EVALUATION OF THE FEASIBILITY AND ACCEPTABILITY OF AN EDUCATIONAL INTERVENTION IN NURSING: PROTOCOL OF A PILOT STUDY

ABSTRACT
Objective: to explain the protocol of a pilot study that aims to evaluate the feasibility and acceptability of a nursing educational intervention to promote health behaviors in cancer survivors. Method: the protocol was developed based on the Standard Protocol Items: Recommendations for Interventional Trials 2013 - SPIRIT 2013 Statement, in Porto, Portugal in 2022. Results: the protocol would support the implementation of the pilot study in order to assess the feasibility and acceptability of the procedures defined for the intervention, estimate the recruitment and retention of participants, and define the sample size so that possible reformulations of the educational intervention could be considered and proceed to the evaluation phase. Conclusion: this study has laid the structural foundations and content for conducting a pilot study and may later influence the decision to conduct a randomized controlled trial.

DESCRIPTORS: Nursing; Nursing Practical; Oncology Nursing; Healthy Lifestyle; Health Promotion.

HOW TO REFERENCE THIS ARTICLE:
INTRODUCTION

Cancer survival rates have been steadily increasing. Cancer survivors are defined as people with cancer who have completed treatments with curative intent\(^1\). During this period, people face adverse effects of cancer and treatments, which can potentiate existing comorbidities, causing worsening psychological distress, greater use of health care services, and higher costs. In addition, there is a higher prevalence of multiple chronic conditions in survivors when compared to similar groups without cancer. In survivors, the risk of developing secondary cancers, cardiovascular, renal, musculoskeletal, and endocrine diseases higher when compared to the population that never had cancer\(^2\).

Uncertainty about the future provokes feelings of ambivalence in cancer survivors because, on the one hand, they feel they must engage in healthy behaviors, but on the other hand, the fears imposed by the disease create very difficult conditions that prevent them from understanding their needs and capabilities. In this sense, although survivors report making health behavior changes, they rarely self-initiate behavioral changes\(^3\). Therefore, the Centers for Disease Control and Prevention recommends that people with cancer should receive an individualized survivorship care plan that includes guidelines for monitoring and maintaining health\(^4\).

From this perspective, nurses are professionals capable of implementing educational interventions making survivors engage in relevant self-care practices. These interventions in survivors refer to individualized support from nurses to individuals in the transition from the cancer center to the community, helping them anticipate issues related to their own health\(^5\).

Although there is evidence that educational nursing interventions enhance cancer survivors’ health and quality of life, minimize long-term risks, and reduce the risk of recurrence, many actions need to be taken to avoid gaps\(^5\). In Portugal, the National Program for Oncologic Diseases reinforces that survivors have needs\(^6\), but does not present goals, strategies, or action plans.

The educational interventions found in the literature that focus on improving health behaviors in survivors are relevant; however, they are not adapted to the Portuguese population\(^7\). These actions fall within the conceptual models of complex interventions and should include a vital preliminary and preparatory assessment, the piloting. Piloting includes procedures for testing acceptability, estimating likely recruitment and retention rates, and calculating sample sizes that reflect adequate analysis before the evaluation phase\(^8\).

This article aims to explain the protocol of a pilot study, in which the purpose is to design the evaluation of the feasibility and acceptability of a nursing educational intervention to promote health behaviors in cancer survivors.

The protocol was developed to plan the assessment of the a) Feasibility recruitment and study procedures, b) Fidelity of the intervention, and c) Acceptability of the intervention and pilot study procedures. The protocol includes a secondary evaluation that will influence the decision to proceed with a randomized controlled trial.

METHOD

A protocol was developed based on the SPIRIT2013 Statement\(^9\) (version 1.0 dated 07.15.2022). The SPIRIT2013 Statement provides recommendations for defining the minimum content of a clinical trial protocol and is widely used as an international standard\(^9\).
The pilot study protocol presented, describes a single-group study, with the following research question: What is the acceptability and feasibility of the Nursing Educational Intervention to promote Health Behaviors in Cancer Survivors? The educational intervention will be implemented in a hospital in Portugal. The intervention is based on the Health Promotion Model\textsuperscript{10}, includes a set of eight educational sessions conducted by specialist nurses, and includes the necessary ethical and legal aspects\textsuperscript{11}.

The study encompasses two types of samples, the specialist nurses, and the cancer survivors. The sample size of survivors (n=30) is lined up with international recommendations\textsuperscript{12}. The recruitment will be done by the nursing team of an outpatient service of the hospital, in order of referral, who will invite the users who meet the eligibility criteria. Survivors who agree to participate will be referred to the research team, which will conduct an initial screening to verify eligibility, present the study, and sign the informed consent. The eligibility criteria for survivors are presented in Chart 1.

Chart 1 - Eligibility criteria of survivors. Porto, District of Porto, Portugal, 2022

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
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<tbody>
<tr>
<td>Be an adult (age &gt; 18 years).</td>
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<tr>
<td>Have a diagnosis of oncologic disease.</td>
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<tr>
<td>Be in the last 3 sessions of treatment with curative intent.</td>
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<tr>
<td>Be willing to participate in the sessions.</td>
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<tr>
<td>Be willing to sign a health contract.</td>
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<tr>
<th>Exclusion criteria</th>
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<tbody>
<tr>
<td>Inability to speak, read or write in Portuguese.</td>
</tr>
<tr>
<td>Medical contraindication for physical exercise.</td>
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<tr>
<td>Having altered cognitive capacity that does not allow decision making and/or limits the understanding of the information transmitted.</td>
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<tr>
<td>Having had tumor or tissue extraction surgery less than 1 month ago.</td>
</tr>
<tr>
<td>Being in the palliative phase.</td>
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<tr>
<td>Having a diagnosis of uncompensated psychiatric illness.</td>
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</table>

Source: The authors (2022).

The specialist nurses (five) who will perform the intervention will be recruited from an outpatient service of the hospital (Day Hospital). In order to be eligible, they should: a) be specialist nurses in Medical-Surgical Nursing registered in the “Ordem dos Enfermeiros” (Portuguese Nurses Association), regardless of their employment status and years of work, b) reveal availability, c) agree to participate, d) participate in a two-hour training session held by the researchers, e) follow the session guidelines provided by the researchers, f) accept the researchers’ supervision, and g) participate in a debriefing.

Eligible survivors and nurse specialists will receive an email requesting their participation in the study and informing them about the objectives, duration and intervention procedures. After agreeing to participate, they will be contacted by phone to schedule the first session and the two-hour training session, respectively. The intervention will take place over eight weeks, with weekly sessions, which can be a) group or b) individual or with a family member (Charts 2 and 3).
Chart 2 - Structure of the group sessions. Porto, District of Porto, Portugal, 2022

<table>
<thead>
<tr>
<th>Duration</th>
<th>Contents</th>
<th>Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 min</td>
<td>Initiation of the session</td>
<td>Greeting/accomplishment. Review of the subjects covered in the previous session. Communication of the objectives of the session.</td>
</tr>
<tr>
<td></td>
<td>Promotion of health behaviors</td>
<td>Exposure of concepts related to the session/health. Presentation of the benefit associated with salutogenic behavior. Promotion of involvement / adherence to the plan. Promotion of motivation and self-efficacy. Sharing of experiences with peers.</td>
</tr>
<tr>
<td>5 min</td>
<td>Ending the session</td>
<td>Summary and analysis of the session. Information about the next session.</td>
</tr>
</tbody>
</table>

Source: The authors (2022).

Chart 3 - Structure of the individual sessions or with a family member. Porto, District of Porto, Portugal, 2022

<table>
<thead>
<tr>
<th>Duration</th>
<th>Contents</th>
<th>Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 min</td>
<td>Initiation of the session</td>
<td>Greeting/accomplishment. Review of the subjects covered in the previous session. Communication of the objectives of the session.</td>
</tr>
<tr>
<td></td>
<td>Promotion of behavior change</td>
<td>Identify the individual characteristics and experiences of survivors. Identify cognitions and affect specific to health behaviors (benefits, barriers, self-efficacy, activity-related feelings, and interpersonal and situational constraints). Identification and support of behavioral outcomes (commitment to the plan and health promoting behaviors).</td>
</tr>
<tr>
<td>5 min</td>
<td>Ending the session</td>
<td>Abstract and analysis of the session. Information about the next session.</td>
</tr>
</tbody>
</table>

Source: The authors (2022).

The educational intervention will be supported by the Health Promotion Model\textsuperscript{10}, encompasses professional actions related to engagement, adherence to the plan, motivation, and self-efficacy\textsuperscript{10}. The sessions are composed of a set of focus, i.e., area of nursing care, and interventions previously validated by a group of experts\textsuperscript{13} and built based on the International Classification for Nursing Practice (ICNP)\textsuperscript{14}. The sessions (Chart 4) will be conducted by the interventionist nurses after previous preparation, provided by the researchers, and according to the flowchart shown (Figure 1).

The individual sessions (one, two and eight) will take place in an office, lasting 30 minutes. Survivors may choose to have a family member present. In these sessions, nurse interventionists focus on the affect and cognitions of behavior change, individual goal setting, and the construction of an individualized behavior change plan.

In session one the health contract will be presented to the participant, in session two the contract will be signed by both. In Session eight the nurse interventionist will reinforce the benefits of behavior change and identify the incentives for maintaining the
health behaviors by remembering the signed contract.

The group sessions (three to seven) will be held in an auditorium, will have a duration of one hour and will include an expository approach to health promotion concepts, sharing experiences and strategies to promote motivation and involvement. In these five group sessions the benefits, potential risks, and recommendations of health-promoting behaviors such as exercise, nutrition, weight status, and substance abuse will be presented. Available health resources, the benefits of professional support, and the importance of support groups will be presented. In every group session participant will be reminded of the content of the previous session. Participants will use the group to share experiences, strengthen self-efficacy, and receive peer support.

Figure 1 - Flowchart of the intervention. Porto, District of Porto, Portugal, 2022
Source: The authors (2022).

During the group sessions a researcher will be present but will not intervene. Participants who miss individual sessions will be rescheduled. If any participant misses a group session, the content and objectives of the session will be sent to the participant to minimize loss of follow-up.

Chart 4 - Domains, objectives, and materials of the sessions. Porto, District of Porto, Portugal, 2022
### SESSION 01 (individual or with family member)

- **Focus:**
  - Acceptance Of Health Status: (ICN code: 10044273)
  - Health Belief: (10022058)
  - Health Seeking Behavior: (10008782)
  - Attitude Toward Health Status: (10040627)
  - Self Efficacy: (10024911)
  - Awareness: (10003083)

- **Nursing Interventions:**
  - Establishing trust (10024396)
  - Supporting Beliefs (10026458)
  - Supporting Decision-Making (10024589)
  - Assessing Preferences (10040586)
  - Teaching Family About Health Seeking Behaviour (10033119)
  - Teaching About Health Seeking Behaviour (10032956)
  - Prioritising (treatment) Regime (10024438)
  - Promoting Self Efficacy (10035962)

- **Objectives:**
  - Health Behavior Change I
  - Summarize the data from the survivor’s health assessment.
  - Emphasize the survivor’s strengths and competencies.
  - Identify health goals and behavioral change options.
  - Identify behavioral or health outcomes to indicate the success of the plan.
  - Develop a behavior change plan based on client preferences.
  - Present the health care contract.

### Session 1 Accompanying Document
Office

### SESSION 2 (individual or with family member)

- **Focus:**
  - Adherence to Therapeutic Regimen: (10030365)
  - Meaninglessness: (10023900)
  - Barriers To Adherence: (10024768)
  - Initiative: (10010250)
  - Knowledge Of Behaviour Change Process: (10024907)
  - Volition: (10020855)

- **Nursing Interventions:**
  - Reinforcing Adherence (10024562)
  - Teaching About Impulse Control (10036148)
  - Reinforcing Priority Setting (10026188)
  - Contracting For Adherence (10024349)
  - Facilitating Access To Treatment (10024401)
  - Promoting Limit Setting (10026334)

- **Objectives:**
  - Health Behavior Change II
  - Reinforce the benefits of change and identify the incentives for change from the survivor’s perspective.
  - Address environmental and interpersonal facilitators and barriers to behavior change.
  - Define with the survivor a plan implementation period.
  - Formalize a commitment to the behavior change goals and make available the support needed to achieve them.
  - Sign the health care contract.

### Session 2 Accompanying Document
Office

### SESSION 3 (group)

- **Focus:**
  - Health-promoting behavior: Physical exercise
  - Present the health benefits of physical activity in survivors.
  - Present potential risks associated with physical activity in survivors’ health.
  - Expose international recommendations/guidelines on physical activity in cancer survivors.
  - Relate data on genetics, environment, and exercise in survivors.
  - Promote physical exercise throughout the survivorship plan.
  - Enhance engagement, motivation, and self-efficacy.
  - Enable the sharing of experiences.
  - Enable the sharing of feelings associated with action.

- **Accompanying document to Session 3**
Auditorium
Audiovisual and didactic resources (Computer and projector)
### Focus:
- Adherence To Exercise Regime (10030320)
- Attitude Towards Exercise Regime (10023549)
- Knowledge Of Exercise Regime (10023793)
- Managing Exercise Regime (10023890)
- Exercise Regime (10023667)

### Nursing Interventions:
- Teaching How To Increase Activity Tolerance (10024660)
- Teaching About Exercise (10040125)
- Teaching About Fatigue (10050996)
- Promoting Adherence To Exercise Regime (10041628)
- Promoting Self Efficacy (10035962)

### SESSION 4

**Focus:**
- Adherence To Exercise Regime (10030320)
- Attitude Towards Exercise Regime (10023549)
- Knowledge Of Exercise Regime (10023793)
- Managing Exercise Regime (10023890)
- Exercise Regime (10023667)

**Nursing Interventions:**
- Teaching How To Increase Activity Tolerance (10024660)
- Teaching About Exercise (10040125)
- Teaching About Fatigue (10050996)
- Promoting Adherence To Exercise Regime (10041628)
- Promoting Self Efficacy (10035962)

**SESSON 4 (group)**

- Health promotion behavior: Nutrition and diet
- Present the health benefits of healthy eating in survivors.
- Present nutritional needs of cancer survivors.
- Present potential risks associated with diet in the health of survivors.
- Expose potential risks associated with diet in cancer survivors.
- Promote dietary change throughout the survivorship plan.
- Enhance engagement, motivation, and self-efficacy.
- Enable the sharing of experiences.
- Enable sharing of feelings associated with action.

### Accompanying document to Session 4
- Auditorium
- Audiovisual and didactic resources (Computer and projector)

### Focus:
- Adherence To Dietary Regime (10030312)
- Attitude Toward Dietary Regime (10022418)
- Attitude Towards Nutritional Status (10002976)
- Knowledge Of Dietary Regime (10021902)
- Food Intake (10008101)
- Nutritional Intake (10013403)
- Dietary regime (10005951)
- Nutritional status (10013419)

### Nursing Interventions:
- Collaborating On Dietary Regime (10026190)
- Teaching About Diet (10046533)
- Teaching About Nutrition (10024618)
- Teaching About Eating Pattern (10032918)
- Promoting Positive Nutritional Intake (10051875)
- Promoting Self Efficacy (10035962)

### SESSION 5

**Focus:**
- Adherence To Dietary Regime (10030312)
- Attitude Toward Dietary Regime (10022418)
- Attitude Towards Nutritional Status (10002976)
- Knowledge Of Dietary Regime (10021902)
- Food Intake (10008101)
- Nutritional Intake (10013403)
- Dietary regime (10005951)
- Nutritional status (10013419)

**Nursing Interventions:**
- Collaborating On Dietary Regime (10026190)
- Teaching About Diet (10046533)
- Teaching About Nutrition (10024618)
- Teaching About Eating Pattern (10032918)
- Promoting Positive Nutritional Intake (10051875)
- Promoting Self Efficacy (10035962)

**SESSION 5 (group)**

- Health promotion behavior: Weight status
- Present the health benefits of maintaining / improving body weight in survivors.
- Present strategies for maintaining a recommended body weight.
- Expose the international recommendations / guidelines on body weight
- Present strategies for initiating a body weight reduction program.
- Promote control of weight status throughout the survivorship plan.
- Enhance engagement, motivation, and self-efficacy.
- Enable the sharing of experiences.
- Enable sharing of feelings associated with action.

### Accompanying document to Session 5
- Auditorium
- Audiovisual and didactic resources (Computer and projector)

### Focus:
- Self Control (10017690)
- Self Monitoring (10052146)
- Underweight (10020263)
- Energy (10006899)
- Overweight (10013899)
- Metabolism (10012005)
- Weight (10021034)
- Effective weight (10027385)

### Nursing Interventions:
- Collaborating With Nutritionist (10040435)
- Teaching Self Monitoring (10046994)
- Teaching About Effective Weight (10033001)
- Promoting Positive Nutritional Status (10050920)
- Referring To Nutritionist (10046788)
- Promoting Self Efficacy (10035962)
<table>
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<tr>
<th>SESSION 6 (group)</th>
<th>Health promotion behavior: Use of substances</th>
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<tr>
<td></td>
<td>● Present the benefits of smoking and alcohol cessation in cancer survivors.</td>
</tr>
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<td></td>
<td>● Present strategies for smoking and alcohol cessation.</td>
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<tr>
<td></td>
<td>● Present strategies for initiating a smoking and alcohol cessation program.</td>
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<td></td>
<td>● Promote self-control throughout the survivorship plan.</td>
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<td></td>
<td>● Raise awareness about the risks of tobacco and alcohol exposure.</td>
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<td></td>
<td>● Enhance involvement, motivation, and self-efficacy.</td>
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<td>● Enable the sharing of experiences.</td>
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<td>● Enable the sharing of feelings associated with the action.</td>
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<tr>
<th>SESSION 7 (group)</th>
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<td>Previous Tobacco Use (10038858)</td>
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<td></td>
<td>Substance Abuse (10018992)</td>
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<td></td>
<td>Alcohol Abuse (10002137)</td>
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<td></td>
<td>Tobacco Abuse (10019766)</td>
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<td></td>
<td>Smoking Cessation (10038756)</td>
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<td></td>
<td>Knowledge Of Drug Abuse (10042576)</td>
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<td></td>
<td>Knowledge Of Alcohol abuse (10042553)</td>
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<td></td>
<td>Alcohol Dependence (10041375)</td>
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<td></td>
<td>Readiness For Smoking Cessation (10038610)</td>
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<tr>
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<th>Nursing Interventions:</th>
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<tr>
<td></td>
<td>Teaching About Substance Abuse (10024639)</td>
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<td></td>
<td>Teaching About Alcohol abuse (10044900)</td>
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<tr>
<td></td>
<td>Teaching About Smoking Cessation (10038647)</td>
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<tr>
<td></td>
<td>Teaching About Tobacco Use (10038843)</td>
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<td></td>
<td>Promoting Smoking Cessation (10050954)</td>
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<tr>
<td></td>
<td>Managing Substance Abuse (10050879)</td>
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<td></td>
<td>Managing Alcohol Abuse (10050674)</td>
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<td></td>
<td>Referring To Health Care Provider (10032567)</td>
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<td></td>
<td>Promoting Self Efficacy (10035962)</td>
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<tr>
<th>SESSION 8 (individual or with family member)</th>
<th>Focus:</th>
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<tbody>
<tr>
<td></td>
<td>Family Support (10023680)</td>
</tr>
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<td></td>
<td>Social Support Act (10018434)</td>
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<td></td>
<td>Spiritual Support (10027033)</td>
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<td></td>
<td>Health Seeking Behavior (10008782)</td>
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<td></td>
<td>Social Support Role (10026979)</td>
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<td></td>
<td>Community Service (10027359)</td>
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<td></td>
<td>Self Help Service (10038760)</td>
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<tbody>
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<td>Teaching About Health Service (10050965)</td>
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<td></td>
<td>Promoting Social Support (10024464)</td>
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<td>Promoting Effective Family Process (10036084)</td>
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<td></td>
<td>Providing Social Support (10027046)</td>
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<td></td>
<td>Referring To Community Service (10038385)</td>
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<td></td>
<td>Referring To Support Group Therapy (10024558)</td>
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<td></td>
<td>Referring To Occupational Therapy (10026415)</td>
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<td></td>
<td>Promoting Self Efficacy (10035962)</td>
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<thead>
<tr>
<th></th>
<th>Accompanying document to Session 8</th>
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<tbody>
<tr>
<td></td>
<td>Auditorium</td>
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<tr>
<td></td>
<td>Audiovisual and didactic resources (Computer and projector)</td>
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<tr>
<th></th>
<th>Health Behavior Change III</th>
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<tbody>
<tr>
<td></td>
<td>To summarize the data from the survivor’s health assessment</td>
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<tr>
<td></td>
<td>Identify behavioral outcomes.</td>
</tr>
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<td></td>
<td>Verify achievement of behavior change goals.</td>
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<td></td>
<td>Reinforce the benefits of change and identify incentives for maintaining behaviors.</td>
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<td></td>
<td>Recall the health care contract.</td>
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<tr>
<th></th>
<th>Accompanying document to Session 8</th>
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<td>Office</td>
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Evaluation of the feasibility and acceptability of an educational intervention in nursing: protocol of a pilot study
Peixoto NM dos SM, Peixoto TA dos SM, Pinto CAS, Santos CSV de B.
Focus:  
Adherence To Therapeutic Regimen (10030365)  
Maintaining Health (10046580)  
Self Management Of Risk For Disease (10035255)  
Volition (10020855)  

Nursing Interventions:  
Reinforcing Behavioural Regime (10039002)  
Teaching About Relapse Prevention (10038668)  
Promoting Self Esteem (10024455)  
Reinforcing Self Efficacy (10022537)  
Reinforcing Capabilities (10026436)  
Reinforcing Positive Behaviour (10036176)  
Reinforcing Achievements (10026427)  
Reinforcing Impulse Control (10036107)  

Source: The authors (2022).

Primary evaluation

The primary evaluation contemplates the assessment of feasibility, fidelity, and acceptability. Based on the recommendations, the following items were defined to assess the feasibility of the intervention and the study procedures: 1) Recruitment rate (no. participants recruited/no. potential participants identified x 100); 2) Retention rate (no. participants completing the intervention/no. participants recruited x 100); 3) Adherence rate (no. participants starting the intervention/no. participants recruited x 100); 4) Time required to recruit participants; 5) Number of eligible participants needed to recruit the defined sample size; 6) Intervention completion rate (no. participants who completed all intervention sessions/no. participants who started the intervention x 100); 7) Feasibility analysis of data collection and recruitment procedures.

The evaluation of the fidelity of the intervention involves determining whether it is possible to carry out the intervention as planned (intervention delivery). To do this, sessions will be audio-recorded, transcribed, coded, and analyzed by two members of the research team. An intervention content verification matrix will be used to evaluate the delivery of the intervention, verify the aspects addressed by the Interventionist nurse, guide the wording of the items in the sessions’ document, facilitate the assessment of adherence, and validate the Interventionist Nurses’ competence to carry out the intervention. If there is deviation in the delivery of the intervention, meetings will be held with the nurse specialists for analysis and standardization of procedures before implementation in the randomized controlled trial.

The acceptability of the intervention and study procedures will be evaluated both quantitatively and qualitatively. Considering the recommendations. It was defined that:

(a) Acceptability Questionnaire of seven dimensions on a five-point Likert scale will be applied to participants and intervention nurses: 1) affection; 2) perceived effort to complete the intervention; 3) ethical issues; 4) opportunity; 5) perceived effectiveness; 6) self-efficacy; and 7) impact of the intervention.

b) Interviews will be conducted with 10 participants to obtain their opinions and experiences with the intervention, including what they perceive as barriers and facilitating factors of the intervention.

c) Interviews will be conducted with 3 Nurse Interventionists immediately following the conclusion of the intervention period to explore the acceptability of the intervention.

The interviews will allow the nurses to share stories and challenges, to discuss the skills they must improve to develop this type of intervention, to discuss the use of the session tracking documents and the ontology used.
Secondary Evaluation

Relative to the secondary assessment, an assessment of Quality of Life and variability of health behaviors will be performed. It will be used: a) the Health-Promoting Lifestyle Profile-II (HPLP-II)\textsuperscript{16} translated and validated for the Portuguese population in 2015\textsuperscript{17} - a questionnaire composed of 52 items divided into six subscales that allows monitoring behaviors in the theoretical dimensions of the health-promoting lifestyle, namely spiritual growth, interpersonal relationships, nutrition, physical activity, responsibility for health and stress management\textsuperscript{16}; b) the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core-30\textsuperscript{18} translated and validated for the Portuguese population in 2008\textsuperscript{19} - a 30-item instrument widely used in assessing QoL of adults with cancer and may allow comparability with other studies\textsuperscript{18}; c) a five-item Likert scale to assess alcohol consumption and tobacco use; d) Body Mass Index and, e) participants’ body weight.

Data collection, management, and analysis

The collection, management and analysis of the primary and secondary data will allow inferring the possibility of implementing the educational intervention in a randomized controlled trial. Primary data collection will occur in different ways and at different times (Figure 1), namely through: 1) collecting data regarding participation in the sessions, 2) audio recording the sessions, 3) applying questionnaires and conducting interviews with the participants and intervention nurses after the intervention.

The analysis of the feasibility data, especially the percentages of recruitment, adherence, and intervention completion rates, will allow us to understand, among other things, if the recruitment of participants is adjusted. If a recruitment rate of more than 80% is not achieved, the participant screening data will be analyzed to see if too few potential participants were contacted, if the recruited participants did not meet the eligibility criteria, or if they simply did not want to participate in the study or did not accept the conditions of the study.

The analysis of the data concerning acceptability will result from the application of the Acceptability Questionnaire of seven dimensions to the participants and interventionist nurses, but also from the content analysis of the interviews conducted with them, according to Bardin’s methodological assumptions\textsuperscript{20}.

The interviews will be transcribed by members of the research team. The transcriptions will provide data on the participants’ and interventionist nurses’ perceptions of the intervention. Data on the affection, opportunity, impact, and effort generated by the intervention on participants and nurses will allow researchers to optimize and restructure the intervention.

For the analysis of the fidelity of the intervention, all sessions will be recorded, transcribed, and compared. The text excerpts of the recordings will be allocated to a verification matrix of the intervention’s content to assess the operationalization of the intervention, in other words if it includes the items selected for the session, if the interventionist nurses follow the protocol and if participants feel their needs were met. We also intend to verify the skills that interventionist nurses use or need to improve, to optimize the formative session, which was performed by the researchers prior to the intervention.

Secondary data collection will be performed through the instruments already mentioned in three moments: the first before the intervention (T0-before the first session), the second after the last session of the intervention (T1), and the third three months after the end of the intervention (T2) to put into perspective the changes in Quality of Life (QoL) and variability of health behaviors imposed by the intervention. Data will be grouped and will be subject to quantitative analysis.
Ethical Aspects

The protocol was built based on the Helsinki Declaration\textsuperscript{11}. The investigation project was submitted to the joint Ethics Committee of CHUPorto and Instituto de Ciências Biomédicas Abel Salazar (ICBAS)-University of Porto and was approved under reference 2020/CE/P009(P321/CETI/ICBAS). The consent of all participants is essential through the signature of a free, voluntary, and informed consent form. Confidentiality will be ensured, and participants may withdraw from the research at any time if they wish. The data will be used only for the intended purpose and will be destroyed later. The intervention presented was not recorded in any platform intended for this purpose.

RESULTS

As a pilot study protocol, the results are only expected. The protocol will support the implementation of the pilot study to assess the feasibility and acceptability of the procedures defined for the intervention, to estimate recruitment and retention of participants, and to define the sample size so that possible reformulations of the educational intervention can be considered and proceed to the evaluation phase\textsuperscript{8}.

With the mixture of previously selected data collection methods, it is expected that the primary results of the study will support the understanding of the fidelity of the intervention and its acceptability, and that the barriers, affection, perceived effectiveness, and impact of the intervention on participants and intervention nurses will be understood. Secondary data will allow us to interpret changes in participants’ QoL and health-promoting behaviors and put into perspective their variability when the intervention is applied in a clinical trial.

DISCUSSION

Educational intervention provides cancer survivors with an individualized educational plan and ongoing professional support for health behavior change, essential to prevent cancer-associated comorbidities and improve quality of life.

The structure and content of the planned intervention has a strong influence on the central aspects of behavior change\textsuperscript{10}, which leads to participants feeling more motivated and involved and better understanding the benefits and barriers to action, improving self-efficacy, and developing feelings related to the action itself.

The nurse-participant health contract promotes an environment of co-responsibility, with shared decision-making, and the survivor feels an integral and active part of their health project\textsuperscript{21}. Health contracts provide health gains, psychological comfort, and a better understanding of what they are expected to do\textsuperscript{22}.

A strength of the intervention is its ICNP\textsuperscript{14} structuring, as it produces a standard of documentation with international replicability\textsuperscript{23}. A possible barrier to the intervention is the preparation and standardization of skills of the intervention nurses that may affect the delivery of the intervention. However, given that the focus is on the survivor and the survivor-nurse relationship, no acceptability assessment activities were developed with family members, and this is a limitation of the study. Results will also be limited by the lack of a control group.
FINAL CONSIDERATIONS

The protocol presented is unique in the national landscape and defines the structure and content, assessment procedures, data collection, management, and analysis for conducting a pilot study. This study will determine the feasibility and acceptability of the nursing education intervention to promote health behaviors in cancer survivors and will yield information for the development and implementation of a subsequent randomized controlled trial.

Based on this, it is believed that this study can support and contribute to the implementation of future and varied educational interventions for cancer survivors. At the same time, it is hoped that it can be considered a starting point for new and future studies that seek to demonstrate the effectiveness and applicability of educational interventions and that aim at improving the quality of life of people with cancer.

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Evaluation of the feasibility and acceptability of an educational intervention in nursing: protocol of a pilot study

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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
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- Peixoto NM 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 NM dos SM. All authors approved the final version of the text.

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