

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)

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+98 61 4364 9301

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr Mohammad Badvi

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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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Person responsible for scientific inquiries

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Person responsible for updating data

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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