

# 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

**Street address**

Amaniyeh, corner of Bahman Street

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Khouzestan  
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+98 61 3333 9194  
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vchhealth@ajums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
Dr. Mehdi Ahmadi Moghadam  
**Street address**  
Golestan Blvd., Esfand St., Jundishapur University of  
Medical Sciences  
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iitc@ajums.ac.ir

#### 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**

Bachelor  
**Other areas of specialty/work**  
Midwifery  
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www.hosseinii.m@ajums.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
Mitra Tadayon Najafabadi  
**Position**  
the coach  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Midwifery  
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Golestan Blvd., School of Nursing and Midwifery,  
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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
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**Position**  
University student  
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Khouzestan

**Postal code**

6133933657

**Phone**

+98 61 3311 4325

**Email**

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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**