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A person-centered support program (RESPECT intervention) for women treated with endocrine therapy: A feasibility study

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Complete List of Authors:	Ahlstedt Karlsson, Susanne; Sahlgrenska Academy, Health Care Sciences Henoch, Ingela; Goteborgs Universitet, Institute of health and care sciences Olofsson Bagge, Roger; Sahlgrenska Academy, Clinical Sciences Wallengren, Catarina ; Sahlgrenska Academy, Health Care Sciences
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3 **A person-centered support program (RESPECT intervention) for women treated with**
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7 **endocrine therapy: A feasibility study**
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11 Ahlstedt Karlsson, Susanne^{1,2} Orcid ID: 0000-0001-5436-5476; Henoeh, Ingela² Orcid ID: 0000-0002-1987-
12 5419; Olofsson Bagge, Roger^{1,3} Orcid ID: 0000-0001-5795-0355; Wallengren, Catarina² Orcid ID: 0000-0002-
13 8124-1572
14
15

16
17
18 ¹Department of Surgery, Sahlgrenska University Hospital, Gothenburg, Sweden.

19 ²Institute of Health and Care Sciences, Sahlgrenska Academy at the University of Gothenburg, University of
20 Gothenburg, Gothenburg, Sweden

21 ³Department of Surgery, Institute of Clinical Sciences, Sahlgrenska Academy at the University of Gothenburg,
22 Gothenburg, Sweden.
23
24

25
26 # Correspondence to: Ahlstedt Karlsson, Institute of Health and Care Sciences, Sahlgrenska Academy at the
27 University of Gothenburg, University of Gothenburg, Gothenburg, Sweden

28
29 E-mail: susanne.ahlstedt.karlsson@gu.se

30 Telephone: +46 704153666
31
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ABSTRACT

Objective: The aim of the study was to explore the feasibility of the trial design and patient acceptability of the intervention and outcome measures and to provide data to estimate the parameters required to design the final intervention.

Design: A controlled before-and-after design following the CONSORT 2010 statement for feasibility trials.

Setting: A surgical out-patient clinic in Sweden.

Participants: Forty-one patients (aged 47 – 85) treated with endocrine therapy.

Interventions: Eligible patients were assigned to the control group or intervention group, which included individual education material, an individualized learning plan, and a personalized reminder letter using a person-centered approach. The intervention could be delivered as a telephone or digital follow-up.

Outcome measures: The aims were to determine the recruitment rate, assess the rate of retention, explore whether the intervention was delivered according to the protocol, assess the preferred form of educational support, rate of education sessions, length per education session, and length between each education session, determine the distribution of education materials, and assess completion rates of patient-report instruments, including the General Self-efficacy Scale, the Quality of Care from the Patient's Perspective questionnaire, and the Memorial Symptom Assessment Scale.

Results: Eighty-six percent of the patients in the intervention group completed the intervention and completed the questionnaires three months after their inclusion. The call attendance was 90%. During the intervention, the nurse navigator was compliant with the intervention protocol. For self-efficacy, symptoms, and quality of care, there were no differences in effect size between the control and intervention groups.

Conclusions

This intervention seems to be feasible and acceptable among patients, and a telephone follow-up intervention also seems to be the preferred way to administer the intervention.

Article summary

Strengths and limitations of this study

- This is the first study to investigate the feasibility of a person-centered support model for patients with endocrine therapy.
- This study uses the CONSORT 2010 statement for feasibility trials.
- This study reports the recruitment rate, assess the rate of retention, explore whether the intervention was delivered according to the protocol, assess the preferred form of educational support, rate of education sessions, length per education session, and length between each education session, determine the distribution of education materials, and assess completion rates of patient-report instruments.
- Due to COVID-19 pandemic face-to-face sessions was restricted.
- This study did not identify when the intervention should stop.

A person-centered support program (RESPECT intervention) for women treated with endocrine therapy: A feasibility study

BACKGROUND

For women diagnosed with hormone receptor-positive breast cancer, endocrine therapy (ET), i.e., the use of tamoxifen or aromatase inhibitors, is recommended for at least five years to reduce recurrence and rates of mortality¹. A previous study reported that up to 91% of patients experience side effects from ET², such as sleeping difficulties, hot flashes^{3 4} and musculoskeletal symptoms⁵. Difficulties in managing these side effects have been reported to be obstacles to staying in treatment⁶. Other challenges that have been identified include older age⁷, medicine costs, or a general dislike of taking a regular medicine⁸. As ET is a long-lasting treatment, women may request support in managing challenges⁹. To manage challenges with ET, a partnership with health care professionals could be appropriate, as a previous study¹⁰ identified that women with ET want to be able to manage their treatment but need guidance to do so.

Regarding the management of ET-related symptoms, previous studies have investigated the effect of symptom management interventions for patients prescribed ET¹¹⁻¹³. A study identified management needs for ET symptoms, emotional needs, and needs for information acquisition and found that patients' relationship with health care providers was important¹². A combination of information with cognitive behavioral therapy (CBT) to manage the side effects of tamoxifen showed successful results for the development of management skills in patients who were unable to stay in treatment¹¹. Managing a disease and its additional challenges requires self-care knowledge and skills gained from a partnership with health care professionals¹⁴. Self-care involves the ability to both care for oneself and to achieve, promote and maintain optimal health¹⁵. A common feature of self-care and person-centered care (PCC) is an ability to view humans as the agent and the subject of action^{16 17}. To include aspects of treatment important to the individual patient, such as different side effects, health care structures, fear of side effects, and lack of management skills and for support, a person-centered support program was developed¹⁰. As self-care requires knowledge and skills¹⁴, PCC could be appropriate for use in a support

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3 program. Self-care requisites are described as all elements that individuals need at all stages in life to care for
4 themselves, i.e., air, food, water; self-care requisites also depend on how individuals react to illness¹⁴. PCC can
5 be a preferable way of identifying those requisites, as they can be identified in the narratives and used in the
6 patient-health care provider partnership¹⁷. Patients are often motivated to engage in self-care, as they have
7 personal interest in acquiring requisite knowledge and skills for performing self-care operations to reach their
8 intended health goals¹⁴. It has been shown that when self-care capabilities increase¹⁸, self-efficacy and
9 adherence to ET also increase^{19 20}. Self-efficacy constitutes the self-image of the person and affects how people
10 experience and behave in specific situations²¹. Previous studies using PCC have improved patients' self-efficacy
11 22-24.

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17 It is important for patients to not only identify accurate information but also assess and integrate the information
18 to gain increased knowledge, self-efficacy, and self-care skills¹⁰. Moreover, in addition to the emotional needs
19 identified by Kim et al. (2020), it is important to assess the amount of needed information and to explore
20 patients' understanding of the diagnosis and treatment²⁵. For written health education materials to be effective,
21 the patient must be able to apply the new information to her own life. This can be achieved by providing
22 understandable examples and presenting the information so the patient sees its relevance to her situation²⁶, as
23 the ultimate reason for educating patients is to improve health²⁷.

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28 A previous study developed a person-centered support program in collaboration among patients, health care
29 professionals, researchers and managers with ET experience¹⁰ and need to be tested in a feasibility study using
30 the TIDieR checklist²⁸ and the CONSORT 2010 statement²⁹. Previous studies have used feasibility studies prior
31 to conducting a study in a larger setting^{9 30}. The intervention was developed to encourage patients to be more
32 actively involved in their care and wellbeing as partners with their nurse navigator¹⁰.

33 34 35 36 37 **Aim**

38 In this feasibility trial, the aim was to explore the feasibility of the study design and the patient acceptability of
39 the Person-centered Support Program Endocrine Therapy (RESPECT) intervention and outcome measures and to
40 provide data to estimate the parameters required to design the final intervention.

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44 The feasibility outcomes were as follows:

- 45 1. Determine recruitment rate
- 46 2. Assess the rate of retention
- 47 3. Explore whether the RESPECT intervention was delivered according to the protocol
- 48 4. Assess the preferred form of educational support
- 49 5. Assess the rate of education sessions
- 50 6. Assess the length per education session
- 51 7. Assess the length between each education session
- 52 8. Determine the distribution of education materials
- 53 9. Assess the completion rates of patient-report instruments, including of the General Self-efficacy Scale
54 (GSE), the Quality from the Patient's Perspective questionnaire (QPP), and the Memorial Symptom
55 Assessment Scale (MSAS)
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3 10. Investigate whether self-efficacy, symptoms and satisfaction with care can be assessed appropriately by
4 using the patient-report GSE, QPP, and MSAS.
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13 **METHODS**

14 15 16 17 *Study design*

18 This was a feasibility trial using a controlled before-and-after design ³¹ to investigate the feasibility of the
19 intervention, a person-centered support program aimed at empowering patients prescribed ET to manage ET-
20 related symptoms and problems.
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23 *Patient and public involvement*

24 Patients and health care professionals was involved in the design and development of the person-centered
25 support model ¹⁰. However, there was no patient involvement in the evaluation of the person-centered support
26 model presented in this study.
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30 *Participants*

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33 Based on the recommendations for feasibility studies and an expected attrition rate of 20%, the sample size was
34 set to 20 participants in each group ³². Between September 2020 and June 2021, 66 potential female patients
35 from one outpatient clinic at one university hospital in Sweden were identified as eligible for inclusion. The
36 inclusion criteria were women > 18 years who had been diagnosed with breast cancer and treated with ET after
37 surgery. Patients receiving adjuvant chemotherapy were excluded. All patients were contacted by a nurse
38 navigator and were invited by telephone to participate in the study approximately three weeks after their surgery
39 (Figures 1 and 2; Table 1). All patients were given verbal and written information about the study, and after
40 agreeing to have an informed consent form sent to them by mail, they all provided written, informed consent. If
41 the patient agreed to participate, she sent the informed consent form back using a prepaid envelope.
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Table 1. Demographic and clinical characteristics of the participants in the control group (n=20) and intervention group (n=21) in the RESPECT project.

Demographic characteristics	Control group n=20	Intervention group n=21
<i>Median age, years (range)</i>	65 (50-85)	66 (47-79)
<i>Civil status, n (%)</i>		
<i>Married/cohabiting</i>	12 (63%)	16 (76%)
<i>Single</i>	8 (37%)	5 (23%)
<i>Ancestral homeland, n (%)</i>		
<i>Sweden</i>	16 (80%)	18 (86%)
<i>Scandinavian countries</i>	1 (5%)	1 (5%)
<i>Europe</i>	1 (5%)	2 (10%)
<i>Outside Europe</i>	1 (5%)	0 (0%)
<i>Education, n (%)</i>		
<i>University</i>	9 (45%)	10 (48%)
<i>High school</i>	8 (40%)	8 (38%)
<i>Elementary school</i>	3 (15%)	3 (14%)
<i>Radiation therapy, n (%)</i>	16 (80%)	21 (100%)
<i>Chemotherapy, n (%)</i>	0 (0%)	0 (0%)
<i>Tumor size, median mm (range)</i>	14 (4-45)	12 (1-19)
<i>Breast surgery</i>		
<i>Mastectomy</i>	4 (20%)	2 (10%)
<i>Partial mastectomy</i>	15 (75%)	19 (90%)
<i>Axillary lymph node dissection</i>	1 (0.5%)	0 (0%)
<i>Tamoxifen, n (%)</i>	9 (45%)	9 (43%)
<i>Aromatase inhibitor, n (%)</i>	11 (55%)	12 (57)

Control group

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3 Usual care (UC) involves patients being allocated a nurse navigator (an experienced undergraduate nurse or
4 postgraduate nurse in surgical care), as the Swedish Patient Act ³³ gives patients a statutory right to permanent
5 contact with health care. Patients can contact the nurse navigator all weekdays by telephone or by using a
6 national digital tool, 1177.se ³⁴. All patients receive written information as a brochure or a digital “My care and
7 rehabilitation plan” when diagnosed with breast cancer. Support in usual care aims to give patients information
8 about their state of health, available methods for examinations, care, and treatments, as well as information about
9 at which time point she can expect to receive care and a permanent contact with the health care. The nurse
10 navigator writes down the information that is available before surgery, such as tumor characteristics and surgery
11 preparations. The patient can also write down questions to bring to the oncoming appointments. Usual care is
12 based on patients’ initiative to make contact (Figure 3).
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21 *Intervention group*

22 The intervention was provided in a surgical outpatient clinic in western Sweden from December 2020-June
23 2021. The goal of the intervention is to empower patients prescribed ET to manage ET-related symptoms and
24 problems. In addition to the UC, a 12-week intervention was offered to the participants in the intervention group
25 (Figure 3):
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30 *Step 1- Individual education material*

31 Using a PCC approach ¹⁷, the nurse navigator listened to patients narratives regarding their individual needs for
32 knowledge and understanding, resources, goals and needs for support from the nurse navigator. The timing of
33 supplying individual educational materials depended on the individual patient’s needs, resources and goals
34 during the 12-week intervention. Mutual trust was demonstrated, and the relationship between the patient and
35 her nurse navigator was reinforced through the assessment of the commonly agreed-upon individualized learning
36 plan ³⁵ study.
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41 *Step 2 - An individualized learning plan (ILP)*

42 An ILP was established depending on the individual patients’ needs for knowledge and understanding about ET
43 and considering the patients’ resources, goals, and needs for education material and support from the nurse
44 navigator. In combination with the individual educational materials (step 1), a follow-up plan was made using
45 telephone and/or digital follow-ups. Physical follow-ups were minimized as the COVID-19 pandemic was
46 ongoing. The number of follow-up sessions and whether relatives were to be included during the 12-week
47 intervention were agreed upon between the patient and the nurse navigator. Patients could also refuse all
48 education material and other materials and only use only the nurse navigator for support.
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53 *Step 3 – A personalized reminder letter*

54 The third part of the support program was a personalized reminder letter after three months including contact
55 information and an invitation for patients to make contact if needed.
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Education of the nurse navigator in the intervention

The aim of the education was to increase the nurse navigator's knowledge and understanding of ET, its problems and symptom management using PCC. Microteaching^{36,37} sessions and seminars were used; the microteaching sessions were adapted to the specific needs of knowledge about endocrine therapy, side effects¹⁰, pedagogy³⁸ and PCC^{17,39}, and the chosen approach was intended to help the nurse navigator take responsibility for her own learning, i.e., student-centered learning⁴⁰. Additionally, practical exercises were used, as the nurse navigator was able to practice her knowledge and understanding in a care setting and reflect on it, and the nurse navigator's curiosity was used as a motivator to gain knowledge³⁸ (Table 2).

Table 2. Description of the education of the nurse navigator.

Before Lecture: The nurse navigator is asked to specifically reflect on the following in the care setting: <i>Problems with endocrine therapy</i> <i>Symptom management</i> <i>Cocreation with patients, barriers, facilitators.</i>			
Sessions	Content	Learning outcomes	Learning activities
1	Core principles about ET, including side effects of endocrine therapy (ET) and symptom management described in research. Symptom management theory.	-Describe symptom management methods. -Suggest strategies for symptom management during ET.	Clinical case discussions, microteaching sessions, dialogs, reflection.
Before Lecture: The nurse navigator is asked to reflect on practical situations in the care setting when <i>applying dialog</i> and <i>person-centered care (PCC)</i> .			
Session	Content	Learning outcomes	Learning activities
2	Pedagogical theory.	- Describe pedagogic strategies using dialog to increase patients' self-care. - Describe pedagogical strategies to increase patient participation. - Describe dialogical methodology that strengthens patient participation. -Evaluate whether chosen pedagogical strategies increase patients' self-management ability.	Clinical case discussions, microteaching sessions, dialogs, reflection.
Before Lecture: The nurse navigator is asked to reflect on practical situations in the care setting using knowledge from Session 2 and <i>relate to PCC</i> in a care setting.			
Session	Content	Learning outcomes	Learning activities
3	PCC in the clinical care setting.	-Describe PCC.	Clinical case discussions, microteaching sessions, dialogs, reflection.
Before Lecture: The nurse navigator evaluates the <i>gained knowledge about PCC</i> in a practical situation in the care setting.			
Session	Content	Learning outcomes	Learning activities
4	The three intervention components, i.e., individual	-Explain the components of the intervention.	Clinical case discussions, dialogs, reflection.

	education material, individualized learning plan, and a personalized reminder letter (Ahlstedt Karlsson, et al. submitted), with a starting point in the nurse navigator's experience from a practical situation in the clinical setting.		
After Lecture: With a starting point in the newly gained knowledge, <i>apply PCC, knowledge about ET, pedagogical theory and the three components</i> in the intervention in a care setting.			
Proficiency goal after completed education: The nurse navigator can: - Evaluate whether the proposed symptom management strategies increase the patient's management of ET-related symptoms. - Assess whether the patient's need for care was met. - Review and evaluate whether selected pedagogical strategies strengthen the patient's self-care ability. - Evaluate the patient's participation in ET symptom management.			
Evaluation ability after completed education: The nurse navigator can: - Suggest strategies for managing symptoms in relation with ET. - Together with the patient, identify care needs. - Apply pedagogical strategies that strengthen patients' self-care ability. - Apply dialogical methodology that strengthens patients' participation.			

Abbreviation: Person-centered care- PCC, Endocrine therapy - ET

Feasibility outcomes

Craig et al. (2013) described several challenging variables that can affect an intervention's results and conclusions. The feasibility classification (process, resources, scientific) and feasibility criteria reported by Thabane et al. (2019) and Lancaster et al. (2004) were used to collect feasibility data. To determine whether the chosen feasibility criteria were successful⁴¹, criteria for success were stated according to the CONSORT 2010 statement²⁹;

The intervention process was assessed with the feasibility criteria as follows:

1. Recruitment was studied to determine whether the patients were willing to participate in the study. The criterion was determined to be successful if the percentage rates of recruitment were > 70%.
2. Retention was studied to determine whether the patients were willing to remain for the entire study period, i.e., 12 weeks. The criterion was determined to be successful if the percentage rates of retention were >70%.
3. Compliance with the intervention protocol was studied to determine if the patients were offered the three parts of the planned intervention, i.e., education materials, learning plan and personalized letter. The criterion was determined to be successful if all three parts of the intervention were offered.

The resources used in the intervention were assessed with the feasibility criteria as follows:

4. Form of educational support was studied to determine the preferred form of educational support during the intervention period, i.e., 12 weeks. The criterion was determined to be successful if all three forms of educational support (face-to face, telephone, and computer) were requested by the patients.
5. Number of educational sessions was studied to determine how many educational opportunities the patient used during the intervention period, i.e., 12 weeks. The criterion determined to be successful if no more than four education sessions were used by each patient.

6. Length per education session was studied to determine how much time the patient used in each education session. The criterion was determined to be successful if < 45 minutes was used per education session.
7. Length between each education session was studied to determine how often women wanted to have education opportunities. The criterion was determined to be successful if there were no more than four weeks between each education session.
8. Distribution of education materials was studied to determine how much of intervention materials the patients received during the study. The criterion was determined to be successful if the distribution of education materials was >70%.

The scientific challenges of the intervention were assessed with the feasibility criteria as follows:

9. Completion rate of questionnaires was studied to determine if the patient was willing to answer the questionnaires, i.e., at baseline and 12 weeks. The criterion was determined to be successful if the percentage rates of patient completion of questionnaires were > 70% at baseline and 12 weeks.
10. The estimated treatment effect was studied to determine if the selected instruments were appropriate to measure patients' self-efficacy, quality of care, and symptoms. The criterion was determined to be successful if there were any changes in the self-report measures between the first and second points of measurement.

Data collection

Data were collected from September 2020 – June 2021. Feasibility outcomes were collected during the whole study period by the trial leader and were documented directly after every session in a trial log to secure the data collection⁴². The trial log contained a summary of the results of the feasibility criteria using Excel (Microsoft® Excel, version 16.50).

The three questionnaires were distributed by mail to patients in the control group (between September 2020 and December 2020) and the intervention group (December 2020 and March 2021). These three questionnaires were distributed at baseline, i.e., at the start of the intervention and ET, and three months after the start of the intervention.

The first questionnaire was the GSE, a 10-item (short form) psychometric scale that assesses optimistic self-beliefs to cope with a variety of demands in life. The GSE is a validated instrument that has been translated into Swedish⁴³ and has previously been used with breast cancer patients⁴⁴. The total score is the mean value of respondents' answer to all items. High scores imply higher self-efficacy.

The second questionnaire was the QPP, a 45-item instrument that measures satisfaction in four dimensions: medical-technical competence, physical-technical conditions, identity-oriented approach, and sociocultural atmosphere^{45 46}. Moreover, to identify patients' views of whether the health care was adapted to their needs rather than health care routines, three items (*I was given the possibility to tell the medical staff how I experienced*

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3 *my situation; I was given the opportunity to participate in the planning of my care/treatment; I received the*
4 *information I needed to be able to participate in decisions about my own care and treatment)* that were
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6 previously used by the Swedish SOM institute were added ⁴⁷. To calculate the execution index, each question is
7 scored in terms of actual experience and subjective importance, each on a four-point Likert scale. The execution
8 index score ranges from 1–7, where one is inadequate quality of care from the patient perspective and seven is
9 good quality of care ⁴⁸.

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13 The last questionnaire was the MSAS, a 32-question instrument for patients to rate their symptoms on a 5-point
14 Likert scale ^{49 50}. The instrument has been validated in Swedish breast cancer patients ⁵⁰ and has previously been
15 used with breast cancer patients ⁴⁴. The total MSAS score is the average of the symptom scores for all 32
16 symptoms. Each symptom score is an average of the dimensions and includes the number of symptoms, how
17 often patients experienced them, the severity of the symptoms and the cause of distress.

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21 Patients included in the study responded to the questionnaires and returned the questionnaires in a prepaid
22 envelope.

23 24 25 **Analysis**

26 To analyze demographic variables, we used descriptive statistics (number, percent, mean, range). We calculated
27 the percentage rates of recruitment, retention, and completion of questionnaires. We calculated the number,
28 median and range of educational sessions, distribution of education materials, length per education session, and
29 length between each education session. As the study was a feasibility test, no hypothesis testing was applied ⁵¹,
30 but p-values were calculated and presented to value their relevance in an RCT. Baseline characteristic were
31 compared by the chi-squared test for categorical characteristics. Descriptive statistical analyses and the Mann-
32 Whitney U-test were performed to identify the experience of symptoms, satisfaction with care and perceived
33 self-efficacy. P-values below .05 were considered statistically significant, and all analyses were performed with
34 IBM® SPSS® Statistics version 27 (IBM SPSS Statistics for Macintosh, Version 27.0).

35 36 37 38 39 40 41 **RESULTS**

42 43 *Participant demographics*

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45 In the control group, the median age was 65 years, 80% of the participants were born in Sweden, 63% were
46 cohabiting and 45% were prescribed tamoxifen. In the intervention group, the median age was 66 years, 86%
47 were born in Sweden, 76% were cohabiting and 43% were prescribed tamoxifen. One hundred percent of the
48 patients in both groups had invasive breast cancer (Table 1).

49 50 51 *Feasibility classification and criteria*

52 Feasibility outcomes are presented in line with the CONSORT 2010 statement as follows:

53 54 55 *1. Recruitment*

56 In the control group, 22 eligible patients were screened, and 20 were approached at the clinic, of whom 20
57 consented to participate (100%). In the intervention group, 44 patients were screened, of whom 24 were
58 approached and 21 consented to participate (88%) (Table 1). Of the three patients who did not consent to
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3 participate in the intervention group, two indicated the number of questions in the questionnaires to be a reason
4 for not participating. One patient gave no reason for not participating (Figure 1, 2).

6 2. Retention

7 In the intervention group, 20 patients completed (95%). One patient dropped out from the intervention because
8 the study reminded her about the breast cancer surgery, which she was trying to forget about (Figure 1).

10 3. Compliance with the intervention protocol

11 In the first session, the patients' needs for knowledge and understanding, resources, goals and support from the
12 nurse navigator were identified in their narratives. Education material was offered accordingly using a written
13 agreement between the patient and nurse navigator and documented in the ILP. Patients decided with the nurse
14 navigator whether they required knowledge. If they required knowledge, they stated when they wanted the
15 education materials and which parts. Their need for knowledge ranged between having everything sent after the
16 first session and having some of the education material sent at the end of the intervention. Patients could state
17 that they did not want any education material at the start of the intervention but would reevaluate their needs
18 during the 12 weeks of the intervention. However, since the ILP was sent home with the patients, any changes in
19 the plan had to be documented by the patient herself. Two patients received the education materials sent to them
20 but did not want to read it, just to have it if they wanted to read it later. Seven patients did not want the
21 intervention for the full 12-week period (33%) but stated that they would make contact if they needed further
22 information during the intervention. One patient wanted her partner to be included. Two patients in the
23 intervention group did not answer the telephone at the scheduled session, making the call attendance 90%. One
24 patient rescheduled a session due to personal reasons. Thirty-three percent of the patients did not want follow-up
25 sessions during the full 12-week intervention. As 90% of the patients wanted all educational materials, 10% of
26 the patients used only the nurse navigator for support and one hundred percent of the patients received a
27 personalized reminder letter (Table 3).

28 Contact information and an invitation for patients (100%) to make contact if needed were sent after 12 weeks in
29 the personalized letter. None of the patients made contact after the 12-week intervention as shown in Table 3.

32 4. Resources

33 None of the patients wanted to have face-to-face sessions. In fact, several of the patients stated that it was
34 important to not have to come for appointments at the hospital. Reasons for not wanting to come to the hospital
35 were related to the COVID-19 pandemic as well as to perceptions of appointments at the hospital being time
36 consuming. All patients but one preferred telephone sessions (Table 3). If a patient had asked for a face-to-face
37 follow-up session, this would have been managed accordingly, with arrangements made to ensure safety in the
38 context of the COVID-19 pandemic. Face-to-face meetings at the hospital with patients were not prohibited but
39 restricted. However, no patient-nurse navigator pairs participated in a face-to-face session; had they done so,
40 both the patient and the nurse navigator would have had to wear face masks, and the nurse navigator would have
41 also had to wear a plastic face shield to prevent transmission of the COVID-19 virus.

43 5. Number of educational sessions

44 The number of educational sessions ranged between two and four sessions (Table 3).

46 6. Length per education session

47 Telephone support sessions ranged between 5 and 60 minutes, and digital support ranged between 30 and 45
48 minutes (Table 3).

7. Length between education sessions

The length between follow-up sessions ranged between 1 and 6 weeks, with a median time of 4 weeks. However, the length between the first and second session had a median time of 2 weeks (Table 3).

8. Distribution of education materials

All patients (100%) wanted part 1 of the individual education material. Ninety-five percent of the patients wanted part 2 of the individual education material, and 90% wanted parts 3-4 of the individual education material. Information about tamoxifen or aromatase inhibitors was wanted by 95% of the patients. Additionally, some additional educational material was distributed about sleep advice and complementary medicine (Table 3).

9. Completion rate of questionnaires

In the control group, 95% completed the first questionnaires at baseline, as one patient questionnaire was lost in the mail. At three months, 95% of patients responded to their surveys. In the intervention group, 100% responded to the first questionnaires, and 86% responded to the follow-up questionnaires after three months (Table 3). At the first measurement point, two reminder messages were sent to three patients in the intervention group before one patient was recorded as a drop out. At the second measurement point, one reminder message was sent to six patients three weeks after the questionnaires were sent. A second reminder message was sent approximately two weeks later to five patients, and as two patients did not return their questionnaires, they were recorded as drop-outs. Two patients in the intervention group did not answer the telephone at the scheduled session, making the call attendance 90%. One patient rescheduled a session due to personal reasons (Table 3).

10. Estimated treatment effect

Differences between the control and intervention groups in perceived self-efficacy (0.5 and 0, $p=0.731$) and reported number of symptoms according to the MSAS (2 and 1, $p=0.724$) after 3 months were observed (Figure 4; Table 4). Quality of care was measured using QPP. Overall, the patients in the control group had higher quality of care index scores than patients in the intervention group (Table 5).

Please insert Figure 3, 4 about here

Table 3. Resource needs for the intervention

RESPECT	
Distributed educational material	
Individual educational material <i>Part 1</i> , <i>n</i>	21
Individual educational material <i>Part 2</i> , <i>n</i>	20
Individual educational material <i>Part 3</i> , <i>n</i>	19
Individual educational material <i>Part 4</i> , <i>n</i>	19
Individual educational material Information about tamoxifen or aromatase inhibitors, <i>n</i>	20
Additional educational material from the patient needs: Complementary medicine, <i>n</i>	1
Sleep advice, <i>n</i>	1
Recommendations about internet sites: Sleep advice, <i>n</i>	2
Form of education and educational sessions per patient	
Face to face (<i>n</i> =0), median (range)	0 (-)
Telephone (<i>n</i> =20), median (range)	3 (2-4)
Digital (<i>n</i> =1), median (range)	1 (1)

Length (minutes) per sessions Telephone (n=20), median (range) Digital (n=1), median (range)	20 (5-60) 30 (30-45)
Length of time (weeks) between each session Telephone follow-up education sessions, weeks, median (range) Digital meeting follow-up sessions, weeks, median (range) <i>Follow-up educational session</i> Time from 1 st session to 2 nd session, weeks, median (range) Time from 2 nd session to 3 rd session, weeks, median (range) Time from 3 rd session to 4 th session, weeks, median (range)	4 (1-6) 4 (-) 2 (1-8) 4 (2-8) 4 (2-5)

Table 4. Secondary outcomes. Median differences at baseline and 3 months in the control group and intervention group.

	Control			Intervention			p-value*
	Baseline No, Median (IQR)	3 months, Median (IQR)	Change from baseline (median)	Baseline No, Median (IQR)	3 months No, Median (IQR)	Change from baseline (median)	
SE, median (IQR)	31 (27-40)	31 (22-39)	0.5	30 (26-35)	30 (30-38)	0	0.731
MSAS, no median (IQR)	6 (3-11)	9 (3-18)	2	7 (3-13)	10 (5-22)	1	0.724
MSAS, often, median (IQR)	11 (2-36)	13 (6-38)	7.5	14 (4-25)	15 (7-49)	2	0.504
MSAS, severe, median (IQR)	12 (0-26)	13 (5-52)	5	10 (3-23)	13 (6-40)	2	0.393
MSAS, distress, median (IQR)	11 (0-28)	12 (3-30)	5.5	8 (2-19)	12 (6-39)	2	0.600

*Mann-Whitney test comparing changes from baseline between the control and intervention groups.

Table 5. Interpretation of the QPP – Percentage agreement in a selection of QPP questions

	Control 3 months, n (%)	Intervention 3 months, n (%)
13. I received useful information on what I needed to be able to participate in my own care	16* (93.75%)	17* (88.24%)
19. I had adequate information about my medicine, so I understood the effect and how to use them	18* (77.78%)	18* (72.22%)
20. I had an opportunity to share my experience with the health care professionals	15* (86.67%)	17* (82.35%)

32. I had a good opportunity to confer in decisions about my own care	14* (85.71%)	15* (73.33%)
33. I had a good opportunity to participate in my own care	15* (86.67%)	12* (75.00%)
34. My care was directed by my needs rather than the health care professionals' routines	16* (100%)	17* (82.35%)

*Caution: If less than 30, the results should be regarded with caution.

To measure perceived reality concerning the quality of care, every question was phrased as a statement. The response alternatives were given as a scale between 4 (Fully agree) and 1 (Do not agree at all).

Percentage in agreement represents the patients who answered 3 (Mostly agree) and 4 (Fully agree) divided by the total number of patients who answered 1-4 on the question. Answer 5 (Not applicable) is not included.

DISCUSSION

The results show that the intervention was feasible regarding the classification process and resources. However, it was less feasible regarding scientific challenges. The recruitment methods used seem to be accurate and feasible for an RCT with the aim of empowering patients prescribed ET to manage ET-related symptoms and problems. As a before-and-after design was used, the risk of contamination between groups was minor, as the trial leader had minor clinical contact with the control group.

The most common problems reported by trial investigators have been identified as a lack of adherence to the trial protocol, difficulties with recruitment, data collection and the intervention itself⁵²; however, during the intervention, the nurse navigator succeeded in adhering to the trial protocol. Moreover, a weakness in interventions has been reported to be a lack of theoretical approach⁵³; to address this challenge, the presented study was founded on a theoretical model¹⁰. Modeling was used to identify pit falls and barriers⁵⁴. The nurse navigator in the intervention pretested the intervention protocol in clinical meetings with patients before launching the support program. It is crucial for health care professionals to have deep insight into the theory and selected methods to increase patients' required knowledge about ET since no one will adhere to a protocol if the protocol is of no significance³⁸. Moreover, a health care context is referred to as a complex adaptive system, as it contains a collection of individuals with the freedom to act in a way that is not always predictable and changes depending on the context. Moreover, a complex adaptive system has fuzzy boundaries, and health care professionals' priorities depend on, for example, their private lives and things they would not sacrifice to follow a study protocol⁵⁵. These challenges need to be addressed, as the intervention is to be applied in a care setting.

Furthermore, as the patients decided, in a partnership with the nurse navigator, how many educational sessions were required, the patient's individuality and resources were a focus, and no patient needed to acquire education than necessary. Moreover, the COVID-19 pandemic has increased the use of digital follow-up, which seems to be well liked among patients⁵⁶⁻⁵⁸. Furthermore, face-to-face sessions were not prohibited during the intervention but were restricted due to the COVID-19 pandemic. If a patient would have asked for a face-to-face session, this would have been managed to not put the patient, fellow patients, or the nurse navigator or other health care

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3 professionals in danger. However, we cannot specifically state that patients would prefer telephone sessions
4 under other circumstances, but telephone follow-up seems to be suitable, as patients indicated physical
5 appointments to be time consuming. A previous study also used telephone follow-up to increase confidence in
6 controlling illness in patients with chronic obstructive pulmonary disease with positive results in controlling
7 symptoms ($p=.028$)⁵⁹, and telephone follow-ups found to be well liked among registered nurses⁶⁰. A previous
8 study using PCC also allowed patients to decide the number of follow-up sessions⁶¹. Thus, this approach could
9 be a preferable way to administer the intervention and could also be more cost-effective, as patients do not need
10 to attend more sessions than required; however, it needs to be evaluated further. Furthermore, all health care
11 professionals do not have a PCC approach, which might affect the responses in the questionnaires and the
12 interpretation of the results. To manage this, the whole care chain needs to structure their work according to
13 PCC, as in a previous study²².

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20 Moreover, the intervention protocol ranged over 12 weeks, as this period has been identified as the most
21 troublesome for patients with ET⁶², and a previous study identified that the start of the ET period could be
22 preferable for an intervention³⁰. As 67% of the patients wanted education during the full 12-week intervention,
23 12 weeks is indicated to be a suitable length for a support program in a future RCT. However, an optional
24 follow-up session after six months, when the patients have more experience with ET, could be appropriate, but
25 measures would need to be taken to help patients stay focused on ET when responding to the questionnaires. A
26 later session could also be preferable for patients who do not want to be educated during the first months
27 undergoing ET³⁰.

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32 To address scientific challenges, two measurement points were used, baseline and three months after being
33 prescribed ET. In an RCT, additional measurement points could be added at six and 12 months. However, there
34 were no differences in self-efficacy between the control and intervention groups; rather, both the control group
35 and the intervention had high self-efficacy scores at baseline, indicating that the ceiling level was reached.
36 Higher education implies higher self-efficacy⁶³ ($p=.017$)⁶⁴. In the present study, 45% of the patients in the
37 control group and 48% of the patients in the intervention group had university education, indicating that the GES
38 may not be suitable as an instrument. General self-efficacy has been increased using PCC in a previous study in
39 patients with acute coronary syndrome⁶¹, indicating that breast cancer patients could also benefit from PCC.
40 This is of importance, as low self-efficacy has been identified as a predictor of terminating ET prematurely⁶⁵
41 due to beliefs about its low influence on health or low satisfaction with involvement in health care⁶⁵. However,
42 as the patients involved in the development of the support program requested help with understanding ET¹⁰, a
43 future RCT could include a self-care questionnaire that could provide valuable information about patients' self-
44 care capabilities. The participants in the previous study¹⁰ could be assumed to have a high self-efficacy score, as
45 they were well educated, but still required empowerment, which implies a more versatile and complex situation
46 demanding new approaches and raising the question "Could patients have high scores in self-efficacy but still be
47 vulnerable?" The high self-efficacy scores indicate that the patients in the intervention group might not have
48 needed a support program, but they participated anyway for several sessions, which implies their need for
49 support and knowledge. Situational vulnerability, caused by stressful circumstances such as cancer, has
50 previously been identified. Even presumably empowered patients, such as physicians, were found to have
51 difficulties remembering, understanding, and processing all information they received as patients⁶⁶, which is
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3 highly interesting as it relates to this study's findings. Moreover, a modified version of a self-efficacy
4 questionnaire to assess women's confidence regarding their ability to cope with symptoms⁶⁷ has been and will
5 be used in a future RCT study^{68 69}. Questions were added for the participants to rate their confidence in their
6 ability to cope with eight symptoms (e.g., aches and pains, hot flashes, and sweating) on a 10-point scale ranging
7 from 10 ("not confident") to 100 ("very confident")⁶⁸. Furthermore, a modified empowerment scale⁷⁰ could be
8 appropriate to use after adjustment to patients with ET.
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13 Moreover, there was no difference in perceived symptoms, indicating either that the MSAS questionnaire was
14 inadequate or that the knowledge itself did not decrease symptoms if patients did not use coping activities. The
15 support program aims to educate and empower patients but does not evaluate whether they use their knowledge.
16 It is also important to determine whether patients do use the coping strategies gained from the follow-up
17 sessions, but the advice just does not work, in which case an adjustment in the provided education is needed.
18 Additionally, it is important to identify whether coping demands could be overwhelming and decrease instead of
19 increase quality of life, leading patients to not pursue coping strategies such as physical activities. This might be
20 a topic to address before an RCT study, using interviews to evaluate participants' use of the gained knowledge.
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26 The study had some limitations. As the COVID-19 pandemic was ongoing, there were restrictions on the
27 patients' ability to have face-to-face sessions with the trial leader. However, several patients stated that they
28 would participate only if there were no mandatory sessions at the hospital. The patients also had the possibility
29 of having their sessions using a digital conference system. As the intervention nurse navigator and the
30 participants almost never met in person, their relationships could have been affected. However, a partnership was
31 established between the patient and the trial leader using a PCC protocol. This might have decreased the effect of
32 not meeting in person. In a future RCT, it will be crucial for patients to have face-to-face relationships with the
33 intervention nurse navigator with whom they will build partnerships. This study did not identify when the
34 intervention should stop, as it was decided before the intervention that it should last for 12 weeks. It might have
35 been important for the patients in the intervention to have given this important information. However, seven of
36 the 21 patients did not use the full 12-week intervention, which implies that a 12-week support program is
37 suitable. No patient actively asked for longer follow up. All patients were allocated a nurse navigator whom they
38 could contact after the intervention if further questions were answered.
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46 Furthermore, there was no measurement regarding the number of contacts the patients in the control group had
47 with their nurse navigator; in a future RCT, this must be controlled to evaluate the economic effectiveness of the
48 intervention. Moreover, using the QPP for the three-month measurement point was troublesome, as patients also
49 had undergone radiation therapy during the same period, and patients also stated that their responses addressed
50 the whole care chain and not only the care given related to ET. This could imply the difficulty of interpreting
51 data from the QPP at the second measurement point. Furthermore, according to the instrument owner, 30
52 patients in each group are required to interpret the data.
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57 The MSAS was developed using 33 symptoms commonly associated with cancer⁴⁹, and it has been validated in
58 the Swedish population using patients diagnosed with breast cancer and treated with chemotherapy, radiotherapy
59 and ET⁵⁰. However, a more specific questionnaire could be appropriate, more accurate and easier for patients to
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3 complete, as the MSAS consists of three dimensions, and some of the participants did not provide responses for
4 all three dimensions included in the questionnaire.
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8 9 **Conclusion**

10 This intervention seems to be feasible regarding its process and resources and acceptable among patients, as 95%
11 completed the 12-week support program and 86% responded to the three-month questionnaire. A telephone
12 follow-up intervention seems to be the preferable way to administer the intervention. However, for self-efficacy
13 and symptoms, there were no differences in effect size between the control and intervention groups, indicating
14 that the intervention was less feasible regarding scientific challenges.
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18 19 *Conflicts of interest*

20 The authors report no conflicts of interest.
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24 *Author Contributions*

25 IH, SAK, ROB, CW conceived the project and assisted with the protocol design. SAK managed the trial
26 including recruitment and data collection. IH, SAK, CW coordinated the intervention program and interpreted
27 the data and drafted the manuscript. ROB, SAK performed statistical analysis. All authors read, edited, and
28 approved the final manuscript as submitted.
29

30 *Ethical approval*

31 Patients were informed, in accordance with the Declaration of Helsinki ⁷¹, that their participation was voluntary
32 and could be terminated at any time without consequences. They were also assured that their confidentiality
33 would be respected throughout the research process. This study was approved by the Swedish Ethical Review
34 Authority (approval no 2020-03239).
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38 *Conflicts of Interest and Source of Funding*

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48 of the surgical outpatient care unit for contributing to finding eligible patients to include in the study.
49

50 *Provenance and peer review*

51 Not commissioned; externally peer reviewed.
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54 *Data availability statement*

55 Data are available upon reasonable request.
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57 *Open access*

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22 Figure 1. Retention - CONSORT Flow diagram for the usual care group. Patients included September 2020 –
23 December 2021.

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26 Figure 2. Retention - CONSORT flow diagram for the person-centered support program group. Patients included
27 December 2020 – March 2021.

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30 Figure 3. The care and measurement chain for the control and intervention groups. Both groups received the
31 content in the blue area (usual care).

32 Abbreviations: Endocrine therapy – ET, Individual learning plan – ILP.

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35 Figure 4. Secondary outcomes boxplot. Baseline and 3-month difference measures in the control and
36 intervention groups for self-efficacy and reported symptoms.

37 Abbreviation: Number – no, Self-efficacy – SE.
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Figure 1. Retention - CONSORT Flow diagram for the usual care group. Patients included September 2020 – December 2021.

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Figure 2. Retention - CONSORT flow diagram for the person-centered support program group. Patients included December 2020 – March 2021.

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Figure 3. The care and measurement chain for the control and intervention groups. Both groups received the content in the blue area (usual care).

Abbreviations: Endocrine therapy – ET, Individual learning plan – ILP.

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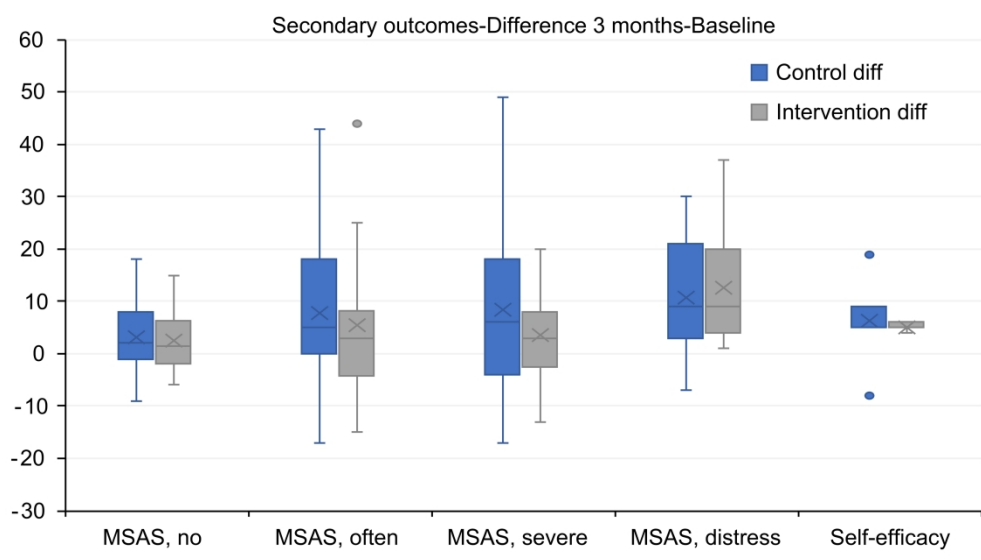


Figure 4. Secondary outcomes boxplot. Baseline and 3-month difference measures in the control and intervention groups for self-efficacy and reported symptoms. Abbreviation: Number – no, Self-efficacy – SE.

159x90mm (600 x 600 DPI)

Reporting checklist for quality improvement in health care.

Based on the SQUIRE guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SQUIRE reporting guidelines, and cite them as:

Ogrinc G, Davies L, Goodman D, Batalden P, Davidoff F, Stevens D. SQUIRE 2.0 (Standards for Quality Improvement Reporting Excellence): revised publication guidelines from a detailed consensus process

	Reporting Item	Page Number
Title		
	#1 Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patientcenteredness, timeliness, cost, efficiency, and equity of healthcare)	1
Abstract		
	#02a Provide adequate information to aid in searching and indexing	2
	#02b Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions	3
Introduction		

1	Problem	#3	Nature and significance of the local problem	4
2	description			
3				
4	Available	#4	Summary of what is currently known about the problem, including	4
5	knowledge		relevant previous studies	
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8	Rationale	#5	Informal or formal frameworks, models, concepts, and / or theories	5
9			used to explain the problem, any reasons or assumptions that were	
10			used to develop the intervention(s), and reasons why the	
11			intervention(s) was expected to work	
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15	Specific aims	#6	Purpose of the project and of this report	5
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18	Methods			
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20	Context	#7	Contextual elements considered important at the outset of introducing	5
21			the intervention(s)	
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24	Intervention(s)	#08a	Description of the intervention(s) in sufficient detail that others could	6
25			reproduce it	
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28	Intervention(s)	#08b	Specifics of the team involved in the work	6
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30	Study of the	#09a	Approach chosen for assessing the impact of the intervention(s)	8
31	Intervention(s)			
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34	Study of the	#09b	Approach used to establish whether the observed outcomes were due	8
35	Intervention(s)		to the intervention(s)	
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38	Measures	#10a	Measures chosen for studying processes and outcomes of the	8
39			intervention(s), including rationale for choosing them, their	
40			operational definitions, and their validity and reliability	
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43	Measures	#10b	Description of the approach to the ongoing assessment of contextual	8
44			elements that contributed to the success, failure, efficiency, and cost	
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47	Measures	#10c	Methods employed for assessing completeness and accuracy of data	8
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49	Analysis	#11a	Qualitative and quantitative methods used to draw inferences from the	9
50			data	
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53	Analysis	#11b	Methods for understanding variation within the data, including the	9
54			effects of time as a variable	
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1	Ethical	#12	Ethical aspects of implementing and studying the intervention(s) and	15
2	considerations		how they were addressed, including, but not limited to, formal ethics	
3			review and potential conflict(s) of interest	
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6	Results			
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9		#13a	Initial steps of the intervention(s) and their evolution over time (e.g.,	1-3
10			time-line diagram, flow chart, or table), including modifications made	
11			to the intervention during the project	
12				
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14		#13b	Details of the process measures and outcome	10-11
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16		#13c	Contextual elements that interacted with the intervention(s)	10-11
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18		#13d	Observed associations between outcomes, interventions, and relevant	10-11
19			contextual elements	
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22		#13e	Unintended consequences such as unexpected benefits, problems,	10-11
23			failures, or costs associated with the intervention(s).	
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26		#13f	Details about missing data	10-11 +
27				tables
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30	Discussion			
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32	Summary	#14a	Key findings, including relevance to the rationale and specific aims	12
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34	Summary	#14b	Particular strengths of the project	12
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37	Interpretation	#15a	Nature of the association between the intervention(s) and the	12-13
38			outcomes	
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41	Interpretation	#15b	Comparison of results with findings from other publications	12-13
42				
43	Interpretation	#15c	Impact of the project on people and systems	13
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45	Interpretation	#15d	Reasons for any differences between observed and anticipated	13
46			outcomes, including the influence of context	
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49	Interpretation	#15e	Costs and strategic trade-offs, including opportunity costs	NA
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51	Limitations	#16a	Limits to the generalizability of the work	13
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53	Limitations	#16b	Factors that might have limited internal validity such as confounding,	14
54			bias, or imprecision in the design, methods, measurement, or analysis	
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57	Limitations	#16c	Efforts made to minimize and adjust for limitations	14
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1	Conclusion	#17a	Usefulness of the work	14
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3	Conclusion	#17b	Sustainability	14
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5	Conclusion	#17c	Potential for spread to other contexts	14
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7	Conclusion	#17d	Implications for practice and for further study in the field	14
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9	Conclusion	#17e	Suggested next steps	14
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Other information

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16	Funding	#18	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting	15
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Notes:

- 13f: 10-11 + tables The SQUIRE 2.0 checklist is distributed under the terms of the Creative Commons Attribution License CC BY-NC 4.0. This checklist was completed on 07. January 2022 using <https://www.goodreports.org/>, a tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)



CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	4
	2b	Specific objectives or research questions for pilot trial	5
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6
	4c	How participants were identified and consented	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-7
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	8
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	NA
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	NA
Sample size	7a	Rationale for numbers in the pilot trial	7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	NA
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	NA
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	NA

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	NA
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	NA
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	9
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	10
	13b	For each group, losses and exclusions after randomisation, together with reasons	10
Recruitment	14a	Dates defining the periods of recruitment and follow-up	10
	14b	Why the pilot trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	Figure 1 and 2
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	NA
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
	19a	If relevant, other important unintended consequences	NA
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	14
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	13
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	13
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	14
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	NA
Protocol	24	Where the pilot trial protocol can be accessed, if available	NA
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	15
	26	Ethical approval or approval by research review committee, confirmed with reference number	15

1 Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

2 *We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important
3 clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological
4 treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.
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BMJ Open

A person-centered support program (RESPECT intervention) for women with breast cancer treated with endocrine therapy: A feasibility study

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Date Submitted by the Author:	08-Jul-2022
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Primary Subject Heading:	Nursing
Secondary Subject Heading:	Nursing, Oncology
Keywords:	Breast tumours < ONCOLOGY, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, QUALITATIVE RESEARCH

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3 **A person-centered support program (RESPECT intervention) for women with breast cancer**
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11 Ahlstedt Karlsson, Susanne^{1,2} Orcid ID: 0000-0001-5436-5476; Henoeh, Ingela² Orcid ID: 0000-0002-1987-
12 5419; Olofsson Bagge, Roger^{1,3} Orcid ID: 0000-0001-5795-0355; Wallengren, Catarina² Orcid ID: 0000-0002-
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14
15

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17
18 ¹Department of Surgery, Sahlgrenska University Hospital, Gothenburg, Sweden.

19 ²Institute of Health and Care Sciences, Sahlgrenska Academy at the University of Gothenburg, University of
20 Gothenburg, Gothenburg, Sweden

21 ³Department of Surgery, Institute of Clinical Sciences, Sahlgrenska Academy at the University of Gothenburg,
22 Gothenburg, Sweden.
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26 # Correspondence to: Ahlstedt Karlsson, Institute of Health and Care Sciences, Sahlgrenska Academy at the
27 University of Gothenburg, University of Gothenburg, Gothenburg, Sweden

28
29 E-mail: susanne.ahlstedt.karlsson@gu.se

30 Telephone: +46 704153666
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ABSTRACT

Objective: The aim of the study was to explore the feasibility of the trial design and patient acceptability of the intervention and outcome measures and to provide data to estimate the parameters required to design the final intervention.

Design: A controlled before-and-after design following the CONSORT 2010 statement for feasibility trials.

Setting: A surgical out-patient clinic in Sweden.

Participants: Forty-one patients (aged 47 – 85) with breast cancer and treated with endocrine therapy.

Interventions: Eligible patients were assigned to the control group or intervention group, which included individual education material, an individualized learning plan, and a personalized reminder letter using a person-centered approach. The intervention could be delivered as a telephone or digital follow-up during a 12 week follow up.

Outcome measures: The aims were to determine the recruitment rate, assess the rate of retention, explore whether the intervention was delivered according to the protocol, assess the preferred form of educational support, rate of education sessions, length per education session, and length between each education session, determine the distribution of education materials, and assess completion rates of patient-report instruments, including the General Self-efficacy Scale, the Quality of Care from the Patient's Perspective questionnaire, and the Memorial Symptom Assessment Scale.

Results: Eighty-six percent of the patients in the intervention group completed the intervention and completed the questionnaires three months after their inclusion. The call attendance was 90%. During the intervention, the contact nurse was compliant with the intervention protocol. For self-efficacy, symptoms, and quality of care, there were no differences in effect size between the control and intervention groups.

Conclusions

This intervention seems to be feasible and acceptable among patients, and a telephone follow-up intervention also seems to be the preferred way to administer the intervention.

Article summary

Strengths and limitations of this study

- This is the first study to investigate the feasibility of a person-centered support model for patients with endocrine therapy.
- This study uses the CONSORT 2010 statement for feasibility trials.
- This study reports the recruitment rate, assess the rate of retention, explore whether the intervention was delivered according to the protocol, assess the preferred form of educational support, rate of education sessions, length per education session, and length between each education session, determine the distribution of education materials, and assess completion rates of patient-report instruments.
- Due to COVID-19 pandemic face-to-face sessions was restricted.

BACKGROUND

For women diagnosed with hormone receptor-positive breast cancer, endocrine therapy (ET), i.e., the use of tamoxifen or aromatase inhibitors, is recommended for at least five years to reduce recurrence and rates of mortality¹. A previous study reported that up to 91% of patients experience side effects from ET², such as sleeping difficulties, hot flashes^{3,4} and musculoskeletal symptoms⁵. Difficulties in managing these side effects have been reported to be obstacles to staying in treatment⁶. Other challenges that have been identified include older age⁷, medicine costs, or a general dislike of taking a regular medicine⁸. As ET is a long-lasting treatment, women may request support in managing challenges⁹. To manage challenges with ET, a partnership with health care professionals could be appropriate, as a previous study¹⁰ identified that women with ET want to be able to manage their treatment but need guidance to do so.

Regarding the management of ET-related symptoms, previous studies have investigated the effect of symptom management interventions for patients prescribed ET¹¹⁻¹³. A study identified management needs for ET symptoms, emotional needs, and needs for information acquisition and found that patients' relationship with health care providers was important¹². A combination of information with cognitive behavioral therapy (CBT) to manage the side effects of tamoxifen showed successful results for the development of management skills in patients who were unable to stay in treatment¹¹. Furthermore, training intervention with a physiotherapist or personal trainer followed by adapted training at home could be effective. However, a problem with this intervention was program adherence, as patients reported difficulty meeting the training goal in frequency and intensity due to other demands in life¹⁴. Also, training has not been found to have effect on musculoskeletal symptoms in patients treated with AIs¹⁵. Managing a disease and its additional challenges requires self-care knowledge and skills gained from a partnership with health care professionals¹⁶. Self-care involves the ability to both care for oneself and to achieve, promote and maintain optimal health¹⁷. A common feature of self-care and person-centered care (PCC) is an ability to view humans as the agent and the subject of action^{18,19}. To include aspects of treatment important to the individual patient, such as different side effects, health care structures, fear of side effects, and lack of management skills and for support, a person-centered support program was developed¹⁰. As self-care requires knowledge and skills¹⁶, PCC could be appropriate for use in a support program. Self-care requisites are described as all elements that individuals need at all stages in life to care for themselves, i.e., air, food, water; self-care requisites also depend on how

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3 individuals react to illness ¹⁶. PCC can be a preferable way of identifying those requisites, as they can
4 be identified in the narratives and used in the patient-health care provider partnership ¹⁹. Patients are
5 often motivated to engage in self-care, as they have personal interest in acquiring requisite knowledge
6 and skills for performing self-care operations to reach their intended health goals ¹⁶. It has been shown
7 that when self-care capabilities increase ²⁰, self-efficacy and adherence to ET also increase ^{21 22}. Self-
8 efficacy constitutes the self-image of the person and affects how people experience and behave in
9 specific situations ²³. Previous studies using PCC have improved patients' self-efficacy ²⁴⁻²⁶.

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15 It is important for patients to not only identify accurate information but also assess and integrate the
16 information to gain increased knowledge, self-efficacy, and self-care skills ¹⁰. Moreover, in addition to
17 the emotional needs identified by Kim et al. (2020), it is important to assess the amount of needed
18 information and to explore patients' understanding of the diagnosis and treatment ²⁷. For written health
19 education materials to be effective, the patient must be able to apply the new information to her own
20 life. This can be achieved by providing understandable examples and presenting the information so the
21 patient sees its relevance to her situation ²⁸, as the ultimate reason for educating patients is to improve
22 health ²⁹.

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25 In Sweden all patients are allocated a contact nurse when being diagnosed with breast cancer. The
26 contact nurse function as main point of contact during the patient's cancer treatments in order to reduce
27 fragmented care and to strength patient involvement in care ³⁰. It has been suggested that contact
28 nurses have a positive impact on care. Contact nurses aims to improve communication between patients
29 and their health care professionals, as well as contact nurses are to improve the care process ³¹. However,
30 it has been reported that other factors seem to decrease contact nurses 'ability to provide the care they
31 are meant to. Named reasons are challenges regarding the lack of information to patients, and lack of
32 supportive care resources. Although the patients had a contact nurse, the patients reported how they
33 lacked in the possibility to influence decisions about their care ³².

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36 A previous study developed a person-centered support program in collaboration among patients, health
37 care professionals, researchers and managers with ET experience ¹⁰ and need to be tested in a feasibility
38 study using the TIDieR checklist ³³ and the CONSORT 2010 statement ³⁴. Previous studies have used
39 feasibility studies prior to conducting a study in a larger setting ^{9 35}. The intervention was developed to
40 encourage patients to be more actively involved in their care and wellbeing as partners with their contact
41 nurse ¹⁰.

42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 **Aim**

57 In this feasibility trial, the aim was to explore the feasibility of the study design and the patient
58 acceptability of the peRson-cEntred Support Program EndoCrine Therapy (RESPECT) intervention and
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3 outcome measures and to provide data to estimate the parameters required to design the final
4 intervention.
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8 The feasibility outcomes, i.e., primary outcomes, were as follows:

- 9 1. Determine recruitment rate
- 10 2. Assess the rate of retention
- 11 3. Explore whether the RESPECT intervention was delivered according to the protocol
- 12 4. Assess the preferred form of educational support
- 13 5. Assess the rate of education sessions
- 14 6. Assess the length per education session
- 15 7. Assess the length between each education session
- 16 8. Determine the distribution of education materials
- 17 9. Assess the completion rates of patient-report instruments, including of the General Self-efficacy
18 Scale (GSE), the Quality from the Patient's Perspective questionnaire (QPP), and the Memorial
19 Symptom Assessment Scale (MSAS)
- 20 10. Investigate whether self-efficacy, symptoms and satisfaction with care can be assessed
21 appropriately by using the patient-report GSE, QPP, and MSAS.
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34 **METHODS**

35 *Study design*

36 This was a feasibility trial using a controlled before-and-after design ³⁶ to investigate the feasibility of
37 the intervention, a person-centered support program aimed at empowering patients prescribed ET to
38 manage ET-related symptoms and problems.
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43 *Patient and public involvement*

44 Patients and health care professionals was involved in the design and development of the person-
45 centered support model ¹⁰. However, there was no patient involvement in the evaluation of the person-
46 centered support model presented in this study.
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51 *Participants*

52 Between September 2020 and June 2021, 66 potential female patients from one outpatient clinic at one
53 university hospital in Sweden were identified as eligible for inclusion. The inclusion criteria were
54 women > 18 years who had been diagnosed with breast cancer and treated with ET after surgery. Patients
55 receiving adjuvant chemotherapy were excluded as the study aimed to investigate an intervention
56 targeting patients treated with ET. All patients were contacted by a contact nurse and were invited by
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telephone to participate in the study approximately three weeks after their surgery when being prescribed ET (Figures 1 and 2; Table 1). All patients were given verbal and written information about the study, and after agreeing to have an informed consent form sent to them by mail, they all provided written, informed consent. If the patient agreed to participate, she sent the informed consent form back using a prepaid envelope.

Please insert figure 1 and 2 about here

Table 1. Demographic and clinical characteristics of the participants in the control group (n=20) and intervention group (n=21) in the RESPECT project.

Demographic characteristics	Control group n=20	Intervention group n=21
<i>Median age, years (range)</i>	65 (50-85)	66 (47-79)
<i>Civil status, n (%)</i>		
<i>Married/cohabiting</i>	12 (63%)	16 (76%)
<i>Single</i>	8 (37%)	5 (23%)
<i>Ancestral homeland, n (%)</i>		
<i>Sweden</i>	16 (80%)	18 (86%)
<i>Scandinavian countries</i>	1 (5%)	1 (5%)
<i>Europe</i>	1 (5%)	2 (10%)
<i>Outside Europe</i>	1 (5%)	0 (0%)
<i>Education, n (%)</i>		
<i>University</i>	9 (45%)	10 (48%)
<i>High school</i>	8 (40%)	8 (38%)
<i>Elementary school</i>	3 (15%)	3 (14%)
<i>Radiation therapy, n (%)</i>	16 (80%)	21 (100%)
<i>Tumor size, median mm (range)</i>	14 (4-45)	12 (1-19)
<i>Breast surgery</i>		
<i>Mastectomy</i>	4 (20%)	2 (10%)
<i>Partial mastectomy</i>	15 (75%)	19 (90%)
<i>Axillary lymph node dissection</i>	1 (0.5%)	0 (0%)
<i>Tamoxifen, n (%)</i>	9 (45%)	9 (43%)
<i>Aromatase inhibitor, n (%)</i>	11 (55%)	12 (57)

Control group

Usual care (UC) involves patients being allocated a contact nurse (an experienced undergraduate nurse or postgraduate nurse in surgical care), as the Swedish Patient Act³⁷ gives patients a statutory right to permanent contact with health care. Internationally the role is called Clinical Nurse Specialist³⁸, and are identified to be a valuable recourse in cancer care³⁹.

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3 Patients can contact the contact nurse all weekdays by telephone or by using a national digital tool,
4 1177.se⁴⁰. All patients receive written information as a brochure or a digital “My care and rehabilitation
5 plan” when diagnosed with breast cancer. Support in usual care aims to give patients information about
6 their state of health, available methods for examinations, care, and treatments, as well as information
7 about at which time point she can expect to receive care and a permanent contact with the health care.
8 The contact nurse writes down the information that is available before surgery, such as tumor
9 characteristics and surgery preparations. The patient can also write down questions to bring to the
10 oncoming appointments. Usual care is based on patients’ initiative to make contact (Figure 3).
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17 *Intervention group*

18 The intervention was provided in a surgical outpatient clinic in western Sweden from December 2020-
19 June 2021. The goal of the intervention is to empower patients prescribed ET to manage ET-related
20 symptoms and problems. In addition to the UC, a 12-week intervention was offered to the participants
21 in the intervention group (Figure 3) as described in a previous study¹⁰:
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26 *Step 1- Individual education material*

27 Using a PCC approach¹⁹, the contact nurse listened to patients narratives regarding their individual
28 needs for knowledge and understanding, resources, goals and needs for support from the contact nurse.
29 The timing of supplying individual educational materials depended on the individual patient’s needs,
30 resources and goals during the 12-week intervention. Mutual trust was demonstrated, and the
31 relationship between the patient and her contact nurse was reinforced through the assessment of the
32 commonly agreed-upon individualized learning plan⁴¹ study.
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39 *Step 2 - An individualized learning plan (ILP)*

40 An ILP was established depending on the individual patients’ needs for knowledge and understanding
41 about ET and considering the patients’ resources, goals, and needs for education material and support
42 from the contact nurse. In combination with the individual educational materials (step 1), a follow-up
43 plan was made using telephone and/or digital follow-ups. Physical follow-ups were minimized as the
44 COVID-19 pandemic was ongoing. The number of follow-up sessions and whether relatives were to be
45 included during the 12-week intervention were agreed upon between the patient and the contact nurse.
46 Patients could also refuse all education material and other materials and only use only the contact nurse
47 for support.
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54 *Step 3 – A personalized reminder letter*

55 The third part of the support program was a personalized reminder letter after three months including
56 contact information and an invitation for patients to make contact if needed.
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Please insert Figure 3 about here

Education of the intervention nurse

The aim of the education was to increase the intervention nurse's knowledge and understanding of ET, its problems and symptom management using PCC. Microteaching^{42 43} sessions and seminars were used; the microteaching sessions were adapted to the specific needs of knowledge about endocrine therapy, side effects⁴⁴, pedagogy⁴⁵ and PCC^{19 46}, and the chosen approach was intended to help the contact nurse take responsibility for her own learning, i.e., student-centered learning⁴⁷. Additionally, practical exercises were used, as the contact nurse was able to practice her knowledge and understanding in a care setting and reflect on it, and the intervention nurse's curiosity was used as a motivator to gain knowledge⁴⁵ (Table 2).

Table 2. Description of the education of the intervention nurse.

Before Lecture: The intervention nurse is asked to specifically reflect on the following in the care setting: <i>Problems with endocrine therapy</i> <i>Symptom management</i> <i>Cocreation with patients, barriers, facilitators.</i>			
Sessions	Content	Learning outcomes	Learning activities
1	Core principles about endocrine therapy (ET ¹), including side effects of ET and symptom management described in research. Symptom management theory.	-Describe symptom management methods. -Suggest strategies for symptom management during ET.	Clinical case discussions, microteaching sessions, dialogs, reflection.
Before Lecture: The intervention nurse is asked to reflect on practical situations in the care setting when <i>applying dialog</i> and <i>person-centered care (PCC²)</i> .			
Session	Content	Learning outcomes	Learning activities
2	Pedagogical theory.	- Describe pedagogic strategies using dialog to increase patients' self-care. - Describe pedagogical strategies to increase patient participation. - Describe dialogical methodology that strengthens patient participation. -Evaluate whether chosen pedagogical strategies increase patients' self-management ability.	Clinical case discussions, microteaching sessions, dialogs, reflection.
Before Lecture: The intervention nurse is asked to reflect on practical situations in the care setting using knowledge from Session 2 and <i>relate to PCC</i> in a care setting.			
Session	Content	Learning outcomes	Learning activities
3	PCC in the clinical care setting.	-Describe PCC.	Clinical case discussions, microteaching sessions, dialogs, reflection.
Before Lecture: The intervention nurse evaluates the <i>gained knowledge about PCC</i> in a practical situation in the care setting.			

Session	Content	Learning outcomes	Learning activities
4	The three intervention components, i.e., individual education material, individualized learning plan, and a personalized reminder letter (Ahlstedt Karlsson, et al, 2022) with a starting point in the contact nurse's experience from a practical situation in the clinical setting.	-Explain the components of the intervention.	Clinical case discussions, dialogs, reflection.
After Lecture: With a starting point in the newly gained knowledge, <i>apply PCC, knowledge about ET, pedagogical theory and the three components</i> in the intervention in a care setting.			
Proficiency goal after completed education: The intervention nurse can: - Evaluate whether the proposed symptom management strategies increase the patient's management of ET-related symptoms. - Assess whether the patient's need for care was met. - Review and evaluate whether selected pedagogical strategies strengthen the patient's self-care ability. - Evaluate the patient's participation in ET symptom management.			
Evaluation ability after completed education: The intervention nurse can: - Suggest strategies for managing symptoms in relation with ET. - Together with the patient, identify care needs. - Apply pedagogical strategies that strengthen patients' self-care ability. - Apply dialogical methodology that strengthens patients' participation.			

Abbreviations: ¹ Endocrine therapy – ET¹, ²Person-centered care- PCC.

Data collection

Data were collected from September 2020 – June 2021. Feasibility outcomes were collected during the whole study period by the intervention nurse and were documented directly after every session in a trial log to secure the data collection⁴⁸. The trial log contained a summary of the results of the feasibility criteria using Excel (Microsoft® Excel, version 16.50).

The three questionnaires were distributed by mail to patients in the control group (between September 2020 and December 2020) and the intervention group (December 2020 and March 2021). These three questionnaires were distributed at baseline, i.e., at the start of the intervention and ET, and three months after the start of the intervention.

The first questionnaire was the GSE, a 10-item (short form) psychometric scale that assesses optimistic self-beliefs to cope with a variety of demands in life. The GSE is a validated instrument that has been translated into Swedish⁴⁹ and has previously been used with breast cancer patients⁵⁰. The total score is the mean value of respondents' answer to all items. High scores imply higher self-efficacy.

The second questionnaire was the QPP, a 45-item instrument that measures satisfaction in four dimensions: medical-technical competence, physical-technical conditions, identity-oriented approach, and sociocultural atmosphere^{51 52}. Moreover, to identify patients' views of whether the health care was adapted to their needs rather than health care routines, three items (*I was given the possibility to tell the medical staff how I experienced my situation; I was given the opportunity to participate in the planning of my care/treatment; I received the information I needed to be able to participate in decisions about*

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3 *my own care and treatment*) that were previously used by the Swedish SOM institute were added⁵³. To
4 calculate the execution index, each question is scored in terms of actual experience and subjective
5 importance, each on a four-point Likert scale. The execution index score ranges from 1–7, where one is
6 inadequate quality of care from the patient perspective and seven is good quality of care⁵⁴.
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10 The last questionnaire was the MSAS, a 32-question instrument for patients to rate their symptoms on
11 a 5-point Likert scale^{55 56}. The instrument has been validated in Swedish breast cancer patients⁵⁶ and
12 has previously been used with breast cancer patients⁵⁰. The total MSAS score is the average of the
13 symptom scores for all 32 symptoms. Each symptom score is an average of the dimensions and includes
14 the number of symptoms, how often patients experienced them, the severity of the symptoms and the
15 cause of distress.
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20 21 *Feasibility outcomes*

22 In this study, feasibility outcomes are defined as primary outcome. Craig et al. (2013) described several
23 challenging variables that can affect an intervention's results and conclusions. The feasibility
24 classification (process, resources, scientific) and feasibility criteria reported by Thabane et al. (2019)
25 and Lancaster et al. (2004) were used to collect feasibility data. Based on the recommendations for
26 feasibility studies and an expected attrition rate of 20%, the sample size was set to 20 participants in
27 each group⁵⁷. To determine whether the chosen feasibility criteria were successful⁵⁸, criteria for
28 success were stated according to the CONSORT 2010 statement³⁴;
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35 The intervention process was assessed with the feasibility criteria as follows:

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37 1. Recruitment was studied to determine whether the patients were willing to participate in the
38 study. It has been suggesting that the loss of participants should be less than 15%⁵⁹. The
39 criterion was determined to be successful if the percentage rates of recruitment were > 70%.
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41 2. Retention was studied to determine whether the patients were willing to remain for the entire
42 study period, i.e., 12 weeks. The criterion was determined to be successful if the percentage
43 rates of retention were >70%.
- 44
45 3. Compliance with the intervention protocol was studied to determine if the patients were offered
46 the three parts of the planned intervention, i.e., education materials, learning plan and
47 personalized letter. The criterion was determined to be successful if all three parts of the
48 intervention were offered.
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54 The resources used in the intervention were assessed with the feasibility criteria as follows:

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56 4. Form of educational support was studied to determine the preferred form of educational support
57 during the intervention period, i.e., 12 weeks. The criterion was determined to be successful if
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one of the three forms of educational support (face-to face, telephone, and digital) were requested by the patients.

5. Number of educational sessions was studied to determine how many educational opportunities the patient used during the intervention period, i.e., 12 weeks. The criterion determined to be successful if no more than four education sessions were used by each patient.
6. Length per education session was studied to determine how much time the patient used in each education session. The criterion was determined to be successful if < 45 minutes was used per education session. The time was clocked by the intervention nurse.
7. Length between each education session was studied to determine how often women wanted to have education opportunities. The criterion was determined to be successful if there were no more than four weeks between each education session.
8. Distribution of education materials was studied to determine how much of intervention materials the patients received during the study. The criterion was determined to be successful if the distribution of education materials was >70%.

The scientific challenges of the intervention were assessed with the feasibility criteria as follows:

9. Completion rate of questionnaires was studied to determine if the patient was willing to answer the questionnaires, i.e., at baseline and 12 weeks. The criterion was determined to be successful if the percentage rates of patient completion of questionnaires were > 70% at baseline and 12 weeks.
10. The estimated treatment effect was studied to determine if the selected instruments were appropriate to measure patients' self-efficacy, quality of care, and symptoms. The criterion was determined to be successful if there were any changes in the self-report measures between the first and second points of measurement.

Patients included in the study responded to the questionnaires and returned the questionnaires in a prepaid envelope.

Analysis

To analyze demographic variables, we used descriptive statistics (number, percent, mean, range). We calculated the percentage rates of recruitment, retention, and completion of questionnaires. We calculated the number, median and range of educational sessions, distribution of education materials, length per education session, and length between each education session. As the study was a feasibility test, no hypothesis testing was applied⁶⁰, but p-values were calculated and presented to value their relevance in an forthcoming RCT. Descriptive statistical analyses and the Mann-Whitney U-test were performed to identify the experience of symptoms, satisfaction with care and perceived self-efficacy. P-

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3 values below .05 were considered statistically significant, and all analyses were performed with IBM®
4 SPSS® Statistics version 27 (IBM SPSS Statistics for Macintosh, Version 27.0).
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13 RESULTS

14 *Participant demographics*

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16 In the control group, the median age was 65 years, 80% of the participants were born in Sweden, 63%
17 were cohabiting and 45% were prescribed tamoxifen. In the intervention group, the median age was 66
18 years, 86% were born in Sweden, 76% were cohabiting and 43% were prescribed tamoxifen (Table 1).
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22 *Feasibility classification and criteria*

23 Feasibility outcomes are presented in line with the CONSORT 2010 statement as follows:
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26 1. *Recruitment*

27 In the control group, 22 eligible patients were screened, and 20 were approached at the clinic, of whom
28 20 consented to participate (100%). In the intervention group, 44 patients were screened, of whom 24
29 were approached and 21 consented to participate (88%) (Table 1), and patients was enrolled from
30 December 2020 – April 2021. Of the three patients who did not consent to participate in the intervention
31 group, two indicated the number of questions in the questionnaires to be a reason for not participating.
32 One patient gave no reason for not participating (Figure 1, 2).
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36 2. *Retention*

37 In the intervention group, 20 patients completed (95%). One patient dropped out from the intervention
38 because the study reminded her about the breast cancer surgery, which she was trying to forget about
39 (Figure 1).
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43 3. *Compliance with the intervention protocol*

44 In the first session, the patients' needs for knowledge and understanding, resources, goals and support
45 from the contact nurse were identified in their narratives. Education material was offered accordingly
46 using a written agreement between the patient and contact nurse and documented in the ILP. Patients
47 decided with the contact nurse whether they required knowledge. If they required knowledge, they stated
48 when they wanted the education materials and which parts. Their need for knowledge ranged between
49 having everything sent after the first session and having some of the education material sent at the end
50 of the intervention. Patients could state that they did not want any education material at the start of the
51 intervention but would reevaluate their needs during the 12 weeks of the intervention. However, since
52 the ILP was sent home with the patients, any changes in the plan had to be documented by the patient
53 herself. Two patients received the education materials sent to them but did not want to read it, just to
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3 have it if they wanted to read it later. Seven patients did not want the intervention for the full 12-week
4 period (33%) but stated that they would make contact if they needed further information during the
5 intervention. One patient wanted her partner to be included. Two patients in the intervention group did
6 not answer the telephone at the scheduled session, making the call attendance 90%. One patient
7 rescheduled a session due to personal reasons. Thirty-three percent of the patients did not want follow-
8 up sessions during the full 12-week intervention. As 90% of the patients wanted all educational
9 materials, 10% of the patients used only the contact nurse for support and one hundred percent of the
10 patients received a personalized reminder letter (Table 3).

11 Contact information and an invitation for patients (100%) to make contact if needed were sent after 12
12 weeks in the personalized letter. None of the patients made contact after the 12-week intervention as
13 shown in Table 3.

21 22 4. *Resources*

23 None of the patients wanted to have face-to-face sessions as educational support. In fact, several of the
24 patients stated that it was important to not have to come for appointments at the hospital. Reasons for
25 not wanting to come to the hospital were related to the COVID-19 pandemic as well as to perceptions
26 of appointments at the hospital being time consuming. All patients but one preferred telephone sessions.
27 If a patient had asked for a face-to-face follow-up session, this would have been managed accordingly,
28 with arrangements made to ensure safety in the context of the COVID-19 pandemic. Face-to-face
29 meetings at the hospital with patients were not prohibited but restricted. However, no patient-contact
30 nurse pairs participated in a face-to-face session; had they done so, both the patient and the contact nurse
31 would have had to wear face masks, and the contact nurse would have also had to wear a plastic face
32 shield to prevent transmission of the COVID-19 virus.

33 34 35 36 37 38 39 5. *Number of educational sessions*

40 The number of educational sessions ranged between two and four sessions (Table 3).

41 42 43 6. *Length per education session*

44 Telephone support sessions ranged between 5 and 60 minutes, and digital support sessions ranged
45 between 30 and 45 minutes (Table 3) and was clocked by the intervention nurse.

46 47 48 7. *Length between education sessions*

49 The length between follow-up sessions ranged between 1 and 6 weeks (Table 3).

50 51 8. *Distribution of education materials*

52 All patients (100%) wanted part 1 of the individual education material. Further description of the
53 distribution is shown in Table 3.

54 55 56 57 58 59 60 9. *Completion rate of questionnaires*

In the control group, 95% completed the first questionnaires at baseline, as one patient questionnaire was lost in the mail. At three months, 95% of patients responded to their surveys. In the intervention group, 100% responded to the first questionnaires, and 86% responded to the follow-up questionnaires after three months. At the first measurement point, two reminder messages were sent to three patients in the intervention group before one patient was recorded as a drop out. At the second measurement point, one reminder message was sent to six patients three weeks after the questionnaires were sent. A second reminder message was sent approximately two weeks later to five patients, and as two patients did not return their questionnaires, they were recorded as drop-outs. Two patients in the intervention group did not answer the telephone at the scheduled session, making the call attendance 90%. One patient rescheduled a session due to personal reasons.

10. Estimated treatment effect

Differences between the control and intervention groups in perceived self-efficacy (0.5 and 0, $p=0.731$) and reported number of symptoms according to the MSAS (2 and 1, $p=0.724$) after 3 months were observed (Figure 4; Table 4). Quality of care was measured using QPP. Overall, the patients in the control group had higher quality of care index scores than patients in the intervention group (Table 5).

Table 3. Resource needs for the intervention

RESPECT	
Distributed educational material	
Individual educational material <i>Part 1</i> , n	21
Individual educational material <i>Part 2</i> , n	20
Individual educational material <i>Part 3</i> , n	19
Individual educational material <i>Part 4</i> , n	19
Individual educational material <i>Information about tamoxifen or aromatase inhibitors</i> , n	20
Additional educational material from the patient needs: Complementary medicine, n	1
Sleep advice, n	1
Recommendations about internet sites: Sleep advice, n	2
Form of education and educational sessions per patient	
Face to face (n=0), median (range)	0 (-)
Telephone (n=20), median (range)	3 (2-4)
Digital (n=1), median (range)	1 (1)
Length (minutes) per sessions	
Telephone (n=20), median (range)	20 (5-60)
Digital (n=1), median (range)	30 (30-45)
Length of time (weeks) between each session	
Telephone follow-up education sessions, weeks, median (range)	4 (1-6)
Digital meeting follow-up sessions, weeks, median (range)	4 (-)
Follow-up educational session	
Time from 1 st session to 2 nd session, weeks, median (range)	2 (1-8)
Time from 2 nd session to 3 rd session, weeks, median (range)	4 (2-8)
Time from 3 rd session to 4 th session, weeks, median (range)	4 (2-5)

Table 4. Median differences at baseline and 3 months in the control group and intervention group.

	Control			Intervention			p-value*
	Baseline No, Median (IQR)	3 months, Median (IQR)	Change from baseline (median)	Baseline No, Median (IQR)	3 months No, Median (IQR)	Change from baseline (median)	
SE, median (IQR)	31 (27-40)	31 (22-39)	0.5	30 (26-35)	30 (30-38)	0	0.731
MSAS, no median (IQR)	6 (3-11)	9 (3-18)	2	7 (3-13)	10 (5-22)	1	0.724
MSAS, often, median (IQR)	11 (2-36)	13 (6-38)	7.5	14 (4-25)	15 (7-49)	2	0.504
MSAS, severe, median (IQR)	12 (0-26)	13 (5-52)	5	10 (3-23)	13 (6-40)	2	0.393
MSAS, distress, median (IQR)	11 (0-28)	12 (3-30)	5.5	8 (2-19)	12 (6-39)	2	0.600

*Mann-Whitney test comparing changes from baseline between the control and intervention groups.

Table 5. Interpretation of the QPP – Percentage agreement in a selection of QPP questions

	Control 3 months, n (%)	Intervention 3 months, n (%)
13. I received useful information on what I needed to be able to participate in my own care	16* (93.75%)	17* (88.24%)
19. I had adequate information about my medicine, so I understood the effect and how to use them	18* (77.78%)	18* (72.22%)
20. I had an opportunity to share my experience with the health care professionals	15* (86.67%)	17* (82.35%)
32. I had a good opportunity to confer in decisions about my own care	14* (85.71%)	15* (73.33%)
33. I had a good opportunity to participate in my own care	15* (86.67%)	12* (75.00%)
34. My care was directed by my needs rather than the health care professionals' routines	16* (100%)	17* (82.35%)

*Caution: If less than 30, the results should be regarded with caution.

To measure perceived reality concerning the quality of care, every question was phrased as a statement. The response alternatives were given as a scale between 4 (Fully agree) and 1 (Do not agree at all). Percentage in agreement represents the patients who answered 3 (Mostly agree) and 4 (Fully agree) divided by the total number of patients who answered 1-4 on the question. Answer 5 (Not applicable) is not included.

Please insert Figure 4 about here

DISCUSSION

The results show that the intervention was feasible regarding the classification process and resources. However, it was less feasible regarding scientific challenges. The recruitment methods used seem to be accurate and feasible for an RCT with the aim of empowering patients prescribed ET to manage ET-related symptoms and problems. As a before-and-after design was used, the risk of contamination between groups was minor, as the intervention nurse had minor clinical contact with the control group.

The most common problems reported by trial investigators have been identified as a lack of adherence to the trial protocol, difficulties with recruitment, data collection and the intervention itself⁶¹; however, during the intervention, the contact nurse succeeded in adhering to the trial protocol. Moreover, a weakness in interventions has been reported to be a lack of theoretical approach⁶²; to address this challenge, the presented study was founded on a theoretical model⁴⁴. Modeling was used to identify pitfalls and barriers⁶³. The contact nurse in the intervention pretested the intervention protocol in clinical meetings with patients before launching the support program. It is crucial for health care professionals to have deep insight into the theory and selected methods to increase patients' required knowledge about ET since no one will adhere to a protocol if the protocol is of no significance⁴⁵. Moreover, a health care context is referred to as a complex adaptive system, as it contains a collection of individuals with the freedom to act in a way that is not always predictable and changes depending on the context. Moreover, a complex adaptive system has fuzzy boundaries, and health care professionals' priorities depend on, for example, their private lives and things they would not sacrifice to follow a study protocol⁶⁴. These challenges need to be addressed, as the intervention is to be applied in a care setting.

Furthermore, as the follow up is flexible and the patients decided, in a partnership with the contact nurse, how many educational sessions were required, the patient's individuality and resources were a focus, and no patient needed to acquire education than necessary. This needed flexibility is another component making the intervention a complex intervention. Moreover, the COVID-19 pandemic has increased the use of digital follow-up, which seems to be well liked among patients⁶⁵⁻⁶⁷. Furthermore, face-to-face sessions were not prohibited during the intervention but were restricted due to the COVID-19 pandemic. If a patient would have asked for a face-to-face session, this would have been managed to not put the patient, fellow patients, or the contact nurse or other health care professionals in danger. However, we cannot specifically state that patients would prefer telephone sessions under other circumstances, but telephone follow-up seems to be suitable, as patients indicated physical appointments to be time consuming. A previous study also used telephone follow-up to increase confidence in controlling illness in patients with chronic obstructive pulmonary disease with positive results in controlling symptoms ($p=.028$)⁶⁸, and telephone follow-ups found to be well liked among registered nurses⁶⁹. A previous study using PCC also allowed patients to decide the number of follow-up sessions⁷⁰. Thus, this approach could be a preferable way to administer the intervention and could also be more cost-effective, as

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3 patients do not need to attend more sessions than required; however, it needs to be evaluated further.
4 Furthermore, all health care professionals do not have a PCC approach, which might affect the responses
5 in the questionnaires and the interpretation of the results. To manage this, the whole care chain needs to
6 structure their work according to PCC, as in a previous study ²⁴.
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10 Moreover, the intervention protocol ranged over 12 weeks, as this period has been identified as the most
11 troublesome for patients with ET ⁷¹, and a previous study identified that the start of the ET period could
12 be preferable for an intervention ³⁵. As 67% of the patients wanted education during the full 12-week
13 intervention, 12 weeks is indicated to be a suitable length for a support program in a future RCT.
14 However, an optional follow-up session after six months, when the patients have more experience with
15 ET, could be appropriate, but measures would need to be taken to help patients stay focused on ET when
16 responding to the questionnaires. A later session could also be preferable for patients who do not want
17 to be educated during the first months undergoing ET ³⁵.
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24 To address scientific challenges, two measurement points were used, baseline and three months after
25 being prescribed ET. In an RCT, additional measurement points could be added at six and 12 months.
26 However, there were no differences in self-efficacy between the control and intervention groups; rather,
27 both the control group and the intervention had high self-efficacy scores at baseline, indicating that the
28 ceiling level was reached. Higher education implies higher self-efficacy ⁷² ($p = .017$) ⁷³. In the present
29 study, 45% of the patients in the control group and 48% of the patients in the intervention group had
30 university education, indicating that the GES may not be suitable as an instrument. General self-efficacy
31 has been increased using PCC in a previous study in patients with acute coronary syndrome ⁷⁰, indicating
32 that breast cancer patients could also benefit from PCC. This is of importance, as low self-efficacy has
33 been identified as a predictor of terminating ET prematurely ⁷⁴ due to beliefs about its low influence on
34 health or low satisfaction with involvement in health care ⁷⁴.
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43 Moreover, there was no difference in perceived symptoms, indicating either that the MSAS
44 questionnaire was inadequate or that the knowledge itself did not decrease symptoms if patients did not
45 use coping activities. The support program aims to educate and empower patients but does not evaluate
46 whether they use their knowledge. It is also important to determine whether patients do use the coping
47 strategies gained from the follow-up sessions, but the advice just does not work, in which case an
48 adjustment in the provided education is needed. Additionally, it is important to identify whether coping
49 demands could be overwhelming and decrease instead of increase quality of life, leading patients to not
50 pursue coping strategies such as physical activities. This might be a topic to address before an RCT
51 study, using interviews to evaluate participants' use of the gained knowledge.
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58 The study had some limitations. As the COVID-19 pandemic was ongoing, there were restrictions on
59 the patients' ability to have face-to-face sessions with the trial leader. However, several patients stated
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3 that they would participate only if there were no mandatory sessions at the hospital. The patients also
4 had the possibility of having their sessions using a digital conference system. As the intervention contact
5 nurse and the participants almost never met in person, their relationships could have been affected.
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7 However, a partnership was established between the patient and the trial leader using a PCC protocol.
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9 This might have decreased the effect of not meeting in person. In a future RCT, it will be crucial for
10 patients to have face-to-face relationships with the intervention contact nurse with whom they will build
11 partnerships. This study did not identify when the intervention should stop, as it was decided before the
12 intervention that it should last for 12 weeks. It might have been important for the patients in the
13 intervention to have given this important information. However, seven of the 21 patients did not use the
14 full 12-week intervention, which implies that a 12-week support program is suitable. No patient actively
15 asked for longer follow up. All patients were allocated a contact nurse whom they could contact after
16 the intervention if further questions were answered.
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20 Furthermore, there was no measurement regarding the number of contacts the patients in the control
21 group had with their contact nurse; in a future RCT, this must be controlled to evaluate the economic
22 effectiveness of the intervention. Moreover, using the QPP for the three-month measurement point was
23 troublesome, as patients also had undergone radiation therapy during the same period, and patients also
24 stated that their responses addressed the whole care chain and not only the care given related to ET. This
25 could imply the difficulty of interpreting data from the QPP at the second measurement point.
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27 Furthermore, according to the instrument owner, 30 patients in each group are required to interpret the
28 data. Also, the patients in the intervention group was included when physical appointments was
29 restrained which imply further difficulty to draw any conclusions from the presented results.
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38 The MSAS was developed using 33 symptoms commonly associated with cancer⁵⁵, and it has been
39 validated in the Swedish population using patients diagnosed with breast cancer and treated with
40 chemotherapy, radiotherapy and ET⁵⁶. However, a more specific questionnaire could be appropriate,
41 more accurate and easier for patients to complete, as the MSAS consists of three dimensions, and some
42 of the participants did not provide responses for all three dimensions included in the questionnaire.
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48 **Conclusion**

49 This intervention seems to be feasible regarding its process and resources and acceptable among
50 patients, as 95% completed the 12-week support program and 86% responded to the three-month
51 questionnaire. A telephone follow-up intervention seems to be the preferable way to administer the
52 intervention. However, for self-efficacy and symptoms, there were no differences in effect size between
53 the control and intervention groups, indicating that the intervention was less feasible regarding scientific
54 challenges.
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5 *Ethical approval*

6 Patients were informed, in accordance with the Declaration of Helsinki ⁷⁵, that their participation was
7 voluntary and could be terminated at any time without consequences. They were also assured that their
8 confidentiality would be respected throughout the research process. This study was approved by the
9 Swedish Ethical Review Authority (approval no 2020-03239).
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14 *Conflicts of Interest*

15 The authors report no conflicts of interest.
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18 *Contributorship statement*

19 IH, SAK, ROB, CW: Conceptualizing and design, IH, SAK, CW: Methodology, SAK: Data
20 Collection, IH, SAK, CW, ROB, Formal Analysis: IH, SAK, CW, ROB: Visualization, IH, SAK, CW,
21 ROB: Writing-review and editing.
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26 *Availability statement*

27 Data are available upon reasonable request.
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31 *Source of Funding*

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42 study.
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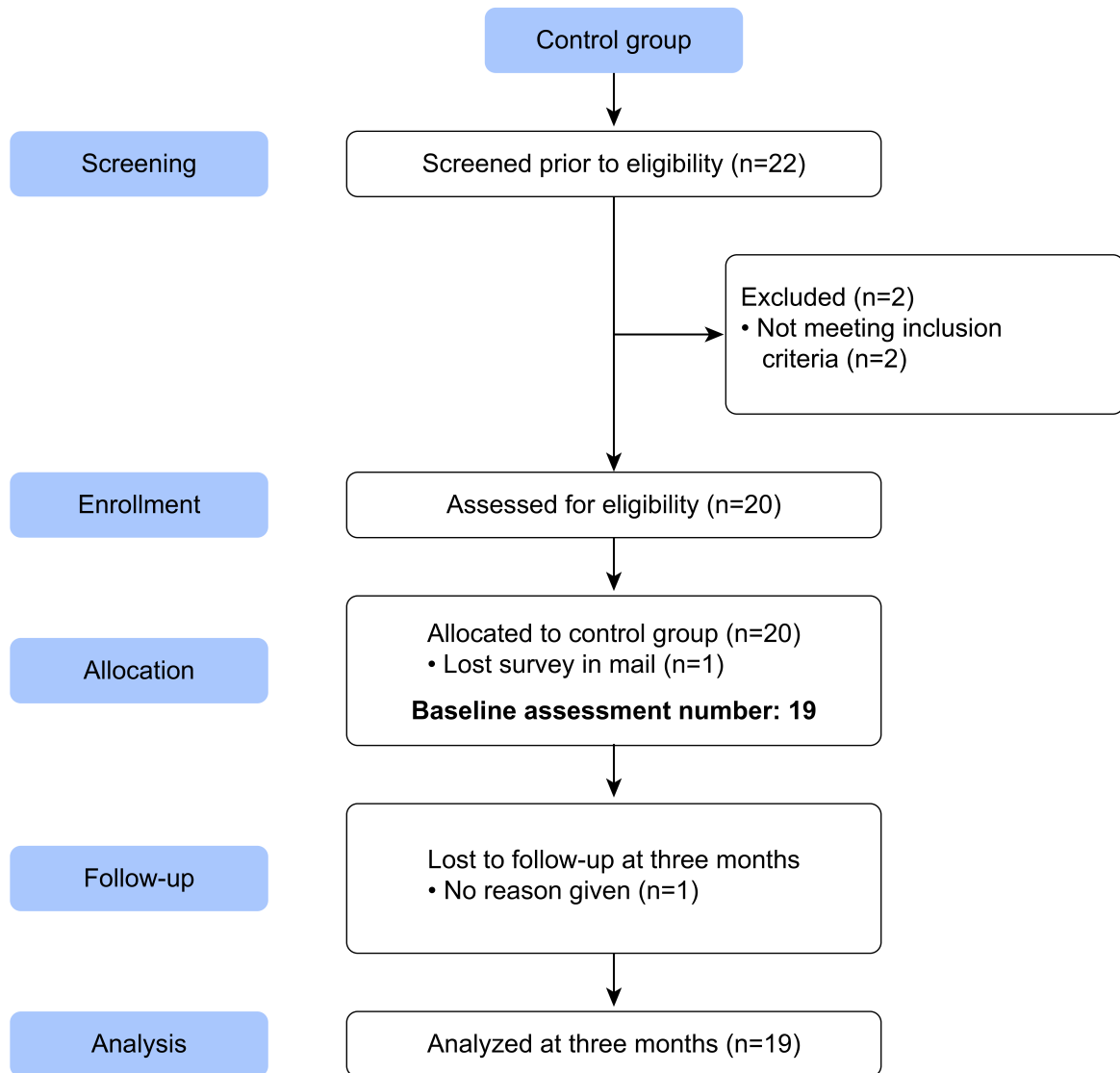
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15 Figure 1. Retention - CONSORT Flow diagram for the usual care group. Patients included September 2020 –
16 December 2021.
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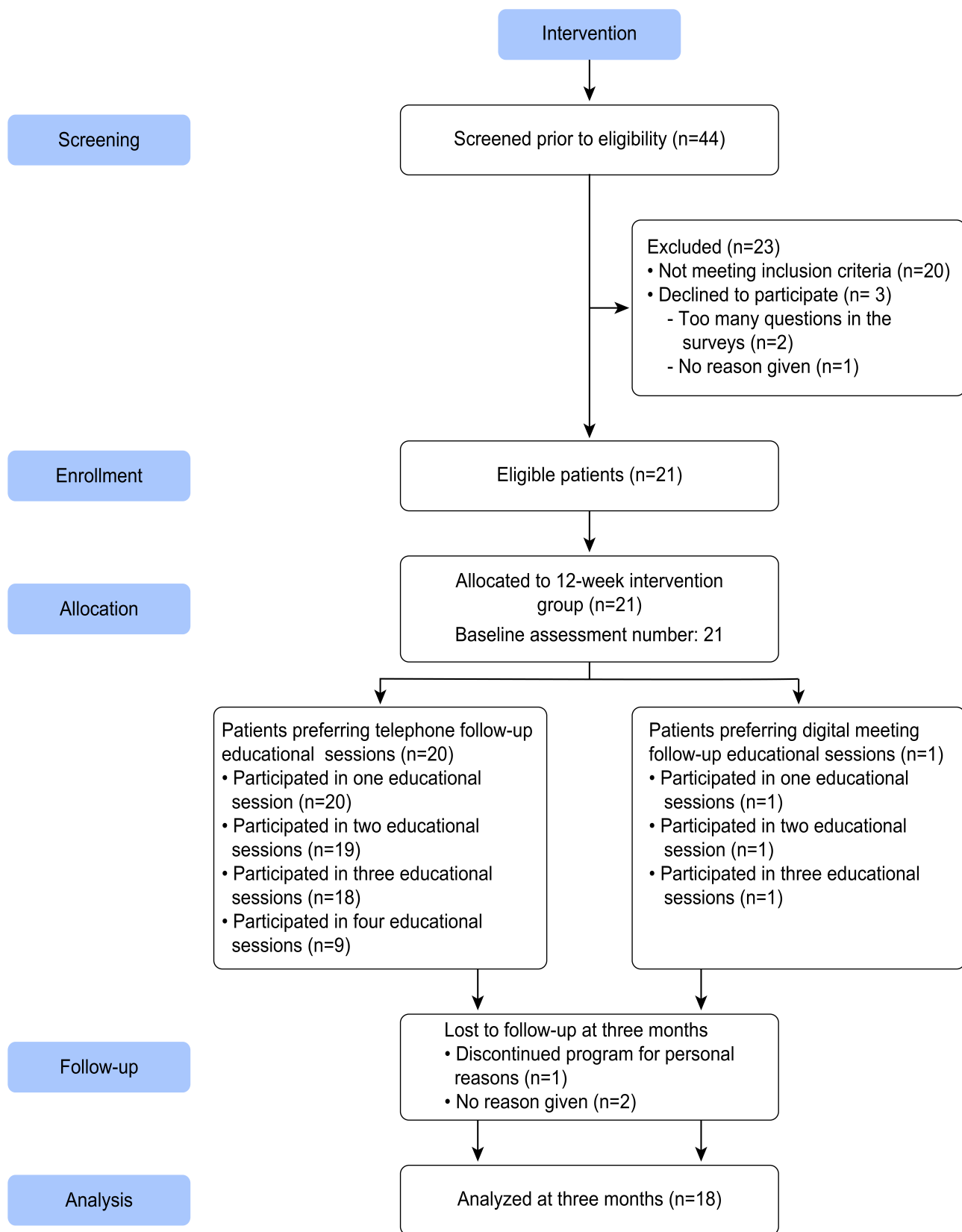
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19 Figure 2. Retention - CONSORT flow diagram for the person-centered support program group. Patients included
20 December 2020 – March 2021.
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23 Figure 3. The care and measurement chain for the control and intervention groups. Both groups received the
24 content in the blue area (usual care).
25 Abbreviations: Endocrine therapy – ET, Individual learning plan – ILP.
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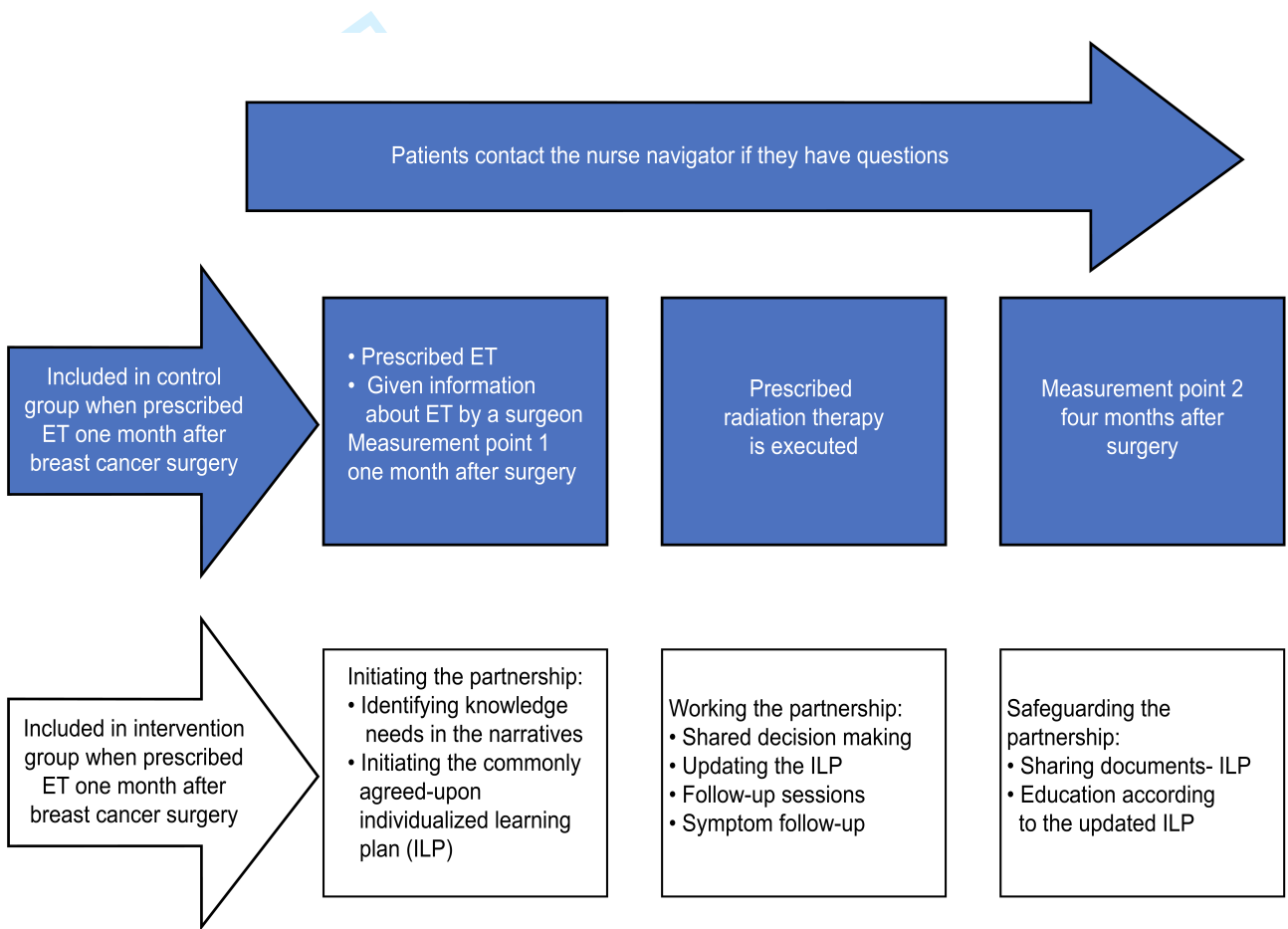
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28 Figure 4. Baseline and 3-month difference measures in the control and intervention groups for self-efficacy and
29 reported symptoms.
30 Abbreviation: Number – no, Self-efficacy – SE.
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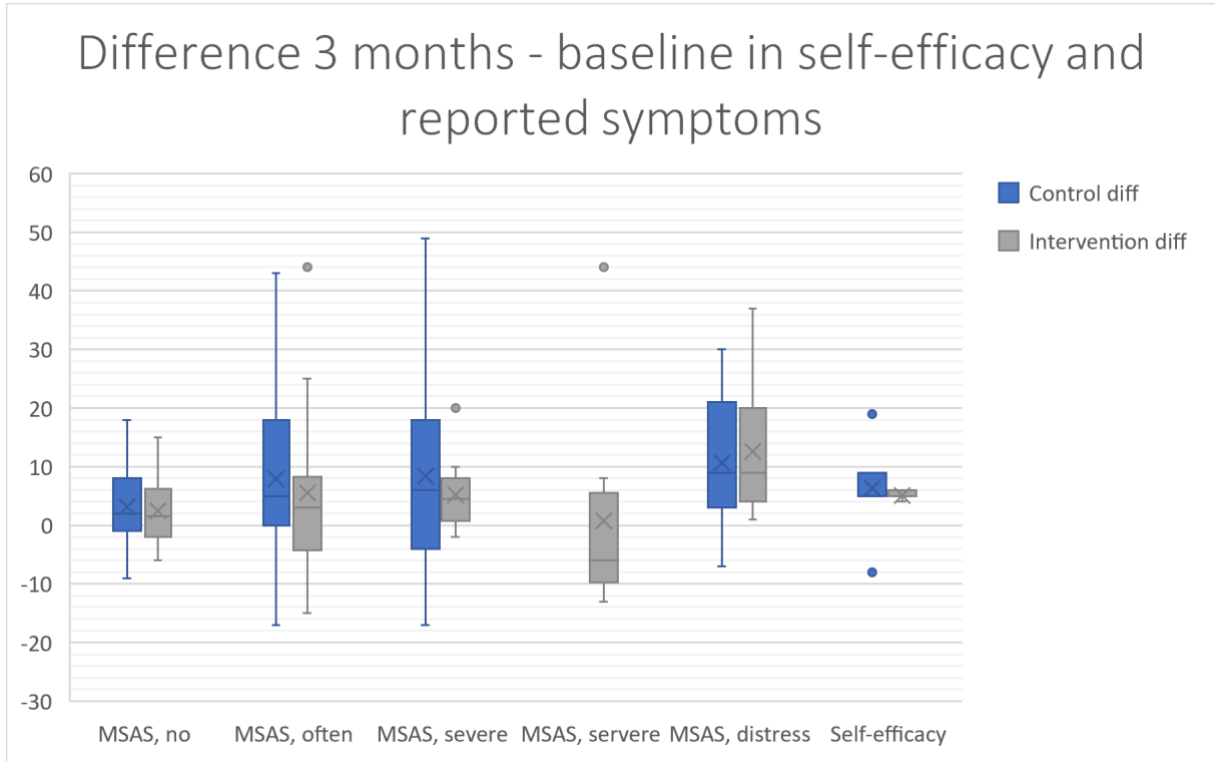
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CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	4
	2b	Specific objectives or research questions for pilot trial	5
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6
	4c	How participants were identified and consented	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-7
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	8
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	NA
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	13-15
Sample size	7a	Rationale for numbers in the pilot trial	7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	NA
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	NA
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	NA

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	NA
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	11
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	6
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1 and 2
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6
	14b	Why the pilot trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	Figure 1 and 2
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	NA
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	15
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
	19a	If relevant, other important unintended consequences	NA
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	19
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	18
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	18
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	18
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	NA
Protocol	24	Where the pilot trial protocol can be accessed, if available	NA
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	20
	26	Ethical approval or approval by research review committee, confirmed with reference number	20

1 Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

2 *We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important
3 clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological
4 treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.
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BMJ Open

A person-centered support program (RESPECT intervention) for women with breast cancer treated with endocrine therapy: A feasibility study

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Keywords:	Breast tumours < ONCOLOGY, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, QUALITATIVE RESEARCH

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4 **A person-centered support program (RESPECT intervention) for women with breast cancer**
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7 **treated with endocrine therapy: A feasibility study**
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11 Ahlstedt Karlsson, Susanne^{1,2} Orcid ID: 0000-0001-5436-5476; Henoeh, Ingela² Orcid ID: 0000-0002-1987-
12 5419; Olofsson Bagge, Roger^{1,3} Orcid ID: 0000-0001-5795-0355; Wallengren, Catarina² Orcid ID: 0000-0002-
13 8124-1572
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18 ¹Department of Surgery, Sahlgrenska University Hospital, Gothenburg, Sweden.

19 ²Institute of Health and Care Sciences, Sahlgrenska Academy at the University of Gothenburg, University of
20 Gothenburg, Gothenburg, Sweden

21 ³Department of Surgery, Institute of Clinical Sciences, Sahlgrenska Academy at the University of Gothenburg,
22 Gothenburg, Sweden.
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26 # Correspondence to: Ahlstedt Karlsson, Institute of Health and Care Sciences, Sahlgrenska Academy at the
27 University of Gothenburg, University of Gothenburg, Gothenburg, Sweden

28
29 E-mail: susanne.ahlstedt.karlsson@gu.se

30 Telephone: +46 704153666
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38 Keywords: Breast cancer, endocrine therapy, intervention, feasibility, person-centered support program
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42 Wordcount: 5299
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ABSTRACT

Objective: The RESPECT intervention is considered to be a complex intervention due to the context. The aim of the study was to explore the feasibility of the trial design and patient acceptability of the intervention and outcome measures and to provide data to estimate the parameters required to design the final intervention.

Design: A controlled before-and-after design following the CONSORT 2010 statement for feasibility trials.

Setting: A surgical out-patient clinic in Sweden.

Participants: Forty-one patients (aged 47 – 85) with breast cancer and treated with endocrine therapy.

Interventions: Eligible patients were assigned to the control group or intervention group, which included individual education material, an individualized learning plan, and a personalized reminder letter using a person-centered approach. The intervention could be delivered as a telephone or digital follow-up during a 12 week follow up.

Outcome measures: The aims were to determine the recruitment rate, assess the rate of retention, explore whether the intervention was delivered according to the protocol, assess the preferred form of educational support, rate of education sessions, length per education session, and length between each education session, determine the distribution of education materials, and assess completion rates of patient-report instruments, including the General Self-efficacy Scale, the Quality of Care from the Patient's Perspective questionnaire, and the Memorial Symptom Assessment Scale.

Results: Eighty-six percent of the patients in the intervention group completed the intervention and completed the questionnaires three months after their inclusion. The call attendance was 90%. During the intervention, the contact nurse was compliant with the intervention protocol. For self-efficacy, symptoms, and quality of care, there were no differences in effect size between the control and intervention groups.

Conclusions: This intervention seems to be feasible and acceptable among patients, and a telephone follow-up intervention also seems to be the preferred way to administer the intervention.

Article summary

Strengths and limitations of this study

- This is the first study to investigate the feasibility of a person-centered support model for patients with breast cancer and treated with endocrine therapy.
- This study uses the CONSORT 2010 statement for feasibility trials.
- This study reports the recruitment rate, assess the rate of retention, explore whether the intervention was delivered according to the protocol, assess the preferred form of educational support, rate of education sessions, length per education session, and length between each education session, determine the distribution of education materials, and assess completion rates of patient-report instruments.
- Due to COVID-19 pandemic face-to-face sessions was restricted.

BACKGROUND

For women diagnosed with hormone receptor-positive breast cancer, endocrine therapy (ET), i.e., the use of tamoxifen or aromatase inhibitors, is recommended for at least five years to reduce recurrence and rates of mortality¹. A previous study reported that up to 91% of patients experience side effects from ET², such as sleeping difficulties, hot flashes^{3,4} and musculoskeletal symptoms⁵. Difficulties in managing these side effects have been reported to be obstacles to staying in treatment⁶. Other challenges that have been identified include older age⁷, medicine costs, or a general dislike of taking a regular medicine⁸. As ET is a long-lasting treatment, women may request support in managing challenges⁹. To manage challenges with ET, a partnership with health care professionals could be appropriate, as a previous study¹⁰ identified that women with ET want to be able to manage their treatment but need guidance to do so.

Regarding the management of ET-related symptoms, previous studies have investigated the effect of symptom management interventions for patients prescribed ET¹¹⁻¹³. A study identified management needs for ET symptoms, emotional needs, and needs for information acquisition and found that patients' relationship with health care providers was important¹². A combination of information with cognitive behavioral therapy (CBT) to manage the side effects of tamoxifen showed successful results for the development of management skills in patients who were unable to stay in treatment¹¹. Furthermore, training intervention with a physiotherapist or personal trainer followed by adapted training at home could be effective. However, a problem with this intervention was program adherence, as patients reported difficulty meeting the training goal in frequency and intensity due to other demands in life¹⁴. Also, training has not been found to have effect on musculoskeletal symptoms in patients treated with AIs¹⁵. Managing a disease and its additional challenges requires self-care knowledge and skills gained from a partnership with health care professionals¹⁶. Self-care involves the ability to both care for oneself and to achieve, promote and maintain optimal health¹⁷. A common feature of self-care and person-centered care (PCC) is an ability to view humans as the agent and the subject of action^{18,19}. To include aspects of treatment important to the individual patient, such as different side effects, health care structures, fear of side effects, and lack of management skills and for support, a person-centered support program was developed¹⁰. As self-care requires knowledge and skills¹⁶, PCC could be appropriate for use in a support program. Self-care requisites are described as all elements that individuals need at all stages in life to care for themselves, i.e., air, food, water; self-care requisites also depend on how

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3 individuals react to illness ¹⁶. PCC can be a preferable way of identifying those requisites, as they can
4 be identified in the narratives and used in the patient-health care provider partnership ¹⁹. Patients are
5 often motivated to engage in self-care, as they have personal interest in acquiring requisite knowledge
6 and skills for performing self-care operations to reach their intended health goals ¹⁶. It has been shown
7 that when self-care capabilities increase ²⁰, self-efficacy and adherence to ET also increase ^{21 22}. Self-
8 efficacy constitutes the self-image of the person and affects how people experience and behave in
9 specific situations ²³. Previous studies using PCC have improved patients' self-efficacy ²⁴⁻²⁶.

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15 It is important for patients to not only identify accurate information but also assess and integrate the
16 information to gain increased knowledge, self-efficacy, and self-care skills ¹⁰. Moreover, in addition to
17 the emotional needs identified by Kim et al. (2020), it is important to assess the amount of needed
18 information and to explore patients' understanding of the diagnosis and treatment ²⁷. For written health
19 education materials to be effective, the patient must be able to apply the new information to her own
20 life. This can be achieved by providing understandable examples and presenting the information so the
21 patient sees its relevance to her situation ²⁸, as the ultimate reason for educating patients is to improve
22 health ²⁹.

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25 In Sweden all patients are allocated a contact nurse when being diagnosed with breast cancer. The
26 contact nurse function as main point of contact during the patient's cancer treatments in order to reduce
27 fragmented care and to strength patient involvement in care ³⁰. It has been suggested that contact
28 nurses have a positive impact on care. Contact nurses aims to improve communication between patients
29 and their health care professionals, as well as contact nurses are to improve the care process ³¹. However,
30 it has been reported that other factors seem to decrease contact nurses 'ability to provide the care they
31 are meant to. Named reasons are challenges regarding the lack of information to patients, and lack of
32 supportive care resources. Although the patients had a contact nurse, the patients reported how they
33 lacked in the possibility to influence decisions about their care ³².

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36 A previous study developed a person-centered support program in collaboration among patients, health
37 care professionals, researchers and managers with ET experience ¹⁰ and need to be tested in a feasibility
38 study using the TIDieR checklist ³³ and the CONSORT 2010 statement ³⁴. Previous studies have used
39 feasibility studies prior to conducting a study in a larger setting ^{9 35}. The intervention was developed to
40 encourage patients to be more actively involved in their care and wellbeing as partners with their contact
41 nurse ¹⁰. It has been stated that an intervention could be considered as complex due to behaviors required
42 by those delivering the intervention ³⁶, i.e., a contact nurse. The complexity is caused by the context
43 where the intervention are to be implemented in rather than the number of parts of the intervention ³⁷. It
44 has been reported that complex interventions require engagements with the care context stakeholders,
45 i.e., patients, and contact nurses, to be able to identify if the intervention could be acceptable, operable,
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3 cost effective, possible to scale up, and transferable across contexts. The development phases are
4 identified including developing or use an existing complex intervention, feasibility, evaluation, and
5 implementation ³⁸.
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13 **Aim**

14 In this feasibility trial, the aim was to explore the feasibility of the study design and the patient
15 acceptability of the peRson-cEntred Support Program EndoCrine Therapy (RESPECT) intervention and
16 outcome measures and to provide data to estimate the parameters required to design the final
17 intervention.
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23 **METHODS**

24 *Study design*

25 This was a feasibility trial using a controlled before-and-after design ³⁹ to investigate the feasibility of
26 the intervention, a person-centered support program aimed at empowering patients prescribed ET to
27 manage ET-related symptoms and problems.
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33 *Patient and public involvement*

34 Patients and health care professionals was involved in the design and development of the person-
35 centered support model ¹⁰. However, there was no patient involvement in the evaluation of the person-
36 centered support model presented in this study.
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41 *Participants*

42 Between September 2020 and June 2021, 66 potential female patients from one outpatient clinic at one
43 university hospital in Sweden were identified as eligible for inclusion when starting ET. The inclusion
44 criteria were women > 18 years who had been diagnosed with breast cancer and treated with ET after
45 surgery. Patients receiving adjuvant chemotherapy were excluded as the study aimed to investigate an
46 intervention targeting patients treated with ET. All patients were contacted by a contact nurse and
47 were invited by telephone to participate in the study approximately three weeks after their surgery
48 when being prescribed ET (Table 1). In the online supplementary materials, the CONSORT flow
49 diagram for the usual care group and person-centered support program group is available
50 (Supplementary file 1 and 2).
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All patients were given verbal and written information about the study, and after agreeing to have an informed consent form sent to them by mail, they all provided written, informed consent. If the patient agreed to participate, she sent the informed consent form back using a prepaid envelope.

Table 1. Demographic and clinical characteristics of the participants in the control group (n=20) and intervention group (n=21) in the RESPECT project.

Demographic characteristics	Control group n=20	Intervention group n=21
<i>Median age, years (range)</i>	65 (50-85)	66 (47-79)
<i>Civil status, n (%)</i>		
<i>Married/cohabiting</i>	12 (63%)	16 (76%)
<i>Single</i>	8 (37%)	5 (23%)
<i>Ancestral homeland, n (%)</i>		
<i>Sweden</i>	16 (80%)	18 (86%)
<i>Scandinavian countries</i>	1 (5%)	1 (5%)
<i>Europe</i>	1 (5%)	2 (10%)
<i>Outside Europe</i>	1 (5%)	0 (0%)
<i>Education, n (%)</i>		
<i>University</i>	9 (45%)	10 (48%)
<i>High school</i>	8 (40%)	8 (38%)
<i>Elementary school</i>	3 (15%)	3 (14%)
<i>Radiation therapy, n (%)</i>	16 (80%)	21 (100%)
<i>Tumor size, median mm (range)</i>	14 (4-45)	12 (1-19)
<i>Breast surgery</i>		
<i>Mastectomy</i>	4 (20%)	2 (10%)
<i>Partial mastectomy</i>	15 (75%)	19 (90%)
<i>Axillary lymph node dissection</i>	1 (0.5%)	0 (0%)
<i>Tamoxifen, n (%)</i>	9 (45%)	9 (43%)
<i>Aromatase inhibitor, n (%)</i>	11 (55%)	12 (57)

Control group

Usual care (UC) involves patients being allocated a contact nurse (an experienced undergraduate nurse or postgraduate nurse in surgical care), as the Swedish Patient Act ⁴⁰ gives patients a statutory right to permanent contact with health care. Internationally the role is called Clinical Nurse Specialist ⁴¹, and are identified to be a valuable recourse in cancer care ⁴².

Patients can contact the contact nurse all weekdays by telephone or by using a national digital tool, 1177.se ⁴³. All patients receive written information as a brochure or a digital "My care and rehabilitation

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3 plan” when diagnosed with breast cancer. Support in usual care aims to give patients information about
4 their state of health, available methods for examinations, care, and treatments, as well as information
5 about at which time point she can expect to receive care and a permanent contact with the health care.
6 The contact nurse writes down the information that is available before surgery, such as tumor
7 characteristics and surgery preparations. The patient can also write down questions to bring to the
8 oncoming appointments. Usual care is based on patients’ initiative to make contact.
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17 *Intervention group*

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19 The intervention was provided in a surgical outpatient clinic in western Sweden from December 2020-
20 June 2021. The goal of the intervention is to empower patients prescribed ET to manage ET-related
21 symptoms and problems. In addition to the UC, a 12-week intervention was offered to the participants
22 in the intervention group as described in a previous study ¹⁰. Figure 1 shows the care and measurement
23 chain for the control and intervention groups.
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28 *Step 1- Individual education material*

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30 Using a PCC approach ¹⁹, the contact nurse listened to patients narratives regarding their individual
31 needs for knowledge and understanding, resources, goals and needs for support from the contact nurse.
32 The timing of supplying individual educational materials depended on the individual patient’s needs,
33 resources and goals during the 12-week intervention. Mutual trust was demonstrated, and the
34 relationship between the patient and her contact nurse was reinforced through the assessment of the
35 commonly agreed-upon individualized learning plan ⁴⁴ study.
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40 *Step 2 - An individualized learning plan (ILP)*

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42 An ILP was established depending on the individual patients’ needs for knowledge and understanding
43 about ET and considering the patients’ resources, goals, and needs for education material and support
44 from the contact nurse. In combination with the individual educational materials (step 1), a follow-up
45 plan was made using telephone and/or digital follow-ups. Physical follow-ups were minimized as the
46 COVID-19 pandemic was ongoing. The number of follow-up sessions and whether relatives were to be
47 included during the 12-week intervention were agreed upon between the patient and the contact nurse.
48 Patients could also refuse all education material and other materials and only use only the contact nurse
49 for support.
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56 *Step 3 – A personalized reminder letter*

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58 The third part of the support program was a personalized reminder letter after three months including
59 contact information and an invitation for patients to make contact if needed.
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9 *Education of the intervention nurse*

10 The aim of the education was to increase the intervention nurse's knowledge and understanding of ET,
11 its problems and symptom management using PCC. Microteaching^{45 46} sessions and seminars were
12 used; the microteaching sessions were adapted to the specific needs of knowledge about endocrine
13 therapy, side effects⁴⁷, pedagogy⁴⁸ and PCC^{19 49}, and the chosen approach was intended to help the
14 contact nurse take responsibility for her own learning, i.e., student-centered learning⁵⁰. Additionally,
15 practical exercises were used, as the contact nurse was able to practice her knowledge and understanding
16 in a care setting and reflect on it, and the intervention nurse's curiosity was used as a motivator to gain
17 knowledge⁴⁸. A full description of the education of the intervention nurse is reported in the online
18 supplementary materials (Supplementary file 3).
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26 *Data collection*

27 Data were collected from September 2020 – June 2021. Feasibility outcomes were collected during the
28 whole study period by the intervention nurse and were documented directly after every session in a trial
29 log to secure the data collection⁵¹. The trial log contained a summary of the results of the feasibility
30 criteria using Excel (Microsoft® Excel, version 16.50).
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35 The three questionnaires were distributed by mail to patients in the control group (between September
36 2020 and December 2020) and the intervention group (December 2020 and March 2021). These three
37 questionnaires were distributed at baseline, i.e., at the start of the intervention and ET, and three months
38 after the start of the intervention.
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42 The first questionnaire was the GSE, a 10-item (short form) psychometric scale that assesses optimistic
43 self-beliefs to cope with a variety of demands in life. The GSE is a validated instrument that has been
44 translated into Swedish⁵² and has previously been used with breast cancer patients⁵³. The total score is
45 the mean value of respondents' answer to all items. High scores imply higher self-efficacy.
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50 The second questionnaire was the QPP, a 45-item instrument that measures satisfaction in four
51 dimensions: medical-technical competence, physical-technical conditions, identity-oriented approach,
52 and sociocultural atmosphere^{54 55}. Moreover, to identify patients' views of whether the health care was
53 adapted to their needs rather than health care routines, three items (*I was given the possibility to tell the*
54 *medical staff how I experienced my situation; I was given the opportunity to participate in the planning*
55 *of my care/treatment; I received the information I needed to be able to participate in decisions about*
56 *my own care and treatment*) that were previously used by the Swedish SOM institute were added⁵⁶. To
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3 calculate the execution index, each question is scored in terms of actual experience and subjective
4 importance, each on a four-point Likert scale. The execution index score ranges from 1–7, where one is
5 inadequate quality of care from the patient perspective and seven is good quality of care ⁵⁷.
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9 The last questionnaire was the MSAS, a 32-question instrument for patients to rate their symptoms on
10 a 5-point Likert scale ^{58 59}. The instrument has been validated in Swedish breast cancer patients ⁵⁹ and
11 has previously been used with breast cancer patients ⁵³. The total MSAS score is the average of the
12 symptom scores for all 32 symptoms. Each symptom score is an average of the dimensions and includes
13 the number of symptoms, how often patients experienced them, the severity of the symptoms and the
14 cause of distress.
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18 19 *Feasibility outcomes*

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21 In this study, feasibility outcomes are defined as primary outcome. Craig et al. (2013) described several
22 challenging variables that can affect an intervention's results and conclusions. The feasibility
23 classification (process, resources, scientific) and feasibility criteria reported by Thabane et al. (2019)
24 and Lancaster et al. (2004) were used to collect feasibility data. Based on the recommendations for
25 feasibility studies and an expected attrition rate of 20%, the sample size was set to 20 participants in
26 each group ⁶⁰. To determine whether the chosen feasibility criteria were successful ⁶¹, criteria for
27 success were stated according to the CONSORT 2010 statement ³⁴;
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33 The intervention process was assessed with the feasibility criteria as follows:

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35 1. Recruitment was studied to determine whether the patients were willing to participate in the
36 study. It has been suggesting that the loss of participants should be less than 15% ⁶². The
37 criterion was determined to be successful if the percentage rates of recruitment were > 70%.
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40 2. Retention was studied to determine whether the patients were willing to remain for the entire
41 study period, i.e., 12 weeks. The criterion was determined to be successful if the percentage
42 rates of retention were >70%.
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45 3. Compliance with the intervention protocol was studied to determine if the patients were offered
46 the three parts of the planned intervention, i.e., education materials, learning plan and
47 personalized letter. The criterion was determined to be successful if all three parts of the
48 intervention were offered.
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53 The resources used in the intervention were assessed with the feasibility criteria as follows:

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55 4. Form of educational support was studied to determine the preferred form of educational support
56 during the intervention period, i.e., 12 weeks. The criterion was determined to be successful if
57 one of the three forms of educational support (face-to face, telephone, and digital) were
58 requested by the patients.
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5. Number of educational sessions was studied to determine how many educational opportunities the patient used during the intervention period, i.e., 12 weeks. The criterion determined to be successful if no more than four education sessions were used by each patient.
6. Length per education session was studied to determine how much time the patient used in each education session. The criterion was determined to be successful if < 45 minutes was used per education session. The time was clocked by the intervention nurse.
7. Length between each education session was studied to determine how often women wanted to have education opportunities. The criterion was determined to be successful if there were no more than four weeks between each education session.
8. Distribution of education materials was studied to determine how much of intervention materials the patients received during the study. The criterion was determined to be successful if the distribution of education materials was >70%.

The scientific challenges of the intervention were assessed with the feasibility criteria as follows:

9. Completion rate of questionnaires was studied to determine if the patient was willing to answer the questionnaires, i.e., at baseline and 12 weeks. The criterion was determined to be successful if the percentage rates of patient completion of questionnaires were > 70% at baseline and 12 weeks.
10. The estimated treatment effect was studied to determine if the selected instruments were appropriate to measure patients' self-efficacy, quality of care, and symptoms. The criterion was determined to be successful if there were any changes in the self-report measures between the first and second points of measurement.

Patients included in the study responded to the questionnaires and returned the questionnaires in a prepaid envelope.

Analysis

To analyze demographic variables, we used descriptive statistics (number, percent, mean, range). We calculated the percentage rates of recruitment, retention, and completion of questionnaires. We calculated the number, median and range of educational sessions, distribution of education materials, length per education session, and length between each education session. As the study was a feasibility test, no hypothesis testing was applied⁶³, but p-values were calculated and presented to value their relevance in an forthcoming RCT. Descriptive statistical analyses and the Mann-Whitney U-test were performed to identify the experience of symptoms, satisfaction with care and perceived self-efficacy. P-values below .05 were considered statistically significant, and all analyses were performed with IBM® SPSS® Statistics version 27 (IBM SPSS Statistics for Macintosh, Version 27.0).

RESULTS

Participant demographics

In the control group, the median age was 65 years, 80% of the participants were born in Sweden, 63% were cohabiting and 45% were prescribed tamoxifen. In the intervention group, the median age was 66 years, 86% were born in Sweden, 76% were cohabiting and 43% were prescribed tamoxifen (Table 1).

Feasibility classification and criteria

Feasibility outcomes are presented in line with the CONSORT 2010 statement as follows:

1. Recruitment

In the control group, 22 eligible patients were screened, and 20 were approached at the clinic, of whom 20 consented to participate (100%). In the intervention group, 44 patients were screened, of whom 24 were approached and 21 consented to participate (88%) (Table 1), and patients was enrolled from December 2020 – April 2021. Of the three patients who did not consent to participate in the intervention group, two indicated the number of questions in the questionnaires to be a reason for not participating. One patient gave no reason for not participating.

2. Retention

In the intervention group, 20 patients completed (95%). One patient dropped out from the intervention because the study reminded her about the breast cancer surgery, which she was trying to forget about.

3. Compliance with the intervention protocol

In the first session, the patients' needs for knowledge and understanding, resources, goals and support from the contact nurse were identified in their narratives. Education material was offered accordingly using a written agreement between the patient and contact nurse and documented in the ILP. Patients decided with the contact nurse whether they required knowledge. If they required knowledge, they stated when they wanted the education materials and which parts. Their need for knowledge ranged between having everything sent after the first session and having some of the education material sent at the end of the intervention. Patients could state that they did not want any education material at the start of the intervention but would reevaluate their needs during the 12 weeks of the intervention. However, since the ILP was sent home with the patients, any changes in the plan had to be documented by the patient herself. Two patients received the education materials sent to them but did not want to read it, just to have it if they wanted to read it later. Seven patients did not want the intervention for the full 12-week period (33%) but stated that they would make contact if they needed further information during the intervention. One patient wanted her partner to be included. Two patients in the intervention group did not answer the telephone at the scheduled session, making the call attendance 90%. One patient rescheduled a session due to personal reasons. Thirty-three percent of the patients did not want follow-up sessions during the full 12-week intervention. As 90% of the patients wanted all educational

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3 materials, 10% of the patients used only the contact nurse for support and one hundred percent of the
4 patients received a personalized reminder letter (Table 2).

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6 Contact information and an invitation for patients (100%) to make contact if needed were sent after 12
7 weeks in the personalized letter. None of the patients made contact after the 12-week intervention as
8 shown in Table 2.
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14 *4. Resources*

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16 None of the patients wanted to have face-to-face sessions as educational support. In fact, several of the
17 patients stated that it was important to not have to come for appointments at the hospital. Reasons for
18 not wanting to come to the hospital were related to the COVID-19 pandemic as well as to perceptions
19 of appointments at the hospital being time consuming. All patients but one preferred telephone sessions.
20 If a patient had asked for a face-to-face follow-up session, this would have been managed accordingly,
21 with arrangements made to ensure safety in the context of the COVID-19 pandemic. Face-to-face
22 meetings at the hospital with patients were not prohibited but restricted. However, no patient-contact
23 nurse pairs participated in a face-to-face session; had they done so, both the patient and the contact nurse
24 would have had to wear face masks, and the contact nurse would have also had to wear a plastic face
25 shield to prevent transmission of the COVID-19 virus.
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31 *5. Number of educational sessions*

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33 The number of educational sessions ranged between two and four sessions (Table 2).

34 *6. Length per education session*

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36 Telephone support sessions ranged between 5 and 60 minutes, and digital support sessions ranged
37 between 30 and 45 minutes (Table 2) and was clocked by the intervention nurse.

38 *7. Length between education sessions*

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40 The length between follow-up sessions ranged between 1 and 6 weeks (Table 2).

41 *8. Distribution of education materials*

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43 All patients (100%) wanted part 1 of the individual education material. Further description of the
44 distribution is shown in Table 2.
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47 *9. Completion rate of questionnaires*

In the control group, 95% completed the first questionnaires at baseline, as one patient questionnaire was lost in the mail. At three months, 95% of patients responded to their surveys. In the intervention group, 100% responded to the first questionnaires, and 86% responded to the follow-up questionnaires after three months. At the first measurement point, two reminder messages were sent to three patients in the intervention group before one patient was recorded as a drop out. At the second measurement point, one reminder message was sent to six patients three weeks after the questionnaires were sent. A second reminder message was sent approximately two weeks later to five patients, and as two patients did not return their questionnaires, they were recorded as drop-outs. Two patients in the intervention group did not answer the telephone at the scheduled session, making the call attendance 90%. One patient rescheduled a session due to personal reasons.

10. Estimated treatment effect

Differences between the control and intervention groups in perceived self-efficacy (0.5 and 0, $p=0.731$) and reported number of symptoms according to the MSAS (2 and 1, $p=0.724$) after 3 months were observed (Figure 2). Median differences at baseline and 3 months in the control group and intervention group is also reported in the online supplementary materials (Supplementary file 4).

Quality of care was measured using QPP, and these results in shown in the online supplementary materials (Supplementary file 5). Overall, the patients in the control group had higher quality of care index scores than patients in the intervention group.

Table 2. Resource needs for the intervention

RESPECT	
Distributed educational material	
Individual educational material <i>Part 1, n</i>	21
Individual educational material <i>Part 2, n</i>	20
Individual educational material <i>Part 3, n</i>	19
Individual educational material <i>Part 4, n</i>	19
Individual educational material <i>Information about tamoxifen or aromatase inhibitors, n</i>	20
Additional educational material from the patient needs:	
Complementary medicine, n	1
Sleep advice, n	1
Recommendations about internet sites:	
Sleep advice, n	2
Form of education and educational sessions per patient	
Face to face (n=0), median (range)	0 (-)
Telephone (n=20), median (range)	3 (2-4)
Digital (n=1), median (range)	1 (1)
Length (minutes) per sessions	
Telephone (n=20), median (range)	20 (5-60)
Digital (n=1), median (range)	30 (30-45)

Length of time (weeks) between each session	
Telephone follow-up education sessions, weeks, median (range)	4 (1-6)
Digital meeting follow-up sessions, weeks, median (range)	4 (-)
<i>Follow-up educational session</i>	
Time from 1 st session to 2 nd session, weeks, median (range)	2 (1-8)
Time from 2 nd session to 3 rd session, weeks, median (range)	4 (2-8)
Time from 3 rd session to 4 th session, weeks, median (range)	4 (2-5)

Please insert Figure 2 about here

DISCUSSION

The results show that the intervention was feasible regarding the classification process and resources. However, it was less feasible regarding scientific challenges. The recruitment methods used seem to be accurate and feasible for an RCT with the aim of empowering patients prescribed ET to manage ET-related symptoms and problems. As a before-and-after design was used, the risk of contamination between groups was minor, as the intervention nurse had minor clinical contact with the control group.

The most common problems reported by trial investigators have been identified as a lack of adherence to the trial protocol, difficulties with recruitment, data collection and the intervention itself⁶⁴; however, during the intervention, the contact nurse succeeded in adhering to the trial protocol. Moreover, a weakness in interventions has been reported to be a lack of theoretical approach⁶⁵; to address this challenge, the presented study was founded on a theoretical model⁴⁷. Modeling was used to identify pit falls and barriers⁶⁶. The contact nurse in the intervention pretested the intervention protocol in clinical meetings with patients before launching the support program. It is crucial for health care professionals to have deep insight into the theory and selected methods to increase patients' required knowledge about ET since no one will adhere to a protocol if the protocol is of no significance⁴⁸. Moreover, a health care context is referred to as a complex adaptive system, as it contains a collection of individuals with the freedom to act in a way that is not always predictable and changes depending on the context. Moreover, a complex adaptive system has fuzzy boundaries, and health care professionals' priorities depend on, for example, their private lives and things they would not sacrifice to follow a study protocol⁶⁷. These challenges need to be addressed, as the intervention is to be applied in a care setting.

Furthermore, as the follow up is flexible and the patients decided, in a partnership with the contact nurse, how many educational sessions were required, the patient's individuality and resources were a focus, and no patient needed to acquire education than necessary. This needed flexibility is another component making the intervention a complex intervention. Moreover, the COVID-19 pandemic has increased the use of digital follow-up, which seems to be well liked among patients⁶⁸⁻⁷⁰. Furthermore, face-to-face

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3 sessions were not prohibited during the intervention but were restricted due to the COVID-19 pandemic.
4 If a patient would have asked for a face-to-face session, this would have been managed to not put the
5 patient, fellow patients, or the contact nurse or other health care professionals in danger. However, we
6 cannot specifically state that patients would prefer telephone sessions under other circumstances, but
7 telephone follow-up seems to be suitable, as patients indicated physical appointments to be time
8 consuming. A previous study also used telephone follow-up to increase confidence in controlling illness
9 in patients with chronic obstructive pulmonary disease with positive results in controlling symptoms
10 ($p=.028$)⁷¹, and telephone follow-ups found to be well liked among registered nurses⁷². A previous
11 study using PCC also allowed patients to decide the number of follow-up sessions⁷³. Thus, this approach
12 could be a preferable way to administer the intervention and could also be more cost-effective, as
13 patients do not need to attend more sessions than required; however, it needs to be evaluated further.
14 Furthermore, all health care professionals do not have a PCC approach, which might affect the responses
15 in the questionnaires and the interpretation of the results. To manage this, the whole care chain needs to
16 structure their work according to PCC, as in a previous study²⁴.

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26 Moreover, the intervention protocol ranged over 12 weeks, as this period has been identified as the most
27 troublesome for patients with ET⁷⁴, and a previous study identified that the start of the ET period could
28 be preferable for an intervention³⁵. As 67% of the patients wanted education during the full 12-week
29 intervention, 12 weeks is indicated to be a suitable length for a support program in a future RCT.
30 However, an optional follow-up session after six months, when the patients have more experience with
31 ET, could be appropriate, but measures would need to be taken to help patients stay focused on ET when
32 responding to the questionnaires. A later session could also be preferable for patients who do not want
33 to be educated during the first months undergoing ET³⁵.

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40 To address scientific challenges, two measurement points were used, baseline and three months after
41 being prescribed ET. In an RCT, additional measurement points could be added at six and 12 months.
42 However, there were no differences in self-efficacy between the control and intervention groups; rather,
43 both the control group and the intervention had high self-efficacy scores at baseline, indicating that the
44 ceiling level was reached. Higher education implies higher self-efficacy⁷⁵ ($p=.017$)⁷⁶. In the present
45 study, 45% of the patients in the control group and 48% of the patients in the intervention group had
46 university education, indicating that the GES may not be suitable as an instrument. General self-efficacy
47 has been increased using PCC in a previous study in patients with acute coronary syndrome⁷³, indicating
48 that breast cancer patients could also benefit from PCC. This is of importance, as low self-efficacy has
49 been identified as a predictor of terminating ET prematurely⁷⁷ due to beliefs about its low influence on
50 health or low satisfaction with involvement in health care⁷⁷.

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59 The study had some limitations. As the COVID-19 pandemic was ongoing, there were restrictions on
60 the patients' ability to have face-to-face sessions with the trial leader. However, several patients stated

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3 that they would participate only if there were no mandatory sessions at the hospital. The patients also
4 had the possibility of having their sessions using a digital conference system. As the intervention contact
5 nurse and the participants almost never met in person, their relationships could have been affected.
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7 However, a partnership was established between the patient and the trial leader using a PCC protocol.
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9 This might have decreased the effect of not meeting in person. In a future RCT, it will be crucial for
10 patients to have face-to-face relationships with the intervention contact nurse with whom they will build
11 partnerships. This study did not identify when the intervention should stop, as it was decided before the
12 intervention that it should last for 12 weeks. It might have been important for the patients in the
13 intervention to have given this important information. However, seven of the 21 patients did not use the
14 full 12-week intervention, which implies that a 12-week support program is suitable. No patient actively
15 asked for longer follow up. All patients were allocated a contact nurse whom they could contact after
16 the intervention if further questions were answered.
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23 **Conclusion**

24 This intervention seems to be feasible regarding its process and resources and acceptable among
25 patients, as 95% completed the 12-week support program and 86% responded to the three-month
26 questionnaire. A telephone follow-up intervention seems to be the preferable way to administer the
27 intervention. However, for self-efficacy and symptoms, there were no differences in effect size between
28 the control and intervention groups, indicating that the intervention was less feasible regarding scientific
29 challenges.
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34 *Ethical approval*

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36 Patients were informed that their participation was voluntary and could be terminated at any time
37 without consequences. They were also assured that their confidentiality would be respected throughout
38 the research process. This study was approved by the Swedish Ethical Review Authority (approval no
39 2020-03239).
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45 *Conflicts of Interest*

46 The authors report no conflicts of interest.
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50 *Contributorship statement*

51 IH, SAK, ROB, CW: Conceptualizing and design, IH, SAK, CW: Methodology, SAK: Data
52 Collection, IH, SAK, CW, ROB, Formal Analysis: IH, SAK, CW, ROB: Visualization, IH, SAK, CW,
53 ROB: Writing-review and editing.
54
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56

57 *Availability statement*

58 Data are available upon reasonable request.
59
60

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55 Figure 1. The care and measurement chain for the control and intervention groups. Both groups received the
56 content in the blue area (usual care).

57 Abbreviations: Endocrine therapy – ET, Individual learning plan – ILP.
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3 Figure 2. Baseline and 3-month difference measures in the control and intervention groups for self-efficacy and
4 reported symptoms.

5 Abbreviation: no – Number, SE – Self-efficacy.
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10 Supplementary material:

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12 Supplementary file 1. Retention - CONSORT Flow diagram for the usual care group. Patients included
13 September 2020 – December 2021.
14

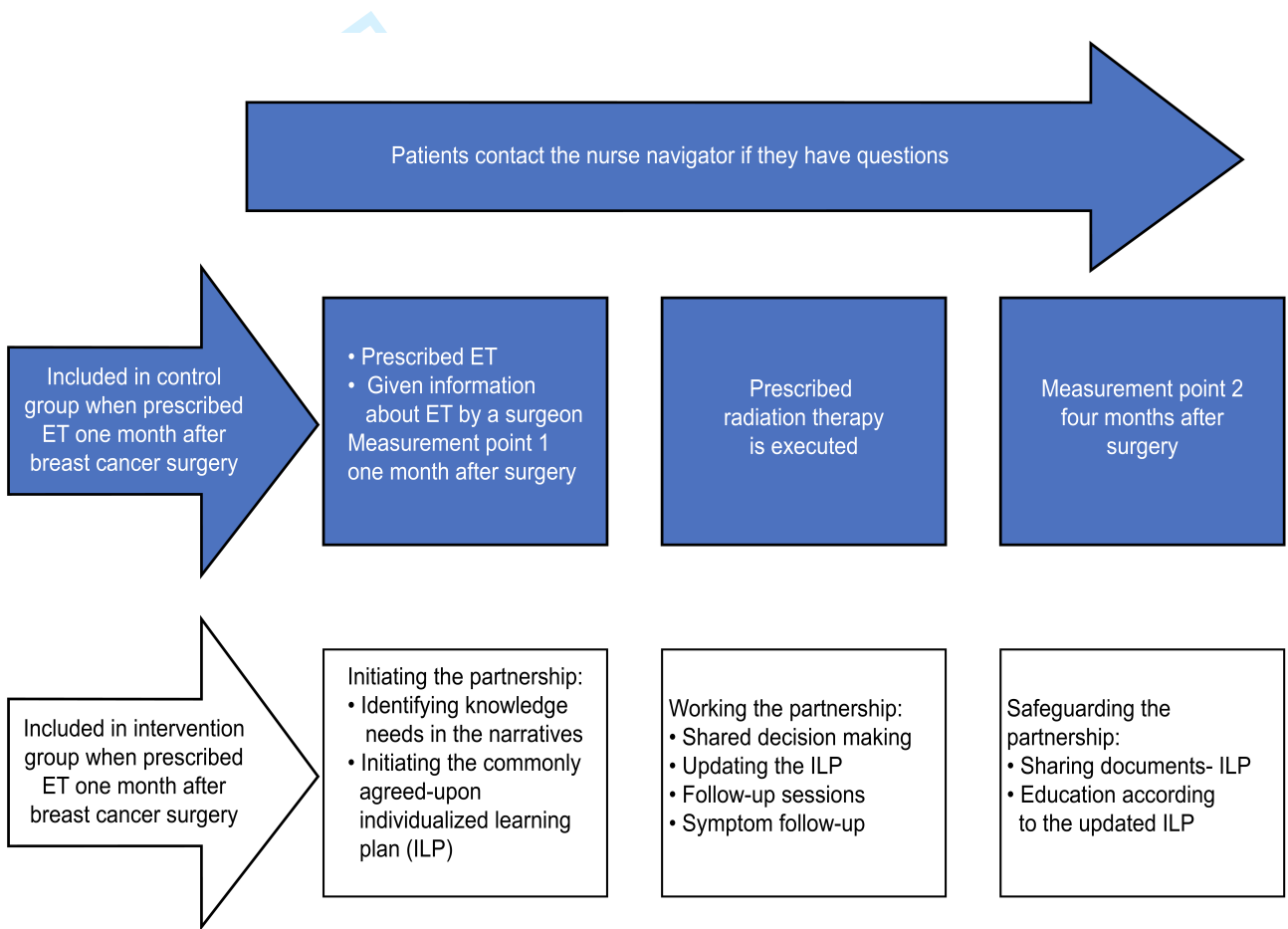
15 Supplementary file 2. Retention - CONSORT flow diagram for the person-centered support program group.
16 Patients included December 2020 – March 2021.
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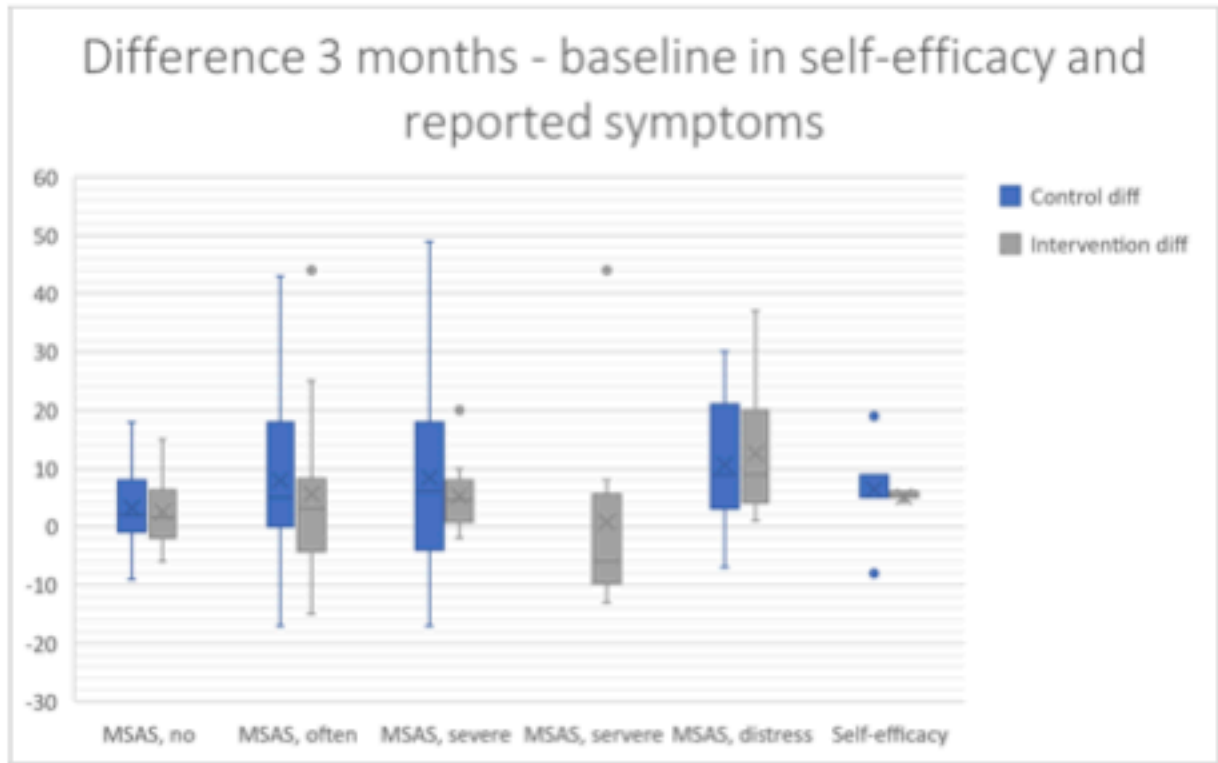
18 Supplementary file 3. Description of the education of the intervention nurse.
19

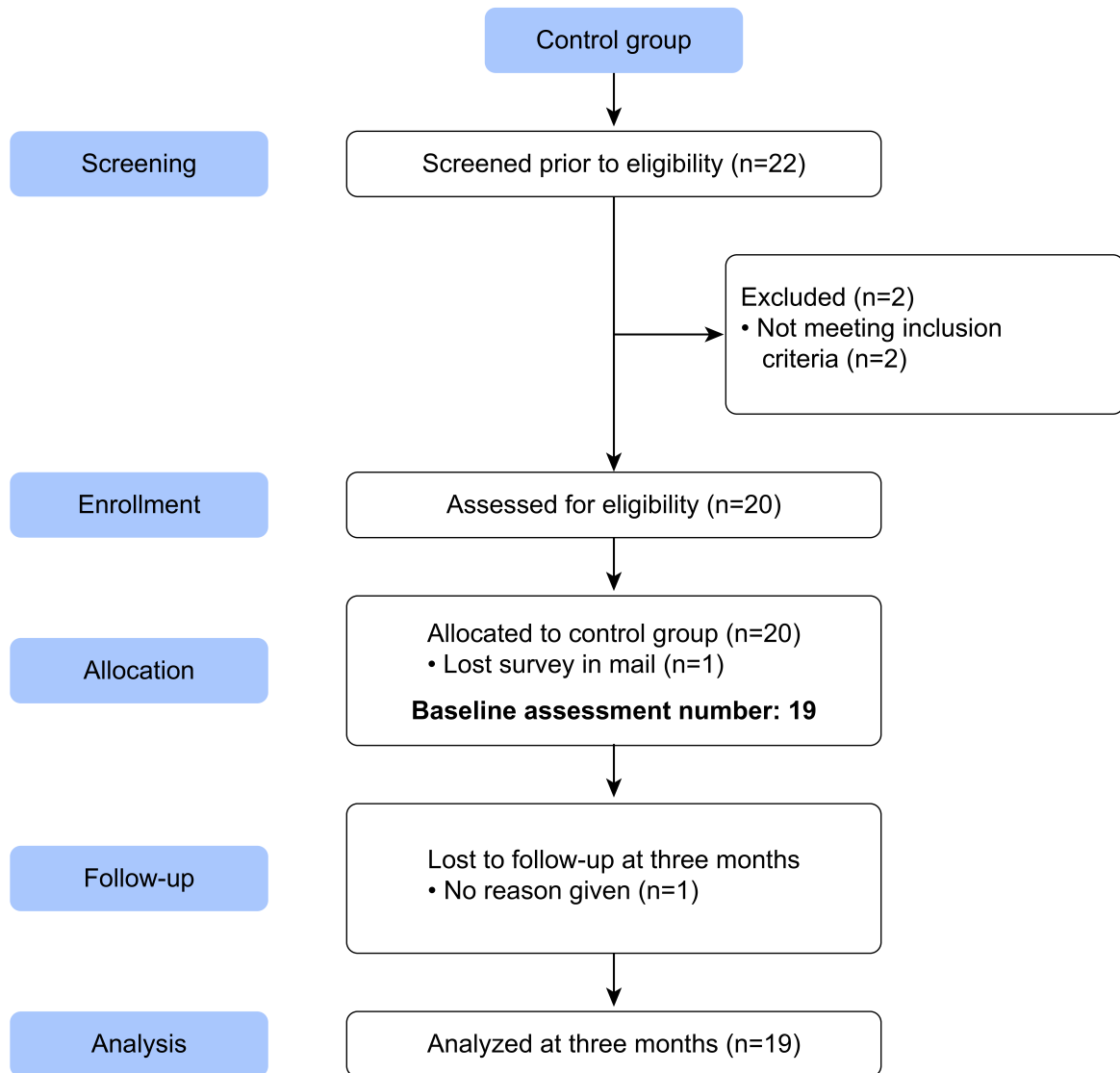
20 Supplementary file 4. Median differences at baseline and 3 months in the control group and intervention group.
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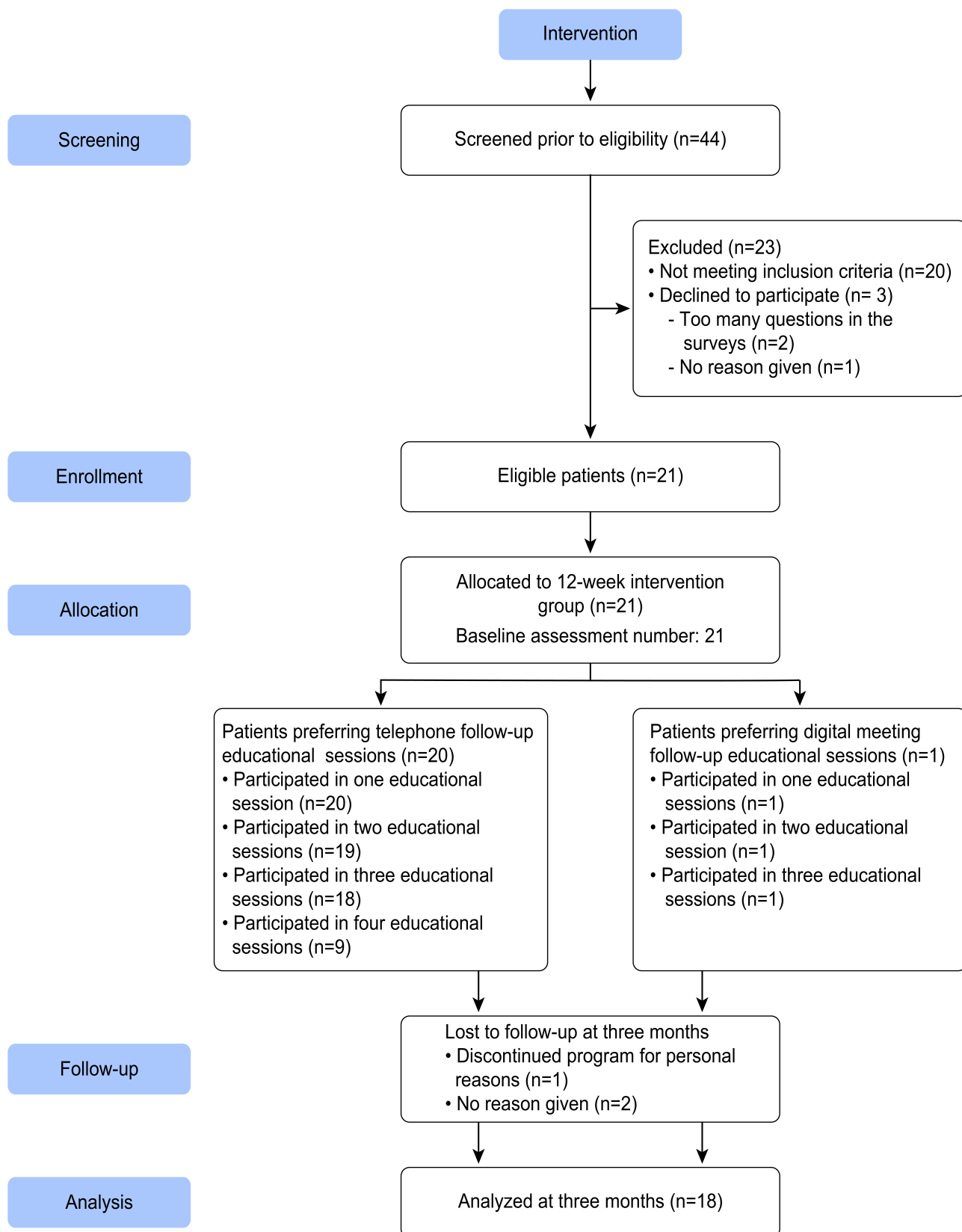
22 Supplementary file 5. Interpretation of the QPP – Percentage agreement in a selection of QPP questions
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Supplementary file 3. Description of the education of the intervention nurse.

Before Lecture: The intervention nurse is asked to specifically reflect on the following in the care setting: <i>Problems with endocrine therapy</i> <i>Symptom management</i> <i>Cocreation with patients, barriers, facilitators.</i>			
Sessions	Content	Learning outcomes	Learning activities
1	Core principles about endocrine therapy (ET ¹), including side effects of ET and symptom management described in research. Symptom management theory.	-Describe symptom management methods. -Suggest strategies for symptom management during ET.	Clinical case discussions, microteaching sessions, dialogs, reflection.
Before Lecture: The intervention nurse is asked to reflect on practical situations in the care setting when <i>applying dialog and person-centered care (PCC²)</i> .			
Session	Content	Learning outcomes	Learning activities
2	Pedagogical theory.	- Describe pedagogic strategies using dialog to increase patients' self-care. - Describe pedagogical strategies to increase patient participation. - Describe dialogical methodology that strengthens patient participation. -Evaluate whether chosen pedagogical strategies increase patients' self-management ability.	Clinical case discussions, microteaching sessions, dialogs, reflection.
Before Lecture: The intervention nurse is asked to reflect on practical situations in the care setting using knowledge from Session 2 and <i>relate to PCC</i> in a care setting.			
Session	Content	Learning outcomes	Learning activities
3	PCC in the clinical care setting.	-Describe PCC.	Clinical case discussions, microteaching sessions, dialogs, reflection.
Before Lecture: The intervention nurse evaluates the <i>gained knowledge about PCC</i> in a practical situation in the care setting.			
Session	Content	Learning outcomes	Learning activities
4	The three intervention components, i.e., individual education material, individualized learning plan, and a personalized reminder letter (Ahlstedt Karlsson, et al, 2022) with a starting point in the contact nurse's experience from a practical situation in the clinical setting.	-Explain the components of the intervention.	Clinical case discussions, dialogs, reflection.
After Lecture: With a starting point in the newly gained knowledge, <i>apply PCC, knowledge about ET, pedagogical theory and the three components</i> in the intervention in a care setting.			
Proficiency goal after completed education: The intervention nurse can: - Evaluate whether the proposed symptom management strategies increase the patient's management of ET-related symptoms. - Assess whether the patient's need for care was met. - Review and evaluate whether selected pedagogical strategies strengthen the patient's self-care ability. - Evaluate the patient's participation in ET symptom management.			
Evaluation ability after completed education: The intervention nurse can: - Suggest strategies for managing symptoms in relation with ET. - Together with the patient, identify care needs. - Apply pedagogical strategies that strengthen patients' self-care ability. - Apply dialogical methodology that strengthens patients' participation.			

Abbreviations: ET – Endocrine therapy, PCC – Person-centered care.

Supplementary file 4. Median differences at baseline and 3 months in the control group and intervention group.

	Control			Intervention			p-value*
	Baseline No, Median (IQR)	3 months, Median (IQR)	Change from baseline (median)	Baseline No, Median (IQR)	3 months No, Median (IQR)	Change from baseline (median)	
SE, median (IQR)	31 (27-40)	31 (22-39)	0.5	30 (26-35)	30 (30-38)	0	0.731
MSAS, no median (IQR)	6 (3-11)	9 (3-18)	2	7 (3-13)	10 (5-22)	1	0.724
MSAS, often, median (IQR)	11 (2-36)	13 (6-38)	7.5	14 (4-25)	15 (7-49)	2	0.504
MSAS, severe, median (IQR)	12 (0-26)	13 (5-52)	5	10 (3-23)	13 (6-40)	2	0.393
MSAS, distress, median (IQR)	11 (0-28)	12 (3-30)	5.5	8 (2-19)	12 (6-39)	2	0.600

*Mann-Whitney test comparing changes from baseline between the control and intervention groups.

Abbreviation: Often- How often the patient had a symptom, Severe- How severe was the symptom usually experienced by the patient, Distress- How much did the experienced symptom distress or bother the patient.

Supplementary file 5. Interpretation of the QPP – Percentage agreement in a selection of QPP questions

	Control 3 months, n (%)	Intervention 3 months, n (%)
13. I received useful information on what I needed to be able to participate in my own care	16* (93.75%)	17* (88.24%)
19. I had adequate information about my medicine, so I understood the effect and how to use them	18* (77.78%)	18* (72.22%)
20. I had an opportunity to share my experience with the health care professionals	15* (86.67%)	17* (82.35%)
32. I had a good opportunity to confer in decisions about my own care	14* (85.71%)	15* (73.33%)
33. I had a good opportunity to participate in my own care	15* (86.67%)	12* (75.00%)
34. My care was directed by my needs rather than the health care professionals' routines	16* (100%)	17* (82.35%)

*Caution: If less than 30, the results should be regarded with caution.

To measure perceived reality concerning the quality of care, every question was phrased as a statement. The response alternatives were given as a scale between 4 (Fully agree) and 1 (Do not agree at all). Percentage in agreement represents the patients who answered 3 (Mostly agree) and 4 (Fully agree) divided by the total number of patients who answered 1-4 on the question. Answer 5 (Not applicable) is not included.



CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	4
	2b	Specific objectives or research questions for pilot trial	5
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6
	4c	How participants were identified and consented	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-7
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	8
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	NA
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	NA
Sample size	7a	Rationale for numbers in the pilot trial	7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	NA
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	NA
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	NA

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	NA
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	NA
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	9
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	10
	13b	For each group, losses and exclusions after randomisation, together with reasons	10
Recruitment	14a	Dates defining the periods of recruitment and follow-up	10
	14b	Why the pilot trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	Figure 1 and 2. Supplementary file
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	NA
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
	19a	If relevant, other important unintended consequences	NA
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	14
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	13
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	13
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	14
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	NA
Protocol	24	Where the pilot trial protocol can be accessed, if available	NA
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	15

	26	Ethical approval or approval by research review committee, confirmed with reference number	15
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3 Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *BMJ*. 2016;355.
4 *We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important
5 clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological
6 treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.
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A person-centered support program (RESPECT intervention) for women with breast cancer treated with endocrine therapy: A feasibility study

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4 **A person-centered support program (RESPECT intervention) for women with breast cancer**
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11 Ahlstedt Karlsson, Susanne^{1,2} Orcid ID: 0000-0001-5436-5476; Henoeh, Ingela² Orcid ID: 0000-0002-1987-
12 5419; Olofsson Bagge, Roger^{1,3} Orcid ID: 0000-0001-5795-0355; Wallengren, Catarina² Orcid ID: 0000-0002-
13 8124-1572
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15

16
17
18 ¹Department of Surgery, Sahlgrenska University Hospital, Gothenburg, Sweden.

19 ²Institute of Health and Care Sciences, Sahlgrenska Academy at the University of Gothenburg, University of
20 Gothenburg, Gothenburg, Sweden

21 ³Department of Surgery, Institute of Clinical Sciences, Sahlgrenska Academy at the University of Gothenburg,
22 Gothenburg, Sweden.
23
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25
26 # Correspondence to: Susanne Ahlstedt Karlsson, Institute of Health and Care Sciences, Sahlgrenska Academy
27 at the University of Gothenburg, University of Gothenburg, Gothenburg, Sweden

28
29 E-mail: susanne.ahlstedt.karlsson@gu.se

30 Telephone: +46 704153666
31
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ABSTRACT

Objective: The peRson-cEntred Support Program EndoCrine Therapy (RESPECT) intervention is a complex intervention encompassing a person-centered support program for patients with breast cancer being treated with endocrine therapy. The aim of this study was to explore the feasibility of the trial design and patient acceptability of the intervention and outcome measures and to provide data to estimate the parameters required to design the final intervention.

Design: A controlled before-and-after design following the CONSORT 2010 statement for feasibility trials.

Setting: A surgical outpatient clinic in Sweden.

Participants: Forty-one patients (aged 47–85) with breast cancer who were treated with endocrine therapy.

Interventions: Eligible patients were assigned to the control group or intervention group, which included individual education material, an individualized learning plan, and a personalized reminder letter using a person-centered approach. The intervention could be delivered as a telephone or digital follow-up during a 12-week follow-up.

Outcome measures: The aims were to determine the recruitment rate, assess the rate of retention, explore whether the intervention was delivered according to the protocol, assess the preferred form of educational support, rate of education sessions, length per education session, and length between each education session, determine the distribution of education materials, and assess completion rates of patient-report instruments, including the General Self-efficacy Scale, the Quality of Care from the Patient's Perspective questionnaire, and the Memorial Symptom Assessment Scale.

Results: Eighty-six percent of the patients in the intervention group completed the intervention and questionnaires three months after their inclusion. The call attendance was 90%. During the intervention, the contact nurse complied with the intervention protocol. For self-efficacy, symptoms, and quality of care, there were no differences in effect size between the control and intervention groups.

Conclusions: This intervention seems to be feasible and acceptable among patients.

Article summary

Strengths and limitations of this study

- This is the first study to investigate the feasibility of a person-centered support model for patients with breast cancer treated with endocrine therapy.
- This study uses the CONSORT 2010 statement for feasibility trials.
- This study reports the recruitment rate, assesses the rate of retention, explores whether the intervention was delivered according to the protocol, assesses the preferred form of educational support, rate of education sessions, length per education session, and length between each education session, determines the distribution of education materials, and assesses completion rates of patient-report instruments.
- Due to the COVID-19 pandemic, face-to-face sessions were restricted.

BACKGROUND

For women diagnosed with hormone receptor-positive breast cancer, endocrine therapy (ET), i.e., the use of tamoxifen or aromatase inhibitors, is recommended for at least five years to reduce recurrence and rates of mortality¹. A previous study reported that up to 91% of patients experience side effects from ET², such as sleeping difficulties, hot flashes^{3,4} and musculoskeletal symptoms⁵. Difficulties in managing these side effects have been reported to be obstacles to staying in treatment⁶. Other challenges that have been identified include older age⁷, medicine costs, or a general dislike of taking a regular medicine⁸. As ET is a long-lasting treatment, women may request support in managing challenges⁹. To manage challenges with ET, a partnership with health care professionals could be appropriate, as a previous study¹⁰ identified that women with ET want to be able to manage their treatment but need guidance to do so.

Regarding the management of ET-related symptoms, previous studies have investigated the effect of symptom management interventions for patients prescribed ET¹¹⁻¹³. A study identified management needs for ET symptoms, emotional needs, and needs for information acquisition and found that patients' relationship with health care providers was important¹². A combination of information with cognitive behavioral therapy (CBT) to manage the side effects of tamoxifen showed successful results for the development of management skills among patients who were unable to stay in treatment¹¹. Furthermore, training intervention with a physiotherapist or personal trainer followed by adapted training at home could be effective. However, a problem with this intervention was program adherence, as patients reported difficulty meeting the training goal in frequency and intensity due to other demands in life¹⁴. Additionally, training has not been found to have an effect on musculoskeletal symptoms in patients treated with AIs¹⁵. Managing a disease and its additional challenges requires self-care knowledge and skills gained from a partnership with health care professionals¹⁶. Self-care involves the ability to both care for oneself and to achieve, promote and maintain optimal health¹⁷. A common feature of self-care and person-centered care (PCC) is the ability to view humans as the agent and the subject of action^{18,19}. To include aspects of treatment important to the individual patient, such as different side effects, health care structures, fear of side effects, and lack of management skills and for support, a person-centered support program was developed¹⁰. As self-care requires knowledge and skills¹⁶, PCC could be appropriate for use in a support program. Self-care requisites are described as all elements that individuals need at all stages in life to care for themselves, i.e., air, food, and water; self-care requisites also depend on how individuals react to illness¹⁶. PCC can be a preferable way of identifying those requisites, as they can be identified in the narratives and used in the patient-health care provider

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3 partnership¹⁹. Patients are often motivated to engage in self-care, as they have personal interest in
4 acquiring requisite knowledge and skills for performing self-care operations to reach their intended
5 health goals¹⁶. It has been shown that when self-care capabilities increase²⁰, self-efficacy and adherence
6 to ET also increase^{21 22}. Self-efficacy constitutes the self-image of the person and affects how people
7 experience and behave in specific situations²³. Previous studies using PCC have improved patients'
8 self-efficacy²⁴⁻²⁶.

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13 It is important for patients to not only identify accurate information but also assess and integrate the
14 information to gain increased knowledge, self-efficacy, and self-care skills¹⁰. Moreover, in addition to
15 the emotional needs identified by Kim et al. (2020), it is important to assess the amount of needed
16 information and to explore patients' understanding of diagnosis and treatment²⁷. For written health
17 education materials to be effective, the patient must be able to apply the new information to her own
18 life. This can be achieved by providing understandable examples and presenting the information so the
19 patient sees its relevance to her situation²⁸, as the ultimate reason for educating patients is to improve
20 health²⁹.

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27 In Sweden, all patients are allocated a contact nurse when diagnosed with breast cancer. The contact
28 nurse functions as the main point of contact during the patient's cancer treatments to reduce fragmented
29 care and to strengthen patient involvement in care³⁰. It has been suggested that contact nurses have a
30 positive impact on care. Contact nurses aim to improve communication between patients and their health
31 care professionals, as well as improve the care process³¹. However, it has been reported that other factors
32 seem to decrease contact nurses' ability to provide the care they are meant to. Named reasons are
33 challenges regarding the lack of information to patients and lack of supportive care resources. Although
34 the patients had a contact nurse, the patients reported how they lacked the possibility to influence
35 decisions about their care³².

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43 A previous study developed a person-centered support program in collaboration among patients, health
44 care professionals, researchers and managers with ET experience¹⁰ that needed to be tested in a
45 feasibility study using the TIDieR checklist³³ and the CONSORT 2010 statement³⁴. Previous studies
46 have used feasibility studies prior to conducting a study in a larger setting^{9 35}. The intervention was
47 developed to encourage patients to be more actively involved in their care and wellbeing as partners
48 with their contact nurse¹⁰. It has been stated that an intervention could be considered complex due to
49 the behaviors required by those delivering the intervention³⁶, i.e., a contact nurse. The complexity is
50 caused by the context in which the intervention is to be implemented rather than the number of parts of
51 the intervention³⁷. It has been reported that complex interventions require engagements with the care
52 context stakeholders, i.e., patients and contact nurses, to be able to identify if the intervention could be
53 acceptable, operable, cost-effective, possible to scale up, and transferable across contexts. The
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3 development phases were identified, including developing or using an existing complex intervention,
4 feasibility, evaluation, and implementation ³⁸.
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10 **Aim**

11 In this feasibility trial, the aim was to explore the feasibility of the study design and the patient
12 acceptability of the peRson-cEntred Support Program EndoCrine Therapy (RESPECT) intervention and
13 outcome measures and to provide data to estimate the parameters required to design the final
14 intervention.
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19 **METHODS**

20 *Study design*

21 This was a feasibility trial using a controlled before-and-after design ³⁹ to investigate the feasibility of
22 the intervention, a person-centered support program aimed at empowering patients prescribed ET to
23 manage ET-related symptoms and problems. Allocation was based on inclusion time and not on patient
24 preferences.
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30 *Patient and public involvement*

31 Patients and health care professionals were involved in the design and development of the person-
32 centered support model ¹⁰. However, there was no patient involvement in the evaluation of the person-
33 centered support model presented in this study.
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38 *Participants*

39 Between September 2020 and June 2021, 66 potential female patients from one outpatient clinic at one
40 university hospital in Sweden were identified as eligible for inclusion when starting ET. Patients in the
41 control group were included from September 2020 to December 2021, while patients in the
42 intervention group were included from December 2021 to March 2021. The inclusion criteria were
43 women > 18 years of age who had been diagnosed with breast cancer and treated with ET after
44 surgery. Patients receiving adjuvant chemotherapy were excluded as the study aimed to investigate an
45 intervention targeting patients treated with ET. All patients were contacted by a contact nurse and
46 were invited by telephone to participate in the study approximately three weeks after their surgery
47 when prescribed ET (Table 1). In the online supplementary materials, the CONSORT flow diagrams
48 for the usual care group and person-centered support program group are available (Supplementary
49 files 1 and 2).
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All patients were given verbal and written information about the study, and after agreeing to have an informed consent form sent to them by mail, they all provided written informed consent. If the patient agreed to participate, she sent the informed consent form back using a prepaid envelope.

Table 1. Demographic and clinical characteristics of the participants in the control group (n=20) and intervention group (n=21) in the RESPECT project.

Demographic characteristics	Control group n=20	Intervention group n=21
<i>Median age, years (range)</i>	65 (50-85)	66 (47-79)
<i>Civil status, n (%)</i>		
<i>Married/cohabiting</i>	12 (63%)	16 (76%)
<i>Single</i>	8 (37%)	5 (23%)
<i>Ancestral homeland, n (%)</i>		
<i>Sweden</i>	16 (80%)	18 (86%)
<i>Scandinavian countries</i>	1 (5%)	1 (5%)
<i>Europe</i>	1 (5%)	2 (10%)
<i>Outside Europe</i>	1 (5%)	0 (0%)
<i>Education, n (%)</i>		
<i>University</i>	9 (45%)	10 (48%)
<i>High school</i>	8 (40%)	8 (38%)
<i>Elementary school</i>	3 (15%)	3 (14%)
<i>Radiation therapy, n (%)</i>	16 (80%)	21 (100%)
<i>Tumor size, median mm (range)</i>	14 (4-45)	12 (1-19)
<i>Breast surgery</i>		
<i>Mastectomy</i>	4 (20%)	2 (10%)
<i>Partial mastectomy</i>	15 (75%)	19 (90%)
<i>Axillary lymph node dissection</i>	1 (0.5%)	0 (0%)
<i>Tamoxifen, n (%)</i>	9 (45%)	9 (43%)
<i>Aromatase inhibitor, n (%)</i>	11 (55%)	12 (57)

Control group

Usual care (UC) involves patients being allocated a contact nurse (an experienced undergraduate nurse or postgraduate nurse in surgical care), as the Swedish Patient Act ⁴⁰ gives patients a statutory right to permanent contact with a health care professional. Internationally, the role is called Clinical Nurse Specialist ⁴¹ and is identified as a valuable resource in cancer care ⁴².

Patients can contact the contact nurse all weekdays by telephone or by using a nationwide digital tool, 1177.se ⁴³. All patients receive written information as a brochure or a digital “My care and rehabilitation plan” when diagnosed with breast cancer. Support in usual care aims to give patients information about their state of health, available methods for examinations, care, and treatments, as well as information about at which time point she can expect to receive care and permanent contact with the health care provider. The contact nurse writes down the information that is available before surgery, such as tumor

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3 characteristics and surgery preparations. The patient can also write down questions to bring to upcoming
4 appointments. Usual care is based on patients' initiative to make contact.
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10 *Intervention group*

11 The intervention was provided in a surgical outpatient clinic in western Sweden from December 2020-
12 June 2021. The goal of the intervention was to empower patients prescribed ET to manage ET-related
13 symptoms and problems. In addition to UC, a 12-week intervention was offered to the participants in
14 the intervention group as described in a previous study ¹⁰. Figure 1 shows the care and measurement
15 chain for the control and intervention groups.
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22 *Step 1- Individual education material*

23 Using a PCC approach ¹⁹, the contact nurse listened to patients' narratives regarding their individual
24 needs for knowledge and understanding, resources, goals and needs for support from the contact nurse.
25 The timing of the supply of individual educational materials depended on the individual patient's needs,
26 resources and goals during the 12-week intervention. Mutual trust was demonstrated, and the
27 relationship between the patient and her contact nurse was reinforced through the assessment of the
28 commonly agreed upon individualized learning plan ⁴⁴.
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34 *Step 2 - An individualized learning plan (ILP)*

35 An ILP was established depending on the individual patient's needs for knowledge and understanding
36 about ET and considering the patient's resources, goals, and needs for education material and support
37 from the contact nurse. In combination with the individual educational materials (Step 1), a follow-up
38 plan was made using telephone and/or digital follow-up. Physical follow-ups were minimized as the
39 COVID-19 pandemic was ongoing. The number of follow-up sessions and whether relatives were to be
40 included during the 12-week intervention were agreed upon between the patient and the contact nurse.
41 Patients could also refuse all educational material and other materials and only use the contact nurse for
42 support.
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50 *Step 3 – A personalized reminder letter*

51 The third part of the support program was a personalized reminder letter after three months, including
52 contact information and an invitation for patients to make contact if needed.
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Education of the intervention nurse

The aim of the education was to increase the intervention nurse's knowledge and understanding of ET, its problems and symptom management using PCC. Microteaching^{45 46} sessions and seminars were used; the microteaching sessions were adapted to the specific needs of knowledge about endocrine therapy, side effects⁴⁷, pedagogy⁴⁸ and PCC^{19 49}, and the chosen approach was intended to help the contact nurse take responsibility for her own learning, i.e., student-centered learning⁵⁰. Additionally, practical exercises were used, as the contact nurse was able to practice her knowledge and understanding in a care setting and reflect on it, and the intervention nurse's curiosity was used as a motivator to gain knowledge⁴⁸. A full description of the education of the intervention nurse is reported in the online supplementary materials (Supplementary file 3).

Data collection

Data were collected from September 2020-June 2021. Feasibility outcomes were collected during the whole study period by the intervention nurse and were documented directly after every session in a trial log to secure the data collection⁵¹. The trial log contained a summary of the results of the feasibility criteria using Excel (Microsoft® Excel, version 16.50).

The three questionnaires were distributed by mail to patients in the control group (between September 2020 and December 2020) and the intervention group (December 2020 and March 2021). These three questionnaires were distributed at baseline, i.e., at the start of the intervention and ET, and three months after the start of the intervention.

The first questionnaire was the GSE, a 10-item (short form) psychometric scale that assesses optimistic self-beliefs to cope with a variety of demands in life. The GSE is a validated instrument that has been translated into Swedish⁵² and has previously been used with breast cancer patients⁵³. The total score is the mean value of respondents' answers to all items. High scores imply higher self-efficacy.

The second questionnaire was the QPP, a 45-item instrument that measures satisfaction in four dimensions: medical-technical competence, physical-technical conditions, identity-oriented approach, and sociocultural atmosphere^{54 55}. Moreover, to identify patients' views of whether the health care was adapted to their needs rather than health care routines, three items (*I was given the possibility to tell the medical staff how I experienced my situation; I was given the opportunity to participate in the planning of my care/treatment; I received the information I needed to be able to participate in decisions about my own care and treatment*) that were previously used by the Swedish SOM Institute were added⁵⁶. To calculate the execution index, each question is scored in terms of actual experience and subjective importance, each on a four-point Likert scale. The execution index score ranges from 1–7, where one is inadequate quality of care from the patient perspective and seven is good quality of care⁵⁷.

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3 The last questionnaire was the MSAS, a 32-question instrument for patients to rate their symptoms on
4 a 5-point Likert scale ^{58 59}. The instrument has been validated in Swedish breast cancer patients ⁵⁹ and
5 has previously been used with breast cancer patients ⁵³. The total MSAS score is the average of the
6 symptom scores for all 32 symptoms. Each symptom score is an average of the dimensions and includes
7 the number of symptoms, how often patients experienced them, the severity of the symptoms and the
8 cause of distress.
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13 *Feasibility outcomes*

14 In this study, feasibility outcomes were defined as the primary outcome. Craig et al. (2013) described
15 several challenging variables that can affect an intervention's results and conclusions. The feasibility
16 classification (process, resources, scientific) and feasibility criteria reported by Thabane et al. (2019)
17 and Lancaster et al. (2004) were used to collect feasibility data. Based on the recommendations for
18 feasibility studies and an expected attrition rate of 20%, the sample size was set to 20 participants in
19 each group ⁶⁰. To determine whether the chosen feasibility criteria were successful ⁶¹, criteria for success
20 were stated according to the CONSORT 2010 statement ³⁴.
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28 The intervention process was assessed with the feasibility criteria as follows:

- 29 1. Recruitment was studied to determine whether the patients were willing to participate in this
30 study. It has been suggested that the loss of participants should be less than 15% ⁶². The criterion
31 was determined to be successful if the percentage rates of recruitment were > 70%.
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- 33 2. Retention was studied to determine whether the patients were willing to remain for the entire
34 study period, i.e., 12 weeks. The criterion was determined to be successful if the percentage
35 rates of retention were >70%.
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- 37 3. Compliance with the intervention protocol was studied to determine if the patients were offered
38 the three parts of the planned intervention, i.e., education materials, learning plan and
39 personalized letter. The criterion was determined to be successful if all three parts of the
40 intervention were offered.
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47 The resources used in the intervention were assessed with the feasibility criteria as follows:

- 48 4. The form of educational support was studied to determine the preferred form of educational
49 support during the intervention period, i.e., 12 weeks. The criterion was determined to be
50 successful if one of the three forms of educational support (face-to face, telephone, and digital)
51 were requested by the patients.
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- 53 5. The number of educational sessions was studied to determine how many educational
54 opportunities the patient used during the intervention period, i.e., 12 weeks. The criterion was
55 determined to be successful if no more than four education sessions were used by each patient.
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6. The length per education session was studied to determine how much time the patient spent in each education session. The criterion was determined to be successful if < 45 minutes was used per education session. The time was clocked by the intervention nurse.
7. The length between each education session was studied to determine how often women wanted to have education opportunities. The criterion was determined to be successful if there were no more than four weeks between each education session.
8. The distribution of education materials was studied to determine how much intervention materials the patients received during the study. The criterion was determined to be successful if the distribution of education materials was >70%.

The scientific challenges of the intervention were assessed with the following feasibility criteria:

9. The completion rate of questionnaires was studied to determine if the patient was willing to answer the questionnaires, i.e., at baseline and 12 weeks. The criterion was determined to be successful if the percentage rates of patient completion of questionnaires were > 70% at baseline and 12 weeks.
10. The estimated treatment effect was studied to determine if the selected instruments were appropriate to measure patients' self-efficacy, quality of care, and symptoms. The criterion was determined to be successful if there were any changes in the self-report measures between the first and second points of measurement.

Patients included in the study responded to the questionnaires and returned the questionnaires in a prepaid envelope.

Analysis

To analyze demographic variables, we used descriptive statistics (numbers, percentages, means, ranges). We calculated the percentage rates of recruitment, retention, and completion of questionnaires. We calculated the number, median and range of educational sessions, distribution of education materials, length per education session, and length between each education session. As the study was a feasibility test, no hypothesis testing was applied⁶³, but p values were calculated and presented to evaluate their relevance in a forthcoming RCT. Descriptive statistical analyses and the Mann–Whitney U test were performed to identify the experience of symptoms, satisfaction with care and perceived self-efficacy. P values below .05 were considered statistically significant, and all analyses were performed with IBM® SPSS® Statistics version 27 (IBM SPSS Statistics for Macintosh, Version 27.0).

RESULTS

Participant demographics

In the control group, the median age was 65 years, 80% of the participants were born in Sweden, 63% were cohabiting and 45% were prescribed tamoxifen. In the intervention group, the median age was 66 years, 86% were born in Sweden, 76% were cohabiting and 43% were prescribed tamoxifen (Table 1).

Feasibility classification and criteria

Feasibility outcomes are presented in line with the CONSORT 2010 statement as follows:

1. Recruitment

In the control group, 22 eligible patients were screened, and 20 were approached at the clinic, of whom 20 consented to participate (100%). In the intervention group, 44 patients were screened, of whom 24 were approached and 21 consented to participate (88%) (Table 1), and patients were enrolled from December 2020-April 2021. Of the three patients who did not consent to participate in the intervention group, two indicated the number of questions in the questionnaires to be a reason for not participating. One patient gave no reason for not participating.

2. Retention

In the intervention group, 20 patients completed the questionnaire (95%). One patient dropped out from the intervention because the study reminded her about breast cancer surgery, which she was trying to forget.

3. Compliance with the intervention protocol

In the first session, the patients' needs for knowledge and understanding, resources, goals and support from the contact nurse were identified in their narratives. Education material was offered accordingly using a written agreement between the patient and contact nurse and documented in the ILP. Patients decided with the contact nurse whether they needed knowledge. If they needed knowledge, they stated when they wanted the education materials and which parts. Their need for knowledge ranged between having everything sent after the first session and having some of the education material sent at the end of the intervention. Patients could state that they did not want any education material at the start of the intervention but would reevaluate their needs during the 12 weeks of the intervention. However, since the ILP was sent home with the patients, any changes in the plan had to be documented by the patient herself. Two patients received the education materials sent to them but did not want to read it, just to have it if they wanted to read it later. Seven patients did not want the intervention for the full 12-week

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3 period (33%) but stated that they would make contact if they needed further information during the
4 intervention. One patient wanted her partner to be included. Two patients in the intervention group did
5 not answer the telephone at the scheduled session, making the call attendance 90%. One patient
6 rescheduled a session for personal reasons. Thirty-three percent of the patients did not want follow-up
7 sessions during the full 12-week intervention. As 90% of the patients wanted all educational materials,
8 10% of the patients used only the contact nurse for support, and one hundred percent of the patients
9 received a personalized reminder letter (Table 2).

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12 Contact information and an invitation for patients (100%) to make contact if needed were sent after 12
13 weeks in the personalized letter. None of the patients made contact after the 12-week intervention, as
14 shown in Table 2.

15 16 17 18 19 *4. Resources*

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21 None of the patients wanted to have face-to-face sessions as educational support. In fact, several of the
22 patients stated that it was important to not have to come for appointments at the hospital. Reasons for
23 not wanting to come to the hospital were related to the COVID-19 pandemic as well as to perceptions
24 of appointments at the hospital being time consuming. All patients but one preferred telephone sessions.
25 If a patient had asked for a face-to-face follow-up session, this would have been managed accordingly,
26 with arrangements made to ensure safety in the context of the COVID-19 pandemic. Face-to-face
27 meetings at the hospital with patients were not prohibited but restricted. However, no patient-contact
28 nurse pairs participated in a face-to-face session; had they done so, both the patient and the contact nurse
29 would have had to wear face masks, and the contact nurse would have also had to wear a plastic face
30 shield to prevent transmission of the COVID-19 virus.

31 32 33 34 35 36 37 *5. Number of educational sessions*

38 The number of educational sessions ranged between two and four sessions (Table 2).

39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 *6. Length per education session*

Telephone support sessions ranged between 5 and 60 minutes, and digital support sessions ranged
between 30 and 45 minutes (Table 2) and were clocked by the intervention nurse.

7. Length between education sessions

The length between follow-up sessions ranged between 1 and 6 weeks (Table 2).

8. Distribution of education materials

All patients (100%) wanted part 1 of the individual education material. A further description of the
distribution is shown in Table 2.

9. Completion rate of questionnaires

In the control group, 95% completed the first questionnaires at baseline, as one patient questionnaire
was lost in the mail. At three months, 95% of patients responded to their surveys. In the intervention
group, 100% responded to the first questionnaires, and 86% responded to the follow-up questionnaires
after three months. At the first measurement point, two reminder messages were sent to three patients
in the intervention group before one patient was recorded as a drop out. At the second measurement

point, one reminder message was sent to six patients three weeks after the questionnaires were sent. A second reminder message was sent approximately two weeks later to five patients, and as two patients did not return their questionnaires, they were recorded as drop-outs. Two patients in the intervention group did not answer the telephone at the scheduled session, making the call attendance 90%. One patient rescheduled a session for personal reasons.

10. Estimated treatment effect

Differences between the control and intervention groups in perceived self-efficacy (0.5 and 0, $p=0.731$) and reported number of symptoms according to the MSAS (2 and 1, $p=0.724$) after 3 months were observed (Figure 2). Median differences at baseline and 3 months in the control group and intervention group are also reported in the online supplementary materials (Supplementary file 4).

Quality of care was measured using the QPP, and these results are shown in the online supplementary materials (Supplementary file 5). Overall, the patients in the control group had higher quality of care index scores than patients in the intervention group.

Table 2. Resource needs for the intervention

RESPECT	
Distributed educational material	
Individual educational material <i>Part 1</i> , <i>n</i>	21
Individual educational material <i>Part 2</i> , <i>n</i>	20
Individual educational material <i>Part 3</i> , <i>n</i>	19
Individual educational material <i>Part 4</i> , <i>n</i>	19
Individual educational material <i>Information about tamoxifen or aromatase inhibitors</i> , <i>n</i>	20
Additional educational material from patient needs:	
Complementary medicine, <i>n</i>	1
Sleep advice, <i>n</i>	1
Recommendations about internet sites:	
Sleep advice, <i>n</i>	2
Form of education and educational sessions per patient	
Face to face ($n=0$), median (range)	0 (-)
Telephone ($n=20$), median (range)	3 (2-4)
Digital ($n=1$), median (range)	1 (1)
Length (minutes) per session	
Telephone ($n=20$), median (range)	20 (5-60)
Digital ($n=1$), median (range)	30 (30-45)
Length of time (weeks) between each session	
Telephone follow-up education sessions, weeks, median (range)	4 (1-6)
Digital meeting follow-up sessions, weeks, median (range)	4 (-)
<i>Follow-up educational session</i>	
Time from 1 st session to 2 nd session, weeks, median (range)	2 (1-8)
Time from 2 nd session to 3 rd session, weeks, median (range)	4 (2-8)
Time from 3 rd session to 4 th session, weeks, median (range)	4 (2-5)

Please insert Figure 2 about here

DISCUSSION

The results show that the intervention was feasible regarding the classification process and resources. However, it was less feasible regarding scientific challenges. The recruitment methods used seem to be accurate and feasible for an RCT with the aim of empowering patients prescribed ET to manage ET-related symptoms and problems. As a before-and-after design was used, the risk of contamination between groups was minor, as the intervention nurse had minor clinical contact with the control group.

The most common problems reported by trial investigators were a lack of adherence to the trial protocol, difficulties with recruitment, data collection and the intervention itself ⁶⁴; however, during the intervention, the contact nurse succeeded in adhering to the trial protocol. Moreover, a weakness in interventions has been reported to be a lack of a theoretical approach ⁶⁵; to address this challenge, the present study was founded on a theoretical model ⁴⁷. Modeling was used to identify pit falls and barriers ⁶⁶. The contact nurse in the intervention pretested the intervention protocol in clinical meetings with patients before launching the support program. It is crucial for health care professionals to have deep insight into the theory and selected methods to increase patients' required knowledge about ET since no one will adhere to a protocol if the protocol is of no significance ⁴⁸. Moreover, a health care context is referred to as a complex adaptive system, as it contains a collection of individuals with the freedom to act in a way that is not always predictable and changes depending on the context. Moreover, a complex adaptive system has fuzzy boundaries, and health care professionals' priorities depend on, for example, their private lives and things they would not sacrifice to follow a study protocol ⁶⁷. These challenges need to be addressed, as the intervention is to be applied in a care setting.

Furthermore, as the follow-up is flexible and the patients decided, in a partnership with the contact nurse, how many educational sessions were needed, the patient's individuality and resources were a focus, and no patient needed to acquire education than necessary. This needed flexibility is another component making the intervention a complex intervention. Moreover, the COVID-19 pandemic has increased the use of digital follow-up, which seems to be well liked among patients ⁶⁸⁻⁷⁰. Furthermore, face-to-face sessions were not prohibited during the intervention but were restricted due to the COVID-19 pandemic. If a patient would have asked for a face-to-face session, this would have been managed to not put the patient, fellow patients, or the contact nurse or other health care professionals in danger. However, we cannot specifically state that patients would prefer telephone sessions under other circumstances, but telephone follow-up seems to be suitable, as patients indicated physical appointments to be time

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3 consuming. A previous study also used telephone follow-up to increase confidence in controlling illness
4 in patients with chronic obstructive pulmonary disease with positive results in controlling symptoms
5 ($p=.028$)⁷¹, and telephone follow-ups were found to be well liked among registered nurses⁷². A previous
6 study using PCC also allowed patients to decide the number of follow-up sessions⁷³. Thus, this approach
7 could be a preferable way to administer the intervention and could also be more cost-effective, as
8 patients do not need to attend more sessions than needed; however, it needs to be evaluated further.
9 Furthermore, not all health care professionals have a PCC approach, which might affect the responses
10 to the questionnaires and the interpretation of the results. To manage this, the whole care chain needs to
11 structure its work according to PCC, as in a previous study²⁴.

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18 Moreover, the intervention protocol ranged over 12 weeks, as this period has been identified as the most
19 troublesome for patients with ET⁷⁴, and a previous study identified that the start of the ET period could
20 be preferable for an intervention³⁵. As 67% of the patients wanted education during the full 12-week
21 intervention, 12 weeks is indicated to be a suitable length for a support program in a future RCT.
22 However, an optional follow-up session after six months, when the patients have more experience with
23 ET, could be appropriate, but measures would need to be taken to help patients stay focused on ET when
24 responding to the questionnaires. A later session could also be preferable for patients who do not want
25 to be educated during the first months undergoing ET³⁵.

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32 To address scientific challenges, two measurement points were used, baseline and three months after
33 being prescribed ET. In an RCT, additional measurement points could be added at six and 12 months.
34 However, there were no differences in self-efficacy between the control and intervention groups; rather,
35 both the control group and the intervention had high self-efficacy scores at baseline, indicating that the
36 ceiling level was reached. Higher education implies higher self-efficacy⁷⁵ ($p=.017$)⁷⁶. In the present
37 study, 45% of the patients in the control group and 48% of the patients in the intervention group had
38 university education, indicating that the GES may not be suitable as an instrument. General self-efficacy
39 has been increased using PCC in a previous study in patients with acute coronary syndrome⁷³, indicating
40 that breast cancer patients could also benefit from PCC. This is of importance, as low self-efficacy has
41 been identified as a predictor of terminating ET prematurely⁷⁷ due to beliefs about its low influence on
42 health or low satisfaction with involvement in health care⁷⁷.

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51 The study had some limitations. As the COVID-19 pandemic was ongoing, there were restrictions on
52 the patients' ability to have face-to-face sessions with the trial leader. However, several patients stated
53 that they would participate only if there were no mandatory sessions at the hospital. The patients also
54 had the possibility of having their sessions using a digital conference system. As the intervention contact
55 nurse and the participants almost never met in person, their relationships could have been affected.
56 However, a partnership was established between the patient and the trial leader using a PCC protocol.
57 This might have decreased the effect of not meeting in person. In a future RCT, it will be crucial for
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3 patients to have face-to-face relationships with the intervention contact nurse with whom they will build
4 partnerships. This study did not identify when the intervention should stop, as it was decided before the
5 intervention that it should last for 12 weeks. It might have been important for the patients in the
6 intervention to have given this important information. However, seven of the 21 patients did not use the
7 full 12-week intervention, which implies that a 12-week support program is suitable. No patient actively
8 asked for longer follow-up. All patients were allocated a contact nurse whom they could contact after
9 the intervention if further questions were answered.
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15 **Conclusion**

16 This intervention seems to be feasible regarding its process and resources and acceptable among
17 patients, as 95% completed the 12-week support program and 86% responded to the three-month
18 questionnaire. A telephone follow-up intervention seems to be the preferable way to administer the
19 intervention. However, for self-efficacy and symptoms, there were no differences in effect size between
20 the control and intervention groups, indicating that the intervention was less feasible regarding scientific
21 challenges.
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28 *Ethical approval*

29 Patients were informed that their participation was voluntary and could be terminated at any time
30 without consequences. They were also assured that their confidentiality would be respected throughout
31 the research process. This study was approved by the Swedish Ethical Review Authority (approval no
32 2020-03239).
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36 *Conflicts of Interest*

37 The authors report no conflicts of interest.
38

39 *Contributorship statement*

40 IH, SAK, ROB, CW: Conceptualization and design, IH, SAK, CW: Methodology, SAK: Data
41 collection, IH, SAK, CW, ROB, Formal analysis: IH, SAK, CW, ROB: Visualization, IH, SAK, CW,
42 ROB: Writing—review and editing.
43
44

45 *Data availability statement*

46 Data are available upon reasonable request.
47

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56 *Acknowledgments*

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Figure 1. The care and measurement chain for the control and intervention groups. Both groups received the content in the blue area (usual care).

Abbreviations: Endocrine therapy: ET, Individualized learning plan: ILP.

Figure 2. Baseline and 3-month difference measures in the control and intervention groups for self-efficacy and reported symptoms.

Abbreviations: no: number of symptoms, SE: self-efficacy, Often: how often the patient had a symptom, Severe: how severe the symptom usually experienced by the patient was, Distress: how much the experienced symptom distressed or bothered the patient.

Supplementary material:

Supplementary file 1. Retention - CONSORT flow diagram for the usual care group. Patients included September 2020-December 2021.

Supplementary file 2. Retention - CONSORT flow diagram for the person-centered support program group. Patients included December 2020-March 2021.

Supplementary file 3. Description of the education of the intervention nurse.

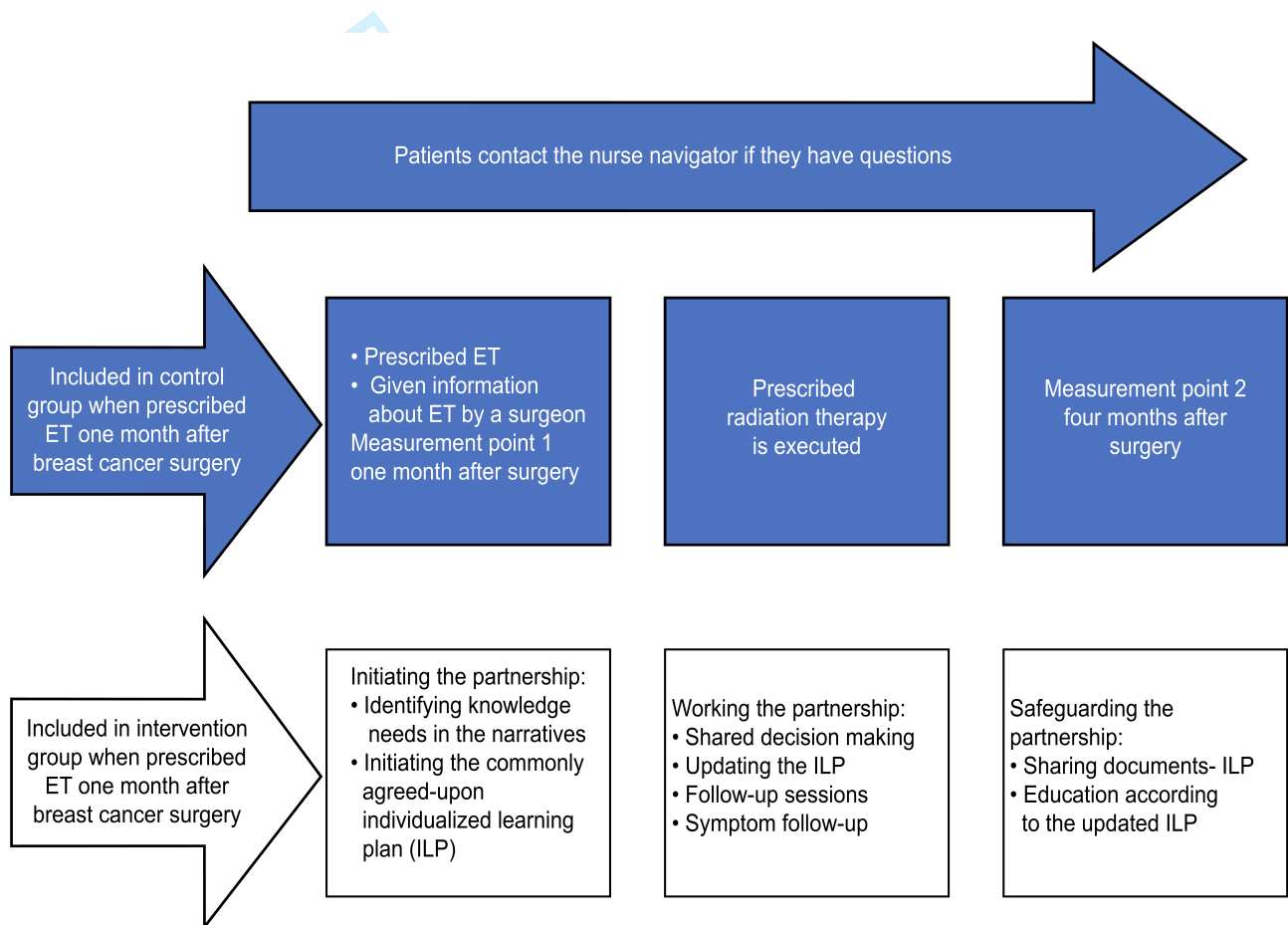
Supplementary file 4. Median differences at baseline and 3 months in the control group and intervention group.

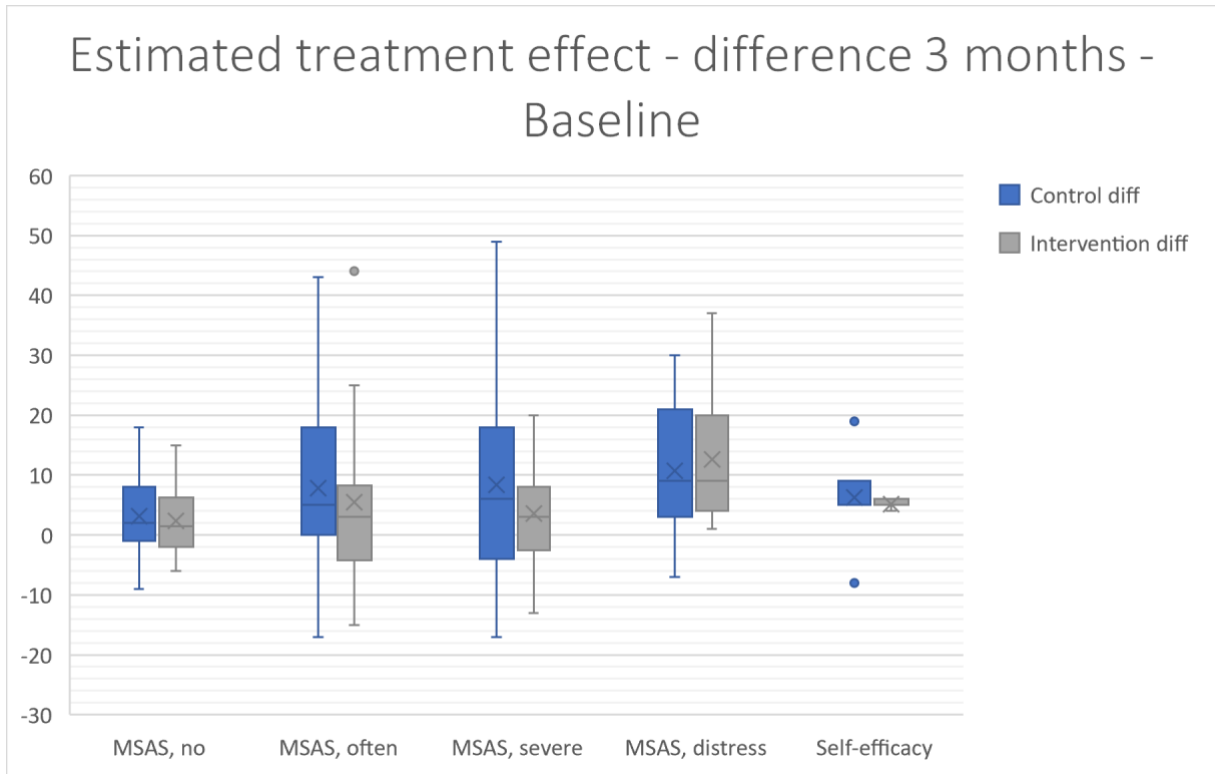
Supplementary file 5. Interpretation of the QPP – Percentage agreement in a selection of QPP questions

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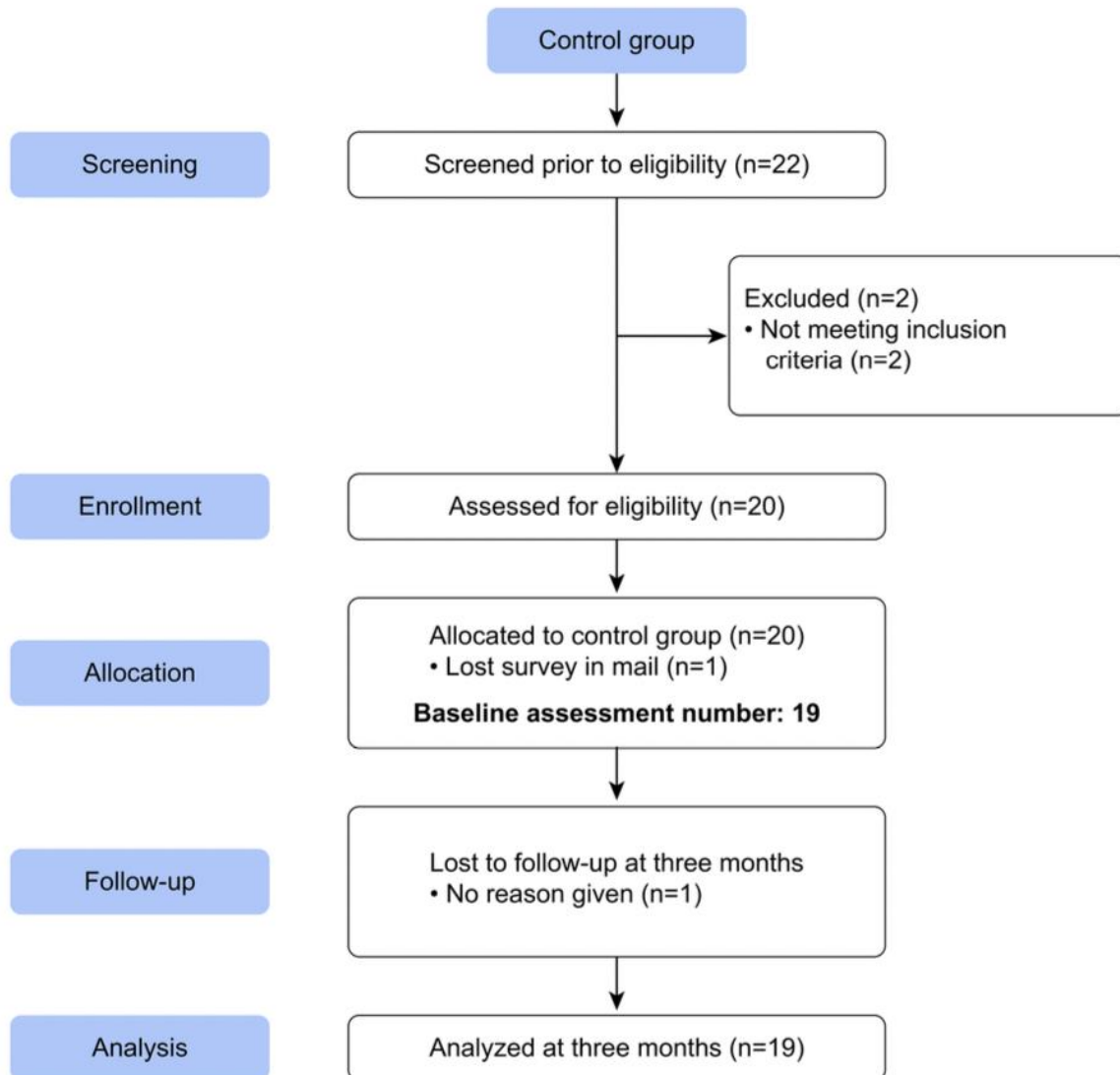
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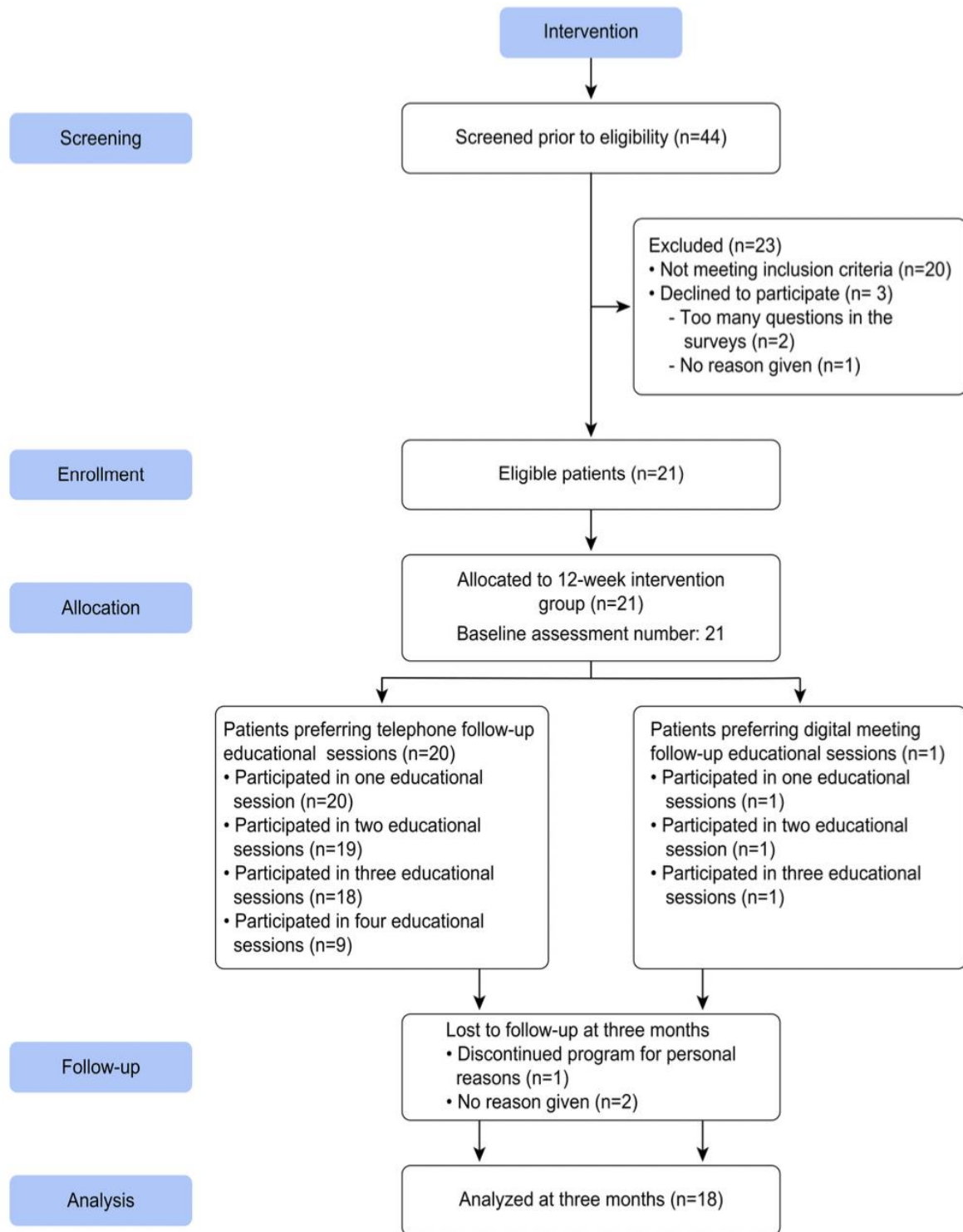


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45 Supplementary file 1. Retention - CONSORT Flow diagram for the usual care group. Patients included
46 September 2020 – December 2021.



Supplementary file 2. Retention - CONSORT flow diagram for the person-centered support program group. Patients included December 2020 – March 2021.

Supplementary file 3. Description of the education of the intervention nurse.

Before Lecture: The intervention nurse is asked to specifically reflect on the following in the care setting: <i>Problems with endocrine therapy</i> <i>Symptom management</i> <i>Cocreation with patients, barriers, facilitators.</i>			
Sessions	Content	Learning outcomes	Learning activities
1	Core principles about endocrine therapy (ET ¹), including side effects of ET and symptom management described in research. Symptom management theory.	-Describe symptom management methods. -Suggest strategies for symptom management during ET.	Clinical case discussions, microteaching sessions, dialogs, reflection.
Before Lecture: The intervention nurse is asked to reflect on practical situations in the care setting when <i>applying dialog and person-centered care (PCC²)</i> .			
Session	Content	Learning outcomes	Learning activities
2	Pedagogical theory.	- Describe pedagogic strategies using dialog to increase patients' self-care. - Describe pedagogical strategies to increase patient participation. - Describe dialogical methodology that strengthens patient participation. -Evaluate whether chosen pedagogical strategies increase patients' self-management ability.	Clinical case discussions, microteaching sessions, dialogs, reflection.
Before Lecture: The intervention nurse is asked to reflect on practical situations in the care setting using knowledge from Session 2 and <i>relate to PCC</i> in a care setting.			
Session	Content	Learning outcomes	Learning activities
3	PCC in the clinical care setting.	-Describe PCC.	Clinical case discussions, microteaching sessions, dialogs, reflection.
Before Lecture: The intervention nurse evaluates the <i>gained knowledge about PCC</i> in a practical situation in the care setting.			
Session	Content	Learning outcomes	Learning activities
4	The three intervention components, i.e., individual education material, individualized learning plan, and a personalized reminder letter (Ahlstedt Karlsson et al. 2022) with a starting point in the contact nurse's experience from a practical situation in the clinical setting.	-Explain the components of the intervention.	Clinical case discussions, dialogs, reflection.
After Lecture: With a starting point in the newly gained knowledge, <i>apply PCC, knowledge about ET, pedagogical theory and the three components</i> in the intervention in a care setting.			
Proficiency goal after completed education: The intervention nurse can: - Evaluate whether the proposed symptom management strategies increase the patient's management of ET-related symptoms. - Assess whether the patient's need for care was met. - Review and evaluate whether selected pedagogical strategies strengthen the patient's self-care ability. - Evaluate the patient's participation in ET symptom management.			
Evaluation ability after completed education: The intervention nurse can: - Suggest strategies for managing symptoms in relation with ET. - Together with the patient, identify care needs. - Apply pedagogical strategies that strengthen patients' self-care ability. - Apply dialogical methodology that strengthens patients' participation.			

Abbreviations: ET: Endocrine therapy, PCC: Person-centered care.

Supplementary file 4. Median differences at baseline and 3 months in the control group and intervention group.

	Control			Intervention			p value*
	Baseline no, Median (IQR)	3 months, Median (IQR)	Change from baseline (median)	Baseline no, Median (IQR)	3-month no, Median (IQR)	Change from baseline (median)	
SE, median (IQR)	31 (27-40)	31 (22-39)	0.5	30 (26-35)	30 (30-38)	0	0.731
MSAS, no median (IQR)	6 (3-11)	9 (3-18)	2	7 (3-13)	10 (5-22)	1	0.724
MSAS, often, median (IQR)	11 (2-36)	13 (6-38)	7.5	14 (4-25)	15 (7-49)	2	0.504
MSAS, severe, median (IQR)	12 (0-26)	13 (5-52)	5	10 (3-23)	13 (6-40)	2	0.393
MSAS, distress, median (IQR)	11 (0-28)	12 (3-30)	5.5	8 (2-19)	12 (6-39)	2	0.600

*Mann–Whitney U test comparing changes from baseline between the control and intervention groups.

Abbreviations: Often: how often the patient had a symptom, Severe: how severe the symptom usually experienced by the patient was, Distress: how much the experienced symptom distressed or bothered the patient.

Supplementary file 5. Interpretation of the QPP – Percentage agreement in a selection of QPP questions

	Control 3 months, n (%)	Intervention 3 months, n (%)
13. I received useful information on what I needed to be able to participate in my own care	16* (93.75%)	17* (88.24%)
19. I had adequate information about my medicines, so I understood the effect and how to use them	18* (77.78%)	18* (72.22%)
20. I had an opportunity to share my experience with health care professionals	15* (86.67%)	17* (82.35%)
32. I had a good opportunity to confer in decisions about my own care	14* (85.71%)	15* (73.33%)
33. I had a good opportunity to participate in my own care	15* (86.67%)	12* (75.00%)
34. My care was directed by my needs rather than the health care professionals' routines	16* (100%)	17* (82.35%)

*Caution: If less than 30, the results should be regarded with caution.

To measure perceived reality concerning the quality of care, every question was phrased as a statement. The response alternatives were given on a scale between 4 (Fully agree) and 1 (Do not agree at all).

Percentage in agreement represents the patients who answered 3 (Mostly agree) and 4 (Fully agree) divided by the total number of patients who answered 1-4 on the question. Answer 5 (Not applicable) is not included.



CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	4
	2b	Specific objectives or research questions for pilot trial	5
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6
	4c	How participants were identified and consented	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-7
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	8
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	NA
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	NA
Sample size	7a	Rationale for numbers in the pilot trial	7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	NA
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	NA
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	NA

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	NA
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	NA
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	9
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	10
	13b	For each group, losses and exclusions after randomisation, together with reasons	10
Recruitment	14a	Dates defining the periods of recruitment and follow-up	10
	14b	Why the pilot trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	Figure 1 and 2. Supplementary file
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	NA
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
	19a	If relevant, other important unintended consequences	NA
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	14
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	13
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	13
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	14
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	NA
Protocol	24	Where the pilot trial protocol can be accessed, if available	NA
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	15

	26	Ethical approval or approval by research review committee, confirmed with reference number	15
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Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *BMJ*. 2016;355.
 *We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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