RESEARCH PROJECT

Research title: “Study of the impact of nutritional reeducation towards a Mediterranean diet plan on the evolution of weight loss in subjects after intragastric endoscopic treatment”.

Index:

Date: January 25, 2020

1.1 Study Protocol

Eligibility criteria included: ≥18 years old, Body mass index > 30 kg/m², no previous gastric intervention, no hiatus hernias, not being pregnant or in breastfeeding, having no cardiac problems, regular values in coagulation and blood count, and positive psychological evaluation. Participants followed a liquid diet plan during the first week after the endoscopic bariatric procedure (BioEnterics Intragastric Balloon and Primary Obesity Surgery Endoluminal). Subjects are randomly assigned either a Mediterranean-style or a protein-style diet plan. Energy intake was calculated according to the Spanish Consensus on Bariatric Endoscopy and the percentage macronutrients (expressed as % of the total caloric content) was as follows: Mediterranean-style diet plan: 22% proteins, 53% carbohydrates, and 25% of lipids, and the protein diet plan: 40% proteins, 29% carbohydrates, and 31% of lipids.

The postoperative follow-up of the patient consists of a visit every week for 24 weeks. During these visits, the dietitian-nutritionist monitors the anthropometric parameters and explains to the patient the pertinent dietary guidelines that the patient should follow. At the end of the bariatric treatment, the patient is re-visited at 12 weeks for a final assessment of both anthropometric parameters and dietary intake. This point will be the end of the study. The data collection will consist of: anthropometric measurements (weight, percentage of fat and muscle mass, using the scale of muscle mass, using the TANITA impedance scale, waist and hip diameters with a standardized metric with standardized metric tapes) and assessment of dietary intake (through 24-hour reminders and dietary and dietary records) and adherence to the Mediterranean diet filling a questionnaire. Figure 1 shows the CONSORT flow diagram of participants.

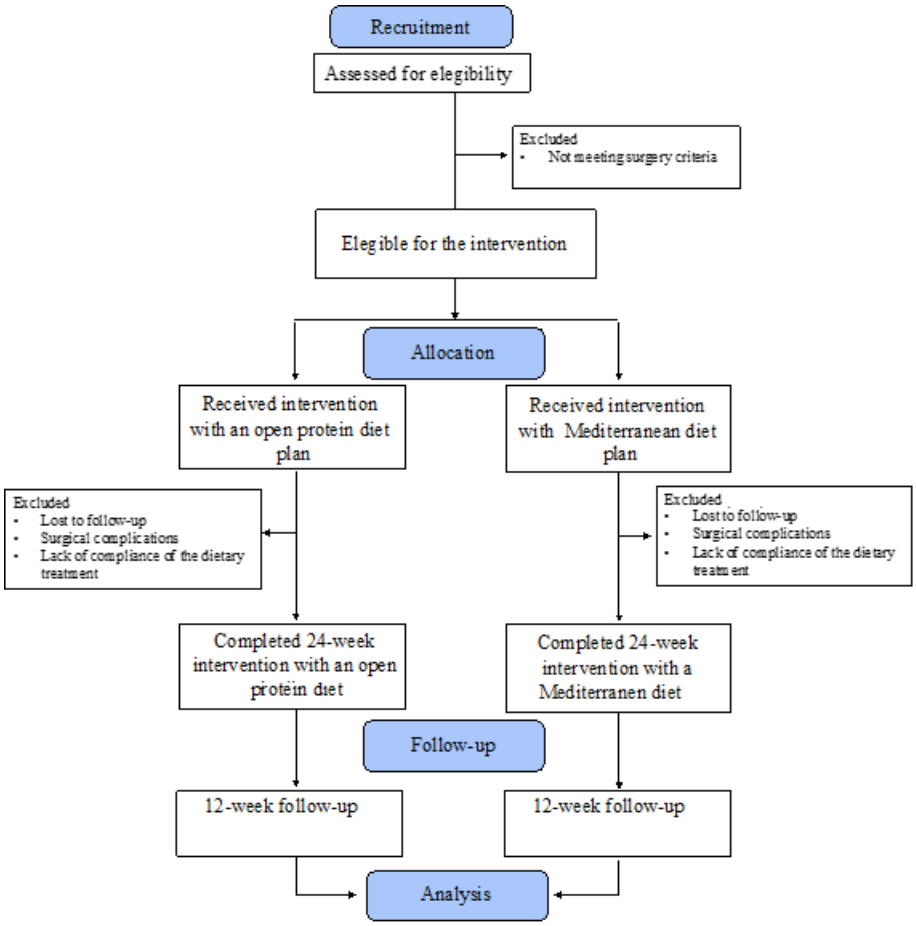

Figure 1. CONSORT flow diagram of participants

1.2 Statistical Analysis Plan

The data obtained will be included in a database, entirely coded to ensure the participants' anonymity and will be treated according to the Data Protection Law. Once the study has been completed, the database will be cleaned to minimize errors and statistical analysis will be carried out using SPSS 25 software. A descriptive analysis will be performed for qualitative variables using frequencies and percentages, particularly for quantitative variables, the mean, median, and standard deviation will be determined. Also, multivariate linear regression models will be considered to adjust for confounding factors. Dependence between qualitative variables will be tested by the chi-square test and adjusted for confounding factors by multivariate logistic or multinomial multivariate regression models. We will work with a confidence level of 95% and the difference between variables will be considered significant when the degree of significance p-value is less than 0.05.

The data obtained in this study will not be transferred to other studies. Neither the patients nor the patients nor any researcher of the team will receive financial or any other type of compensation for participating in the project.

1.3 PARTICIPANT INFORMATION SHEET

Research title: Study of the impact of nutritional reeducation towards a Mediterranean diet plan on the evolution of weight loss in subjects after intragastric endoscopic treatment.

Date:.....

You have been invited to participate in a research protocol that aims to determine the impact of nutritional reeducation on the Mediterranean diet on the evolution of weight loss in people with obesity after intragastric endoscopic treatment.

The study consists of a nutritional follow-up in which you will be given guidelines on the type of diet you should follow for 24 weeks after intragastric endoscopy. The data collection will consist of anthropometric measurements (weight, percentage of fat and muscle mass, using the scale of muscle mass, using the TANITA impedance scale, waist and hip diameters with a standardized metric with standardized metric tapes) and assessment of dietary intake (through 24-hour reminders and dietary and dietary records) and adherence to the Mediterranean diet filling a questionnaire. Three months after finishing the treatment, you will be contacted again to re-record your anthropometric measurements. This point will be the end of the study. All these measurements are non-invasive.

The procedure to which you will be submitted does not entail any benefit or risk to your health, nor are there any contraindications for the test's performance. No specific extraordinary test will be performed for this study. The Principal Investigator of this Project and his collaborators are at your disposal to clarify any doubts you may have before giving your consent. You may contact the Principal Investigator by calling the telephone number listed on this document's last page.

It is understood that both your possible participation in the study and your refusal to participate in it do not have any repercussions on future medical acts. If you wish to participate, this does not entail any obligation to terminate the experiment, so that you are free to terminate your participation at any time you want to. After your withdrawal, no further data will be collected about you, but the data already collected will be used.

Confidentiality and privacy

The information collected during the study will be coded. Any data that can identify you (name, social security number, NIF, etc...) will be eliminated and replaced by a code. The list of codes in which the participants are identified will be accessible only to the study investigators and, in exceptional cases, to members of the Research Ethics Committee and Health Authorities. Your data will, therefore, be given in the coded form.

The processing, communication and transfer of personal data of all participating subjects will follow the regulation 15/1999 of 13th December to protect personal data. The data will be collected in a research centre file and processed solely and exclusively in the context of their participation in this study.

Following the regulation of data protection legislation, you may exercise your rights of access, modification, opposition and cancellation of data by contacting your study doctor.

Only the data collected for the study will not be transmitted to third parties and other countries. In no case will it contain information that can directly identify you, such as name and surname, initials, address, social security number, etc. If this transfer occurs, it will be for the study's same purposes described and guaranteeing confidentiality.

Financial compensation:

No financial compensation is considered in this study.

Principal Investigator:

Contact phone number:

Date and place:

1.4 INFORMED CONSENT FORM

TITLE: EFFECTIVENESS OF THE MEDITERRANEAN-STYLE DIET PLAN ON WEIGHT LOSS IN PATIENTS WITH OBESITY AFTER ENDOSCOPIC BARIATRIC TREATMENT

The undersigned,

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declares that:

- I have read the information sheet regarding the project and have been able to ask questions about the study and received sufficient information about it.

- I have been able to ask questions about the study and have received sufficient information about it.

- It has been explained to me that my participation in the study is entirely voluntary

- I can withdraw from the study at any time I consider it appropriate, without giving explanations and without this having any repercussions on my future medical care.

- In accordance with the provisions of the Organic Law 15/1999 of 13th December 1999 on the Protection of Personal Data (Article 3, point 6 of Royal Decree 223/2004), I declare that I have been informed of the existence of a file or processing of personal data, the purpose of the collection of such data and the recipients of the information.

Therefore, after having spoken with the principal investigator,

Signature of the participant.

Date: ____/____/____/____

Signature of a family member in charge (in case of the participant's disability).

Date: ____/____/____/____

Signature of Principal Investigator.

Date: ____/____/____

Relationship.....