

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### The Effect of a period of high intensity interval training and moderate intensity continuous training on plasma levels of Spexin and Insulin in overweight women

#### Protocol summary

##### Study aim

The Effect of a period of high intensity interval training and moderate intensity continuous training on plasma levels of Spexin and Insulin in overweight women

##### Design

Clinical trial with high intensity interval training group (n = 15), the moderate intensity continuous training group (n = 15) and the control group (n = 15), Single blind, randomised trial

##### Settings and conduct

This is a clinical trial. This study will be a single blind study. The population of the study is overweight women in the city. 45 members of the sports clubs are selected. They were randomly assigned to the high intensity interval training group (n = 15), the moderate intensity continuous training group (n = 15) and the control group (n = 15). This research will be conducted in Zahedan Sports Club.

##### Participants/Inclusion and exclusion criteria

Participants included obese and overweight women. The study involved 45 eligible people. They will be randomly assigned to the high intensity interval training group (n = 15), the moderate intensity continuous training group (n = 15) and the control group (n = 15). Inclusion criteria: General physical and mental health, Body mass index (BMI) More than 25 kg / m<sup>2</sup>, Not having regular exercise for 6 months before starting training Participation in exercise activities, disease during exercise, pregnancy during exercise, and non-participation in each of the test groups Exclusion criteria: Participate in regular sports activities, Disease during exercise, Pregnancy during exercise, Refusing to continue cooperation

##### Intervention groups

high intensity interval training (n = 15), the moderate intensity continuous training (n = 15) and the control (n = 15). Subjects will perform the exercise for 8 weeks and three sessions each week. The training program

includes: warm-up, Specific training protocol and cool-down.

##### Main outcome variables

Spexin and Insulin

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160813029322N3**

Registration date: **2021-05-30, 1400/03/09**

Registration timing: **prospective**

Last update: **2021-05-30, 1400/03/09**

Update count: **0**

##### Registration date

2021-05-30, 1400/03/09

##### Registrant information

##### Name

Hossein Nakhei

##### Name of organization / entity

University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 54 3341 1374

##### Email address

h.nakhaei@zaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-05-31, 1400/03/10

##### Expected recruitment end date

2021-07-01, 1400/04/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The Effect of a period of high intensity interval training and moderate intensity continuous training on plasma levels of Spexin and Insulin in overweight women

**Public title**

The effect of exercise on the Spexin and Insulin hormone in overweight women

**Purpose**

Prevention

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

Being 40-25 years old Having General physical and mental health Body mass index (BMI) more than 25 kg / m<sup>2</sup> Not having regular exercise for 6 months before starting training Not having diseases: cardiovascular, diabetes, hormonal disorders, kidney and liver diseases, surgery No smoking and any medical intervention

**Exclusion criteria:**

Participate in regular sports activities Disease during exercise Pregnancy during exercise Refusing to continue cooperation

**Age**From **25 years** old to **40 years** old**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**Target sample size: **45****Randomization (investigator's opinion)**

Randomized

**Randomization description**

Permuted block

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Blood samples are collected. It is coded on the samples. Samples are taken to the laboratory for hormone measurement.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

university/regional research Ethics committee  
Zahedan University of medical sciences

**Street address**

Main campus, Zahedan, Sistan and Baluchestan, Iran

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816743463

**Approval date**

2021-05-02, 1400/02/12

**Ethics committee reference number**

IR.ZAUMS.REC.1400.055

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

Obesity and overweight

**ICD-10 code**

E66

**ICD-10 code description**

Overweight and obesity

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

Insulin

**Timepoint**

Before the intervention and two months after the intervention

**Method of measurement**

ParsAzmon Kit (mg/dl)

**2****Description**Body Mass Index (BMI) Kg/m<sup>2</sup>**Timepoint**

Before the intervention and two months after the intervention

**Method of measurement**

The body mass (Kg) divided by the square of the body height (m)

**Secondary outcomes****1****Description**

Plasma levels of Spexin

**Timepoint**

Before the intervention and two months after the intervention

**Method of measurement**

Spexin Kit (ELISA ng/ml)

**Intervention groups****1****Description**

Intervention group: High intensity interval training, It will take eight weeks (three days a week, one hour each session).

**Category**

Rehabilitation

**2****Description**

Intervention group: Moderate intensity continuous training, It will take eight weeks (three days a week, one hour each session).

**Category**

Rehabilitation

**3****Description**

Control group: Control group, It will take eight weeks (three days a week, one hour each session).

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Zahedan University of Medical Sciences

**Full name of responsible person**

Hossein Nakhaei

**Street address**

Main campus- Dr. Hesabi Square

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Zahedan

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Sistan-va-Balouchestan

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**Phone**

+98 54 3329 5765

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hossiennakhaie@yahoo.com

**Sponsors / Funding sources****1****Sponsor**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Dr Seyed Mohammad Hashemi Shahri

**Street address**

Main campus, Dr. Hessabi Square

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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**

Zahedan 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**

Zahedan University of Medical Sciences

**Full name of responsible person**

Hossein Nakhaei

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiology

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Main campus, Dr. Hassabi Square

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Hossein Nakhaei

**Position**

Assistant Professor

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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**

All data including: (IPD), study protocol, statistical analysis map, informed consent form, clinical study report and data dictionary will be published upon completion of the study. This data will be published in a valid journal article format.

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

Data will be available immediately upon completion of the project. It will probably be released in 1401.

**To whom data/document is available**

For researchers of academic and scientific institutions

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

For the development of related sciences

**From where data/document is obtainable**

Refer to Zahedan University of Medical Sciences by

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

Submit a valid letter from the scientific centres

**Comments**