

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effectiveness of nutritional counselling among post-op Mini-gastric Bypass patients in terms of Quality of life.

#### Protocol summary

##### Study aim

The aim of this study is to compare improvement in Quality of life after nutritional counselling among post-op MGB patients.

##### Design

Prospective comparative study

##### Settings and conduct

The study will be conducted in General Surgery Department, Ammar Medical complex Lahore, Pakistan.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria • Patients with either gender with age group ranging between 18 to 60 years. • Patients with bariatric surgery which was not older than 6 months. • Patients with no fracture or limbs issue. • No previous bariatric surgical history • No coexisting diseases affecting the function of the limbs. Exclusion criteria • Patients below 18 and above 60 years of age. • Patients with bariatric surgery more than 6 months. • Patients with fractures of limbs. • Pregnant ladies after a bariatric surgery were not a part of it. • Patients who were suffering from depression and taking anti-depressant medication. • Patients who refuse our protocol.

##### Intervention groups

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 MGB will encourage the demand of this minimally invasive counselling.

##### Main outcome variables

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 MGB will encourage the demand of this minimally invasive counselling

#### General information

##### Reason for update

##### Acronym

NCT

##### IRCT registration information

IRCT registration number: **IRCT20240415061496N1**

Registration date: **2024-05-18, 1403/02/29**

Registration timing: **registered\_while\_recruiting**

Last update: **2024-05-18, 1403/02/29**

Update count: **0**

##### Registration date

2024-05-18, 1403/02/29

##### 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

2024-05-04, 1403/02/15

##### Expected recruitment end date

2024-10-04, 1403/07/13

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Effectiveness of nutritional counselling among post-op Mini-gastric Bypass patients in terms of Quality of life.

## Public title

Effectiveness of nutritional counselling among post-op Mini-gastric Bypass patients in terms of Quality of life.

## Purpose

Basic science

## Inclusion/Exclusion criteria

### Inclusion criteria:

• Patients with either gender with age group ranging between 18 to 60 years. • Patients with bariatric surgery which was not older than 6 months. • Patients with no fracture or limbs issue. • No previous bariatric surgical history • No coexisting diseases affecting the function of the limbs.

### Exclusion criteria:

• Patients below 18 and above 60 years of age. • Patients with bariatric surgery more than 6 months. • Patients with fractures of limbs. • Pregnant ladies after a bariatric surgery were not a part of it. • Patients who were suffering from depression and taking anti-depressant medication. • Patients who refuse our protocol.

## Age

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

## Gender

Both

## Phase

0

## Groups that have been masked

No information

## Sample size

Target sample size: **120**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Simple random sampling using lottery method.

## 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

ammar medical complex etjcal committee

##### Street address

Ammar Medical Complex, Lahore

##### City

lahore

## Postal code

54000

## Approval date

2024-05-07, 1403/02/18

## Ethics committee reference number

1004

## Health conditions studied

### 1

#### Description of health condition studied

bariatric surgery post op patients

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

. The purpose of this study is to contribute to the literature by comparing nutritional counselling.

#### Timepoint

4 months after surgery

#### Method of measurement

The clinical proforma (annexure-I) will collect data, fed into, assessed, and analyzed using the SPSS software version 22. Quantitative data will be described as means and standard deviations. Percentages and frequencies would be determined for qualitative data. Linear regression analysis will be performed to determine correlation of age, gender and clinical outcome

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group:

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

The study will be conducted in General Surgery Department, Ammar Medical complex Lahore.

##### Full name of responsible person

dr amna amar butt

##### Street address

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

##### City

lahore  
**Postal code**  
54000  
**Phone**  
+92 335 4614376  
**Email**  
amaramarbutt123@gmail.com

lahore  
**Province**  
punjab  
**Postal code**  
54782  
**Phone**  
+92 335 4614376  
**Email**  
dramnaamarbutt@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
ammar medical complex  
**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?**  
Yes  
**Title of funding source**  
ammar medical complex  
**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**  
Persons

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**  
ammar medical complex  
**Full name of responsible person**  
dr amna amar butt  
**Position**  
bariatric dietitian  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nutrition  
**Street address**  
122,A,C-2, johar town lahore  
**City**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
ammar medical complex  
**Full name of responsible person**  
prof dr maaz ul hassan  
**Position**  
general surgeon  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
General Surgery  
**Street address**  
ammar medical complex  
**City**  
lahore  
**Province**  
punjab  
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54000  
**Phone**  
+92 300 9421994  
**Email**  
drmaaz@hotmail.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
ammar medical complex  
**Full name of responsible person**  
dr amna amar butt  
**Position**  
bariatric dietitian  
**Latest degree**  
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54782  
**Phone**  
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**Email**  
dramnaamarbutt@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

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

Effectiveness Of Nutritional Counselling Among Post-Op

Mini Gastric Bypass Patients In Terms Of Quality Of Life

This study was a six-month randomized control trial

conducted in the General Surgery Department at Ammar

Medical Complex Lahore. The study included 145 eligible participants who had undergone bariatric surgery within six months and had no prior bariatric surgery, fractures, limb issues, or coexisting diseases affecting limb function. The participants were randomly divided into two groups, one receiving nutritional counseling and the other not. The data were analyzed using SPSS software version 22, and descriptive statistics were calculated

### When the data will become available and for how long

after 4 months

### To whom data/document is available

to dr amna amar butt

### Under which criteria data/document could be used

for publication purpose only

### From where data/document is obtainable

from hospital

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

application form

### Comments