

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Effect of Motivational Interviewing (MI) to Improve Physiological Indicators and Cardio-respiratory Fitness among Overweight and Obese Women who attended to nutrition clinics

Protocol summary

Summary

Background and Aim: Obesity has dramatically become a public health problem across the world. The current survey explored the effects of motivational interviewing (MI) on physiological parameters and cardio-respiratory fitness among women with overweight and obesity who attended to nutrition clinics. Materials and Methods: We conducted a single-blind randomized clinical trial study on 64 women with overweight and obesity randomly assigned to MI (n=32) or control (n= 32) group. The Rockport Walk Test was used to evaluate VO2 max, LDL-C, HDL-C and total cholesterol were also tested in subjects trained to fast for 12 hours and avoid alcohol consumption in 24 hours before blood test. The total cholesterol, LDL-C, HDL-C and cardio-respiratory fitness were investigated at baseline and at 12 months follow-up. Descriptive analysis was run to describe the mean and standard deviation of the demographic characteristics.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062217736N8**

Registration date: **2016-07-01, 1395/04/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-07-01, 1395/04/11

Registrant information

Name

Seyed Kamaladdin Mirkarimi

Name of organization / entity

Golestan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 17 1553 2872

Email address

k.mirkarimi@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Golestan University of Medical Science

Expected recruitment start date

2014-09-27, 1393/07/05

Expected recruitment end date

2015-10-01, 1394/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Motivational Interviewing (MI) to Improve Physiological Indicators and Cardio-respiratory Fitness among Overweight and Obese Women who attended to nutrition clinics

Public title

Effect of Motivational Interviewing (MI) to Improve Physiological Indicators and Cardio-respiratory Fitness

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria were as follow: 1) hyperlipidemia diagnosed by a fasting LDL-C (130 mg/dl or higher), 2) ability to read, 3) access to a telephone, 4) no history of nutritional intervention such as motivational

interviewing, and 5) no history of drug use (drugs for controlling cholesterol, LDL and HDL). Exclusion criterion was as follow: participants with absence more than two sessions (standard and MI) .

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 64

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

1

Registry name

خير

Secondary trial Id

خير

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Golestan University of Medical Science

Street address

Kilometer 4 Gorgan-Sari Road, Educational campus of Falsafi, Vice Chancellor for Research, Gorgan City, Golestan Province, Iran

City

Gorgan

Postal code

Approval date

2013-09-23, 1392/07/01

Ethics committee reference number

920807108

Health conditions studied

1

Description of health condition studied

Hyperlipidemia

ICD-10 code

E78.6

ICD-10 code description

Lipoprotein deficiency

Primary outcomes

1

Description

Cholesterol, HDL-C, LDL-C

Timepoint

Baseline and 12 months follow-up

Method of measurement

Fasting Blood Sugar (FBS)

Secondary outcomes

1

Description

cardio-respiratory fitness

Timepoint

Baseline and 12 Months follow-up

Method of measurement

Rockport Walk test

Intervention groups

1

Description

Motivational interviewing group: they were educated using written materials including pamphlet and brochure in terms of (a) behaviors that may decrease cholesterol (b) the components of LDL-C and HDL-C (c) a definition of cholesterol (d) some of usual misconceptions in terms of cholesterol (e) the principle components of a healthy diet for the heart (f) basic dietary guidelines [15] (g) the role of physical activity and dietary fats in reducing cholesterol (h) shopping and food preparation tips (i) an exercise plan. This arm was provided by five sessions of MI with a psychologist based on seven key points of MI 3 weeks after the first intervention (written material). In overall, between 8 and 12 subjects participated in each session (each session consisted of 30 to 45 minutes). These steps were as follow: (a) people motivate and persuade to change, voluntarily; (b) it is the client's role to resolve their ambivalence; (c) direct persuasion is not a beneficial technique to resolve ambivalence; (d) the counselor is a directive method to help clients to explore and resolve ambivalence; (e) the counseling style is a eliciting and quiet approach; (f) readiness to change is a fluctuating product of interpersonal interaction and (g) the therapeutic relation was more similar to a partnership than expert- recipient roles

Category

Prevention

2

Description

Control group was educated using written materials including pamphlet and brochure in terms of (a) behaviors that may decrease cholesterol (b) the components of LDL-C and HDL-C (c) a definition of cholesterol (d) some of usual misconceptions in terms of cholesterol (e) the principle components of a healthy diet for the heart (f) basic dietary guidelines [15] (g) the role of physical activity and dietary fats in reducing cholesterol (h) shopping and food preparation tips (i) an exercise plan. in the control group received five follow-up telephone session 3 weeks after the first intervention (written material). This session was 30 to 45 minutes and was also delivered by an instructed person to adhere to the script provided.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Private Nutrition clinic

Full name of responsible person**Street address****City**

Gorgan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Golestan University of Medical Science

Full name of responsible person

Mohammad Parang

Street address

Vice Chancellor of Information and Technology,
Educational campus of Falsafi, Kilometer 4 Gorgan-
Sari Road, Gorgan City, Golestan Province

City

Gorgan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Golestan University of Medical Science

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**

Golestan University of Medical Science

Full name of responsible person

Seyyed Kamal Mirkarimi

Position

Ph.D of Health Education and Promotion

Other areas of specialty/work**Street address**

No 19- 3rd Alley- 57Avenue- Gorgan City- Golestan
Province- Iran

City

Gorgan

Postal code

4917

Phone

+98 17 3242 4377

Fax**Email**

ak.mirkarimi@gmail.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Golestan University of Medical Science

Full name of responsible person

Seyyed Kamal Mirkarimi

Position

Ph.D of Health Education and Promotion

Other areas of specialty/work**Street address**

No 19- 3rd Alley- 57Avenue- Gorgan City- Golestan
Province- Iran

City

Gorgan

Postal code

4917

Phone

+98 17 3242 4377

Fax**Email**

ak.mirkarimi@gmail.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Golestan University of Medical Science

Full name of responsible person

Seyyed Kamal Mirkarimi

Position

Ph.D of Health Education and Promotion

Other areas of specialty/work**Street address**

No 19- 3rd Alley- 57 Avenue- Gorgan City- Golestan
Province- Iran

City

Gorgan

Postal code

4917

Phone

+98 17 3242 4377

Fax**Email**

ak.mirkarimi@gmail.com

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