a year Monogamy Missing menopause at age 40 Not having acute heart disease and any acute mental illness in couples Lack of stressful experiences in the last three months The normal nature of the spouse's sexual power, according to one's own words Not taking herbal remedies containing phytoestrogens or sexual enhancers in any form. غیبت بیش از دو جلسه در جلسات CBT.

Exclusion criteria:

Missing more than two sessions at CBT sessions The occurrence of stressful events during the study Wife's death or separation from her during study

AgeFrom **45 years** old to **60 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

The sampling method in this research is multi-stage. The first step is selected in a cluster of three areas of the city of Kashan, six centers (from each district of two centers) by lot, and in the next stage, between the two centers, based on the drawing of one The center will be the control group as the intervention group and the other center. In the next step, the researcher will attend the centers from the first to the weekend from 8 am to 12 noon, and will be sampling in the appropriate manner among eligible postmenopausal women who are willing to participate in the research. The questionnaire will then be completed by the clients and screening for sexual function will be performed and those who score less than 28 will enter the research plan. Sampling will continue as

long as the prescribed sample size reaches the quid pro quo.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Iran University of Medical Sciences

Street address

Hemmat Highway

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

Approval date

2018-11-26, 1397/09/05

Ethics committee reference number

IR.IUMS.REC.1397.532

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

The Impact of Sexual Counseling on the Cognitive-Behavioral Approach of Postmenopausal Women

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Cognitive behavioral counseling

Timepoint

Immediately after intervention, 1 month and two months after intervention

Method of measurement

Sexual Function of Women's Sexual Function Index (FSFI)

Secondary outcomes

1

Description

Sexual function

Timepoint

Immediately after intervention, 1 month and two months after intervention

Method of measurement

Questionnaire 19 questions (FSFI)

Intervention groups

1

Description

Intervention group: The sample size is 60. The members of the two intervention and control groups complete the pre-test in the first session. Then, the intervention team participates in interventional sessions based on a cognitive-behavioral approach that includes 8 sessions. The control group does not receive intervention. At the end of the sessions, both groups respond to the post-test. Also, in the follow up phase immediately after the intervention, one month and two months later, the two groups will again respond to the questionnaire questions.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Akramian Health Center

Full name of responsible person

Leila Neissani Samani

Street address

Martyr Morteza Akramian Alley, Opposite Bu-Ali Specialized Polyclinic, 22 Bahman Ave

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2

Recruitment center

Name of recruitment center

Shahid Manavi Health Center

Full name of responsible person

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3

Recruitment center

Name of recruitment center

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Name of recruitment center

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Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

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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
Iran University of Medical Sciences
Proportion provided by this source
1
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
Iran University of Medical Sciences
Full name of responsible person
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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Sexual function and its components will be calculated in both groups at the time of entering the research and after the intervention. Using descriptive statistics methods, the two-dimensional frequency distribution tables are set and the quantitative indices of the quantitative variables are also divided into two Calculate the group and then homogeneity tests, homogeneity of the two groups of evaluators. Then, using the t test, we will compare the variables of the two groups. Meanwhile, the pairwise exits will be used to compare before and after quantitative variables. Covariance analysis will be used to control covetails and will be used in the SPSS16 software version.

When the data will become available and for how long

18 months

To whom data/document is available

Dr. Zahra Zanjani - Dr Hamid Haqani

Under which criteria data/document could be used

To analyze

From where data/document is obtainable

Dr. Zahra Zanjani - Dr Hamid Haghani - Dr. Leila Neissani

What processes are involved for a request to access data/document

1/5 years

Comments