

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

### The Effect of Eight Weeks of Aerobics Exercise on Depression, Anxiety, and Stress in Women with Subclinical Hypothyroidism

#### Protocol summary

##### Study aim

The aim of this study will investigate the effect of eight weeks of aerobic exercise on depression, anxiety, and stress in women with hypothyroidism.

##### Design

41 patients with hypothyroidism will be selected by simple randomization and will be divided into experimental (n=23) and control groups (n = 18).

##### Settings and conduct

The present study was a semi-experimental study with pre-test-posttest design with control group. The subjects were randomly divided into two experimental groups (23 patients) and control (n = 18) from among the patients referred to Rasoul-e-Akram Hospital in Abadan city. All subjects participated in this study after informing about the process and the way of doing research and signing written consent. At first, a pre-test was taken from the samples by answering the questions of the DASS-21 questionnaire. The experimental group then participated in an aerobic exercise program for eight weeks, three 60-minute sessions each week. The control group did not participate in any sporting activity properly. After completing the exercise protocol, again, from both groups, the post-test was measured.

##### Participants/Inclusion and exclusion criteria

Patients with subclinical hypothyroidism can participate in the study, and people with orthopedic problems and heart disease cannot participate in the study.

##### Intervention groups

Experimental and control groups. The experimental group will participate in an aerobic exercise program for eight weeks, three 60-minute sessions per week. The control group doesn't participate in any sporting activity properly.

##### Main outcome variables

Depression, anxiety and stress

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20161129031165N3**

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

Registration timing: **retrospective**

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

Update count: **0**

##### Registration date

2019-08-12, 1398/05/21

##### Registrant information

##### Name

Vahid Valiipour Dehnou

##### Name of organization / entity

Lorestan University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 66 3312 0086

##### Email address

valipour.v@lu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-02-03, 1397/11/14

##### Expected recruitment end date

2019-04-04, 1398/01/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

The Effect of Eight Weeks of Aerobics Exercise on Depression, Anxiety, and Stress in Women with Subclinical Hypothyroidism

**Public title**

The Effect of Exercise on Depression, Anxiety, and Stress

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age from 30 to 45 years  
Consume at least 6 months of Levothyroxine regularly  
Female gender

**Exclusion criteria:**

cardiovascular disease and diabetes  
alcohol and tobacco use  
Orthopedic problems

**Age**

From **30 years** old to **45 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **41**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

After referring to the Rasool Akram Hospital in Abadan city, the subjects will be selected based on their availability and after obtaining consent, and using simple randomization method (Flip the coin) assigned into two groups: experimental group (eight weeks aerobic training) and control group (doing daily activities).

**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 Lorestan University of Medical Sciences

**Street address**

Lorestan province, Khorramabad city, Lorestan university of medical sciences

**City**

Khorramabad

**Province**

Lorestan

**Postal code**

6813833946

**Approval date**

2017-10-15, 1396/07/23

**Ethics committee reference number**

IR.LUM.REC.1396.312

**Health conditions studied****1****Description of health condition studied**

Subclinical Hypothyroidism

**ICD-10 code**

E02

**ICD-10 code description**

Subclinical iodine-deficiency hypothyroidism

**Primary outcomes****1****Description**

Depression

**Timepoint**

At the beginning of the study and 8 weeks after the intervention

**Method of measurement**

Depression, Anxiety and Stress Questionnaire with 21 items

**2****Description**

Anxiety

**Timepoint**

At the beginning of the study and 8 weeks after the intervention

**Method of measurement**

Depression, Anxiety and Stress Questionnaire with 21 items

**3****Description**

stress

**Timepoint**

At the beginning of the study and 8 weeks after the intervention

**Method of measurement**

Depression, Anxiety and Stress Questionnaire with 21 items

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

Intervention group: The experimental group will participate in an Aerobics exercise program for three sessions (60 min) per week for eight weeks. Both groups will take levothyroxine tablets.

### Category

Prevention

## 2

### Description

Control group: Control subjects will not participate in any kind of activity regularly and will only take levothyroxine for 8 weeks.

### Category

N/A

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

University of Lorestan

#### Full name of responsible person

Vahid Valipour Dehnou

#### Street address

Km 5 of Tehran road - Khorramabad city - Lorestan province

#### City

Khorramabad

#### Province

Lorestan

#### Postal code

44316-68151

#### Phone

+98 66 3312 0106

#### Email

valipour.v@lu.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Lorestan university

#### Full name of responsible person

Vahid Valipour Dehnou

#### Street address

Lorestan university, Khorramabad

#### City

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#### Province

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#### Fax

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#### Email

valipour.v@lu.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Lorestan 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

Lorestan University

#### Full name of responsible person

Vahid Valiopour Dehnou

#### Position

Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Physiology

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## Person responsible for scientific inquiries

### Contact

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Lorestan University

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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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

The only consequence of this is the sharing of data

**When the data will become available and for how long**

Start the access period after printing the results

**To whom data/document is available**

Researchers

**Under which criteria data/document could be used**

-

**From where data/document is obtainable**

-

**What processes are involved for a request to access data/document**

-

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Lorestan University

**Full name of responsible person**

Vahid Valiopour Dehnou

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiology

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