Original Article

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Application of Personal Health Record in Enhancing the Quality of Life in Patients With Breast Cancer Who Received Adjuvant Hormonal Therapy

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ABSTRACT

Objective: Recently, personal health records (PHR) have become a communication tool between patients and medical professionals. PHR applications (PHR app) can be installed on smartphones to record patient-reported outcomes (PROs). This study prospectively examined whether patients with breast cancer could record PROs, including subjective and objective symptoms, on PHR app.

Materials and Methods: Patients who received adjuvant hormonal therapy were enrolled. The patients were asked to collect PROs related to physical conditions, symptoms, and medications on their PHR app from the beginning of therapy for one month. Quality of life (QoL) was evaluated before treatment initiation and one month after. Patients completed a questionnaire of their opinions concerning the PHR app after use.

Results: Fourteen patients were enrolled between October and December 2020. All patients could use the PHR app during the study period without any negative effects on QoL. Eleven (79%) patients fully recorded their PROs on the app. Typical side effects induced by hormonal therapy to reduce the QoL were observed (hot flash in two patients, 14.3%). The questionnaire revealed that approximately 70% wanted to use the PHR app in the future to communicate with medical staff and to report adverse events. Specifically, 90% of patients who experienced difficulty communicating with medical staff wanted to use the PHR app. Some patients wanted to utilize the PHR app to set reminders to take medications.

Conclusion: The PHR app can be applied as a communication tool between patients taking adjuvant hormonal therapy and medical professionals.

Keywords: Breast cancer; quality of life; personal health records; hormonal therapy; patient reported outcome; adverse event

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Key Points

- To appropriately manage the QoL of breast cancer patients who receive adjuvant hormonal therapy, it is important for medical professionals to know the physical conditions and/or symptoms, including adverse events (patient-reported outcomes, PROs), of patients.
- Personal health record application (PHR app) is an electronic note that can be installed on smartphones to record PROs.
- We prospectively examined whether patients could record their PROs on the PHR app.
- All patients could record PROs on the PHR app without affecting their QoL.
- Most of the patients, especially those who had difficulty communicating with medical staff, wanted to use the PHR app to share their adverse events with medical staff.

Introduction

Many clinical studies have demonstrated the efficacy of adjuvant hormonal therapy for patients with hormone receptor-positive breast cancer (1-3). Although hormonal therapy has demonstrable advantages in terms of lower recurrence rate and longer survival, many patients experience adverse events, such as menopausal symptoms including hot flashes, joint pain, and night sweats caused by the blockade of hormone receptors (4). These side effects induced by adjuvant hormonal therapy decrease the quality of life (QoL) of patients and occasionally cause early discontinuation of the treatment (5-7). It has been reported that patients should continue the adjuvant hormonal therapy for at least 5 years to

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prevent recurrence and/or death (8). Therefore, adequate management of adverse events induced by hormonal therapy is required.

In order to complete long-term adjuvant hormonal therapy without lowering the QoL of patients, physicians need to collect information on adverse events from patients and make appropriate treatment plans at the right time. However, patients are often reluctant to report menopausal symptoms to their physicians (9).

Recently, the importance of the management of adverse events occurring in patients, based on patient-reported outcomes (PROs), which are subjective patient evaluation of adverse events and/or QoL, has been recognized (10). In the United States, the use of web-based PRO reporting was demonstrated to improve the QoL of patients who received routine chemotherapy in the outpatient setting for advanced solid tumors (11). Clinicians and nurses were able to evaluate the symptoms of patients through PROs and give appropriate advice to the patients, which led to an improvement in their QoL.

The personal health record (PHR) is an electronic recorder that allows patients to record their physician's diagnoses, symptoms, and/or medications during therapy (12). Patients and their family members can share these lines of medical information using PHR. By recording the symptoms and physical conditions that occur during adjuvant hormonal therapy on the PHR, patients can share the recorded information with their physicians. Then, physicians can easily collect these lines of information on patients occurring at home, based on the records on PHR. Therefore, we used PHR as a tool for patients to easily interact with their physicians when receiving adjuvant hormonal therapy.

The use of both PHR and PRO was expected to help medical staff recognize any side effects early, and thus facilitate prompt and effective management of negative adverse events, resulting in the improvement not only of the quality of hormonal therapy but also the QoL of the patient. However, it has not yet been confirmed whether PHR is easily useable and convenient for breast cancer patients as a device to record their status, including adverse events and medication, during adjuvant hormonal therapy.

Therefore, the present study investigated whether patients who received adjuvant hormonal therapy could record their physical condition and daily medications as PRO on the PHR application (PHR app) during treatment. The patients were asked to input symptoms at home and daily records of medication into the PHR app. The effect of using the PHR app on the QoL of patients was assessed. Furthermore, patients were asked to answer a questionnaire to collect opinions on the use of the PHR app after the study period.

Materials and Methods

Study Design

This was a prospective study conducted at Showa University Hospital in patients with breast cancer who were treated with adjuvant hormonal therapy. The study period was set to one month from the initiation of adjuvant hormonal therapy. Before the beginning of the study period, patients installed the PHR app on their smartphones or tablets. We employed the cancer notebook application "Welby MyKarte ONC"" (Welby, Tokyo, Japan), which can be freely used by anyone, as a PHR app (Figure 1). Researchers examined the daily medications and symptoms of patients recorded on the PHR app during the study period. Patients were also asked to complete a questionnaire to collect impressions and opinions regarding the PHR app after use.

The study protocol was approved by the Ethics Committee of Showa University (approval no: 3235). All patients provided written informed consent to use their medical information and PHR app data for research purposes. The study was registered at the University Hospital Medical Information Network-Clinical Trials Registry Japan (UMIN000042365).

Patients

All patients, who were diagnosed with breast cancer and underwent any type of surgery at Showa University Hospital before starting adjuvant hormonal therapy and were aged 20 years or older were asked to participate. Patients who received radiotherapy between surgery and initiation of hormonal therapy were also eligible for the study. These patients were administered tamoxifen, anastrozole, letrozole, or exemestane as adjuvant hormonal therapy.

Treatment

The adjuvant hormonal therapy administered to patients was as follows: (1) tamoxifen at a dose of 20–40 mg once daily (1); (2) anastrozole at a dose of 1 mg once daily; (3) letrozole at a dose of 2.5 mg once daily; or (4) exemestane at a dose of 25 mg once daily (13).

QOL Measures

The Functional Assessment of Cancer Therapy-Breast (FACT-B) was used to evaluate the QoL of patients, because the FACT-B has been confirmed for its reliability and validity in a QoL study, and the FACT-B questionnaire was translated into Japanese (14-16). QoL was evaluated twice during the one-month of study period, firstly, just before the initiation of the hormonal therapy, 'before the use of PHR app (defined as Pre)', and secondly, one-month after the initiation of the therapy, 'after the use of PHR app (defined as Post)'.

The Records of Daily Medications

The records of daily medications were calculated by dividing the number of days that the patients recorded their medications on the PHR app by the number of treatment days (31 days).

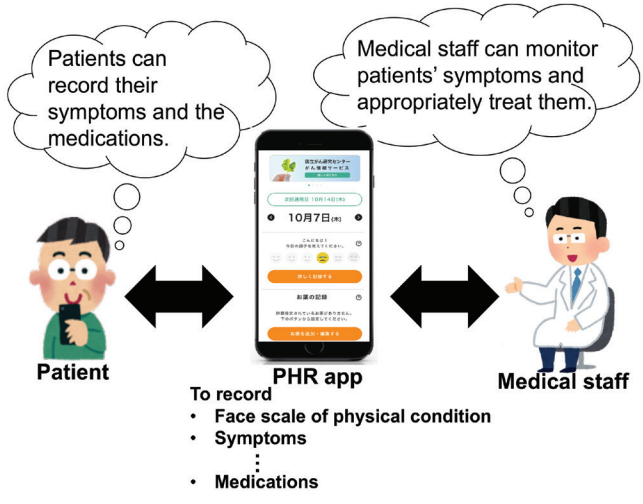

Figure 1. Interaction of patients with medical staffs using PHR app (Welby MyKarte ONC®).

PHR: the personal health record; app: application

The records of PROs

Patients recorded physical conditions and symptoms as PROs occurring at home during the one-month of study period on the PHR app.

Questionnaire

The questionnaire was collected via e-mail after completing the use of the PHR app. The questionnaire was designed to ask the following questions: 1) whether the patients usually feel a difficulty in communicating with medical staff, 2) whether the patients want to use the PHR app to communicate with medical staff to report their adverse events in the future, and 3) whether the patients want to use the PHR app in their daily lives.

Statistical Analysis

All **s**tatistical analyses were performed using JMP Pro software, version 15.0.0 (SAS Institute, Cary, NC, USA). The intra-patient changes in QoL scores between the beginning and the end of the study were analyzed using paired non-parametric Wilcoxon signed-rank test.

Results

Patient Characteristics

Fourteen patients were assessed between October 2020 and December 2020 for their eligibility to participate in this study. Table 1 shows the characteristics of the patients included in this study. All patients were positive for hormone receptors and received tamoxifen, anastrozole, or letrozole as adjuvant hormonal therapy. Nine patients were administered tamoxifen, four patients letrozole, and one patient anastrozole. Three and ten patients received neoadjuvant chemotherapy and radiotherapy, respectively, before starting adjuvant hormonal therapy.

QOL Scores Recorded Before and After the Use of PHR App

All 14 patients could use the PHR app installed on their smartphones or tablets for the study period. QoL scores of patients evaluated with FACT-B were recorded before (pre) and after (post) the use of the PHR app and are shown in Figures 2a to 2j. Physical well-being (PWB) scores were significantly higher at Post than at Pre ($p = 0.035$). In one patient, the PWB score at Post was 10 points higher than that at Pre. PWB scores calculated without this patient were not significantly different between pre and post. We investigated the causes of the 10-point increase in PWB score from pre to post observed in this patient and it was found that this patient had the lowest pre-PWB score among all patients (Figure 2a). Therefore, we first focused on the background of this patient before initiating hormonal therapy to determine the causes of these phenomena. Scores observed at pre for questions 3, 4, 5, and 6 were two points lower than the corresponding post score. According to the medical record, this patient received radiotherapy from the surgery performed a month earlier until just before starting the adjuvant hormonal therapy. The patient suffered from itching, dryness, and redness of the skin on the last day of radiotherapy, probably due to radiation exposure, which is thought to be the reason behind the low PWB score at pre. Details of the changes in the respective scores are shown in Table 2. The scores for social well-being (SWB), emotional well-being (EWB), functional well-being (FWB), and breast cancer subscale (BCS) were not significantly different between pre and post.

Overall, the results indicated that the use of the PHR app did not negatively affect the QoL of patients.

Analysis of Questionnaire Performed After the Use of PHR App

The questionnaire responses conducted after the use of the PHR app are shown in Table 3. According to the answers to question 1 (whether the patients usually feel difficulties communicating with medical staff), there were seven patients who usually felt difficulty communicating with medical staff. Six (86%) out of these seven patients answered that they wanted to use the PHR app to communicate with medical staff (question 2, whether the patients wanted to use the PHR app

Table 1. The demographic and clinical characteristics of the fourteen patients participating in the study

		n (%)
Median age (range), years		50.7 (31–65)[a]
Marital status	Yes/no	9/5 (64.3/35.7)
Number of pregnancies	0 / ≥1	6/8 (42.9/57.2)
Working	Yes/no	12/2 (85.7/14.3)
Menopausal status	Pre/post	10/4 (71.4/28.6)
Comorbidity	(+)/(-)	6/8 (42.9/57.1)
Mastectomy	Partial/total	7/7 (50.0/50.0)
Stage group	I/II	9/5 (64.3/35.7)
Lymph node metastasis	Yes/no	5/9 (35.7/64.3)
Neoadjuvant chemotherapy	Yes/no	3/11 (21.4/78.6)
Radiotherapy	Yes/no	10/4 (71.4/28.6)
Drug for adjuvant hormonal therapy and daily doses	Tamoxifen 20 mg	9 (64.3)
	Anastrozole 1 mg	1 (7.15)
	Letrozole 2.5 mg	3 (21.4)
	Letrozole 2.5 mg + leuprorelin 11.25 mg	1 (7.15)

[a] : median (range); n: number

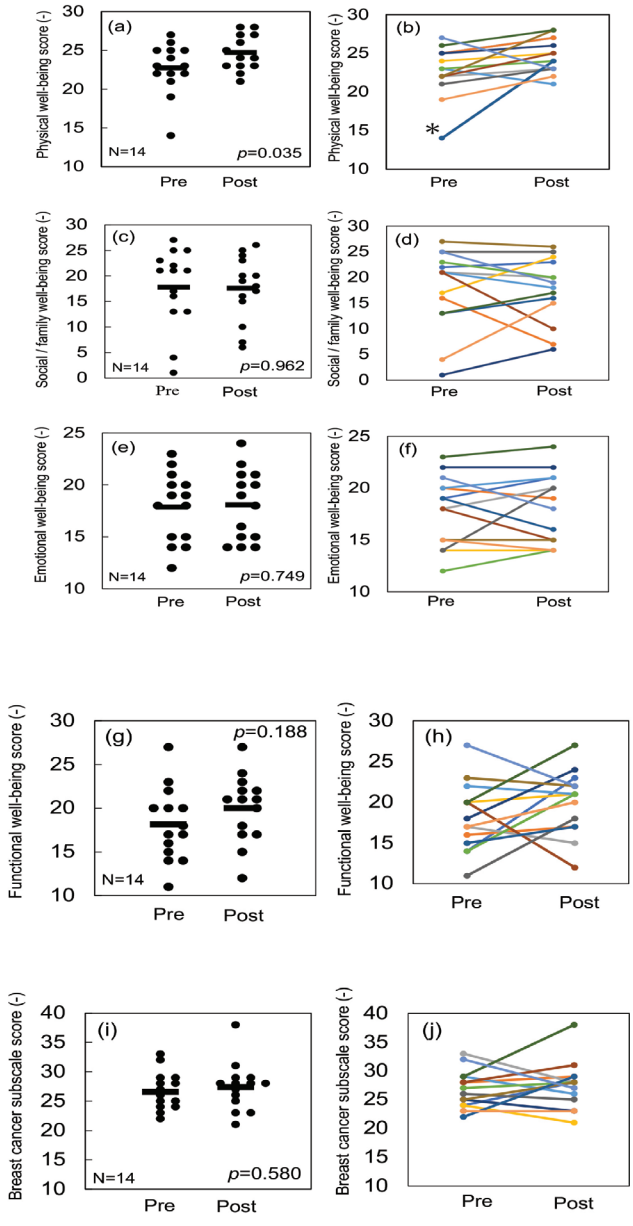

Figure 2. Effects of the PHR app use on QoL. Changes in QoL between pre and post were evaluated in 14 patients.

Panel **(a)** shows the plots of the PWB scores at pre and post. Panel **(b)** depicts the changes in the PWB observed in each patient from pre to post. One patient showed a 10-point increase in PWB from pre to post (*). Pairs of panels **(c, d), (e, f), (g, h)**, and **(i, j)** show similar results to **(a, b)** for social well-being (SWB), emotional well-being (EWB), functional well-being (FWB), and breast cancer subscale (BCS), respectively. The statistical differences in the respective scores between pre and post shown in panels a, c, e, g, and i were analyzed using the Wilcoxon test.

pre: Just before the initiation of the hormonal therapy, that is, before the use of the PHR app; post: One month after the initiation of the therapy, that is, after the use of the PHR app. Bars indicate mean values; PHR: the personal health record; app: application; QoL: quality of life; PWB: physical well-being

to communicate with medical staff to inform their adverse events in the future). In addition, the reasons why patients answered "Yes" to question 2 are shown in Figure 3. Six patients wanted to use the PHR app as a communication tool for reasons, including: (1) to easily record their physical conditions; and (2) to avoid forgetting to share their physical conditions with medical staff. These results indicate that patients who have difficulty communicating with medical staff, want to use the PHR app to conveniently communicate with medical practitioners. On the other hand, three of six patients who did not feel difficulties in communicating with medical staff (question 1) answered "Yes" to question 2. According to Figure 3, these patients wanted to use the PHR app to communicate with medical staff in a timely and precise manner, even though they did not feel difficulties communicating with medical staff previously.

Next, we asked patients whether they wanted to continuously use the PHR app in the future (question 3) (Figure 4). In this question we did not restrict the use of the PHR app as a communication tool with medical staff as in question 2. Among the nine patients who answered "Yes" to question 2, eight (89%) wanted to continuously use PHR app in their future daily life. Four out of eight (50%) patients answered that they could record daily physical conditions on the PHR app and easily communicate with medical staff, similar to their answer to question 2. On the other hand, two of eight patients (25%) wanted to use the PHR app to avoid forgetting to take tablets during adjuvant hormonal therapy, suggesting there would be an improvement in medication adherence when using this application.

Daily Medications Recorded on PHR App

The daily records of medications reported on the PHR app are shown in Figure 5. Seventy-nine percent (11/14) recorded the intake of medicine for more than 28 days (≥ 90% of the days) during the study period (31 days). Two patients who wanted to use the PHR app to avoid forgetting to take a medicine (question 3) recorded 94 and 100% ($ sign in Figure 5). In contrast, two patients who recorded 0 and 40% did not want to use the PHR app in their daily lives (# sign in Figure 5). These results suggest that the use of the PHR app may support the maintenance of medication adherence for patients who would like to use the PHR app and to keep records of medication on it.

The PROs Recorded on PHR App

The physical conditions and symptoms recorded on the PHR app during the study period are shown in Table 4. The most typical adverse events of hormonal therapy are indicated by asterisks. Typical side effects induced by hormonal therapy, such as joint pain, hot flashes, and depression, occurred which worsen the QoL of the patients.

Discussion and Conclusion

In this prospective study, we examined whether patients with breast cancer could record their PROs, including their physical conditions and adverse events, on the PHR app during adjuvant hormonal therapy. We also examined the effects of the use of the PHR app on patients perceived QoL. The findings indicate that all patients could use the PHR app installed on their smartphones or tablets during the study period, without any negative effects on their QoL (Figure 2). The results suggest that PHR app-based interventions are feasible for patients who receive adjuvant hormonal therapy. Furthermore, the answers of patients to the questionnaire conducted after the use of the PHR app showed that approximately 70% wanted to use the PHR app in the future to communicate with medical staff to

report adverse events (Table 3). Ninety percent of these patients felt they experienced difficulty when communicating with medical staff (Figure 3). However, one patient who usually experienced difficulties in communicating with medical staff did not want to use the PHR app, because this patient usually recorded her physical conditions in a notebook. These results suggest that the PHR app might be a useful communication tool, especially for patients who cannot easily communicate with medical staff and do not have other means of recording that they have taken their medications. Additionally, two patients wanted to use the PHR app to remind themselves and to avoid forgetting to take medicines (Figure 4). Patients can record the intake of medical drugs on the PHR app and later they can confirm the entered data by themselves weekly. The PHR app also has an alarm function that allows patients to set the time they are supposed to take

Table 2. Change in each PWB score from Pre to Post in a patient with an increase in total PWB score of 10 points

Physical well-being questionnaire	PWB scores	
	Pre	Post
1. I have a lack of energy.	2	3
2. I have nausea.	4	4
3. Because of my physical condition, I have trouble meeting the needs of my family.	2	4
4. I have pain.	1	3
5. I am bothered by side effects of treatment.	1	3
6. I feel ill.	1	3
7. I am forced to spend time in bed.	3	4
Total	14	24

Pre: just before the initiation of the hormonal therapy, that is, before the use of PHR app; Post: one-month after the initiation of the therapy, that is, after the use of PHR app; PWB: physical well-being

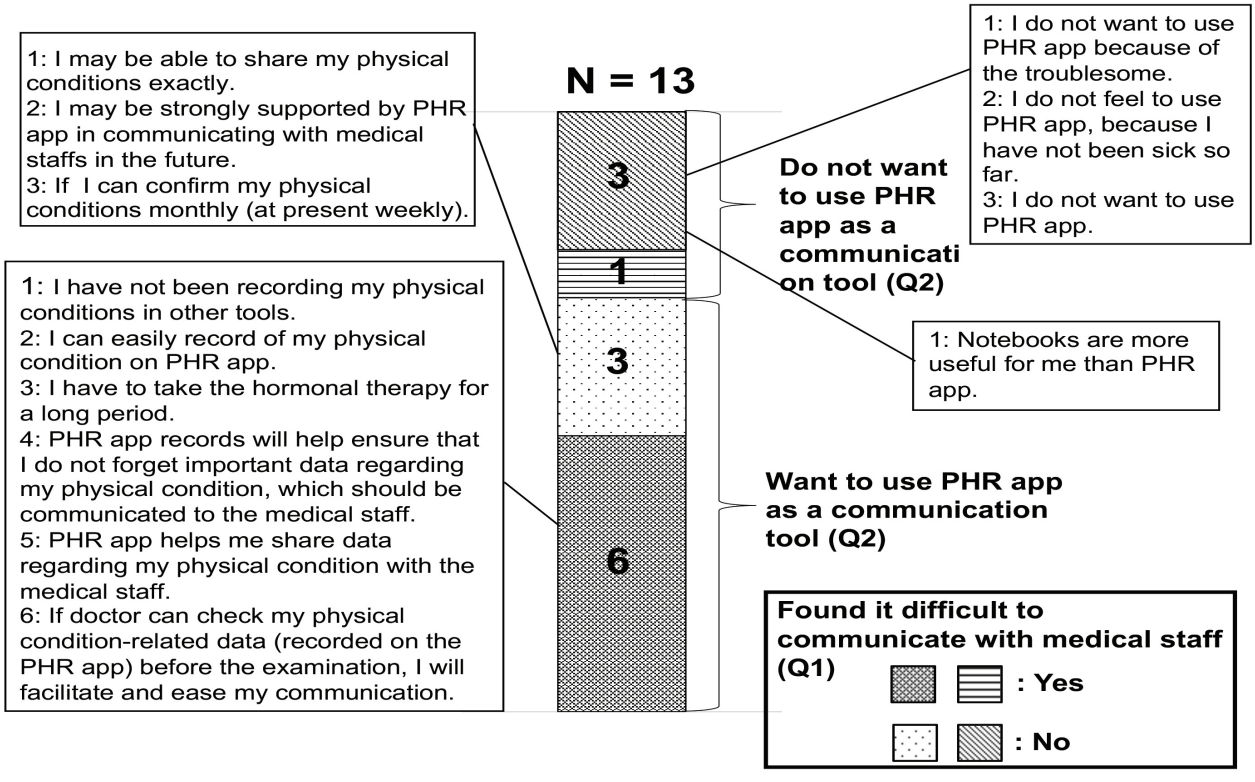

Figure 3. The answers of patients to question 2

Question 2: Whether the patients want to use the PHR app to communicate with medical staffs to inform their adverse events in the future.

PHR: the personal health record; app: application; N: number

their medicines. These PHR app functions will help prevent patients from forgetting to take their medications. Therefore, we believe that the PHR app may support medication adherence. Finally, the PROs recorded by the subjects on the PHR app were similar to the typical side effects induced by hormonal therapy, which lead to reduced QoL for patients (5). Taking these results into account, the PHR app might be a useful tool in terms of helping patients to communicate with medical staff and maintain their medication adherence.

One of the features of PHR use is that medical staff can monitor patient conditions remotely, unlike when patients use a written personal notebook. In other words, if patients continuously report severe adverse events on PHR, medical staff can reply promptly to any inquires they have and offer proper advice.

We believe that the following strategies might increase the usefulness of the PHR app in managing hormonal therapy. Firstly, to maintain patients' QoL effectively, it is necessary to establish a system where the medical staff routinely monitor PROs recorded on the PHR app and appropriately and promptly examine patients to avoid deterioration of the symptoms. There has been an attempt to monitor chemotherapy-induced side effects in patients with breast or colorectal cancer that occurred at home by using an online system on their personal computer or mobile device (17). In the study, nurses called patients to hear their

Table 3. Answers of 13 patients to the questions 1 to 3

Question	Answer	n (%)
1. Whether the patients usually feel difficulties to communicate with medical staff.	Yes	7 (53.8)
	No	6 (46.2)
2. Whether the patients want to use the PHR app to communicate with medical staff to report their adverse events in the future.	Yes	9 (69.2)
	No	4 (30.8)
3. Whether the patients want to use the PHR app in their daily lives.	Yes	8 (61.5)
	No	5 (38.5)

n: number; PHR: the personal health record; app: application

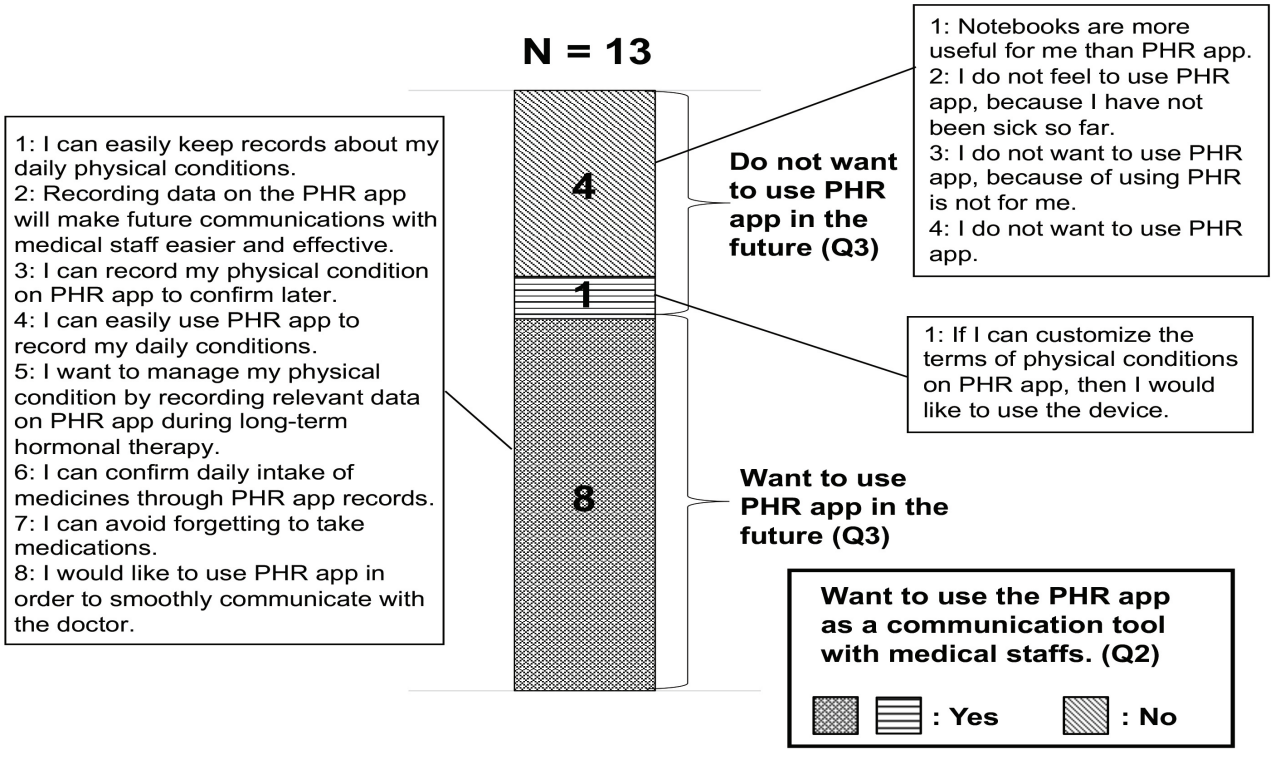

Figure 4. The answers of patients to question 3

Question 3: Whether the patients want to use the PHR app in their daily lives.

PHR: the personal health record; app: application; N: number

Table 4. The symptoms reported by 14 patients during the study period which ran for 31 days

Treatment periods of hormonal therapy (days)							
1 to 7		**8 to 14**		**15 to 21**		**22 to 31**	
Sleepiness	5 (35.7)[a]	Sleepiness	4 (28.6)	Hot flashes*	2 (14.3)	Headache	2 (14.3)
Dullness	3 (21.4)	Dullness	4 (28.6)	Headache	2 (14.3)		
Pain	3 (21.4)	Headache	3 (21.4)	Dullness	2 (14.3)		
Headache	2 (14.3)	Hot flashes*	2 (14.3)	Sleepiness	2 (14.3)		
Nausea	2 (14.3)	Nausea	2 (14.3)	Anxiety*	1 (7.15)		
Difficulty breathing	2 (14.3)	Joint pain*	1 (7.15)				
Itchy skin	2 (14.3)	Mood swings*	1 (7.15)				
Mood swings*	2 (14.3)	Anxiety*	1 (7.15)				
Anxiety*	2 (14.3)						
Joint pain*	1 (7.15)						

[a]Number of patients who recorded symptoms during the study periods (%); *Typical side effects induced by hormonal therapy which are known to be associated with the decrease in QoL; QoL: Quality of life

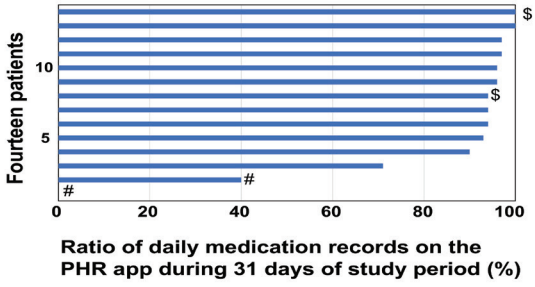

Figure 5. Ratio of daily medication records on the PHR app during study period. The daily medication records were measured in 14 patients. The ratio was calculated from number of days on which the patients recorded their medications on the PHR app divided by 31 days, which was the total study period.

$: Two patients who answered question 3 as "Yes", that is these patients wanted to use PHR app to prevent forgetting to take medicines; #: Two patients who answered question 3 as "No", that is these patients did not want to use PHR app

PHR: the personal health record; app: application

conditions when the medical staff recognized the patient reports indicating grade 3 or higher side effects, graded by PRO-common terminology criteria for adverse events. Appropriate and timely advice from nurses to patients could improve their QoL. Patients who receive hormonal therapy generally visit the hospital less frequently than those who are treated with chemotherapy. Consequently, medical staff have limited opportunities to understand the conditions of patients. Therefore, the use of the PHR app in hormonal therapy may have the potential to appropriately manage patients staying at home to maintain their QoL. It may be helpful for medical staff to monitor PROs if the system is incorporated into the electronic medical record system. A second strategy to appropriately maintain medication adherence of patients could involve medical professionals confirming the daily medication records that are reported on the PHR app by patients and provide advice based on the records. In a meta-analysis, mutual sharing of information related to medical adherence between patients and medical staff effectively improved medication adherence in adjuvant hormonal therapy (18). Considering this previous result, we believe that a system where patients and their doctors can share the daily medication records on the PHR app would be beneficial.

The present study had several limitations. First, the sample size was small, because this was an exploratory study, although it was performed in a prospective manner. Second, the study period was relatively short (one month). To evaluate the usefulness of the PHR app during the entire period of hormonal therapy, it is necessary to examine whether the patients can continuously use the PHR app for a long period. Third, this single-arm prospective study did not include control patients who did not use the PHR app. To overcome these limitations, we have already started a randomized control trial with a large number of patients.

In conclusion, all patients were able to use the PHR app without any negative effects on the reported QoL. PROs were recorded appropriately on the PHR app by most patients. The questionnaire revealed that most patients, especially those who had difficulty communicating with medical staff previously, wanted to use the PHR app to share their adverse events with medical staff. Some patients wanted to utilize the PHR app in order to avoid forgetting to take medications. Taken together, we conclude that the PHR app can be applied as a communication tool between patients and medical professionals in adjuvant hormonal therapy.

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Ethics Committee Approval: The study protocol was approved by the Ethics Committee of Showa University (approval no: 3235). The study was registered at the University Hospital Medical Information Network-Clinical Trials Registry Japan (UMIN000042365).

Informed Consent: All patients provided written informed consent to use their medical information and PHR app data for research purposes.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Concept: F.T., H.O., S.N., K.F.; Design: F.T., H.O., S.N., K.F.; Data Collection and/or Processing: F.T., H.O.; Analysis and/or Interpretation: F.T., H.O., S.N., K.F.; Literature Search: F.T., H.O.; Writing: F.T., H.O., S.N., K.F.

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