**Project: Multidisciplinary path of nutritional education, motivational support and adapted physical activity as a therapeutic tool in obese subjects undergoing bariatric surgery**

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**Background**

Obesity is a multifactorial condition: genetic, environmental and individual factors contribute to determine an alteration of caloric intake and energy use, with consequent excessive fat accumulation. Worldwide, the prevalence of obesity has doubled since 1980. In 2014, more than 11% of adult men and 15% of women were obese. In 2013, more than 42 millions children aged ≤5 years were overweight.

In 2014, more than on third of the adult Italian population (36,1%) was overweight, and one person out of ten (10,3%) was obese (http://dati.istat.it/).

Obesity increases the risk of diabetes, hypertension, cardiovascular diseases and some type of cancer, and has important socio-economic costs. The European Chart on Fighting Obesity Actions states that obesity and overweight in adults are responsible for the 8% of the healthcare costs in the European Region; indirect costs, related to human lives, productivity and gaining lost, are more than double of direct costs for hospitalization and care.

Scientific literature shows that bariatric surgery may be a useful instrument to contrast severe obesity, by limiting its clinical and economic consequences.

However, surgery is not always sufficient to resolve obesity: in order to maximize its outcomes is necessary to encourage in patients the adoption of correct dietary habits, by reducing fat and sugar intake and increasing fruit and vegetables assumption, and the increase of physical activity levels, to control weight. These strategies may integrate and remodulate the therapeutic path of obese patient, in order to improve his quality of life.

In the last decades, structured educational interventions aimed at improving unhealthy habits in bariatric patients have been implemented in the USA and in several European countries.

These interventions have evidenced the importance of adapted physical activity together with counseling after surgery in supporting patients to adopt healthy choices regarding food intake and physical activity.

Employing a multidisciplinary intervention as an instrument to promote health may be considered a real health technology and be evaluated. In this case the intervention can be assessed by an

economic perspective in order to evaluate its sustainability and the achievable savings through a health technology assessment approach.

**Subjects**

Adult obese patients undergoing bariatric surgery with or without comorbidities, who do not refer psychological or physical limitations to physical activity.

**Objectives**

To design an integrated exercise-based motivational and educational path to promote lifestyle changes in bariatric patients.

Specific aims:

- communicate the importance of physical activity in the therapeutic path;
- provide information about nutrition in order to make patients aware of unhealthy habits;
- improve the adherence to the guidelines of mediterranean diet;
- provide useful instruments for weight control;
- improve self-esteem and self-efficacy to promote the ability of the subjects in taking the right decisions for their own health;
- address patients to exercise and motivate them to increase their compliance;
- improve health and health perception by promoting the adoption of healthy behaviors;
- evaluate economic benefits deriving by this multidisciplinary intervention.

**Materials and methods**

Bariatric patients will be invited no more than six months after surgery.

Those who will agreed to participate will be asked to give their informed consent (Attachment 1).

Patients will be voluntarily allocated in two groups: the intervention group, which will be addressed to the integrated path of exercise (adapted moderate-to-vigorous physical activity for 2-3 60 min. sessions per week) and educational/motivational support, and the control group, which will undergo Treatment As Usual (TAU). Patients will be recruited progressively. The minimum sample size is 6 (intervention/control ratio 1:2) to reach a power of 90% with a 95%IC.

Participants to the intervention will be asked to provide a medical certification for physical conditions.

The exercise program will consist of 60-minute training sessions carried out two times per week and supervised by exercise specialists with expertise in adapted physical activity. Training protocols will be tailored to participants' conditions; the intensity of exercise will be periodically increased

according to the advances of the subjects. Each session will be composed by five phases: warm-up (10 min) including continuous walking or marching and exercises for joint activation; aerobic training (25 min) consisting of moderate and high-intensity brisk walking targeted at the level 4 of the Borg's scale; exercises (15 min) to enhance strength of lower and upper limbs at 70-85% of repetition maximum (2 exercises, 3 sets of 12 repetitions); cool-down phase with agility/balance exercises (5 min) and flexibility static and dynamic exercises (5 min).

As for the motivational support, it will be performed 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 will be focused on the reciprocal introduction of participants and on their readiness for change; subsequently their knowledge, attitudes and beliefs regarding PA and diet will be explored.

The nutritional program will be conducted through monthly group meetings lasting 90 minutes with a trained nutritionist. It will be structured in three moments:

- the assessment of the nutritional habits of participants
- the discussion of the effects of diet on weight management
- the proposal of healthy food choices and solutions to manage nutrition through an adequate daily distribution of meals and nutrients.

Before to starting the activities in participants will be evaluated:

- physical conditions, through the assessment of blood pressure, anthropometric indexes, drug use and blood levels of glucose, glycated haemoglobin, triglycerides, cholesterol;
- psychological conditions, through the use of the Binge Eating Scale (BES) to assess the presence of binge eating disorder, of the Obesity Related Well-Being (ORWELL 97) questionnaire to evaluate quality of life, and of the Dropout Risk Profile (DRP) questionnaire to explore the motivation for behavioral change;
- nutrition, through the calculation of individual energy balance by analyzing food intake and body composition, together with daily energy requirements;
- physical activity levels, through the International Physical Activity Questionnaire;
- aerobic capacity (Test di Rockport), perceived exertion (Borg's scale), upper (dynamometer) and lower (Squat Test) limbs strength, flexibility of shoulder, elbow, ankle and knee (Range of Motion through a goniometer);
- disability deriving from back pain, through the Oswestry Low Back Pain Disability Questionnaire (OLBPDQ);
- foot posture, through the use of carbon paper.

These measurements will be repeated after 12 months since the start of the intervention.

The physical and psychological outcomes obtained from the two groups will be compared to evaluate the effectiveness of the multidisciplinary intervention. A health technology assessment will be carried out to evaluate its economic benefits.

**Statistical analyses**

For each group, mean values ± SD of continuous variables at the start and at the end of the intervention will be calculated. These values will be compared through the Student's *t* test for repeated measures, while the comparison between the two groups will be made through ANCOVA. Categorical variables will be analyzed through the chi squared test.

The significance level assumed will be p=0.05.

**Timing**

The intervention will last 12 months. At least 2 months before and 2 months after will be required for patients' recruitment and data collection and analysis.

**Required resources**

At least a psychologist, a nutritionist and two movement science experts will be needed, on the basis of participants' number.

A facility with a room for group meetings and a room equipped for physical activity is also required.

**Expected results**

We expected significant differences in surgery outcomes between intervention and TAU groups.

The considered outcomes will be:

- anthropometric measures
- quality of life and binge eating disorder
- dietary habits
- physical activity levels
- aerobic capacity, limbs strength, flexibility, disability and feet posture
- achievable savings.

**Expected issues**

Low compliance of participants to the intervention and drop-out at follow-up.

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