

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Effectiveness of Cognitive- Behavioral Therapy on Quality of Life in Women with Hypothyroidism in Reproductive Ages

Protocol summary

Study aim

Effectiveness of Cognitive-Behavioral Therapy on the Quality of Life in Women with Hypothyroidism in the Reproductive Ages

Design

96 individual (48 in each group) of hypothyroid women with inclusion criteria will be visited in the Endocrine Clinic of Imam Khomeini Hospital in Ahvaz. Participants will be divided into intervention and control groups by block randomization method with block size 4.

Settings and conduct

This study is an interventional study with a control and an intervention groups. The hypothyroidism women will admitted to the Endocrinology Clinics of Ahvaz Imam Khomeini Hospital randomly assigned using block randomization with a block size of 4 and a 1: 1 ratio in the intervention and control groups. For allocation concealment the unique codes will be used and kept in the opaque envelopes by secretary of clinic. In this way, the researcher and the participant will not aware of allocation until the intervention begins.

Participants/Inclusion and exclusion criteria

Inclusion criteria are as follows: Ages between 18 to 45 years; having at least high school education; hypothyroidism diagnosed by an Endocrinologist; consent to participate in the study; under medication with levothyroxine; scores less than 50 from SF-36 Quality of Life Questionnaire. Exclusion criteria are as follows: pregnancy; thyroid malignancy; known mental illness (dementia-depression); chronic and high-risk diseases such as cancer, multiple sclerosis, pulmonary and renal disease, congestive heart failure, smoking, alcohol or drug abuse and under medication with psychotropic and neuropsychiatric drugs; The occurrence of abnormal stress due to the life-threatening events such as death of a spouse or a family member in the past six months.

Intervention groups

The intervention group received 8 sessions of Cognitive-

behavioral Therapy, and no treatment for control group

Main outcome variables

Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190323043101N1**

Registration date: **2019-08-12, 1398/05/21**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-12, 1398/05/21**

Update count: **0**

Registration date

2019-08-12, 1398/05/21

Registrant information

Name

Soheila Rezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3446 1523

Email address

rezaei.s@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-11, 1398/05/20

Expected recruitment end date

2019-10-12, 1398/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effectiveness of Cognitive- Behavioral Therapy on Quality of Life in Women with Hypothyroidism in Reproductive Ages

Public title
Effectiveness of Cognitive-Behavioral Therapy on Quality of Life in Women with Hypothyroidism

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Ages between 18 to 45 years Diagnose of Hypothyroidism by Endocrinologist Conscious consent to participate in the study Under medication with levothyroxine Scores less than 50 from SF-36 Quality of Life Questionnaire At least high school education
Exclusion criteria:
Pregnancy Diagnosis of malignancy in thyroid Known mental illness (dementia-depression) Chronic and high-risk diseases such as cancer-multiple sclerosis-pulmonary and renal disease-congestive heart failure Smoking, Alcohol or drug abuse and under medication with Psychotropic and Neuropsychiatric drugs The occurrence of abnormal stress due to life-threatening events such as the death of a spouse or a family member in the past six months

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: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of assigning intervention to patients is randomly using block randomization with block size of 4 and a ratio of 1: 1. For allocation concealment, the unique codes in the opaque envelopes will be used. The envelopes will be remained with the secretary of the clinic until the time of intervention. In this way, the researcher and the participant will not aware of allocation until the intervention begins. All patients will be screened regarding the inclusion criteria and eligible patients will be randomized into one of the intervention and control groups base on the randomization list.

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 and Health Services

Street address

Ahvaz Jundishapur University of Medical Sciences and Health Services, Golestan Blvd, Ahvaz, Iran

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2019-03-16, 1397/12/25

Ethics committee reference number

IR.AJUMS.REC.1397.968

Health conditions studied

1

Description of health condition studied

Hypothyroidism

ICD-10 code

E01;E02;E0

ICD-10 code description

Iodine-deficiency related thyroid disorders and allied conditions; subclinical iodine-deficiency hypothyroidism; Other hypothyroidism

Primary outcomes

1

Description

Quality of Life

Timepoint

At the beginning of the study (before the intervention) and after the intervention

Method of measurement

Ware & Sherbourne Quality of Life Questionnaire (SF-36)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Participants in the intervention group will received 8 sessions of cognitive-behavioral therapy about the psychological complications of Hypothyroidism such as sadness and depression by the researcher. The treatment will be included an explanation of the cognitive behavioral therapy model, cognitive reconstruction, self-control and mood enhancement activities, muscle relaxation exercises, imagination, positive self-esteem, diaphragmatic breathing, meditation, introducing effective coping steps. There will be one session (90 minutes) each week. After completion of the sessions post-test will be taken.

Category

Behavior

2

Description

Control group: No treatment for control group. The post test will be taken from the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Soheila Rezaei

Street address

Imam Khomeini Hospital, Azadegan Street, Ahvaz, Iran

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Phone

+98 61 3373 8395

Fax

+98 61 3373 8333

Email

rezaei.s@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

Ahvaz Jundishapur University of Medical Science and Health Services, Golestan BLVD, Ahvaz, Iran

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Phone

+98 61 3373 8395

Fax

+98 61 3373 8333

Email

info@ajums.ac.ir

Grant name

Grant of faculty members

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

Soheila Rezaei

Position

Ms.c Student in Midwifery Consultant

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Ahvaz, Jundishapur University of Medical Science and Health Services, Golestan BLVD, Ahvaz, Iran

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Phone

+98 61 3373 8395

Fax

+98 61 3373 8333

Email

rezaei.s@ajums.ac.ir

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Soheila Rezaei

Position

Ms.c Student in consultant Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Ahvaz, Jundishapur University of Medical Science and Health Services, Golestan BLVD, Ahvaz, Iran

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Phone

+98 61 3373 8395

Fax

+98 61 3373 8333

Email

rezaei.s@ajums.ac.ir

61357-15794

Phone

+98 61 3373 8395

Fax

+98 61 3373 8333

Email

rezaei.s@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, Vice-Chancellor of Research and Technology, Dr. Mohammad Badvi, Postal code 61357-15794 Phone 0098613311 Email info@ajums.ac.ir

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

Person responsible for updating data

Contact**Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Soheila Rezaei

Position

Ms.c Student in consultant Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Ahvaz, Jundishapur University of Medical Science ,Iran

City

Ahvaz

Province

Khouzestan

Postal code