

Design and Evaluation of a New Nurse-Led Intervention for the Management of Bariatric Surgery Patients

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Abstract — Obesity has an increasing incidence and bariatric surgery emerges as a treatment for severe and morbid obesity, as well as for its associated diseases, with proven success rates. In this context, patient follow-up by a case manager, who guides the provision of specialized care focused on adapting the patient to the new reality, can prove to be essential to achieve positive results. This study, guided by the *Design Science Research Methodology (DSRM)*, will have as main objective to design an intervention [*Case-managing program*] aimed at patients undergoing bariatric surgery. In the evaluation phase of the intervention, an experimental, controlled, and randomized study will be developed, with intervention group and control group. This project aims to be the first study to investigate the effect of specialized interventions on patients who are candidates for bariatric surgery, with evidence based on mixed, face-to-face, and e-health programs, on the management and results of bariatric surgery.

Keywords- e-health; case manager; perioperative care; bariatric surgery; nurse case management.

I. INTRODUCTION

Obesity is considered a 21st century epidemic, with more than 4 million deaths worldwide [1]. It manifests itself as a chronic disease, but also as a risk factor for numerous other pathologies and consequently worse health outcomes. Its prevalence justifies the priority in its treatment. Bariatric surgery is one of the most effective long-term treatments for obesity [2]. The success of bariatric surgery is usually measured by the percentage of weight lost. However, this success is dependent on several factors, such as the preparation for surgery. This path involves multidisciplinary guidance, namely related to health promotion, well-being and self-care, functional readaptation, and pre-rehabilitation, consistent with patient satisfaction [3].

It is essential to begin health education to prepare patients for surgery, but also to guide for adaptations, risks, and benefits. The use of educational strategies, with organized and systematized information before bariatric surgery, allows stimulating an attitude of self-care and lifestyle changes [4]. Empowering patients with this knowledge, allows them to realize that weight loss and lifestyle changes need to be maintained in the long term [5]. Working on these changes' pre-surgery increases the likelihood of a successful intervention [6].

In the follow-up of patients with chronic diseases and other comorbidities, the "case manager" nurses or nurse-led case-management interventions, improved the health of these

patients, with improvement of health indicators. The figure of these specialized nurses induces quality of care and reduces health costs [7][8].

Good results of bariatric surgery depend on how patients experience, understand and accept the changes that develop in the postoperative period. It is in this context that nurse-led case-management may allow better management of the surgical process, through health education and promotion of healthy lifestyles, supported by a multidisciplinary team. These interventions have the potential to bring very positive results in self-reported quality of life, mental health, and reduction of cardiometabolic risk [9]. Thus, we intend to verify how a new eHealth nurse-led intervention can contribute to the quality of life, adaptation process and maintenance of weight loss of post bariatric surgery patients.

This paper's aim is to present the methodology of a research project that will design and evaluate this nurse-led intervention. After the Introduction in section I the methodology is described in section II, with an emphasis on the study design and the flow of the evaluation stage.

II. METHODS

This research project will follow a mixed method approach, supported by a cycle of Design Science Research Methodology (DSRM) [10], that will allow us to design and evaluate a new intervention of specialized "nurse-led case-management" (Table 1).

TABLE I. DESIGN SCIENCE RESEARCH METHODOLOGY CYCLE

DSRM Activity	DESIGN SCIENCE RESEARCH METHODOLOGY CYCLE	
	Objectives	Method/Tasks
Activity 1	Identification of the problem and motivation	Systematic review of the literature Know the context under study
Activity 2	Set objectives for the intervention	Focus Group - Brainstorming Method
Activity 3	Design and development of the NURLIFE program	E-health nurse-led case management program
Activity 4	Demonstration of NURLIFE intervention	Short-term control case study
Activity 5	Evaluation the results of the NURLIFE	RCT study, with intervention groups and control group, lasting approximately 14 months
Activity 6	Communication of results	Communicate results from all development points

A. Study design

Activity 1- A systematic review of the literature with meta-analysis will be carried out with the objective of

identifying interventions directed at bariatric surgery patients and the respective outcomes. There will also be interviews with patients who underwent surgery, as well as with professionals who are part of the current follow-up protocol, to understand the context where the intervention is developed and uncover possible points for improvement.

Activity 2 - Conduct two to three focus groups with representatives of the various stakeholders (patients and health professionals) in order to identify what the objectives for a new intervention should be. These objectives are expected to be related to the set of endpoints interest that will be used to measure the results of the intervention in the evaluation stage.

Activity 3 - In this activity, a nurse-led case-management intervention program is expected to be developed (NURLIFE). The aim of this intervention is to improve the management of the bariatric surgery process by patients in collaboration with the health care team, with a view to improving health and adoption of healthy lifestyles that enhance better outcomes. During this stage, the initial protocol of interprofessional collaboration, the skill mix of the multidisciplinary team, and the requirements of the web-platform where most of the communication with patients will occur, will be set.

Activity 4 - Conducting a short-term case-control study. The objective of this study will be to test the intervention designed in the previous step with a reduced number of participants, to optimize the intervention.

Activity 5 - Evaluating the results of the NURLIFE program. To proceed with this activity, a randomized clinical trial (RCT) will be conducted, with division of the participants into two groups (Figure 1).

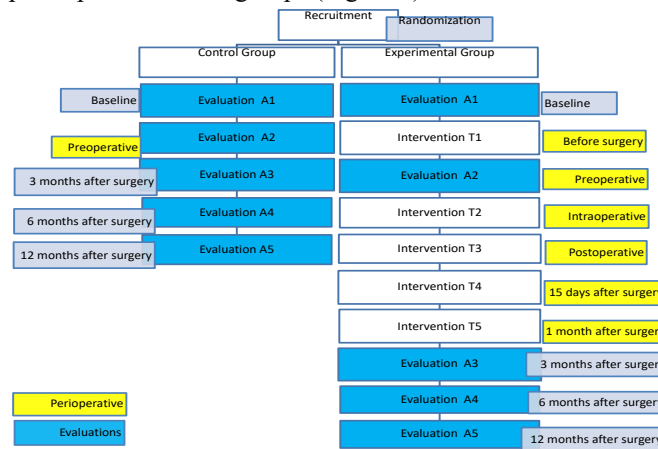


Figure 1. Prediction of the evolution and recruitment plan of the RCT study to evaluate the intervention

The predicted process and timeline for the RCT will be developed in all perioperative period.

B. Sample

The sample size is based on the number of patients who had bariatric surgery in previous years, with the reference

value of 100 patients per year, the usual in the context of the hospital. As inclusion criteria in the sample, participants will have to be enrolled for bariatric surgery at the Hospital of Évora, Portugal and agree to participate in the study. The main non-inclusion criteria will be patients with secondary bariatric surgery, with severe psychiatric or neurologic disease, and patients who do not agree to participate.

C. Randomization

Each participant will be randomly assigned to each group after signing the informed consent and conducting the initial assessments. All data collected will be de-identified with identification ID, safeguarding confidentiality of the collected data.

D. Outcomes

The primary endpoint of the RCT will be the proportion of patients who maintain their primary weight loss at the end of the first year.

For the measurement of clinical data, anthropometric parameters, surgical data, and a health data questionnaire will be used. The remaining variables will be defined based on activity 2 of the DSRM cycle, and may include life quality, physical activity, sedentary behavior, comorbidities.

III. CONCLUSION

This project aims to be the first study to investigate the effect of specialized interventions on patients who are candidates for bariatric surgery. It is expected that this project will provide evidence of the impact of evidence-based mixed, face-to-face and e-health programs, on the long term maintenance of bariatric surgery results.

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