Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of lifestyle modification on The control of gastrointestinal complications and psychological disorders post sleeve gastrectomy surgery

Protocol summary

Study aim
Determining the effect of lifestyle modification on control of gastrointestinal complications and psychological disorders after sleeveogastrectomy

Design
Clinic trial will do with randomised, a control group,

Settings and conduct
The lifestyle modification training accomplish as a face to face with slide and pamfelete in the General Surgery Department of Valiasr Hospital in Naja before and after surgery in two sessions 45 minute. there is no blinding in our study.

Participants/Inclusion and exclusion criteria
include criteria: 1.All patients who have had a sleeve gastrectomy by the method of laparoscopic surgery 2.Patient to be have age group between 18 to 50 3.Participants to be have the minimum literacy and communication skills 4.patient not to have drug addiction 5.Patients who have got a final score of 0 to 59 according to DASS 21 (normal to moderate). exclude: 1.Patients who taking weight-loss medications concurrently

Intervention groups
Intervention group contain patients who will get education of life style modification. control group include the patients who get intera partial routine education of sleevegastrectomy.

Main outcome variables
1- Gastrointestinal complications (nausea,vomite, diaria and damping syndrom) after a slug gastrectomy is esteemed. 2- Psychological disorders (stress, anxiety and depression) after a slug gastrectomy is measured.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190528043738N1**
Registration date: **2020-06-06, 1399/03/17**
Registration timing: **retrospective**

Last update: **2020-06-06, 1399/03/17**
Update count: **0**

Registration date
2020-06-06, 1399/03/17

Registrant information

Name
Robabe Khalili

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8248 3505

Email address
khalili1120@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-06, 1398/07/14

Expected recruitment end date
2020-03-04, 1398/12/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of lifestyle modification on The control of gastrointestinal complications and psychological disorders post sleeve gastrectomy surgery

Public title
Lifestyle modification of patient with sleeve gasterectomy
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
All patients who have had a sleeve gastrectomy by the method of laparoscopic surgery Patient to be have age group between 18 to 50 participants do not have drug addiction Participants to be have the minimum literacy and communication skills patient not to have drug addiction Patients who have got a final score of 0 to 59 according to DASS 21 (normal to moderate).
Exclusion criteria:
Patients who taking weight-loss medications concurrently.
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants were selected through available sampling, so that eligible patients were included in the study process and divided into groups A and B. Group A was the control group and group B was the test group. For this division, the blocking method was used, in which 35 cards called A and 35 cards called B were placed in an envelope. When the patient entered to the study, the patients took one of the cards and were placed in the control or test group according to the card they took (A or B). After taking each card by the patient, the card was discarded. In this way, all patients had the same chance to enter both control and test groups.
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
Ethics committee of Baqiyatllah University of Medical Sciences
Street address
Nosrati alley., South Sheikh Bahaei ave.,vanak square.,Tehran.
City
Tehran
Province
Tehran
Postal code
1435916471
Approval date
2019-09-02, 1398/06/11
Ethics committee reference number
IR.BMSU.REC.1398.176

Health conditions studied

1

Description of health condition studied
life style modification in patients with sleeve gastrectomy
ICD-10 code
K95
ICD-10 code description
Complications of bariatric procedures

Primary outcomes

1

Description
The percentage of Gastrointestinal Complications (nausea, vomite, dumping syndrom, constipation) after sleeve gasterectomy
Timepoint
Pre and 2 month after educational intervention
Method of measurement
researcher made Questionnaire of Gastrointestinal Complications

2

Description
The score of Psychological complication (stress, anxiety, depression) after sleeve gasterectomy
Timepoint
Pre and 2 month after educational intervention
Method of measurement
The Depression, Anxiety and Stress Scale - 21 Items (DAS S21)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Life style training content to patient

with sleeve gastrectomy surgery is done through face-to-face and by using an educational pamphlet during four one-hour sessions (two sessions before surgery and two sessions after surgery) in the clinic's training room.The content of the training includes lifestyle modification in four dimensions: physical health and nutrition (diet and achieving and maintaining optimal weight), exercise and physical activity, mental health and mental health, which is prepared and based on the evidence and opinion of experts in this field. It will also be evaluated by the research team and will be implemented after approval.

Category

Lifestyle

2

Description

Control group: Routine training into setting to patient with sleeve gastrectomy surgery is given through Face to face once or twice for fifteen minutes and also an educational pamphlet is given while discharing.The content of routine training into setting includes following a diet and how to take care of nutrition and how to physical activity and referal time to therapeutic doctor.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Naja Hospital

Full name of responsible person

Doctor Ayatollah Ebadi

Street address

Above the intersection of Mirdamad, Zafar avenue.,Valiasr street., Tehran.

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Web page address

https://www.drsosha.com/مراکز-درمانی/بیمارستان-ولیعصر

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Doctor Alireza Jalali

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Nosrati alley., South Sheikh Bahaei ave.,vanak square.,Tehran.

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nresearch94@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Doctor Robabe Khalli

Position

Assistant 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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Doctor Robabe Khalili
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Undecided - It is not yet known if there will be 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
The part of data related to cheif consequences will be shared after unrecognization of patients.
When the data will become available and for how long
6 month after results publuishing in dissertation booklet.
To whom data/document is available
Student, Researchers,Patients and their Families.
Under which criteria data/document could be used
Written request to the research and Obtaining a license, can access to the part of data from researcher. Also, datas can just be used for scientific and research goals.
From where data/document is obtainable
Refer to researcher of research project with Email address:zkamali1358@gmail.com.
What processes are involved for a request to access data/document
Accomplish written Request to research assistant in university and department and after that reviewing by Research Team, and decision will make about that.
Comments