

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Efficacy of Cognitive Behavior Therapy on Sexual function and satisfaction among post-menopausal women

Protocol summary

Summary

Menopause is one of the factors that can affect on sexual function. Many menopause women suffer from sexual dysfunction at this time. The purpose of the present study is the impact of Cognitive Behavior Therapy on Sexual function and satisfaction of post-menopausal women. This study is a single-case design (multiple baseline) according to the cognitive behavior therapy. The study samples are 4 post menopause women aged 50 to 65 with sexual dysfunction (score < 26 of FSFI questionnaire) and Lack of sexual satisfaction or low sexual satisfaction (score <75 of Index of Sexual Satisfaction) that will select base on inclusion and exclusion criteria. To gather the data a demographic questionnaire, Female Sexual Function Index (FSFI) and Index of Sexual Satisfaction (ISS) will used. samples after determining baselines for the dependent variable will be entered for cognitive-behavioral therapy for 8 sessions of 90 minutes, with one session per week. All participants will complete Questionnaires in sessions 2, 4, 6 and immediately after treatment . In order to follow up, all women will re-evaluate two months after treatment, every 20 days.To analyze the data, visuals, Reliable change index (RCI) and percent recovery formulas will used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015100324322N1**

Registration date: **2016-07-08, 1395/04/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-07-08, 1395/04/18

Registrant information

Name

Hajar Haghghi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Research Development Ahvaz Jundishapur University of
Medical Sciences

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Cognitive Behavior Therapy on Sexual
function and satisfaction among post-menopausal
women

Public title

Efficacy of Cognitive Behavior Therapy on Sexual
function and satisfaction among post-menopausal
women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: menopausal women aged between 45-60 year old (at least one year after amenorrhea); married with stable life with her husband; first married; natural menopause; monogamy; FSFI<26; ISS<75; minimum education: diploma and accessible for 6 months.
Exclusion criteria: not having sex during the study; vaginal/ cervical/ pelvic infection(by examination); diagnosed psychological illness; history of sexual abuse or sexual harassment; addiction (alcohol, drugs and other psychotropic drugs); occurrence of mishap events (death, accidents with disabilities, treason, etc.) during the last 6 months; chronic diseases affect sexuality for menopausal women or her husband such as diabetes, cardiovascular disease, hypertension, cancer, vascular damage caused by accidents, thyroid disorders, spinal disorders, parkinson's disease, MS; the use of hormone replacement therapy (HRT) or topical estrogen for last 6 months.

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: **4**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Ahvaz Jundishapur University of Medical Sciences,
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Street address

Ahvaz- Golestan Blvd

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Postal code

61357-15749

Approval date

2015-06-20, 1394/03/30

Ethics committee reference number

IR.AJUMS.REC.1394.240

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

Menopause sexual dysfunction

ICD-10 code

N95.8

ICD-10 code description

Other specified menopausal and perimenopausal disorders

Primary outcomes**1****Description**

Menopausal sexual function

Timepoint

Before intervention, during intervention, two months after intervention

Method of measurement

Female sexual function index (FSFI)

2**Description**

Menopausal sexual satisfaction

Timepoint

Before intervention, during intervention, two months after intervention

Method of measurement

Female sexual function index (FSFI)

3**Description**

Menopausal sexual distress

Timepoint

Before intervention, during intervention, two months after intervention

Method of measurement

Female sexual function index (FSFI)

Secondary outcomes**1****Description**

Sexual desire in menopausal wemon

Timepoint

Before intervention, during intervention, two months after intervention

Method of measurement

Female Sexual Function Index

2**Description**

Sexual arousal in menopausal wemon

Timepoint

Before intervention, during intervention, two months

after intervention
Method of measurement
Female Sexual Function Index

3

Description
Sexual lubrication in menopausal wemon
Timepoint
Before intervention, during intervention, two months after intervention
Method of measurement
Female Sexual Function Index

4

Description
Orgasm in menopausal wemon
Timepoint
Before intervention, during intervention, two months after intervention
Method of measurement
Female Sexual Function Index

5

Description
Sexual satisfaction in menopausal wemon
Timepoint
Before intervention, during intervention, two months after intervention
Method of measurement
Female Sexual Function Index

6

Description
Sexual pain in menopausal wemon
Timepoint
Before intervention, during intervention, two months after intervention
Method of measurement
Female Sexual Function Index

Intervention groups

1

Description
Single case(multiple baseline), intervention will be held 8 sessions of 90 minutes according to researcher-made protocol based on cognitive behavioral therapy for every four participants held weekly.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center

Women's Clinic of Haj Azizi Hospital- Private obstetricians clinic
Full name of responsible person
Hajar Haghighi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Committee, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran
Full name of responsible person
Mr Fatalizadeh
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Ahvaz, Academic city. Research Committee of Ahvaz Jundishapur University of Medical Sciences
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Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Committee, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran
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

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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