

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effectiveness Of Nutritional Counselling Among Post-Op Sleeve Gastrectomy Patients In Terms Of Quality Of Life.

Protocol summary

Study aim

The aim of this study was to investigate the impact of nutritional counselling on the quality of life of patients who have undergone Sleeve Gastrectomy.

Design

Randomized Control Trial (RCT) was performed utilized a simple random sampling using lottery method. The study compared the quality of life of post-op patients that have undergone sleeve gastrectomy and who received nutritional counselling with those who did not receive any counselling.

Settings and conduct

The study was conducted in the General Surgery Department at Ammar Medical Complex Lahore and had a duration of 6 months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The study's inclusion criteria included male and female patients aged between 18 to 60 years who have undergone bariatric surgery within 6 months, with no prior bariatric surgery, fractures or limb issues, and no coexisting diseases that affect limb function. This criteria helped in reducing confounding variables
Exclusion criteria: Patients under the age of 18 or older than 60, those with a history of bariatric surgery that lasted longer than six months, those with limb fractures, pregnant women with a history of bariatric surgery, those taking antidepressants, and those who refused to adhere to the study's protocol were all excluded from the study. These requirements helped to accurately represent the study's target group and to reduce any potential confounding variables that might have had a detrimental impact on the study's findings.

Intervention groups

A crucial component of sleeve gastrectomy is nutritional counselling, which assists patients in adjusting to dietary changes and achieving the best possible results in terms of weight loss and health

Main outcome variables

effectiveness of nutritional counselling

General information

Reason for update

Acronym

rct

IRCT registration information

IRCT registration number: **IRCT20240415061496N2**

Registration date: **2024-06-08, 1403/03/19**

Registration timing: **registered_while_recruiting**

Last update: **2024-06-08, 1403/03/19**

Update count: **0**

Registration date

2024-06-08, 1403/03/19

Registrant information

Name

Dr amna amar butt

Name of organization / entity

Ammar medical complex

Country

Pakistan

Phone

+92 335 4614376

Email address

amaramarbutt123@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-06-03, 1403/03/14

Expected recruitment end date

2024-10-03, 1403/07/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness Of Nutritional Counselling Among Post-Op Sleeve Gastrectomy Patients In Terms Of Quality Of Life.

Public title

Effectiveness Of Nutritional Counselling Among Post-Op Sleeve Gastrectomy Patients In Terms Of Quality Of Life

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

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Patients under the age of 18 or older than 60, those with a history of bariatric surgery that lasted longer than six months, those with limb fractures, pregnant women with a history of bariatric surgery, those taking antidepressants, and those who refused to adhere to the study's protocol were all excluded from the study. These requirements helped to accurately represent the study's target group and to reduce any potential confounding variables that might have had a detrimental impact on the study's findings

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **145**

Randomization (investigator's opinion)

Randomized

Randomization description

This study will be based on six-month randomized control trial conducted in the General Surgery Department at Ammar Medical Complex Lahore with 145 eligible participants who were randomly divided into two groups. will be selected through lottery methord

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

interventional

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethical committee of Ammar Medical Complex, Lahore

Street address

G8MV+X55 Ammar Medical Complex:, Jail Rd, Gulberg V, Lahore, Punjab

City

lahore

Postal code

54000

Approval date

2024-06-03, 1403/03/14

Ethics committee reference number

10006

Health conditions studied

1

Description of health condition studied

sleeve gastrectomy patients

ICD-10 code

E90*

ICD-10 code description

Nutritional and metabolic disorders in diseases classified elsewhere

Primary outcomes

1

Description

Any difference in results between the groups has the potential to enhance current practice and patient life significantly. The purpose of this study is to contribute to the literature by comparing nutritional counselling. In nutritional counselling group, better results with the sleeve gastrectomy will encourage the demand of this minimally invasive counselling

Timepoint

4 months

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: While the other group in the trial did not receive any nutritional counselling, one group in the study received nutritional counselling for six months after surgery

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Ammar Medical Complex, Lahore

Full name of responsible person

dr amna amar butt

Street address

110,A,C-2, johar town lahore

City

lahore

Postal code

54782

Phone

+92 335 4614376

Email

amaramarbutt123@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ammar Medical Complex, Lahore

Full name of responsible person

dr maaz ul hassan

Street address

110,A,C-2, johar town lahore

City

lahore

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amaramarbutt123@gmail.com

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

No

Title of funding source

educational research

Proportion provided by this source

100

Public or private sector

Private

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

Ammar Medical Complex, Lahore

Full name of responsible person

dr amna amar butt

Position

bariatric dietitian

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

110,A,C-2, johar town lahore

City

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Province

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Postal code

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Phone

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Email

dramnaamarbutt@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ammar Medical Complex, Lahore

Full name of responsible person

dr maaz ul hassan

Position

general surgeon

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

110,A,C-2, johar town lahore

City

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Province

punjab

Postal code

54782

Phone

+92 335 4614376

Email

amaramarbutt123@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Ammar Medical Complex, Lahore

Full name of responsible person

dr amna amar butt

Position

bariatric dietitian

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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

No - There is not 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

Effectiveness of nutritional counselling among post-op

Mini-gastric Bypass patients in terms of Quality of life

When the data will become available and for how long

after 6 months

To whom data/document is available

to the research investigator

Under which criteria data/document could be used

Data will be gathered using the meticulously created clinical proforma, which were then entered into, evaluated, and analyzed using the SPSS programmer version 22. Means and standard deviations were used to describe quantitative data.

From where data/document is obtainable

dramnaamarbutt@gmail.com

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

application

Comments