

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of a balanced low-calorie diet on depression score evaluated by Beck questionnaire in overweight and obese patients

Protocol summary

Study aim

Determination of the effect of balanced low calorie diet on depression score evaluated by Beck questionnaire in overweight and obese patients

Design

Clinical trial ,without control group design of 78 participants, with simple random sampling method and table of random numbers, have been enrolled between December 2022 and June 2023, and have been following for 3months

Settings and conduct

The samples required for the present study are selected from among the outpatients referred to the nutrition and diet therapy clinic who meet the criteria for entering the study using non-probability sampling method.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 20-60 years BMI>27
Depression score evaluated by Beck questionnaire>13
Willingness to participate in the study
Exclusion criteria:
pregnancy and lactation
Taking anti depressant drugs
Taking multi vitamins and minerals
Having any severe systemic disease, endocrine or metabolic disorders
Having been on a weight loss diet for the past 6 months
Professional athlete

Intervention groups

The group receives a balanced low-calorie diet

Main outcome variables

Weight loss
Decreasing in depression score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230316057733N1**

Registration date: **2023-08-18, 1402/05/27**

Registration timing: **prospective**

Last update: **2023-08-18, 1402/05/27**

Update count: **0**

Registration date

2023-08-18, 1402/05/27

Registrant information

Name

Maryam Ranjbar Zahedani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5226 9320

Email address

m.ranjbar@larums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of a balanced low-calorie diet on depression score evaluated by Beck questionnaire in overweight and obese patients

Public title

Effect of balanced low calorie diet on depression score

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 20-60 years BMI>27 Depression score evaluated by Beck questionnaire>13 Willingness to participate in the study

Exclusion criteria:
 Pregnancy and Lactation Taking anti depressant drugs
 Taking multi vitamins and minerals Having any severe systemic disease, endocrine or metabolic disorders
 Having been on a weight loss diet for the past 6 months
 Professional athlete

Age
 From **20 years** old to **60 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **78**

Randomization (investigator's opinion)
 N/A

Randomization description

Blinding (investigator's opinion)
 Not blinded

Blinding description

Placebo
 Not used

Assignment
 Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Larestan University of Medical Sciences

Street address

Larestan University Of Medical Sciences,behind the Larestan Grand Market,Karmand St,North Ghadir Blvd,Shahr_ejadid,Larestan,Fars,Iran.

City

Larestan

Province

Fars

Postal code

7153675541

Approval date

2022-11-07, 1401/08/16

Ethics committee reference number

IR.LARUMS.REC.1401.010

Health conditions studied

1

Description of health condition studied

Overweight and Obesity

ICD-10 code

E66.9

ICD-10 code description

Obesity, unspecified

Primary outcomes

1

Description

Decreasing in depression score

Timepoint

In the beginning and the end of the study

Method of measurement

Beck questionnaire

2

Description

Weight

Timepoint

Every 2 weeks

Method of measurement

Scale

Secondary outcomes

empty

Intervention groups

1

Description

The current study is a 12-week randomized clinical trial with the overall goal of determining the effects of a low-calorie balanced diet on depression score based on Beck's standard questionnaire, anthropometry and body composition in overweight and obese patients. The patients will be recruited among the outpatients living in Lar city with overweight and obesity (BMI≥27) referring to Nutrition and Diet therapy Center of Larestan University of Medical Sciences with easy non-probability sampling method and based on the inclusion criteria. Written informed consent forms for participation in the trial will be obtained from all participants. The patients will be provided with a balanced weight loss diet based on individual indicators (height, weight, gender and physical activity level) and Harris-Benedict equation by subtracting 500 kcal/day from their estimated energy requirements for weight maintenance. Moreover, the participants will be asked to complete a study questionnaire, which included questions regarding their demographic and socioeconomic characteristics (age, sex, occupation, education level, marital status, and family history of Diabetes Mellitus(DM), Hypertension(HTN) and Cardio Vascular Diseases(CVD)) The participants will be also asked not to change their physical activity levels, and avoid starting to take any

medicine or nutritional supplement or changing their food habits during the follow-up period. Patients following up in order to check them in terms of adherence to the diet, answering their questions and preventing samples from falling will be also done every week by phone and also by visiting patients once every two weeks. Also, to check the state of mood of the participants in the study, Beck's standard depression questionnaire will be used at the beginning and end of the intervention. Weight, height, and waist and hip circumferences (WC; HC) of subjects will be measured based upon standard protocol at the time they will be enrolled in the study (to the nearest 0.1 Kg and 0.5 cm for weight, height, WC and HC respectively). Both WC and HC were measured using a flexible non-elastic tape above the iliac crests and at the maximal buttocks, respectively. Body mass index (BMI), defined as weight (kg) divided by square of height (m²), was then calculated from these measures. Moreover, the indicators related to body composition (body fat mass) are calculated using the following formula: Body fat%: $(1.2 \times \text{BMI}) + (0.23 \times \text{age}) - (10.8 \times \text{g}) = 0$ for women $\text{g} = 1$ for men

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Nutrition and Diet therapy Center of Larestan University of Medical Sciences

Full name of responsible person

Somayeh Yousai

Street address

Larestan University Of Medical Sciences, Behind the Larestan Grand Market, Karmand St, North Ghadir Blvd, Shahr_ejadid, Larestan, Fars, Iran.

City

Larestan

Province

Fars

Postal code

7153675541

Phone

+98 917 192 8520

Email

s_yousai@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Larestan University of Medical Sciences

Full name of responsible person

Dr. Mohsen Salmanpoor

Street address

Larestan University Of Medical Sciences, behind the

Larestan Grand Market, Karmand St, North Ghadir Blvd, Shahr_ejadid, Larestan, Fars, Iran.

City

Larestan

Province

Fars

Postal code

7153675541

Phone

+98 71 5225 5512

Email

s_yousai@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Larestan 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

Larestan University of Medical Sciences

Full name of responsible person

Somayeh Yousai

Position

Assistant Professor in Nutrition Science

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Larestan University Of Medical Sciences, behind the Larestan Grand Market, Karmand St, North Ghadir Blvd, Shahr_ejadid, Larestan, Fars, Iran.

City

Larestan

Province

Fars

Postal code

7153675541

Phone

+98 71 5225 5512

Email

s_yousai@yahoo.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Larestan University of Medical Sciences

Full name of responsible person

Somayeh Yousai

Position

Assistant Professor in Nutrition Science

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Larestan University Of Medical Sciences,behind the
Larestan Grand Market,Karmand St,North Ghadir
Blvd,Shahr_ejadid,Larestan,Fars,Iran.

City

larestan

Province

Fars

Postal code

7153675541

Phone

+98 71 5225 5512

Email

s_yousai@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Larestan University of Medical Sciences

Full name of responsible person

Maryam Ranjbar Zahedani

Position

Assistant Professor in Nutrition Science

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Larestan University Of Medical Sciences,behind the
Larestan Grand Market,Karmand St,North Ghadir

Blvd,Shahr_ejadid,Larestan,Fars,Iran.

City

Larestan

Province

Fars

Postal code

7153675541

Phone

+98 71 5225 5512

Email

ranjbarmaryam29@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No plan to release it

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

No plan to release it

When the data will become available and for how long

No plan to release it

To whom data/document is available

No plan to release it

Under which criteria data/document could be used

No plan to release it

From where data/document is obtainable

No plan to release it

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

No plan to release it

Comments