

Construction and validation of an instruction manual of nutritional care for severely obese people in the Unified Health System

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Abstract *This article describes the construction and validation of an instruction manual geared toward nutritional care (NC) for people with severe obesity in the Brazilian Unified Health System (SUS). In the production of this instruction manual, a broad literature review was conducted for the identification and discussion of topics to be treated. The content and appearance validity were conducted according to the Delphi technique and to focus groups, respectively, with evaluators who were nutritionists and practitioners, from different regions of Brazil. According to the Delphi technique, the instruction attributes and their content as a whole were properly and sufficiently evaluated according to values obtained for the Content Validity Index (CVI > 0.8). In the focus groups, the saturation of content was reached. Furthermore, discussions considering the reality of SUS were conducted and subsequently incorporated into the instructions in order to adequate the final version of the instructions to SUS professionals' needs. In conclusion, the instruction manual produced to fill the gap regarding nutritional care for people with severe obesity presents an adequate content in terms of both quality and topics of interest (content validation), and is applicable within the reality of SUS nutritionists (appearance validity).*

Key words Validation, Health professional, Nutritionist, Health service, Unified Health System

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Introduction

Severe obesity, characterized by body mass index (BMI) ≥ 35 kg/m², with comorbidities, or BMI ≥ 40 kg/m², regardless of comorbidities, is a chronic and progressive disease, with a high risk of complications, thus compromising one's quality of life and reducing the life expectancy of individuals. It has a direct impact on health expenses and generates cost in terms of productivity loss^{1,2}. Its etiology is a result of the interaction of a series of factors³, indicating that the care for severely obese people (SOPS) must involve strategic and political interventions in health, conducted by capacitated multidisciplinary teams¹.

The current guidelines for the treatment of severe obesity establish a broad approach, including diet, physical activity, and behavioral strategies, and recommend that individuals receive nutritional support for at least two years before undergoing surgery⁴. Therefore, the organization of the nutritional care (NC) for SOPSs must take into consideration the context in which these individuals are inserted, aiming at better adherence to and success of the treatment⁵.

Although there are documents concerning the care for obese people in the Brazilian Unified Health System (SUS)⁶⁻¹¹, there is still a lack of official documentation geared toward the treatment of severe obesity.

To ensure the production of quality material that can properly reach the intended targets, the material must be evaluated in terms of effectiveness and applicability, passing through validation by professionals and specialists. Such a process enables the measurement of the quality of the information and establishes its applicability for health services¹². Therefore, the present study aims to describe the process of the production and validation of an instruction manual of the NC for SOPSs in SUS.

Methodology

Formulating the instruction manual

To develop a robust material that meets the needs of nutritionists involved in care for SOPSs, the construction of the manual included six stages (Figure 1).

An investigation of the main aspects of NC for SOPS was conducted and an executive summary was produced. The topics were conceived

after having conducted an exploratory literary review in the digital libraries of the Ministry of Health (MH), sites of the World Health Organization (WHO), and site of the World Obesity Federation (<https://www.worldobesity.org>), as well as through a search in digital databanks with scientific relevance to the health area. The words used in the search were "severe obesity", "obesity", "overweight", "bariatric surgery", "directives", "recommendation", "practical directives", "nutritional treatment", searched individually or in a combined manner.

Considering that the material concerns the NC for SUS users, the manual was based on recommendations that were specific for or adapted to the Brazilian population. When there was lack of information, or when the material was pertinent, international guidelines and scientific articles were used with adaptation.

Once the documents and articles had been selected, extraction of content was performed. The manual was written based on the resulting material, followed by revisions and corrections by the responsible researchers until a preliminary version of the manual had been produced, which was then forwarded to the validation process.

Validation procedures

Validation took place in stages. The first stage, content validation, was conducted using the Delphi technique¹³, with specialists in the nutritional treatment of obesity, bariatric surgery, and collective health. The second was the appearance validity, conducted by a focus group with experts in the field and nutritionists from the Health Care Network (*Rede de Atenção à Saúde – RAS*)^{14,15}.

Content validation took place between January and May 2022, and appearance validity, between April and May 2022. 35 nutritionists participated, being 15 in the content validation stage and 20 in the appearance validity stage. This study was approved by the Research Ethics Committee from Universidade Federal de Viçosa (CAAE: 50925321.8.0000.5153/Protocol no.: 4.992.877).

Selection of evaluators

The evaluators were selected by means of an analysis of the Lattes Curriculum Vitae (CV); searches in records from municipal governments, Regional Nutrition Councils (*Conselhos Regionais de Nutrição – CRN*), and hospitals; and by recommendation of the invited

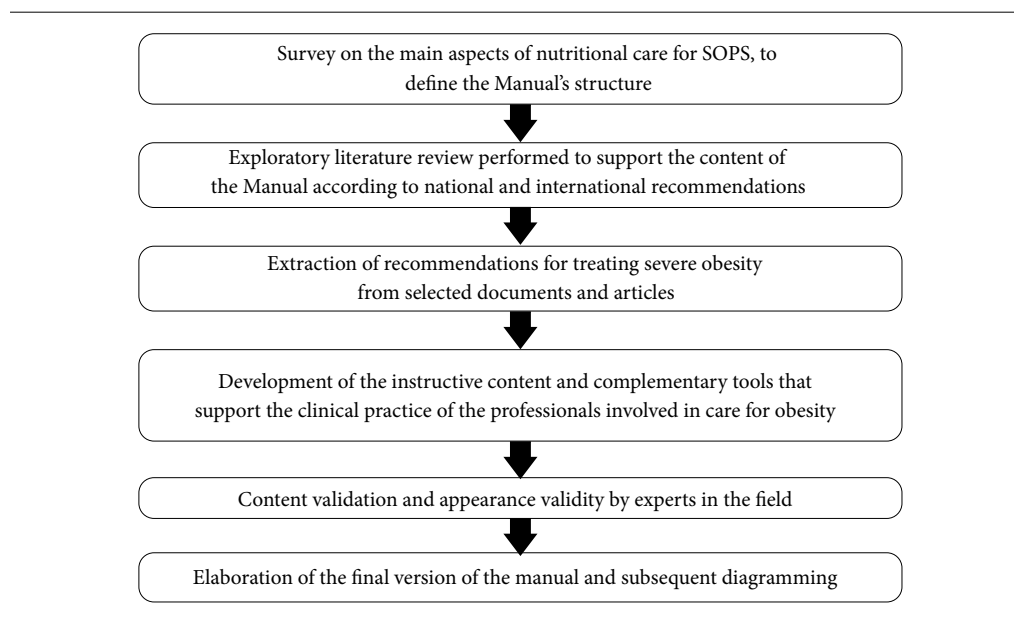


Figure 1. Stages in the construction of the instruction Manual.

Source: Authors.

professionals themselves, using the snowball methodology¹⁶. This study considered experts, nutritionists, and college professors from public federal universities who have experience in obesity. Professional nutritionists, who worked in primary and specialized care, were also invited. The study contacted nutritionists from all regions of the country so that the sample would represent the Brazilian population as a whole.

Contact with the participants was established via e-mail and/or mobile app (WhatsApp). All of the official information, however, was sent via e-mail. All of the participants were informed about the objectives of the research and the nature of data collection, and all participants electronically signed a Free and Informed Consent Form (FICF) in each of the two stages. Additionally, during the focus group, all participants verbally declared that they had understood the (FICF) and that they agreed to having the meeting recorded.

Content validation

For content validation, a complete version (not diagrammed) of the manual and an executive summary (diagrammed) for appearance validity were sent to the evaluators, as was the FICF and the evaluation questionnaire.

The evaluation questionnaire consisted of statements that should be judged based on a

Likert scale, with scores 1 to 5, in which “1” means “totally disagree”; “2”, “partially disagree”; “3”, “indifferent”; “4”, “partially agree”; and “5”, “totally agree”. For each statement, the evaluators were also allowed to leave comments. The attributes considered in the questionnaire were usability, functionality, content, relevance, and appearance of the manual¹⁷⁻¹⁹.

Based on the answers, the Content Validity Index (CVIi) was calculated for each item and of the scale (CVIt). For each attribute, we calculated the proportion of evaluators that attributed the highest scores (4 and 5) for each item, considering that the average of the items was the CVIi. The CVIt, by contrast, was produced from the average of all the CVIis for each attribute. In both cases, we considered as adequate CVIs ≥ 0.80 ¹⁵.

The evaluation (performed by the evaluators) took place in two rounds of content evaluation, until the CVI reached a value above 0.80 in all of the questions. Since that value was reached in the second round, there was no need for further rounds²⁰.

Appearance validity

The appearance validity seeks to evaluate the applicability of the material produced¹⁴. To achieve this, our study resorted to listening workshops, which favor the process of in-depth

discussion. Three focus groups were conducted via Google Meet, on two separate days and times, defined in mutual agreement with the participants and the organizing team. Each group had a mediator, responsible for the elaboration of the manual, and an observer, responsible for technical support and the drafting of a synthesis of the group's discussions. The mediators and the observer were the same for all of the groups. As performed in the content validation, the participants received material to read and evaluate, along with an evaluation questionnaire. The systematization of the answers to the questionnaire was placed in debate in an interactive perspective, encouraging retro-feeding of the produced results in order to reach a consensus. Based on the themes with the highest level of disagreement in the questionnaire, evaluated by the CVIi, a script was created to guide the groups' discussions²¹. Throughout the discussions, the groups established their consensus regarding the proposed questions.

Analysis of the focus groups

The software IRaMuTeQ (*Interface de R pour les Analyses Multidimensionnelles de Textes et de Questionnaires*) was used to conduct textual analysis of the data, considering that this method uses statistical calculations to analyze qualitative variables, overcoming dichotomy between quantitative and qualitative data²². It is a free software, which uses R software statistical environment and python language (www.python.org).

The use of IRaMuTeQ enabled the calculation of word frequency, the hierarchic descending classification (HDC) for similarity analysis, and the formulation of word clouds. In the HDC, the results are expressed in dendrograms, which are produced based on classes defined by statistical tests²². In these, the titles of the classes are generated from text sections of the corpus of the text²³, and the closer the dendrogram classes are, the more affinity they have between each other²⁴. All of the words in the dendrogram are related to the textual corpus ($p\text{-value} < 0.05$) and appear in descending order of connection, in other words, the higher the chi-square value, the greater the association between the word and the remainder of the corpus. The similarity analysis graphically identified occurrences of words and the connection between them. The size of each word indicates its importance in the corpus, and the thickness of the lines which connect the groupings indicates the level of as-

sociation between them. Hence, the thicker the line, the greater the intensity of association. The nuclei or groupings incite the similarity between the words^{22,25}. Finally, the word cloud graphically identifies the main elements of the corpus. The formatting and size of the words in the cloud are proportional to their frequency in the corpus. Therefore, the more central and bigger the word, the more prevalent it was in the discussions²².

To insert the textual material into IRaMuTeQ, a previous preparation was necessary. First, the texts which corresponded to the corpus of analysis were identified (which have homogenous textual content)²². The focus groups were then transcribed, and the articles were divided into four themes, to be worked on for each of the questions put into discussion. Therefore, four corpuses were organized, two for HDC, one for similarity, and one for the word cloud. After the definition of the text corresponding to the corpus, the file was organized into a WORD document, with the answers for the questions referring to the theme of each of the focus groups, and a codification line was inserted with information about that text in a language that is recognizable by the software.

With all the texts in the same file, the subsequent stage was content organization. Finally, the file was converted into .txt (non-formatted text) with the selection of another codification, by selecting the option UTF-8. The formatted corpus was inserted and read by the software, and the aforementioned analyses were then conducted.

Results

Construction of the manual

The manual was structured in nine topics, with the purpose of contemplating the main aspects of NC in the three levels of care provided at SUS. Its appendices contain new tools that are extremely relevant and will aid nutritionists in their daily work (Chart 1). The choice of these topics is line with the needs of the public targeted by the Instructions Manual, hence it was legitimized by the statements of the evaluators during the focus groups' meetings.

The topic "Nutritional Care" covers the bases in terms of promoting NC for SOPs, including evaluation, nutritional diagnosis, and the establishment of targets to follow up and evaluate adherence to the treatment. Moreover, it is

Chart 1. Content of the manual for nutritional care of severely obese people at the SUS.

Chapters	Content	Objectives
Presentation	- Authors of the Instruction Manual - Objective of the Instructions	- To contextualize the process formulating the Instructions, presenting the Institutions involved, the assisted population, and the proposed objectives.
Introduction	- Complexity of treatment - Interdisciplinary care - Organization of lines of care for overweight and obesity	- To present the challenges and perspectives in the treatment of severe obesity, such as stigma, lack of responsiveness to conventional treatment and nutritional environment; - To value the positive impact of multidisciplinary care; - To bring awareness regarding integrality and longitudinality of actions in eating and nutrition
Nutritional care	- Nutritional evaluation and diagnosis - Overall view of the individual - Establishment of connections - Establishment of goals for change of habits - Evaluation of adherence to nutritional follow-up - Individual and collective approaches	- To describe the work of the nutritionist in specifics, such as the obesity stigma, nutritional deficiencies, sarcopenia, and loss of control of hunger and satiety; - To present the main disorders affecting SOPs with suggested behaviors; - To approach the impact of nutritional behavior within food ingestion control; - To describe specificities and indicators in the nutritional evaluation of SOPs; - To value the search for integrative approaches to SOPs through detailed anamneses; - To present support strategies for changes in lifestyle, according to the readiness conditions; - To discuss how to set achievable targets for SOPs; - To present strategies and tools which facilitate nutritional follow-up
Recommendations for adequate and healthy eating	- Nutrition Guide for the Brazilian Population (NGBP) - Use protocols for the NGBP in the orientation of severely obese people - Cardioprotective nutrition - The act of eating - Contraindications	- To value the NGBP recommendations, applying those recommendations for SOPs; - To describe the NOVA classification of foods; - To present publications and protocols that can guide adequate and health nutrition of SOPs; - To describe cardioprotective nutrition and its use in nutritional care for SOPs; - To discuss the conducts that should not be followed in nutritional care for SOPs
Nutritional planning	- Organization of eating - Nutritional and energetic needs - Caloric restriction - Micronutrients that are at risk of being deficient in SOPs	- To present general recommendations regarding eating and nutrition for SOPs; - To show the different models of caloric restriction, according to their limitations and possible indications; - To describe different manner of doing the calculation of daily energy needs; - To present the reference values and food sources of macro and micronutrients
Organization of nutritional care in Primary Health Care (PHC)	- Matrix support for eating and nutrition - Organization of care for SOPs at the PHC level - Nutritional follow-up - Referral to EAA	- To discuss PHC as the preferred entry way for individuals into SUS; - To present activities that can be done in PHC to follow up on SOPs; - SOP identification, approach, reception, initial evaluation, and referral to the EAC; - Individualized nutritional care
Organization of nutritional care in Specialized	- Organization of SOPs care in PHC - Nutritional follow-up - Eligibility for bariatric surgery	- To describe the nutritional approach to be used in EAC; - To present the calculation of excess weight loss during nutritional care; - To detail nutritional behavior to be followed in the first appointment and in the follow-up appointments; - To discuss how to investigate the eligibility criteria for bariatric surgery

it continues

Chart 1. Content of the manual for nutritional care of severely obese people at the SUS.

Chapters	Content	Objectives
Organization of nutritional care in Specialized Hospital Care	- Production of Nutritional Report - Nutritional follow-up - Pre-surgery nutritional behavior - Post-surgery nutritional behavior - Nutritional behavior in post-surgery complications - Hospital discharge for PHC	- To contextualize the indication criteria and the varieties of bariatric surgery in Brazil; - To present a model for the production of nutritional reports; - To approach the specificities of the pre-surgery nutritional behavior; - To indicate the exams to be done during the preparation for bariatric surgery; - To present the 5 stages of nutrition after bariatric surgery; - To provide guidance regarding habits for the late post-surgery period; - To show the most prevalent nutritional deficiencies during post-surgery, as well as the most indicated supplements; - To approach handling and behavior in case of possible post-surgery complications
Appendices	- Protein content and household measurements of in natura foods - Proposal of pre-surgery eating and nutritional education activity for bariatric surgeries. - Educational slides - Nutritional report model	- To construct and make available adequate materials for the treatment of SOPs

Where: EAA: Specialized Outpatient Care; PHC: Primary Health Care; NGBP: Nutrition Guidelines for the Brazilian Population; SOPs: Severely Obese Person/People..

Source: Authors.

important to highlight the full view of the individual during embracement and establish connections with patients, which serves to improve adherence to and success of the treatment. In the statements of the evaluators, it can be observed that the professional must have “an active listening, identifying the specificities of each (patient), interacting, having empathy” since the patient “has already tried dieting a thousand times, and it always failed; therefore, she (patient) feels incompetent, she (patient) feels like a failure because she (patient) has no discipline, no will power”.

Therefore, the Manual follows the approach that treatment must be reconsidered by nutritionists, as we can see in the statement “sometimes we even move away from the focus on weight, so that they can understand what the health parameters for them are”. The treatment targets should not be restricted to weight loss, and the nutritionist must be prepared to deal with oscillations during the treatment, helping the patient in different situations.

The topic “Recommendations for adequate and healthy eating” guides nutritionists on how to apply the concept of adequate and healthy eating for the SOPs. The recommendations of

the Eating Guide for the Brazilian Population and of Cardioprotective Eating is discussed, as are reflections regarding the act of eating.

Adequate and healthy eating requires changes in behavior. To make that happen effectively, the nutritionist must follow up on the SOPs more regularly, both before and after bariatric surgery. As the evaluators mentioned, the nutritionists should “help the patient understand the need for change, the before and after of bariatric surgery, so that the post-bariatric surgery is easier”. After all, “those habits (which contributed to the development of severe obesity) were acquired long ago, so it is difficult for (the patient), all of a sudden, in an outpatient scenario, in front of a nutritionist, to change completely”.

Next, in the item “Nutritional Planning”, the manual presents the nutritional recommendations for SOPs, the reasons for indicating caloric restriction, and the factors that may help in the choice of modality of restrictions to be adopted. During nutritional planning, nutritionists must also be aware of the nutritional deficiencies that are characteristic of SOPs, following the statements of evaluators, for instance, “hair is falling out, fingernails are breaking, that means, the clinical exam, the physical exam, and the obser-

vation of the symptoms during the appointment are essential to providing us those clues". In this section of the material, there is an emphasis on the foods and the ways of cooking, which enable nutritionists to talk about nutritional deficiencies. After all, as reported by the evaluators, "for patients in the post-bariatric surgery stage, the use of this or that supplement is required. (However), there are patients who cannot afford these supplements [...], this is complicated and also very risky".

As observed in the statement "[...] I have never cooked so many recipes with egg whites [...]. I have never used so much egg white and lean powder milk", the prescription of "practical recipes" by nutritionists is a required strategy for professionals that follow up on SOPs. Therefore, the manual presents a table with the main sources of protein, as well as with information about those foods in household measurements, grams of foods and grams of protein, in order to increase the options of protein sources to be used and to facilitate guidance for the patient.

The subsequent topics approach the specificities in the organization of NC at each level of the SUS healthcare network. The item "Organization of Nutritional Care in Primary Health Care" emphasizes Primary Health Care (PHC) as the guide for care and the entryway of patients into SUS.

Next, in the topic "Organization of Nutritional Care in Specialized Outpatient Care", specialized care, preferential reference places for initial investigation of the eligibility criteria for bariatric surgery, and the provision of non-surgical treatment for a minimum of two years are discussed. Intensive NC must be practiced, taking into consideration the challenges faced by SOPS.

The final topic, 'Organization of Nutritional Care in Specialized Hospital Care' discusses the nutritional conduct in the pre and post-surgery periods, the behavior to be adopted by the PHC, in order to ensure the continued success of the surgery, as well as a semi-structured model of nutritional report.

Finally, the manual comes with appendixes, which are tools for a dynamic follow-up of severe obesity and the promotion of behavior changes, which must be maintained for the rest of one's life.

Validation process

Content validation

In the first stage, 13 questions did not achieve the adequate CVI. In the second stage, the questions discussed were those in which CVI had not reached the desirable minimum in the first stage, and agreement was reached in all of the evaluated items. Therefore, that version of the manual was used for the appearance validity stage.

Appearance validity

The statements from the evaluators were similar, meaning that content saturation had been reached, as can be observed in the hapax coefficient of 3.56%. This means that only 3.56% of the words in the corpus had a single occurrence, thus reinforcing the similarities in the statements.

Considering that obesity is a multifactorial disease, which is challenging and complex to manage, the need to evaluate the willingness for behavior changes was discussed. The content referring to this theme was transcribed in the corpus "willingness for behavioral change", which had 8,567 occurrences, with 1,447 distinctive words and an average frequency of 34.96 forms for text segment (TS). That corpus was submitted to HDC, obtaining 205 TS, corresponding to 83.67% of retention.

In the HDC, a dendrogram was generated, with five classes. Class 4 had the highest number of TS, 23.9%, followed by classes 1 and 3 with 21.46% each. Classes 5 and 2 had, respectively, 17.07% and 16.1% of the TS. Due to the proximity, classes 2 and 3, and classes 4 and 5, showed greater affinity (Figure 2).

The second topic covered in the focus group was the need for supplemental proteins and micronutrients after bariatric surgery. The content of this question was transcribed in the corpus "need for supplements", presenting 4,523 occurrences, with 1,072 distinctive words and an average frequency of 34.96 forms for TS.

A frequent question asked by health professionals concerned the organization of NC at the different levels of SUS. To help understand this theme, chapters were included, referring to the specificities of each of the SUS levels of care. To analyze the theme, a similarity graph was created (Figure 3), highlighting two nuclei, those with the keywords "primary care" (n = 50) and "patient" (n = 34).

In the end, a discussion regarding the treatment for obesity took place (Figure 4).

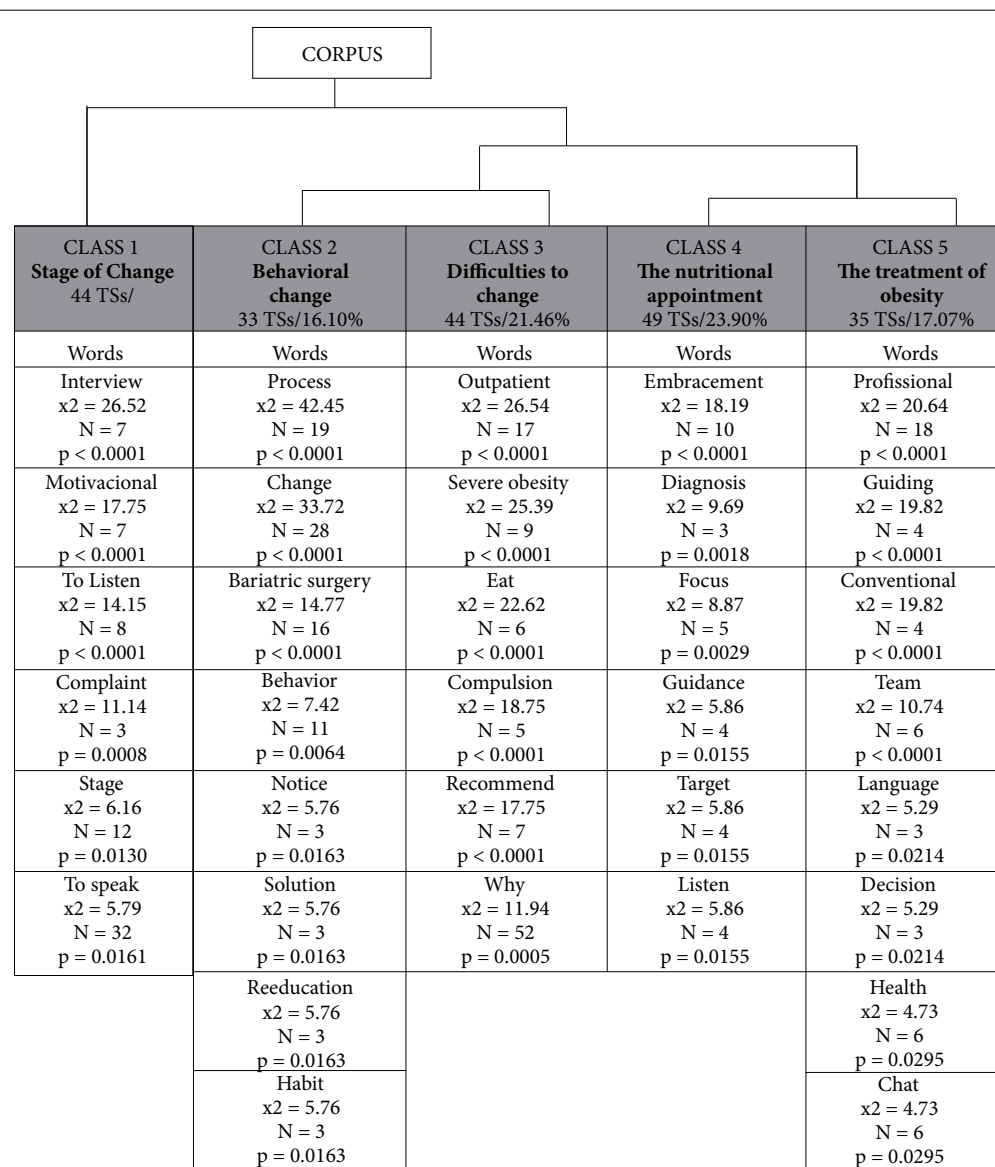


Figure 2. Dendrogram of HDC related to the corpus “willingness for behavioral change”.

Source: Authors.

Discussion

First and foremost, this study presents the construction of an instructive document for the NC of SOPs at SUS. Severe obesity is associated with multimorbidity and incapacity, consequently resulting in reductions of life quality and life expectancy^{1,2,26}. The burden of this disease produces multifaceted demands on health services, raising both direct and indirect costs^{1,2,27}.

In terms of care for SOPs, the strategies which target only the reduction of caloric ingestion and the increase in energy expenditure show a limited efficiency for SOPs, due to the complex systems of hormonal, metabolic and neurochemical adaptation, which defend the individual against weight loss and promote weight regain^{3,28}. Multidisciplinary interventions are required, as is the adoption of new lifestyles in terms of eating and physical activities, and the

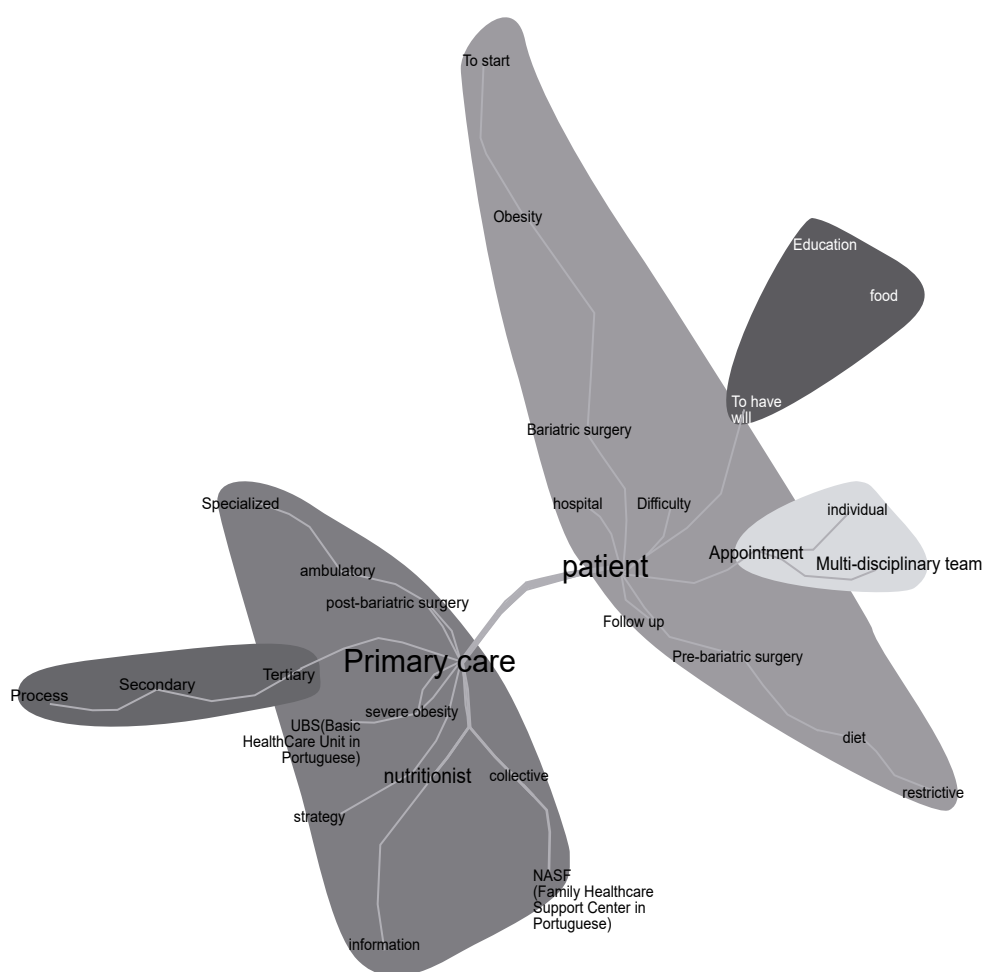


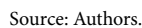
Figure 3. Similarity analysis of the corpus “primary and specialized healthcare”.

Source: Authors.

understanding of social and economic aspects that may be integrated into the care provided to SOPS, all important elements in order to gather a set of promising care strategies^{8,9,29-31}. Bariatric surgery, although efficient in terms of weight loss for SOPS, has important nutritional repercussions during the pre, peri and post-surgery periods, besides the need to change one's lifestyle in order to maintain post-operative weight loss over the long term^{32,33}. In this context of many challenges in NC for SOPS, this instruction manual can serve to qualify nutritionists who work in the three components of healthcare (PHC, EAA, and AEH) at SUS, in identifying obstacles during NC; in providing nutritional counseling that meets individual needs; and in promoting adequate and healthy

eating habits, which involves nutritional, environmental, and behavioral aspects. Another relevant point in the discussion is the satisfactory result in terms of content validation and appearance validity of the manual, emphasizing the quality of the content and its applicability. After two stages of content validation, agreement was reached in relation to all of the evaluated items, in other words, in terms of usability, functionality, content, relevance, and appearance, which allowed the material to be used in the appearance validity.

The focal group enabled us to evaluate how the possible users of the material would interpret the items for their application in practical situations³⁴. It was noticed that, due to its complexity, there was a need to formulate materials that



The focus on the patient is even more essential when we consider the stigma to which SOPs

are susceptible. Prejudice, discrimination, marginalization, and blame negatively impact the success of obesity treatment, thereby compromising the development of the patients' self-esteem and self-confidence^{7,8,11}. Consequently, individuals who suffer stigma because of their body weight, end up developing greater weight gain and worsening in terms of biochemical parameters related to obesity and psychological disorders. This type of stigma also discourages people from seeking professional help, further contributing to the development of obesity^{5,42}.

Finally, the success of the obesity treatment is discussed. According to the Brazilian Association for the Study of Obesity and Metabolic Syndrome (*Associação Brasileira para o Estudo da Obesidade e da Síndrome Metabólica* – ABE-SO), the measure of success in obesity treatment is a weight loss of at least 5% to 10%, estimated to be enough to impact positively on diseases related to obesity, such as Type 2 diabetes, hypertension, and dyslipidemia^{43,44}. It is important to mention that weight was an important indicator, since this word was mentioned 32 times in the corpus. However, the evaluators themselves also mentioned the need to value achievements other than weight loss. This broader focus was widely discussed in the manual, which states that the treatment must not be restricted to weight loss and should also include aspects related to wellbeing, self-esteem, self-image of the body, mobility, social life, love relationships, work productivity, intestinal function, cognitive function, willingness, quality of sleep, blood pressure, and laboratory exams^{5,9}.

Limitations and strong points

As a limitation in this study, the graphic design (layout/visual) of the manual was only evaluated in the first stage of the Delphi Technique. Since the material was supposed to be di-

agrammed only after the final version had been concluded, it was inevitable that the evaluators judged the appearance of the material. However, the answers and comments regarding improvements in this aspect supported the decisions about formatting, number of pages, and visual appearance of the final version of the manual. Other limitations were the low representativity of participants from the North region of the country, and the larger presence of expert professionals in comparison to practitioners. However, content saturation was reached with the comments, which is a strong point in the validation process, indicating that all of the most relevant questions were discussed until they had been exhausted. Another strong point refers to the fact that two techniques were used in the evaluation – the Delphi Technique and the Focus Groups – as well as the fact that unanimous agreement was observed among all of the participants, in both evaluation techniques.

Conclusion

The methodology used in this study enabled the elaboration of adequate materials for the NC of SOPs, and the applicability of the materials at SUS. The content covered in the manual is sufficient and adequate, according to the content evaluation, and is aligned with the practical reality (appearance validity), resulting in a material that is coherent with the needs of SUS nutritionists.

It is our belief that the publication of this manual will provide technical support for SUS nutritionists, enabling NC for SOPs to be conducted in a more effective and adequate manner. We also foresee improvements in nutritional interventions for SOPs and more effective elements for the creation of specific public health policies for this group.

Contributions

MMD participated in the conception and design, analysis and interpretation of data, writing of the article and approval of the version to be published. OGLC participated in the conception and design, writing of the article and approval of the version to be published. FGC participated in the conception and design. HHMH participated in the conception and design, critical review of the article and approval of the version to be published.

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