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A multimodal mixed-methods approach for holistic insights in Roux-en-Y gastric bypass patients: Protocol for a patient-centered framework ☆,☆☆

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ABSTRACT

This protocol outlines the methodological approach for a multimodal mixed-methods study to investigate how social determinants impact the pre-and post-operative biochemical parameters and experiences of patients undergoing RYGB. It integrates quantitative and qualitative data from patients in a public hospital. Biochemical, anthropometric, and body composition data will be collected from 717 clinical records of patients who underwent RYGB from 2020 to 2024, with data extracted 30 days before and six months after surgery. Semi-structured interviews will be conducted with patients to explore their experiences and perspectives before and after surgery. To complement patient perceptions, a focus group will be conducted with nutritionists experienced in managing post-bariatric surgery patients to gather insights into nutritional challenges and post-surgical care strategies. The findings of this study will provide a comprehensive analysis of the short-term biochemical, anthropometric, and body composition changes in patients following RYGB surgery while shedding light on the social determinants that influence these outcomes.

- This is one of the first multimodal mixed-methods studies in Brazil exploring both biochemical outcomes and lived experiences of RYGB patients in the public health system.
- This study targets a vulnerable population by addressing non-communicable disease prevention through improved bariatric care.

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Background

Metabolic surgery, particularly Roux-en-Y gastric bypass (RYGB), is widely recognized as an effective intervention for severe obesity [1]. This procedure involves modifications to the digestive system that lead to substantial weight loss and improvements in metabolic parameters and quality of life [2]. However, post-surgical weight loss varies significantly between individuals, making it challenging to accurately predict long-term outcomes [3]. Additionally, dietary restrictions and altered nutrient absorption following RYGB can result in notable changes in anthropometric, biochemical, and metabolic parameters, potentially affect patients' nutritional status [4,5].

While the short-term effectiveness of RYGB is well-documented [6,7], research on long-term biochemical, anthropometric, and body composition changes remain limited. Furthermore, environmental and social factors—such as geographic location, home environment, eating habits, and physical activity levels—play a decisive role in maintaining post-surgical outcomes [8,9]. Investigating these qualitative variables is essential to understanding how they can either enhance or limit the benefits of bariatric surgery, ultimately guiding the development of more personalized and effective interventions for patients in a public hospital in a southeastern Brazilian capital.

This study protocol builds upon research conducted by the Laboratory of Studies in Obesity and Nutrition at the Federal University of Espírito Santo, Brazil, which has systematically collected quantitative data over eight years from patients who have undergone bariatric surgery at a university hospital. These data have provided valuable insights into the anthropometric and biochemical changes associated with post-surgical outcomes, with findings already published [10–12]. However, while these studies have advanced the understanding of the clinical and metabolic effects of bariatric surgery, they do not capture the behavioral, psychological, and social factors influencing long-term patient outcomes. This protocol aims to bridge this gap through a retrospective analysis of clinical records from patients who underwent RYGB surgery between 2020 and 2024, integrating quantitative data from these records with qualitative insights obtained from patient interviews and focus group discussions with certified nutritionists.

Method details

Study design

This study follows an explanatory sequential mixed-methods design [13], as illustrated in the graphical abstract, conducted in two distinct phases. The first phase involves collecting and analyzing quantitative data to observe the anthropometric measurements, body composition assessments, and biochemical parameters changes in patients' post-surgery, followed by a qualitative phase [14], to further explore and interpret the findings from the quantitative phase.

To get comprehensive information, three complementary data collection methods will be applied as follows: extraction of sociodemographic and clinical data from patient records, semi-structured interviews with post-bariatric patients, and focus group discussions with nutritionists.

Study phases and sample composition

Quantitative phase

The quantitative phase will be conducted based on the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines for observational studies. Although these guidelines are initially intended for data reporting, they provide a solid basis for ensuring methodological rigor, especially in a retrospective approach such as the present one, in which two measurements were taken over a six-month period.

Quantitative sample composition

Seven hundred seventeen (717) clinical records of patients who underwent bariatric surgery in a university hospital in the southwest Brazilian region from 2020 to 2024 will be reviewed. Patients will be included if they are aged between 18 and 60, have a BMI >40 kg/m^2 or >35 kg/m^2 with associated comorbidities, and have undergone both anthropometric and biochemical evaluations at two points: one month before surgery (T0) and six months after surgery (T1). Clinical records with incomplete data on biochemical measurements or lack of follow-up information will be excluded. Missing data will be addressed using imputation techniques where appropriate, to maximize sample retention and minimize bias. For variables with <5 % missing data and approximately normal distribution, mean imputation will be used [15]. If missing data exceeds 5 % or the distribution is not normal, multiple imputation will be performed using the Multivariate Imputation by Chained Equations (MICE) package in R software [16]. Imputation will only be performed when justified and unlikely to introduce significant bias. Sensitivity analyses will be conducted to assess the impact of

imputation strategies on study outcomes. Exclusion from analysis will be limited to cases missing critical variables at both T0 and T1, or where imputation is not appropriate.

Quantitative data collection

Source of data. The following variables will be collected from the clinical records:

- Sociodemographic data: sex, age, educational level, income level, marital status, employment status, and ethnicity/race.
- Clinical variables: presence of comorbidities, current medications, and smoking status.
- Anthropometric measurements: body composition assessments, and biochemical parameters were routinely evaluated during preoperative consultations and postoperative follow-up visits. The assessments were performed using the following procedures:

Anthropometry and body composition. Body weight was measured on an anthropometric scale with an accuracy of 0.05 kg, and height was measured on a wall stadiometer at the nearest 0.1 cm. BMI will be calculated by dividing weight (kg) by height (m^2). Fat-free mass (FFM) and fat mass (FM) (kg) were obtained by bioelectrical impedance analysis using the Biodynamics 450® analyzer (Biodynamics et al., USA) at a single frequency of 50 kHz. FFM was calculated using the formula for people with obesity proposed by Segal and colleagues [17] and expressed in kg. FM was calculated using the formula: FM = total body weight – FFM, also expressed in kg. These procedures followed the guidelines of the European Society for Clinical Nutrition and Metabolism (ESPEN) [18].

Biological material and biochemical parameters. Biochemical data will be obtained from clinical records based on routine blood tests performed according to the hospital's protocol. It is acknowledged that variations in fasting duration can influence biochemical results; however, no global consensus or standardized fasting protocol currently exists. Thus, the hospital's 8 to 12-hour protocol was followed consistently for all patients to maintain internal consistency. Following sample collection, serum was obtained via centrifugation and stored at −80 °C for analysis. The following biochemical parameters, analyzed using Wiener Lab® commercial kits (Santa Fee, Argentina), will be extracted from the clinical records:

- Nutritional markers: Albumin, transthyretin (TTR).
- Inflammatory marker: C-reactive protein (CRP), alpha-1-acid glycoprotein (AGP).
- Liver function markers: Aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase (ALP).
- Metabolic markers: Glucose, triglycerides, total cholesterol (TC), high-density lipoprotein (HDL), and low-density lipoprotein (LDL).

Statistical analysis

Data normality will be assessed using the Shapiro-Wilk test. Depending on the results, Paired *t*-tests or Wilcoxon tests will be applied appropriately, with a significance level set at $p < 0.05$. The analysis will be carried out using the package in R software.

Qualitative phase

This step will be guided by the COREQ (Consolidated Criteria for Reporting Qualitative Research) criteria, which, although initially a checklist for presenting qualitative data offers a solid basis for ensuring transparency and methodological rigor throughout the process.

Qualitative data collection instruments

Two qualitative data collection tools will be used: semi-structured interviews with patients and a focus group with nutritionists, described as follows:

Semi-structured interviews

Participant recruitment

Initially, the research team planned to invite patients to participate in semi-structured interviews during their in-person follow-up assessments at the hospital. However, after analyzing the logistical challenges, including variations in appointment schedules, potential delays in medical procedures, and the primary focus of patients on their follow- up care, it was determined that in-person recruitment might not be the most efficient approach.

Based on existing evidence supporting WhatsApp as a tool in research participant recruitment [19,20], and to ensure a more convenient and flexible process for participants, the research team reached a consensus to use this tool. This will minimize disruptions during hospital visits, provide patients with time to consider participation and schedule the interview at their convenience, reach a broader group of eligible participants, including those who may not have immediate follow-up appointments scheduled.

Patients will receive a WhatsApp message introducing the study and inviting them to participate in a short interview. Those who express interest will be provided with additional details, including the study objectives, confidentiality assurances, and scheduling options. If no response is received within 48–72 hours, a follow-up message or phone call will be made to confirm their interest.

Table 1
Guiding questions for the Semi-structured interviews.

Semi-structured interviews
1. How do you feel about your health?
2. How do you describe your health after surgery?
3. What changes did you notice six months after surgery?
4. How did the surgery impact your routine and life?
5. Would you like to report any health challenges or unexpected results after surgery?
6. What emotions and feelings did you experience before and after surgery?
7. Are there emotional challenges you would like to share with us?
8. How was the support received at home before and after surgery?
9. Were there any obstacles you would like to describe?
10. Looking back, what was most challenging for you during this process?
11. How did your family, friends, and healthcare professionals support you in this process?

Semi-structured interview implementation

We will conduct between 10 and 12 in-depth, semi-structured interviews with individuals who have undergone RYGB surgery, voluntarily agreed to participate and completed the T0 and T1 assessments. The evidence suggests that this number is optimal and has been shown to be sufficient for identifying major themes and achieving theoretical saturation in qualitative studies [21,22].

To foster rapport and comfort, the interview will begin by thanking participants for their time and emphasizing the value of their input. For example: “Thank you for agreeing to participate in this interview. Your responses are precious and will help us better understand the experiences of individuals after bariatric surgery, guiding improvements in post-surgical care”. Beginning with gratitude will set a positive, allowing for smoother engagement [23], encourage openness, and respects the emotional nature of the topic.

The interview will then transition to open-ended questions about their experiences before and after the surgery. This approach aligns with best practices in qualitative research, where rapport-building and participant comfort are prioritized to elicit rich, meaningful data [24]. The guiding questions will address the theme of the study and were selected in consensus with the department’s researchers, including feedback from a medical doctor, nutritionist, nurse, psychologist, and speech therapist (Table 1).

The guiding questions will serve as a flexible framework, giving the interviewer the freedom to gather the information to meet the study objectives, minimizing improvisation and keeping the interviews focused. Rubin and Rubin [25] suggest that flexibility in the number and type of questions facilitates a natural flow, encouraging participants to engage in broader discussions.

Interviews will be conducted either in person or virtually, depending on each patient’s availability and preference. Recordings will be made only after obtaining prior consent. The estimated duration for each interview is 30 to 45 min, focusing primarily on capturing the patients’ narratives. The video recordings resulting from the semi-structured interviews, along with their corresponding transcriptions, will be kept in the custody of the principal investigator. The original recordings will be deleted after transcription. The primary researcher will save all information in a protected file and make a backup of the data.

Patients will be informed in advance that two researchers will participate in the interviews: one with extensive experience in conducting semi-structured interviews and another less experienced researcher. This collaborative approach benefits both researchers [26]. The experienced researcher will lead the conversation, ensuring alignment with the study objectives, while the less experienced researcher will observe, take notes, and gradually learn the nuances of conducting interviews.

A pilot phase will consist of three initial interviews. This pilot will help fine-tune the approach for initiating the conversation, assess the flow of dialogue, and test technical aspects such as audio quality and recording reliability.

Focus group

To complement the perceptions of the patients, we will carry out a focus group [27] with 6 to 8 nutritionists to collect professional perceptions on nutritional challenges and post-surgical care strategies. Eligible participants are registered nutritionists with at least two years of experience working with bariatric patients in a clinical setting. Participants must be willing to share their experiences and perspectives in a group environment and provide informed consent to participate in the focus group. Nutritionists who could not appear in the scheduled session or had time restrictions limiting their full participation would be excluded. Recruitment for the focus group will employ a non-probabilistic, convenience sampling approach, commencing with nutritionists actively engaged with bariatric patients at the affiliated University Hospital and outpatient clinics. This methodology has been selected due to the logistical difficulties associated with convening a group of qualified professionals possessing specialized expertise in post-bariatric care. Initially, eligible nutritionists will be approached verbally to explain the purpose of the study and assess their interest in participating. Those who express interest will then receive a formal invitation via email, including detailed study information and a link to the electronic informed consent form. Additionally, these professionals will be asked to recommend other colleagues with relevant experience who may also be eligible to participate.

The focus group will be held virtually due to the difficulty of bringing together participants in person, allowing the participants to be from different locations and facilitating logistics. The estimated time for collecting information will be between 60 and 70 min. The moderator will be someone not part of the research group but with experience in conducting this dynamic type, guaranteeing

Table 2
Guiding questions for the Focus group section with nutritionists.

Focus group section
1. What are the most common challenges seen in post-bariatric patients regarding diet and nutrition? How do you work with your patients to manage these situations?
2. What strategies do you use to help patients stick to the diet long-term?
3. Can you share with us the behavioral factors that influence patients in following the diet?
4. What patterns do you observe in patients who are successful in maintaining their diet after surgery?
5. What do you think are the biggest challenges faced by nutritionists in the management of bariatric patients?
6. What recommendations would you make to improve the clinical outcomes of post-bariatric patients?

that all participants can express their opinions. The section will be recorded with the consent of the participants. After transcription, all original video files will be erased. Transcripts and accompanying data will be stored in secure, password-protected files, with backups created to ensure data integrity. To guide the focus group discussions, we have developed a preliminary set of questions, as outlined in Table 2. These guiding questions serve as a foundation for the discussions; however, the focus group design remains flexible to incorporate emerging themes identified in the semi-structured interviews with patients. Based on the responses gathered, additional topics and refined questions will be integrated into the focus group discussions.

Analysis and interpretation of qualitative data

We will use a narrative approach to analyze and interpret the semi-structured interviews. According to Peng [28], narrative analysis preserves the context of people's experiences and allows us to explore coherence and structure of narratives, which can be particularly useful in understanding the expectations and experiences of post-surgical patients. This approach focuses on the structure, content, and meaning of stories. Firstly, the interviews will be transcribed.

The content will be carefully read by two researchers to identify key elements, ideas, values, and messages [29], then they will use Taguette software [30], a free and open-source qualitative data analysis tool, to systematically code and categorize the qualitative data. After independent coding, researchers will compare and refine their findings. The analysis will also consider the social and personal context of each narrative. The final step is to draw conclusions based on patterns and meanings identified [31].

Integration of quantitative and qualitative data

Quantitative and qualitative results will be integrated to generate a more comprehensive understanding of how qualitative factors influence post-bariatric patient outcomes. This approach allows for a more nuanced interpretation of how psychological, social, and behavioral factors interact with clinical outcomes, providing a richer perspective on patient experiences. As highlighted by Creswell & Tashakkori [14], combining both methods enhances the depth of analysis, offering insights that neither approach could fully capture on its own.

Method validation

This study employs a retrospective design, enabling the analysis of five years of clinical records from a well-established public university hospital. The use of this extensive dataset enhances the reliability of findings by capturing real-world post-surgical outcomes in a diverse patient population. The study follows a mixed-methods approach, integrating both quantitative and qualitative data collection instruments to ensure comprehensive analysis.

To ensure methodological rigor, this study serves as a foundational framework for postgraduate research projects in the Nutrition and Health program at the Federal University of Espírito Santo (UFES). Students will contribute by conducting literature reviews and further analyzing specific aspects of the dataset, reinforcing the study's validity through multiple investigative approaches.

The research findings will undergo internal validation through presentations at UFES research events and dissemination at national and international congresses focused on obesity, nutrition, and public health. Additionally, the final results will be submitted for peer-reviewed publication in scientific journals, ensuring that the study adheres to rigorous academic and institutional standards.

Limitations

The quantitative component of this study has certain inherent limitations. The clinical records correspond to post-bariatric patients from a single hospital, representing a unicentric, non-probabilistic, purposive sample. As a result, the findings cannot be generalized to other regions of Brazil. However, since this hospital is part of the public healthcare system (Sistema Único de Saúde – SUS), the results remain highly relevant for informing and tailoring care practices for patients undergoing bariatric surgery within similar public healthcare settings.

The 10–12 semi-structured interviews will provide rich, in-depth insights into patient experiences. However, these findings may not be generalizable to broader populations or different healthcare environments. Additionally, the interpretation of participants' responses may be influenced by researcher perspectives.

A potential limitation is recalling bias, as patients will be asked about their experiences before and after surgery. Over time, certain details may be forgotten or distorted. Furthermore, participants may provide responses that they perceive as socially acceptable, particularly regarding post-surgical lifestyle changes, rather than fully reflecting their lived experiences.

Declaration of competing 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.

Data availability

No data was used for the research described in the article.

Ethics statements

The Research Ethics Committee of the university hospital approved the study (CAAE: 59075722.7.0000.5071), in accordance with the Declaration of Helsinki. The study was also registered in the Brazilian Registry of Clinical Trials (ReBEC) under protocol RBR-26chs2g on May 22, 2022. Informed consent will be obtained from all participants, as detailed in the Methods section. Confidentiality will be maintained throughout the study: identifying information will be removed during transcription, and no personal data will appear in study outputs. Focus group and semi-structured interviews will be conducted via Google Meet, a secure platform licensed through the university's institutional agreement. Recordings will be used exclusively for transcription. Anonymized transcripts will be securely stored [32] under the custody of the Head of Department responsable for the project, in accordance with institutional and ethical standards.

CRediT author statement

Conceptualization and original Draft: BEGD. Qualitative Phase Review, Writing, and Formatting: LRC, BBdeB, MCdaCP. Methodology, Qualitative Phase Review, Writing, and Editing: JMC, TCM. Clinical protocols: GPSM, Writing and Critical Review of the Overall Manuscript: LBS, ABL. Supervision and guidance: FKH. All authors reviewed, edited, and approved the final version of the manuscript. They also contributed to refining and finalizing the manuscript.

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All images used in this manuscript were selected from the Microsoft Office package.

Declaration of generative AI and AI-assisted technologies in the writing process

During the preparation of this work the author(s) used Grammarly software in order to assist in writing and editing in English. After using this tool/service, the author(s) reviewed and edited the content as needed and take(s) full responsibility for the content of the publication.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.mex.2025.103367.

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