

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of laparoscopic sleeve gastrectomy on level of depression and dignity in adults who attended to Shiraz Ghadir Mother and ChildSubspecialized Hospital

Protocol summary

Study aim

Investigate the effects of laparoscopic sleeve gastrectomy on level of depression and dignity in adults who attended to Shiraz Ghadir Mother and Child Sub specialized Hospital

Design

The design of this research is a follow-up pre-test post-test with control group

Settings and conduct

The statistical population of this study is all obese patients who underwent laparoscopic surgery from November 2012 to September 2012 in Mother and Child Hospital in Ghadir, Shiraz. Using 60 available sampling methods, 60 of them will be selected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age range 21 to 55 years, BMI Top 35 Having at least education in reading and writing, patient consent with written consent for participation in research
Exclusion criteria: Severe psychiatric disorders and their related problems

Intervention groups

The experimental group will undergo surgery and the control group will not intervene After the end of the research, the control group will also undergo surgery

Main outcome variables

Self-esteem, Depression, energy loss, disturbance of concentration, sleep disturbances and appetite, physical pains, headaches and problems Gastrointestinal tract.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180523039802N1**

Registration date: **2018-08-12, 1397/05/21**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-12, 1397/05/21**

Update count: **0**

Registration date

2018-08-12, 1397/05/21

Registrant information

Name

Zahra Sobhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3227 9711

Email address

zahrasobhani120@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-21, 1396/08/30

Expected recruitment end date

2018-11-21, 1397/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of laparoscopic sleeve gastrectomy on level of depression and dignity in adults who attended to Shiraz Ghadir Mother and ChildSubspecialized Hospital

Public title

Effects of laparoscopic sleeve gastrectomy on level of depression and dignity in adults who attended to Shiraz Ghadir Mother and ChildSubspecialized Hospital

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age range of 21-55 years, BMI greater than 35, ability to read and write and patient agreement by submitting a written consent for participation in the research

Exclusion criteria:

Diabetes mellitus, Hypertension, Thyroid disorders
Psychosis, Mania, schizophrenia Inability to read and write Disagreement with the patient to participate in the research

Age

From **21 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

With power analysis, sixty of statistical population will be selected by using available sampling method and randomly simply with registration software in the hospital with matching divide into two groups (experimental and control).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

The statistical population will include all obese patients (BMI \geq 35) who are literate (at least reading and writing) and are aged 21 to 55 years (mean 28.23 and standard deviation 87.9); also, they are applicants for laparoscopic sleeve gastrectomy in Shiraz Ghadir Mother and Child Hospital during spring and summer of 2017. Sixty of them will be selected by using available sampling method and randomly with matching divide into two groups (experimental and control).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Zand Street, Shiraz University of Medical Sciences

City

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Postal code

71348-14336

Approval date

2017-08-05, 1396/05/14

Ethics committee reference number

IR.SUMS.REC.1396.S391

Health conditions studied

1

Description of health condition studied

obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

Depression

Timepoint

Before bariatric surgery and 3 to 6 months after bariatric surgery

Method of measurement

Beck Depression Inventory

2

Description

Self-esteem

Timepoint

Before bariatric surgery and 3 to 6 months after bariatric surgery

Method of measurement

3- Rosenberg Self-Esteem Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The group will undergo for bariatric surgery .

Category

Treatment - Surgery

2

Description

Control group: This group will not receive any

intervention.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Obesity Clinic of Shiraz University Of Medical Sciences

Full name of responsible person

Zahra Sobhani

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laparoscopy Research Center, Mother and Child Hospital Ghadir, above gate Quran, First Town Gulshan, Shiraz, iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Zahra Sobhani

Position

Ph.D non-faculty

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Professor

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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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

Due to the fact that the study is not yet done, so there is
no data file for publication

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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable