Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

The Effect of Counseling Based on Cognitive-Behavioral Therapy (CBT) on Sexual Satisfaction, Sexual Function and Sexual Self-efficacy among Women at Reproductive Age with Hypothyroidism

Protocol summary

Study aim
Determining the effect of counseling based on cognitive-behavioral therapy on sexual satisfaction, sexual function and sexual self-efficacy of women of reproductive age with hypothyroidism

Design
Clinical trial with pretest-post test design with control group, single-blind, and randomized with quadruple blocks on 66 women with hypothyroidism. Participants will be divided into intervention and control groups by block randomization method with block of size 4.

Settings and conduct
The research field in this clinical trial is Health Center No. 1, Comprehensive Health Service Center No. 4 in Izeh city. No blinding was performed in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Having reading and writing ability; Age range between 18 and 45 years; Hypothyroidism according to thyroid stimulating hormone (TSH) levels based on the diagnosis of an internal medicine specialist; Getting a sexual function score less than 26.5 from the Female Sexual Function Index (FSFI). Exclusion criteria: Participate in training courses based on cognitive-behavioral approach in the past; Having a history of known chronic and acute physical and mental illnesses; taking psychotropic drugs prescribed by a doctor or psychiatrist

Intervention groups
The intervention group will receive 8 90-120 minute sessions of group cognitive-behavioral counseling, once a week and on a specific day. The control group does not receive the intervention but after the end of the study, they will receive an educational CD of meetings for observance of ethical standards.

Main outcome variables
Sexual satisfaction; Sexual function; Sexual self-efficacy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200706048030N1**
Registration date: **2020-09-01, 1399/06/11**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-01, 1399/06/11**
Update count: **0**

Registration date
2020-09-01, 1399/06/11

Registrant information

Name
Azam Sheikhmiri

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 4364 9301

Email address
sheikhmiri.a@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-18, 1399/05/28

Expected recruitment end date
2020-10-19, 1399/07/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Counseling Based on Cognitive-Behavioral Therapy (CBT) on Sexual Satisfaction, Sexual Function and Sexual Self-efficacy among Women at Reproductive Age with Hypothyroidism

Public title
Effect of Cognitive-Behavioral Therapy (CBT) on Sexual Satisfaction, Sexual Function and Sexual Self-efficacy in Women

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having reading and writing ability Age range between 18 and 45 years old Hypothyroidism according to thyroid stimulating hormone (TSH) levels based on the diagnosis of an internal medicine specialist Getting a sexual function score less than 26.5 from the Female Sexual Function Index (FSFI)

Exclusion criteria:
Participate in training courses based on cognitive-behavioral approach in the past Having a history of known chronic and acute physical and mental illnesses Taking psychotropic drugs prescribed by a doctor or psychiatrist

Age
From **18 years** old to **45 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
Allocation of samples to each of the intervention and control groups was performed by block random method using quadruple blocks (By the table for random permutations). Also, opaque envelopes which are numbered sequentially, will be used to hide random allocation. Accordingly, the participants will be given codes and assigned into the intervention and control groups.

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 Ahvaz Jundishapur University of Medical Sciences

Street address
School of Nursing and Midwifery; Golestan Blvd

City
Ahvaz

Province
Khouzestan

Postal code
61357-15794

Approval date
2019-08-19, 1398/05/28

Ethics committee reference number
IR.AJUMS.REC.1398.387

Health conditions studied

1

Description of health condition studied
Hypothyroidism

ICD-10 code
E01

ICD-10 code description
Iodine-deficiency related thyroid disorders and allied conditions

2

Description of health condition studied
Hypothyroidism

ICD-10 code
E02

ICD-10 code description
Subclinical iodine-deficiency hypothyroidism

3

Description of health condition studied
Hypothyroidism

ICD-10 code
E03

ICD-10 code description
Other hypothyroidism

Primary outcomes

1

Description
Sexual satisfaction

Timepoint
Before the intervention and after the intervention

Method of measurement
Larson Sexual Satisfaction Questionnaire (LSSQ)

2

Description
Sexual function
Timepoint
Before the intervention and after the intervention
Method of measurement
Female Sexual Function Index (FSFI)

3

Description
Sexual Self-efficacy
Timepoint
Before the intervention and after the intervention
Method of measurement
Sexual Self-Efficacy Questionnaire (SSEQ)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The test group will receive 8 90-120 minute sessions of group cognitive-behavioral counseling, once a week and on a specific day. The sessions will be conducted by a researcher who has received the necessary training and certification in cognitive-behavioral counseling and the consultant will attend some of the sessions to ensure the correctness of the intervention. Finally, After completion of the sessions post-test will be taken.
Category
Behavior

2

Description
Control group: The control group does not receive intervention. The post test will be taken from the control group and after the end of the study, they will receive an educational CD of meetings for observance of ethical standards.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Health base No. 1, Comprehensive Health Service Center No. 4 of Izeh city
Full name of responsible person
Marzieh Mousavi
Street address
Third alley., Shahid Tahmasebi alley., Ashkboos Naderi avenue
City
Izeh
Province
Khouzestan
Postal code
63916-56764
Phone
+98 61 4362 6357
Email
sheikhmiri.a@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr Mohammad Badvi
Street address
Golestan Blvd., Ahvaz Jundishapur University of Medical Sciences
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Phone
+98 61 3336 2414
Fax
+98 61 3336 2414
Email
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
Azam Sheikhmiri
Position

Student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Golestan Blvd., School of Nursing and Midwifery., Ahvaz Jundishapur University of Medical Sciences

City
Ahvaz

Province
Khouzestan

Postal code
61357-15794

Phone
+98 61 3336 2414

Email
sheikhmiri.a@ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Dr Mina Iravani

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

Street address
Golestan Blvd., School of Nursing and Midwifery., Ahvaz Jundishapur University of Medical Sciences

City
Ahvaz

Province
Khouzestan

Postal code
61357-15794

Phone
+98 61 3336 2414

Email
iravani-m@ajums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Azam Sheikhmiri

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Golestan Blvd., School of Nursing and Midwifery., Ahvaz Jundishapur University of Medical Sciences

City
Ahvaz

Province
Khouzestan

Postal code
61357-15794

Phone
+98 61 3336 2414

Email
sheikhmiri.a@ajums.ac.ir

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 unrecognizable the participants, the information of original outcome will be shared.

When the data will become available and for how long
The publication of the information will be possible six months after the publication of the results.

To whom data/document is available
Access to research documentation for research centers and researchers and therapists is possible.

Under which criteria data/document could be used
Approve Ahvaz University of Medical Sciences, Appropriateness of Information Required with Health Promotion Programs

From where data/document is obtainable
Ahvaz University of Medical Sciences, School of Nursing and Midwifery, Dr. Mina Iravani Phone number: 0098613311 Email: iravani-m@ajums.ac.ir Postal code: 61357-15794

What processes are involved for a request to access data/document
Following the correspondence with the research deputy of Ahvaz University of Medical Sciences, the results will be available to the applicants.

Comments