



# **EFFECTIVENESS OF HEALTH EDUCATION AS A NURSING INTERVENTION IN INCREASING QUALITY OF LIFE AND REDUCING SYMPTOMS OF ANXIETY AND DEPRESSION IN PATIENTS UNDERGOING OSTOMATES AFTER DIGESTIVE SURGERY. A QUASI- EXPERIMENTAL STUDY.**

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## Summary

The project presented is a prospective quasi-experimental study that will be carried out in the Ostomy Clinic of the University Hospital Complex of Santiago de Compostela. The main objective is to evaluate the effectiveness of health education as a nursing intervention to reduce anxiety and depression and improve the quality of life of ostomy patients after digestive surgery. It will focus on adult patients who have undergone an ostomy elimination, excluding terminally ill patients and those with cognitive limitations.

The study proposes a clinical follow-up of patients from admission until several months after receiving the health education program. Validated scales will be used to measure quality of life, anxiety, and depression. The intervention will include health education workshops and continuous monitoring by specialized nurses.

**MeSH Terms:** Ostomy, Quality of Life, Anxiety, Depression, Nursing Care, Patient Education, Stoma Care.

## Background and justification

Ostomy is defined as a route created by surgery, which, due to accidental or disease reasons, allows a patient to recover respiratory, eliminatory (feces or urine) or feeding function.<sup>1</sup>

An elimination ostomy is the creation of a hole in the abdomen by surgical procedure to eliminate waste products, externalizing a portion of viscera, responsible for expelling feces, urine or any type of secretion into a bag, called a stoma. Bull 2.3

The group of elimination ostomies are the most frequent, with similar numbers worldwide and nationally. The highest percentage is colostomies (~55%), followed by ileostomies (~31-35%) and urostomies (~14-10%). Overall, due to their permanence, temporary contracts predominate in 60-80% of cases and permanent contracts in 20-40%. The prevalence in Galicia can be seen in Table 1:<sup>4,5</sup>

Table 1. Prevalence of elimination ostomies in Galicia.

	A Coruña	Ourense	Pontevedra	Santiago
Temporary	45,8%	65%	40.5%	98%
Definitive	54,2%	35%	59.5%	2%

The etiologies that justify an ostomy are cancer (69.5%), Crohn's disease (8.1%), diverticulitis (7.2%), ulcerative colitis (3%) and other diseases (12%). In 2018, it was estimated that 70,000 to 100,000 people with ostomates were estimated in Spain, with

an incidence of 0.34 thousand inhabitants/year, with a rate of 1.5 ostomates per 1,000 inhabitants <sup>4,5</sup>

The creation of a removal ostomy affects the patient's quality of life in different aspects:

- Physical factors: skin complications, difficulty in handling the stoma and devices, alterations in activities of daily living.
- Social challenges: Social isolation and difficulties in interpersonal relationships.
- Impact on spiritual well-being
- Psychological Challenges: Anxiety, depression, sadness, changes in self-image and low self-esteem appear. <sup>6, 7, 8</sup>

Ostomy patients can manage the changes associated with their new condition through the use of adaptive mechanisms. Without these mechanisms, patients are at a higher risk of experiencing an increase in stress, anxiety, and depression. They also report anguish, low self-esteem, interruption of communication, stigma, loss of self-image, hopelessness, insecurity and, in very serious cases, suicidal ideation. This psychological affectation seriously harms the patient's quality of life and is related to the impact of the new reality and self-care, so the importance of interventions and supports that promote effective adaptation is justified. <sup>9</sup>

Initial support and health education in the ostomy consultation is a benchmark in the Good Clinical Practice Guidelines for a significant improvement in the patient's independence and quality of life thanks to the essential contributions of nursing care plans and patient guidance in their new reality. <sup>Acts 3, 10</sup>

The stoma therapist nurse, through a comprehensive evaluation, design of personalized care plans and collaboration with a multidisciplinary team, offers pre- and post-operative training, marks the location of the stoma, evaluates and controls complications, and teaches the management of necessary devices and care, with continuous monitoring and nutritional advice to optimize the patient's health and self-efficacy. <sup>2</sup>

94% of patients and 95% of nurses consider the existence of specialized ostomy care necessary, but it is estimated that 35% of ostomy patients do not have an ostomy consultation in their reference hospital, which represents a 50% increase in health expenditure compared to patients who do have a stoma therapist nurse. <sup>Acts 4, 5</sup>

	Patients with ostomy consultation	Patients without ostomy consultation	
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Type of Cost	Group I	Group II	Difference Group I vs Group II
Direct healthcare	€218	€674	-68%
Materials	€307	€342	-10%

Type of Cost	Group I	Group II	Difference Group I vs Group II
Total Direct Costs	€525	€1,016	-48%

Image 1 : Cost-Effectiveness Study of Specialty Ostomy Care

All of the above justifies this work focused on increasing the patient's quality of life with health education and nursing interventions to reduce symptoms of anxiety and depression in patients with elimination ostomies.

The increase in life expectancy and the success of cancer screening programmes, which in Galicia allow 7 out of 10 tumours to be detected early, mean that chronic diseases such as colorectal cancer or IBD are more prevalent. The surgeries necessary to treat these diseases and the ostomy resulting from the therapeutic process translate into increasing numbers of people with ostomies.<sup>4</sup>

The ostomy has a psychological and social impact that can cause self-care problems, decreased self-esteem, changes in body image and alterations in family and work relationships. These changes require a great effort of adaptation on the part of the patient.

Nurses play a crucial role in helping patients adjust to their new reality. This includes providing comprehensive and individualized care, as well as pre- and post-operative education for the patient and their family, a fundamental pillar to reduce postoperative complications, promoting dialogue and family cohesion and, consequently, improving quality of life. Continuous monitoring by the nurse is essential to ensure a correct adaptation of the patient to their new situation.

However, ostomy patients cannot be pigeonholed, as they have different needs and concerns, they come from different social, cultural and religious circles where they have been taught different lifestyles and attitudes to face the disease, which will make the individual a unique being, who will require individualized care, and some will accept their stoma better than others.<sup>11</sup>

Identifying and treating anxiety and depression in these patients is crucial to improving their quality of life and facilitating their adaptation to the new lifestyle. There are studies that identify other risk factors for increased anxiety and depression such as not having contact with other ostomates or not having a pre-surgery stoma marking and protective factors such as an active work situation.<sup>12</sup>

Deepening the interventions that increase the quality of life of ostomy patients allows the creation of health education strategies and follow-up of patients according to their specific and personal needs, which will result in a reduction in symptoms of anxiety and depression after stoma is performed.

The aim of this study is to assess the interventions carried out to reduce or minimise the psychological impact of the stoma on ostomy patients and improve their quality of life, not only as a fundamental basis for care but also in post-discharge surveillance.<sup>11</sup>

### **Study hypothesis**

The implementation of health education workshops will reduce the symptoms of anxiety and depression and improve the quality of life in ostomy patients.

### **Objective**

#### **General objective**

To assess the effectiveness of health education as a nursing intervention for the reduction of anxiety and depression symptoms and the increase in quality of life in patients ostomized after digestive surgery.

#### **Specific objectives**

1. To assess and compare the level of insomnia in ostomy patients before the educational intervention and at 3 months after the intervention.
2. To assess and compare the levels of anxiety and depression before the intervention and at 3 months after the intervention, in ostomy patients.
3. To assess and compare quality of life before surgery and at 3 months after surgery in ostomy patients.
4. To assess and compare the risk of suicide before the intervention and at 3 months after the intervention in ostomy patients.
5. To establish and compare symptoms of anxiety and depression before the intervention and at 3 months after the intervention in ostomy patients.
6. To reduce the psychological impact of anxiety and depression in ostomy patients.

### **TYPE OF STUDY**

A prospective quasi-experimental analytical study without randomization is proposed, to be carried out in the Ostomy Clinic of the University Hospital Complex of Santiago de Compostela belonging to the health area of Santiago and Barbanza.

### **MATERIAL AND METHODS**

This is a quasi-experimental, longitudinal and prospective study, which will be carried out in patients who have been ostomized and treated in the ostomy unit at the University Hospital Complex of Santiago de Compostela, collected consecutively by physicians or nurses from the Ostomy and Digestive Surgery Service.

The period of inclusion of patients who will receive the health education program will be from the authorization of the ethics committee until approximately April 15, 2025 (failing this, the inclusion period will be extended until 83 patients are obtained). For each patient, a clinical follow-up is carried out on admission, discharge, three months and after the completion of the health education program.

### Population

For the preparation of this study, the target population has been taken as patients undergoing digestive surgery with the need for an elimination ostomy, treated in the ostomy consultation of the CHUS from the favorable resolution of the Ethics Committee until April 15, 2025, in any case the study may be increased until the minimum sample size is completed.

### Patient Selection

All patients with ostomy after digestive surgery who have an elimination ostomy and attend the Ostomy Clinic of the CHUS, recruited by these nurses, will be selected.

The inclusion criteria will be

- Adults
- Patients who have undergone a permanent or permanent ostomy for more than 6 months or have undergone a temporary ostomy for more than 6 months
- Volunteers for the study with definitive digestive ostomy in the health area of Santiago and Barbanza
- Patients who agree to participate in the study

Exclusion criteria:

- Hospice patients
- Patients with cognitive limitations

### Variables

- Socio-epidemiological data: sex, age, level of education, marital status, occupation, income level, race...
- Data related to quality of life: physical function and role, body pain, general health, vitality, social function, emotional role, and mental health.
- Data related to the ostomy: type, date of placement, function, type of surgery...
- Main symptoms of anxiety and depression: Physical symptoms, Emotional symptoms, Cognitive symptoms and behavioral symptoms.
- The patient's level of knowledge about their ostomy, addressing feeding, device management, and identification of stoma/skin complication and skills

### Instruments

### BAI Scale (Beck Anxiety Inventory)

This scale is used to measure the degree of anxiety, independently of those symptoms that may be shared with depression. It has mainly been designed for an adult target population. According to Cronbach's alpha value, the internal consistency of this scale is higher than 0.8, which is a high value of internal validity. It consists of 21 items evaluated from 0 to 3 points, thus its maximum score of 63 (15).

Depending on the score obtained, four cut-off points are established (15):

- 0-7 points: minimal anxiety.
- 8-15 points: mild anxiety.
- 16-25 points: moderate anxiety.
- 26-63 points: severe anxiety.

### BDI Scale (Beck Depression Inventory)

This scale assesses the presence of depression-related symptoms in the individual (such as feelings of guilt, sadness, sense of failure, suicidal ideation, or pessimism) using 21 items with 4 response options in each (corresponding to the absence of the symptom or a mild, moderate or severe condition). Each of the items has a value of 0 to 3 points, thus being possible to obtain a score between 0 and 63 points. This scale has adequate internal consistency, with Cronbach's alpha values ranging from 0.78 to 0.92 (16).

We can determine 4 cut-off points on this scale according to the score obtained (16): - 0-13 points: minimal depression.

- 14-19 points: mild depression.
- 20-28 points: moderate depression.
- 29-63 points: severe depression.

### EADG SCALE (Goldberg Anxiety and Depression Scale)

This scale arises as a modification of the Psychiatric Assessment Schedule, in order to obtain a scale that is easier to perform. It is made up of two subscales, an anxiety subscale, and a depression subscale. This scale has a sensitivity of 83.1%, a specificity of 81.8%, and a positive predictive value of 95%. Its Cronbach's alpha value is 0.758 (17).

Each subscale consists of 9 dichotomous response items (yes/no). It consists of two main cut-off points (17):

- > 4 points on the anxiety scale
- > 2 points on the depression scale



## SF-36 Scale (Quality of Life)

The SF-36 is scored in two steps. The pre-coded numeric values are first recoded according to the score key in Table 1. Note that each item is scored, and that a higher number indicates that the subject is in better overall health. In addition, each item is graded on a scale of 0 to 100, with 0 and 100 being the lowest and highest possible scores. The scores show the proportion of the possible score that was actually obtained. The scores of the eight scales are obtained in step 2 by averaging the items of the same scale. Table 2 shows the components that were averaged to obtain each scale. Scale scores are not based on items with omitted data (items that are left blank).

Therefore, the scale scores represent the average of all the items on the scale to which the respondent has responded.

### Outcome measures

- SF-36 Scale: Overall score  $\geq 75$  points
- BAI scale for anxiety: the values are 7 points or less.
- BDI scale for depression: values are 13 points or less
- EADG scale for depression and anxiety: values for anxiety are 4 points or less, and values for depression are 2 points or less

## COLLECTION AND ARCHIVING OF INFORMATION.

The data will be completed in all cases by the principal investigator and linked to SERGAS (Galician Health Service), and will only be accessible by the researcher himself and by the doctoral student who will carry out the analysis of the data. No one outside the investigator may make changes to the data collected relating to the patient. The doctoral student will not have identification data of the patients and will follow aspects related to their confidentiality.

Data will be entered into a database created for this purpose in the Microsoft Excel 2013 program. Prior to the start of the data analysis, the database will be validated to ensure its quality and once validated, it will be closed. Subsequently, the IBM SPSS 24 statistical program will be used for data processing and analysis.

The recruitment procedure will be carried out at the University Hospital Complex of Santiago de Compostela, patients with ostomies will be recruited in the ostomy nursing consultation. There is also the possibility of the collaboration of the surgeons who carry out the digestive surgery consultation in recruitment.

## DATA ANALYSIS.

A descriptive analysis will be carried out using measures of central tendency (mean (M) or median) and dispersion (standard deviation (SD) when deemed appropriate for quantitative variables, and percentages for qualitative variables. To analyze the differences between groups, the Chi2 test was used for qualitative variables. ). To establish correlation between groups, the Chi2 test was used for qualitative variables and

the Kruskal-Wallis test for quantitative variables. To establish differences between the groups, the Mann Whitney U technique was used. A significance level of 0.05 was chosen to select the variables finally included in the binary logistic regression model. All analyses and calculations will be performed using the PASW statistical package (version 24.0; SPSS Inc., Chicago, Illinois).

## Timeline

<b>Task</b>	<b>Previous</b>	<b>MONTH 1</b>	<b>MONTH 2</b>	<b>BREAK MONTHS</b>	<b>BREAK MONTHS</b>	<b>MONTH</b>
<b>Literature review</b>	June 2024					
<b>Study design</b>	August 2024					
<b>Submission of documentation</b>		September 2024				
<b>Database design</b>			September 2024			
<b>Patient recruitment</b>				November 2024 to April 15, 2025		
<b>Statistical analysis</b>					December 2024 to May 2025	
<b>Scientific dissemination</b>						June 2025

## Sample size justification

The CHUS serves 381,457 people (Annex I), taking into account the rate of 1.5 ostomized people per 1000 inhabitants we obtain a figure of 572 users with ostomy in the CHUS. Using the formula to calculate the sample size, with a confidence level of 95% and a margin of error of 10%, a minimum sample of 83 patients is estimated to ensure the representativeness and validity of the study results.

$$\text{Sample size} = \frac{\frac{z^2 * P(1-P)}{e^2}}{1 + (\frac{z^2 * P(1-P)}{e^2 N})}$$

## **Informed consent**

The informed consent forms have been drafted, to be delivered individually to the participants.

## **Ethical-legal aspects**

The review and approval of the research plan by the Santiago-Lugo Research Ethics Committee is requested, following local and international regulations in the field of medical research and the standards established by the Declaration of Helsinki.

The development of this thesis will be carried out respecting the Declaration of Helsinki of the World Medical Association of 1964 and ratifications of the following assemblies on ethical principles for medical research on human beings, RD 1090/2015, of December 24, on clinical trials, specifically in the provisions of its article 38 on good clinical practices, and the Convention on Human Rights and Biomedicine, signed in Oviedo on 4 April 1997 and subsequent proceedings. The researchers participating in this study undertake that all clinical data collected from the study subjects will be separated from the personally identifiable data, so that the anonymity of the patients is ensured; respecting the Law on the Protection of Personal Data and Guarantee of Digital Rights (Organic Law 3/2018, of 5 December), Law 41/2002, of 14 November (basic regulation of patient autonomy and rights and obligations in terms of clinical information and documentation), as well as Law 3/2001, of 28 May (regulating informed consent and clinical documentation), as well as Law 3/2005, of 7 March, amending Law 3/2001 and Decree 29/2009 of 5 February, which regulates access to electronic medical records. The patient's data will be collected by the investigator in the study-specific data collection notebook (CRD). Each CRD will be encrypted, protecting the patient's identity. Only the research team and the health authorities, who have a duty to maintain confidentiality, will have access to all the data collected for the study. Information may only be transmitted to third parties that cannot be identified.

An Information Sheet will be provided to the participants and informed consent.

Information regarding the identity of patients will be and is considered confidential for all purposes. In order to properly maintain confidentiality with respect to patient information, an appropriate coding and identification dissociation will be carried

out in the database, so that only the researcher may associate such data with an identified or identifiable person. The database that will generate the study will not contain any identification of the patient. Once the study is complete, the database will be deleted.

With regard to the data of the study, the provisions of the Organic Law on "Protection of Personal Data" in force will be followed.

## **Commitment to dissemination of results**

The results of this study will be disseminated as communications or conference posters, potential scientific articles and as academic work regardless of the results obtained.

## **Economic report**

Not applicable.

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## Data collection notebook

Patient Number:

Age					
Sex	Male <input type="checkbox"/>	Women's <input type="checkbox"/>	I prefer not to say it <input type="checkbox"/>		
Gender	Man <input type="checkbox"/>	Woman <input type="checkbox"/>	Non-binary <input type="checkbox"/>	Other <input type="checkbox"/> (specify)	I prefer not to say it <input type="checkbox"/>
Marital status	Single <input type="checkbox"/>	Married <input type="checkbox"/>	Widow/ <input type="checkbox"/>	Divorced <input type="checkbox"/>	I prefer not to say it <input type="checkbox"/>
	Other <input type="checkbox"/> (specify)				
Level of studies completed	No <input type="checkbox"/> studies	Ed. Primaria <input type="checkbox"/>	Secondary Ed. <input type="checkbox"/>	Vocational Training <input type="checkbox"/>	Univ. or higher studies <input type="checkbox"/>
Employment status	Student <input type="checkbox"/>	Active <input type="checkbox"/>	Retired <input type="checkbox"/>	Unemployed <input type="checkbox"/>	Other <input type="checkbox"/> (specify)
Type of surgery	Scheduled <input type="checkbox"/>	Urgency <input type="checkbox"/>			
Type of ostomy	Definitive <input type="checkbox"/>	Temporary <input type="checkbox"/>			

## SF-36 HEALTH SURVEY

Please mark only one answer:

1. In general, would you say your health is:
  - Excellent
  - Very good
  - Good
  - Fair
  - Poor
2. How would you rate your current health compared to a year ago?
  - Much better now than a year ago
  - Somewhat better now than a year ago

- About the same as a year ago
- Somewhat worse now than a year ago
- Much worse now than a year ago

The following questions refer to activities or things you might do on a normal day:

3. Does your current health limit you in vigorous activities, such as running, lifting heavy objects, or participating in strenuous sports?
  - Yes, it limits me a lot
  - Yes, it limits me a little
  - No, it does not limit me at all
4. Does your current health limit you in moderate activities, such as moving a table, vacuuming, bowling, or walking more than an hour?
  - Yes, it limits me a lot
  - Yes, it limits me a little
  - No, it does not limit me at all
5. Does your current health limit you in carrying or lifting groceries?
  - Yes, it limits me a lot
  - Yes, it limits me a little
  - No, it does not limit me at all
6. Does your current health limit you in climbing several flights of stairs?
  - Yes, it limits me a lot
  - Yes, it limits me a little
  - No, it does not limit me at all
7. Does your current health limit you in climbing one flight of stairs?
  - Yes, it limits me a lot
  - Yes, it limits me a little
  - No, it does not limit me at all
8. Does your current health limit you in bending or kneeling?
  - Yes, it limits me a lot
  - Yes, it limits me a little
  - No, it does not limit me at all
9. Does your current health limit you in walking more than a kilometer?
  - Yes, it limits me a lot

- Yes, it limits me a little
- No, it does not limit me at all

10. Does your current health limit you in walking several blocks (hundreds of meters)?

- Yes, it limits me a lot
- Yes, it limits me a little
- No, it does not limit me at all

11. Does your current health limit you in walking one block (about 100 meters)?

- Yes, it limits me a lot
- Yes, it limits me a little
- No, it does not limit me at all

12. Does your current health limit you in bathing or dressing yourself?

- Yes, it limits me a lot
- Yes, it limits me a little
- No, it does not limit me at all

The following questions refer to problems in your work or daily activities:

13. During the past 4 weeks, have you had to reduce the time spent on work or other daily activities due to your physical health?

- Yes
- No

14. During the past 4 weeks, have you done less than you would have liked to do because of your physical health?

- Yes
- No

15. During the past 4 weeks, have you stopped doing some tasks at work or other daily activities due to your physical health?

- Yes
- No

16. During the past 4 weeks, have you had difficulty performing work or daily activities (e.g., it was more difficult than usual) due to your physical health?

- Yes
- No



17. During the past 4 weeks, have you had to reduce the time spent on work or other daily activities due to any emotional problems (such as feeling depressed, anxious, or nervous)?
- Yes
  - No
18. During the past 4 weeks, have you done less than you would have liked due to emotional problems (such as feeling depressed, anxious, or nervous)?
- Yes
  - No
19. During the past 4 weeks, have you not done your work or daily activities as carefully as usual due to emotional problems (such as feeling depressed, anxious, or nervous)?
- Yes
  - No
20. During the past 4 weeks, to what extent have physical health or emotional problems interfered with your usual social activities with family, friends, neighbors, or others?
- Not at all
  - Slightly
  - Moderately
  - Quite a bit
  - Extremely
21. Did you have pain in any part of your body during the past 4 weeks?
- No, none
  - Yes, very little
  - Yes, a little
  - Yes, moderate
  - Yes, a lot
  - Yes, very severe
22. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?
- Not at all
  - Slightly
  - Moderately
  - Quite a bit

- Extremely

The following questions refer to how you have been feeling and how things have been going for you during the past 4 weeks. For each question, please answer what most closely matches how you have felt:

23. During the past 4 weeks, how often did you feel full of energy?

- Always
- Almost always
- Often
- Sometimes
- Occasionally
- Never

24. During the past 4 weeks, how often did you feel very nervous?

- Always
- Almost always
- Often
- Sometimes
- Occasionally
- Never

25. During the past 4 weeks, how often did you feel so down that nothing could cheer you up?

- Always
- Almost always
- Often
- Sometimes
- Occasionally
- Never

26. During the past 4 weeks, how often did you feel calm and peaceful?

- Always
- Almost always
- Often
- Sometimes
- Occasionally

- Never

27. During the past 4 weeks, how often did you feel full of energy?

- Always
- Almost always
- Often
- Sometimes
- Occasionally
- Never

28. During the past 4 weeks, how often did you feel downhearted and blue?

- Always
- Almost always
- Often
- Sometimes
- Occasionally
- Never

29. During the past 4 weeks, how often did you feel worn out?

- Always
- Almost always
- Often
- Sometimes
- Occasionally
- Never

30. During the past 4 weeks, how often did you feel happy?

- Always
- Almost always
- Often
- Sometimes
- Occasionally
- Never

31. During the past 4 weeks, how often did you feel tired?

- Always

- Almost always
- Often
- Sometimes
- Occasionally
- Never

32. During the past 4 weeks, how often have physical health or emotional problems interfered with your social activities (such as visiting friends or relatives)?

- Always
- Almost always
- Often
- Sometimes
- Occasionally
- Never

Please indicate whether you think the following statements are true or false:

33. I seem to get sick easier than other people.

- Absolutely true
- Mostly true
- Don't know
- Mostly false
- Absolutely false

34. I am as healthy as anybody I know.

- Absolutely true
- Mostly true
- Don't know
- Mostly false
- Absolutely false

35. I expect my health to get worse.

- Absolutely true
- Mostly true
- Don't know
- Mostly false

- Absolutely false

36. My health is excellent.

- Absolutely true
- Mostly true
- Don't know
- Mostly false
- Absolutely false

## BECK ANXIETY INVENTORY (BAI)

Indicate the degree to which you have been affected by each of the following symptoms during the past week and at the present moment. Choose the option that best corresponds:

- 0 = Not at all
- 1 = Slightly, it doesn't bother me much
- 2 = Moderately, it was very unpleasant, but I could bear it
- 3 = Severely, I could hardly bear it

Symptom	0	1	2	3
1. Tingling or numbness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Feeling of heat	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Shaking legs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Inability to relax	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Fear that something terrible will happen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Dizziness or lightheadedness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Palpitations or tachycardia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Feeling of instability or physical insecurity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Terrors	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Nervousness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Feeling of suffocation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Hand tremors	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Generalized shaking or trembling	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Fear of losing control	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Difficulty breathing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Symptom	0	1	2	3
16. Fear of dying	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Startling	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Digestive or abdominal discomfort	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Pallor	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Facial flushing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. Sweating (not due to heat)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**TOTAL:**

**A.F.:**

**A.S.:**

## BECK DEPRESSION INVENTORY (BDI)

This questionnaire contains several groups of statements. Please read each group carefully. Indicate which of the statements in each group best describes how you have felt during the past week, including today. If more than one statement in a group applies to you, mark them as well. Make sure to read all the statements in each group before making your choice.

---

**1.**

- ☐ I do not feel sad.
- ☐ I feel sad.
- ☐ I feel sad all the time and I can't snap out of it.
- ☐ I feel so sad and unhappy that I can't bear it.

---

**2.**

- ☐ I am not particularly discouraged about the future.
- ☐ I feel discouraged about the future.
- ☐ I feel I have nothing to look forward to.
- ☐ I feel that the future is hopeless and things cannot improve.

---

**3.**

- ☐ I do not feel like a failure.
  - ☐ I feel I have failed more than most people.
  - ☐ As I look back, I see a lot of failures.
  - ☐ I feel I am a complete failure as a person.
- 

4.

- ☐ I get as much satisfaction out of things as I used to.
  - ☐ I don't enjoy things as much as I used to.
  - ☐ I don't get real satisfaction out of anything anymore.
  - ☐ I am dissatisfied or bored with everything.
- 

5.

- ☐ I don't feel particularly guilty.
  - ☐ I feel guilty a good part of the time.
  - ☐ I feel guilty most of the time.
  - ☐ I feel guilty all the time.
- 

6.

- ☐ I don't feel I am being punished.
  - ☐ I feel I may be punished.
  - ☐ I expect to be punished.
  - ☐ I feel I am being punished.
- 

7.

- ☐ I am not disappointed in myself.
  - ☐ I am disappointed in myself.
  - ☐ I am disgusted with myself.
  - ☐ I hate myself.
- 

8.



- ☐ I don't feel I am worse than anybody else.
  - ☐ I am critical of myself for my weaknesses or mistakes.
  - ☐ I blame myself all the time for my faults.
  - ☐ I blame myself for everything bad that happens.
- 

**9.**

- ☐ I don't have any thoughts of killing myself.
  - ☐ I have thoughts of killing myself, but I would not carry them out.
  - ☐ I would like to kill myself.
  - ☐ I would kill myself if I had the chance.
- 

**10.**

- ☐ I don't cry any more than I used to.
  - ☐ I cry more now than I used to.
  - ☐ I cry all the time now.
  - ☐ I used to be able to cry, but now I can't, even though I want to.
- 

**11.**

- ☐ I am no more irritated by things than I ever was.
  - ☐ I am slightly more irritated now than usual.
  - ☐ I feel irritated all the time.
  - ☐ I am not irritated at all by things that used to irritate me.
- 

**12.**

- ☐ I have not lost interest in other people.
  - ☐ I am less interested in other people than I used to be.
  - ☐ I have lost most of my interest in other people.
  - ☐ I have lost all interest in other people.
- 

**13.**

- ☐ I make decisions about as well as I ever could.
  - ☐ I put off making decisions more than I used to.
  - ☐ I have greater difficulty in making decisions than before.
  - ☐ I can't make decisions at all anymore.
- 

**14.**

- ☐ I don't feel that I look any worse than I used to.
  - ☐ I am worried that I am looking old or unattractive.
  - ☐ I believe there are permanent changes in my appearance that make me look unattractive.
  - ☐ I believe that I look ugly.
- 

**15.**

- ☐ I work about as well as before.
  - ☐ It takes extra effort to get started at doing something.
  - ☐ I have to push myself very hard to do anything.
  - ☐ I can't do any work at all.
- 

**16.**

- ☐ I can sleep as well as usual.
  - ☐ I don't sleep as well as I used to.
  - ☐ I wake up 1-2 hours earlier than usual and find it hard to get back to sleep.
  - ☐ I wake up several hours earlier than usual and cannot get back to sleep.
- 

**17.**

- ☐ I don't feel more tired than usual.
  - ☐ I get tired more easily than I used to.
  - ☐ I get tired from doing almost anything.
  - ☐ I am too tired to do anything.
-

**18.**

- ☐ My appetite is no worse than usual.
  - ☐ I don't eat as much as I used to.
  - ☐ I have a much smaller appetite now.
  - ☐ I have no appetite at all anymore.
- 

**19.**

- ☐ I haven't lost much weight, or I have gained weight recently.
- ☐ I have lost more than 2.5 kilograms.
- ☐ I have lost more than 4 kilograms.
- ☐ I have lost more than 7 kilograms.

Are you on a diet to lose weight?

- ☐ YES
  - ☐ NO
- 

**20.**

- ☐ I am no more concerned about my health than usual.
  - ☐ I am concerned about physical problems like aches, pains, upset stomach, or constipation.
  - ☐ I am so concerned about my physical problems that it is hard to think of much else.
  - ☐ I am so concerned about my physical problems that I cannot think of anything else.
- 

**21.**

- ☐ I have not noticed any recent change in my interest in sex.
- ☐ I am less interested in sex than I used to be.
- ☐ I am much less interested in sex now.
- ☐ I have lost all interest in sex.

**TOTAL:**

## EADG (Goldberg Anxiety and depression scale)

"If you don't mind, I would like to ask you some questions to find out if you have experienced any of the following symptoms in the last two weeks." Symptoms lasting less than two weeks or of mild intensity will not be scored.

---

### ANXIETY SUBSCALE

1. Have you felt very excited, nervous, or tense?
    - ☐ Yes
    - ☐ No
  2. Have you been very worried about something?
    - ☐ Yes
    - ☐ No
  3. Have you felt very irritable?
    - ☐ Yes
    - ☐ No
  4. Have you had difficulty relaxing?
    - ☐ Yes
    - ☐ No
- 

**If there are 2 or more affirmative answers, continue asking:**

5. Have you slept poorly or had difficulty sleeping?
  - ☐ Yes
  - ☐ No
6. Have you had headaches or neck pain?
  - ☐ Yes
  - ☐ No
7. Have you experienced any of the following symptoms: tremors, tingling, dizziness, sweating, or diarrhea? (vegetative symptoms)
  - ☐ Yes
  - ☐ No
8. Have you been worried about your health?

- ☐ Yes
- ☐ No

9. Have you had any difficulty falling asleep or staying asleep?

- ☐ Yes
- ☐ No

---

**DEPRESSION SUBSCALE**

1. Have you felt low on energy?

- ☐ Yes
- ☐ No

2. Have you lost interest in things?

- ☐ Yes
- ☐ No

3. Have you lost confidence in yourself?

- ☐ Yes
- ☐ No

4. Have you felt hopeless?

- ☐ Yes
- ☐ No

---

**(If there are affirmative answers to any of the above questions, continue asking):**

5. Have you had difficulty concentrating?

- ☐ Yes
- ☐ No

6. Have you lost weight (due to lack of appetite)?

- ☐ Yes
- ☐ No

7. Have you been waking up too early?

- ☐ Yes
- ☐ No

8. Have you felt slowed down?

- ☐ Yes
- ☐ No

9. Do you feel you tend to feel worse in the mornings?

- ☐ Yes
- ☐ No

---

**ANXIETY SCORE:**

**DEPRESSION SCORE:**

### **Applicability and dissemination of results**

Publication in scientific journals and conferences/posters.

## **ANNEX I. Development of interventions**

### **Session 1 (60 minutes)**

1. Review of the patient's level of knowledge about their ostomy, addressing feeding, device management and early identification of stoma and skin complications.
2. Feedback on what they have learned in the ostomy consultation and theoretical support if necessary in those areas in which patients need more help.
3. Ostomy Management Skills Training Workshop:
  - It will increase confidence and self-efficacy in daily care.
  - It reduces anxiety related to possible accidents or complications.

### **Session 2 (60 minutes)**

- 1- Anxiety and Depression - Identifying and Managing Symptoms/Improving Quality of Life
- 2- Inform patients about the relationship between ostomy and mental health.
- 3- Identify symptoms of anxiety and depression.
- 4- Provide strategies for managing anxiety and depression.
- 5- To promote healthy lifestyle habits adapted to the needs of ostomy patients.
- 6- Facilitate social integration and participation in daily activities.
- 7- Workshops to be carried out, abdominal breathing and guided visualization.
  - 1- Introduction and emotional check-in
    - Welcome and brief presentation of the purpose of the workshop
    - Quick round of how participants feel
  - 2- Mindfulness and relaxation techniques:
    - It helps manage stress and anxiety related to daily ostomy care.
    - Improvement in the acceptance of the new body situation.
    - Mindfulness and Mindful Breathing

- A brief explanation of mindfulness and its benefits
- Guided Breath Attention Exercise
- Emphasis on the acceptance of bodily sensations
- 3- Skills Training: Managing Stress in Everyday Situations
  - Brief discussion of common situations that generate stress
  - Teaching a quick stress management technique (e.g., breathing)
  - Examples of how to apply it in ostomy-related situations
- 4- Guided visualization for acceptance and trust
  - Guidance through visualization focused on body acceptance and confidence building
  - Incorporating Healing and Strength Imagery
- 5- Closure and personal action plan
  - Summary of the techniques learned
  - Invitation to participants to choose a technique to practice regularly
  - Short round of sharing about how they feel at the end of the session

Additional considerations:

1. Provide a summary booklet with the techniques practiced and suggestions for their daily application.
2. Adapt language and instructions to be inclusive and responsive to the needs of ostomy patients.
3. Be prepared to handle possible emotional reactions during the session.
4. Offer additional resources or support group information upon completion.
5. Offer a communication channel (e.g., a WhatsApp group) for questions between sessions

### **Session 3. Workshop: Full Life with Ostomy: Healthy Habits and Social Integration**

#### 1. Introduction

- Welcome and brief explanation of the objective of the workshop.

#### 2. Adapted Healthy Lifestyle Habits

- a) Food
- b) Physical Exercise
- c) Rest and Stress Management

#### 3. Social Integration and Activities of Daily Living

- a) Effective Communication
- b) Participation in Activities
- c) Construction of Support Network

#### 4. Closure and Additional Resources

Facilitation Techniques:

1. Use an interactive approach: Ask quick questions to the group to maintain participation.
2. Use concrete and relatable examples for each point.
3. Provide a summary booklet with key points and additional resources.
4. Encourage participants to briefly share their own experiences or advice, if time permits.