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Investigating the effect of combining motivational, nutritional and exercise programs on weight loss following surgery to treat obesity

Submission date
01/12/2018

Recruitment status
No longer recruiting

Registration date
27/03/2019

Overall study status
Completed

Last Edited
12/08/2022

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Bariatric surgery is surgery to increase weight loss in obese people. This includes gastric band and gastric sleeve surgery, in which the size of the stomach is reduced so that it can only handle small amounts of food eaten slowly. Weight loss after bariatric (obesity) surgery can be hampered by unhealthy behaviors such as poor diet and physical inactivity. The aims of the study were to investigate how well a motivational, nutritional and exercise program works in terms of improving weight loss and physical condition in patients after surgery.

Who can participate?
Adults who had had gastric band or gastric sleeve surgery in the previous 1-6 months.

What does the study involve?
Participants who chose to take part in the activities had monthly motivational group meetings with a psychologist, monthly nutritional group meetings with a dietician, and twice-weekly group sessions of adapted exercise guided by exercise professionals. Weight, body measurements, diet, attitudes towards food, physical activity and quality of life, and physical strength and range of movement were measured before the start of the program, at the end of the program (1 year later) and at follow-up (2 years after the start of the program). Patients who agreed to participate in the study but were unable to take part in the activities provided the same information.

What are the possible benefits and risks of participating?
The treatment was educational and motivational. Physical activity protocols were personalized to each patient to avoid any possible risk. Participants might improve their health and speed up their weight loss.

Where is the study run from?
University of Naples Parthenope (Italy)

When is the study starting and how long is it expected to run for?
September 2015 to November 2017

Who is funding the study?
The University of Naples Parthenope

Who is the main contact?
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Contact information

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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Lifestyle Intervention after Obesity Surgery (LIOS): Educational and motivational exercise-based program to improve surgery outcomes in bariatric patients.

Acronym
LIOS

Study objectives
A multidisciplinary lifestyle intervention may prevent weight regain and improve health and quality of life in bariatric patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Board of the Department of Movement Sciences and Wellbeing of the University of Naples Parthenope and of the Hospital Villa Betania in Naples, 18/12/2014, ref 998/2014)

Study design
Single-centre interventional controlled non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Obesity

Interventions

The structured intervention lasted 12 months and included a motivational program, a nutritional program and an exercise program.
1.The motivational program was carried out through periodical series of bi-weekly group meetings lasting 90 minutes and guided by a psychologist with expertise on motivational interviewing for behavior change. The first sessions were focused on the reciprocal introduction of participants and on their readiness for change; subsequently their knowledge, attitudes and beliefs regarding physical activity and diet were explored.
2. The nutritional program was conducted through monthly group meetings lasting 90 minutes with a trained nutritionist. It was structured in a first phase aimed to investigate the nutritional habits of participants and in a subsequent intervention including the discussion of the effects of diet on weight management and the suggestion of healthy food choices and solutions to manage nutrition through an adequate daily distribution of meals and nutrients.
3. The exercise program was provided through one-hour training group sessions performed two times per week on non-consecutive days and guided by exercise professionals. Training was adapted to participants' conditions and periodically modified based on their advances. It included moderate-to-vigorous aerobic and resistance exercises.
All the activities were performed in the same facility and by the same operators throughout the whole intervention.
The protocol for control patients consisted of a meeting with their bariatric surgeon at 12 months after surgery.

Intervention Type
Behavioural

Primary outcome measure
Weight at at the start of the intervention (0 months), the end of the intervention (12 months) and at follow-up (24 months)

Secondary outcome measures
1. Food choices and dietary patterns were estimated by asking participants to record the type and amount of food and beverage consumed for 7 days before
2. Eating behaviors and feeling/cognitions regarding binge eating episodes were explored through the 16-item Binge Eating Scale
3. Quality of life and attitudes towards physical activity assessed using Obesity-Related WELL-being questionnaire (ORWELL-97)
4. Physical fitness assessed using squat test, dynamometer for grip strength, and Rockport walking test
5. Posture assessed using carbon paper
6. Functional disabilities assessed using the Oswestry Low Back Pain Disability Questionnaire
7. Body mass index calculated from weight and height measurements
8. Waist and hip circumference assessed using carbon paper
9. Articular range of motion assessed using a medical goniometer
All outcome measures were recorded at the start of the intervention (0 months), the end of the intervention (12 months) and at follow-up (24 months)

Overall study start date
01/09/2015

Completion date
30/11/2017

Eligibility

Key inclusion criteria
Undergoing first bariatric surgery (laparoscopic sleeve gastrectomy or laparoscopic adjustable gastric banding)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
20

Total final enrolment
82

Key exclusion criteria
1. Substance dependence
2. Current treatment for psychiatric/psychological disorders
3. Physical unsuitability

Date of first enrolment
01/11/2015

Date of final enrolment
30/11/2015

Locations

Countries of recruitment
Italy

Study participating centre
Hospital Villa Betania
Via Argine
Naples
Italy
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Sponsor information

Organisation
University of Naples Parthenope, Department of Movement Sciences and Wellbeing

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Sponsor type
University/education

ROR
https://ror.org/05pcv4v03

Funder(s)

Funder type
University/education

Funder Name
University of Naples Parthenope

Results and Publications

Publication and dissemination plan
Planned publication of the results in high-impact peer-reviewed international journals in 2019.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon detailed and well-motivated request to the representatives of the study. They will be shared in an aggregate form, respecting the anonymity guaranteed to the participants through the informed consent.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/10/2020	15/02/2021	Yes	No

Protocol file	12/08/2022	No	No