


FREE COMMUNICATION

EDUCATIONAL NURSING INTERVENTION TO PROMOTE ADAPTATION IN CANCER SURVIVORS: PROTOCOL FOR PILOT STUDY


HIGHLIGHTS

1. An intervention promoting adaptation of cancer survivors was developed.
2. The intervention emphasizes the educational component and professional support.
3. The protocol to assess the feasibility and acceptability of the intervention is presented.

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ABSTRACT

Objective: to present the protocol of a pilot study that aims to evaluate the feasibility and acceptability of an educational nursing intervention to promote the adaptation of cancer survivors, focused on coping and anxiety. **Method:** this protocol was developed based on the Protocol Items: Recommendations for Interventional Trials 2013 (SPIRIT2013) Statement, in the city of Porto - Portugal, in 2022. **Results:** the design, structure, content, strategies, and evaluation instruments of the intervention to be implemented were defined. **Conclusion:** This article provides in detail the structure and content of an educational nursing intervention to promote the adaptation of cancer survivors that can be integrated into the piloting phase procedures. It can also be considered a stimulus for the development of new interventions and intervention programs in this phase of the cancer disease.

DESCRIPTORS: Nursing; Neoplasms; Survivorship; Adaptation, Psychological; Health Education.

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INTRODUCTION

Over the past decades, there has been an increase in cancer survival rates, which is largely due to the progress made in the prevention, diagnosis, and treatment of the disease¹. One of the main challenges is to ensure that survivors receive the necessary care and follow-up after treatment, and it is important that health authorities and healthcare providers develop and implement measures to address this growing demand.

Physical, psychological, social, financial, and existential implications related to the disease and its treatments are experienced by cancer survivors and these, with the potential to influence multiple quality of life domains, may remain for several years². In addition, the literature documents the existence of a broad set of unmet needs among cancer survivors³.

Although in Portugal, there are few recommendations or plans for professional assistance to cancer survivors, several institutions worldwide advise the development of educational programs as a means of enhancing the quality of life of this population⁴. Despite the beneficial effects of psychological, educational and/or supportive interventions in the lives of cancer survivors, gaps persist regarding the full response to their needs. Therefore, it is essential to rethink such interventions in attempt to achieve more satisfactory results⁵.

To contribute to the improvement of knowledge on adaptation of cancer survivors and to improve quality of life and professional response, more specifically that of nurses, for this population, it was decided to initiate a series of studies, supported by the Medical Research Council (MRC) guidelines for the development and evaluation of complex interventions⁶.

Before the realization of this study, a literature review, an exploratory study using the focus group technique and a descriptive study using the Delphi technique were carried out, which allowed to know the state of the art, to draw an outline and to validate the structure and content of an educational intervention⁷⁻⁹.

The procedures to be implemented in the pilot study will be defined, which will have as primary objectives: a) to assess the feasibility of recruiting participants (cancer survivors); b) to assess the acceptability of the intervention and procedures; c) to assess adherence and completion of the intervention; d) to assess whether the intervention was delivered and received as planned (fidelity); and e) to perform a qualitative evaluation of the process with participants and nurses delivering the intervention to identify barriers and facilitating factors. Additionally, we intend to assess the variability of participants' quality of life, coping, anxiety, and adaptation.

To provide a better understanding of this statement, a cancer survivor was assumed to be the person diagnosed with cancer who has completed the active phase of treatments with curative intent, and the concept of adaptation to cancer refers to the ability of an individual to adjust and cope with the physical, psychological, and social effects of the disease¹⁰⁻¹¹. This article presents the protocol of a pilot study whose objective will be to evaluate the feasibility and acceptability of the Nursing Educational Intervention to Promote Adaptation in Cancer Survivors, focused on coping and anxiety.

METHOD

A protocol (version 1.0 of 20.05.2022) was developed based on the SPIRIT2013 Statement. The SPIRIT2013 Statement consists of a set of guidelines that, with the purpose of improving the content and quality of clinical trial protocols, provides a checklist of recommended items to be included in the development of these types of protocols¹².

As a research question, it was defined: What is the acceptability and feasibility of the Nursing Educational Intervention to Promote Adaptation in Cancer Survivors? To answer it, a single-group pilot study will be developed whose implementation of the educational intervention will be carried out in a hospital in Portugal.

The educational intervention is based on three important theories: Transition Theory by Afaf Meleis^{13,14}; Adaptation Model by Roy and Andrews¹⁵; and Cancer Survivor Adaptation Model by Naus and contributors¹¹.

The intervention includes a set of eight health education sessions conducted by specialist nurses. All sessions were designed using the International Classification for Nursing Practice (ICNP)¹⁶. The sample size (n=30) was decided according to international recommendations. The participants, present in the last three sessions of the oncologic treatment, will be recruited in the outpatient service of the hospital, considering the defined eligibility criteria.

The eligibility criteria of the participants and the nurses implementing the intervention are presented in Figure 1.

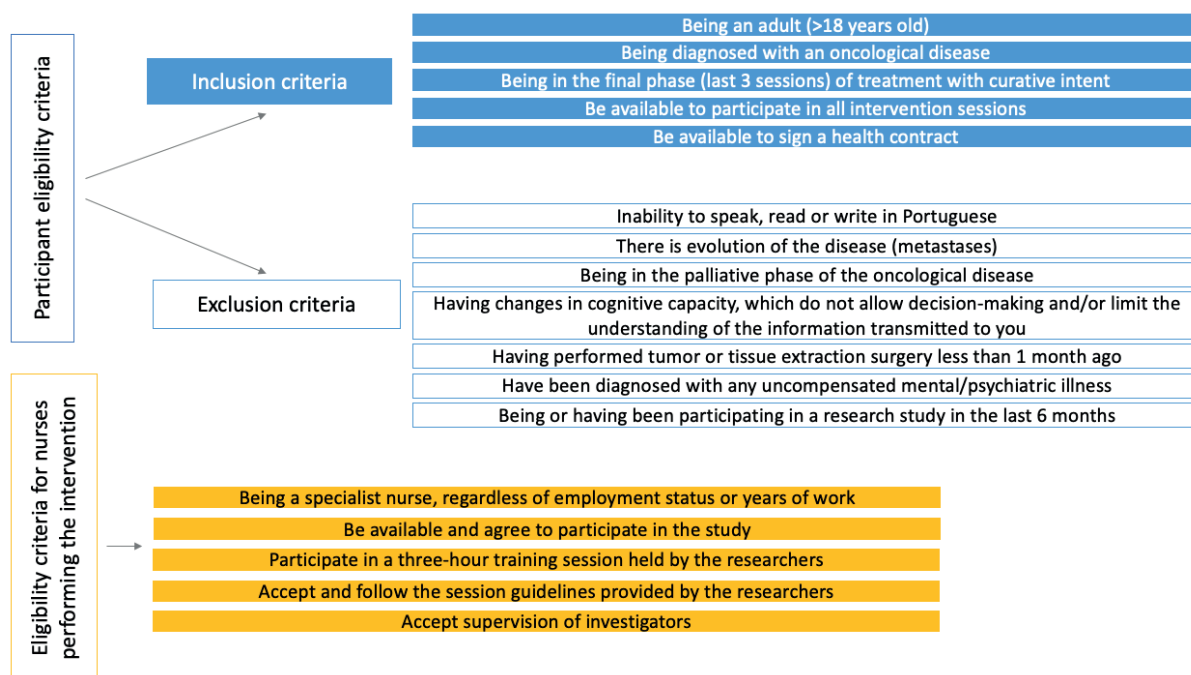


Figure 1 - Eligibility criteria. Porto, District of Porto, Portugal, 2022

Source: The authors (2022).

It is important to mention that during the implementation of the intervention, if participants no longer meet the mentioned criteria, they will be excluded from the study, as they may affect the validity and accuracy of the results.

The eight sessions that integrate the educational intervention, developed over eight weeks, will be divided into group interventions (Figure 2) carried out in an auditorium context, always by the same nurse, and individual interventions (Figure 3) with the possibility of including a significant family member carried out in a consultation context, where each nurse executing the intervention would always accompany the same group of participants,

to enhance the results to be obtained.

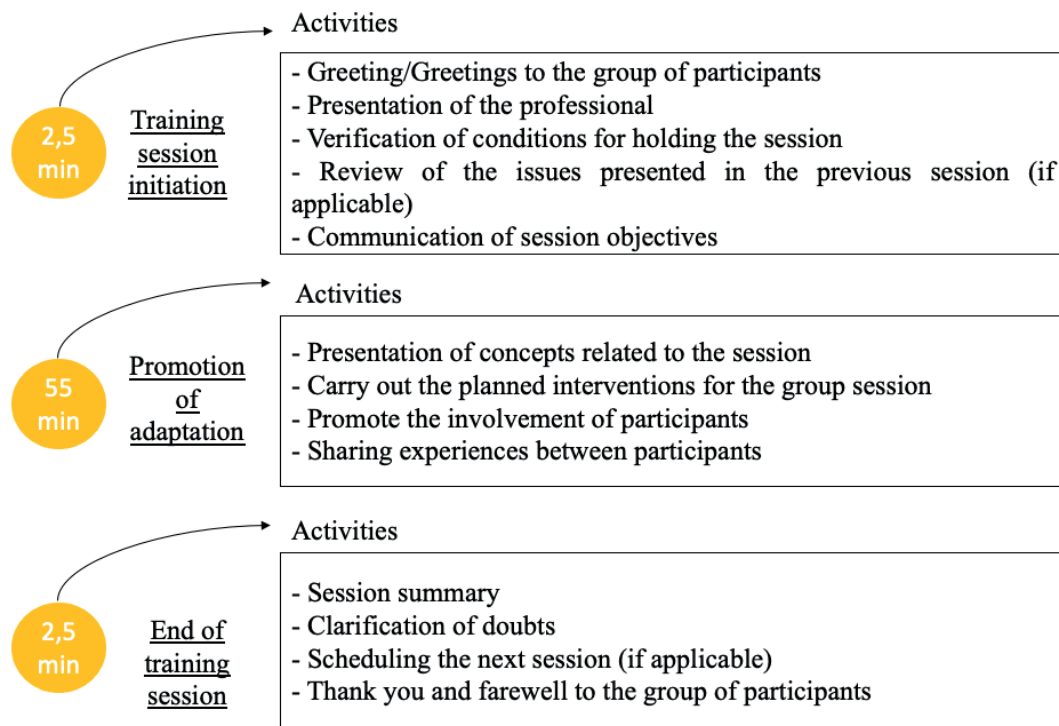


Figure 2 - Structure of the group sessions. Porto, District of Porto, Portugal, 2022

Source: Authors (2022).

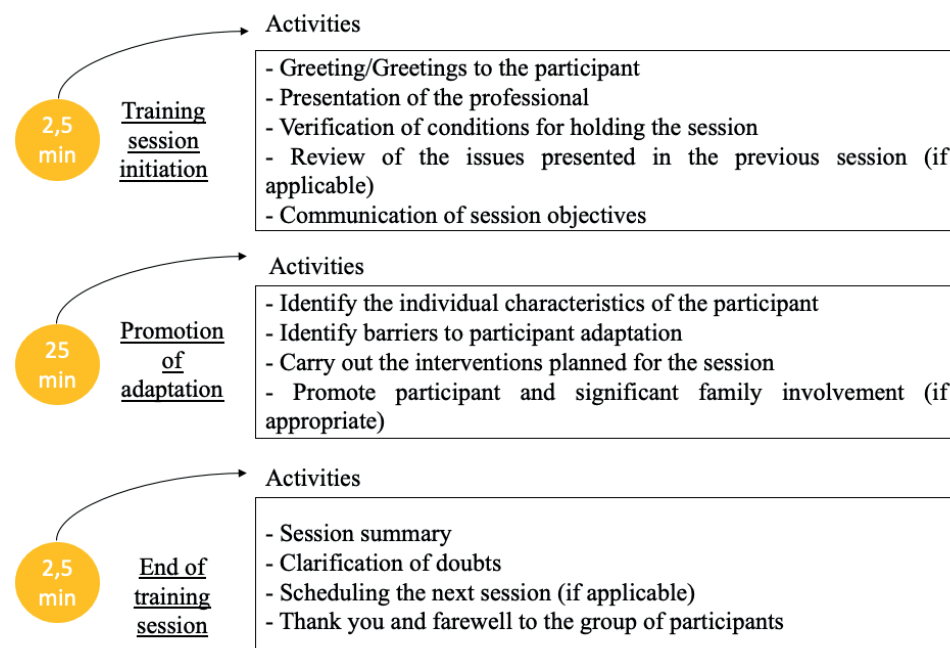


Figure 3 - Structure of individual or family sessions. Porto, District of Porto, Portugal, 2022

Source: Authors (2022).

All sessions will be held in a quiet and private place that allows the activities to take place without interruption. The nurse implementing the intervention will have a guide with specific indications for the intervention in each of the sessions. In the first session, a health contract will be signed between the nurse and the participant to create an environment of greater responsibility and commitment.

The first session of each domain (sessions 1, 3, 5 and 7), carried out in a group and with the use of audiovisual media, has a more expository approach, favoring the sharing of experiences, peer support and the involvement of participants. The second session of each domain (sessions 2, 4, 6 and 8), carried out individually or with a significant family member (always the same throughout the intervention), has a more individualized approach, creating space to adapt the knowledge acquired to the specific condition of the participant.

Chart 1 presents the content, objectives, and structure of sessions 1 and 2.

Chart 1 - Details of sessions 1 and 2 of the educational intervention. Porto, Porto District, Portugal, 2022

Domain: Adaptation	
Focus of attention to be considered: Acceptance Of Health Status (10044273); Adaptation (10001741); Self Management (10046837); Ability To Adjust (10000047); Health Knowledge (10008753); Knowledge Of Behaviour Change Process (10024907); Awareness (10003083)	
Session 1 - Group intervention	
Objectives- Present and conclude the health contract between nurse and participant - Promote awareness of the new health condition - survivorship - Promote knowledge about health status - Promote the learning of adaptation techniques - Promote healthy adaptation processes in the context of cancer survivorship - Promote positive psychological responses in the process of transition to survivorship	Interventions: - Contracting For Positive Behaviour (10035771) - Teaching About Health Seeking Behaviour (10032956) - Teaching About Disease (10024116) - Teaching About Clinical Pathway (10050977) - Teaching About Treatment Regime (10024625) - Teaching Adaptation Techniques (10023717) - Facilitating Learning (10051139) - Promoting Acceptance Of Health Status (10037783) - Promoting Self Awareness (10036097) - Promoting Self Efficacy (10035962) - Promoting Self Esteem (10024455) - Providing Instructional Material (10024493)
Session 2 - Intervention with an individual or significant family member	
Objectives: - Assist the participant to identify the most appropriate adaptive strategies for the individual condition - Providing support in the implementation of adaptation techniques - Integrate the significant family member in the participant's adaptation process - Provide space for the participant to express their emotions in the face of the adaptation process - Reinforce the importance of knowledge about the disease in the adaptation process	Interventions: - Supporting Beliefs (10026458) - Supporting Positive Body Image (10044531) - Supporting Decision Making Process (10024589) - Involving In Decision Making Process (10026323) - Establishing Trust (10024396) - Presencing (10015575) - Facilitating Ability To Participate In Care Planning (10040501) - Providing Self Management Support (10046960) - Reinforcing Self Efficacy (10022537) - Reinforcing Capabilities (10026436) - Reinforcing Personal Identity (10026443) - Reinforcing Behavioural Regime (10039002)

Source: The authors (2022).

Chart 2 presents the content, objectives, and structure of sessions 3 and 4

Chart 2 - Details of sessions 3 and 4 of the educational intervention. Porto, Porto District, Portugal, 2022

Domain: Attitude/Coping	
Focus of attention to be considered: Skill Learning (10018225); Attitude Toward Health Status (10040627); Self Management Of Symptoms (10046859); Ability To Communicate Needs (10038183); Ability To Communicate Feelings (10026587); Ability To Manage Stress (10044124); Coping (10005208); Stress (10018888)	
Session 3 - Group intervention	
Objectives: <ul style="list-style-type: none"> - Promote learning of symptom/emotion self-management strategies - Promote knowledge about self-surveillance - Promote effective coping process in the context of cancer survivorship - Promote positive psychological responses in the process of transition to survivorship 	Interventions: <ul style="list-style-type: none"> - Teaching Self Monitoring (10046994) - Teaching About Impulse Control (10036148) - Teaching About Symptom Control (10038080) - Teaching About Reality Orientation Therapy (10043768) - Facilitating Learning (10051139) - Promoting Self Management Of Symptom (10038469) - Promoting Effective Coping (10035936) - Promoting Limit Setting (10026334) - Promoting Positive Relationships (10035759) - Promoting Positive Psychological Status (10032505) - Providing Instructional Material (10024493)
Session 4 - Intervention with individual or significant family member	
Objectives: <ul style="list-style-type: none"> - Assist in identifying the most appropriate coping strategies for the individual condition - Provide support in the implementation of coping strategies - Integrate the significant family member in the coping process of the participant - Provide space for the participant to express difficulty in integrating effective coping strategies - Reinforce the importance of adopting effective coping strategies in the adaptation process 	Interventions: <ul style="list-style-type: none"> - Establishing Trust (10024396) - Presencing (10015575) - Facilitating Family Ability To Participate In Care Plan (10035927) - Facilitating Impulse Control (10035716) - Managing Negative Response to Treatment (10024429) - Identifying Obstruction To Communication (10009683) - Reinforcing Capabilities (10026436) - Reinforcing Positive Behaviour (10036176) - Reinforcing Communication (10050309) - Reinforcing Achievements (10026427) - Reinforcing Impulse Control (10036107) - Reinforcing Priority Setting (10026188)

Source: The authors (2022).

Chart 3 presents the content, objectives, and structure of sessions 5 and 6.

Chart 3 - Details of sessions 5 and 6 of the educational intervention. Porto, Porto District, Portugal, 2022

Domain: Emotion/Anxiety
Focus of attention to be considered: Distress (10006118); Anxiety (10002429); Death Anxiety (10041001); Emotion (10006765); Hope (10009095); Insecurity (10010311); Fear (10007738); Preoccupation (10015466)

Session 5 - Intervention in groups	
Objectives: <ul style="list-style-type: none"> - Promote the learning of anxiety-reducing strategies - Promote knowledge about the impact of anxiety on the adaptation process - Promote anxiety control through stress management techniques in the context of cancer survivorship - Promote positive psychological responses in the process of transition to survivorship 	Interventions: <ul style="list-style-type: none"> - Demonstrating Relaxation Technique (10024365) - Teaching About Stress Management (10038681) - Teaching About Normal Psychological Response (10051028) - Teaching About Diversional Therapy (10043536) - Teaching Relaxation Technique (10038699) - Facilitating Learning (10051139) - Promoting Hope (10024440) - Promoting Resting Behaviour (10050912) - Promoting Activity Therapy (10050908) - Promoting Diversional Therapy (10036045) - Providing Instructional Material (10024493)
Session 6 - Intervention with an individual or significant family member	
Objectives <ul style="list-style-type: none"> - Assist in identifying stress management strategies best suited to the individual condition - Provide advice on emotion management - Provide support in the implementation of anxiety management strategies - Integrate the significant family member in the participant's emotional management process - Provide space for the participant to express difficulty in integrating anxiety management strategies 	Interventions: <ul style="list-style-type: none"> - Counselling About Spiritual Distress (10026231) - Counselling about Hopes (10026212) - Counselling About Fears (10026208) - Supporting Psychological Status (10019161) - Comforting (10004664) - Encouraging Positive Affirmations (10024377) - Encouraging Rest (10041415) - Establishing Trust (10024396) - Presencing (10015575) - Facilitating Ability To Communicate Feelings (10026616) - Providing Emotional Support (10027051) - Providing Spiritual Support (10027067) - Reinforcing Capabilities (10026436)

Source: The authors (2022).

Chart 4 presents the content, objectives, and structure of sessions 7 and 8.

Chart 4 – Details of sessions 7 and 8 of the educational intervention. Porto, Porto District, Portugal, 2022

Domain: Resources
Focus of attention to be considered: Family Support (10023680); Emotional Support (10027022); Social Support (10024074); Community Service (10027359); Spiritual Support (10027033)
Session 7 - Intervention in group

<p>Objectives:</p> <ul style="list-style-type: none"> - Promote the identification of the different resources available - Promote the use of the identified resources in the transition to survival process - Promote knowledge about the importance of resource use in the adaptation process 	<p>Interventions:</p> <ul style="list-style-type: none"> - Teaching About Family Process (10036153) - Teaching About Community Service (10050983) - Teaching About Self Help Service (10038773) - Teaching About Health Service (10050965) - Teaching About Use Of Supporting Device (10040909) - Facilitating Learning (10051139) - Promoting Family Support (10036078) - Promoting Spiritual Support (10038300) - Promoting Social Support (10024464) - Promoting Ability To Socialise (10050898) - Promoting Effective Family Communication (10036066) - Promoting Effective Family Process (10036084) - Providing Instructional Material (10024493)
<p>Session 8 - Intervention with an individual or significant family member</p>	
<p>Objectives:</p> <ul style="list-style-type: none"> - Assist in identifying the most appropriate resources for the individual condition - Provide counseling on the importance of family involvement in the adaptation process - Integrate the significant family member as an important resource - Provide space for the participant to express concerns about individual resources and needs - Reinforce the importance of using available resources in the adaptation process 	<p>Interventions:</p> <ul style="list-style-type: none"> - Supporting Family (10032844) - Supporting Family Decision Making Process (10026462) - Supporting Spiritual Rituals (10024591) - Presencing (10015575) - Facilitating Ability To Communicate Needs (10038196) - Providing Social Support (10027046) - Providing Family Anticipatory Guidance (10026375)

Source: The authors (2022).

Throughout all group sessions, a researcher will be always present and will have no active role. If a participant misses a group session, the content of the session will be made available later. If a participant misses an individual session, its content will be rescheduled. Figure 4 illustrates the flowchart of the study.

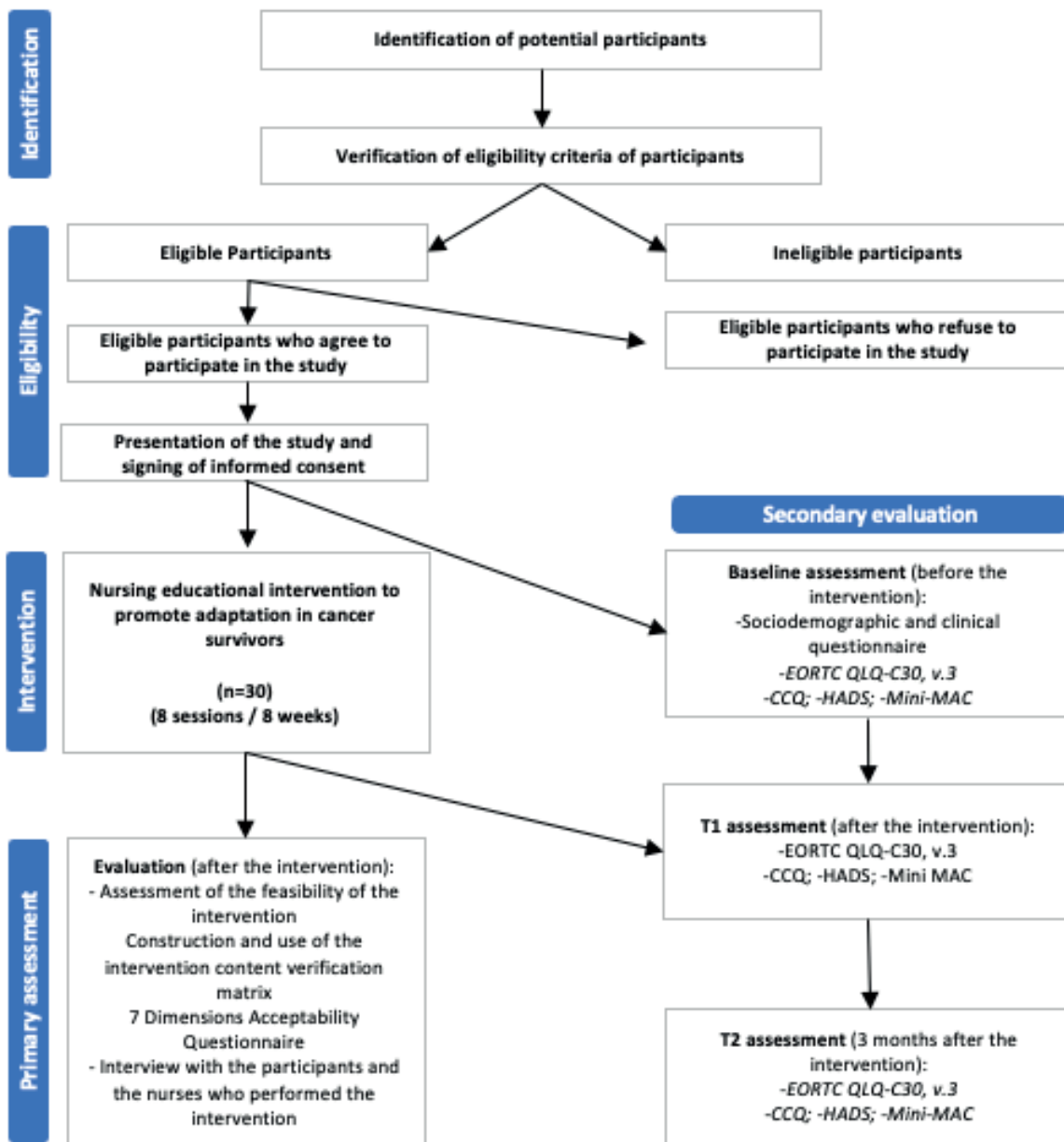


Figure 4 - Flowchart of the study. Porto, District of Porto, Portugal, 2022

Source: The authors (2022).

The evaluation of the intervention will focus on four components: feasibility, fidelity, acceptability, and secondary evaluation. To assess feasibility, the following will be considered: 1) the participant recruitment rate ($100 \times \frac{\text{number of participants recruited}}{\text{potential participants identified}}$); 2) the adherence rate ($100 \times \frac{\text{no. of participants starting the intervention}}{\text{no. of participants recruited}}$); 3) the retention rate ($100 \times \frac{\text{no. of participants completing the intervention}}{\text{no. of participants recruited}}$); 4) the time needed to recruit the participants; 5) the time needed to recruit participants recruited; 5) the required number of eligible participants to recruit the defined sample ($n = 30$); 6) the intervention completion rate ($100 \times \frac{\text{no. of participants who completed all intervention sessions}}{\text{no. of participants who started the intervention}}$); 7) the feasibility analysis of the data collection and recruitment procedures.

To evaluate fidelity, audio record all sessions. In this way, it is possible to analyze whether the intervention can be implemented in its entirety. The content of the recordings will be coded and analyzed by two members of the research team. For this purpose, a verification matrix of the intervention content will be constructed and used. To assess

the acceptability of the intervention and the procedures, a qualitative and quantitative evaluation will be carried out at the end of the intervention.

Following the recommendations of the MRC⁷, it was decided to apply to the participants and to the nurses executing the intervention an Acceptability Questionnaire with seven dimensions (affectivity; perception of effort to complete the intervention; ethical issues; timeliness; perception of effectiveness; self-efficacy and impact of the intervention) in a five-point likert scale.

In addition, semi-structured interviews will be conducted with ten participants after the end of the intervention, with the aim of knowing the opinions about important aspects, such as the main barriers and the factors that facilitated participation in the intervention, and semi-structured interviews with three nurses executing the intervention after the end of the intervention, with the aim of collecting the opinions about the structure and organization of the intervention.

Regarding the secondary evaluation, the assessment of quality of life, coping, anxiety, and adaptation of the participants will be carried out, in an attempt to test the use of the instruments, to obtain preliminary results, to know the variability of the results throughout the intervention and to predict what may be the real effects of the intervention.

Different instruments will be used, including the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core-30 (EORTC QLQ-C30), the Cancer Coping Questionnaire (CCQ), the Hospital Anxiety and Depression Scale (HADS) and the Mental Adjustment to Cancer Scale (Mini-MAC), translated and validated for the Portuguese population¹⁷⁻²⁴.

The data obtained throughout the study will be analyzed in order to 1) calculate and interpret feasibility rates and identify the factors that interfered with these data; 2) compare the content of the intervention planned and actually executed, and 3) verify the acceptability of the intervention by analyzing the data resulting from the application of the Acceptability Questionnaire and the content analysis of the interviews, using the content analysis technique proposed by Bardin²⁵.

These analyses will allow us to predict the number of participants to be recruited and the completion rate when the intervention is implemented on a large scale, to rectify the eligibility criteria, to evaluate the operationalization of the intervention, to verify whether the nurses implementing the intervention will need training on a larger scale for the implementation of the protocol intervention and to know the aspects of the intervention that should be improved, both in terms of structure and content.

The secondary assessment data collection will be carried out in three different moments: the first (baseline) will take place before the beginning of the intervention and will integrate the sociodemographic and clinical assessment, as well as the assessment of quality of life, coping, anxiety and adaptation; the second (t1) will take place immediately after the end of the eight intervention sessions; and the third (t2) will take place three months after the end of the intervention. In these last two, only the assessment of quality of life, coping, anxiety, and adaptation will be carried out. Data from the secondary evaluation will be analyzed quantitatively.

This protocol was developed based on the Declaration of Helsinki (13), the intervention development project was submitted for review by the joint Ethics Committee of the University Hospital Center of Porto and the Institute of Biomedical Sciences Abel Salazar - University of Porto and received a positive opinion with reference 2020/CE/P008(P320/CETI/ICBAS). There is no previous registration of this intervention on any platform for this purpose.

RESULTS

The design, structure, content, strategies, and evaluation tools of the educational intervention were defined. It is expected that the results of this study will provide valuable information for the possible rectification of the intervention before its large-scale implementation, to know the opinion of the participants and the nurses implementing the intervention about the implementation, and to envision how the results of the intervention will vary when it is applied on a large scale.

DISCUSSION

There is evidence documenting that cancer survivors have substantial unmet needs from professionals (for example, attention received in relation to issues such as fatigue, pain, mental health concerns, financial difficulties, return to work and sexual health information) and cumulatively feel dissatisfied with the attention given to such information⁽²⁶⁾.

Psychosocial needs not met lead to increased morbidity and mortality and compromised behaviors to manage the disease and ensure health⁽²⁷⁾.

Thus, the success of initial cancer treatment may be undermined by not anticipating or predicting the detrimental effects in the medium to long term, and efforts should also be made to avoid a disconnect between initial therapy and long-term follow-up care⁽²⁸⁾.

Nurses are in a privileged position to provide relevant professional support to this population, yet many still show some lack of preparation²⁹⁻³⁰.

In an ideal scenario, cancer survivors should have access to high-quality programs that provide a broader vision of survivorship and prepare them to deal with the long-term consequences of the disease and treatments, as well as to cope with the psychosocial implications they impose.

The development of educational strategies to provide information to cancer survivors and, consequently, empower them to actively participate in care and make informed decisions about their health, is an important lever to decrease cancer recurrence, as well as to improve the management of the effects of the disease on survival and quality of life. However, educational programs can be overly complex, and this may be the main barrier to the cancer survivor's grasp and practical application of the information.

The intervention presented in this protocol attempts to circumscribe and delimit the fields of action to the domains of adaptation, coping, anxiety, and resources, using a consistent foundation, adapted to the context and needs of survivors.

The main limitation of the intervention is the passive role imposed by the intervention structure on the participant's significant family member.

FINAL CONSIDERATIONS

Throughout the work previously developed, it was realized that although recently, scientific evidence reinforces the idea that educational interventions can produce positive effects on adaptation processes, management of coping strategies and anxiety, as well as quality of life, few nursing interventions in this area have been developed.

This fact is possibly justified by the complexity inherent in the development of this type of intervention. The interactions between the various components of the intervention, the difficulties related to the behaviors of those who implement or receive the intervention, the different organizational levels of the intervention, the variability of the results and the degree of flexibility/adaptation of the intervention are factors that characterize complex interventions, where precisely this educational intervention is inserted.

Developing, piloting, evaluating, reporting, and implementing a complex intervention is a lengthy process, where the process is more important than the outcome. The publication of this protocol allows making the link between the development phase and the feasibility/piloting phase of the complex intervention.

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Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work - **Peixoto TA dos SM, Peixoto NM dos SM**. Drafting the work or revising it critically for important intellectual content - **Peixoto TA dos SM, Pinto CAS, Santos CSV de B**. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved - **Peixoto TA dos SM, Peixoto NM dos SM**. All authors approved the final version of the text.

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