Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Treatment - Other

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
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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
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Email
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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
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Ammar Medical Complex, Lahore
Full name of responsible person
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Position
general surgeon
Latest degree
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Person responsible for updating data

Contact

Name of organization / entity
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bariatric dietitian

Latest degree
Bachelor
Other areas of specialty/work
Nutrition
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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 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