Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)
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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

Age
From **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
۱۴۴۹۶۱۴۵۳۵

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
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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
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3

Recruitment center
Name of recruitment center
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5

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6

Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

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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

Leila Neissani Samani

Position

Assistant Professor

Latest degree

Master

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

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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