EFFECT OF MOBILE TRAINING ON THE QUALITY OF LIFE FOR WOMEN WITH BREAST CANCER

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Abstract

Background: Mobile applications are playing an increasing role in patient care, and their use in the oncologic field opens up promising possibilities in the fields of supportive cancer care and patient education. The objective of our study was to determine the effects on quality of life (QOL) of a mobile app–based training for supportive care of women with breast cancer using adjuvant endocrine hormonal therapy. Material and Methods: A single-blinded and randomized design was used. Participants were randomly assigned to either control group that receives routine care or intervention group that receives routine care plus access to mobile app–based training support for 12 weeks. QOL and symptom distress were measured before intervention (T0), after 12 weeks (T1) of intervention. This study is the application of three modality combinations: mobile app-based patient education (1), web-based management application (2), and nurse's tracking over the phone and mobile app (3). The mobile app-based training also provides basic information about breast cancer, symptom diary and lifestyle recommendations (adequate and balanced nutrition, regular physical activity, deal with stress effectively). Results: QOL of the treatment group after intervention increased and distress level was low compared to the control group; these results were statistically significant. The majority of the patients reported that the mobile application was "informative and useful". Conclusions: This demonstrated that the mobile app is an effective intervention for supportive care in women with breast cancer. The mobile app–based training, which is an innovative intervention, is recommended as a supportive care initiative for women with breast cancer.

What's known

Mobile applications use in the oncologic field opens up promising possibilities in the fields of supportive cancer care and patient education.

What' s new

- Mobile apps could contribute patients address EHT-related problems, provide easy access to the health-care provider, and report and manage their problems in a timely manner.
- Mobile app–based training could contribute patients symptom management and improving QOL.

BACKROUND

Breast cancer is the most commonly diagnosed cancer among women in the world. Worldwide, there are approximately 2.1 million (2,088,849) newly diagnosed breast cancer cases in 2018, and about one in four cancer cases among women is breast cancer [1, 2]. Of the women with breast cancer, approximately two out of three are hormone receptor- positive (ER + and / or PgR +) [3]. EHT is recommended for women with hormone receptor positive (ER + and / or PgR +) and to use Tamoxifen or Aromatase Inhibitor (AI) hormonal agents for at least five years [3-5]. EHT causes problems such as hot flashes and/or night sweats, headaches, nausea, pain, vaginal dryness, or discharge [3]. Although the effectiveness of EHT approach has been proven, these

common side effects are not life threatening but can negatively affect the quality of life[5, 6]. EHT side effects can affect the physical, emotional, and social well-being of patients [6]. Oncology nurses should undertake the tasks of developing skills and providing emotional support by effectively communicating with patients, and providing adequate knowledge and training to improve the QOL of women with breast cancer [7].

Mobile health (mHealth) is a widely accessible method that provides healthcare services through portable devices [8]. In the management of cancer patients, the development of new eHealth and mHealth initiatives has been reported to be promising, especially in the context of supportive care and follow-up [9]. These applications are important for oncology nurses to be aware[10]. It has been shown that the use of mHealth practices in health care management of women with breast cancer has positive effects. It also emphasizes that mHealth practices can play an important role in the care of women with breast cancer[8].

Many studies were aimed to assess mHealth apps and their impact on quality of life of women with breast cancer [11- 15]. Zhu et al. studied the effectiveness of the mobile application-based breast cancer e-support program to support women with breast cancer who received chemotherapy [12, 13]. They found that mobile application intervention is more effective in increasing self-efficacy and QOL and reducing symptom burden during chemotherapy[13]. Given the physical limitations in accessing healthcare or geographic distance, it has been reported that individuals use mobile applications as an additional intervention[11]. In a systematic review, in breast cancer care and addressed prevention and survivorship mHealth practices have been shown to have an effect on controlling weight, improving QOL and reducing stress levels [8]. However, the effectiveness of mobile application was not found significant when compared with routine care in terms of social support, symptom severity, anxiety, and depression among patients receiving breast cancer treatment [13]. In Foley et al., it was determined that training materials about surgical treatments including mobile information application had an alarming effect on the anxiety levels of women with breast cancer in the preoperative period [16].

To our knowledge, there is no standardized mobile app for the management of patients receiving EHT, possible side effects, symptom management, and QOL and requirements regarding follow and supportive care. The purpose of this study to find the effect of mobile app-based training on the QOL in women with breast cancer using EHT.

The hypotheses for the study is:

H1: Mobile training influences the quality of life of women with breast cancer.

LIMITATIONS

The limitations of the study are as the following; first the study took place in a single center with participants who owned a smartphone. Second, we could not measure how much time a participant spends on using the mobile app and which specific features of the mobile app they use.

Methods

Study Design and Setting

The study was conducted in a state hospital in Turkey, between January 2018 to July 2018. A single-blinded, single-centered and randomized design were used. This study was registered at the ClinicalTrials.gov (register number: NCT04315012). Ethical Committee Permit (The Ethics Committee of the University of Balıkesir, 2017/143) and institution permit were received for this study. Participants were randomly assigned to either control group that receives routine care or intervention group that receives routine care plus access to mobile app–based training support for 12 weeks (Figure 1). Moderated by an specialist nurse, the mobile app-based training program supported women with breast cancer for 12 weeks. QOL and symptom distress were measured before intervention (T0), after 12 weeks (T1) of intervention.

Figure 1.

This study is the application of three modality combinations:

(1) Mobile app-based patient education: Based on a literature research with respect to the subject matter; health care needs and coping methods were determined for the symptom management of women with breast cancer using adjuvant EHT (Picture 1). The Mobile app- based training provides 8 topics on symptoms management for problems in EHT including 1) how to deal with hot flashes / night sweats; 2) vaginal dryness, itching and bleeding management; 3) fatigue management; 4) how to deal with mood changes; 5) pain management; 6) sleep management; 7) how to deal with sexual ıssues; 8) how to deal with upper limber lymphoedema. Mobile app-based training also provides basic information about breast cancer, treatment options, symptom diary and lifestyle recommendations (adequate and balanced nutrition, regular physical activity, deal with stress effectively). The mobile app- based training included NCCN Distress Management algorithm [17, 18]. Distress levels of patients involved in study and their reasons were determined and information related to distress management ("coping with stress", "effective changes-recommendations", "healthy lifestyle recommendations") was included in the app. Out of the recommendations; providing training for the patients regarding the disease, coping methods such as relaxation techniques (relaxation exercises CD of 30 minutes which include breathing and muscle exercises) and guided imaginary were installed in the app. The guided imaginary CD contained natural views accompanied by relaxing, restful, slow music of 12 minutes oriented for the oncology patients.

Picture 1.

(2) Web-based management application: This program is where user information and logins are commanded, monitored, consulting activities are managed (question, answer, reminder) by mobile app manager (an specialist nurse). Questions, opinions, and report of symptoms sent by the participants over the mobile app were answered. In addition, participants were informed in a timely manner by a specialist nurse from the web-based app panel. Regarding this, many reminder messages have been sent to participants for any advice about self-care and supportive care. The researcher collaborated with a multidisciplinary team (medical oncologist, radiation oncologist, psychologist, oncology training nurse, radiotherapy training nurse, physiotherapist, dietician).

(3) Nurse's tracking over the phone and mobile app: By arranging one-to-one phone calls every two weeks between a specialist nurse and a participant; counseling was provided on patients' problems with the mobile app, with EHT, QOL, and their symptoms stated in the symptom diary and results of monitoring.

Participants

The population was composed of women with breast cancer using adjuvant EHT consulting the Medical Oncology Clinic. Power analysis was conducted and it was determined that 64 patients were required in the study; treatment group (n=31) and control group (n=33). Participants, aged 18- 65, diagnosed with primary breast cancer, non-metastatic, hormone receptor positive (ER + and / or PgR +) and treatment with EHT used at least for three months, having a smartphone that meets the app requirements were included.

Procedure and Measurements

Stages followed within the process of data collection are as follows:

Structuring the Mobile Application: Support has been received from Technopark Office for the mobile app. An appropriate human-computer interface design has been incorporated into the mobile app. The mobile app, which was sent to the patients of the treatment group as a short message (SMS), was installed by directly downloading the file with an extension ".apk" to their smartphones. The participants can sign into the app with their given username and password. The main page of the app consists of six segments; "my training, my questions, symptom diary, my opinions, my reminds, my profile". Mobile app allows patients to record daily symptoms with an indication of severity.

*Mobile Application Usability***:** Font type, size, style and color selection was selected carefully for the readability and the visibility of the app on the screen. Especially, pink color was selected as the font and heading color in the mobile application since it is the symbol of breast cancer reflecting hope and happiness.

Mobile Application User Training: A training on the how to download and use of mobile app was organized face-to-face for the treatment group before the intervention.

Data Collection Instruments*:* Data collection instruments were introduced to the participants their consent was taken by informing them about the purpose of the research. Data were collected from the treatment and control group simultaneously at baseline (T0) then 12 weeks (T1) post-intervention. Data was collected with the method of face to face interview by using the following measurement instruments: Participants Introductory Information Form, Functional Assessment for the Cancer Treatment – Endocrine Symptoms Quality of Life Scale (FACT-ES QLS) and NCCN Distress Thermometer. Data collection time varied between 20 to 50 minutes. A flow diagram of the research is shown in Figure 2.

Figure 2.

Participants Information Form: The form was prepared by the researcher by analyzing the relevant studies [9, 19- 23].related to the QOL of women with breast cancer. There are 20 questions related to sociodemographic characteristics such as age, marital status, education status, number of children and medical history and clinical features related to the treatment. One question concerned with the opinions of the the participants about the installation and the use of the app after the intervention.

FACT-ES Quality of Life Scale (FACT-ES QLS): The scale is designed to measure the side effects and the potential benefits of the treatment for women with breast cancer using EHT. Validity and reliability of the scale were verified by Fallowfieldet et al.and translated into different languages other than English[24]. The scale includes five sub dimensions and total of 46 items measuring the well-being of patients within the course of the last 7 days. There are sub dimensions for each of the following: physical well-being (7 items, 0-28 points), social/family well-being (7 items, 0- 28 points), emotional well-being (6 items, 0-24 points), functional well-being (7 items, 0-28 points) and endocrine symptoms (19 items, 0-76 points). Endocrine symptoms' subdimension contains symptoms related to the side effects of EHT. Total Cronbach alpha value was found as 0.92. Scale subdimensions' Cronbach alpha values range from 0.65 and 0.91 [24]. Turkish translation and permissions were received from the administrator of the web site. The range of total points of the scale is 0-184. It shows that QOL increases as total points of the scale increase.

NCCN Distress Thermometer: This is a measurement instrument improved in 1998 by Roth et. al., to determine the distress level of cancer patients [25]. Distress level is graded in between 0 and 10 on a 'thermometer'. Patients may specify the severity of the distress level they experienced related to their problems, with these numbers, within the course of the last 7 days. No distress is specified with "0" point, a severe amount of distress is specified with "10" points. 5 and more points of NCCN scale shows that there is distress and follow up and assessment of the individuals should be made.

Data Analysis

Data were assessed in IBM SPSS Version 25. Descriptive statistics related to the factors were presented with numbers (n), percentage (%) and continuous variables with mean ±standard deviation, median (minimum–maximum) values. For the calculation of categorical variables, chi-square analysis, ANOVA test for repeated measurements, parametric and non-parametric tests were used. Student t-test and Mann Whitney U tests were used for the comparison of two independent groups. All statistics were assessed at the significance level, %95.

Results

Sample Characteristics

Average age of the patients involved in the research is 45.7±9.0 (min:30- max:65), mean disease duration is 30.1±22.6 (min:5-max:120) months and mean EHT duration is18.1±17.3 (min:3-max:84) months. 46.8% of them are primary school graduates, breast conserving surgery (BCS) was experienced by 62.5% of participants and it was determined that 76.6% of the patients had taken chemotherapy (CT), radiotherapy (RT), surgical therapy (ST), and EHT. No significant difference was found between groups according to age, education

status, marital status, disease duration, breast cancer stage, medicine group administered in EHT (Tamoxifen and aromatase inhibitors), and menopause cause related to the patients in treatment and control groups ($p<0.05$) (Table 1).

Table 1.

When total FACT-ES QLS points of the participants and point means of sub dimensions were compared; no significant difference was found in between groups at T1 ($p>0,05$) (Table 2). A significant difference ($p<0,05$) was determined statistically after intervention (T2) (Table 3) in FACT-ES QLS total points; physical, emotional well-being and endocrine symptom sub dimensions mean points of the participants in the treatment group, compared with the period before intervention (T1). There was no significant difference found in T2 compared with T1 in social/family well-being sub dimension average points ($p=0,336$).

Table 2.

Table 3.

FACT-ES QLS total average points of both groups at T1 and T2 were compared (T1:t=- 1,76, p=0,083; T2:t=2,987, p=0,004). The repeated measurement analysis (ANOVA) of mean score, variance was found significant (F=35,883 $p<0,001$). Interaction of time and groups were determined as statistically significant ($p<0,05$). As FACT-ES QLS mean score increased in the treatment group, it decreased in the control group.

FACT-ES QLS mean score of patients statistically significantly increased level ($p<0,05$) in the treatment group, after mobile app-based training (T2) was provided, in all age groups, at secondary education, bachelor's degree and master degree levels, at all stages of breast cancer (I-II-III), for whom surgical therapy (mastectomy and MKC) was received, EHT was used (Tamoxifen and AI), and menopause as a result of chemotherapy/surgical therapy, who does not have any chronic disease.

NCCN Distress Thermometer mean score of half of the participants (50%) involved in the study were determined as [?]5 before intervention (T1). In the correlation analysis; as distress points increase, it was determined that QOL points decreased (r=-,527, p=0,002). When NCCN Distress Thermometer mean scores were compared; there was no statistically significant difference in between both groups at T1 (p=0,320). There was a statistically significant difference between both groups at T2 (p=0,027). Interaction of time and groups was found statistically significant ($p<0,001$). While distress mean score decreased in the treatment group after intervention (T2), it increased in the control group.

Participants' opinion in the treatment group where mobile- based app training and individual consultancy were provided, were sought related to the app and availability, learning and readability of the app. Most participants (87,1%) mentioned that app was "an informative and beneficial training" and 12,9% of them mentioned that "it was such a training to be provided at the beginning of EHT.

Cooperation was made with the multidisciplinary team (medical oncologist, radiation oncologist, psychologist, oncology training nurse, radiotherapy training nurse, physiotherapist, dietician) related to the training and consultancy provided by the researcher. Within the course of the consultancy period; some patients were directed to the relevant specialist in the following departments: Smoking Cessation Clinic (n=2), Life with Celiac Association (n=1), Nutrition and Diet Specialist (n=3), Surgery Clinic (n=3) and (for the breast prosthesis) Reconstructive Surgery Clinic (n=2).

Discussion

Innovative, standardized, efficient, cost effective, supportive cancer care methods should be administered to improve the QOL of patients. Mobile health apps are appealing to the patients because of their cost-effectiveness, flexible and high quality services for the benefit of the patients, presenting an opportunity for remote monitoring and training of patients, reachable at any place at any time[26]. Our study is the first made in Turkey which analyzes the effect of a mobile- app based training to improve the QOL of women with breast cancer using EHT.

It was determined after the intervention (T2) that FACT-ES QLS total points, physical well-being, emotional well-being and endocrine symptom mean scores were increased significantly for the treatment group to whom mobile- app based training was provided, compared with the control group. In addition, social/family well-being and functional well-being mean scores were found high although those were not statistically significant. While the QOL improved for the treatment group, there was a decline in the control group.

Sajjad et. al. mentioned that training provided to women with breast cancer by the nurses improved the QOL of patients [27]. It was determined in a meta-analysis study conducted by Suh & Lee that telephone-based training provided by nurses improved quality of life[21]. Similar results were also found in our study. It was determined that psychological interventions by Badger et. al., provided with telephone training and individual consultancy to the breast cancer patients for whom a recent diagnosis was made, significantly decreased depression and physical symptoms of participants and increased social and spiritual well-being [19]. Ryhanen et. al. found, in a randomized controlled study where QOL, anxiety and coping with side effects related to the treatment were assessed for the internet-based patient training program in order to strengthen women with breast cancer [20].,that internet-based patient training program did not decrease the anxiety level of women with breast cancer or side effects of the treatment and that it did not improve QOL sub dimensions. Our study differs from Ryhanen et. al. in the sense that mobile- app based training provided to the treatment group to whom EHT adjuvant was used, has improved the QOL[20].

It was determined in the literature that sociodemographic and clinic characteristics such as age, education level, social support, financial status, working status, disease stage are factors affecting QOL[21, 28]. Our study also found that FACT-ES QLS mean score of patients who are provided with mobile- app based training significantly affected sociodemographic and clinic characteristics.

Distress results from physical, cognitive, behavioral, emotional, social, and spiritual factors and it is directly related to the sub dimensions of QOL [17, 18]. While a decrease was noted for the distress level of the treatment group taking mobile- app based training, there was an increase in the control group. As a result, QOL was decreased for the participants whose distress level was increased. Visser et al. differs from our study, a tablet-based online app was observed to have no significant effect on distress [29]. Rosen et al., mobile app-based mindfulness training improved QOL and decreased distress for women with breast cancer [11]. In a study conducted by Zhu et al., women with breast cancer were less distressed as given professional support available with mobile app-based[12]. Similar results were also found in our study.

In a multi-centered prospective study made for the purpose of supportive care and provided with a mobile app to the cancer patients, it was noted that most of the participants were strongly interested in the use of mobile app [9]. In our study most participants (87,1%) expressed that mobile- app based training was beneficial. Participants in the treatment group stated that the app was very beneficial in the sense that it was important to learn about the side effects of EHT and share their problems. The participants reported that the support of a specialist nurse was very comfortable at any moment. In addition, the participants added that they were pleased with receiving counseling and support by the nurse. These opinions are satisfactory, and it is thought that, besides the mobile app, regular telephone monitoring and assessment of the problems with a multidisciplinary team boosted participant's satisfaction. In Zhu et al. too, participants emphasized that the mobile app strengthens information, increases the level of trust and supports emotional well-being. In addition, participants suggested implementing message reminders in Zhu et al. study[12]. Our study differs from Zhu et al in terms of sending the participants message reminders through the mobile app. These messages included advice about personal care and supportive care.

Conclusion

As a result of the study, women with breast cancer to whom EHT was used, and a mobile- app based training and individual consultancy was provided in line with their physical, social, psychosocial and spiritual needs, QOL increased for these patients, at the same time their distress level decreased. Mobile application use in health institutions is recommended as these applications, can easily be used by the patient and the nurse. It is considered that supportive care provided for oncology patients with mobile- app based training increases

the satisfaction level of patients and that it strengthens trust and communication in between patient and nurse.

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Conflicts of interest: None.

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Table 1 . Distribution and Comparison of Patients in Treatment and Control Groups in Accordance with Their Descriptive and Clinical Characteristics

	X± SS	X± SS	U

	Treatment
FACT-ES QOL	**X± SS**
Total Points	122.03±24.85
Physical Well Being	21±5.32
Social/ Family Well Being	17.97±6.48
Emotional Well Being	12.97±4.48
Functional Well Being	19.84±3.96
Endocrine Symptoms	50.26±10.53
t*: Dependent sample test statistics.X : *Average*.SS : *Standard Deviation*. p**: p<0.05 Significance level.	t*: Dependen

Table 3. Comparison of FACT-ES QLS Total and Average Sub-Dimension Points Related to Post-Test (T2) Data of Treatment and Control Group

	Treatment
FACT-ES QOL	**X± SS**
Total Points	137,58±16,94
Physical Well Being	24,1±3,51
Social/ Family Well Being	18,06±6,24
Emotional Well Being	15,29±4,22
Functional Well Being	20,68±4,39
Endocrine Symptoms	59,45±7,61
t*: Dependent sample test statistics.X : *Average*.SS : *Standard Deviation*. p**: p<0.05 Significance level.	t*: Dependen

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`CONSORT-2010-Flow-Diagram-MS-19.05.2020.doc` available at https://authorea.com/users/338590/articles/465062-effect-of-mobile-training-on-the-quality-of-life-for-women-with-breast-cancer

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