

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Dec 2023

### 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

Khuzestan

##### 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**

Khuzestan

#### **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**

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+98 61 3336 2414

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##### **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  
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Golestan Blvd., School of Nursing and Midwifery.,  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
Dr Mina Iravani  
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Associate professor  
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Ph.D.  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
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Azam Sheikhmiri  
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**Latest degree**

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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 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