Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)>25kg/m2; 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

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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/m2; 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/ა

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
basline.6 and 9 months after
Method of measurement
digital scale (kg) ,Tape(cm)

2

Description
Lifestyle
Timepoint
basline.6 and 9 months after
Method of measurement
questionnaire

3

Description
Social -cognitive theory constructs
Timepoint
basline.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 and9 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 programe” 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 programe” 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
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Jalal Abdi
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Person responsible for scientific inquiries

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Name of organization / entity
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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