Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Haghighi
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran
Country
Iran (Islamic Republic of)
Phone
+98 61 3367 5436
Email address
haghighi.h@ajums.ac.ir

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 amenorrea); 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, Ahvaz, Iran

Street address
Ahvaz- Golestan Blvd

City
Ahvaz

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

Street address

Juibar, Qhaemshahr

City

Juibar, Qhaemshahr

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

Street address

Ahvaz, Academic city. Research Committee of Ahvaz Jundishapur University of Medical Sciences

City

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

Name of organization / entity

Ahwaz Jundishapur University of Medical Sciences

Full name of responsible person

Hajar Haghighi

Position

Msc student of counseling in midwifery

Other areas of specialty/work

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.

City

Ahwaz

Postal code

61357-15794

Phone

+98 611336754360

Fax

Email

haghighi.h@ajums.ac.ir; negar8606@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Nursing & Midwifery, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

Full name of responsible person

Dr. Parvin Abedi

Position

PhD in Community Nutrition, Associate Professor

Other areas of specialty/work

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.

City

Ahvaz

Postal code

Phone

+98 61 3373 8331

Fax

+98 61 3373 8333

Email

parvinabedi@ymail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Hajar Haghighi

Position

MSc student

Other areas of specialty/work

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.

City

Ahwaz

Postal code

Phone

Fax

Email

haghighi.h@ajums.ac.ir

Web page address

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