

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Aug 2026

### Development and Evaluation of the Effectiveness of an Intervention Based on New Communication Technologies and the Social-Cognitive Theory on the Weight Control and Lifestyle of the Employees With Overweight and Obesity

#### Protocol summary

##### Summary

Aim: The aim of this study is to evaluate the effect of the intervention based on new communication technologies and the social cognitive theory on the life style and weight control in the governmental employees of Hamadan City, western Iran. The most important inclusion criteria are: Body Mass Index (BMI) > 25 kg/m<sup>2</sup>; working for at least 8 hours per week; having computer and to be familiar with working with computer; access to the telephone, cell phone, and the Internet, and familiarity with working with these technologies; and age above 18 years. The exclusion criteria are pregnancy; depression; and other disorders leading to physical inactivity. The study population consists of 1200 employees from fifty organizations. Based on the primary studies, the sample size for the study is estimated at 435 employee with overweight or obesity. Intervention: The educational intervention will be performed for 6 months under the title of "lifestyle program". Primary outcomes of the study are BMI, life style and social -cognitive theory constructs. This is a controlled trial, with randomization to three arms: telephone- assisted intervention", "web- assisted intervention ", and "control" groups. Participants will be assessed at baseline and after six and nine months.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014083118989N1**  
Registration date: **2016-01-02, 1394/10/12**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-01-02, 1394/10/12

##### Registrant information

###### Name

Jalal Abdi

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 918 817 5446

###### Email address

j-abdi@razi.tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Tehran University of Medical Sciences

##### Expected recruitment start date

2013-12-22, 1392/10/01

##### Expected recruitment end date

2014-05-22, 1393/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Development and Evaluation of the Effectiveness of an Intervention Based on New Communication Technologies and the Social-Cognitive Theory on the Weight Control and Lifestyle of the Employees With Overweight and Obesity

## Public title

Effect of the New Technologies-based Education on the life style and Obesity of Employees

## Purpose

Prevention

## Inclusion/Exclusion criteria

The most important inclusion criteria are: Body Mass Index(BMI)>25kg/m<sup>2</sup>; working for at least 8 hours per week; having computer and to be familiar with working with computer ; access to the telephone, cell phone, and the Internet, and familiarity with working with these technologies; and age above 18 years. The exclusion criteria are pregnancy; depression; and other disorders leading to physical inactivity

## Age

From **18 years** old to **65 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **435**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Vice Chancellor for Research, Tehran University of Medical Sciences

##### Street address

Vice Chancellor for Research, Tehran University of Medical Sciences, Keshavarz Boulevard, Engelab Square.Tehran,Iran

##### City

Tehran

##### Postal code

#### Approval date

2014-08-13, 1393/05/22

#### Ethics committee reference number

1139/130/93/

## Health conditions studied

### 1

#### Description of health condition studied

Obesity

#### ICD-10 code

E66.0

#### ICD-10 code description

Obesity due to excess calories

### 2

#### Description of health condition studied

lifestyle

#### ICD-10 code

z72

#### ICD-10 code description

Problems related to lifestyle

## Primary outcomes

### 1

#### Description

Body Mass Index

#### Timepoint

baseline.6 and 9 months after

#### Method of measurement

digital scale (kg) ,Tape(cm)

### 2

#### Description

Lifestyle

#### Timepoint

baseline.6 and 9 months after

#### Method of measurement

questionnaire

### 3

#### Description

Social -cognitive theory constructs

#### Timepoint

baseline.6 and 9 months after

#### Method of measurement

Questionnaire

## Secondary outcomes

### 1

#### Description

Blood Pressure

#### Timepoint

Baseline,6 and9 months after intervention

#### Method of measurement

sphygmomanometer(mmHg)

## 2

### **Description**

Waist circumference

### **Timepoint**

Baseline, 6 and 9 months after intervention

### **Method of measurement**

Tape(cm)

## **Intervention groups**

### 1

#### **Description**

Phone intervention: The intervention starts when the personal counsellor first calls the participant. The "lifestyle programme" consists of 10 modules (lessons) that provide the participants with information on the nutrition and physical activity. The assignments teach the participants how to use the strategies in their daily lives. The intervention will be continued for 6 months. Subjects in the telephone- assisted group will be received the lessons via the SMS. Telephone consultations will be provided at the end of every two weeks.

#### **Category**

Behavior

### 2

#### **Description**

Internet intervention: A website is developed for the intervention, With unique username and password for each participants. The employee is asked to fill out some personal details for the counselor. The 'lifestyle programme' consists of 10 modules (lessons) that provide the participants with information on the nutrition and physical activity. The intervention will be continued for 6 months. Subjects in the web- assisted group will be received the lessons via the web. E-mail consultations will be provided at the end of every two weeks.

#### **Category**

Treatment - Drugs

### 3

#### **Description**

Control group: The control group will be received general brochures about lifestyle and overweight although they do not receive the lifestyle program.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Hamadan University of Medical Sciences

##### **Full name of responsible person**

Jalal Abdi

##### **Street address**

### **City**

Hamadan

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Vice Chansellor for Research, Tehran University of Medical Sciences

##### **Full name of responsible person**

Massod Yonesian

##### **Street address**

Vice Chancellor for Research, Tehran University of Medical Sciences, Keshavarz Boulevard, Engelab Square. Tehran, Iran

##### **City**

Tehran

##### **Grant name**

##### **Grant code / Reference number**

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

Yes

##### **Title of funding source**

Vice Chansellor for Research, Tehran University of Medical Sciences

##### **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**

Department of Health Education and Promotion, School of Public Health, Tehran University of Medical

##### **Full name of responsible person**

Jalal Abdi

##### **Position**

Ph.D candidate

##### **Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

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Hassan Eftekhari

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M.D

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

Jalal Abdi

**Position**

Ph.D candidate

**Other areas of specialty/work**

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**Web page address**

## 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*