ACTA ONCOLOGICA
2019, VOL. 58, NO. 5, 619–626
https://doi.org/10.1080/0284186X.2018.1563717

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ORIGINAL ARTICLE

MyHealth: specialist nurse-led follow-up in breast cancer. A randomized controlled trial – development and feasibility

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ABSTRACT

Background: Traditionally, women treated for breast cancer (BC) have been followed up through regular oncologist-led visits in outpatient clinics, focusing on detection of recurrences, new primary BC, symptom management, and psychological support. However, this follow-up routine is expensive and its effectiveness has been questioned. Consequently, alternative follow-up programs have been tested. The Guided Self-Determination method (GSD), which facilitates partnership between health-care provider and patient, has been shown to improve self-management in patients with chronic conditions, including cancer. Patient-reported outcomes (PRO) is another increasingly used tool to improve patient–provider communication, symptom monitoring and control. In combination, GSD and PRO may have the potential to meet the objectives of BC follow-up. To test this, we developed the MyHealth study, a randomized controlled trial comparing a nurse-led follow-up program based on GSD, collection of PRO, and patient navigation with routine oncologist-led follow-up. Here we describe how we developed the intervention and are currently testing the feasibility of the MyHealth protocol in terms of recruitment, adherence to the intervention, collection of PRO, and patient navigation.

Material and methods: We have invited the first 25 consecutively enrolled patients to test the MyHealth intervention. This consists of (1) 3–5 initial GSD appointments with a nurse, (2) collection of PRO, and (3) symptom management and patient navigation. The randomized trial was launched in January 2017 and is still recruiting.

Results of the feasibility study: Of 32 patients invited, 25 accepted participation. At 18-month follow-up, two patients have withdrawn, 143 PRO questionnaires have been completed (mean 5.7/patient) resulting in 59 nurse contacts (mean 2.4 per patient) and 14 project physician contacts (mean 0.6 per patient).

Conclusion: A high recruitment rate and response rate to PRO indicate that follow-up led by specialist nurses, based on collection of PRO is feasible and acceptable for patients treated for early stage BC.

ARTICLE HISTORY
Received 25 November 2018
Accepted 19 December 2018

Background

Each year approximately 2 million women worldwide are diagnosed with breast cancer (BC), the most frequent malignant disease among women [1]. The vast majority of BC patients receive curatively intended treatment and are subsequently enrolled in a follow-up program that focuses on detection of recurrences and new primary cancers, but also on symptom management and psychological support [2–4]. However, the most effective and resource-efficient method of follow-up has not yet been established. A review of 12 observational studies found that 30–40% of loco-regional BC recurrences were detected by the patients themselves between follow-up visits [5] while a retrospective study among 115 patients with recurrent BC found that 83% of distant BC recurrences were identified by the patients [6]. Furthermore, studies suggest that follow-up programs may not sufficiently address physical and psychological symptoms [7]. Research on different follow-up strategies has focused on frequency of visits, type of provider, or patient-initiated follow-up visits [2–4,8–12]. These studies suggest that follow-up programs that include physical examinations and annual mammography are equally effective as more intensive approaches and that regular or on-demand follow-up led by GPs or nurses is comparable to oncologist-led follow-up in terms of quality of life, detection of recurrence, and overall survival [2–4,8–12]. An important theme for patients in cancer follow-up is to be able to recognize symptoms of recurrence and obtain self-management skills to handle late effects of cancer. A systematic review [13] that included 42 studies of self-management education for cancer patients (16 studies concerning BC) suggests that self-management interventions may reduce symptoms of fatigue, pain, depression, anxiety, and emotional distress and increase quality of life [13].

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Supplemental data for this article can be accessed here.

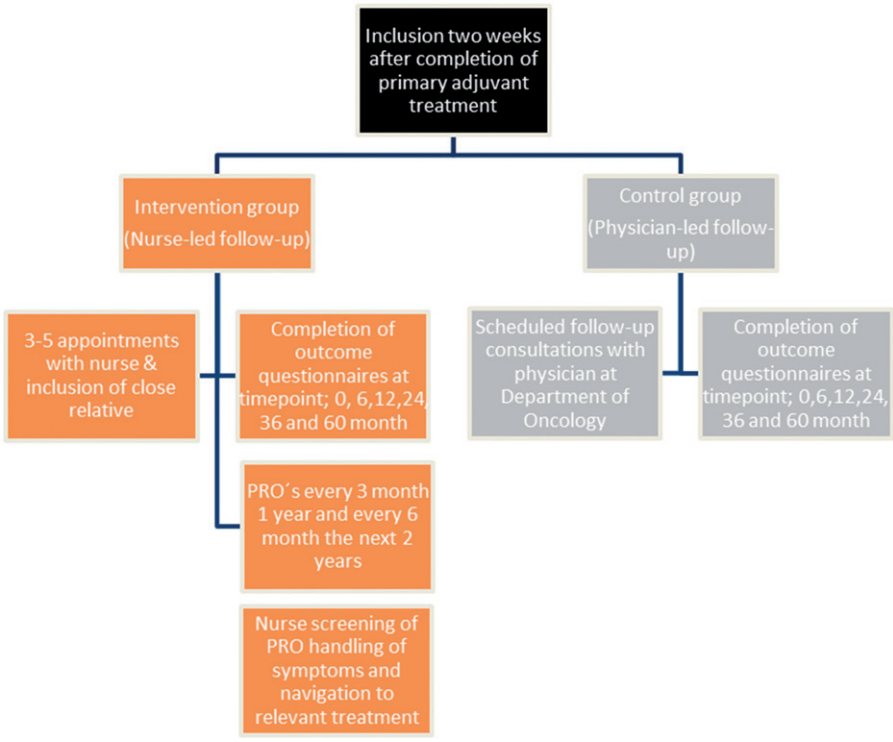

Figure 1. Study flow.

The Guided Self-Determination method (GSD) has proven effective in empowering and improving self-management in patients with chronic conditions [14,15] including cancer [16]. Further, patient-reported outcomes (PRO) have increasingly been used to improve symptom monitoring and control and to increase patient–provider communication [17,18].

We hypothesized that a combination of the GSD method and collection of PRO would support patients in their ability to manage symptoms, detect signs of recurrence, and improve self-management. The MyHealth study was developed to investigate if a nurse-led symptom management program and regular collecting of PRO compared with routine physician-led follow-up would significantly reduce physical and psychological symptoms and increase breast cancer-specific health-related quality of life without increasing time to detection of recurrence.

The aim of this paper is to describe the development of the intervention program and to examine the feasibility of the protocol with regard to (1) recruitment of participants, (2) participation in and adherence to the intervention, (3) response rates of PRO, and (4) the number of subsequent clinical examinations and referrals to treatment up to 18 months of follow-up.

Material and methods

Design

MyHealth is a two-armed randomized controlled trial with study-specific follow-up for 3 years and outcomes measured for 5 years (Figure 1). Patients are randomized to the intervention arm, which involves individual appointments based on the GSD method with a specialist nurse, collection of PRO and support in symptom management and patient navigation, or the control arm, which involves regular visits in the outpatient clinic with physical examinations led by oncologists.

Patients in both arms are recommended to follow the national mammography screening program, which involves clinical mammography once a year for women under 50 years of age and ordinary mammography every second year until the age of 80. Study participation does not influence treatment with endocrine therapy, Trastuzumab or Zoledronic acid.

Participants

From January 2017 to January 2019, all eligible patients in the Department of Clinical Oncology at Zealand University Hospital have been or will be invited to participate. Eligible patients must fulfill the following criteria: female, completed primary treatment for early BC (stages I–II) without clinical sign of recurrent disease, performance status ≤ 3 by the Eastern Cooperative Oncology Group (ECOG) scale, sufficient proficiency in Danish, and written informed consent. Exclusion criteria are the following: age <40 years at diagnosis, genetic predisposition for BC, in follow-up after recurrent BC, presence of other active cancers except non-melanoma skin cancer, severe cognitive problems such as dementia and severe psychiatric disease requiring treatment, e.g., schizophrenia, alcohol abuse, or narcotic dependence.

Participation of close relatives

Patients are asked to invite a close relative to participate in the study together with them. Participating relatives in both arms are asked to complete two questionnaires, one at the study entrance and one after 6 months. Further, relatives of

patients in the intervention arm are invited to participate in the second appointment with the nurse.

Recruitment

At the initial follow-up visit, the project physician provides verbal and written information about MyHealth in addition to information about standard follow-up care. The initial follow-up visit takes place 1 month after surgery for patients who receive only surgery, after completion of radiotherapy for patients who receive radiotherapy but not chemotherapy, and between chemotherapy and radiotherapy for patients who receive both. Patients who agree to participate are randomized after submission of the informed consent form and completion of the baseline questionnaire. Patients who decline to participate are invited to complete the baseline questionnaire.

Randomization

The project nurse randomizes the patients using a computer-generated sequence of 1:1 in blocks of randomly varying sizes of six, eight, or 10 patients, stratified by age and human epidermal growth factor receptor 2 (HER2) status. Since patients with HER2-positive tumors have several appointments in the clinic for Trastuzumab infusion and standard cardiac function evaluations by multigated acquisition scanning (MUGA), these extra contacts with health professionals are taken into account in the randomization. Allocation is concealed from the nurse until after randomization, when she will inform patients about arm allocation by phone.

The MyHealth intervention program

In the intervention arm, routine follow-up visits are replaced by the MyHealth program.

The intervention consists of

- 3–5 individual appointments with a specialist nurse;
- regular collecting of PRO;
- support in symptom management and patient navigation.

Individual appointments

Within the first 6 months after randomization, the nurse meets with the patient for 3–5 scheduled needs-based appointments based on the GSD method. GSD facilitates a partnership between patient and health care provider and aims to enhance the patient's life skills (including personal, social, cognitive, and physical skills) in order to enable patients to control and direct their lives [14,15]. Patients are prompted to explore and express their difficulties relating to BC through words and drawings on worksheets designed to augment their ability to participate actively in the appointments (Supplementary 1). Differing viewpoints between nurses and patients are made explicit, as they are regarded as holding a potential for change that could be further exploited in the relationship between patient and provider. Relatives fill out reflection sheets before participation in the second appointment with the nurse. Besides the topics raised by the patients and their relatives, the following subjects are discussed during the appointments:

- Information on symptoms of recurrence and late effects and how to react to these.
- Training in self-examination of the breast.
- Instructions on how to report PRO on the electronic platform.
- Management of mild-to-moderate symptoms of anxiety, depression, and distress.
- Information on how health behaviors influence physical and psychological wellbeing.
- Involvement and communication with close relatives in order to address caregiver burdens.

Collecting of PRO

The patients in the intervention arm perform PRO (including symptoms of recurrence, adverse effects, and late effects of BC treatment) every three months during the first year and every six months the subsequent two years. The nurse receives an alert when a patient has performed PRO presenting symptoms exceeding a predefined threshold whereupon she contacts the patient by phone. If patients experience a new symptom or worry about a symptom between PRO, they can contact the nurse. Nurses are alerted if patients do not respond to a PRO invitation and two subsequent reminders, whereupon the nurse will contact the patient by phone. Patients who do not have access to a computer receive the questionnaires in paper. The patients are followed for three years and are then enrolled in the standard follow-up program described below.

Support for symptom management and patient navigation

A predefined response algorithm guides nurses in assessing PRO, and, in the event of any doubt, they can consult the project physician. Nurses assess whether or not the symptoms require a clinical examination by the project physician or referral to additional examinations, i.e., CT or MR scans. If there are symptoms of late effects, the nurse can advise the patient how to manage these or refer the patient to physical exercise or lymphedema therapy by physiotherapist, acupuncture, or other relevant rehabilitation. If patients' symptoms are related to the adjuvant treatment, the nurse may adjust the treatment.

The control arm

Patients in the control arm are invited to follow-up appointments with a physician in the outpatient clinic every 6 months for three years, after which they are enrolled in the standard follow-up program described below.

Standard follow-up

Patients who decline to participate in the MyHealth study are offered the standard follow-up care consisting of consultations with a physician 6 and 12 months after surgery and subsequently either biannual consultations with a nurse or a patient-initiated follow-up without prescheduled consultations [19].

Development of the MyHealth program

Training of the nurses

In the MyHealth intervention, specialist nurses lead the follow-up care and thereby assume some of the functions of a physician. To prepare the nurses for this increased responsibility, they attended a 6-d course specifically developed for this study focusing on treatment of breast cancer, symptoms of recurrence, and late effects, how to manage these in terms of referral to diagnostic imaging and treatment, and the GSD method [14] including 3–5 GSD training appointments with two patients (Table 1).

Development of PRO and response algorithm

The purpose of the PRO questionnaire is to detect symptoms of recurrence as well as adverse and late effects requiring treatment. Questions concerning adverse and late effects were derived from the EORTC QLQ-C30 [20] and EORTC QLQ-BR23 [21] questionnaires, but no validated scales or single items exist focusing on symptoms of BC recurrence. Thus, a pool of 23 items measuring symptoms relevant for detection of recurrence has been developed in collaboration with six experienced BC consultants. To ensure that the nurse navigation complies with clinical guidelines, the nurses follow a detailed response algorithm, developed in collaboration with two experienced oncology consultants.

Patient panel

The MyHealth study preparations included establishment of a panel of eight BC survivors participating in the standard follow-up program. Through individual and focus group interviews panel members gave feedback to the researchers on the written study information, questionnaires, recruitment procedures, and usefulness of the IT platform as reported elsewhere [22].

Table 1. Curriculum for the nurse training course.

Topics	No. of lessons (45 min per lesson)
Research methodology	2
Guided self-determination	27
Breast cancer, treatment, and symptoms of recurrence	3
Patient-reported outcomes and navigation	3
Rehabilitation and health behavior	2
Social inequality in cancer and comorbidity	3
Psychological aspects of cancer	4
Legal aspects of the reassignment of tasks	1

Measures

Questionnaire outcomes

Patients in both arms complete questionnaires at baseline, 6, 12, 24, 36, and 60 months following the date of inclusion. The baseline questionnaire includes information on age, body mass index (BMI), education, employment, cohabitation status, and number of children. The primary outcome is breast cancer-specific health-related quality of life as measured by the Trial Outcome Index-Physical/Functional/Breast (TOI-PFB) score of the Danish version of the Functional Assessment of Cancer Therapy-Breast (FACT-B) [23] 2 years after study entry [24]. The TOI-PFB score is a composite of domains on physical well-being, functional wellbeing, and specific BC symptoms and is a commonly used trial endpoint because it is particularly responsive to changes in physical and functional outcomes [24]. Secondary outcomes include time to detection of recurrence, health behaviors and status, depression, anxiety, and fear of recurrence (Table 2).

The questionnaires for close relatives are collected at baseline and 6 months and contain information on sex, age, BMI, education, employment, cohabitation status, number of children, and relation to the patient (partner, family, or friend). The primary outcome is caregiver burden, and secondary outcomes include anxiety, depression, work ability, dyadic coping, and health behavior (Table 2).

National registries and clinical databases

Data on censoring outcomes (death and emigration) will be obtained from The Danish Civil Registration System (CPR) [25]. Information on clinical data at time of diagnosis (BC characteristics including tumor size, receptor status, etc.) are obtained from medical records. In order to obtain complete information about recurrent BC or new primary cancer, data from medical records will be supplemented with data collected from (1) The Danish Breast Cancer Cooperative Group (DBCG) [26], (2) The Danish Pathology Registry (DPR) [27], and (3) The Danish National Patient Register (NPR) [28]. Information on health care utilization (number and length of hospital admissions, use of general practitioner, psychologist, or physiotherapist) will be obtained from NPR and from The Danish Health Insurance Registry (HIR) [29].

Power considerations

For the TOI-PFB the minimal important difference, defined as the smallest difference that patients perceive as important (beneficial or harmful) is reported as 5–6 points [30]. Assuming a mean TOI-PFB at baseline of 72.3 (SD 13.83) [31] and a difference of 5 points on the TOI-PFB, we calculated the sample size for the primary outcome to be 494 at 80% power allowing for a 20% dropout rate. To keep an overall probability of making a type 1 error at 0.05 the level of significance was adjusted to 0.005 using the Bonferroni correction due to the high number of planned analyses of both primary and secondary outcomes.

Table 2. Primary and secondary outcome measures collected at different time points among patients and relatives in the MyHealth study.

	Outcome measures	Baseline	6 months	12 months	24 months	36 months	60 months
Primary outcome measures (questionnaires)	• Trial Outcome Index – Physical/Functional/ Breast (TOI-PFB) score of the Functional Assessment of Cancer Therapy – Breast (FACT-B)	×	×	×	×	×	×
Secondary outcome measures (questionnaires)	• Functional Assessment of Cancer Therapy – Breast (FACT-B)	×	×	×	×	×	×
	• Patient Activation Measure (PAM)	×	×	×	×	×	
	• Anxiety Generalized (GAD-7)[a]	×	×	×	×	×	
	• The Health Education Impact Questionnaire (heiQ)	×	×	×	×	×	
	• Fear of recurrence: Concerns About Recurrence Questionnaire (CARQ-4)	×	×	×	×	×	
	• Depression: The Patient Health Questionnaire (PHQ-9)[a]	×	×	×	×	×	
	• Work ability: Work Ability Index (WAI)[a]	×	×	×	×	×	
	• Health status: EQ-5D-5L	×	×	×	×	×	
	• Weight, diet, smoking, alcohol use, physical activity[a]	×	×	×	×	×	
	• Study-specific items on health care use						×
	• Dyadic coping inventory – short[a]	×	×	×	×	×	
	• Coping with Health Injuries and Problems (CHIP)	×	×	×		×	
	• Health Literacy Questionnaire (HLQ)	×	×				
	• Modified Medical Outcomes Study Social Support Scale	×					
	• Zarit Burden Interview[b] Caregiver burden	×	×				

[a]Also used in questionnaire for relatives at baseline and 6 months follow-up.
[b]Only used in questionnaire for relatives at baseline and 6 months follow-up.

Descriptive analyses will be conducted on sociodemographic and clinical characteristics including comparison between participants and decliners who agree to complete the baseline questionnaire. Mean values for the primary and secondary outcomes (continuous variables) will be estimated at baseline, 6, 12, 24, 36, and 60 months. Multiple linear regressions models will be used to estimate the effect of the intervention on primary and secondary outcomes in intention to treat analyses (ITT) at each follow-up time, and mixed multiple linear regression models will be used for repeated measures comparing outcomes from the two treatment arms adjusted for baseline values and clinical and demographic characteristics. We will handle missing data by multiple imputations.

Ethics

The MyHealth study has been approved by the Danish Ethical Committee System (registration number H-16035885) and complies with the ethical principles in the Helsinki Declaration. The study is registered on ClinicalTrials.gov identifier NCT 02949167.

Aim of the feasibility study

The aim of the feasibility study is to test the study procedures and the components of the MyHealth intervention with regard to (1) feasibility of recruitment, (2) participation in and adherence to the GSD appointments with the nurse, (3) the response rates to PRO, and (4) the number of subsequent referrals to clinical examinations and treatment.

From 1 November to 31 December 2016, all consecutive patients who met the MyHealth inclusion criteria were invited to participate in a non-randomized feasibility study. Participants in the feasibility study were all followed up in the same way as participants in the MyHealth intervention arm.

Measures in the feasibility study

All measures of feasibility are descriptive. Sociodemographic characteristics of participants were obtained from questionnaires and clinical data were retrieved from medical records. The number of GSD appointments, PRO questionnaires obtained, contacts with nurses and project physician as well as the frequency of referrals to diagnostic imaging, general practitioner, and specific treatments was registered by simple counting.

Results of the feasibility study

A total of 25 out of 32 eligible patients (78%) accepted participation. Relatives participated together with 20 out of 25 patients (80%) and were either partners (80%), family (15%), or friends (5%). Patients have to date been followed for almost 2 years and, during this period, one patient withdrew and one was excluded due to having developed a second primary cancer.

Sociodemographic and clinical characteristics of participants in the feasibility study are presented in Table 3. A total of 86 GSD appointments were carried out: two patients had <3 appointments, 15 had three appointments and eight had >3 GSD appointments.

Table 3. Baseline characteristics of participants in the feasibility study.

Characteristics	n (%)
Age (years); mean (range)	56.0 (44–73)
Education at baseline	
Basic or high school	5 (20)
Vocational training	4 (16)
Higher education	16 (64)
Cohabitation	
Yes	20 (80)
No	5 (20)
Relatives participating	
Yes	20 (80)
No	5 (20)
Tumor size (mm)	
≤20	18 (72)
21-49	7 (28)
Histology	
Ductal	23 (92)
Lobular	2 (8)
Grade of malignancy	
I	4 (16)
II	15 (60)
III	5 (20)
Unknown	1 (4)
Stage	
I	13 (52)
II	12 (48)
ER status	
Positive[a]	22 (88)
Negative	3 (12)
HER2 status	
Normal	23 (92)
Positive[b]	2 (8)
No. of positive lymph nodes	
0	16 (64)
1–3	5 (20)
≥4	4 (16)
Type of surgery	
Mastectomy	7 (28)
Lumpectomy	18 (72)
Radiation therapy	
Yes	20 (80)
No	5 (20)
Chemotherapy	
Yes	20 (80)
No	5 (20)
Number of GSD appointments	
<3	2 (8)
=3	15 (60)
>3	8 (32)

[a]All 22 patients received endocrine therapy.
[b]Both patients received Trastuzumab.

Out of potentially 150, 143 PRO questionnaires were completed (mean 5.7 per patient) resulting in 59 contacts with the nurse (mean 2.4 per patient) and 14 contacts with the project physician (mean 0.6 per patient). Symptoms that required contact with the nurse at first and subsequently with the physician were simply registered as physician contacts. Between time-points for performance of PRO patients could contact the nurse at any time if they had new symptoms or concerns. In 15 cases, these contacts were handled by the nurse alone (mean 0.6 per patient) and, in 24 cases, they resulted in contacts with the physician (mean 1.0 per patient). The subjects and outcomes of the contacts are presented in Table 4. Extra diagnostic imaging was performed 20 times (mean 0.8 per patient). In 16 cases, patients were referred to their general practitioner and in six cases to other medical specialists. One patient was referred to lymphedema therapy, two patients to a physiotherapist and three patients were referred to acupuncture for hot flushes (Table 4).

Discussion

The feasibility study demonstrates a fairly high recruitment and a low dropout rate, indicating that the intervention is feasible and acceptable for BC patients. Likewise, the high rate of PRO (95%) confirms that follow-up based on regular collection of PRO is feasible. The high participation and adherence rate could be attributed to the organization of the study in which patients were invited by a single dedicated project physician and subsequently followed by the same physician and five specialist nurses. This increased focus on continuity of care may appeal to BC patients, who have proved to have a high prevalence of unmet needs [7]. Furthermore, participants in both arms of the study were offered a closer contact to the outpatient clinic than that in the standard follow-up and this may have increased recruitment. Fifty percent of all answered PRO resulted in either a nurse or a physician contact. The majority of PRO-initiated contacts (81%) were handled by the nurse alone, whereas 62% of contacts between PRO were forwarded to the project physician. This rather high number of PRO-initiated contacts probably reflects a considerable symptom burden among patients who have recently undergone primary treatment for BC. As shown in Table 4, there was a considerable range in the contacts with a few of the patients accounting for numerous contacts. Moreover, symptoms reported in PRO were often recognized by the nurse as expected adverse or late effects whereas symptoms causing the patients to contact the nurse between PRO were likely to be of more serious concern to the patient, or related to complex symptoms requiring assessment by a physician. Assessment of patients' symptoms and clinical decision-making is traditionally perceived as the physician's responsibility, but here we examined the effect of a reassignment of tasks. As per protocol, participants in the feasibility study were offered 3–5 GSD appointments with the nurse. The fact that more than half of the patients had three appointments and one-third had >3 indicates that the number of appointments offered was appropriate.

Various self-management interventions have been proposed, but most often in addition to standard of care follow-up [13]. In the present study, the physician-led follow-up is replaced by the GSD self-management intervention in combination with collection of PRO and navigation to further examinations or specific treatments according to symptoms. To the best of our knowledge, this has never been undertaken before. As a tool for the detection of recurrence in cancer follow-up, PRO has not yet been properly studied. Denis et al. showed a significant survival benefit using PRO among progression-free lung cancer patients [32]. However, 63% of the included patients had metastatic lung cancer and thus PRO was used as a surveillance tool during or between treatments rather than to detect relapse in follow-up for the majority of participants [32].

Table 4. Number and type of contacts for the 25 participants in the feasibility study at 18 months follow-up.

Type of contacts	Number of contacts			Symptoms causing suspicion of recurrence[a]			Symptoms assessed as adverse or late effects			Symptoms not related to recurrence or treatment		
	Total (*N*)	Mean	Median (range)	Total (*N*)	Clinical action (*N*)	Referrals (*N*)	Total (*N*)	Clinical action (*N*)	Referrals (*N*)	Total (*N*)	Clinical action (*N*)	Referrals (*N*)
Nurse contacts due to PRO	59	2.4	2 (0–5)	5	Mammography (1) MRI (2) CT (1) Bone scintigraphy (1)	Specialist (1) Physiotherapist (1)	30	Advice (24) ET-adjusted (6)	Acupuncture (2)	24	Advice (24)	GP (4)
Physician contacts due to PRO	14	0.6	0 (0–3)	5	Mammography (1) CT scan (3) Bone scintigraphy (1)	GP (2)	6	Advice (5) ET-adjusted (1)	0	3	Advice (3)	GP (1) Specialist (1)
Nurse contacts between PRO	15	0.6	0 (0–9)	2	MRI scan (2)	GP (1)	8	Advice (4) Dexa scan (1) ET-adjusted (3)	Physiotherapy (1)	5	Advice (5)	GP(5)
Physician contacts between PRO	24	1.0	1 (0–6)	5	Mammography (3) CT scan (2) MRI scan (1)	GP (1) Specialist (1) Lymphedema therapist(1)	14	Advice (6) ET adjusted (7) T-adjusted (1)	Specialist (1) Acupuncture (1)	5	X-ray (1)	GP (2) Specialist (2)
All contacts	112	4.5	4 (1–19)	17	Mammography (5) MRI (5) CT (6) Bone scintigraphy (2)	GP (4) Specialist (2) Physiotherapist(1) Lymphedema therapist(1)	58	Advice (39) Dexa scan (1) ET adjusted (17) T-adjusted (1)	Specialist (1) Physiotherapist(1) Acupuncture (3)	37	Advice (32) X-ray (1)	GP (12) Specialist(3)

PRO: patient reported outcomes; MRI: magnetic resonance imaging; CT: computed tomography; ET: endocrine therapy; GP: general practitioner; DEXA: bone densitometry; T: trastuzumab.
[a]No recurrences have been detected to date.

The MyHealth intervention provides individualized follow-up involving patients actively in the recognition of symptoms in the post-treatment phase, both in order to manage symptoms of distress and late effects and also to detect recurrences as early as possible. We recognize that loco-regional and distant recurrences are two distinct scenarios. Loco-regional recurrences are most often detected either by routine mammography, which is not altered in this study, or by patients themselves. Clinical examinations have played a decreasing role in detection of recurrences over the years [5]. Distant recurrences are almost exclusively detected due to symptoms reported by the patient, since blood samples and diagnostic imaging except for mammographies are not part of the follow-up. Consequently, by initiating this active involvement of patients in the reporting of symptoms, the MyHealth intervention may support an even earlier detection of recurrence. In addition, the systematic use of PRO supports an individual needs assessment with regard to identification of late effects and the patients' actual need for rehabilitation. We will test if the MyHealth intervention is more effective both regarding detection of recurrences and late effects requiring treatment and also if the reassignment of tasks from physicians to nurses is less expensive.

The strength of the feasibility study is the high recruitment and adherence rate proving the reorganization of follow-up possible and the elements in the intervention acceptable and relevant for BC patients. Further, we showed that nurses are able and willing to assume increased responsibility for symptom management in the follow-up of BC patients. The limitations of the feasibility study include its relatively small sample and the lack of a control group. Thus, we are not yet able to report whether the MyHealth intervention will result in better symptom management after treatment for BC.

Conclusion

On the basis of the experiences gained from the feasibility study, several minor changes have been made to optimize the study flow. No changes to the protocol were made based on the GSD appointments carried out or with regard to the patient navigation algorithm. Although the MyHealth study comprises a complex intervention requiring systematic changes including training of nurses and establishment of systematic collection of PRO as the basis for patient navigation, this feasibility study has suggested the MyHealth intervention to be both feasible and acceptable for patients treated for early BC. Recruitment to the MyHealth study is ongoing and expected to be completed in January 2019 and results are expected ready for publication by the end of 2021.

Acknowledgments

The authors thank participating patients and project nurses.

Disclosure statement

No potential conflict of interest was reported by the authors.

Funding

MyHealth is supported by the Region Zealand Funds and The Danish Cancer Society and Kræftens Bekæmpelse.

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