

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

The comparison of the effectiveness of approach CBT and ACT on sexual function and sexual schemas in postmenopausal women

Protocol summary

Study aim

The purpose of this study is to compare the effectiveness of approach CBT and ACT on sexual function and sexual schemas in postmenopausal women.

Design

The research method is semi-experimental and the research design is three groups with pre-test, post-test, and follow-up 3 months later.

Settings and conduct

The statistical population of study consist of postmenopausal women that have menopause in 5 past year and have sexual problems and are attending in the health center in zanzan in 2020. The sample consist of 45 individuals who will randomly assign to three groups of 15. In the implementation of the research, the control group will not receive any intervention, while the other two groups are the experimental ones, one of which will receive cognitive behavioral therapy and the other group will receive acceptance and commitment treatment for 8 sessions.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Married women; Menopausal women that have menopause in 5 past year; Sexual performance score below 28; Completed Secondary education level; monogamy. Exclusion Criteria: Having known physical and mental illness according; Consumption of drugs affecting sexual relationships; Addiction; Participate in other similar studies; Occurrence of unpleasant event.

Intervention groups

Intervention Group 1: CBT - (Cognitive-Behavioral Therapy): Treatment sessions are performed in 8 sessions (each session approximately 2 hours per week) according to the protocol (Kaplan, 1974; Kennedy, 2012). Intervention Group 2: (ACT - Acceptance and Commitment-Based Therapy): Treatment sessions are performed in 8 sessions (each session approximately 2 hours per week) according to the protocol (Kaplan 1974; Foreman and Herbert 2008). Control group: No intervention is performed and is only for comparison with

the intervention groups.

Main outcome variables

sexual function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200428047230N1**

Registration date: **2020-05-05, 1399/02/16**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-05, 1399/02/16**

Update count: **0**

Registration date

2020-05-05, 1399/02/16

Registrant information

Name

Fatemeh Rostamkhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3377 6533

Email address

frostamkhani47@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-02, 1398/10/12

Expected recruitment end date

2020-06-19, 1399/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The comparison of the effectiveness of approach CBT and ACT on sexual function and sexual schemas in postmenopausal women

Public title
The comparison of the effectiveness of approach CBT and ACT on sexual function and sexual schemas in postmenopausal women

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
-Married women -Menopausal women that have menopause in 5 past year -Sexual performance score below 28 with FSFI questionnaire -Completed Secondary education level -Have willingness to participate in the study -Being monogamy
Exclusion criteria:
-Having known physical and mental illness according to self-reported -Consumption of drugs affecting sexual relationships -Addiction -Participate in other similar studies -Occurrence of unpleasant event

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
The researcher randomly selected 3 centers out of 18 health centers in Zanjan by writing numbers on paper by drawing lots, then by referring to the mentioned health center, 45 of them were selected by available sampling method and coded from 1-45. Using randomly assigned block allocation methods, they were divided into 3 groups of 15 people (2 intervention groups and one control group). How to do it: First we encode the groups based on the Latin letters as follows: A = cognitive-behavioral therapy, B = acceptance and commitment treatment and C = control group In this study with three groups A, B and C, the following six groups were created: And we assign the numbers 1 to 6 to each: ABC-ACB-BAC-BCA-CAB-CBA Then we contract using a table of random numbers, whenever the numbers 1, 2, 3, 4, 5, and 6, respectively. It appeared that one of these blocks would be selected, and if another number appeared, we assumed it to be null and void and moved on to the next selection. In fact, we get a random sequence of numbers with a table of random numbers, which we consider the order of the assigned allocation for each number. In this way, the number of people in the groups is almost equal.

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 zanjan University of Medical Sciences
Street address
Azadi Square, Zanjan University of Medical Sciences
City
Zanjan
Province
Zanjan
Postal code
45156-13191

Approval date
2019-10-15, 1398/07/23

Ethics committee reference number
IR.ZUMS.REC.1398.328

Health conditions studied

1

Description of health condition studied
Sexual Function

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Menopausal women who receive sexual performance scores less than 28 with FSFI Questionnaire

Timepoint
Pre-test, post _test and follow up

Method of measurement
FSFI Questionnaire

Secondary outcomes

1

Description
sexual schemas

Timepoint

Pre-test, Post-test and follow up

Method of measurement

Women's sexual self-schema Questionnaire

Intervention groups**1****Description**

Intervention group: Intervention Group 1 CBT - (Cognitive-Behavioral Therapy), Treatment sessions are performed in 8 sessions (each session approximately 2 hours per week for 2 months) according to the protocol (Kaplan, 1974; Kennedy, 2012). Measurements are taken with pre-test, post-test and follow-up 3 months later.

Category

Treatment - Other

2**Description**

Intervention group: Intervention Group 2: ACT - (Acceptance and Commitment-Based Therapy), Treatment sessions are performed in 8 sessions (each session approximately 2 hours per week for 2 months) according to the protocol (Kaplan 1974; Foreman and Herbert 2008). Measurements are taken with pre-test, post-test and follow-up 3 months later.

Category

Treatment - Other

3**Description**

Control group: Control group: A 15-member control group, on which no intervention is performed and is only for comparison with the intervention groups. Measurements are taken with pre-test, post-test and follow-up 3 months later.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

The health center in zanzan

Full name of responsible person

Fatema Rostamkhani

Street address

Unit 4, No 4, Kowsar 7 st, Niksazan, Zanzan

City

Zanzan

Province

Zanzan

Postal code

4515996746

Phone

+98 24 3377 6533

Email

frostamkhani47@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Mehdi Rahnema

Street address

Student Square, Zanzan Branch, Islamic Azad University

City

Zanzan

Province

Zanzan

Postal code

4515996746

Phone

+98 24 3377 6533

Email

frostamkhani47@gmail.com

Grant name

Vice Chancellor for Research, Islamic Azad University of Zanzan

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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**

Islamic Azad University

Full name of responsible person

Fatemeh Rostamkhani

Position

Abhar Branch, Islamic Azad University, Faculty of Humanities, Counseling ph.D candidate

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Transit Road Km 4 Abhar- Khorram Dareh

City
Abhar
Province
Zanjan
Postal code
4561934367
Phone
+98 24 3522 6080
Email
frostamkhani47@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Fatemeh Rostamkhani
Position
MS of Midwifery, Academic member of Nursing and Midwifery Faculty, Zanjan Azad University
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
Student Square, Zanjan Branch, Islamic Azad University
City
Zanjan
Province
Zanjan
Postal code
45156-58145
Phone
+98 24 3346 5007
Email
frostamkhani47@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Fatemeh Rostamkhani
Position
MS of Midwifery, Academic member of Nursing and Midwifery Faculty, Zanjan Branch, Islamic Azad Unive
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
Unit 4, No 4, Kowsar 7 st, Niksazan, Zanjan
City
Zanjan
Province
Zanjan
Postal code
4515996746
Phone
+98 24 3377 6533
Email
frostamkhani47@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable