

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

The Effect of High and Low Frequency of Physical Activity on Long Term Efficacy of Weight Loss in Healthy Overweight and Obese Women

Protocol summary

Summary

The role of physical activity with diet to lose weight is clear . The purpose of this study was to evaluate the effect of high and low frequency of physical activity on weight loss in healthy obese and overweight women . For this purpose, 60 eligible healthy obese and overweight women (Body mass index 27-35 kg/m²), age 18-50 years, no regular exercise, no self-report of acute or chronic disease, no evidence of amenorrhea were selected and divided into two groups (n=30); 1) physical activity with high frequency (6 days / 50 min) and 2) physical activity with low frequency (3 days / 100 min). Participants are involved in other weight loss programs with dietary regimen intervention as a component, are anemic (Hematocrit < 34%), report total cholesterol > 300 mg/dl, report triglyceride > 350 mg/dl will be excluded. During the study period, all of the participants will follow a diet with caloric restriction (500 kcal less than BMR). Before and after the study, blood parameters including triglycerides, total cholesterol, HDL, LDL, fibrinogen, and HOMA-IR are measured. Weight and waist circumference is measured at the beginning of the study and every two weeks . Physical activity adherence is controlled by pedometer.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201402157754N4**

Registration date: **2014-03-11, 1392/12/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-03-11, 1392/12/20

Registrant information

Name

Leila Shafiei Neek

Name of organization / entity

Faculty of Physical Education and Sport Sciences,
University of Tehran

Country

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Recruitment status

Recruitment complete

Funding source

Novin Diet Clinic (Dr. Farshchi)

Expected recruitment start date

2014-02-20, 1392/12/01

Expected recruitment end date

2014-08-23, 1393/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of High and Low Frequency of Physical Activity
on Long Term Efficacy of Weight Loss in Healthy
Overweight and Obese Women

Public title

Effects of exercise on weight loss

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Body mass index 27-35 kg/m²; Age
18-50 years; No regular exercise (> 1 bout of
exercise/wk or participation in any sporting activities > 1

hr/wk.); No self-report of acute or chronic disease (diabetes, heart diseases, and joint problems in particular); For females; No evidence of amenorrhea (Regular menstrual cycles of 21-35 days). Exclusion Criteria: Sedentary or are involved with other weight loss programs with dietary regimen intervention as a component; Anemia (Hematocrit < 34%); Total cholesterol > 300 mg/dl; Triglyceride > 350 mg/dl.

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**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 Digestive Disease Research Institute

Street address

Shariati Hospital, North Kargar Ave.

City

Tehran

Postal code**Approval date**

2014-01-28, 1392/11/08

Ethics committee reference number

FWA00001331

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

Obesity

ICD-10 code

E66

ICD-10 code description

Obesity due to excess calories

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

Weight

Timepoint

At the beginning of the study and every two weeks

Method of measurement

Scale

2**Description**

Waist circumference

Timepoint

At the beginning of the study and every two weeks

Method of measurement

meter

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

Triglyceride

Timepoint

At the beginning of study and after 6 month

Method of measurement

Blood testing

2**Description**

Total cholesterol

Timepoint

At the beginning of study and after 6 month

Method of measurement

Blood testing

3**Description**

HDL

Timepoint

At the beginning of study and after 6 month

Method of measurement

Blood testing

4**Description**

LDL

Timepoint

At the beginning of study and after 6 month

Method of measurement

Blood testing

5

Description

HOMA-IR

Timepoint

At the beginning of study and after 6 month

Method of measurement

Blood testing

6

Description

Fibrinogen

Timepoint

At the beginning of study and after 6 month

Method of measurement

Blood testing

Intervention groups

1

Description

walking with low frequency (3 days a week and a day, 100 minutes, 300 minutes per week) followed a restricted diet (500 calorie less than BMR). The participants are asked to record their daily step count. Diet and physical activity will follow every two weeks.

Category

Behavior

2

Description

walking with high frequency (5 days per week and a daily 50-minute, 300 minutes per week) followed a restricted diet (500 calorie less than BMR). The participants are asked to record their daily step count. Diet and physical activity will follow every two weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Novin Diet Clinic

Full name of responsible person

Dr.Hamidreza Farshchi

Street address

No.5, 4th Floor, Nikan Bldg., Shariati Ave.,

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Novin Diet Clinic

Full name of responsible person

Dr. Hamidreza Farshchi

Street address

No.5, 4th Floor, Nikan Bldg., Shariati Ave.,

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Novin Diet Clinic

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Novin Diet Clinic

Full name of responsible person

Dr.Seyedeh Ameneh Majd

Position

Pharmacologist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Novin Diet Clinic

Full name of responsible person

Dr.Hamidreza Farshchi

Position

Clinical Nutritionist & Metabolism

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Person responsible for updating data

Contact

Name of organization / entity
Novin Diet Clinic
Full name of responsible person
Leila Shafiei Neek
Position
PhD student of exercise physiology
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty