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

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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 mortality [1]. A previous study reported that up to 91% of patients experience side effects from ET [2], such as sleeping difficulties, hot flashes [3 4] and musculoskeletal symptoms [5]. Difficulties in managing these side effects have been reported to be obstacles to staying in treatment [6]. Other challenges that have been identified include older age [7], medicine costs, or a general dislike of taking a regular medicine [8]. As ET is a long-lasting treatment, women may request support in managing challenges [9]. To manage challenges with ET, a partnership with health care professionals could be appropriate, as a previous study [10] 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 ET [11-13]. 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 important [12]. 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 treatment [11]. Managing a disease and its additional challenges requires self-care knowledge and skills gained from a partnership with health care professionals [14]. Self-care involves the ability to both care for oneself and to achieve, promote and maintain optimal health [15]. 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 developed [10]. As self-care requires knowledge and skills [14], 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 individuals react to illness [14]. 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 partnership [17]. Patients are often motivated to engage in self-care, as they have personal interest in acquiring requisite knowledge and skills for performing self-care operations to reach their intended health goals [14]. It has been shown that when self-care capabilities increase [18], self-efficacy and adherence to ET also increase [19 20]. Self-efficacy constitutes the self-image of the person and affects how people experience and behave in specific situations [21]. Previous studies using PCC have improved patients' self-efficacy [22-24].

It is important for patients to not only identify accurate information but also assess and integrate the information to gain increased knowledge, self-efficacy, and self-care skills [10]. Moreover, in addition to the emotional needs identified by Kim et al. (2020), it is important to assess the amount of needed information and to explore patients' understanding of the diagnosis and treatment [25]. For written health education materials to be effective, the patient must be able to apply the new information to her own life. This can be achieved by providing understandable examples and presenting the information so the patient sees its relevance to her situation [26], as the ultimate reason for educating patients is to improve health [27].

A previous study developed a person-centered support program in collaboration among patients, health care professionals, researchers and managers with ET experience [10] and need to be tested in a feasibility study using the TIDieR checklist [28] and the CONSORT 2010 statement [29]. Previous studies have used feasibility studies prior to conducting a study in a larger setting [9 30]. The intervention was developed to encourage patients to be more actively involved in their care and wellbeing as partners with their nurse navigator [10].

Aim

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

The feasibility outcomes were as follows:

1. Determine recruitment rate
2. Assess the rate of retention
3. Explore whether the RESPECT intervention was delivered according to the protocol
4. Assess the preferred form of educational support
5. Assess the rate of education sessions
6. Assess the length per education session
7. Assess the length between each education session
8. Determine the distribution of education materials
9. Assess the completion rates of patient-report instruments, including of the General Self-efficacy Scale (GSE), the Quality from the Patient's Perspective questionnaire (QPP), and the Memorial Symptom Assessment Scale (MSAS)

10. Investigate whether self-efficacy, symptoms and satisfaction with care can be assessed appropriately by using the patient-report GSE, QPP, and MSAS.

METHODS

Study design

This was a feasibility trial using a controlled before-and-after design [31] to investigate the feasibility of the intervention, a person-centered support program aimed at empowering patients prescribed ET to manage ET-related symptoms and problems.

Patient and public involvement

Patients and health care professionals was involved in the design and development of the person-centered support model [10]. However, there was no patient involvement in the evaluation of the person-centered support model presented in this study.

Participants

Based on the recommendations for feasibility studies and an expected attrition rate of 20%, the sample size was set to 20 participants in each group [32]. Between September 2020 and June 2021, 66 potential female patients from one outpatient clinic at one university hospital in Sweden were identified as eligible for inclusion. The inclusion criteria were women > 18 years who had been diagnosed with breast cancer and treated with ET after surgery. Patients receiving adjuvant chemotherapy were excluded. All patients were contacted by a nurse navigator and were invited by telephone to participate in the study approximately three weeks after their surgery (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**
Median age, years (range)	65 (50-85)	66 (47-79)
Civil status, n (%) *Married/cohabiting* *Single*	 12 (63%) 8 (37%)	 16 (76%) 5 (23%)
Ancestral homeland, n (%) *Sweden* *Scandinavian countries* *Europe* *Outside Europe*	 16 (80%) 1 (5%) 1 (5%) 1 (5%)	 18 (86%) 1 (5%) 2 (10%) 0 (0%)
Education, n (%) *University* *High school* *Elementary school*	 9 (45%) 8 (40%) 3 (15%)	 10 (48%) 8 (38%) 3 (14%)
Radiation therapy, n (%)	16 (80%)	21 (100%)
Chemotherapy, n (%)	0 (0%)	0 (0%)
Tumor size, median mm (range)	14 (4-45)	12 (1-19)
Breast surgery *Mastectomy* *Partial mastectomy* *Axillary lymph node dissection*	 4 (20%) 15 (75%) 1 (0.5%)	 2 (10%) 19 (90%) 0 (0%)
Tamoxifen, n (%)	9 (45%)	9 (43%)
Aromatase inhibitor, n (%)	11 (55%)	12 (57)

Control group

Usual care (UC) involves patients being allocated a nurse navigator (an experienced undergraduate nurse or postgraduate nurse in surgical care), as the Swedish Patient Act [33] gives patients a statutory right to permanent contact with health care. Patients can contact the nurse navigator all weekdays by telephone or by using a national digital tool, 1177.se [34]. 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 a permanent contact with the health care. The nurse navigator writes down the information that is available before surgery, such as tumor characteristics and surgery preparations. The patient can also write down questions to bring to the oncoming appointments. Usual care is based on patients' initiative to make contact (Figure 3).

Intervention group

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

Step 1- Individual education material

Using a PCC approach [17], the nurse navigator listened to patients narratives regarding their individual needs for knowledge and understanding, resources, goals and needs for support from the nurse navigator. The timing of supplying individual educational materials depended on the individual patient's needs, resources and goals during the 12-week intervention. Mutual trust was demonstrated, and the relationship between the patient and her nurse navigator was reinforced through the assessment of the commonly agreed-upon individualized learning plan [35] study.

Step 2 - An individualized learning plan (ILP)

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

Step 3 – A personalized reminder letter

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

Please insert Figure 3 about here

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 effects [10], pedagogy [38] 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 learning [40]. 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 knowledge [38] (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: *Problems with endocrine therapy* *Symptom management* *Cocreation with patients, barriers, facilitators*.			
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 *applying dialog* and *person-centered care (PCC).*			
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 *relate to PCC* 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 *gained knowledge about PCC* 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, *apply PCC, knowledge about ET, pedagogical theory and the three components* 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 successful [41], criteria for success were stated according to the CONSORT 2010 statement [29];

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 collection [42]. 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 Swedish [43] and has previously been used with breast cancer patients [44]. 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*

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 added [47]. 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 care [48].

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

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 applied [51], but p-values were calculated and presented to value their relevance in an RCT. Baseline characteristic were compared by the chi-squared test for categorical characteristics. 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. One hundred percent of the patients in both groups had invasive breast cancer (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). 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 (Figure 1, 2).

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 (Figure 1).

3. Compliance with the intervention protocol

In the first session, the patients' needs for knowledge and understanding, resources, goals and support from the nurse navigator were identified in their narratives. Education material was offered accordingly using a written agreement between the patient and nurse navigator and documented in the ILP. Patients decided with the nurse navigator 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 materials, 10% of the patients used only the nurse navigator for support and one hundred percent of the patients received a personalized reminder letter (Table 3).

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

4. Resources

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

5. Number of educational sessions

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

6. Length per education session

Telephone support sessions ranged between 5 and 60 minutes, and digital support ranged between 30 and 45 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 questionaries

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 *Part 1, n*	21
Individual educational material *Part 2, n*	20
Individual educational material *Part 3, n*	19
Individual educational material *Part 4, n*	19
Individual educational material	
Information about tamoxifen or aromatase inhibitors, n	
Additional educational material from the patient needs:	20
Complementary medicine, n	
Sleep advice, n	1
Recommendations about internet sites:	
Sleep advice, n	1
	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 1st session to 2nd session, weeks, median (range)	2 (1-8)
Time from 2nd session to 3rd session, weeks, median (range)	4 (2–8)
Time from 3rd session to 4th session, weeks, median (range)	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 itself [52]; 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 approach [53]; to address this challenge, the presented study was founded on a theoretical model [10]. Modeling was used to identify pit falls and barriers [54]. 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 significance [38]. 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 [55]. 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 patients [56-58]. 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

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) [59], and telephone follow-ups found to be well liked among registered nurses [60]. A previous study using PCC also allowed patients to decide the number of follow-up sessions [61]. Thus, this approach could be a preferable way to administer the intervention and could also be more cost-effective, as patients do not need to attend more sessions than required; however, it needs to be evaluated further. Furthermore, all health care professionals do not have a PCC approach, which might affect the responses in the questionnaires and the interpretation of the results. To manage this, the whole care chain needs to structure their work according to PCC, as in a previous study [22].

Moreover, the intervention protocol ranged over 12 weeks, as this period has been identified as the most troublesome for patients with ET [62], and a previous study identified that the start of the ET period could be preferable for an intervention [30]. As 67% of the patients wanted education during the full 12-week intervention, 12 weeks is indicated to be a suitable length for a support program in a future RCT. However, an optional follow-up session after six months, when the patients have more experience with ET, could be appropriate, but measures would need to be taken to help patients stay focused on ET when responding to the questionnaires. A later session could also be preferable for patients who do not want to be educated during the first months undergoing ET [30].

To address scientific challenges, two measurement points were used, baseline and three months after being prescribed ET. In an RCT, additional measurement points could be added at six and 12 months. However, there were no differences in self-efficacy between the control and intervention groups; rather, both the control group and the intervention had high self-efficacy scores at baseline, indicating that the ceiling level was reached. Higher education implies higher self-efficacy [63] (p= .017) [64]. In the present study, 45% of the patients in the control group and 48% of the patients in the intervention group had university education, indicating that the GES may not be suitable as an instrument. General self-efficacy has been increased using PCC in a previous study in patients with acute coronary syndrome [61], indicating that breast cancer patients could also benefit from PCC. This is of importance, as low self-efficacy has been identified as a predictor of terminating ET prematurely [65] due to beliefs about its low influence on health or low satisfaction with involvement in health care [65]. However, as the patients involved in the development of the support program requested help with understanding ET [10], a future RCT could include a self-care questionnaire that could provide valuable information about patients' self-care capabilities. The participants in the previous study [10] could be assumed to have a high self-efficacy score, as they were well educated, but still required empowerment, which implies a more versatile and complex situation demanding new approaches and raising the question "Could patients have high scores in self-efficacy but still be vulnerable?" The high self-efficacy scores indicate that the patients in the intervention group might not have needed a support program, but they participated anyway for several sessions, which implies their need for support and knowledge. Situational vulnerability, caused by stressful circumstances such as cancer, has previously been identified. Even presumably empowered patients, such as physicians, were found to have difficulties remembering, understanding, and processing all information they received as patients [66], which is

highly interesting as it relates to this study's findings. Moreover, a modified version of a self-efficacy questionnaire to assess women's confidence regarding their ability to cope with symptoms [67] has been and will be used in a future RCT study [68 69]. Questions were added for the participants to rate their confidence in their ability to cope with eight symptoms (e.g., aches and pains, hot flashes, and sweating) on a 10-point scale ranging from 10 ("not confident") to 100 ("very confident") [68]. Furthermore, a modified empowerment scale [70] could be appropriate to use after adjustment to patients with ET.

Moreover, there was no difference in perceived symptoms, indicating either that the MSAS questionnaire was inadequate or that the knowledge itself did not decrease symptoms if patients did not use coping activities. The support program aims to educate and empower patients but does not evaluate whether they use their knowledge. It is also important to determine whether patients do use the coping strategies gained from the follow-up sessions, but the advice just does not work, in which case an adjustment in the provided education is needed. Additionally, it is important to identify whether coping demands could be overwhelming and decrease instead of increase quality of life, leading patients to not pursue coping strategies such as physical activities. This might be a topic to address before an RCT study, using interviews to evaluate participants' use of the gained knowledge.

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

Furthermore, there was no measurement regarding the number of contacts the patients in the control group had with their nurse navigator; in a future RCT, this must be controlled to evaluate the economic effectiveness of the intervention. Moreover, using the QPP for the three-month measurement point was troublesome, as patients also had undergone radiation therapy during the same period, and patients also stated that their responses addressed the whole care chain and not only the care given related to ET. This could imply the difficulty of interpreting data from the QPP at the second measurement point. Furthermore, according to the instrument owner, 30 patients in each group are required to interpret the data.

The MSAS was developed using 33 symptoms commonly associated with cancer [49], and it has been validated in the Swedish population using patients diagnosed with breast cancer and treated with chemotherapy, radiotherapy and ET [50]. However, a more specific questionnaire could be appropriate, more accurate and easier for patients to

complete, as the MSAS consists of three dimensions, and some of the participants did not provide responses for all three dimensions included in the questionnaire.

Conclusion

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

Conflicts of interest

The authors report no conflicts of interest.

Author Contributions

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

Ethical approval

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

Conflicts of Interest and Source of Funding

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Provenance and peer review

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Data availability statement

Data are available upon reasonable request.

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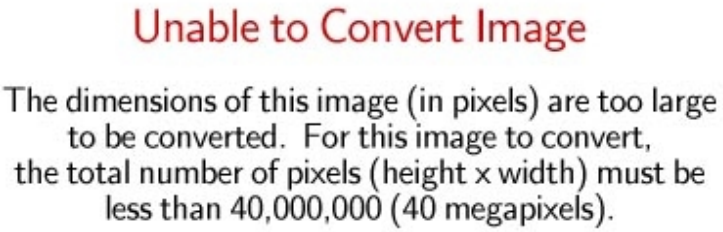
Figure 1. Retention - CONSORT Flow diagram for the usual care group. Patients included September 2020 – December 2021.

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

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.

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.



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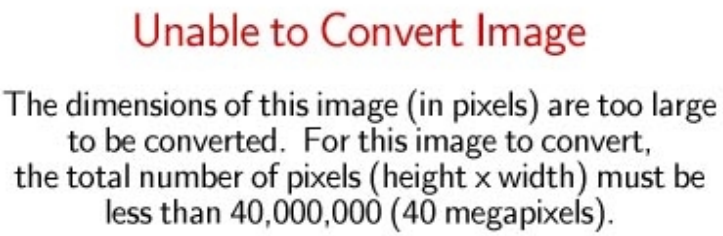
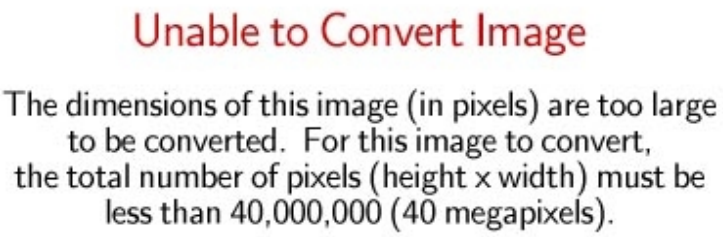


Figure 2. Retention - CONSORT flow diagram for the person-centered support program group. Patients included December 2020 – March 2021.



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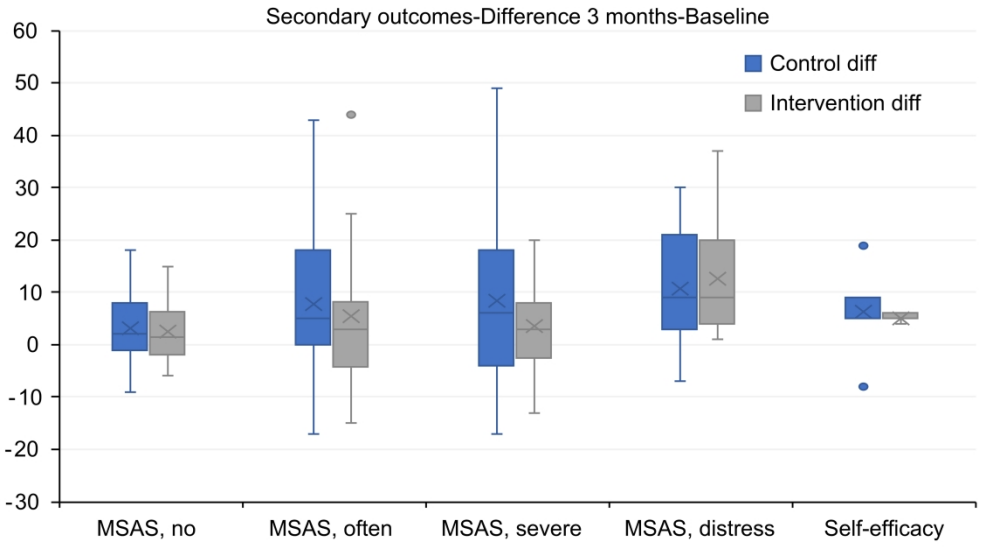

Figure 4. Secondary outcomes boxplot. Baseline and 3-month difference measures in the control and intervention groups for self-efficacy and reported symptoms.
Abbreviation: Number – no, Self-efficacy – SE.

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.

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		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			

Problem description	#3	Nature and significance of the local problem	4
Available knowledge	#4	Summary of what is currently known about the problem, including relevant previous studies	4
Rationale	#5	Informal or formal frameworks, models, concepts, and / or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work	5
Specific aims	#6	Purpose of the project and of this report	5
Methods			
Context	#7	Contextual elements considered important at the outset of introducing the intervention(s)	5
Intervention(s)	#08a	Description of the intervention(s) in sufficient detail that others could reproduce it	6
Intervention(s)	#08b	Specifics of the team involved in the work	6
Study of the Intervention(s)	#09a	Approach chosen for assessing the impact of the intervention(s)	8
Study of the Intervention(s)	#09b	Approach used to establish whether the observed outcomes were due to the intervention(s)	8
Measures	#10a	Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability	8
Measures	#10b	Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost	8
Measures	#10c	Methods employed for assessing completeness and accuracy of data	8
Analysis	#11a	Qualitative and quantitative methods used to draw inferences from the data	9
Analysis	#11b	Methods for understanding variation within the data, including the effects of time as a variable	9

Ethical considerations	#12	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest	15
Results			
	#13a	Initial steps of the intervention(s) and their evolution over time (e.g., time-line diagram, flow chart, or table), including modifications made to the intervention during the project	1-3
	#13b	Details of the process measures and outcome	10-11
	#13c	Contextual elements that interacted with the intervention(s)	10-11
	#13d	Observed associations between outcomes, interventions, and relevant contextual elements	10-11
	#13e	Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s).	10-11
	#13f	Details about missing data	10-11 + tables
Discussion			
Summary	#14a	Key findings, including relevance to the rationale and specific aims	12
Summary	#14b	Particular strengths of the project	12
Interpretation	#15a	Nature of the association between the intervention(s) and the outcomes	12-13
Interpretation	#15b	Comparison of results with findings from other publications	12-13
Interpretation	#15c	Impact of the project on people and systems	13
Interpretation	#15d	Reasons for any differences between observed and anticipated outcomes, including the influence of context	13
Interpretation	#15e	Costs and strategic trade-offs, including opportunity costs	NA
Limitations	#16a	Limits to the generalizability of the work	13
Limitations	#16b	Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis	14
Limitations	#16c	Efforts made to minimize and adjust for limitations	14

Conclusion	#17a	Usefulness of the work	14
Conclusion	#17b	Sustainability	14
Conclusion	#17c	Potential for spread to other contexts	14
Conclusion	#17d	Implications for practice and for further study in the field	14
Conclusion	#17e	Suggested next steps	14
Other information			
Funding	#18	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting	15

Notes:

- 13f: 10-11 + tables 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

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.

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

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Keywords: Breast cancer, endocrine therapy, intervention, feasibility, person-centered support program

Wordcount: 5590

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 mortality [1]. A previous study reported that up to 91% of patients experience side effects from ET [2], such as sleeping difficulties, hot flashes [3 4] and musculoskeletal symptoms [5]. Difficulties in managing these side effects have been reported to be obstacles to staying in treatment [6]. Other challenges that have been identified include older age [7], medicine costs, or a general dislike of taking a regular medicine [8]. As ET is a long-lasting treatment, women may request support in managing challenges [9]. To manage challenges with ET, a partnership with health care professionals could be appropriate, as a previous study [10] 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 ET [11-13]. 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 important [12]. 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 treatment [11]. 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 life [14] Also, training has not been found to have effect on musculoskeletal symptoms in patients treated with AIs [15]. Managing a disease and its additional challenges requires self-care knowledge and skills gained from a partnership with health care professionals [16]. Self-care involves the ability to both care for oneself and to achieve, promote and maintain optimal health [17]. 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 developed [10]. As self-care requires knowledge and skills [16], 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

individuals react to illness [16]. 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 partnership [19]. Patients are often motivated to engage in self-care, as they have personal interest in acquiring requisite knowledge and skills for performing self-care operations to reach their intended health goals [16]. It has been shown that when self-care capabilities increase [20], self-efficacy and adherence to ET also increase [21 22]. Self-efficacy constitutes the self-image of the person and affects how people experience and behave in specific situations [23]. Previous studies using PCC have improved patients' self-efficacy [24-26].

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

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

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

Aim

In this feasibility trial, the aim was to explore the feasibility of the study design and the patient acceptability of the peRson-cEntred Support Program EndoCrine Therapy (RESPECT) intervention and

outcome measures and to provide data to estimate the parameters required to design the final intervention.

The feasibility outcomes, i.e., primary outcomes, were as follows:

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

METHODS

Study design

This was a feasibility trial using a controlled before-and-after design [36] to investigate the feasibility of the intervention, a person-centered support program aimed at empowering patients prescribed ET to manage ET-related symptoms and problems.

Patient and public involvement

Patients and health care professionals was involved in the design and development of the person-centered support model [10]. However, there was no patient involvement in the evaluation of the person-centered support model presented in this study.

Participants

Between September 2020 and June 2021, 66 potential female patients from one outpatient clinic at one university hospital in Sweden were identified as eligible for inclusion. The inclusion criteria were women > 18 years who had been diagnosed with breast cancer and treated with ET after surgery. Patients receiving adjuvant chemotherapy were excluded as the study aimed to investigate an intervention targeting patients treated with ET. All patients were contacted by a contact nurse and were invited by

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**
Median age, years (range)	65 (50-85)	66 (47-79)
Civil status, n (%) *Married/cohabiting* *Single*	 12 (63%) 8 (37%)	 16 (76%) 5 (23%)
Ancestral homeland, n (%) *Sweden* *Scandinavian countries* *Europe* *Outside Europe*	 16 (80%) 1 (5%) 1 (5%) 1 (5%)	 18 (86%) 1 (5%) 2 (10%) 0 (0%)
Education, n (%) *University* *High school* *Elementary school*	 9 (45%) 8 (40%) 3 (15%)	 10 (48%) 8 (38%) 3 (14%)
Radiation therapy, n (%)	16 (80%)	21 (100%)
Tumor size, median mm (range)	14 (4-45)	12 (1-19)
Breast surgery *Mastectomy* *Partial mastectomy* *Axillary lymph node dissection*	 4 (20%) 15 (75%) 1 (0.5%)	 2 (10%) 19 (90%) 0 (0%)
Tamoxifen, n (%)	9 (45%)	9 (43%)
Aromatase inhibitor, n (%)	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 [37] gives patients a statutory right to permanent contact with health care. Internationally the role is called Clinical Nurse Specialist [38], and are identified to be a valuable recourse in cancer care [39].

Patients can contact the contact nurse all weekdays by telephone or by using a national digital tool, 1177.se [40]. 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 a permanent contact with the health care. The contact nurse writes down the information that is available before surgery, such as tumor characteristics and surgery preparations. The patient can also write down questions to bring to the oncoming appointments. Usual care is based on patients' initiative to make contact (Figure 3).

Intervention group

The intervention was provided in a surgical outpatient clinic in western Sweden from December 2020-June 2021. The goal of the intervention is to empower patients prescribed ET to manage ET-related symptoms and problems. In addition to the UC, a 12-week intervention was offered to the participants in the intervention group (Figure 3) as described in a previous study [10]:

Step 1- Individual education material

Using a PCC approach [19], the contact nurse listened to patients narratives regarding their individual needs for knowledge and understanding, resources, goals and needs for support from the contact nurse. The timing of supplying individual educational materials depended on the individual patient's needs, resources and goals during the 12-week intervention. Mutual trust was demonstrated, and the relationship between the patient and her contact nurse was reinforced through the assessment of the commonly agreed-upon individualized learning plan [41] study.

Step 2 - An individualized learning plan (ILP)

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

Step 3 – A personalized reminder letter

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

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 effects [44], pedagogy [45] 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 learning [47]. 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 knowledge [45] (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: *Problems with endocrine therapy* *Symptom management* *Cocreation with patients, barriers, facilitators.*			
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 *applying dialog* and *person-centered care (PCC[2]).*			
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 *relate to PCC* 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 *gained knowledge about PCC* 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, *apply PCC, knowledge about ET, pedagogical theory and the three components* 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 – ET[1], [2] Person-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 collection [48]. 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 Swedish [49] and has previously been used with breast cancer patients [50]. 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*

my own care and treatment) that were previously used by the Swedish SOM institute were added [53]. 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 care [54].

The last questionnaire was the MSAS, a 32-question instrument for patients to rate their symptoms on a 5-point Likert scale [55 56]. The instrument has been validated in Swedish breast cancer patients [56] and has previously been used with breast cancer patients [50]. The total MSAS score is the average of the symptom scores for all 32 symptoms. Each symptom score is an average of the dimensions and includes the number of symptoms, how often patients experienced them, the severity of the symptoms and the cause of distress.

Feasibility outcomes

In this study, feasibility outcomes are defined as primary outcome. 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. Based on the recommendations for feasibility studies and an expected attrition rate of 20%, the sample size was set to 20 participants in each group [57]. To determine whether the chosen feasibility criteria were successful [58], criteria for success were stated according to the CONSORT 2010 statement [34];

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. It has been suggesting that the loss of participants should be less than 15% [59]. 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

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 applied [60], 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 (Figure 1, 2).

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 (Figure 1).

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

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

4. *Resources*

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

5. *Number of educational sessions*

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

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 3) and was clocked by the intervention nurse.

7. *Length between education sessions*

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

8. *Distribution of education materials*

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

9. *Completion rate of questionaries*

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 *Part 1, n*	21
Individual educational material *Part 2, n*	20
Individual educational material *Part 3, n*	19
Individual educational material *Part 4, n*	19
Individual educational material *Information about tamoxifen or aromatase inhibitors, 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 1st session to 2nd session, weeks, median (range)	2 (1-8)
Time from 2nd session to 3rd session, weeks, median (range)	4 (2–8)
Time from 3rd session to 4th 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 itself [61]; 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 approach [62]; to address this challenge, the presented study was founded on a theoretical model [44]. Modeling was used to identify pit falls and barriers [63]. 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 [45]. 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 [64]. 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 patients [65-67]. 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 nurses [69]. A previous study using PCC also allowed patients to decide the number of follow-up sessions [70]. Thus, this approach could be a preferable way to administer the intervention and could also be more cost-effective, as

patients do not need to attend more sessions than required; however, it needs to be evaluated further. Furthermore, all health care professionals do not have a PCC approach, which might affect the responses in the questionnaires and the interpretation of the results. To manage this, the whole care chain needs to structure their work according to PCC, as in a previous study [24].

Moreover, the intervention protocol ranged over 12 weeks, as this period has been identified as the most troublesome for patients with ET [71], and a previous study identified that the start of the ET period could be preferable for an intervention [35]. As 67% of the patients wanted education during the full 12-week intervention, 12 weeks is indicated to be a suitable length for a support program in a future RCT. However, an optional follow-up session after six months, when the patients have more experience with ET, could be appropriate, but measures would need to be taken to help patients stay focused on ET when responding to the questionnaires. A later session could also be preferable for patients who do not want to be educated during the first months undergoing ET [35].

To address scientific challenges, two measurement points were used, baseline and three months after being prescribed ET. In an RCT, additional measurement points could be added at six and 12 months. However, there were no differences in self-efficacy between the control and intervention groups; rather, both the control group and the intervention had high self-efficacy scores at baseline, indicating that the ceiling level was reached. Higher education implies higher self-efficacy [72] (p= .017) [73]. In the present study, 45% of the patients in the control group and 48% of the patients in the intervention group had university education, indicating that the GES may not be suitable as an instrument. General self-efficacy has been increased using PCC in a previous study in patients with acute coronary syndrome [70], indicating that breast cancer patients could also benefit from PCC. This is of importance, as low self-efficacy has been identified as a predictor of terminating ET prematurely [74] due to beliefs about its low influence on health or low satisfaction with involvement in health care [74].

Moreover, there was no difference in perceived symptoms, indicating either that the MSAS questionnaire was inadequate or that the knowledge itself did not decrease symptoms if patients did not use coping activities. The support program aims to educate and empower patients but does not evaluate whether they use their knowledge. It is also important to determine whether patients do use the coping strategies gained from the follow-up sessions, but the advice just does not work, in which case an adjustment in the provided education is needed. Additionally, it is important to identify whether coping demands could be overwhelming and decrease instead of increase quality of life, leading patients to not pursue coping strategies such as physical activities. This might be a topic to address before an RCT study, using interviews to evaluate participants' use of the gained knowledge.

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

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

Furthermore, there was no measurement regarding the number of contacts the patients in the control group had with their contact nurse; in a future RCT, this must be controlled to evaluate the economic effectiveness of the intervention. Moreover, using the QPP for the three-month measurement point was troublesome, as patients also had undergone radiation therapy during the same period, and patients also stated that their responses addressed the whole care chain and not only the care given related to ET. This could imply the difficulty of interpreting data from the QPP at the second measurement point. Furthermore, according to the instrument owner, 30 patients in each group are required to interpret the data. Also, the patients in the intervention group was included when physical appointments was restrained which imply further difficulty to draw any conclusions from the presented results.

The MSAS was developed using 33 symptoms commonly associated with cancer [55], and it has been validated in the Swedish population using patients diagnosed with breast cancer and treated with chemotherapy, radiotherapy and ET [56]. However, a more specific questionnaire could be appropriate, more accurate and easier for patients to complete, as the MSAS consists of three dimensions, and some of the participants did not provide responses for all three dimensions included in the questionnaire.

Conclusion

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

Ethical approval

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

Conflicts of Interest

The authors report no conflicts of interest.

Contributorship statement

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

Availability statement

Data are available upon reasonable request.

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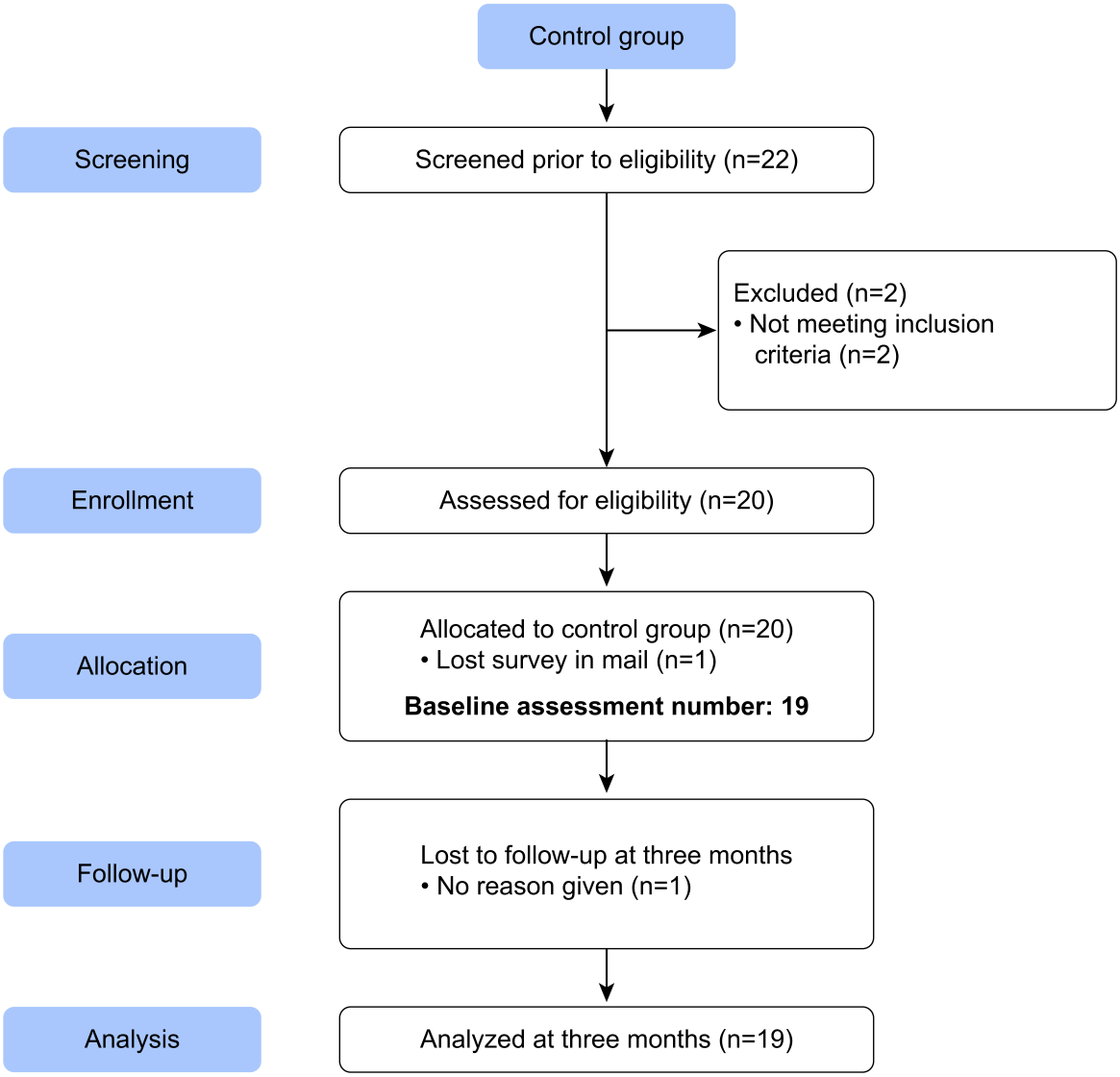
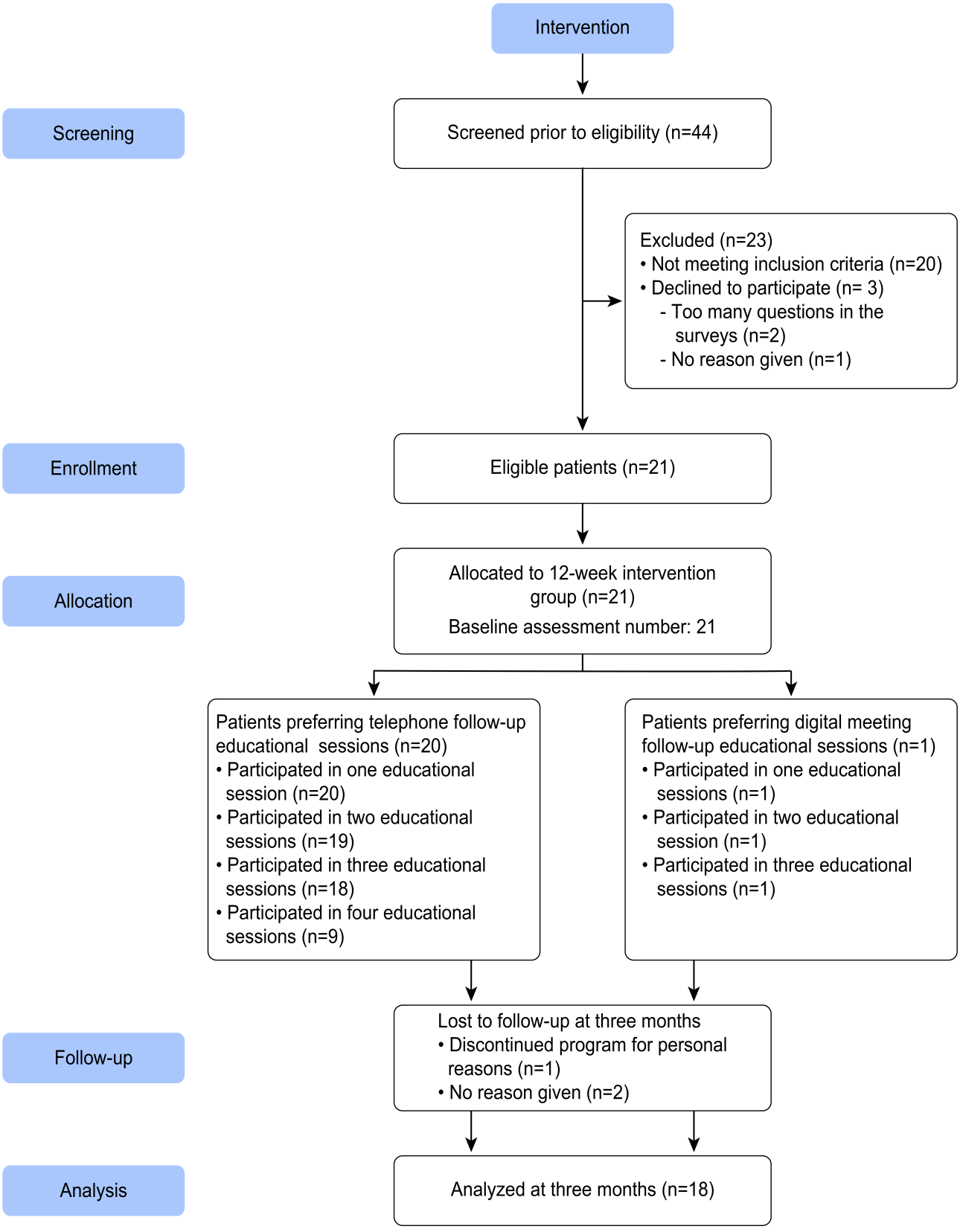
Figure 1. Retention - CONSORT Flow diagram for the usual care group. Patients included September 2020 – December 2021.

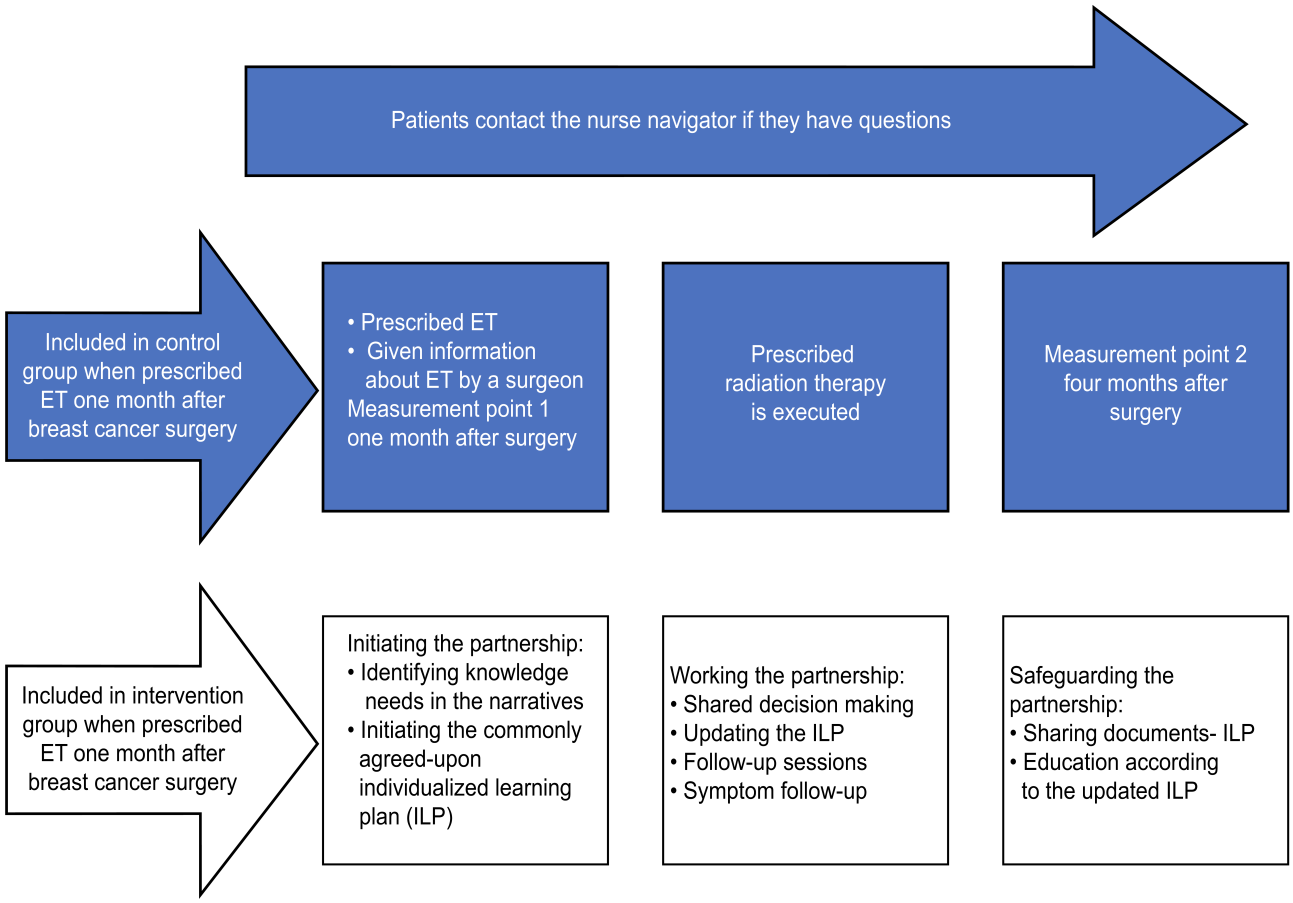
Figure 2. Retention - CONSORT flow diagram for the person-centered support program group. Patients included December 2020 – March 2021.

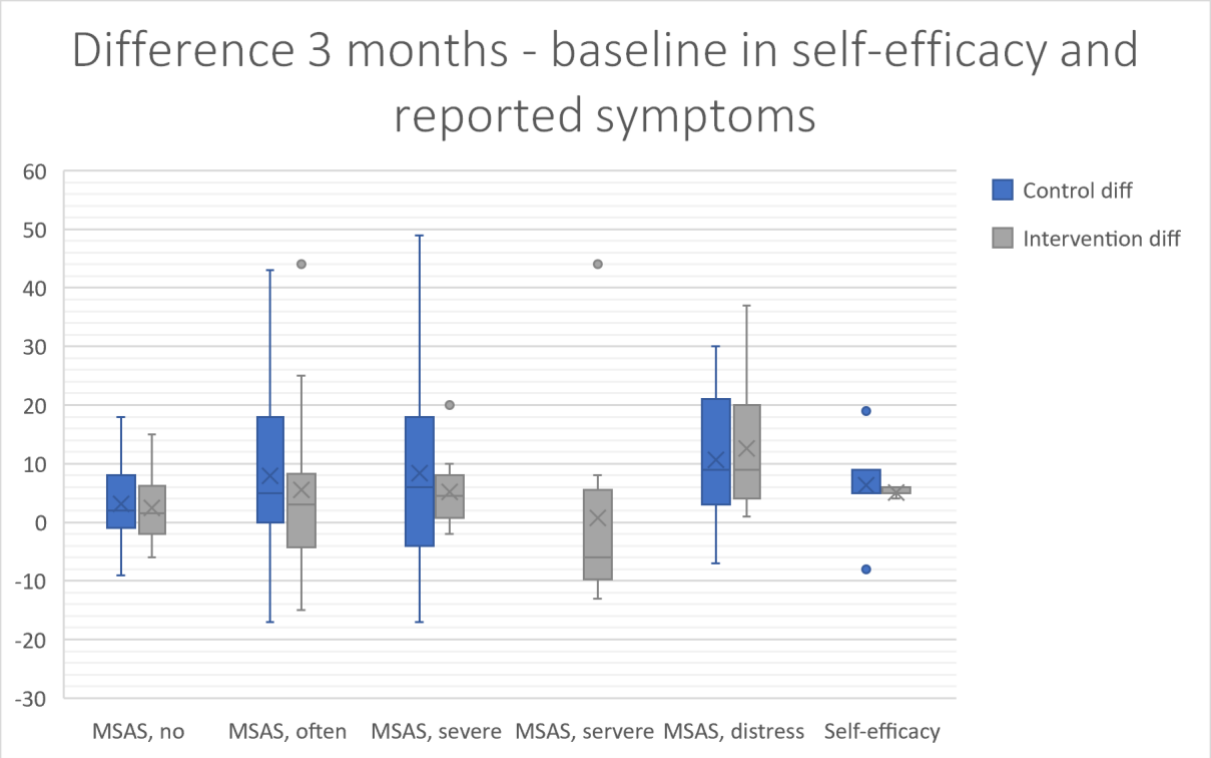
Figure 3. The care and measurement chain for the control and intervention groups. Both groups received the content in the blue area (usual care).
Abbreviations: Endocrine therapy – ET, Individual learning plan – ILP.

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


Control group
Screening
Screened prior to eligibility (n=22)
Excluded (n=2)
• Not meeting inclusion criteria (n=2)
Enrollment
Assessed for eligibility (n=20)
Allocation
Allocated to control group (n=20)
• Lost survey in mail (n=1)
Baseline assessment number: 19
Follow-up
Lost to follow-up at three months
• No reason given (n=1)
Analysis
Analyzed at three months (n=19)


Intervention
Screening
Screened prior to eligibility (n=44)
Excluded (n=23)
• Not meeting inclusion criteria (n=20)
• Declined to participate (n= 3)
- Too many questions in the surveys (n=2)
- No reason given (n=1)
Enrollment
Eligible patients (n=21)
Allocation
Allocated to 12-week intervention group (n=21)
Baseline assessment number: 21
Patients preferring telephone follow-up educational sessions (n=20)
• Participated in one educational session (n=20)
• Participated in two educational sessions (n=19)
• Participated in three educational sessions (n=18)
• Participated in four educational sessions (n=9)
Patients preferring digital meeting follow-up educational sessions (n=1)
• Participated in one educational sessions (n=1)
• Participated in two educational session (n=1)
• Participated in three educational sessions (n=1)
Follow-up
Lost to follow-up at three months
• Discontinued program for personal reasons (n=1)
• No reason given (n=2)
Analysis
Analyzed at three months (n=18)


Patients contact the nurse navigator if they have questions
Included in control group when prescribed ET one month after breast cancer surgery
• Prescribed ET
• Given information about ET by a surgeon
Measurement point 1 one month after surgery
Prescribed radiation therapy is executed
Measurement point 2 four months after surgery
Included in intervention group when prescribed ET one month after breast cancer surgery
Initiating the partnership:
• Identifying knowledge needs in the narratives
• Initiating the commonly agreed-upon individualized learning plan (ILP)
Working the partnership:
• Shared decision making
• Updating the ILP
• Follow-up sessions
• Symptom follow-up
Safeguarding the partnership:
• Sharing documents- ILP
• Education according to the updated ILP



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

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.

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

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Keywords: Breast cancer, endocrine therapy, intervention, feasibility, person-centered support program

Wordcount: 5299

ABSTRACT

Objective: The RESPECT intervention is considerate to be 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 mortality [1]. A previous study reported that up to 91% of patients experience side effects from ET [2], such as sleeping difficulties, hot flashes [3 4] and musculoskeletal symptoms [5]. Difficulties in managing these side effects have been reported to be obstacles to staying in treatment [6]. Other challenges that have been identified include older age [7], medicine costs, or a general dislike of taking a regular medicine [8]. As ET is a long-lasting treatment, women may request support in managing challenges [9]. To manage challenges with ET, a partnership with health care professionals could be appropriate, as a previous study [10] 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 ET [11-13]. 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 important [12]. 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 treatment [11]. 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 life [14] Also, training has not been found to have effect on musculoskeletal symptoms in patients treated with AIs [15]. Managing a disease and its additional challenges requires self-care knowledge and skills gained from a partnership with health care professionals [16]. Self-care involves the ability to both care for oneself and to achieve, promote and maintain optimal health [17]. 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 developed [10]. As self-care requires knowledge and skills [16], 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

individuals react to illness [16]. 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 partnership [19]. Patients are often motivated to engage in self-care, as they have personal interest in acquiring requisite knowledge and skills for performing self-care operations to reach their intended health goals [16]. It has been shown that when self-care capabilities increase [20], self-efficacy and adherence to ET also increase [21 22]. Self-efficacy constitutes the self-image of the person and affects how people experience and behave in specific situations [23]. Previous studies using PCC have improved patients' self-efficacy [24-26].

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

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

A previous study developed a person-centered support program in collaboration among patients, health care professionals, researchers and managers with ET experience [10] and need to be tested in a feasibility study using the TIDieR checklist [33] and the CONSORT 2010 statement [34]. Previous studies have used feasibility studies prior to conducting a study in a larger setting [9 35]. The intervention was developed to encourage patients to be more actively involved in their care and wellbeing as partners with their contact nurse [10]. It has been stated that an intervention could be considered as complex due to behaviors required by those delivering the intervention [36], i.e., a contact nurse. The complexity is caused by the context where the intervention are to be implemented in rather than the number of parts of the intervention [37]. It has been reported that complex interventions require engagements with the care context stakeholders, i.e., patients, and contact nurses, to be able to identify if the intervention could be acceptable, operable,

cost effective, possible to scale up, and transferable across contexts. The development phases are identified including developing or use an existing complex intervention, feasibility, evaluation, and implementation [38].

Aim

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

METHODS

Study design

This was a feasibility trial using a controlled before-and-after design [39] to investigate the feasibility of the intervention, a person-centered support program aimed at empowering patients prescribed ET to manage ET-related symptoms and problems.

Patient and public involvement

Patients and health care professionals was involved in the design and development of the person-centered support model [10]. However, there was no patient involvement in the evaluation of the person-centered support model presented in this study.

Participants

Between September 2020 and June 2021, 66 potential female patients from one outpatient clinic at one university hospital in Sweden were identified as eligible for inclusion when starting ET. The inclusion criteria were women > 18 years who had been diagnosed with breast cancer and treated with ET after surgery. Patients receiving adjuvant chemotherapy were excluded as the study aimed to investigate an intervention targeting patients treated with ET. All patients were contacted by a contact nurse and were invited by telephone to participate in the study approximately three weeks after their surgery when being prescribed ET (Table 1). In the online supplementary materials, the CONSORT flow diagram for the usual care group and person-centered support program group is available (Supplementary file 1 and 2).

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

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 a permanent contact with the health care. The contact nurse writes down the information that is available before surgery, such as tumor characteristics and surgery preparations. The patient can also write down questions to bring to the oncoming appointments. Usual care is based on patients' initiative to make contact.

Intervention group

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

Step 1- Individual education material

Using a PCC approach [19], the contact nurse listened to patients narratives regarding their individual needs for knowledge and understanding, resources, goals and needs for support from the contact nurse. The timing of supplying individual educational materials depended on the individual patient's needs, resources and goals during the 12-week intervention. Mutual trust was demonstrated, and the relationship between the patient and her contact nurse was reinforced through the assessment of the commonly agreed-upon individualized learning plan [44] study.

Step 2 - An individualized learning plan (ILP)

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

Step 3 – A personalized reminder letter

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

Please insert Figure 1 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 [45 46] sessions and seminars were used; the microteaching sessions were adapted to the specific needs of knowledge about endocrine therapy, side effects [47], pedagogy [48] 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 learning [50]. 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 knowledge [48]. 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 collection [51]. 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 Swedish [52] and has previously been used with breast cancer patients [53]. 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 [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 added [56]. 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 care [57].

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

Feasibility outcomes

In this study, feasibility outcomes are defined as primary outcome. 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. Based on the recommendations for feasibility studies and an expected attrition rate of 20%, the sample size was set to 20 participants in each group [60]. To determine whether the chosen feasibility criteria were successful [61], criteria for success were stated according to the CONSORT 2010 statement [34];

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. It has been suggesting that the loss of participants should be less than 15% [62]. 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 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 applied [63], 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

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

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

4. *Resources*

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

5. *Number of educational sessions*

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

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 was 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. Further description of the distribution is shown in Table 2.

9. *Completion rate of questionaries*

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 *Part 1, n*	21
Individual educational material *Part 2, n*	20
Individual educational material *Part 3, n*	19
Individual educational material *Part 4, n*	19
Individual educational material *Information about tamoxifen or aromatase inhibitors, 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 1st session to 2nd session, weeks, median (range)	2 (1-8)
Time from 2nd session to 3rd session, weeks, median (range)	4 (2–8)
Time from 3rd session to 4th 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 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 theoretical approach [65]; to address this challenge, the presented 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 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 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 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) [71], and telephone follow-ups found to be well liked among registered nurses [72]. A previous study using PCC also allowed patients to decide the number of follow-up sessions [73]. Thus, this approach could be a preferable way to administer the intervention and could also be more cost-effective, as patients do not need to attend more sessions than required; however, it needs to be evaluated further. Furthermore, all health care professionals do not have a PCC approach, which might affect the responses in the questionnaires and the interpretation of the results. To manage this, the whole care chain needs to structure their work according to PCC, as in a previous study [24].

Moreover, the intervention protocol ranged over 12 weeks, as this period has been identified as the most troublesome for patients with ET [74], and a previous study identified that the start of the ET period could be preferable for an intervention [35]. As 67% of the patients wanted education during the full 12-week intervention, 12 weeks is indicated to be a suitable length for a support program in a future RCT. However, an optional follow-up session after six months, when the patients have more experience with ET, could be appropriate, but measures would need to be taken to help patients stay focused on ET when responding to the questionnaires. A later session could also be preferable for patients who do not want to be educated during the first months undergoing ET [35].

To address scientific challenges, two measurement points were used, baseline and three months after being prescribed ET. In an RCT, additional measurement points could be added at six and 12 months. However, there were no differences in self-efficacy between the control and intervention groups; rather, both the control group and the intervention had high self-efficacy scores at baseline, indicating that the ceiling level was reached. Higher education implies higher self-efficacy [75] (p= .017) [76]. In the present study, 45% of the patients in the control group and 48% of the patients in the intervention group had university education, indicating that the GES may not be suitable as an instrument. General self-efficacy has been increased using PCC in a previous study in patients with acute coronary syndrome [73], indicating that breast cancer patients could also benefit from PCC. This is of importance, as low self-efficacy has been identified as a predictor of terminating ET prematurely [77] due to beliefs about its low influence on health or low satisfaction with involvement in health care [77].

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

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

Conclusion

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

Ethical approval

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

Conflicts of Interest

The authors report no conflicts of interest.

Contributorship statement

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

Availability statement

Data are available upon reasonable request.

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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, Individual learning plan – ILP.

Figure 2. Baseline and 3-month difference measures in the control and intervention groups for self-efficacy and reported symptoms.
Abbreviation: no – Number, SE – Self-efficacy.

Supplementary material:

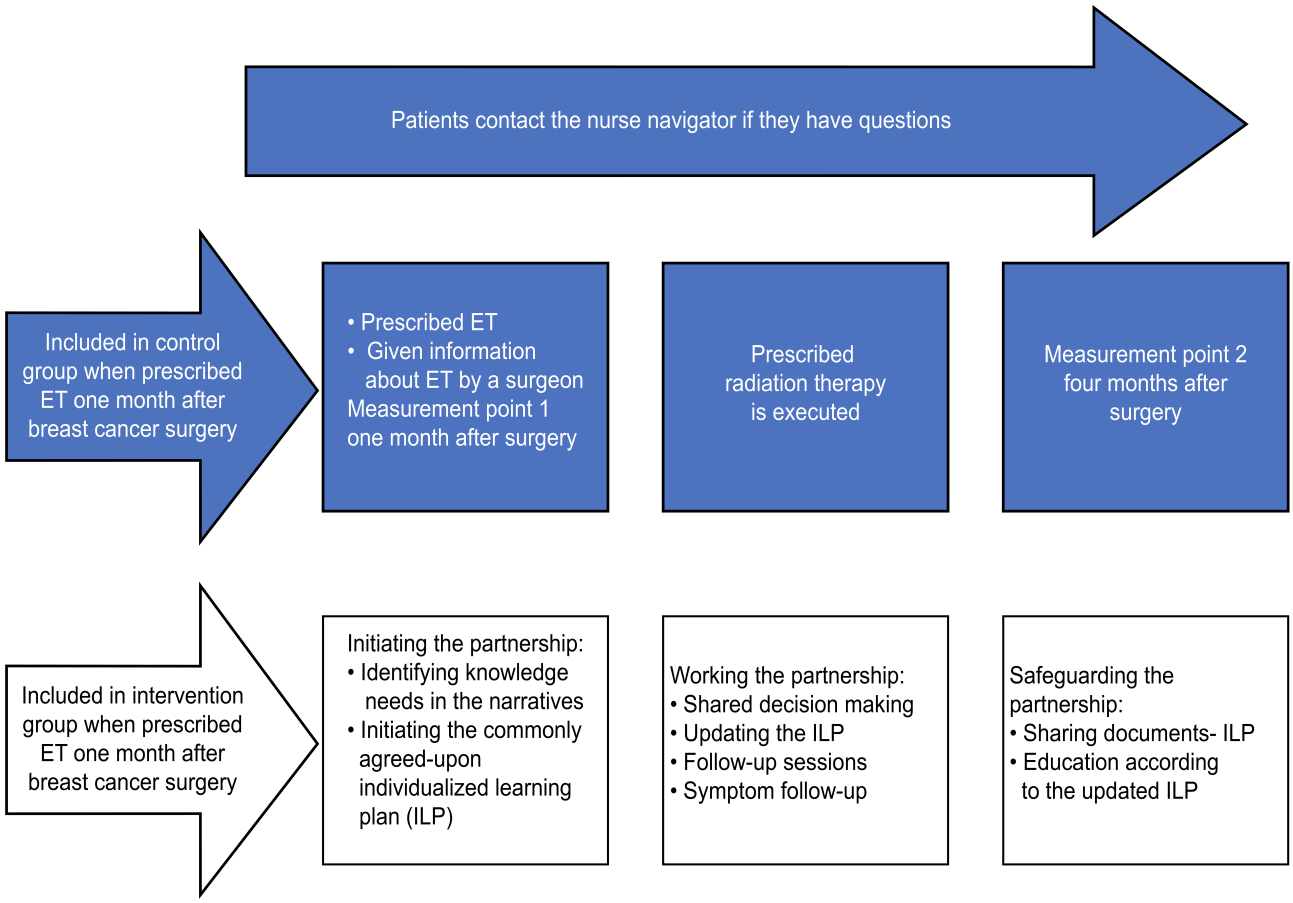
Supplementary file 1. Retention - CONSORT Flow diagram for the usual care group. Patients included September 2020 – December 2021.

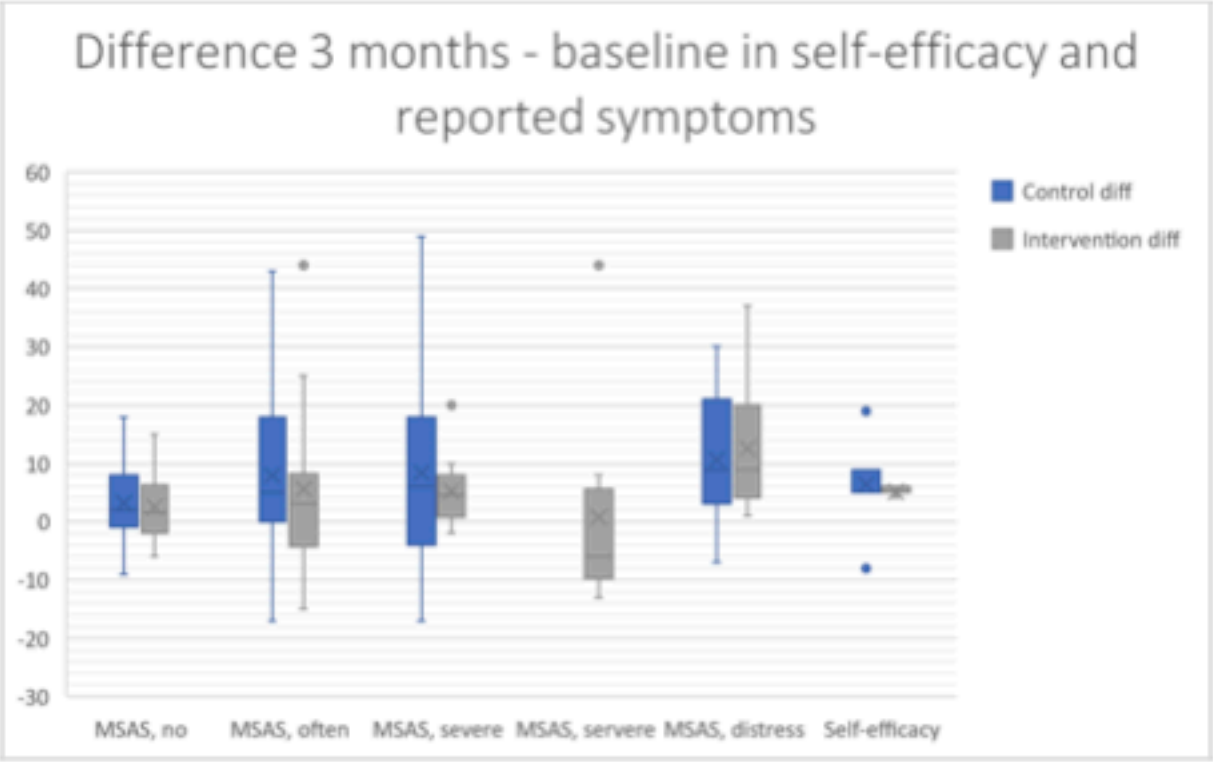
Supplementary file 2. Retention - CONSORT flow diagram for the person-centered support program group. Patients included December 2020 – March 2021.

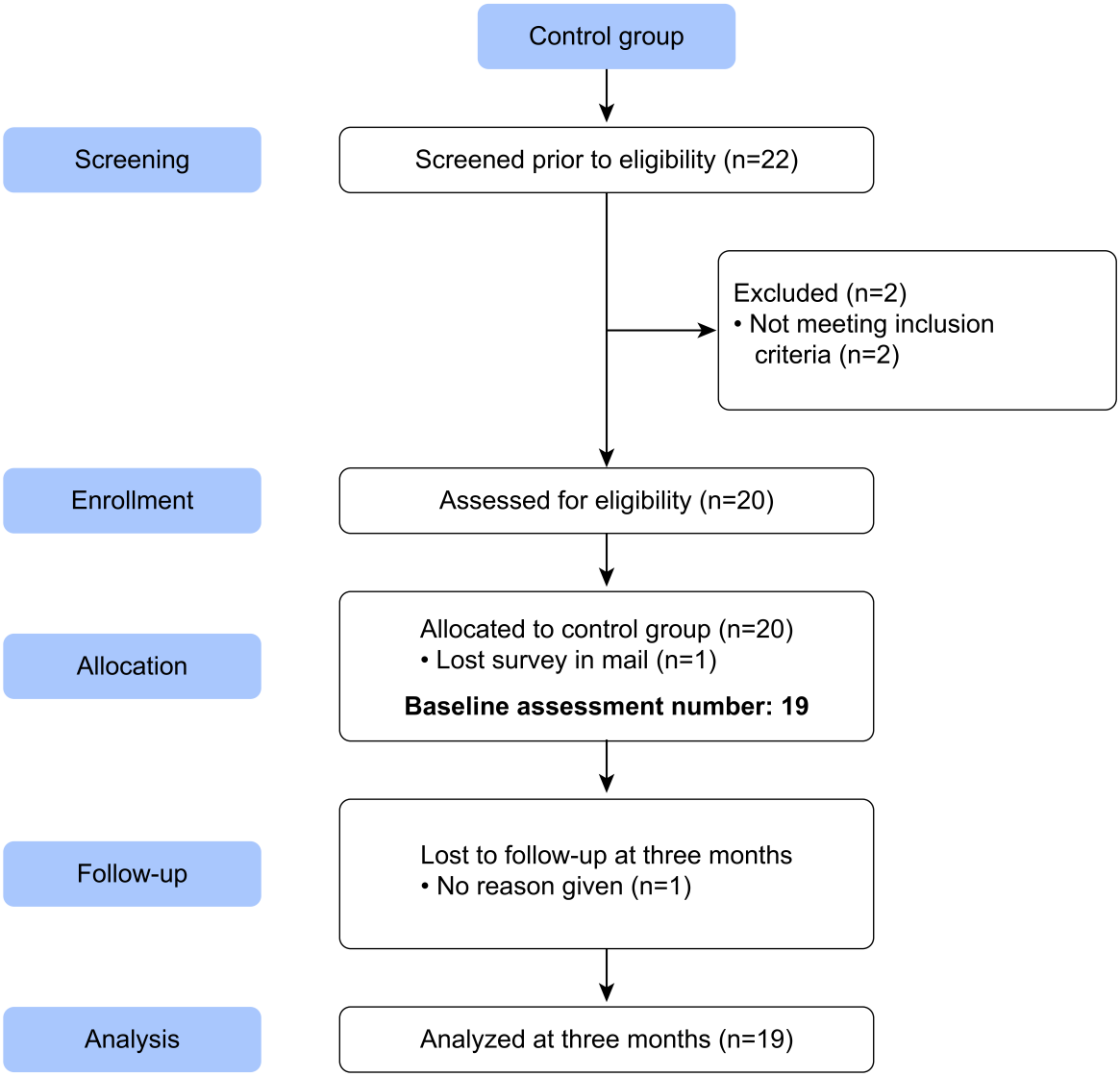
Supplementary file 3. Description of the education of the intervention nurse.

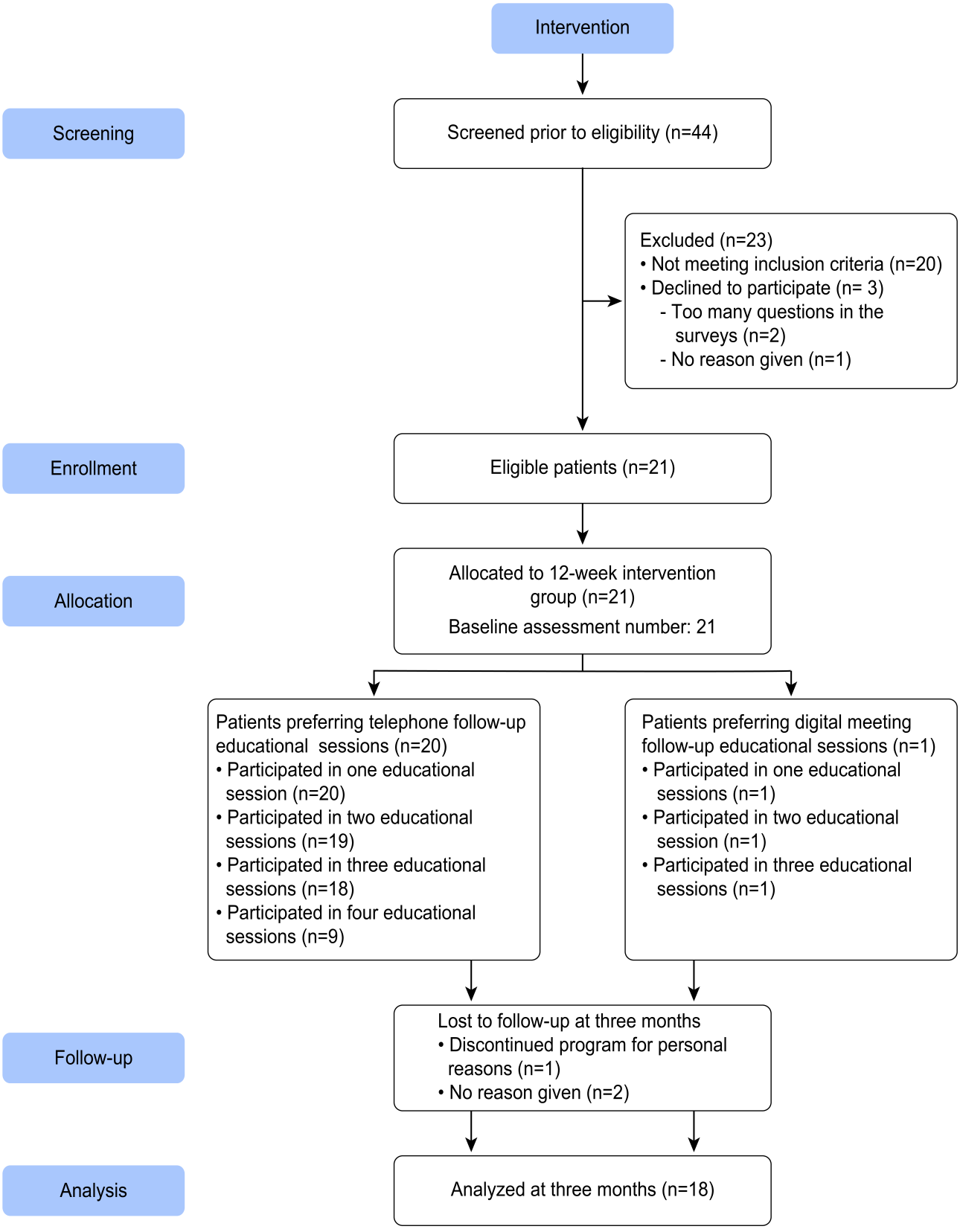
Supplementary file 4. Median differences at baseline and 3 months in the control group and intervention group.

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


Patients contact the nurse navigator if they have questions
Included in control group when prescribed ET one month after breast cancer surgery
• Prescribed ET
• Given information about ET by a surgeon
Measurement point 1 one month after surgery
Prescribed radiation therapy is executed
Measurement point 2 four months after surgery
Included in intervention group when prescribed ET one month after breast cancer surgery
Initiating the partnership:
• Identifying knowledge needs in the narratives
• Initiating the commonly agreed-upon individualized learning plan (ILP)
Working the partnership:
• Shared decision making
• Updating the ILP
• Follow-up sessions
• Symptom follow-up
Safeguarding the partnership:
• Sharing documents- ILP
• Education according to the updated ILP


Difference 3 months - baseline in self-efficacy and reported symptoms
60
50
40
30
20
10
0
-10
-20
-30
MSAS, no
MSAS, often
MSAS, severe
MSAS, servere
MSAS, distress
Self-efficacy
Control diff
Intervention diff


Control group
Screening
Screened prior to eligibility (n=22)
Excluded (n=2)
• Not meeting inclusion criteria (n=2)
Enrollment
Assessed for eligibility (n=20)
Allocation
Allocated to control group (n=20)
• Lost survey in mail (n=1)
Baseline assessment number: 19
Follow-up
Lost to follow-up at three months
• No reason given (n=1)
Analysis
Analyzed at three months (n=19)


Intervention
Screening
Screened prior to eligibility (n=44)
Excluded (n=23)
• Not meeting inclusion criteria (n=20)
• Declined to participate (n= 3)
- Too many questions in the surveys (n=2)
- No reason given (n=1)
Enrollment
Eligible patients (n=21)
Allocation
Allocated to 12-week intervention group (n=21)
Baseline assessment number: 21
Patients preferring telephone follow-up educational sessions (n=20)
• Participated in one educational session (n=20)
• Participated in two educational sessions (n=19)
• Participated in three educational sessions (n=18)
• Participated in four educational sessions (n=9)
Patients preferring digital meeting follow-up educational sessions (n=1)
• Participated in one educational sessions (n=1)
• Participated in two educational session (n=1)
• Participated in three educational sessions (n=1)
Follow-up
Lost to follow-up at three months
• Discontinued program for personal reasons (n=1)
• No reason given (n=2)
Analysis
Analyzed at three months (n=18)

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: *Problems with endocrine therapy* *Symptom management* *Cocreation with patients, barriers, facilitators.*			
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 *applying dialog* and *person-centered care (PCC[2]).*			
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 *relate to PCC* 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 *gained knowledge about PCC* 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, *apply PCC, knowledge about ET, pedagogical theory and the three components* 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

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

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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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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 mortality [1]. A previous study reported that up to 91% of patients experience side effects from ET [2], such as sleeping difficulties, hot flashes [3 4] and musculoskeletal symptoms [5]. Difficulties in managing these side effects have been reported to be obstacles to staying in treatment [6]. Other challenges that have been identified include older age [7], medicine costs, or a general dislike of taking a regular medicine [8]. As ET is a long-lasting treatment, women may request support in managing challenges [9]. To manage challenges with ET, a partnership with health care professionals could be appropriate, as a previous study [10] 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 ET [11-13]. 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 important [12]. 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 treatment [11]. 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 life [14] Additionally, training has not been found to have an effect on musculoskeletal symptoms in patients treated with AIs [15]. Managing a disease and its additional challenges requires self-care knowledge and skills gained from a partnership with health care professionals [16]. Self-care involves the ability to both care for oneself and to achieve, promote and maintain optimal health [17]. 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 developed [10]. As self-care requires knowledge and skills [16], 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 illness [16]. 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

partnership [19]. Patients are often motivated to engage in self-care, as they have personal interest in acquiring requisite knowledge and skills for performing self-care operations to reach their intended health goals [16]. It has been shown that when self-care capabilities increase [20], self-efficacy and adherence to ET also increase [21 22]. Self-efficacy constitutes the self-image of the person and affects how people experience and behave in specific situations [23]. Previous studies using PCC have improved patients' self-efficacy [24-26].

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

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

A previous study developed a person-centered support program in collaboration among patients, health care professionals, researchers and managers with ET experience [10] that needed to be tested in a feasibility study using the TIDieR checklist [33] and the CONSORT 2010 statement [34]. Previous studies have used feasibility studies prior to conducting a study in a larger setting [9 35]. The intervention was developed to encourage patients to be more actively involved in their care and wellbeing as partners with their contact nurse [10]. It has been stated that an intervention could be considered complex due to the behaviors required by those delivering the intervention [36], i.e., a contact nurse. The complexity is caused by the context in which the intervention is to be implemented rather than the number of parts of the intervention [37]. It has been reported that complex interventions require engagements with the care context stakeholders, i.e., patients and contact nurses, to be able to identify if the intervention could be acceptable, operable, cost-effective, possible to scale up, and transferable across contexts. The

development phases were identified, including developing or using an existing complex intervention, feasibility, evaluation, and implementation [38].

Aim

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

METHODS

Study design

This was a feasibility trial using a controlled before-and-after design [39] to investigate the feasibility of the intervention, a person-centered support program aimed at empowering patients prescribed ET to manage ET-related symptoms and problems. Allocation was based on inclusion time and not on patient preferences.

Patient and public involvement

Patients and health care professionals were involved in the design and development of the person-centered support model [10]. However, there was no patient involvement in the evaluation of the person-centered support model presented in this study.

Participants

Between September 2020 and June 2021, 66 potential female patients from one outpatient clinic at one university hospital in Sweden were identified as eligible for inclusion when starting ET. Patients in the control group were included from September 2020 to December 2021, while patients in the intervention group were included from December 2021 to March 2021. The inclusion criteria were women > 18 years of age who had been diagnosed with breast cancer and treated with ET after surgery. Patients receiving adjuvant chemotherapy were excluded as the study aimed to investigate an intervention targeting patients treated with ET. All patients were contacted by a contact nurse and were invited by telephone to participate in the study approximately three weeks after their surgery when prescribed ET (Table 1). In the online supplementary materials, the CONSORT flow diagrams for the usual care group and person-centered support program group are available (Supplementary files 1 and 2).

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

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

Intervention group

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

Step 1- Individual education material

Using a PCC approach [19], the contact nurse listened to patients' narratives regarding their individual needs for knowledge and understanding, resources, goals and needs for support from the contact nurse. The timing of the supply of individual educational materials depended on the individual patient's needs, resources and goals during the 12-week intervention. Mutual trust was demonstrated, and the relationship between the patient and her contact nurse was reinforced through the assessment of the commonly agreed upon individualized learning plan [44].

Step 2 - An individualized learning plan (ILP)

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

Step 3 – A personalized reminder letter

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

Please insert Figure 1 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 [45 46] sessions and seminars were used; the microteaching sessions were adapted to the specific needs of knowledge about endocrine therapy, side effects [47], pedagogy [48] 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 learning [50]. 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 knowledge [48]. 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 collection [51]. 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 Swedish [52] and has previously been used with breast cancer patients [53]. 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 added [56]. 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 care [57].

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

Feasibility outcomes

In this study, feasibility outcomes were defined as the primary outcome. 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. Based on the recommendations for feasibility studies and an expected attrition rate of 20%, the sample size was set to 20 participants in each group [60]. To determine whether the chosen feasibility criteria were successful [61], criteria for success were stated according to the CONSORT 2010 statement [34].

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 this study. It has been suggested that the loss of participants should be less than 15% [62]. 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. The 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 one of the three forms of educational support (face-to face, telephone, and digital) were requested by the patients.
5. The 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 was determined to be successful if no more than four education sessions were used by each patient.

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 applied [63], 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

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

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

4. Resources

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

5. Number of educational sessions

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

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 *Part 1, n*	21
Individual educational material *Part 2, n*	20
Individual educational material *Part 3, n*	19
Individual educational material *Part 4, n*	19
Individual educational material *Information about tamoxifen or aromatase inhibitors, n*	20
Additional educational material from 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 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 (-)
Follow-up educational session	
Time from 1st session to 2nd session, weeks, median (range)	2 (1-8)
Time from 2nd session to 3rd session, weeks, median (range)	4 (2–8)
Time from 3rd session to 4th 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

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) [71], and telephone follow-ups were found to be well liked among registered nurses [72]. A previous study using PCC also allowed patients to decide the number of follow-up sessions [73]. Thus, this approach could be a preferable way to administer the intervention and could also be more cost-effective, as patients do not need to attend more sessions than needed; however, it needs to be evaluated further. Furthermore, not all health care professionals have a PCC approach, which might affect the responses to the questionnaires and the interpretation of the results. To manage this, the whole care chain needs to structure its work according to PCC, as in a previous study [24].

Moreover, the intervention protocol ranged over 12 weeks, as this period has been identified as the most troublesome for patients with ET [74], and a previous study identified that the start of the ET period could be preferable for an intervention [35]. As 67% of the patients wanted education during the full 12-week intervention, 12 weeks is indicated to be a suitable length for a support program in a future RCT. However, an optional follow-up session after six months, when the patients have more experience with ET, could be appropriate, but measures would need to be taken to help patients stay focused on ET when responding to the questionnaires. A later session could also be preferable for patients who do not want to be educated during the first months undergoing ET [35].

To address scientific challenges, two measurement points were used, baseline and three months after being prescribed ET. In an RCT, additional measurement points could be added at six and 12 months. However, there were no differences in self-efficacy between the control and intervention groups; rather, both the control group and the intervention had high self-efficacy scores at baseline, indicating that the ceiling level was reached. Higher education implies higher self-efficacy [75] (p=.017) [76]. In the present study, 45% of the patients in the control group and 48% of the patients in the intervention group had university education, indicating that the GES may not be suitable as an instrument. General self-efficacy has been increased using PCC in a previous study in patients with acute coronary syndrome [73], indicating that breast cancer patients could also benefit from PCC. This is of importance, as low self-efficacy has been identified as a predictor of terminating ET prematurely [77] due to beliefs about its low influence on health or low satisfaction with involvement in health care [77].

The study had some limitations. As the COVID-19 pandemic was ongoing, there were restrictions on the patients' ability to have face-to-face sessions with the trial leader. However, several patients stated that they would participate only if there were no mandatory sessions at the hospital. The patients also had the possibility of having their sessions using a digital conference system. As the intervention contact nurse and the participants almost never met in person, their relationships could have been affected. However, a partnership was established between the patient and the trial leader using a PCC protocol. This might have decreased the effect of not meeting in person. In a future RCT, it will be crucial for

patients to have face-to-face relationships with the intervention contact nurse with whom they will build partnerships. This study did not identify when the intervention should stop, as it was decided before the intervention that it should last for 12 weeks. It might have been important for the patients in the intervention to have given this important information. However, seven of the 21 patients did not use the full 12-week intervention, which implies that a 12-week support program is suitable. No patient actively asked for longer follow-up. All patients were allocated a contact nurse whom they could contact after the intervention if further questions were answered.

Conclusion

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

Ethical approval

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

Conflicts of Interest

The authors report no conflicts of interest.

Contributorship statement

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

Data availability statement

Data are available upon reasonable request.

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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: ow much the experienced symptom distressed or bothered the patient.

Supplementary material:

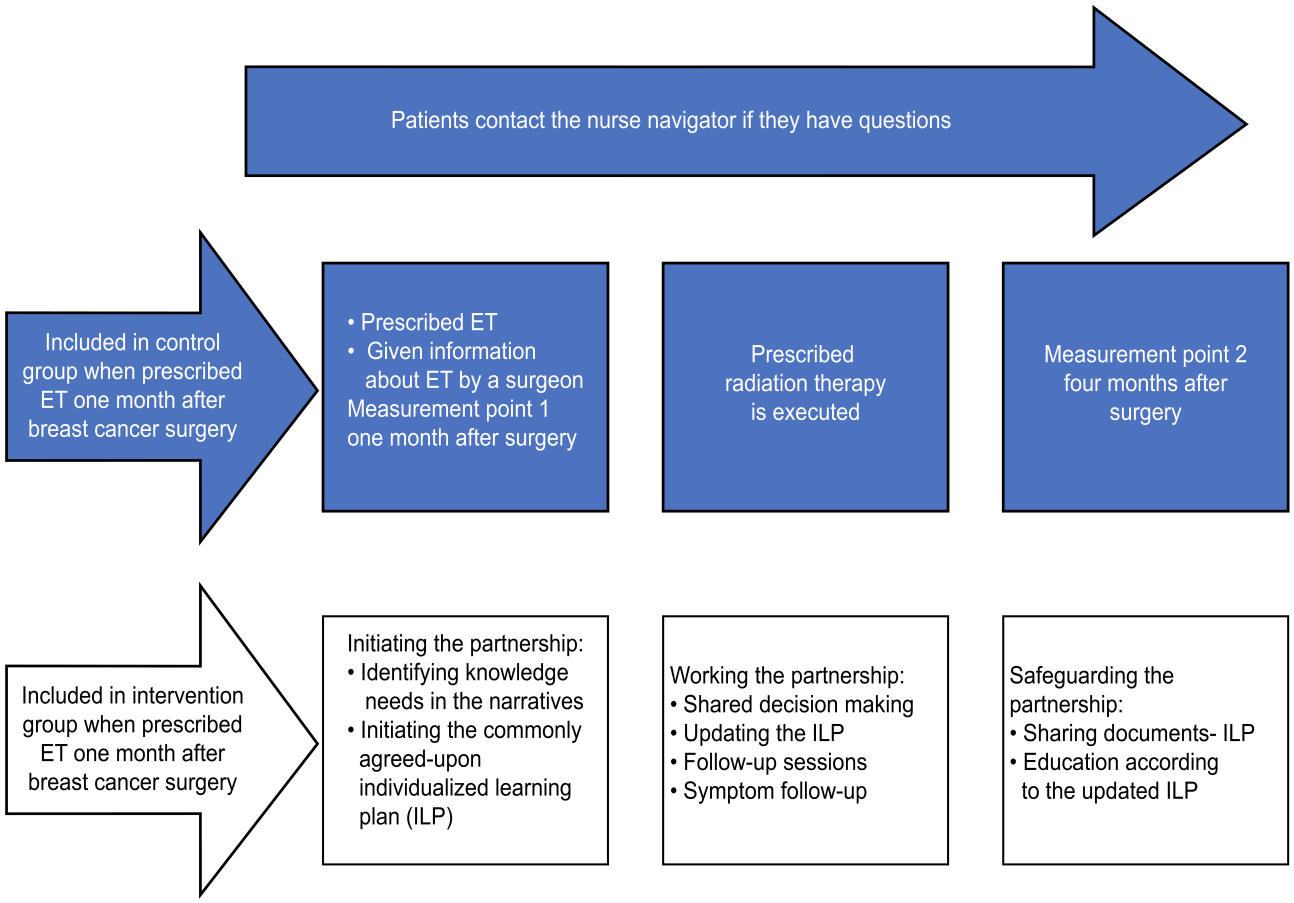
Supplementary file 1. Retention - CONSORT flow diagram for the usual care group. Patients included September 2020-December 2021.

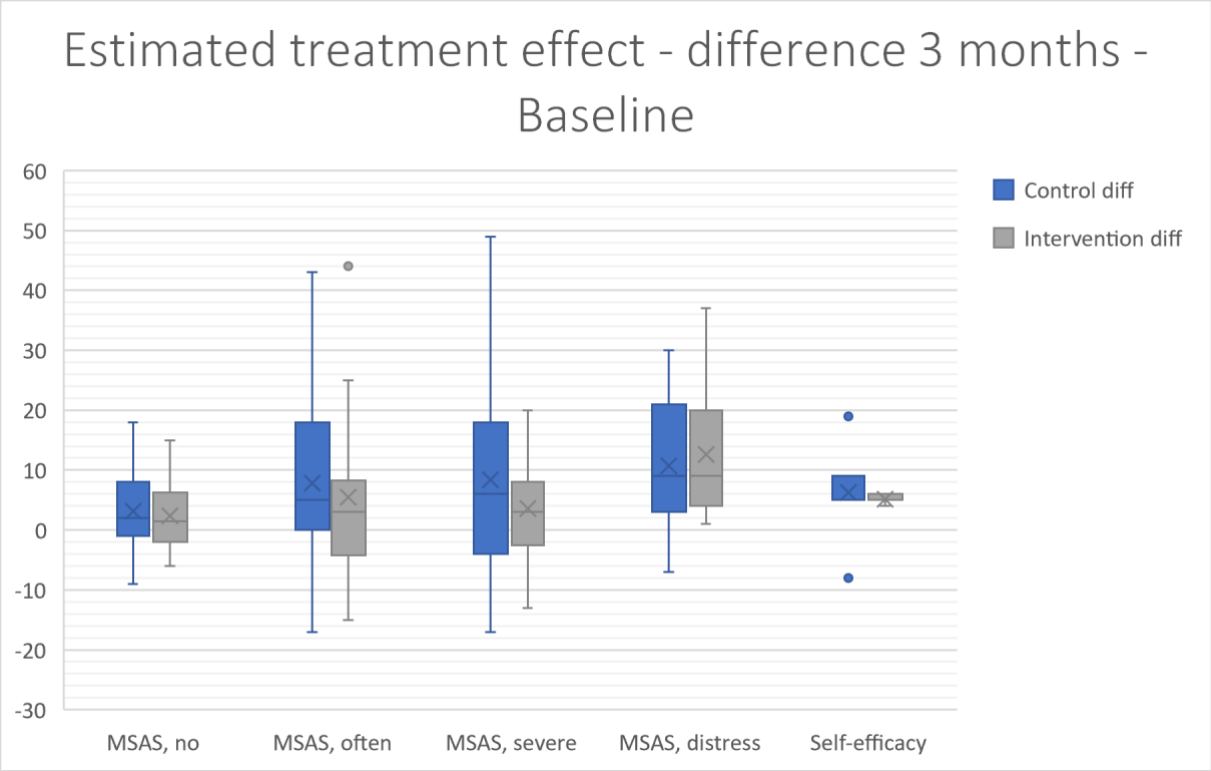
Supplementary file 2. Retention - CONSORT flow diagram for the person-centered support program group. Patients included December 2020-March 2021.

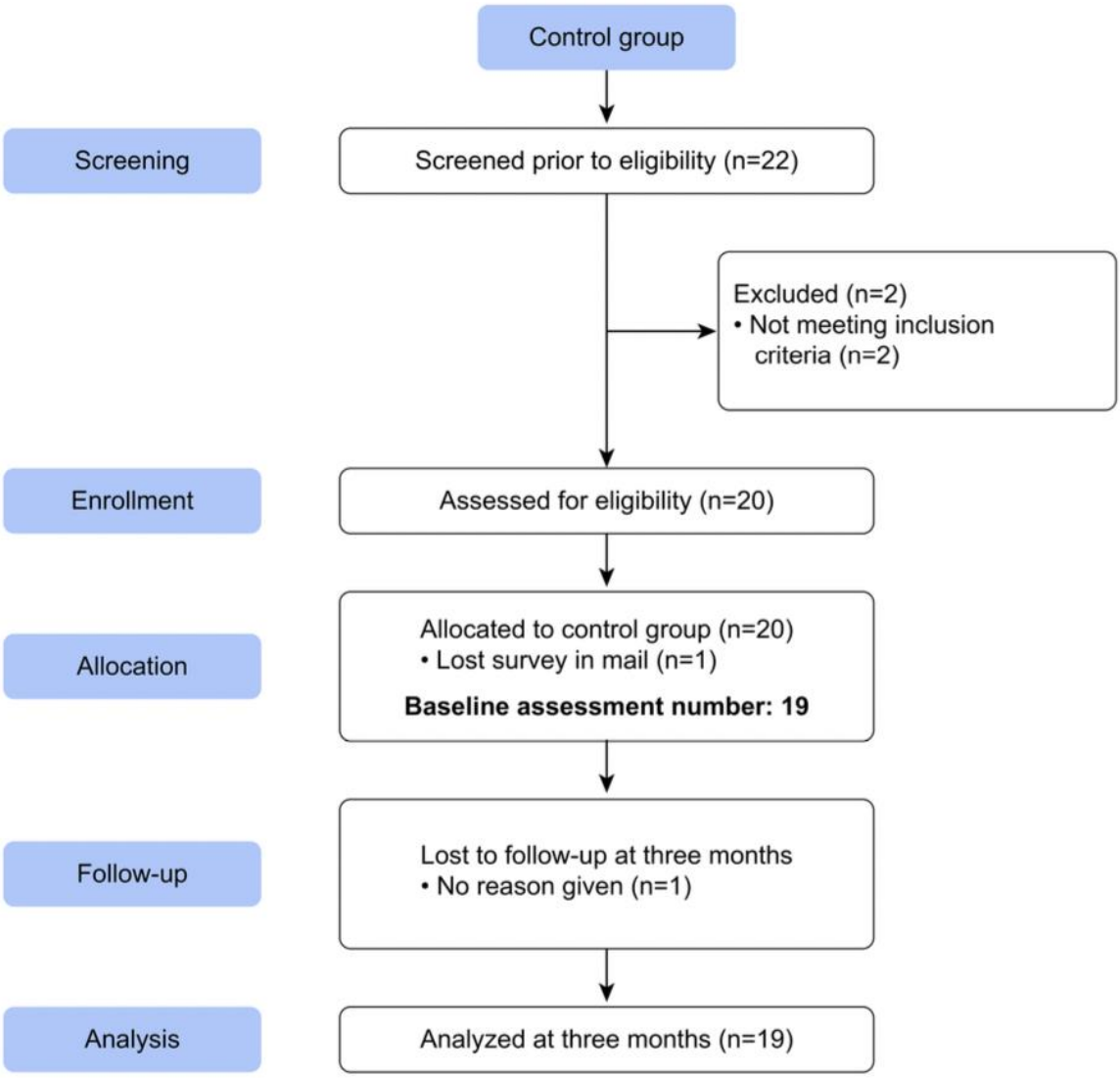
Supplementary file 3. Description of the education of the intervention nurse.

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

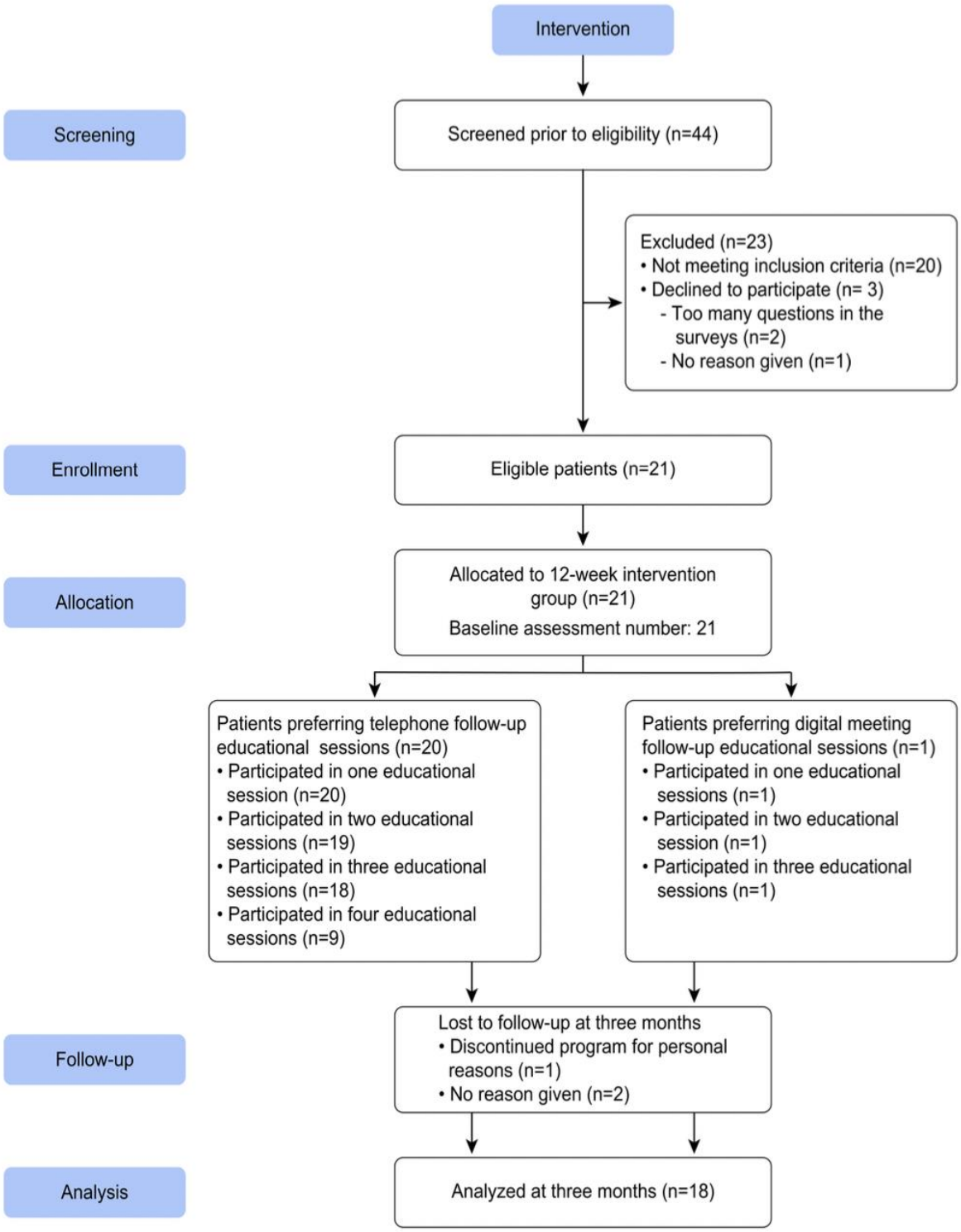
Supplementary file 5. Interpretation of the QPP – Percentage agreement in a selection of QPP questions


Patients contact the nurse navigator if they have questions
Included in control group when prescribed ET one month after breast cancer surgery
• Prescribed ET
• Given information about ET by a surgeon
Measurement point 1 one month after surgery
Prescribed radiation therapy is executed
Measurement point 2 four months after surgery
Included in intervention group when prescribed ET one month after breast cancer surgery
Initiating the partnership:
• Identifying knowledge needs in the narratives
• Initiating the commonly agreed-upon individualized learning plan (ILP)
Working the partnership:
• Shared decision making
• Updating the ILP
• Follow-up sessions
• Symptom follow-up
Safeguarding the partnership:
• Sharing documents- ILP
• Education according to the updated ILP





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.

Before Lecture: The intervention nurse is asked to specifically reflect on the following in the care setting: *Problems with endocrine therapy* *Symptom management* *Cocreation with patients, barriers, facilitators*.			
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 *applying dialog* and *person-centered care (PCC[2]).*			
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 *relate to PCC* 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 *gained knowledge about PCC* 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, *apply PCC, knowledge about ET, pedagogical theory and the three components* 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

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.