Nutritional and Educational Intervention to Recover a Healthy Eating Pattern Reducing Clinical Ileostomy-Related Complications

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Abstract: The aim of this study was to evaluate a diet intervention implemented by our hospital in order to determine its capacity to improve the eating pattern of patients with an ileostomy, facilitating the implementation of new eating-related behaviors, reducing doubt and dissatisfaction and other complications. The study was conducted with a quasi-experimental design in a tertiary level hospital. The elaboration and implementation of a nutritional intervention consisting of a Mediterranean-diet-based set of menus duly modified that was reinforced by specific counseling at the reintroduction of oral diet, hospital discharge and first follow-up appointment. Descriptive, bivariate and multivariate analyses were performed. The protocol was approved by the competent Ethics Committee. The patients of the intervention group considered that the diet facilitated eating five or more meals a day and diminished doubt and concerns related to eating pattern. Most patients (86%) had a favorable experience regarding weight recovery and a significant reduction of all-cause readmissions and readmission with dehydration ($p = 0.015$ and $p < 0.001$, respectively). The intervention helped an effective self-management of eating pattern by patients who had a physical improvement related to hydration status, which, together with an improvement in weight regain, decreased the probability of readmissions.

Keywords: ileostomy; eating pattern; self-management; organism hydration status; body weight; hospital readmission

1. Introduction

In the management of colorectal cancer (CRC) or inflammatory bowel disease (IBD), it may be necessary to perform an ileostomy, which is a skin exteriorization from an ileal segment to eliminate feces either temporarily or permanently [1].

On average, 50% of the cases present clinical complications, however, this percentage can rise to 96% during the first three post-operative weeks where hydroelectrolytic alterations account for 20–29% [2]. In this period, up to 16% of these patients will present high fecal outputs through the stoma (>2000 mL/24 h), which supposes higher risk of dehydration, electrolyte imbalance and malnutrition [2]. Thus, readmission 60 days after discharge is common in these patients [3].

Factors such as the surgery, the underlying pathology and other treatment options are related to the nutritional and hydroelectric changes reported. Micronutrient deficit, malabsorption of bile fats and salts, caloric malnutrition and hydroelectric and weight losses are
associated with the surgical procedure [4,5]. Reduced intake and metabolic changes, as well as higher energy expenditure, are described in CRC [6,7]; energy and protein malnutrition with deficit of essential micronutrients is common in IBD [8], whereas chemotherapy and radiotherapy produce symptoms related to a higher risk of malnutrition [9].

Early physiological enteral nutrition must be the first option since it eases the process of intestinal adaptation, preserves the intestinal flora and the enteric immune system, presents fewer complications and is cost effective when compared with other options [10]. In general, these patients will be able to follow a normal diet avoiding certain food products and introducing some changes in their habits aimed at preventing stoma obstruction, dehydration and gastrointestinal discomfort or food intolerance [11].

The physical and psychosocial implications associated with the implantation of the stoma, together with the absence of sound diet recommendations, leads many patients to adopt heterogeneous strategies of doubtful value based on their experiences or on myths about the properties of certain food products, which exert a negative impact on their nutritional state [12]. They frequently report receiving scarce or no information, and sometimes contradictory information about diet guidelines, which generates anxiety, confusion and/or frustration in them, thus increasing dissatisfaction with the care received [13]. In addition, providing them with strong diet recommendations to which they can adhere would be fundamental to avoid future complications and readmissions [14].

In this sense, an inadequate health education limits their ability to assume responsibility for self-care in an effective manner [15,16]. Self-efficacy has shown to be an indispensable factor in habit change related to motivation, adherence to treatment and, ultimately, with the improvement of outcomes [17].

Based on this, the aim of this study was to evaluate a diet intervention implemented by our hospital in order to determine its capacity to improve the eating patterns of patients with an ileostomy, facilitating the implementation of the diet guidelines, minimizing the doubts in relation to their diet, and reducing their levels of concern, dissatisfaction and complications. This type of intervention could improve the patients’ autonomy in the management of their disease, which would suppose an advancement of great interest in clinical practice.

2. Materials and Methods

2.1. Setting

The study was conducted in the General Digestive Surgery Unit of a tertiary level hospital where 166 ileostomies were performed in adults from 2019 to 2020. To improve the care provided to patients with ileostomy, this unit, working collaboratively with the Endocrinology and Nutrition Unit, developed a nutritional intervention consisting of a health education session and a set of menus as support material home care (Appendix B) for patients, who previously only received brief written instructions at discharge (Appendix A).

2.2. Design

A quasi-experimental design of unpaired samples was carried out. To ensure the methodological quality of the study, recommendations from the Methodological Index for Non-Randomized Studies (MINORS) [18] and from the Joanna Briggs Institute’s Critical Appraisal Checklist for Quasi-Experimental Studies (non-randomized studies) were followed [19].

2.3. Sample Size

Sample size was calculated by maximizing the parameters for the comparisons of proportions and means (for outcomes measured with a 5-point Likert scale). The calculation that rendered the largest sample size was chosen. The ability to detect a 1-point difference in the Likert scale with a 5-point variance was pre-fixed, assuming a 10% loss (estimation of refusals to sign the informed consent). For a bilateral test with 90% power and 95% statistical power, the calculation indicated 117 patients.
2.4. Intervention

The elaboration and implementation of this intervention included endocrinologists, nutrition technicians and stoma therapists. A specific oral diet with a Mediterranean pattern was designed due to its widely proved beneficial effects to health, and for being the characteristic eating pattern of this region, easing adherence. Liquid, initial, soft (taken during hospitalization) and basal (taken at home) variants were elaborated to allow its progressive and successful introduction. For each variant, autumn/winter and spring/summer models were elaborated, allowing the use of seasonal food products in its preparation. For basal diets, 14 full menus were designed for lunch and dinner, as well as examples for breakfast and teatime, which were handed in to the patients after discharge (Appendix B).

Furthermore, patients received an educational session three times in different moments (reintroduction of diet after surgery, at discharge and during first visit after discharge). All lasted around 30–35 min where the stoma therapist explained key information on nutrition and eating habits to avoid complications during the first session. The key messages were summarized and provided in writing to the patient in the first session (Appendix B) and served as a follow-up script for the remaining sessions when the stoma therapist received feedback on the habits implemented and difficulties or complications associated with the eating dimension, providing solutions and reinforcing positive habits.

2.5. Procedures

The design of the menus and the health education session, as well as their approval by the hospital management, lasted from October 2017 to April 2018. The implementation of the intervention began in April 2018, when the prospective recruitment of patients for the intervention group began, and lasted until July 2020. The patients were recruited after surgery according to inclusion criteria (adults with ileostomy who signed the informed consent form, followed-up in our unit and who stated their intention to follow the diet proposed). Subjects with sensory/cognitive constraints and non-Spanish speakers were excluded due to the risk of misunderstanding the indications.

The control group was recruited retrospectively during their medical review visits between January and July 2018, excluding patients who underwent surgery before 2016 to minimize the memory bias.

A 23-item survey was elaborated, where sociodemographic (age, gender, marital status, schooling level, occupation, family situation), clinical (type of ileostomy, centimeters of ileum removed, etiology, chemotherapy treatment, incidence of gastrointestinal symptoms in case of chemotherapy treatment, self-care level) and anthropometric (weight and BMI) variables were measured. Due to the absence of a validated scale to determine the self-care level in these patients, this is usually determined by the stoma therapist through observation and interviews with the patients, who were assigned autonomous, semi-dependent or dependent levels.

2.6. Outcomes

To assess outcomes related to eating pattern management a 5-point Likert scale was used to determine the difficulty to implement the diet recommendations and the usefulness of the intervention by the patients. Additionally, onset of gastrointestinal problems related to the diet, compliance of the diet guidelines received, emergence of doubts in relation to the food products to eat and to their preparation, and if they considered that the diet was adequate were collected as dichotomous (yes/no) questions. The number of meals eaten per day and evolution of weight were also collected. The control group patients were asked if they recalled having gained, lost or maintained weight after 1–3 months of the ileostomy. The intervention group was followed up obtaining BMI values at the time of the surgery (baseline), weight at discharge, and at the first and second scheduled appointments (7–14 days and 30–60 days after discharge, respectively). Readmissions at 60 days after
discharge, including dehydration among causes, were collected from clinical digital records from our emergency department.

2.7. Data Analysis

Data were analyzed in the strictest confidentiality with IBM SPSS software v22 (IBM, Chicago, USA). A descriptive analysis by absolute and relative frequencies and median and interquartile range was applied as appropriate. Pearson’s chi-square test was used to evaluate the association in qualitative variables. Wilcoxon signed-rank test and Kruskal–Wallis test were performed for comparison of means checking normality tests beforehand. Finally, multivariate models were implemented to elucidate possible confounding bias. Statistical significance was defined as obtaining a \( p \)-value under 0.05.

2.8. Ethical Aspects

The Declaration of Helsinki and Guides for a Good Clinical Practice were taken into account to conduct this study. Protocol was approved by the competent Ethics Committee. The patients were informed about the study objectives and dynamics prior to their inclusion. This information was offered together with the informed consent document on the follow-up visits for the control group patients, and after the surgery in the intervention group patients.

3. Results

The number of patients included was 253, with 117 in the control group (71% of all the patients seen during the inclusion period) and 136 in the intervention group, where, initially, 164 met the inclusion criteria, but there were 28 losses (5 refusals to participate, 2 problems with language, 3 relevant missing data, 6 high-debit ileostomy, 9 unfavorable life prognosis and 3 deaths).

Age ranged between 18–89 years old, distributed with a mean and standard deviation of 58.5 ± 17.5 and 59.3 ± 15.6 in the control and intervention groups, respectively, without differences between them \( (p = 0.854) \). Except for the educational level \( (p = 0.042) \), no statistically significant differences were found between the groups for the sociodemographic characteristics (Table 1).

Table 1. Sociodemographic features.

| Variable                   | Total n (%) | Control n (%) | Intervention n (%) | \( p \) Value | OR (CI95%) |
|---------------------------|-------------|---------------|-------------------|--------------|------------|
| Sex, male                 | 253 (100)   | 117 (71.1)    | 136 (53.8)        | 0.002        | 0.97 (0.57–1.65) |
| Marital Status            |             |               |                   |              |            |
| Single                    | 41 (16.2)   | 19 (16.2)     | 22 (16.2)         | 0.933        | ref        |
| Married/Partner           | 179 (70.8)  | 82 (70.1)     | 97 (71.3)         | 1.02 (0.47–2.13) |
| Divorced/Separated        | 12 (4.7)    | 5 (4.3)       | 7 (5.1)           | 1.1 (0.28–5.67) |
| Widowed                   | 21 (8.3)    | 11 (9.4)      | 10 (7.4)          | 0.79 (0.24–2.56) |
| Education                 |             |               |                   | 0.042        | ref        |
| None                      | 28 (11.1)   | 16 (13.7)     | 12 (8.8)          | ref          |            |
| Primary                   | 113 (44.7)  | 59 (50.4)     | 54 (39.7)         | 1.2 (0.49–3.10) |
| Secondary                 | 78 (30.8)   | 26 (22.2)     | 52 (38.2)         | 2.6 (1.00–7.10) |
| Higher                    | 34 (13.4)   | 16 (13.7)     | 18 (13.2)         | 1.5 (0.49–4.63) |
| Occupation                |             |               |                   | NA           |            |
| Student                   | 6 (2.4)     | 1 (0.9)       | 5 (3.7)           | ref          |            |
| Employed                  | 63 (24.9)   | 20 (17.1)     | 43 (31.6)         | 0.43 (0.08–4.26) |
| Unemployed                | 41 (16.2)   | 23 (19.7)     | 18 (13.2)         | 0.16 (0.03–1.64) |
| Retired                   | 143 (56.5)  | 73 (62.4)     | 70 (51.5)         | 0.19 (0.04–1.19) |
| Whom do you live with?    |             |               |                   | 0.299        |            |
| Alone                     | 28 (11.1)   | 16 (13.7)     | 12 (8.8)          | ref          |            |
| Couple                    | 181 (71.5)  | 84 (71.8)     | 97 (71.3)         | 1.54 (0.64–3.78) |
| Son/Daughter              | 15 (5.9)    | 4 (3.4)       | 11 (8.1)          | 3.55 (0.8–19.27) |
| Parents                   | 29 (11.5)   | 13 (11.1)     | 16 (11.8)         | 1.63 (0.51–5.32) |
| With Familial/Social Support | 26 (92.9) | 14 (87.5)    | 12 (100)          | 0.492        | NA         |

* This was only answered by patients who reported living alone.
Table 2 shows the descriptive analysis of the clinical, anthropometric and outcome variables. No significant differences related to etiology, type of ileostomy or autonomy in care were observed between groups. There was difference for the “centimeters of ileum removed”, whose mean and standard deviation were 20.5 ± 43.1 and 10.7 ± 18.6 cm in the control and intervention groups ($p = 0.016$), respectively.

**Table 2. Clinic, anthropometric and satisfaction variables.**

| Variable                                           | Total n (%) | Control n (%) | Intervention n (%) | OR (CI95%) |
|----------------------------------------------------|-------------|---------------|--------------------|------------|
| Type of ileostomy, temporary                        | 238 (94.1)  | 110 (94.0)    | 128 (94.1)         | 0.973      |
| Self-care autonomy                                   |             |               |                    | 0.321      |
| Autonomy                                            | 133 (52.6)  | 61 (52.1)     | 72 (52.9)          | reference  |
| Semi-independent                                    | 95 (37.5)   | 41 (35.0)     | 54 (39.7)          | 1.16 (0.65–1.96) |
| Dependent                                           | 25 (9.9)    | 15 (12.8)     | 10 (7.4)           | 0.57 (0.21–1.46) |
| Ileostomy aetiology                                 |             |               |                    | 0.101      |
| Cancer                                              | 154 (60.9)  | 65 (55.6)     | 89 (65.4)          | reference  |
| Inflammatory pathology                              | 69 (27.3)   | 33 (28.2)     | 36 (26.1)          | 1.25 (0.67–2.32) |
| Other                                               | 30 (11.8)   | 19 (16.2)     | 11 (8.1)           | 2.35 (0.99–5.88) |
| If cancer CT Trt? *                                  | 44 (28.6)   | 24 (36.9)     | 20 (22.5)          | 0.023      |
| If CT Trt GI symptoms? *                            | 21 (47.7)   | 11 (45.8)     | 10 (50.0)          | 0.783      |
| GI problems related with eating, yes                | 111 (43.9)  | 89 (76.1)     | 22 (16.2)          | <0.001     |
| If GI problems, earlier appointment, yes *          | 9 (8.1)     | 8 (9.0)       | 1 (4.5)            | 0.988      |
| Follow diet guidelines, yes                         | 243 (96.0)  | 108 (92.3)    | 135 (99.3)         | 0.005      |
| Follow diet guidelines, yes                         | 117 (46.2)  | 88 (75.2)     | 29 (21.3)          | <0.001     |
| Doubts about feeding, yes                           | 62 (24.5)   | 54 (46.2)     | 8 (5.9)            | <0.001     |
| Concern about meal preparation, yes                 | 207 (81.8)  | 84 (71.8)     | 123 (90.0)         | <0.001     |
| Adequate diet, yes                                  |              |               |                    | 3.68 (1.67–8.13) |
| Number of daily meals                               |              |               |                    | <0.001     |
| <3                                                  | 1 (0.004)   | 1 (0.01)      | 0 (0.0)            | NA         |
| 3                                                   | 23 (9.1)    | 23 (19.7)     | 0 (0.0)            | NA         |
| 4                                                   | 72 (28.5)   | 56 (47.9)     | 16 (11.8)          | 0.13 (0.06–0.27) |
| 5                                                   | 100 (39.5)  | 31 (26.5)     | 69 (50.7)          | reference  |
| ≥6                                                  | 57 (22.5)   | 6 (5.1)       | 51 (37.5)          | 3.79 (1.42–11.96) |
| Difficulty to implement dietary recommendations, Likert 1–5 | | | | <0.001 |
| 1                                                   | 86 (34.0)   | 13 (11.1)     | 73 (53.7)          | Reference  |
| 2                                                   | 76 (30.0)   | 34 (29.1)     | 42 (30.9)          | 0.22 (0.10–0.49) |
| 3                                                   | 58 (22.9)   | 42 (35.9)     | 16 (11.8)          | 0.07 (0.03–0.17) |
| 4                                                   | 22 (8.7)    | 18 (15.4)     | 4 (2.9)            | 0.04 (0.01–0.15) |
| 5                                                   | 11 (4.3)    | 10 (8.5)      | 1 (0.7)            | 0.02 (0.004–0.15) |
| Utility of new diet, Likert 1–5                     |              |               |                    | Non comparable |
| 3                                                   | 11 (4.3)    | 8 (6.8)       | 3 (2.2)            |            |
| 4                                                   | 95 (37.5)   | 44 (37.6)     | 51 (37.5)          |            |
| 5                                                   | 147 (58.1)  | 65 (55.6)     | 82 (60.3)          |            |
| Ileostomy (cm removed), mean (sd)                   | 20.5 ± 43.1 | 10.7 ± 18.6   | 10.7 ± 18.6        | 0.016      |

CT trt: chemotherapy treatment, GI: gastrointestinal, OR: odds ratio, CI95%: confidence interval 95%, NA: not available because data are insufficient for this analysis, cm: centimeters, sd: standard deviation. * These frequencies and percentages were calculated based on the number of patients included in the categories or variables to which they are conditioned.

The most frequent etiology was CRC (60.9%) followed by inflammatory disease (27.3%) and other causes (11.8%) where different types of trauma were included. However, no differences were observed between groups regarding etiology. On the other hand, statistically significant differences were found for all outcomes, always in favor of the intervention group. Patients in the control group were asked if they thought that such an intervention would have been useful for a better management of their eating pattern. Among them, 109/117 (93.1%) assessed possible usefulness with four and five points (Likert scale). These points were assigned by 133/136 (98%) of the intervention group patients. It was not possible to assess statistical differences due to that, in the control group, the question explored the need, and in the intervention group, it was confirmatory of usefulness.
In the logistic regression models the intervention was identified as a risk factor to consider that the diet was adequate, and as a protective factor for eating five meals or more a day, being concerned when preparing the meals and having doubts in relation to the diet. A linear regression model showed that the intervention maintains an inverse relationship with the difficulty to implement the recommendations (Table 3).

Table 3. Multivariate models for outcomes.

| Multivariate Regression Logistic Models | Model 1 | Model 2 | Model 3 | Model 4 | Model 5 |
|----------------------------------------|---------|---------|---------|---------|---------|
| AIC: 228.86                            |         |         |         |         |         |
| AIC: 217.77                            |         |         |         |         |         |
| AIC: 259.99                            |         |         |         |         |         |
| AIC: 271.74                            |         |         |         |         |         |
| AIC: 71.74                             |         |         |         |         |         |
| aOR (CI95%)                            | aOR (CI95%) | aOR (CI95%) | aOR (CI95%) | aOR (CI95%) |
| Group (Intervention)                   | 3.72 *** | 0.05 *** | 0.05 *** | 0.08 *** |
|                                        | (1.88–7.71) | (0.02–0.12) | (0.02–0.10) | (0.04–0.14) |
| Education                              | 1.88 **  | 0.62 *   | 1.52 *   |         |
|                                        | (1.27–2.86) | (0.41–0.91) | (1.06–2.24) |         |
| Ileost. (Temporary)                    | 0.26 *   |         |         |         |
|                                        | (0.07–0.94) |         |         |         |
| Marital St (Single)                    | 1.02     |         |         |         |
|                                        | (0.40–2.56) |         |         |         |
| Marital St (Div/Sep)                   | 9.68 *   |         |         |         |
|                                        | (2.22–46.78) |         |         |         |
| Marital St (Widowed)                   | 1.99     |         |         |         |
|                                        | (0.64–6.45) |         |         |         |
| Self-Care Autonomy                     | 1.52 *   |         |         |         |
|                                        | (1.06–2.24) |         |         |         |
| GI probl r/w eating                    | 8.55 *   |         |         |         |
|                                        | (1.78–154.12) |         |         |         |
| Multivariate lineal regression model (Difficulty to implement dietary recommendations) |         |         |         |         |
| coef | p-value (model) | Adjusted R² |
| β0 | 2.58 (*** ) | (*** ) | 0.26 |
| Group (Intervention)                  | −0.97 (***) | | |
| GI probl r/w eating                   | 0.31 ( * ) | | |

Model 1: adequate diet, Model 2: concern about meals preparation, Model 3: number of daily meals ≥5, Model 4: doubts, Model 5: follow diet guidelines, Ileost: ileostomy, St: status, Div/Sep: divorced/separate, GI probl r/w eating: gastrointestinal problems related with eating, coef: coefficient, OR: odds ratio, CI: confident interval, * p < 0.05; ** p < 0.01; *** p < 0.001.

Weight gain and weight loss was reported by 43 (36.75%) and 69 (58.97%) control patients, respectively, leaving only 5 (4.27%) with a stable weight after the surgery. In the intervention group (Table 4) significant differences were observed at discharge and follow-up appointments 1 and 2, although this only involved significant differences in the weight loss percentage in the last assessment coinciding with significant difference in days from baseline to this timepoint. Among them, 92% attended the first scheduled review appointment at 10.5 ± 4.8 days and 96% attended the second appointment at 42.5 ± 10.9 days (mean and SD).
Regarding readmissions at 60 days after discharge, patients in the control group had a readmission rate of 29.7%, with the specific rate of readmission due to dehydration being 17.8%. This values for intervention group were 16.2% and 4.4%, respectively. A statistically significant reduction between groups was observed for theses outcomes ($p < 0.001$, respectively). Odd ratios (CI95%) for intervention regarding the control group were 0.52 ($0.74$, 0.35) and 0.46 ($0.87$, 0.24) for total readmissions and 0.21 (0.07–0.56) for specific readmission due to dehydration.

### 4. Discussion

This is a quasi-experimental study that has assessed a nutritional intervention in patients with an ileostomy. Usually, these patients simply receive a list of non-recommendable food products and culinary techniques, previous to their nutritional assessment [12,17,20–23]. However, we have not found papers that offer an instrument to mitigate the patient’s uncertainties during the elaboration of meals and improve the self-management of their eating pattern while inducing improvements related to weight and fluid balance.

#### 4.1. Patients’ Profiles

It was similar (57.7% men and 59 ± 16.5 years old) to other Western countries with the predominance of CRC patients (55.6% in the control group and 65.4% in the intervention group, $p > 0.05$) [24,25].

Educational level was lower in the control group, which could affect the understanding of the recommendations. Although 52% of the subjects were considered as autonomous patients in self-care, only two individuals stated living alone and without the support of family members, implying that most of them would have their care needs covered.

The main etiology was malignant pathology (55.6% in the control group and 65.4% in the intervention group), as previously reported [26]. Although there was no statistical difference in the cancer prevalence between the groups, it was verified by the number of patients who underwent chemotherapy ($p = 0.049$); however, the rates of gastrointestinal symptoms were similar, excluding this as a possible bias to improve the eating pattern.

### Table 4. Analysis of the weight gain.

| BMI cat. (n) | Baseline | Discharge | Follow-Up App 1 | Follow-Up App 2 |
|--------------|----------|-----------|-----------------|-----------------|
|              | Weight $\bar{x} \pm SD$ | Weight $\bar{x} \pm SD$ | Weight $\bar{x} \pm SD$ (avg %) | Days | Weight $\bar{x} \pm SD$ | Weight $\bar{x} \pm SD$ (avg %) | Days | Weight $\bar{x} \pm SD$ | Weight $\bar{x} \pm SD$ (avg %) | Days |
| Inadequate (5) | 17.9 ± 0.6 | 68.3 ± 12.2 | −2.7 ± 1.5 (−5.6) | 10.6 ± 6.5 | 69.2 ± 11.8 | −2.8 ± 1.5 (−5.8) | 19.4 ± 8.1 | 48.6 ± 5.5 | −0.3 ± 2.1 (−0.8) | 70.0 ± 22.5 |
| Healthy (53) | 22.3 ± 1.8 | 66.7 ± 13.7 | −3.6 ± 3.4 (−5.6) | 12.1 ± 7.9 | 65.8 ± 14.1 | −3.6 ± 4.0 (−5.9) | 23.0 ± 13.3 | 62.4 ± 8.2 | −0.8 ± 4.9 (−0.9) | 49.8 ± 12.9 |
| Overweight (51) | 27.5 ± 1.4 | 67.3 ± 12.7 | −4.3 ± 3.1 (−5.5) | 13.4 ± 10.5 | 67.4 ± 12.7 | −5.1 ± 3.8 (−6.8) | 22.1 ± 10.0 | 72.2 ± 10.7 | −3.2 ± 3.9 (−4.3) | 56.5 ± 14.1 |
| Obese (27) | 32.9 ± 2.3 | 70.9 ± 14.8 | −5.8 ± 3.6 (−6.6) | 10.1 ± 5.5 | 70.4 ± 13.8 | −6.8 ± 4.6 (−7.8) | 22.3 ± 7.4 | 82.2 ± 14.0 | −6.3 ± 6.2 (−7.5) | 58.5 ± 9.8 |

$p$-Value (KW test) | 0.04 (0.719) | 0.7862 | 0.02 (0.782) | 0.7862 | <0.001 (0.007) | <0.001 |

Multivariate regression lineal models

| Independent Variables | Coefficient | $p$-Value | Adjusted R Square | Coefficient | $p$-Value | Adjusted R Square |
|-----------------------|-------------|-----------|-------------------|-------------|-----------|-------------------|
| $\beta_0$             | 10.68       | <0.001    | 0.2026            | 12.56       | <0.001    | 0.1538            |
| IMC category          | −0.52       | 0.748     | −0.06             | <0.001      | 0.748     |                   |
| days                  | 0.004       | 0.889     | 0.013             | 0.748       |           |                   |

BMI cat.: body mass index categories; KW test: Kruskall–Wallis test; App: appointment; $\bar{x}$: mean; SD: standard deviation; WG: weigh gain; Avg: average.
4.2. Outcomes

The multivariate models showed that the intervention is a highly protective factor regarding the patients’ concern at the time of preparing the meals (OR: 0.05, 95%CI: 0.02–0.12), and the doubts related to the food products (OR: 0.08, 95%CI: 0.04–0.14). This is a positive result since patients with ileostomy feel anxiety, confusion and frustration in relation to how to address diet [13]. Thus, this could lead them to adapt recommendations to their lifestyles and preferences on their own [27], increasing the risk of doing so inadequately. An inverse relationship was observed between belonging to intervention group and having difficulties in implementing the recommendations. These benefits are corroborated with the results observed in Models 1 and 3 (Table 3). In addition, our research significantly reduced the proportion of patients with gastrointestinal problems related to diet (OR:0.06, 95%CI:0.03–0.37).

Reducing the amount of food eaten in each meal and increasing the number of meals per day is beneficial for these patients [28,29]. Thus, Mukhopadhyay recommended an oral diet with six–eight meals/day with a reduction in the amounts eaten, leading all patients to recover their pre-surgery weight within 3 months [10].

Intestinal adaptation favors a partial recovering of intestinal function. This process is conditioned by the presence of food and secretions and begins 2–3 months after surgery [5]. Observational studies including patients, showed weight gain with respect to their pre-surgery weight 12 and 8 weeks after the procedure [10,21]. Likewise, in a retrospective study 13.3% of the patients lost weight after surgery and 68% presented normal weight at reconstruction surgery [22]. Vasilopoulos observed severe weight loss (>3 kg) in 53.8% of patients 3 weeks after the surgery [17]. At 6 weeks, this percentage rose to 70% when severe weight loss was defined as that higher than 7.5% of the pre-surgery weight [23]. Our results show a weight loss >7.5% regarding pre-surgery weight in 28.7% of the intervention group patients at 12.2 ± 8.3 days (discharge). This rose to 35.3% at 22.4 ± 10.8 days (first appointment), meaning an improvement compared with those previously reported. At 54.8 ± 13.9 days (second appointment) this ratio decreased to 25%. These severe weight losses could be a consequence of the post-surgical anatomical and functional loss and the absence of the intestinal adaptation process.

Other authors used the day of ileostomy as baseline to assesses the weight gain. However, we adopted the weight at discharge because it involved the self-management of the eating pattern, allowing observation of the results of the diets and nutritional guidelines implemented. All the weight assessments were within 90 days after ileostomy, with a mean and standard deviation of 54.8 ± 13.9 days. In the intervention group, 95 (69.85%) patients presented higher weight at the second appointment (42.5 ± 10.9 days).

The multivariate analysis shows that the weight loss differences were associated with pre-surgical BMI (higher in overweight and obese patients) rather than differences in days to attend the appointment. This could be prompted by the previous need to lose weight for the patients, who took advantage to obtain a healthy weight according to the clinical recommendations.

These results evidence, as previously, that early and maintained implementation of an oral diet is successful in recovering a patient’s weight and/or to steer their BMI into a healthy range [10,21].

The intervention involved a significant reduction in readmission rate for all causes and due to dehydration (p = 0.015 and p < 0.001, respectively). A recent systematic review that included 27,089 patients showed that the global incidence of 30- and 60-day readmission with dehydration were 5.0% (range 2.1–13.2%) and 10.3% (range 7.3–14.1%), respectively [30]. In our study, the 60-day readmission with dehydration rates were 4.4% for intervention and 17.8% for the control group. The rate of readmission with dehydration in our intervention group was significant lower than three studies (marked in bold) that reported similar results to our control group. However, our control group showed a more increased rate than most of the studies included, but our intervention reduced the rate so that no significant differences were observed for the group that received it (Table 5). These
improvements could be related to the increase in the number of intakes observed in the intervention group, since these could also be accompanied by a higher water intake.

Table 5. Comparison between rates of readmission with dehydration in intervention and control groups with previous studies.

| Study                      | Rate Reported | Intervention Group (Rate: 4.4%) OR (CI95%) | Note | Control Group (Rate: 17.8%) OR (CI95%) | Note |
|----------------------------|---------------|--------------------------------------------|------|---------------------------------------|------|
| Alqahtani et al. 2020      | 2.1           | 2.2 (0.08–4.9) nsd                         |      | 9.7 (5.7–15.9) ssi                    |      |
| Charak et al. 2018         | 14.1          | 0.28 (0.08–0.82) ssr                      |      | 1.31 (0.6–2.98) nsd                   |      |
| Chen et al. 2018           | 2.9           | 1.5 (0.54–3.46) nsd                       |      | 7.14 (4.16–11.78) ss                  |      |
| Fish et al. 2017           | 11.5          | 0.35 (0.12–0.86) ssr                      |      | 1.66 (0.90–2.99) nsd                  |      |
| Glasgow et al. 2014        | 13.2          | 0.31 (0.08–1.12) nsd                      |      | 1.42 (0.53–4.25) nsd                  |      |
| Justiniano et al. 2018     | 11.1          | 0.37 (0.12–0.94) ssr                      |      | 1.17 (0.89–3.33) nsd                  |      |
| Li et al. 2017             | 3             | 1.49 (0.57–3.35) nsd                      |      | 6.98 (3.74–12.77) ss                  |      |
| McKenna et al. 2017        | 4.6           | 0.95 (0.33–2.34) nsd                      |      | 4.47 (2.41–8.09) ss                   |      |
| Messari et al. 2012        | 7.3           | 0.59 (0.20–1.42) nsd                      |      | 2.75 (1.48–4.96) ss                   |      |
| Paquette et al. 2013       | 7.5           | 0.57 (0.18–1.61) nsd                      |      | 2.68 (1.25–5.85) ssi                  |      |

OR: odd ratio, CI95%: confidence interval 95%, nsd: no significant differences, ss: statistically significant reduction, ss: statistically significant increase. * Information taken from Liu et al., 2021 [30].

4.3. Strengths/Limitations

An experimental design to compare the intervention vs. standard care was not possible because the hospital management ordered the intervention to be applied to all patients, considering that it was beneficial enough to exclude it in a group of subjects. For this reason, we were forced to retrospectively choose a control group prior to the implementation of the protocol in the service.

Although significant differences were observed regarding the number of cm of ileus removed (greater in the control group), they were a number small enough to have clinical repercussions regarding the nutrition and hydration of the patients, since good tolerance of the loss has been described up to the middle of the small intestine (usual length from 6–8 m) [5]; none of the included patients lost lengths higher than 350 cm.

Our design represents an advantage over most previous studies, which were observational and did not contemplate a multivariate analysis to control the confusion bias derived from obtaining differences between groups such as “cm removed” or “educational level”. Moreover, our sample size is larger than those previously reported, and this is the reason why we consider that there was high statistical power.

The lower rate of readmissions to the emergency room due to dehydration could be attributed to the fact that the intervention group was discharged during the COVID-19 pandemic and patients were afraid to go to the hospital; however, in our country during the confinement primary care services delivered telehealth care only. In addition, dehydration in this type of patient is severe and requires intravenous fluid therapy and being admitted to the hospital, so we ruled out that the patients would stay at home.

Finally, our intervention is complex because through the menus and recommendations we work on the nutrients provided that are of interest to these patients (fiber or fat), types of food and eating-related behaviors, making it difficult to identify a specific factor responsible for the improvement of results. However, this is common in the clinical context, where, unlike a laboratory, not only one variable is controlled, but many with the intention of offering comprehensive care to the patient.

5. Conclusions

This study is pioneering in proving the effectiveness of a nutritional intervention consisting of a Mediterranean-diet-based set of menus duly modified to allow for a progressive and effective self-management of the eating pattern of patients with an ileostomy.
This was complemented with recommendations provided in an initial educational session and reinforced in two subsequent sessions; in addition, a brief written guide on these recommendations was added as documentation for home.

The success of this complex and multiapproach intervention has been evidenced through physical improvements observed in weight recovery, an improved hydration and a lower proportion of patients with gastrointestinal problems, behavioral improvements that were reflected in an increase in the number of intakes, decreased number of doubts regarding food selection/preparation, and readmission rate. The patients’ satisfaction level was reflected through the positive assessment of the usefulness of the intervention and the consideration of having followed an adequate diet.

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**Informed Consent Statement:** Informed consent has been obtained from the patients.

**Data Availability Statement:** Not applicable.

**Conflicts of Interest:** The authors declare no conflict of interest.

**Appendix A. Information Managed by Patients in the Control Group**

Recommendations in case of diarrhea or liquid stools:

Liquid stools are common with ileostomies and are also a normal occurrence after chemotherapy or radiotherapy treatments. On the other hand, an ileostomy patient, like any other person, can experience diarrhea after having eaten a certain food.

The recommended foods in case of diarrhea are:

- White and toasted bread with crude oil.
- Plenty of fluids: water, astringent infusions, fruit and vegetable smoothies (since they do not provide fiber).
- Quince.
- Potatoes.
- White rice and pasta.
- Ripe bananas (without the heart, which is where the fiber is).
- Grated or boiled apple.
- Meat and fish without fat.
- Carrots.
- Vegetable milk (soy, almonds . . . ). Rice milk is especially recommended for its astringent power.

Foods not recommended in case of diarrhea are:

- Whole milk and vegetable oat milk.
- Raw fruits, especially citrus.
- Raw and boiled vegetables.
- Legumes.

Recommendations for flatulence and bad odors:

For a person with an ostomy, having excessive flatulence or gases can be annoying since they will not be able to control the moment they are expelled. So, it is important to know what foods cause them in order to try to avoid them if it is of social interest.
- Brussels sprouts, cabbage, cauliflower and broccoli.
- Onions.
- Artichokes.
- Garlic.
- Asparagus.
- Fermented cheeses.
- Whole legumes.
- Carbonated drinks.
- Other vegetables according to personal sensitivity: cucumber, lettuce . . .
- Other foods: eggs, pork and nuts.

Gases and bad odors are reduced by incorporating into the diet:
- Butter.
- Parsley.
- Yogurt

Appendix B. Information Managed by Patients of Intervention Group

1100—Nutrition management

As an ileostomy carrier you will need to make some changes to your eating habits. In this way, you will avoid complications such as stoma obstruction, in addition to ensuring that your diet is capable of providing you with the nutritional requirements that you need for your day-to-day life.

Remember:
- Eat a varied and balanced diet, this will help your speedy recovery, as well as the healing of the ostomy and the surgical wound.
- Increase the number of daily meals, make a minimum of 5 or 6, reducing the amount eaten in the main meals.
- Eat slowly, chewing food very well.
- Avoid foods high in fat and fiber.
- Introduce new foods one at a time and always in small amounts. Avoid introducing them at night.
- Drink plenty of fluids (water, infusions, juices, isotonic drinks . . . ) and always outside mealtimes.
- Avoid carbonated drinks.
- In general, in foods of plant origin, you should remove the skin, seeds, filaments or threads, and all those parts that do not decompose well during digestion, as they could obstruct the stoma.
- Avoid nuts, popcorn, dried fruit, mushrooms, sweet corn, coconut, orange albedo, celery, bean sprouts, peas, and raw vegetables in general, as these are incompletely digestible foods and could obstruct the ostomy
- It is advisable to take fruit in juice or puree, avoiding pulp and seeds.
- In the usual way prepare vegetables, legumes and vegetables in puree.
- Avoid all those foods that have caused gastrointestinal discomfort or intolerance.

Basal Diet:
Its main objective is to provide a balanced and varied diet to the ileostomy patient who has satisfactorily tolerated the progression of the diet. This avoids those foods that can obstruct the ostomy, in this sense, vegetables and legumes are presented crushed and sifted. The fruit included attends to its characteristics and digestibility.

Brief Nutritional Assessment:
- Calories: 2975 Kcal/día
- Carbohydrates: 355 g/día (58% of total caloric value)
- Proteins: 132 g/día (23% of total caloric value)
- Lipids: 119 g/día (19% total caloric value)
- Fibre: 25 g/día
• Iron: 14 mg/día

**Information delivered by the Endocrinology and Nutrition Unit**

**Autumn/winter menus to patients with ileostomy**

**Choices for Breakfast**

**Option 1**
- Lactose free milk with decaffeinated coffee or cocoa powder,
- White bread,
- Olive oil,
- Soft cheese (Burgos cheese).

**Option 2**
- Lactose free milk with decaffeinated coffee or cocoa powder,
- White bread,
- Butter and fruit jam.

**Option 3**
- Lactose free milk with decaffeinated coffee or cocoa powder,
- Soft milk bun,
- Butter and fruit jam.

**Choices for Afternoon Snack**

**Option 1**
- Lactose free milk with cocoa powder or decaffeinated coffee,
- Banana and apple puree,
- Foie grass (duck pate) sandwich.

**Option 2**
- Lactose free milk with cocoa powder or decaffeinated coffee,
- Banana and apple puree,
- Plain ‘María’ cookies.

**Option 3**
- Lactose free milk with cocoa powder or decaffeinated coffee,
- Banana and apple puree,
- Cheese sandwich.

**Option 4**
- Lactose free milk with cocoa powder or decaffeinated coffee,
- Banana and apple puree,
- Smoked ham and cheese sandwich.

**Option 5**
- Lactose free milk with cocoa powder or decaffeinated coffee,
- Banana and apple puree,
- Smoked ham sandwich.

**Choices for Lunch**

**Option 1**
- Starter: Chickpea puree.
- Main course: Hamburger in white wine sauce and white bread roll.
- Dessert: Pear compote.

**Option 2**
- Starter: Fish stew.
- Main course: Crumbed pork loin and white bread roll.
- Dessert: Peaches in syrup.
Option 3
- Starter: Lentil puree.
- Main course: Grilled chicken and white bread roll.
- Dessert: Baked pear.

Option 4
- Starter: Pasta (macaroni) with tomato sauce.
- Main course: Grilled white fish and white bread roll.
- Dessert: Piece of fruit (e.g., golden apple).

Option 5
- Starter: Crumbed fish and boiled potatoes.
- Main course: Hamburger in sauce and white bread roll.
- Dessert: Piece of fruit (e.g., banana).

Option 6
- Starter: Bean cream.
- Main course: Meatloaf and white bread roll.
- Dessert: Flavored yogurt.

Option 7
- Starter: Chicken with rice and carrots.
- Main course: Fried codfish and white bread roll.
- Dessert: Piece of fruit (e.g., golden apple).

Option 8
- Starter: Beef stew with potatoes.
- Main course: Chicken burger in wine sauce and white bread roll.
- Dessert: Pear compote.

Option 9
- Starter: Pasta (macaroni) with tomato sauce.
- Main course: Grilled chicken and white bread roll.
- Dessert: Peaches in syrup.

Option 10
- Starter: Chickpea puree.
- Main course: Swordfish in sauce and white bread roll.
- Dessert: Piece of fruit (e.g., banana).

Option 11
- Starter: Fish stew
- Main course: Grilled beef burger, French fries and white bread roll.
- Dessert: Baked pear.

Option 12
- Starter: Cuttlefish with potatoes.
- Main course: Chicken breast in sauce and white bread roll.
- Dessert: Piece of fruit (e.g., golden apple).

Option 13
- Starter: Beef stew with potatoes.
- Main course: Meatloaf and white bread roll.
- Dessert: Flavored yogurt.

Option 14
- Starter: Pasta (macaroni) with deli turkey and oregano.
Main course: Fried white fish ("Acedías") and white bread roll.
• Dessert: Apple and apricot compote.

Choices for Dinner
Option 1

• Main course: Fried hake fillets with mayonnaise and white bread roll.
• Dessert: Custard.

Option 2

• Main course: Fish in wine sauce, French fries, and white bread roll.
• Dessert: Egg pudding ("Flan")

Option 3

• Main course: Iberian ham omelette, soft cheese (Burgos cheese), and white bread roll.
• Dessert: Peaches in syrup.

Option 4

• Main course: Chicken, mashed potatoes, and boiled eggs.
• Dessert: Fried codfish, baby carrots and white bread roll.

Option 5

• Main course: Scrambled eggs, potatoes and white bread roll.
• Dessert: Rice pudding.

Option 6

• Main course: French omelette, smoked ham, and white bread roll.
• Dessert: Curd with honey.

Option 7

• Main course: Iberian ham omelette, baby carrots and white bread roll.
• Dessert: Rice pudding.

Option 8

• Main course: Fried hake fillets with mayonnaise and white bread roll.
• Dessert: Vanilla egg pudding ("Flan").

Option 9

• Main course: French omelette, crispy fries, and white bread roll.
• Dessert: Chocolate pudding.
  Option 12
• Starter: Noodle soup.
• Main course: Chicken breast in white wine sauce, stir fried rice with turkey, and white bread roll.
• Dessert: Custard.
  Option 13
• Starter: Pumpkin soup.
• Main course: Grilled fish ("Acedías"), country potatoes and white bread roll.
• Dessert: Pear compote.
  Option 14
• Starter: Fish soup.
• Main course: Grilled fish ("Acedías"), country potatoes and white bread roll.
• Dessert: Chocolate pudding.

Spring/summer menus to patient with ileostomy

Choices for Breakfast
Option 1
• Lactose free milk with decaffeinated coffee or cocoa powder,
• White bread,
• Olive oil,
• Soft cheese (Burgos cheese).
Option 2
• Lactose free milk with decaffeinated coffee or cocoa powder,
• White bread,
• Butter and fruit jam.
Option 3
• Lactose free milk with decaffeinated coffee or cocoa powder,
• Soft milk bun,
• Butter and fruit jam.

Choices for Afternoon Snack
Option 1
• Lactose free milk with cocoa powder or decaffeinated coffee,
• Banana and apple puree,
• Foie gras (duck pate) sandwich.
Option 2
• Lactose free milk with cocoa powder or decaffeinated coffee,
• Banana and apple puree,
• Plan ‘Maria’ cookies.
Option 3
• Lactose free milk with cocoa powder or decaffeinated coffee,
• Banana and apple puree,
• Cheese sandwich.
Option 4
• Lactose free milk with cocoa powder or decaffeinated coffee,
• Banana and apple puree,
• Smoked ham and cheese sandwich.
Option 5
- Lactose free milk with cocoa powder or decaffeinated coffee,
- Banana and apple puree,
- Smoked ham sandwich.

Choices for Lunch
Option 1
- Starter: Beef stew.
- Main course: Hamburger in white sauce and white bread roll.
- Dessert: Pear compote.

Option 2
- Starter: Cold tomato soup.
- Main course: Grilled chicken and white bread roll.
- Dessert: Piece of fruit (e.g., golden apple).

Option 3
- Starter: Chickpea puree.
- Main course: Swordfish in “La Casera” sauce and white bread roll.
- Dessert: Piece of fruit (e.g., banana).

Option 4
- Starter: Fish stew.
- Main course: Grilled chicken burger, French fries, and white bread roll.
- Dessert: Baked pear.

Option 5
- Starter: Cold tomato soup.
- Main course: Chicken breast in sauce with croutons, egg, ham, and white bread roll.
- Dessert: Piece of fruit (e.g., golden apple).

Option 6
- Starter: Pasta (macaroni) with chicken.
- Main course: Boiled fish, potatoes, and white bread roll.
- Dessert: Flavored yogurt.

Option 7
- Starter: Vegetable puree.
- Main course: Grilled fish (“Acedías”) and white bread roll.
- Dessert: Piece of fruit (e.g., banana).

Option 8
- Starter: Chickpea puree.
- Main course: Chicken burger in soft sauce and white bread roll.
- Dessert: Apple puree.

Option 9
- Starter: Fish stew.
- Main course: Crumbed pork loin and white bread roll.
- Dessert: Peaches in syrup.

Option 10
- Starter: Lentil cream soup (“Esaú”).
- Main course: Grilled chicken, French fries, and white bread roll.
- Dessert: Baked pear.
Option 11
- Starter: Pasta (macaroni) with tomato sauce.
- Main course: Grilled fish and white bread roll.
- Dessert: Piece of fruit (e.g., golden apple).

Option 12
- Starter: Fish stew with potatoes.
- Main course: Hamburger in cream sauce and white bread roll.
- Dessert: Piece of fruit (e.g., banana).

Option 13
- Starter: Pasta (macaroni) with turkey.
- Main course: Battered hake fillets and white bread roll.
- Dessert: Flavored yogurt.

Option 14
- Starter: Stir fried rice with chicken and carrots.
- Main course: Fried codfish and white bread roll.
- Dessert: Piece of fruit (e.g., golden apple).

Choices for Dinner
Option 1
- Starter: Pasta soup.
- Main course: Fried hake with mayonnaise and white bread roll.
- Dessert: Custard.

Option 2
- Starter: Chicken broth with pasta.
- Main course: Crumbed fish (“Tilapia”) accompanied by crispy fries, and white bread roll.
- Dessert: Egg pudding (“Flan”).

Option 3
- Starter: Noodle soup.
- Main course: Iberian ham omelette, soft cheese (Burgos cheese), and white bread roll.
- Dessert: Peaches in syrup.

Option 4
- Starter: “Veloute” soup.
- Main course: Grilled hake fillets, baby carrots, and white bread roll.
- Dessert: Custard.

Option 5
- Starter: Pumpkin soup.
- Min course: Scrambled eggs with potatoes and ham, and white bread roll.
- Dessert: Rice pudding.

Option 6
- Starter: Pasta soup.
- Main course: Grilled pork loin, French fries, and white bread roll.
- Dessert: Peach and apple puree.

Option 7
- Starter: Pasta soup.
- Main course: Spanish omelette, seasoned carrots, and white bread roll.
- Dessert: Curd with honey.
Option 8
- Starter: Courgette soup.
- Main course: Salmon pie, roasted potatoes, and white bread roll.
- Dessert: Custard.

Option 9
- Starter: Pasta soup.
- Main course: Iberian ham omelette, baby carrots, and white bread roll.
- Dessert: Rice pudding.

Option 10
- Starter: Vegetable soup.
- Main course: Fried hake with mayonnaise and white bread roll.
- Dessert: Vanilla egg pudding (“Flan”).

Option 11
- Starter: Parmentier (potato soup).
- Main course: French omelette, crispy fries, and white bread roll.
- Dessert: Chocolate pudding.

Option 12
- Starter: Noodle soup.
- Main course: Chicken breast in white wine sauce, stir fried rice with turkey, and white bread roll.
- Dessert: Custard.

Option 13
- Starter: Pumpkin soup.
- Main course: Sirloin steak in whisky sauce, country potatoes and white bread roll.
- Dessert: Pear compote.

Option 14
- Starter: Fish soup.
- Main course: Spanish omelette, smoked jam, and white bread roll.
- Dessert: Vanilla egg pudding (“Flan”).

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