Informed Consent Form

TITLE OF THE STUDY:

Effectiveness of health education as a nursing intervention in increasing quality of life and decreasing the symptomology of anxiety and depression in patients ostomized after digestive surgery. A quasi-experimental study

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CENTER: Hospital Clínico Universitario de Santiago

This document is intended to provide you with information about a **research study** in which you are invited to participate. This study was approved by the Santiago-Lugo Research Ethics Committee

If you decide to participate in it, you should receive personalized information from the researcher, **read this document first**, and ask any questions you need to understand the details about it. If you wish, you can take the document, consult it with other people and take the necessary time to decide whether or not to participate.

Participation in this study is completely **voluntary**. You may choose not to participate or, you agree to do so, change your mind by withdrawing consent at any time without explanation. We assure you that this decision will not affect your relationship with the healthcare professionals who care for you or the healthcare to which you are entitled.

What is the purpose of the study?

We invite you to participate in this study to evaluate the effectiveness of health education with nursing interventions to improve quality of life and reduce symptoms of anxiety and depression in ostomy patients, attending to their personal and specific needs.

Why am I being offered to participate?

You are invited to participate because you are a patient who has undergone an ostomy after digestive surgery, a procedure that entails physical, functional and aesthetic alterations, which could influence psychologically, emotionally and socially. These changes require a great effort to adapt on your part and are associated with many challenges.

For the reasons mentioned above, it is proposed that you participate in this study that aims to evaluate nursing interventions aimed at reducing the symptoms of anxiety and depression, as well as improving the quality of life of ostomy patients.

What does my participation consist of?

Their participation in the study consists of completing three questionnaires in a first interview, attending three health education workshops and then a re-evaluation after the workshops and after three months.

- A questionnaire on anxiety symptoms that consists of 21 points and that you will assess by choosing the options from 0 to 3.

- A depression quiz with 21 statements for you to choose the one that best describes you.

- A health questionnaire composed of 36 items that aim to collect all the relevant aspects that characterize their health. With these questions we will evaluate: Physical Function, Physical Role; Body pain; General Health; Vitality; Social Function; Emotional Role and Mental Health.

You are also invited to participate in three nursing interventions:

- The first is to review the level of knowledge about their ostomy, addressing feeding, device management and early identification of stoma and skin complications. Includes a training workshop on ostomy management skills.

- The second intervention will provide strategies for managing anxiety and depression. With this we aim to improve their quality of life, facilitate social integration and participation in daily activities.

- The third is about healthy lifestyle habits adapted to the needs of ostomy patients

Your participation will have an estimated total duration of 1 hour per health education session + an additional 15 minutes to complete the questionnaires

What discomforts or inconveniences does my participation have?

Their participation does not imply additional inconvenience to those of the usual care practice

Will **I get any benefit from participating?**

You are not expected to get direct benefit from participating in the study. The research aims to uncover unknown or unclear aspects of quality of life and symptoms of anxiety and depression in ostomized people. This information may be useful in the future for others.

Will I receive the information I get from the study?

If you wish, you will be provided with a summary of the results of the study.

Will the results of this study be published?

The results of this study will be sent to scientific publications for dissemination, but no data will be transmitted that would allow the identification of the participants.

Information regarding your data:

The collection, processing, storage, communication and transfer of your data will be carried out in accordance with the provisions of the General Data Protection Regulation (EU Regulation 2016-679 of the European Parliament and of the Council, of 27 April 2016) and the Spanish regulations on the protection of personal data in force.

The institution in which this research is carried out is responsible for the processing of your data, and you can contact the Data Protection Officer through the following means: email: delegado.proteccion.datos@sergas.es

The data necessary to carry out this study will be collected and stored in such a way: **Pseudonymized (Encrypted),** pseudonymization is the processing of personal data in such a way that it cannot be attributed to a data subject without the use of additional information. In this study, only the research team will know the code that will allow them to know their identity.

The regulations governing the processing of personal data grant you the right to access, oppose, correct, cancel, limit their processing, restrict or request their deletion. You can also request a copy of these or that it be sent to a third party (right of portability).

To exercise these rights, you can contact the Data Protection Officer of the centre through the contact methods indicated above or the main researcher of this study at the email: mariamercedes.andrade.roca@sergas.es

Likewise, you have the right to file a complaint with the Spanish Data Protection Agency when you consider that any of your rights have not been respected.

Only the research team and the health authorities, who have the duty to maintain confidentiality, will have access to all the data collected by the study. Information that cannot be identified may be transmitted to third parties. In the event that any information is transmitted to other countries, it will be done with a level of data protection equivalent to at least that established by Spanish and European regulations.

At the end of the study, or the established legal period, the data collected will be deleted.

Are there any economic interests in this study?

The researcher will not receive specific remuneration for dedication to the study.

You will not be compensated for participating. It is possible that the results of the study may result in commercial products or patents; in this case, you will not participate in the economic benefits generated.

How to contact the research team of this study?

You can contact Tomás Mendoza Caamaño on the 981951047 phone and/or email mariamercedes.andrade.roca@sergas.es

Thank you very much for your collaboration

CONSENT DOCUMENT FOR PARTICIPATION IN A RESEARCH STUDY

TITLE of the study: **Effectiveness of health education as a nursing intervention in increasing quality of life and decreasing the symptomology of anxiety and depression in patients ostomized after digestive surgery. A quasi-experimental study**

Me,.....
.....

- I read the information sheet to the study participant mentioned above that was given to me, I was able to talk with: ..... and ask all the questions about the study.
- I understand that my participation is voluntary, and that I can withdraw from the study whenever I want, without having to give explanations and without this affecting my medical care.
- I agree to the use of my data under the conditions detailed in the participant information sheet.
- I freely consent to participate in this study.

At the end of this study I accept that my data are:

☐ Removed

☐ Anonymized preserves for future use in other research

Signed: The participant,	Signed: The researcher requesting consent
Name and Surname:	Name and Surname:
Date:	Date:

WITNESS CONSENT DOCUMENT FOR PARTICIPATION IN A RESEARCH STUDY (for cases where the participant is unable to read/write)

The impartial witness must identify himself and be a person outside the investigating team.

TITLE of the study: **Effectiveness of health education as a nursing intervention in increasing quality of life and decreasing the symptomology of anxiety and depression in patients ostomized after digestive surgery. A quasi-experimental study**

I,....., as an impartial witness, affirm that in my presence:

- It was read to..... the above study participant information sheet that was given to him, and he was able to ask all the questions about the study.
- She understood that her participation is voluntary, and that she can withdraw from the study whenever she wants, without having to give explanations and without this affecting her medical care.
- You agree to have your data used under the conditions detailed in the participant information sheet.
- You freely agree to participate in this study.

At the end of this study, you agree that your data will be:

☐ Removed

☐ Anonymized preserves for future use in other research

Signed: The witness,	Signed: The researcher requesting consent
Name and surname:	Name and Surname:
Date:	Date:

CONSENT DOCUMENT FOR LEGAL REPRESENTATIVE FOR PARTICIPATION IN A RESEARCH STUDY

TITLE of the study: **Effectiveness of health education as a nursing intervention in increasing quality of life and decreasing the symptomology of anxiety and depression in patients ostomized after digestive surgery. A quasi-experimental study**

I, _____, legal representative of _____

- I read the information sheet to the study participant mentioned above that was given to me, I was able to talk to ..... and ask all the questions about the study.
- I understand that your participation is voluntary, and that you can withdraw from the study at any time, without having to give explanations and without this affecting your medical care.
- I agree to the use of your data under the conditions detailed in the participant information sheet.
- I freely consent to my participation in this study.

At the end of this study, I accept that your data are:

☐ Removed

☐ Anonymized preserves for future use in other research

Signed: The legal representative,	Signed: The researcher requesting consent
Name and surname:	Name and surname:
Date:	Date: