

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The Effect of Cognitive Behavioral Therapy On Sexual Self-Concept in Postmenopausal Women

Protocol summary

Study aim

Determining the effect of cognitive-behavioral therapy on sexual self-concept in postmenopausal women

Design

A clinical trial with a control group, randomized with a quadruple block on 66 postmenopausal women

Settings and conduct

The statistical population of this study in this study will include postmenopausal women referring to Amanieh health. Samples will be selected taking into account the entry and exit criteria. Samples will be randomly assigned with a block design in two groups of intervention (n = 33) and control (n = 33). No blinding was performed in this study.

Participants/Inclusion and exclusion criteria

Admission requirements: middle school and higher education, age range 45 to 55 years, normal menopause (not secondary to medication or surgery), marriage and living with a spouse, being at least 1 year apart and up to 5 years after termination Normal menstruation / conditions of non-entry: exposure to severe stress during the last 6 months, use of anti psychotic drugs, chronic illness, any psychological illness, previous history of using counseling techniques during the last 6 months, use of hormonal supplements During menopause

Intervention groups

The intervention group will receive 8 sessions of cognitive-behavioral counseling for 90 minutes. The control group will not receive any intervention.

Main outcome variables

Sexual self-concept

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201105049272N1**

Registration date: **2021-02-01, 1399/11/13**

Registration timing: **prospective**

Last update: **2021-02-01, 1399/11/13**

Update count: **0**

Registration date

2021-02-01, 1399/11/13

Registrant information

Name

Mahboobeh Hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3336 2414

Email address

www.hosseinii.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-08, 1399/11/20

Expected recruitment end date

2021-05-10, 1400/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Cognitive Behavioral Therapy On Sexual Self-Concept in Postmenopausal Women

Public title

The Effect of Cognitive Behavioral Therapy On Sexual Self-Concept in Postmenopausal Women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Middle education and higher Age range 45 to 55 years
Normal menopause (not secondary to medication or surgery) Married and living with a spouse Being at least 1 year and at most 5 years away from normal menstruation

Exclusion criteria:
Exposure to severe stress during the last 6 months
Taking anti psychotic drugs Chronic disease Having any mental illness Previous history of using counseling techniques in the last 6 months Use of hormonal supplements during menopause

Age
From **45 years** old to **55 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
By assigning samples to each of the intervention and control groups, it will be done by random block method and using quadruple blocks (by the table related to random permutations). Closed envelopes that are numbered will also be used to hide random allocation. In this way, each participant will be assigned a code and will be divided into two groups of control and intervention.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahwaz Jundishapur University of Medical Sciences

Street address

Golestan Blvd., Ahwaz Jundishapur University of Medical Sciences, School of Nursing and Midwifery

City

Ahvaz

Province

Khuzestan

Postal code

61357-15794

Approval date

2020-02-22, 1398/12/03

Ethics committee reference number

IR.AJUMS.REC.1398.899

Health conditions studied

1

Description of health condition studied

Sexual self-concept

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sexual self-concept based on MSSCQ questionnaire

Timepoint

Before the intervention and after the intervention

Method of measurement

MSSCQ questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The experimental group will receive 8 sessions of cognitive-behavioral counseling as a group for 90 minutes. The sessions will be held by a researcher who has received the necessary training and certification in cognitive-behavioral counseling, and the counseling professor will attend some sessions to ensure the correctness of the intervention, and finally a post-test will be taken after the sessions.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Health Center No. 9

Full name of responsible person

مهرداد شریفی

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Amaniyeh, corner of Bahman Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
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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

Ahvaz University of Medical Sciences

Proportion provided by this source

100

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
Ahvaz University of Medical Sciences
Full name of responsible person
Mahboobeh Hosseini
Position
University student
Latest degree

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After identifying the participants, information related to the main outcome will be shared.

When the data will become available and for how long

The publication of information will be possible 6 months after the publication of the results.

To whom data/document is available

Access to research documents is possible for research centers and researchers and therapists.

Under which criteria data/document could be used

Data are available with reference to the researcher's name and clinical and research procedures.

From where data/document is obtainable

Ahvaz University of Medical Sciences, School of Nursing and Midwifery, Ms. Mitra Tadayon Najafabadi Mobile: 09166182793 Email: tadayon-m@ajums.ac.ir

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

After correspondence with the Vice Chancellor for Research of Ahvaz University of Medical Sciences, the results are available.

Comments