

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Comparative study of the effectiveness of self-management and group management on weight loss by low calorie diet in Nurses : A simultaneous combined study

#### Protocol summary

##### Study aim

Comparative determination of self-management and group management effectiveness on weight loss of nurses

##### Design

96 nurses and each hospital, for an intervention method, and assigning samples to study groups non-randomly: In each group: group diet , individual and control diet: 32 nurses

##### Settings and conduct

The nurses from Poursina, Razi, Al-Zahra, Heshmat and Shafa hospitals.. Nurses at Poursina and Razi hospitals: individual diets, nurses at Heshmat and Shafa hospitals: group diets. The nurses of Al-Zahra Hospital: control group will not receive any intervention.

##### Participants/Inclusion and exclusion criteria

BMI of more than 25 kg /m<sup>2</sup>, age over 18 years, not having a weight loss program in the last 6 months, not using other weight loss methods such as medication and exercise during the study period. People with diabetes, cancer, kidney failure, and patients taking nonsteroidal anti-inflammatory drugs are not included in the study  
Criteria for non-inclusion: Personal reluctance to participate in the study and pregnancy and lactation

##### Intervention groups

Poursina & Razi hospitals: diet individual management, Heshmat & Shafa hospitals: group management, Al-Zahra hospital: control group. For intervention group are prescribed 8 weeks of diet (55% carbohydrate, 15% protein & 30% fat) to lose weight. The energy required at the beginning, will be given to the person based on the person's age, height, current weight and 1000 calories less. Individual will be prohibited from taking weight loss drugs and strenuous physical activity and will be asked to walk 30 minutes a day. At the beginning, weeks 4 (middle of the study) & week 8 (end of the study), weight, height, waist were measured with valid and

reliable tools and BMI was calculated and no intervention was performed in the control group. The consequences of the individual regimen and group regimens are compared.

##### Main outcome variables

Weight Loss

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210528051417N1**

Registration date: **2021-08-20, 1400/05/29**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-08-20, 1400/05/29**

Update count: **0**

##### Registration date

2021-08-20, 1400/05/29

##### Registrant information

##### Name

Parand Pourghane

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 4256 5052

##### Email address

pourghanep@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-06-10, 1400/03/20

##### Expected recruitment end date

2022-05-10, 1401/02/20  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Comparative study of the effectiveness of self-management and group management on weight loss by low calorie diet in Nurses : A simultaneous combined study

**Public title**  
Comparative study of the effectiveness of self-management and group management on weight loss by low calorie diet in Nurses

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Having a body mass index of more than 25 kg / m<sup>2</sup> Age over 18 years Not having a weight loss program in the last 6 months Not using weight loss medication Not having exercise during the study period Not having diabetes Not having cancer Not having kidney failure Not having not take non steroidal anti-inflammatory drugs

**Exclusion criteria:**

Personal reluctance to participate in the study pregnancy lactation

**Age**  
From **60 years** old

**Gender**  
Both

**Phase**  
0

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **64**

**Randomization (investigator's opinion)**  
Not 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**  
کمیته اخلاق در پژوهش دانشگاه علوم پزشکی گیلان  
**Street address**  
Shahid Sheikhi  
**City**  
Guilan. Langroud  
**Province**  
Guilan  
**Postal code**  
4477166595  
**Approval date**  
2021-05-30, 1400/03/09  
**Ethics committee reference number**  
IR.GUMS.REC.1399.463

**Health conditions studied**

1  
**Description of health condition studied**  
Obesity  
**ICD-10 code**  
**ICD-10 code description**

**Primary outcomes**

1  
**Description**  
Weight Loss  
**Timepoint**  
Along with recording demographic information, at the beginning of the study, week 4 (middle of the study) and week 8 after the start of the study (actually the end of the study), weight, height, waist indices and body mass index are also calculated.  
**Method of measurement**  
To measure the height and weight of the subjects, a lever scale with an accuracy of 0.1 kg connected to a calibrated height gauge with an accuracy of 0.1 cm is used. The height and weight of people are measured without shoes and with minimal clothing. Finally, the Body Mass Index is calculated based on the formula. People's waist is also measured using a tape measure

**Secondary outcomes**  
empty

**Intervention groups**

1  
**Description**  
In the individual diet therapy group, diet training will be by an individual nutritionist. Educational content is determined based on demographic information and the amount of weight loss required. In face-to-face training sessions, at the beginning of the study, the fourth and last week of the study, training sessions are held for an average of one hour. Depending on your weight, diet, and the list of high-calorie foods you should eliminate

from your diet, healthy and low-calorie foods, how to distribute food throughout the day and breakfast, lunch and dinner, and snacks are explained.

### Category

Lifestyle

## 2

### Description

In the group with group therapy regimen, through groups formed in WhatsApp, the necessary information like a individual regime will be provided to individuals and individuals will share their experiences and problems with other members. Also, in the intervals between sessions, communication will be established with group members through social channels to encourage people to follow a diet.

### Category

Lifestyle

## 3

### Description

Control group: Control group: Al-Zahra hospital: control group without intervention

### Category

Lifestyle

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Poursina, Razi, Al-Zahra, Heshmat, Shafa hospitals

#### Full name of responsible person

Parand Pourghane

#### Street address

Shahid Sheikhi. College of Nursing & Midwifery

#### City

لنگرود. گیلان. Langroud

#### Province

Guilan

#### Postal code

4477163485

#### Phone

+98 13 4256 5052

#### Email

pourghanep@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Rasht University of Medical Sciences

#### Full name of responsible person

Dr. Mohammadreza Naghipour

#### Street address

Shahid Sheikhi Street

#### City

Langroud

#### Province

Guilan

#### Postal code

4477163485

#### Phone

+98 13 4256 5052

#### Email

pourghanep@gmail.com

### Grant name

Vice Chancellor for Research, Guilan University of Medical Sciences, Iran

### Grant code / Reference number

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

Yes

### Title of funding source

Rasht 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

Rasht University of Medical Sciences

#### Full name of responsible person

Parand Pourghane

#### Position

Associate professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Nursery

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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

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**Fax****Email**

pourghanep@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

After obtaining the results will be mentioned

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

After publishing the article

**To whom data/document is available**

All applicants

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

Release the effect of the weight loss program / freely

**From where data/document is obtainable**

Individuals can submit a request by sending a message to the first author. Also, the results will be made available to the public in the form of a published article.

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

Demand for first author or correspond author

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Parand Pourghane

**Position**

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Ph.D.

**Other areas of specialty/work**

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