

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 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:**  
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

**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

**Postal code**

54782

**Phone**

+92 335 4614376

**Email**

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**

punjab

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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

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## 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

**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nutrition  
**Street address**  
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amaramarbutt123@gmail.com

## 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 invesigator

### 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