STUDY PROTOCOL

Randomized Clinical Trial to assess the safety and efficacy of a mobile application to accompany and empower patients undergoing bariatric surgery: the **VAMOS** project (**V**irtual **A**ccompaniment for **M**orbid **O**besity **S**urgery)

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PROTOCOL CODE: HUB-CIR-VAMOS

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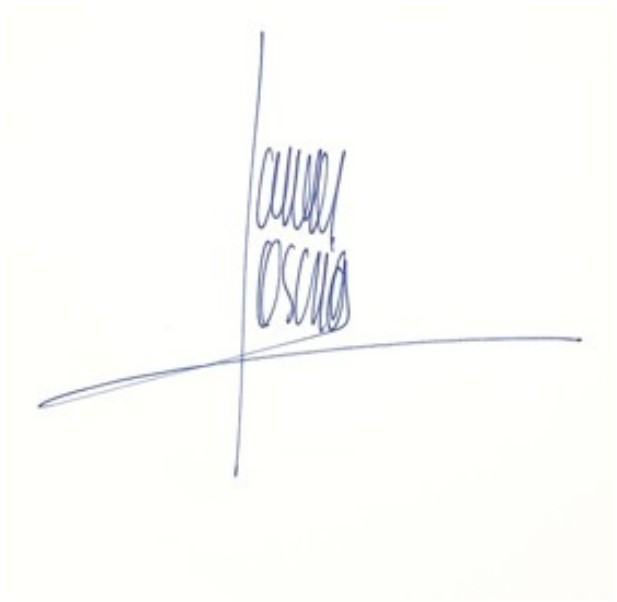
Versión of 09-july- 2022

SIGNATURE Principal investigator:
I have read and agree to the protocol titled: "Randomized Clinical Trial to assess the safety and efficacy of a mobile application to accompany and empower patients undergoing bariatric surgery: the **VAMOS** project (**V**irtual **A**ccompaniment for **M**orbid **O**besity **S**urgery)".

I am informed of my responsibilities as Principal Investigator under Good Clinical Practice (GCP) standards, local legislation and the study protocol. I agree to conduct the study in accordance with these standards, and to properly direct and assist the team under my charge that will conduct the study.

Principal investigator



Signature: Dr. JAVIER OSORIO Date 09/07/2022

1. RESUME

Principal Investigator name: Dr. Javier OSORIO		
STUDY TITLE: Randomized Clinical Trial to assess the safety and efficacy of a mobile application to accompany and empower patients undergoing bariatric surgery: the **VAMOS** project (**V**irtual **A**ccompaniment for **M**orbid **O**besity **S**urgery)		
STUDY TYPE: Randomized Clinical Trial		

INTRODUCTION:

Morbid obesity is considered the great epidemic of our century. It is regarded as the first non-traumatic cause of death in the western population and it is also progressively beginning to affect developing countries. The latest epidemiological studies estimate that in Spain more than 15% of the population has overweight and about 5% has morbid obesity.

Obesity treatment is multidisciplinary, from lifestyle and dietary changes to surgery. Amongst the different available treatments, bariatric surgery is the only cost-effective in patients with morbid obesity. Bariatric surgery provides better results compared to both pharmacological treatments (which are less available and less effective) and lifestyle changes. Furthermore, as well as weight loss, it guarantees a better control of comorbidities, reducing the risk of cardiovascular disease, morbidity and mortality, improving quality of life.

Although surgery is the best treatment option, patient commitment is necessary to achieve satisfactory results. Obtaining patient's comprehension of the importance of healthy lifestyle and equilibrated diet alongside with surgical information is generally difficult. Patient's concern needs to be constantly stressed out. The ongoing protocols that include preoperative meetings with surgeons, endocrinologists and nutritionists have been proved as insufficient, especially during the Covid-19 pandemic, when presential visits were reduced or cancelled.
Preoperative optimization with a healthy lifestyle and a balanced diet few months before surgery potentially reduce intraoperative complications alongside with postoperative morbidity and mortality [1-3]. Level of physical activity, diet and psychological stability could affect surgery's outcome for example reducing liver volume (up to 20%) and mesenteric fat [4-13]. Also, an improvement in patient's preoperative satisfaction, anxiety and commitment to surgery have been suggested [14-16]. Their impact on postoperative outcomes is unclear. There is lack of consensus on a standardized preoperative approach and goals. Many health care professionals worldwide strongly believe that preoperative optimization has an important impact on postoperative outcomes, but the evidence supporting this belief is mixed and most often retrospective. Although a positive relationship between self-monitoring behaviors (such as daily food intake diaries and regular self-weighing) and weight loss has been proved, additional instruction and behavioral intervention are needed. Besides weight loss, other factors such as adherence to self-monitoring of weight, recording food intake, increased physical activity could influence postoperative outcomes [17].

Even though official guidelines for an enhanced recovery (ERAS, Enhanced Recovery After Surgery) in bariatric surgery recommend patient information, education, counseling and preoperative weight loss, the efficacy of these measures has not been proved [18].

Technological development is an important resource that could help improving communications between patients and health care professionals. Nowadays, the use of a smartphone is widely integrated in daily life of most people [19,20]. The number of smartphones used is constantly increasing every year. In 2016, there were more than seven billion users worldwide [21]. The worldwide fast widespread of mobile technology in the last 15 years led to an expansion of the applications (APP) market [22]. To date, the biggest APP market are 'Google Play' (Android), 'App store' (Apple) and 'Blackberry World' (Blackberry) [23].

This technological revolution has progressively affected the health world. An increasing number of medical APP have been designed in the last years, few directly managed from health care providers from public or private centers. ThemHealth (Mobile Health) APP could led to a simpler, real-time connection between patients and health care professionals alongside with a bidirectional data flow and a steadily monitorization of patients' evolution that couldobtain a better preoperative follow-up without increasing the costs [24-26].

The present randomized clinical trial aims to prove the safety and efficacy of an interactive mobile application (Care4Today®) to obtain sufficient weight loss and empower patients with morbid obesity before being submitted to a gastric by-pass.

HYPOTHESIS:

Main hypothesis: The preoperative use of the Care4Today (C4T) application in addition to standard protocol, in patients with a grade II-III obesity (BMI between 35 and 50 Kg/m2) achieves greater preoperative weight loss than standard protocols.

Secondary Hypothesis: Use of the Care4Today (C4T) application in the preoperative setting achieves:

- less intra- and post-operative complications at 30 and 90 days;

- less technical complexity and duration of surgery;

- better patients' information and satisfaction;

- better medical team coordination and satisfaction;

- better weight loss outcomes at mid-term (1, 3 and 5 years).

AIMS:

Main goal: To compare patients' preoperative weight loss after using the C4T APP in addition to standard protocol versus the standard preoperative protocol.

Secondary goals:

1. Compare patients' information / satisfaction using the APP vs. standard protocol.
2. Compare complications in the immediate postoperative period (30- and 90-days post-intervention) after the preoperative use of APP vs. standard protocol.
3. Compare medical team coordination / satisfaction using the APP vs. standard protocol.
4. Compare patients' weight loss 3 months after surgery using the APP vs. standard protocol.

STUDY DESIGN: Randomized Clinical Trial to assess the safety and efficacy of a mobile application to monitor patients undergoing bariatric surgery.

All patients will receive the standard preoperative protocol that consist in optimization of associated complications with an active management of obesity-related comorbidities, optimization of preoperative weight loss through a hypocaloric diet carried out during the 10-15 days prior to surgery and an informative and educational group session prior to surgery (EDUBAR). The C4T APP will be provided four months before surgery to all the patients randomized in the APP group. All the contents in the APP have been properly selected and modified by the multidisciplinary team (endocrinologist, pneumologist, anaesthesiologist, psychiatrist, nutritionist, nursery). Specifically, the APP contents include informative articles covering the nutritional, behavioral, and surgical fields, exercises, interactive charts, instructional videos, surgical animations, checklists, and frequently asked questions. The format of the APP will lead the patient through a virtual journey in the world of bariatric surgery, allowing to understand all the basic information about the preoperative period, the surgery and hospitalization and the postoperative follow-up. The use of the APP will influence preoperative weight loss through all the information provided, designed in an intuitive way so that the patient progresses in their level of knowledge and can assess through a checklist if they are doing the correct training. It will allow patients to set specific goals and assess their scope. Making patients aware of the importance of preoperative weight loss through training will be the key to obtaining correct adherence to the program and satisfactory preoperative weight loss. No patient data will be saved on the APP.

To assess the impact of the APP, in addition to standard protocol, in the pre- and postoperative period, we will compare:

- preoperative total weight loss percentage
- level of patient information
- level of patient satisfaction
- level of medical team satisfaction
- 30th and 90th days postoperative morbidity and mortality
- percentage of weight loss 3 months after surgery

CHRONOGRAM:

OBSERVATION PERIOD

Recruitment period of the study is expected to be 18 months, with additional 6 months to perform surgeries and follow-up. All information's will be obtained using the application flow of data alongside with presential meeting with surgeons, endocrinologists, nutritionists.

S. All the contents in the APP have been properly selected and modified by the multidisciplinary team. The day of surgery all the data about weight loss, patient and medical team satisfaction will be collected. Then, patients will be followed in observation of our standard postoperative protocol to assess the 30th and 90th postoperative morbidity and mortality alongside with weight loss evolution. The PhD student has been directly involved in the APP design and contents creation. He will perform the preoperative presential meeting to provide and explain the APP functioning to the patients in the APP group. Furthermore, he will collect the data on the day of surgery, during surgery and will be directly involved in postoperative follow-up of all patients.

STUDY POPULATION:

Inclusion criteria:

- Patients older than 18 and younger than 65 years who meet criteria to undergo bariatric surgery
- BMI between 35 and 50 kg/m^2 and indication of one-time surgery
- Signing the informed consent of the study
- Patient suitable for laparoscopic surgery
- Patient who demonstrates accessibility to a smartphone and basic digital competence (Appendix 1).

Exclusion criteria:

- Previous bariatric surgery
- Two-step surgery
- Patient without resources to access the use of a Smartphone or without basic digital competence
- Contraindication for surgery
- Other surgical procedures associated with the same intervention

Retirement criteria:

- None

EXPERIMENTAL TREATMENT: Use of a mobile application to accompany and empower patients in the preoperative period.

EVALUATION CRITERIA:

Main criteria (for the main goal): Preoperative percentage of excess weight lost (%EWL), considering ideal BMI = 25, will be recorded.

Following the follow-up protocol in General Surgery Outpatient Consultations, patients' weight will be measured 4 months before surgery and on the same day of surgery; then at 3, 6 and 12 months, and then every year up to 5 years of follow-up to calculate BMI and percentage of overweight lost, percentage of BMI lost, total weight and BMI lost.

Secondary criteria (for secondary goals):

1. Patients' information and satisfaction using the APP vs. standard protocol will be evaluated using approved questionnaire (appendix 2, appendix 3);
2. Morbidity and mortality: morbidity and mortality will be evaluated using the prospective database of the Bariatric Surgery Unit and the electronic medical record of each patient. All perioperative aspects related to the surgery will be reviewed. Complications will be recorded according to the Clavien-Dindo classification.
3. Metabolic comorbidities: Comorbidities related to metabolic syndrome and morbid obesity will be recorded to study their evolution up to 5 years after the intervention: DM2, hypertension, DL and OSAS.
4. Medical team coordination and satisfaction using the APP vs. standard protocol will be evaluated during multidisciplinary committee.
5. Patients weight loss 3 months after surgery will be evaluated using the prospective database of the Bariatric Surgery Unit and the electronic medical record of each patient.
6. Nutritional and metabolic deficiencies: The analytical studies performed each year on these patients will be evaluated to detect possible deficiencies: protein, iron, phosphocalcic, fat-soluble vitamins and trace elements.

STUDY DURATION:

The study is expected to begin in October 2022
Patient recruitment period is expected from October 2022 to March 2024.
Preoperative follow-up will be completed the day of surgery.
Mid-term follow-up (2 years) will be completed in March 2026.
Long-term follow-up (5 years) will be completed in March 2029.

SAMPLE SIZE:

The sample size was calculated in 142 patients divided into two groups of 71 patients each. It was calculated by comparing a hypothetical reduction of ≥ 5 kg in 55% of patients in the C4T group vs in 39% of patients in the control group [27] with a possible loss of 16% of patients, a confidence level of 95%, and statistical power of 80%.

STATISTICAL ANALYSIS:

Continuous variables will be expressed as mean ± standard deviation or median (interquartile range) as appropriate. Differences between both techniques will be evaluated using a parametric test ($\chi 2$ for categoric variables and t test for continuous variables). We'll use the IBM-SPSS Statistics Version 20 computer software to analyse all the statistics. A p value < 0.05 will be considered statistically significant.

PERSONAL DATA PROTECTION / CONFIDENTIALITY / ETHICAL ASPECTS:

This study may be developed in agreement with protocol and Good Clinical Practice (GCP) guidelines, like is described in Administration 91/507/EECC and Declaration of Helsinki, regarding the investigation with humans ("Ethical Principles for Medical Research Involving Human Subjects"). Researchers accept to follow these instructions and procedures described therein and therefore will comply with the principle of Good Clinical Practice on which it is based.

Informed consent.

A signed informed consent to participate in the study will be obtained (Appendix 4). Each patient will be informed about study nature and will receive an informative document about the study (Appendix 5). Patient will sign the informed consent for diagnostic and therapeutic procedures of the Hospital, as well as the specific consent to accept inclusion in the study.

CONFIDENTIALITY

Patients will be identified by a serial number and by the medical record number. Only study investigators will have access to this database. In any case, all the information (personal and clinical) collected from patients undergoing bariatric surgery will be treated in accordance with REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of April 27, 2016 regarding the protection of persons regarding the processing of personal data and the free circulation of these data, as well as the rest of the laws and regulations in force and applicable, such as Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of the rights digital.

ETHICAL ASPECTS

Approved with Approval number: Ref PR150/22 by the Comité de Ética en Investigación Clínica, of University Hospital of Bellvitge,C/Feixa Llarga s/n 08907 L'Hospitalet de Llobregat, presidenciaceic@bellvitgehospital.cat, +932607389.

BENEFITS OF RESEARCH

To date, preoperative optimization has been considered as an important factor that influences the postoperative outcomes, but the evidence supporting this belief is mixed and most often retrospective.

Our research will provide a clear, high-level evidence about the importance of preoperative weight loss in obese patients to improve short- and long-term outcomes. Furthermore, we aim to demonstrate that technology could be an essential mean to improve patients' and medical team connections to obtain better treatment results.

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Appendix 1: Questionnaire to select patients with enough digital competence:

Technological Profile Labpsitec

Please, mark the option that you think best suits you.
When I handle new technologies, I consider myself to be a person with skill:

	SCARCE or NONE. Most of the time I have to ask someone more expert than me for help.
	SHORT. I defend myself, but with difficulty.
	NORMAL. I get to do the things I need to.
	ADVANCED. I consider that I know how to do more things than the rest of the people.
	EXPERT LEVEL. I have technical training. I am able to create content, program, etc.

Appendix 2: Questionnaire to assess patients' information:

PATIENT UNDERSTANDING QUESTIONNAIRE – VAMOS PROJECT

1. Which of these foods is preferable in the preoperative diet?
   - Fried
   - Precooked
   - Grilled
   - Processed
   - In sauce

2. Weight loss before surgery:
   - Reduces the risk of complications after surgery
   - Worsens scarring
   - Allows you to change the type of surgery
   - Increases risk of malnutrition
   - Is associated with more vitamin deficiencies

3. Bariatric surgery allows:
   - Cure obesity
   - Reduce the volumes of the intakes without feeling so hungry
   - Give up diets and exercise
   - Eat without the need to split the diet
   - Eat without the need to choose healthy foods

4. What is the name of the surgery that I am going to have?
   - Sleeve Gastrectomy
   - Gastroplasy
   - Gastric Bypass
   - Duodenal switch
   - Biliopancreatic diversión

5. In the surgery that I am going to have:
   - Most of the stomach is removed, which is converted into a narrow tuve
   - A horizontal section of the stomach is made approximately through its middle
   - The small intestine is not modified and digestive secretions are not diverted
   - The volume of the stomach is reduced and the secretions of the liver and pancreas are diverted to the small intestine
   - Secretions from the liver and pancreas are passed through the stomach

6. How many days will I be hospitalized if there are no complications?
   - 1
   - 2
   - 3
   - 4
   - 5

7. If there are no complications, what drugs will I **NOT** need after surgery?
   - Heparin
   - Mineral and vitamin supplements
   - Gastric protection (omeprazole)

- Protein supplementation
- Antibiotics

8. After the surgery I will start with a diet:
   - Líquid
   - Shredded
   - Easy digestive
   - Solid
   - Soft

9. The results of bariatric surgery are better if:
   - A vertical or sleeve gastrectomy type surgery is performed
   - A long-term low-calorie diet is adhered to
   - Rest is encouraged
   - Pecking is encouraged
   - Treatment with antiacids is completed

10. I will have to take the vitamin and material supplementation:
    - One week
    - One month
    - Six months
    - One year
    - Indefinitely

Appendix 3: Questionnaire to assess patients' satisfaction:

PATIENT SATISFACTION QUESTIONNAIRE – VAMOS PROJECT

	Scarce	Poor	Good	Very good	Excellent
1. Kindness/Courtesy of the medical team…….....	O	O	O	O	O
2. Explanations of the medical team about your pathology…….……....	O	O	O	O	O
3. Interest that the team has shown in clearing up your doubts and concerns…….	O	O	O	O	O
4. Willingness of the medical team to include you in treatment decisions ..……..	O	O	O	O	O
5. Information provided by the team on the type of medication…….	O	O	O	O	O
6. Instructions provided by the medical team on follow-up……	O	O	O	O	O
7. Comprehensibility of the language of the information received…….	O	O	O	O	O
8. Time that the medical team has dedicated to you…….……..	O	O	O	O	O
9. Your confidence in this medical team……	O	O	O	O	O
10. Probability that you recommend this medical team to other patients…..…….	O	O	O	O	O

Appendix 4: Informed consent

PROSPECTIVE RANDOMIZED STUDY TO ASSESS THE EFFICACY AND SAFETY OF A MOBILE APPLICATION FOR THE ACCOMPANIMENT OF PATIENTS UNDERGOING BARIATRIC SURGERY – VAMOS PROJECT

(Virtual Accompaniment for Morbid Obesity Surgery).

Informed consent

(In accordance with Law 41/2002, of November 14, Basic regulation of patient autonomy and rights and obligations in terms of information and clinical documentation and the Oviedo Convention 4/4/1997)

I, Mr./Ms..…….
(Name and surname of the patient or legal representative)

As, ..., I declare that:
(Relationship with patient)

- I have received and carefully read the information sheet of the study.
- I have been able to ask the appropriate questions about the study.
- I have received sufficient information about the study and I have understood it.
- I authorize access to my clinical history by the research team, for research purposes.

I have been informed by Dr.…….
(Name and nº of the researcher)

I understand that my participation is voluntary and disinterested.

I understand that I may refuse to participate in the study without affecting the assistance I receive

Therefore, I freely give my consent to participate in the study..

Patient signatura (or legal representative) Physician signature

L´Hospitalet de Llobregat

Appendix 5: Informative document for the patient

PROSPECTIVE RANDOMIZED STUDY TO ASSESS THE EFFICACY AND SAFETY OF A MOBILE APPLICATION FOR THE ACCOMPANIMENT OF PATIENTS UNDERGOING BARIATRIC SURGERY – VAMOS PROJECT
(Virtual Accompaniment for Morbid Obesity Surgery).

Patient information sheet

(In accordance with Law 14/2007 on biomedical research and the Declaration of Helsinki revision of Fortaleza, 2013)

You are going to undergo elective laparoscopic surgery to treat your morbid obesity and the diseases derived from it. In his case, after analyzing his clinical characteristics, the possibility of carrying out a preoperative follow-up by using a mobile application to monitor pre-surgical optimization has been indicated.

The treatment of obesity is multidisciplinary, from changes in lifestyle and diet to surgery. Although surgery is the most effective treatment, to obtain the beneficial effects, the commitment of the patient is essential. Preoperative optimization, with a correct lifestyle and a balanced diet in the months before and after surgery reduces the risk of intra- and postoperative complications while improving the effectiveness of surgery. Correct information increases the level of patient satisfaction, reduces the level of anxiety and improves adherence to the preoperative protocol. In this context, mobile technology, already definitively accepted and involved in the daily life of each person through Smartphones, provides a unique tool that allows direct communication, establishing a continuous exchange of information, the resolution of doubts, the assessment of the degree of patient satisfaction, and also educate and monitor patients in real time without leading to a disproportionate increase in costs. At the Bellvitge University Hospital (HUB) we are carrying out a research study on the impact of the use of a mobile application to accompany patients undergoing bariatric surgery with respect to standard preoperative follow-up. (Clinical trial authorized by the HUB Clinical Research Ethics Committee).

As in any abdominal surgery, complications can occur: hemorrhage, wound infection, intestinal fistula, abdominal pain, vomiting, intolerance to oral intake, etc. Like any patient undergoing this type of intervention, you will have all the technical and human resources available at our Center to try to solve any complications that may arise.

If you agree to participate in this study, you will be randomly assigned to one of two groups: Standard Preoperative Protocol or Standard Preoperative Protocol + Mobile App. All aspects of the intervention you will undergo (laparoscopic approach, preparation and postoperative management) will not be affected by this study or the group to which you will be assigned.

Currently there are no scientific data indicating the superiority of one preoperative protocol over another. The objective of the study is to analyze whether there are significant differences between a standard preoperative follow-up or with a mobile application. With the

With the results obtained, we hope to be able to employ the most beneficial preoperative protocol for future patients who, like you, will undergo elective bariatric surgery.

Your participation in this study is completely voluntary and disinterested.

Your personal data will be treated confidentially and will only be used by our team for medical research purposes. Only the part of your clinical history whose data is relevant for the study will be accessed (in accordance with the provisions of Organic Law 3/2018 on Data Protection and Guarantee of Digital Rights, and EU Regulation 2016/679 General of Data Protection). Your data will be totally dissociated from the data that allows your identification. To maintain your anonymity, you will be assigned a code number. Only the research medical team will have access to your data, and, if required, also the Research Ethics Committee and the Health Authorities. The study data is expected to be kept for a period of 20 years. Regarding the data collected for the purpose of the study, you have the right to access, rectify, cancel, oppose, limit the processing of data that is incorrect, request a copy or transfer it to a third party for processing (portability). To exercise your rights, you may contact the principal investigator (josorio@bellvitgehospital.cat) or the institution's Data Protection Officer (dpd@ticsalutsocial.cat). In case of international transfer of data, your confidentiality would always be protected by maintaining your anonymity and identification by means of a numerical code. Finally, you may file a claim with the Catalan Data Protection Authority if you consider that your data protection rights have been violated.

Of course, if you decide not to participate in the study, your medical care will not be affected in any way.

The research team will be willing to clarify all the questions that you wish at any time and phase of the study.

If you agree in participating the study, please sign the attached consent form.