Design and development of a nurse-led program for the management of bariatric surgery patients - The NURLIFE program

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Abstract

**Background:** A nurse-led case-management intervention program may improve the patients' management of the bariatric surgery process. Close collaboration with the healthcare team may improve health and facilitate the adoption of healthy lifestyles, which may enhance surgical results. Completing this project will allow the deepening and exploration of a network, including other areas of assistance, namely mental health and rehabilitation, as well as primary care.

**Aim** The program's primary focus is expected to be health education and motivation for lifestyle changes, promoting healthy lifestyles and physical activity. The improvement of anthropometric data, the lessening of the metabolic risk factors, and quitting smoking and alcohol habits will also be our main achievements.

**Methods** This randomized clinical trial has participants divided into two groups. We use a quantitative outcome evaluation to assess the effectiveness of the intervention and to anticipate indications for future implementation in different clinical settings.

**Discussion** This project aims to be the first study to investigate the effect of a specialist nurse interventions on patient candidates for bariatric surgery, based on practice-based evidence, while using mixed programs, face-to-face and e-health, on the management and results of bariatric surgery. As such, the contribution of a multidisciplinary team managed by a case manager may be the most efficient intervention.

**Trial Registration** Clinicaltrials.gov (NCT06020105) July 10, 2023.

**What is already known?**

- Obesity is a public health issue with high mortality rates.
- Bariatric surgery is the most effective treatment for sustained weight loss and the reduction of comorbidities.
- A multidisciplinary team with expertise in behavioral intervention is recommended for follow-up of bariatric surgery patients.
- Patient involvement is crucial for successful perioperative management and postoperative behavioral changes.

**What this paper adds**

- Behavioral interventions effectively promote weight loss in non-surgical treatments and, thus, could be relevant for bariatric surgery patients.
- Behavioral interventions before and after surgery can make a difference in the results.
Specialist nurse case managers have proven beneficial in managing chronic diseases, self-management of treatment, and improving outcomes before and after bariatric surgery.

**Background**

Because of the high prevalence of obesity, this illness is considered a public health problem. Studies worldwide show that bariatric and metabolic surgery is the most effective weight loss treatment. It has been recommended for the treatment of severe obesity while also obtaining the remission of more than 80% of associated medical diseases [1], [2].

To be as effective as possible it requires good patient involvement during the whole process. The perioperative preparation, beginning in the preoperative phase, is fundamental and should include the needed support from the health professionals working in the process for a successful postoperative period, assuming changes in behavior and patient capacitation. A good patient's self-management helps to achieve behavioral changes to be achieved before and after surgery [3], [4].

Understanding how behavioral interventions, before and after surgery, can impact bariatric surgery results is crucial. The guidelines of the American Association of Clinical Endocrinologists/American College of Endocrinology, The Obesity Society, American Society for Metabolic & Bariatric Surgery, the Obesity Medicine Association, and American Society of Anesthesiologists [5] recommend that a multidisciplinary team with expertise in various areas of behavioral intervention should be involved in the follow-up of these patients [6], [7].

There are few meta-analyses on these assessments and those that exist consider and recommend a multidisciplinary intervention led by one of the team professionals, with screening and referral required, with interventions for no less than six months of follow-up [4], [8].

The available after-surgery evidence show varying results in the postoperative evolution of patients and, occasionally, the need of reoperations and secondary surgeries [9]. These results sometimes show insufficient weight loss or even weight regain, while, some other studies, mention that the weight regain may even occur before six months [10], [11]. Also, 20 to 30% of patients don’t achieve the desired weight loss before five years [12], [13], and about 87% of patients present weight regain at ten years [14], [15], [16]. In this sense, and because we have evidence that behavioral interventions are effective to achieve 5–10% weight loss in non-surgical treatments [17], it is relevant to understand their influence and role in bariatric surgery patients.

The figure of a nurse case manager has proven its benefit in managing several health/disease conditions, especially chronic diseases and self-management of treatment, reducing the number of related hospitalizations, complications, and emergent admissions while promoting quality of life. Chronic diseases such as diabetes and hypertension are conditions that may include more benefits with follow-up by a case manager [18], namely in reducing risk behaviors related to these diseases, such as lifestyle change, smoking cessation, better dietary choices, and physical exercise [19]. The joint teamwork
between nurses and patients may achieve better results. The care is focused on what the patient needs and wants, regardless of the type of communication. A holistic and multidimensional approach shows potential for positive clinical results in managing chronic conditions [4].

Bariatric surgery is a significant medical intervention requiring comprehensive patient education and support. A nurse-led case manager can provide personalized education regarding the surgery, potential risks and benefits, dietary and lifestyle changes needed before and after surgery, and what to expect during recovery. This support is essential for ensuring that patients are well-informed and prepared for the journey ahead.

**Objectives**

*Primary objectives*

- To analyze the effects of a specialized intervention, managed by nurses in the perioperative period, on the self-management outcomes after bariatric surgery.
- To analyze the impact of specialized intervention on weight evolution in the pre-operative and post-operative periods.

*Secondary objectives*

- To characterize how a specialized intervention can contribute to changes in lifestyles, increased well-being and self-care, and the functional adaptation of patients in the perioperative period.
- To promote self-care (maintenance, monitoring and management).
- To promote adapting health behaviors to meet favorable conditions for bariatric surgery and maintain a healthy lifestyle post-surgery.
- To increase the practice of physical activity.
- To improve follow-up with the patient to ensure therapeutic adherence and monitor and evaluate symptoms effectively.

**Methods**

**Study design**

We planned a randomized clinical trial with participants divided in two groups. The population of interest are individuals selected for surgery at the Integrated Responsibility Center for Obesity and Metabolic Surgery at the Hospital do Espírito Santo de Évora. The invitation to participate will be made in the context of a consultation and the individuals who agree to participate in the study will be given a free and well-informed consent form. Participants will be randomly divided into a Control Group and an Intervention Group, with the program starting after the patients register for surgery and ending 12 months after surgery. The IG will receive the NURLIFE intervention, while the control group will receive
routine care. The present study protocol complies with the SPIRIT 2013 recommendations (Standard Protocol Items: Recommendations for International Trials), and a CONSORT flow diagram will be developed to show the progress through phases [20], [21].

Sample

Considering the explorative nature of the study, a formal sample size analysis is not possible. However, this study selected body weight evolution to calculate the effect size. Based on the literature [22], the percentage of excess weight loss 12 months after surgery was 76.9 ± 17.5, with a statistically significant difference (p < 0.001), and an effect size of 1.52 was calculated. In the G*Power software, the number of participants in each group sample was calculated as 17 cases by using two independent samples t-test and taking bilateral $\alpha = 0.05$ and $1-\beta = 0.80$. Considering a dropout rate of 20%, the minimum sample size was therefore derived as 42 patients.

Eligibility Criteria

As inclusion criteria for the sample, participants had to be registered for bariatric surgery at the Surgical Unit and agree to participate in the study. Non-inclusion criteria will be patients who are candidates for secondary bariatric surgery.

Randomization

A Perioperative Specialist nurse will present the study information to patients who satisfy the eligibility criteria, and if a patient agrees verbally to participate, the researchers will explain the information about the study in more detail to the participants, discuss the appropriate timing for the intervention, and provide informed consent.

Each participant will be randomly assigned to each group (Fig. 1), using simple randomization, sequentially through the registration list after signing the informed consent form and completing the initial assessments. All data collected will be identified with an ID, safeguarding the confidentiality of the data collected.

The entire randomization process will be carried out by a researcher who is not involved in the intervention and data analysis. In addition, the study will also control for the possible effects of covariates by balancing baseline characteristics between the two intervention groups, which can reduce the biased results.

********************* Fig. 1*********************

Nursing case management

The control group will receive standard care as provided by the Surgical Unit. The only contact with nurse case management is for evaluations.
In the intervention group, the patient receives management of a nursing case. In addition to started care, patients in the intervention group will receive the NURLIFE program, beginning before the surgery and ending one month after.

From the management activities, the patients receive telephone contacts, nursing consultations, and personal health education. The nursing consultations are implemented before the surgery. The purpose of the consultation is to gather information that can be utilized to draft personal care plans and to set mutually agreed targets. The consultation lasts about an hour and involves targeted health education, the measurement of body composition, waist circumference and blood pressure, and the calculation of BMI. Telephone contact is conducted one month before surgery to reassess patients' healthcare plans. Each telephone meeting lasts about 10 min. These activities focus on developing healthy habits and the theme of educational activities is selected according to patients’ main needs. All information acquired in the nursing management process will be registered in a database.

**Outcomes and variables**

We will conduct a mixed methods evaluation, including a quantitative outcome evaluation to assess the effectiveness of the intervention and a qualitative and quantitative process evaluation to derive indications for future implementation in different clinical settings (Table 1).
<table>
<thead>
<tr>
<th>Measures and outcomes</th>
<th>Tools of Assessment</th>
<th>Data Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sociodemographic data</td>
<td>• Sociodemographic profile</td>
<td>- Sex, age, educational level</td>
</tr>
<tr>
<td>Anthropometric</td>
<td>• Weight scale</td>
<td>- Weight</td>
</tr>
<tr>
<td></td>
<td>• Stadiometer</td>
<td>- height</td>
</tr>
<tr>
<td></td>
<td>• Abdominal measuring tape</td>
<td>- abdominal circumference</td>
</tr>
<tr>
<td>Body composition</td>
<td>• Bioimpedance</td>
<td>- BMI, fat mass, muscle mass, bone mass</td>
</tr>
<tr>
<td>Associated medical diseases and clinical analysis</td>
<td>• Comorbidities</td>
<td>- Number of comorbidities associated with obesity</td>
</tr>
<tr>
<td></td>
<td>• Medication</td>
<td>- Chronic medication</td>
</tr>
<tr>
<td></td>
<td>• Sphygmomanometer</td>
<td>- Mean blood pressure</td>
</tr>
<tr>
<td></td>
<td>• Blood samples</td>
<td>- Inflammatory markets</td>
</tr>
<tr>
<td>Health-related Quality of life</td>
<td>• IWQOL-lite</td>
<td>- 31-item, self-report measure of obesity-specific quality of life in adults</td>
</tr>
<tr>
<td>Physical Function</td>
<td>• Six-Minute Walk Test (6MWT)</td>
<td>- Cardiorespiratory fitness,</td>
</tr>
<tr>
<td></td>
<td>• Sit-to-Stand test</td>
<td>- Muscle strength of lower limbs</td>
</tr>
<tr>
<td></td>
<td>• Hand grip</td>
<td>- Muscle strength of upper limbs</td>
</tr>
<tr>
<td>Physical activity level</td>
<td>• App Google Fit</td>
<td>- Daily time and quantitate of physical activity</td>
</tr>
<tr>
<td>Barriers and facilitators of physical activity</td>
<td>• Barriers and facilitators of physical activity Questionnaire</td>
<td>- 2-item - Open question</td>
</tr>
<tr>
<td>Self-Care</td>
<td>• Self-Care Inventory of Chronic Illness Inventory – Patient Version</td>
<td>- 5-point Likert items with 3 separate scales: self-care maintenance (7 items), self-care monitoring (6 items), self-care management (6 items), and self-efficiency (10 items). Generic measure designed to assess the process of self-care used by individuals with a variety of chronic conditions.</td>
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<tr>
<td></td>
<td>• Self-Care Inventory (ASA_A)</td>
<td>- 24-items questionnaire to assess the process of self-care</td>
</tr>
<tr>
<td>Food-related aspects</td>
<td>• Eating Disorder Questionnaire</td>
<td>- 28-item, self-report questionnaire that aims to investigate attitudes, behaviors and cognitions related to eating disorder symptoms</td>
</tr>
</tbody>
</table>
### Measures and outcomes

<table>
<thead>
<tr>
<th>Measures and outcomes</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Anxiety and depression</td>
<td>• Social appearance anxiety scale (SAAS)</td>
<td>- 16-item self-report measure that asks respondents to rate their anxiety in a variety of situations where their appearance may be evaluated</td>
</tr>
<tr>
<td>Satisfaction with follow-up by nurses</td>
<td>• Patient Satisfaction with Nursing Care Quality Questionnaire</td>
<td>- 19-item questionnaire that would represent the patient’s perspective with content that represented salient features to patients</td>
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<td>• (PSNCQQ)</td>
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*Table 1*

### Intervention

The entire management process and care plan will be based on the International Classification of Nursing Practice - ICNP® version 2.0, with nursing diagnoses, interventions and outcomes based on the terms contained in the ICNP® Seven Axes Model (Focus, Judgment, Client, Action, Means, Location and Time) and the guidelines of the International Council of Nurses. We based ourselves on a clinical taxonomy, a structure about phenomena, about the patient (diagnoses and results) and the nurse’s care (intervention) with a focus on information and knowledge-based health strategy.

The intervention program will take place during the extended perioperative period, starting with the patient's registration for surgery and ending one year after surgery. It will begin with an outpatient nurse visit and the definition of the case manager. Based on other observational and experimental studies, it will be a combination of consultations and face-to-face follow-ups, such as teleconsultations (Table 2).
<table>
<thead>
<tr>
<th>Timing</th>
<th>Quality Standards</th>
<th>Unit of Competence</th>
<th>Concepts of self-care</th>
<th>Self-care Behaviors</th>
</tr>
</thead>
</table>
| T1 – preoperative | - Customer satisfaction  
               - Health Promotion                  | • Empowers the person and family/significant other, for the management of surgical treatment | Self-care maintenance          | - Lifestyle improvement  
               - Motivation  
               - Treatment adherence  
               - Medication management  
               - Comorbidities management  
               - Physical activity  
               - Hydration  
               - Weight control  
               - Body composition management  
               - Smoking cessation  
               - Alcohol use  
               - Sleep improvement  
               - Dietary intake  
               - Psychosocial consequences |
| T2 – Intraoperative | - Prevention of complications  
               - Person safety                  | • Promotes care for the person in a perioperative situation  
               • Develops their interaction from an interdisciplinary perspective | Self-care monitoring           | - Vital signs  
               - Symptoms  
               - Medication intake  
               - Pain management  
               - Nausea and vomiting management |
<table>
<thead>
<tr>
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<th>Self-care Behaviors</th>
</tr>
</thead>
<tbody>
<tr>
<td>T3 – Postoperative</td>
<td>~ Wellness and self-care</td>
<td>• Promotes care for the person in a perioperative situation</td>
<td>Self-care monitoring</td>
<td>- Physical activity</td>
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<td>• Develops their interaction from an interdisciplinary perspective</td>
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<td>- Vital signs</td>
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<td>- Pain management</td>
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<td>- Symptoms</td>
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<td>- Medication intake</td>
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<td>- Smoking cessation</td>
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<td>- Dietary intake</td>
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<td></td>
<td>- Nausea and vomiting management</td>
</tr>
<tr>
<td>T4 – fifteen days after surgery</td>
<td>~ Wellness and self-care</td>
<td>• Empowers the person and family/significant other, for the management of surgical treatment</td>
<td>Self-care monitoring</td>
<td>- Physical activity</td>
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<td></td>
<td>~ Functional readaptation</td>
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<td>- Vital signs and symptoms</td>
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<td>- Nausea and vomiting management</td>
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<tr>
<td>T5 – one month after surgery</td>
<td>~ Functional readaptation</td>
<td>• Empowers the person and family/significant other, for the management of surgical treatment</td>
<td>Self-care management</td>
<td>- Activity changes</td>
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<tr>
<td></td>
<td>~ Customer satisfaction</td>
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<td>- Proprioception and balance</td>
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<td>- Weight control</td>
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<td>- Body composition management</td>
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</table>
A nurse case manager will coordinate the care delivered to bariatric patients based on their health needs and interests. A comprehensive care plan is designed to focus on the patient’s problems, needs and desires. It develops strategies and measurable goals including specific outcomes based on the case management process (Fig. 2).

The disease management and patient empowerment program will be based on quality standards in perioperative nursing. It will promote self-care in the sense that the professional practice of the specialist nurse is characterized by an anticipatory attitude and is based on four axis (Fig. 3) and in the principles of acting with professional responsibility and prudence. The monitoring and intervention will prioritize recognizing others and their empowerment through the establishment of interpersonal relationship and the recognition of the abilities need in order to develop knowledge and self-confidence.

A joint care project plan will acknowledge the person's freedom of choice, foster their autonomy and behavior adjusted to their situation and promote empowerment. It will be essential to take responsibility for care into account, promoting positive outcomes to help the person achieve their best level of function and well-being.

<table>
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<td></td>
<td>- Managing symptoms</td>
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<td>- Medication changes</td>
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<td>- Alcohol use</td>
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<td>- Psychosocial consequences</td>
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<td>- Pain management</td>
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<td>- Managing dietary changes</td>
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<td></td>
<td>- Consulting healthcare provider</td>
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<td></td>
<td>- Nausea and vomiting management</td>
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</tbody>
</table>

*************** Fig. 2**************

*************** Table 2***************
Implementation and data collection

The NURLIFE program is expected to have a maximum of five face-to-face moments, where the evaluation instruments will also be applied, and seven non-face-to-face moments by tele or video consultation for the intervention group.

After the first consultation with the surgeon, each patient will be referred to the Specialist Nurse and case manager, who will carry out the first face-to-face consultation with consequent follow-up and clarification of identified needs. Following the flowchart in Fig. 4, the case manager will function as the central pillar of the process and will monitor each process individually.

******** Fig. 4*****

This first contact with the participants will be at the initial evaluation appointment, where the patient is registered for surgery (A1). At this point, and after acceptance of the informed consent, randomization will take place. Afterwards the IG will begin the intervention protocol and the CG patients will continue with their usual care. CG patients will have face-to-face assessments before surgery (A2), three months (A3) after surgery, at the end of the perioperative period, and finally six months (A4) and twelve months (A5) after surgery. The IG will have the same face-to-face assessments as the CG and will also have a teleconsultation one month before surgery (T1), face-to-face consultations in the intraoperative period (T2), in the immediate postoperative period (T3), fifteen days after surgery they will have a teleconsultation (T4), and another one month after surgery, in the late postoperative period (T5). It will be the last teleconsultation (Fig. 5).

*************** Fig. 5***************

Statistical methods

Statistical software will be used to determine the parameters to be assessed. The normality of the data will be evaluated with the Shapiro-Wilk test and a t-test for paired samples, or the chi-squared test will be used to examine the differences between the groups. Pearson's or Spearman's correlation will be used to elucidate the relationships between the variables. In addition, the effect size will be determined by Cohen's d.

Study Implications

The study's findings are expected to allow for several recommendations for clinical practice. It may be advisable to proactively offer bariatric patients a nurse-led program 1 to 3 years after the surgery due to declining levels of self-management. With modern technology, some patients may even be conducted via remote intervention modes to overcome barriers to participation. In addition, identifying self-efficacy as the variable significantly related to improving self-management and a [23]negative result as being related to poorer self-care, may direct the focus of future case management interventions.
**Results**

The expected results will be based on individual and institutional outcome indicators. We expect better clinical results, namely better control of weight and associated medical diseases, adherence to health behaviors and maintenance of a healthy lifestyle. We also want to decrease infection rate, the use and expense of medication, emergency room visits, number of complications, average length of stay and readmission rates. We aim also to increase knowledge of the treatment process, food control, functional readaptation to the new condition, ability to perform self-care, pain control and stress management.

The main points to be addressed are client satisfaction, health promotion, prevention of complications, well-being self-care and functional readaptation, based on the descriptive statements of specialized nursing care for the perioperative patient.

**Discussion**

A specialist nurse case manager plays a vital role in the bariatric surgery process due to their unique expertise and focus on the specific needs of patients undergoing weight loss surgery. During the bariatric surgery process, providing education, coordination of care, advocacy, monitoring, and psychosocial support to patients is essential. Interventions guided and managed by a nurse case manager are practical and efficient in managing chronic diseases, improving the quality of care and reducing health costs.

A perioperative specialist nurse plays a critical role in bariatric surgery by providing preoperative preparation, intraoperative support, monitoring and managing perioperative complications, postoperative care and recovery, and effective collaboration and communication with the healthcare team. Their expertise and dedication contribute to safer, more successful, and more satisfying outcomes for bariatric surgery patients.

NURLIFE aims to be the first RCT in Portugal to evaluate the effects of specialist nurse interventions on patient candidates for bariatric surgery, with practice-based evidence, using mixed programs, face-to-face and e-health, on the management and results of bariatric surgery. In addition, we intend to contribute to the recommendations of the practice of exercise after bariatric surgery.

**Declarations**

**Ethics approval and consent to participate:** This study followed all the norms and rules of the principles of good clinical practice according to the principles of the World Medical Association's Declaration of Helsinki and subsequent amendments. Informed consent will be obtained from all participants before baseline data collection. Ethical approval was obtained from the ethics committee of the *Unidade Local de Saúde Alentejo Central, EPE* (CES062/22-HESE1635/21/09/2022).

**Human Ethics and Consent to Participate declarations:** not applicable.
Consent for Publication: Not Applicable.

Availability of Data: Due to the nature of the research, this manuscript does not report data generation or analysis.

Competing of Interest: The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Fundings: Not applicable.

Author Contributions All authors: conception and design of the work. CM and JG: data collection. CM, JG, and MC: data analysis. All authors: interpretation of data. CM and JG: Draft of the paper. All authors: critical review and revision of the article.

Acknowledgments: We would like to acknowledge the Hospital committee and Lusofona’s Investigation Center - CBIOS.

Code availability: Not applicable.

References


**Figures**
Figure 1

Flowchart Participants
Figure 2

Nurse-led Case Management Knowledge framework
Figure 3

Main axis of intervention
**Figure 4**

Case Management proposal flow for assistance process

**Figure 5**

Study Flowchart