mHealth self-care interventions: managing symptoms following breast cancer treatment

Mei R. Fu[1,2], Deborah Axelrod[2,3], Amber A. Guth[2,3], Kavita Rampertaap[1,2], Nardin El-Shammaa[1,2], Karen Hiotis[2,3], Joan Scagliola[2], Gary Yu[1], Yao Wang[4]

[1]NYU Rory Meyers College of Nursing, New York University, New York, NY, USA; [2]NYU Laura and Isaac Perlmutter Cancer Center, New York, NY, USA; [3]Department of Surgery, New York University School of Medicine, New York, NY, USA; [4]Department of Electrical and Computer Engineering, Tandon School of Engineering, New York University, New York, NY, USA

Contributions: (I) Conception and design: MR Fu, D Axelrod, AA Guth, Y Wang; (II) Administrative support: J Scagliola; (III) Provision of study material or patients: D Axelrod, AA Guth, K Hiotis, J Scagliola; (IV) Collection and assembly of data: MR Fu, K Rampertaap, N El-Shammaa; (V) Data analysis and interpretation: MR Fu, G Yu; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

Correspondence to: Mei R. Fu, PhD, RN, FAAN. Associate Professor/Tenured, College of Nursing, New York University, 433 First Avenue, 4th Floor, Room 424, New York, NY 10010, USA. Email: mf67@nyu.edu.

Background: Many women suffer from daily distressing symptoms related to lymphedema following breast cancer treatment. Lymphedema, an abnormal accumulation of lymph fluid in the ipsilateral body area or upper limb, remains an ongoing major health problem affecting more than 40% of 3.1 million breast cancer survivors in the United States. Patient-centered care related to lymphedema symptom management is often inadequately addressed in clinical research and practice. mHealth plays a significant role in improving self-care, patient-clinician communication, and access to health information. The-Optimal-Lymph-Flow health IT system (TOLF) is a patient-centered, web-and-mobile-based educational and behavioral mHealth interventions focusing on safe, innovative, and pragmatic electronic assessment and self-care strategies for lymphedema symptom management. The purpose of this paper is to describe the development and test of TOLF system.

Methods: The development of TOLF was guided by the Model of Self-Care for Lymphedema Symptom Management and designed based on principles fostering accessibility, convenience, and efficiency of mHealth system to enhance training and motivating assessment of and self-care for lymphedema symptoms. Test of TOLF was accomplished by conducting a psychometric study to evaluate reliability, validity, and efficiency of the electronic version of Breast Cancer and Lymphedema Symptom Experience Index (BCLE-SEI), a usability testing and a pilot feasibility testing of mHealth self-care interventions.

Results: Findings from the psychometric study with 355 breast cancer survivors demonstrated high internal consistency of the electronic version of the instrument: a Cronbach's alpha coefficient of 0.959 for the total scale, 0.919 for symptom occurrence, and 0.946 for symptom distress. Discriminant validity of the instrument was supported by a significant difference in symptom occurrence ($z=-6.938$, P<0.000), symptom distress ($z=-5.894$, P<0.000), and total scale ($z=-6.547$, P<0.000) between breast cancer survivors with lymphedema and those without it. Findings of usability testing showed that breast cancer survivors were very satisfied with the mHealth self-care interventions: 90% rated the system having no usability problems; 10% noted minor cosmetic problems: spelling errors or text font size. The majority of participants 96.6% strongly agreed that the system was easy to use and effective in helping to learn about lymphedema, symptoms and self-care strategies. Feasibility testing demonstrated that a 12-week one group intervention using TOLF had significantly positive effects on less pain (P=0.031), less soreness (P=0.021), less aching (P=0.024), less tenderness (P=0.039), fewer numbers of lymphedema symptoms (P=0.003), and improved symptom distress (P=0.000) at 12 weeks after intervention. Themes from the qualitative data included empowerment, high quality information, loving avatar simulation videos, easy accessibility, and user-friendliness.

Conclusions: TOLF system using the electronic version of the instrument is able to assess patients'

lymphedema symptoms with high reliability and validity. TOLF system is also able to deliver self-care interventions to enhance self-care strategies for lymphedema symptom management.

Introduction

Breast cancer-related lymphedema (hereafter, lymphedema), an abnormal accumulation of lymph fluid in the ipsilateral body area or upper limb, remains an ongoing major health problem affecting more than 40% of 3.1 million breast cancer survivors in the United States (1-3). Lymphedema is a cardinal sign of an impaired lymphatic system (4-6). Impairment in lymphatic system leads to a chronic disease state with multiple associated symptoms that require ongoing symptom management (7-9). Similar to risk reduction and management of other chronic diseases (e.g., diabetes and prediabetes), proactive and preventive education on signs and symptoms of lymphedema and risk reduction activities is essential for early identification and treatment of lymphedema. Yet, this proactive approach to risk reduction is not a standard of care for those at risk for developing lymphedema associated with breast cancer treatment. Sadly, this leads to patients at risk for lymphedema self-diagnosing lymphedema and seeking professional help only after visible swelling is present. This reduces the opportunity for early identification and treatment which is associated with better patient outcomes. Recent research supports that more than 50% of breast cancer survivors without a diagnosis of lymphedema suffer at least one lymphedema associated symptom, pain (40%), tenderness (47.3%), aching (30%), or soreness (32.7%), tightness (34.7%), limited shoulder movement (28%), arm firmness (24%), arm swelling (17.3%), arm heaviness (14.4%) (4,7-9). This is not surprising, as even breast cancer survivors with lymphedema experience poorly managed symptoms such as pain (45.2%), tenderness (52.4%), aching (61.9%), soreness (31%), tightness (71.4%), limited shoulder movement (52.4%), arm firmness (69%), arm swelling (100%), arm heaviness (71.4%) in the ipsilateral upper limb or body (4,7-9). This profound disparity in the approach to risk reduction and symptom management in patients at risk for lymphedema has been further impeded by factors such as a lack of information about lymphedema symptoms, lack of guidance in how to assess lymphedema symptoms, and lack of standardized and effective interventions for managing lymphedema symptoms (10,11).

More importantly, the experience of lymphedema symptoms is a cardinal sign of an early stage of lymphedema in which changes cannot be detected by current objective measures of limb volume or lymph fluid level (4,7-9). Without timely assessment and intervention in this early disease stage, lymphedema can progress into a chronic condition that no surgical or medical interventions at present can cure (12). Notably, the experience of lymphedema symptoms is an ongoing main debilitating complication that elicits distress and impacts the breast cancer survivors' quality of life (QOL) (13-15). The experience of lymphedema symptoms exerts tremendous limitations on breast cancer survivors' daily living, making activities of daily living a source of intense frustration and unwelcome (13-15). With the increased rate and length of survival from breast cancer, more and more survivors are facing life-long risk of developing lymphedema, thus, managing lymphedema symptoms is essentially needed for breast cancer survivors at risk for lymphedema.

Patient-centered care is an ultimate aim of the healthcare system, and is fundamental to healthcare quality and equity (16). In spite of the growing body of evidence linking the experience of lymphedema symptoms to the higher risk of lymphedema, more distress and poor QOL (13-15), patient-centered care related to lymphedema symptom management is often inadequately addressed in clinical research and practice. The lack of patient-centered care for lymphedema symptoms has been evidenced by more than 40% of breast cancer survivors never receiving information about lymphedema (17,18). Critical to optimizing lymphedema symptom management, lymphedema symptoms should be regularly assessed not only by clinicians but also patients themselves.

mHealth can be broadly defined as the use of information and communication technology that is accessible to
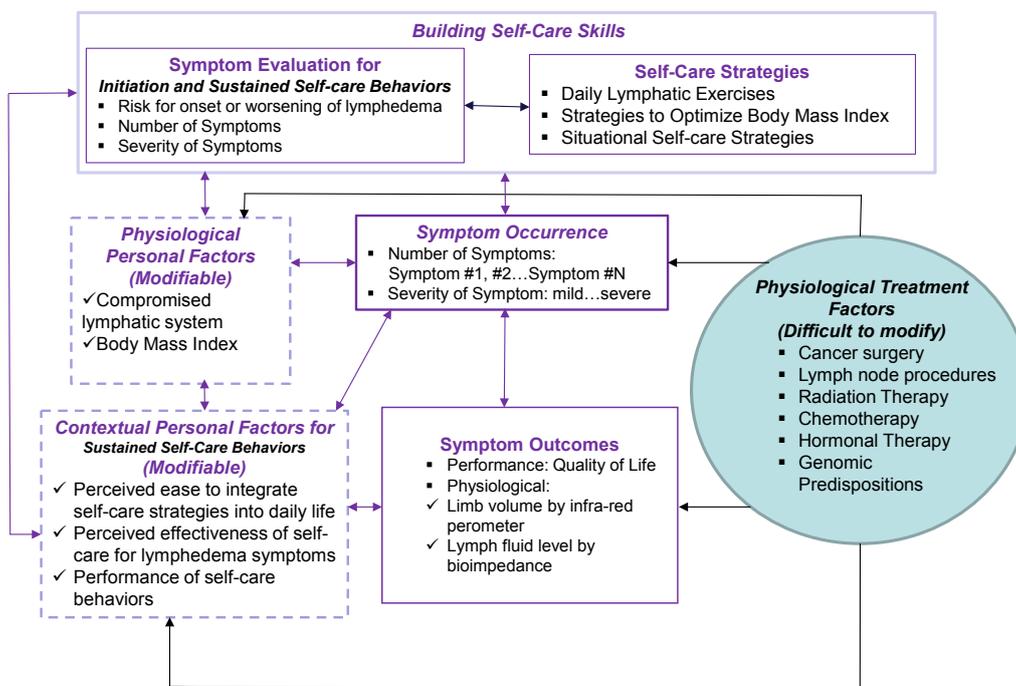
Figure 1 Model of self-care for lymphedema symptom management.

patients or healthcare professionals via mobile technology to support the delivery of patient or population care or to support patient self-management (19-21). mHealth plays a significant role in improving self-care, patient-clinician communication, and access to health information. A growing body of evidence has confirmed the positive impact of mHealth which supports patient-centered care (22-25). The-Optimal-Lymph-Flow health IT system (TOLF) is a patient-centered, web-and-mobile-based educational and behavioral mHealth interventions focusing on safe, innovative, pragmatic, electronic assessment and self-care strategies for lymphedema symptom management (26). The purpose of this paper is to describe the development and test of TOLF system to evaluate reliability, validity, and efficacy of mHealth assessment as well as usability, feasibility, acceptability and efficacy of mHealth self-care interventions for lymphedema symptoms among the end-user of breast cancer survivors.

Methods

Development and design of TOLF

The development of TOLF was motivated by the request from breast cancer survivors in our prior research where

nurse-patient-in-person delivery model was used (27) and guided by the Model of Self-Care for Lymphedema Symptom Management based on our prior research (28-31) (*Figure 1*). Symptoms are viewed as the indicators for abnormal changes in body functioning or side effects from cancer treatment as evidenced by research that lymphedema symptoms are significantly associated with lymphedema defined by >200 mL or 10% limb volume increase (4,7-9). Self-care for lymphedema symptoms refers to activities that individuals initiate and perform for themselves, without professionally administered treatments (e.g., by lymphedema therapists or nurses) (28-31). TOLF focuses on building self-care skills based on research-based, innovative, safe, feasible and easily-integrated-into-daily-routine self-care strategies to lessen lymphedema symptom burden (26,27). Detailed information about self-care skills as well as rationales and self-care actions is described in our prior research (26,27) (*Table 1*). Briefly, self-care skills for lymphedema symptom management consist of symptom evaluation, daily lymphatic exercises, strategies for optimal body mass index (BMI), and situational self-care strategies. To ensure mHealth intervention fidelity and transparency, we used avatar simulation videos to demonstrate lymphatic system, daily lymphatic exercises and strategies for optimal BMI (*Figure 2*). TOLF was designed according to key

Table 1 The-optimal-lymph-flow: self-care strategies, rationales, and actions (Adopted 26,27)

| Strategic category	Strategies	Rationales	Actions
Promote lymph flow	Muscle-tightening deep breathing	The whole body lymph fluid has to be drained through the lymphatic ducts above the heart. Muscle-tightening-deep-breathing stimulates lymphatic ducts and help lymph fluid drain; Lymph fluid drains when muscles move. Muscle-tightening-deep-breathing creates the whole body muscle movements that create muscle milking and pumping action and help to drain lymph fluid	At least twice a day in the morning & at night before brushing teeth or as much as the patient wants throughout the day; Air-Travel: before take-off and after landing; Sedentary life-style: at least every 4 h
	Muscle-tightening pumping	Muscle-tightening pumping exercises create arm muscle pumping. This helps lymph fluid flow and decreases the fluid build-up in the arms; Muscle-tightening pumping exercises build the arm muscle that helps lymph fluid flow and drain	At least twice a day in the morning & at night before brushing teeth or as much as the patient wants throughout the day; Air-Travel: before take-off and after landing; Sedentary life-style: at least every 4 h
	Shoulder exercises	Improved limb mobility after surgery facilitates local muscle movements that create muscle milking and pumping to promote local limb lymph fluid flow and drain	One week after surgery if there is no surgical drains or after the surgical drains are removed; At least twice a day until limb functions are returned to normal; Whenever limb mobility is limited throughout the recovery
	Large muscle exercises	Large muscle exercises (e.g., walking, marching at home, dancing, swimming, yoga, Tai Chi) create muscle milking and pumping to promote overall body lymph fluid flow and drain.	At least 10-min daily; Air-Travel: get up and walk around for flight over 4 h; Sedentary life-style: Get up and walk at least every 4 h
Keep a healthy weight	Eat nutrition—balanced diet (i.e., more vegetables and fruits as well as quality proteins); Maintain portion—appropriate diet (feeling 75% full for each meal)	Overweight or obesity is an important risk factor for lymph fluid accumulation; Having extra weight makes it difficult for lymph flow and drain. This can lead to extra lymph fluid build-up; There are numerous weight management programs available to assist with weight loss; The core actions for keeping a healthy weight are to eat a nutrition-balanced, portion-appropriate diet, to stay hydrated, exercise, and get adequate sleep	Each meal daily; It is important to talk to the nutritionist who can help to find a proper weight reduction programs
	Stay hydrated	People may actually be thirsty, not hungry.	Drink 6 to 8 glasses of water daily; in the morning, before and during meals, and throughout the day; Avoid drinks with calories (e.g., juices); Drink green tea to boost metabolism
	Large muscle exercises	Daily large muscle exercises (e.g., walking, running, swimming, yoga) help to burn more calories; Daily large muscle exercises also promote lymph flow by creating muscle pumps	At least 30-min 3 times a week or daily
	Get enough sleep	Lack of sleep increases the production of the stress hormone cortisol, creates hunger, and leads to overeating; Getting just one more hour of sleep per night reduces belly fat accumulation	At least 7–8 h of sleep per night
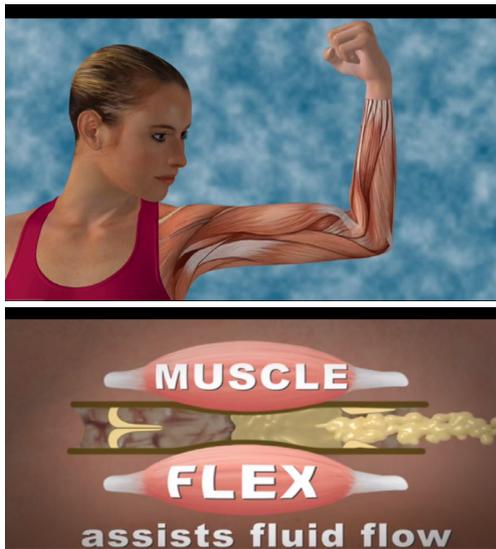
Figure 2 Screenshots from avatar simulation videos.

principles (32-39) that foster accessibility, convenience, and efficiency of mHealth system to enhance training and motivating symptom assessment and self-care for lymphedema symptoms among breast cancer survivors. *Table 2* presents key principles of designing effective mHealth system and the implementation of designing TOLF. The homepage of TOLF that provides the introduction of the system can be accessed via the hyperlink (http://optimallymph.org).

Preliminary heuristic evaluation of TOLF

We completed preliminary heuristic evaluation with a relatively small group of 15 experts, that is, patients who have been formally prepared in human-computer interaction (HCI) and experienced in the design of interfaces, to examine the extent to which a user interface meets Nielsen's principles for usability of the initial prototype of TOLF (32,33). Focus of heuristic evaluation is on visibility of system status, the match between system and the real world, user control and freedom, recognition rather than recall, and flexibility and efficiency of use (32,33). Each expert completed a set of specified tasks designed to explicate system features and also freely explore the prototype. The experts then completed a heuristic evaluation checklist by rating the severity of heuristic violations (no usability problem, cosmetic problem, minor usability problem, major usability problem, usability catastrophe) and provide

additional comments regarding the interface (34). The experts only identified minor cosmetic problems of the system, such as making the font bigger, spelling errors, and comments on repeated information. The system was iteratively refined based upon the feedback of heuristic evaluation.

Testing of TOLF

We designed our testing procedures of TOLF based on the guidelines that foster accessibility, convenience, and efficiency of mHealth system (35-39) to undergo evaluation with usability testing, psychometric research to evaluate the reliability, validity and efficiency of assessment instrument administered by TOLF and pilot feasibility testing of TOLF interventions. Testing reliability, validity, and efficiency of assessment instrument delivered by mHealth system is imperative as the changes of user environment using electronic device may lead to changes of validity and reliability even in the case of using already established validity and reliability in the paper-pencil format.

Institutional Review Board approvals for the usability testing (IRB #14-10208), psychometric evaluation (HS#10-0251) and pilot feasibility testing (s15-00221) were obtained from the institute of the researchers in the metropolitan area of New York. Written informed consent was obtained from all patients in the usability and feasibility studies. For the psychometric evaluation study, the completion of the study served as the participants' consent. We followed the guidelines to protect human subject set forth by the Institutional Review Board and successful recruitment procedures used in our prior studies (4,10,11,15,17,18,26,27,30).

Psychometric testing

TOLF hosts electronic version of major clinical and research assessment instruments, including demographic and clinical information, Breast Cancer and Lymphedema Symptom Experience Index (BCLE-SEI) as well as Self-Care Behavior Checklist for intervention. These instruments were tested to be reliable and valid in pencil-paper format and have been used in several research (4,10,11,13,15,17,18,26,27). We designed a web-based study with cross-sectional design to (I) evaluate the feasibility of collecting data using TOLF system; (II) test the reliability and validity of the electronic version of BCLE-SEI among the end-user of breast cancer survivors.

Table 2 Key principles of designing effective mHealth system (32-39)

Key principles of designing effective mHealth system	Descriptions	Implementation of designing The-Optimal-Lymph-Flow mHealth System (TOLF)
Tailoring/targeting	The targeting of information to a particular patient population or patient subgroup. This encompasses not only content and functionality, but also tool type and media	Targeting of information to breast cancer survivors; Hosting the essential health information needed for building self-care skills for managing lymphedema symptoms; Information includes: lymphedema and symptoms, lymphedema diagnosis and measurement, lymphatic system, risk of lymphedema, self-care to promote lymph flow, symptom assessment, daily lymphatic exercises to promote lymph flow, ask experts, and self-care strategies based on conventional arm precaution recommendations and limb mobility exercises which can serve as standard care or control treatment, and electronic health and symptom assessment instruments (26,27); Designing a novel training system to assist breast cancer survivors using avatar technology in building self-care skills by visually showing how lymph fluid drain in the lymphatic system when performing lymphatic exercises, a request from breast cancer survivors in our proir face-to-face, nurse-delivery study (26,27)
Access and interactivity	The ease of the assessment instruments for patient to complete and adequate level of information for patient to understand and building of self-care skills	Designing TOLF to be able to access via any electronic or mobile devices or smartphones; To minimize potential technical and internet barriers for patients to use TOLF, we iteratively refined TOLF to ensure that even patients with minimal technical skill in using computer or any electronic devices can download TOLF to computers, laptops, iPad or other electronic devices or smartphones; patients can use the system by just scrolling up and down and clicking on or touching icons denoting specific videos or intervention information; Understanding the meaning of the experience of lymphedema symptoms can motivate patients to practice self-care strategies, we designed symptom evaluation using research-based, valid, and reliable instrument for breast cancer survivors to evaluate and monitor their lymphedema symptom experience virtually anytime and anywhere (15,26,27); The avatar model, a fit and healthy woman of more than one race background was chosen for the videos by 35 breast cancer survivors to embrace patients with different backgrounds and healthy image that breast cancer survivors strive for; Patient can learn the daily lymphatic exercises by watching and following the avatar simulation videos; Patient can follow the daily lymphatic exercises avatar simulation videos to complete the daily lymphatic and limb mobility exercises
Fidelity and transparency of the intervention delivery	Consistency of intervention delivery	Using avatar simulation videos to provide training on self-care skills and lymphatic system not only enhances the fidelity and transparency of the intervention delivery but also the reproducibility of the intervention
Patient-centered Care and Autonomy	Providing patient incentives and feedback on progress in order to increase motivation, sustain follow-up, and encourage treatment plan adherence	Patients are able to assess their lymphedema symptoms at anytime and anywhere; Upon the submission of symptom report, the patients will receive a symptom evaluation in terms of fluid accumulation and recommended self-care strategies immediately; Upon completion of daily lymphatic or limb mobility exercises, the screening will display a congratulatory message to motivate patients to maintain the daily lymphatic and limb mobility exercises; The daily lymphatic and limb mobility exercises only take less than 5 min. Patients are recommended to build a routine by performing the lymphatic and limb mobility exercise before brushing teeth in the morning and at night; Patients are encouraged to assess their symptoms daily to determine how many times they need to do the daily lymphatic and limb mobility exercises

Instruments

Demographic and Clinical Information tool is a structured self-repot tool that collects demographic and medical information (4,10,11,13,15,17,18,26,27). The demographic and medical information includes age, education, weight, height, breast cancer diagnosis, surgeries, lymph nodes procedure, radiation, chemotherapy, time since surgery, lymphedema diagnosis/treatment, hormonal therapy, and medications.

BCLE-SEI (4,10,11,13,15,17,18,26,27): a 5-point Likert-type self-report instrument consisting of two parts evaluating the occurrence of and distress from lymphedema symptoms. Part I of the instrument assesses lymphedema symptoms, including impaired limb mobility in shoulder, arm, elbow, wrist, and fingers, arm swelling, breast swelling, chest wall swelling, heaviness, firmness, tightness, stiffness, numbness, tenderness, pain/aching/soreness, stiffness, redness, blistering, burning, stabbing, tingling (pain and needles), hotness, blistering, seroma, limb fatigue, and limb weakness. A total of 25 lymphedema symptoms are evaluated. Each symptom is rated on a Likert-type scale from 0 to 4: 0= no presence of a given symptom; 1= a little severe; 2= somewhat severe; 3= quite a bit, severe; 4= very severe. Each symptom can also be treated as categorical variable with "0" indicating the absence of a given symptom, and "1"to "4" indicating the presence of a given symptom. Part II of the instrument evaluates the symptom distress, that is, the negative impact and suffering evoked by an individual's experience of lymphedema symptoms, including daily living, function, social impact, sleep disturbance, sexuality, emotional/psychological distress, and self-perception.

Study participants

Women were recruited if they were: (I) ≥21 years of age who had surgical treatment (lumpectomy or mastectomy, sentinel lymph node biopsy (SLNB) or axillary lymph node dissection ALND); (II) with or without been diagnosed or treated for lymphedema. Women who received no surgical treatment for breast cancer were excluded since breast surgery and lymph node procedures are main contributing factors for lymphedema (5-7).

Recruitment

An open invitation to participate in the study was sent to more than 600 patient-members of StepUp-SpeakOut. org, an online community of breast cancer survivors with lymphedema or at risk for lymphedema via an electronic newsletter and posted on the organization's website. The mission of the organization is to help breast cancer survivors to reduce their risk of lymphedema and promote effective management of lymphedema. If a member was willing to participate in the study, she would access the study through the link in the newsletter or go to the website. The completion of the study served as the participant's consent. The study was open from April 20, 2010 through August 27, 2010. Of the 417 who accessed the study, only 335 women provided complete study data. Participants were informed of voluntary and anonymous participation.

Data management

Raw data were downloaded using the Excel files. Data cleaning was conducted via the Human-in-the-loop (HITL) method of a two-step process which requires human intervention when dealing with electronic data (10,11,40,41). The first step requires determining the most constant items which reflect the real number of respondents [constant items are those questions for which it is correct to provide only a single answer (such as "Are you currently employed?")]. The second step involves identifying the number of duplicated responses. Data found to be duplicated were not included in the analyses. *Table 3* identifies the key items/study variables that were checked and included in this study.

Data analysis

Statistical tests were estimated at the 0.05 significance level (2-sided) and 95% confidence intervals (CI). Characteristics of the participants were summarized using descriptive statistics [means, standard deviations (SD) for continuous variables and frequency distributions and proportions for qualitative variables]. Demographic and clinical characteristics were compared for patients with and without lymphedema using Chi-squared (χ^2) tests for contingency tables and one-way analysis of variance for continuous variables. Cronbach's alpha was used to assess the internal consistency reliability of the total scale and subscale of symptom occurrence and distress of BCLE-SEI. The discriminant validity of the scale was obtained by nonparametric tests between breast cancer survivors with and without lymphedema. Fisher's exact test followed by Bonferroni adjustment was also performed.

Usability evaluation of TOLF intervention

We conducted usability testing of heuristic evaluation and

Table 3 Items for data cleaning and analyses

Instrument	Items/variables
Demographics	Age group, highest level of education, marital status, employment, racial group, co-morbidities, dominant hand, U.S. state of residence
BCLE-SEI	Breast cancer side treated, all 25 lymphedema symptoms (limited movement of the shoulder, limited movement of the elbow, limited movement of the wrist, limited movement of the fingers, limited movement of the arm, arm or hand swelling, breast swelling, chest wall swelling, firmness, tightness, heaviness, toughness or thickness of the skin, stiffness, tenderness, hotness/increased temperature, redness, blistering, pain, numbness, burning, stabbing, tingling, arm or hand fatigue, arm or hand weakness, and the development of a pocket of fluid)
Clinical treatment	Lymphedema diagnosis before breast cancer, lymphedema diagnosis after breast cancer, breast cancer site, type of surgery (mastectomy or lumpectomy), axillary lymph node dissection, sentinel lymph node biopsy, radiotherapy, breast reconstruction, and length of time since lymphedema diagnosis

end-user testing with breast cancer survivors on TOLF intervention (33-35). We recruited 30 English-speaking breast cancer survivors over 21 years of age who had the various experience of using internet to evaluate TOLF intervention from October to December 2014. Participants provided written informed consent.

Study procedure

Participants completed a short questionnaire regarding demographic information and computer experience and use. Participants were asked to think aloud while completing a set of specified tasks designed to explicate TOLF features and also to freely explore the system either using a laptop or any electronic devices that they preferred. We recorded screen shots and participants' utterances using Morae software™ (Techsmith Corporation, Okemos, MI), which allowed to record and analyze the audio recording and screen shots that were captured during the evaluation. Following completion of the tasks, participants were asked to complete a heuristic evaluation checklist that included ratings of severity of heuristic violations (no usability problem, cosmetic problem, minor usability problem, major usability problem, and usability catastrophe) and provided additional comments regarding the interface. Participants were also asked to complete two brief end-user questionnaires regarding their perceptions of information and system quality, and their behavioral intention to use the system using The Perceived Ease of Use and Usefulness Questionnaire (42,43) and The Post Study System Usability Questionnaire (44). Finally, participants were asked to provide narrative responses to the open-ended questions, "what do you like about the system", "what do you dislike about the system", and "what can be improved?"

Data analysis

We verbatim transcribed and summarized thematically the audio recordings of the think-aloud protocols and qualitative data from heuristic evaluation and responses to the open-ended questions. Descriptive statistics were used to analyze demographic and quantitative data. Items in the Post Study System Usability Questionnaire were eliminated from the analysis as all participants marked "N/A (not applicable)" rather than assigned a numeric rating since the system does not require such functions for end-users to use the system.

Pilot of testing of TOLF intervention

We conducted a pragmatic, one-group, 12-week pilot trial of 20 breast cancer survivors to evaluate feasibility and efficacy of mHealth interventions to enhance self-care for lymphedema symptom management. The rationale for the 12-week intervention is based on research evidence for health habit formation (45,46): (I) It takes an average of 66 days to form a health habit based on daily repetition; (II) it is helpful to tell patients to expect health habit formation based on daily repetition to take around 10 weeks; (III) working effort fully on a new health habit for 2–3 months is an attractive offer for patients, and may help patients in making the health habit part of their daily lives. Building self-care skills for managing lymphedema symptoms is a process of making a health habit in which breast cancer survivors initiate and perform activities to prevent, relieve or decrease lymphedema symptom occurrence (i.e., number and severity of symptoms) and symptom distress as well as improve QOL (26,27). The primary outcomes of the pilot study evaluated by BCLE-SEI were symptom of pain,

soreness, aching, tenderness and numbers of lymphedema symptoms as well as secondary outcome of symptom distress/QOL related to pain and symptoms. The efficacy of building self-care skills to manage pain and lymphedema symptoms was evaluated by patients' report of self-care behaviors using self-care behavior checklist hosted by TOLF. Self-care Behavior Checklist is a structured self-report checklist that quantitatively and qualitatively assess participants' practice of self-care behaviors at the study endpoint of 12 weeks after intervention (18,26,27).

Recruitment and procedures

We recruited participants using the same inclusion and exclusion criteria for the psychometric testing. Participants were recruited face-to-face at point of care during clinical visits at a metropolitan cancer center. To prevent technical skill barriers to access TOLF, researchers helped participants who had any questions or needs to setup or navigate the system. Each participant was given a user manual of a list of tasks to navigate the system. Participants were required to find the information and videos listed in the user manual. Participants had ongoing access to the program during the 12-week study period to review the material as needed using their own computers or laptops or iPad or other electronic tablets or smartphones. Participants were encouraged to enhance their self-care skills by accessing TOLF and following the daily lymphatic exercises during the study period.

Data analysis

Frequency distributions and descriptive statistics were applied to the demographic and clinical characteristics of the sample as well as quantitative data regarding intervention evaluation. McNemar's Chi-square test was performed to determine the effect of the intervention on pain, soreness, tenderness, aching, and symptom distress/QOL at 12 weeks post intervention. Wilcoxon signed-rank test of non-parametric test was used to compare the medians of number of lymphedema symptoms between baseline prior to intervention and 12 weeks post intervention. Alpha level was set at 0.05 (P values <0.05) and 95% CI for all the statistical tests.

Results

Psychometric Testing

Of the 355 women who completed the study, 58.6% (n=208) of the participants reported having lymphedema

after breast cancer treatment. Among the 208 women with lymphedema, 60.6% of them (n=126) had lymphedema more than 1 year and 36.1% (n=75) had lymphedema less than a year but more than 6 months, ranging from 6 months to 10 years of lymphedema history. *Table 4* presents detailed information about the participants.

High internal consistency of the electronic version of BCLE-SEI was demonstrated with a Cronbach's alpha coefficient of 0.959 for the total scale, 0.919 for symptom occurrence, and 0.946 for symptom distress/QOL. Discriminant validity was supported by findings of a significant difference in symptom occurrence (z=−6.938, P<0.000) between breast cancer survivors with lymphedema (mean ± SD =27.22±14.43) and those without it (mean ± SD =17.31±15.51), a significant difference in symptom distress or impact on QOL (z=−5.894, P<0.000) between breast cancer survivors with lymphedema (mean ± SD =30.90±16.34) and those without lymphedema (mean ± SD =20.94±18.66), a significant difference in total scale of BCLE-SEI (z=−6.547, P<0.000) between breast cancer survivors with lymphedema (mean ± SD =58.12±28.22) and those without lymphedema (mean ± SD =38.25±31.75).

The mean number of symptoms experienced by the participants was 11.89 (SD =5.7) with a range of 0–25. By comparing the mean number between participants with and without lymphedema, symptom report was able to distinguish breast cancer survivors with and without lymphedema (t=5.379; P<0.001): Women with lymphedema reported significantly more symptoms (mean ± SD =13.12±4.87; median =14; ranging: 1–24) than those without lymphedema (mean ± SD =9.03±5.51; median =8; ranging: 0–23). *Table 5* presents more detailed information regarding symptoms.

Usability evaluation of TOLF intervention

A total of 30 breast cancer survivors completed the usability study. Participants aged from 31 to 78 years, with mean age of 58.6 years and SD of 11.39. *Table 6* provides more detailed information of the participants. The responses to Neilson's heuristics (33) indicated no major usability problems or usability catastrophe with TOLF: 90% of participants (n=27) rated the system having no usability problems; 10% (n=3) noted minor cosmetic problems, such as spelling errors. We iteratively refined TOLF based on the feedback from the participants. Agreement for ease of use exceeded 93.3% (n=28) assessed by the Perceived Ease of Use and Usefulness Questionnaire. There was no disagreement reported for ease of use except one participant reported neutral. For the

Table 4 Demographic and clinical characteristics (N=355)

Variables	Total (N=355)	Lymphedema (n=208)	Non-lymphedema (n=147)	χ^2	P
Age (%)				0.079	0.006
21–39	37 (10.4)	30 (14.4)	7 (4.8)		
40–59	188 (53.0)	100 (48.1)	88 (60.0)		
60–80	130 (36.6)	78 (37.5)	52 (35.4)		
Education (%)				4.211	0.378
High school or below	37 (10.4)	18 (8.7)	19 (12.9)		
Technical school	16 (4.5)	10 (4.8)	6 (4.1)		
Partial college	65 (18.3)	44 (21.2)	21 (14.3)		
College graduate	117 (33.0)	69 (33.2)	48 (32.7)		
Graduate degree	120 (33.8)	67 (32.2)	53 (36.1)		
Marital status (%)				8.209	0.084
Married	252 (71.0)	140 (67.3)	112 (76.2)		
Partnered	17 (4.8)	8 (3.8)	9 (6.1)		
Divorced or no partner	42 (11.8)	26 (12.5)	16 (10.9)		
Widowed	31 (8.7)	23 (11.1)	8 (5.4)		
Single or never partnered	13 (3.7)	11 (5.3)	2 (1.4)		
Employment status (%)				2.051	0.152
No	156 (43.9)	98 (47.1)	58 (39.5)		
Yes	199 (56.1)	110 (52.9)	89 (60.5)		
Ethnicity (%)				6.329	0.176
Asian	2 (0.6)	1 (0.5)	1 (0.7)		
African American or Black	5 (1.4)	4 (1.9)	1 (0.7)		
White	324 (91.3)	190 (91.3)	134 (91.2)		
Hispanic	5 (1.4)	1 (0.5)	4 (2.7)		
Mixed	19 (5.4)	12 (5.8)	7 (4.8)		
Location of breast cancer (%)				0.232	0.89
Left	159 (44.8)	91 (43.8)	68 (46.3)		
Right	162 (45.6)	97 (46.6)	65 (44.2)		
Both side	34 (9.6)	20 (9.6)	14 (9.5)		
Lymph nodes procedures (%)				32.287	<0.001
None	10 (2.8)	4 (1.9)	6 (4.1)		
SLNB*	116 (32.7)	45 (21.6)	71 (48.3)		
ALND*	95 (26.8)	65 (31.2)	30 (20.4)		
Both SLNB & ALND	134 (37.7)	94 (45.2)	40 (27.2)		
Chemotherapy (%)				8.577	0.035
None	122 (34.4)	59 (28.4)	63 (42.9)		
Prior to Surgery	44 (12.4)	28 (13.5)	16 (10.9)		
Post-Surgery	179 (50.4)	113 (54.3)	66 (44.9)		
Prior & Post Surgery	10 (2.8)	8 (3.8)	2 (1.4)		
Radiation (%)				21.245	<0.001
None	191 (53.8)	92 (44.2)	99 (67.3)		
Yes	164 (46.2)	116 (55.8)	48 (32.7)		
Current BMI (mean ± SD)	28.19±17.59	27.95±5.70	26.55±5.45	0.055 (t/z)	0.815
BMI Prior to Cancer Surgery (mean ± SD)	26.70±5.80	27.29±5.99	26.06±5.28	0.928 (t/z)	0.336

SLNB, sentinel lymph nodes biopsy; ALND, axillary lymph nodes dissection.

Table 5 Comparison of symptom report between lymphedema and non-lymphedema group

Symptom	Lymphedema (n=208) (%)	Non-lymphedema (n=147) (%)	P[†]
Arm/hand swelling	180 (86.5)	53 (36.1)	<0.001
Arm tightness	178 (85.6)	104 (70.7)	0.001
Limb fatigue*	166 (79.8)	78 (53.1)	<0.001
Arm heaviness	164 (78.8)	65 (44.2)	<0.001
Arm tenderness	164 (78.8)	103 (70.1)	0.059
Arm pain/aching/soreness	162 (77.9)	81 (55.1)	<0.001
Limb numbness	159 (76.4)	99 (67.3)	0.058
Limb weakness	157 (75.5)	77 (52.4)	<0.001
Limb stiffness	144 (69.2)	88 (21.8)	0.068
Arm firmness	143 (68.8)	61 (41.5)	<0.001
Limb tingling	142 (68.3)	77 (52.4)	0.002
Chest wall swelling	114 (54.8)	32 (21.8)	<0.001
Limited shoulder movement	106 (51.0)	59 (40.1)	0.044
Breast swelling	95 (45.7)	36 (24.5)	<0.001
Toughness or Thickness of Skin	94 (45.2)	44 (29.9)	0.004
Limited arm movement	93 (44.7)	54 (36.7)	0.133
Increased arm temperature	87 (41.8)	43 (29.3)	0.015
Stabbing in the affected limb	85 (40.9)	51 (34.7)	0.239
Burning in the affected limb	80 (38.5)	40 (27.2)	0.027
Arm redness	68 (32.7)	23 (15.6)	<0.001
Limited finger movement	52 (25.0)	23 (15.6)	0.033
Limited wrist movement	46 (22.1)	15 (10.2)	0.003
Limited elbow movement	37 (17.8)	14 (9.5)	0.029
Seroma/pocket of fluid formation	68 (32.7)	10 (6.8)	<0.001
Blistering in the affected arm	12 (5.8)	7 (4.8)	0.678

*, limb means the affected arm and hand in the same body side in which patients received breast surgery or radiation; [†], Fisher's exact test followed by Bonferroni adjustment, significant difference between the lymphedema group and non-lymphedema group.

Post Study System Usability Questionnaire, average ratings on all the items ranged from 1.1 to 1.4 on a scale ranging from 1 (strongly agree) to 7 (strongly disagree). Importantly, there were no neutral and disagreement scores (>3) on any item. Several themes emerged from the qualitative data analysis. These themes included empowerment, high quality information, loving avatar simulation videos, easy accessibility, user-friendly. *Table 7* provides representative quotes for the identified themes.

Pilot feasibility testing of TOLF intervention

Table 8 provides detailed information regarding participants'
demographic and clinical characteristics. At 12 weeks post intervention, participants reported less pain/tenderness/aching/soreness and lymphedema symptoms (χ^2=6.40; 95% CI, 0.00–0.80; P=0.022) from baseline prior to intervention. Similarly, participants reported less pain at 12 weeks post intervention (χ^2=6.00; 95% CI, 0.00–0.85; P=0.031), less soreness (χ^2=6.40; 95% CI, 0.00–0.80; P=0.021); less aching (χ^2=6.40; 95% CI, 0.00–0.032; P=0.021), and less tenderness (χ^2=5.44; 95% CI, 0.00–0.032; P=0.039). In addition, there was a significant decrease in the count of lymphedema symptoms from baseline prior to intervention (median =6; IQR, 2.25–9.50) to 12 weeks post intervention (median =1; IQR, 0.00–4.75) (P=0.003).

Table 6 Usability testing: demographic characteristics of the participants (N=30)

Variables	Data
Age (years), mean ± SD [range]	58.6±11.4 [31–78]
Internet use (weekly hours), mean ± SD [range]	26.2±16.3 [5–70]
Computer skills (%)	
Almost none	0 (0.0)
Some	0 (0.0)
Functional	5 (16.7)
Very good	21 (70.0)
Outstanding	4 (13.3)
Highest level of education (%)	
High school	1 (3.3)
Partial college	3 (10.0)
Bachelor's degree	13 (43.3)
Master's degree or above	13 (43.3)
English capability—understanding (%)	
Almost none	0 (0.0)
Some	0 (0.0)
Functional	1 (3.3)
Very good	4 (13.3)
Outstanding	25 (83.3)
English capability—reading (%)	
Almost none	0 (0.0)
Some	0 (0.0)
Functional	1 (3.3)
Very good	4 (13.3)
Outstanding	25 (83.3)
English capability—speaking (%)	
Almost none	0 (0.0)
Some	0 (0.0)
Functional	2 (6.7)
Very good	6 (20.0)
Outstanding	22 (73.3)
English capability—writing (%)	
Almost none	0 (0.0)
Some	0 (0.0)
Functional	2 (6.7)
Very good	5 (16.7)
Outstanding	23 (76.7)
Ethnicity (%)	
African American or black	6 (20.0)
White or Caucasian	22 (73.3)
Asian	2 (6.7)

At 12-week post intervention, in terms of symptom distress/QOL, participants reported that pain had less interference with their enjoyment of life (χ^2=7.00; 95% CI, 0.00–0.69; P=0.015), less interference on normal work (χ^2=7.00; 95% CI, 0.00–0.69; P=0.016); less difficulty in completing simple task (χ^2=7.00; 95% CI, 0.00–0.69; P=0.015); less experiences of being fed up and frustrated by pain (χ^2=9.00; 95% CI, 0.00–0.51; P=0.004). In addition, pain had lower negative affect on cleaning house (χ^2=6.00; 95% CI, 0.00–0.85; P=0.031). Pain had less negative impact on emotion of frustration (χ^2=6.00; 95% CI, 0.00–0.85; P=0.031) and being angry (χ^2=7.00; 95% CI, 0.00–0.69; P=0.016). There was a trend that participants experienced lower negative impact of pain on leisure activities (χ^2=4.50; 95% CI, 0.00–1.10; P=0.07). Furthermore, the daily 5-min routine avatar simulation video of lymphatic exercises provided a unique way of helping breast cancer survivors to establish their own self-care routine by following the video. As our patients remarked, "*the video helped to complete the exercises.*" *Table 9* and *Table 10* present Quantitative and Qualitative Evaluation of TOLF intervention.

Discussion

Distressed by lymphedema symptoms and worrying about developing lymphedema or progression to chronic and severe lymphedema has been a daily concern for breast cancer survivors (14,15). Findings of our psychometric testing demonstrate that TOLF system is able to collect data with high reliability and validity of the instrument to assess lymphedema symptoms and symptom distress/QOL in TOLF system. Our 355 participants representing 45 states in the United States demonstrates that it is feasible to collect demographic, health-related, lymphedema symptom data using a user-friendly mHealth system with high reliability and adequate discriminant validity. In the era of online technology, mHealth designed for patients' self-assessment can empower patients to take control of their symptom management as well as risk and progression path of lymphedema. Our study also provides supporting evidences that multiple symptoms have strong associations with lymphedema status and the use of lymphedema symptom report is valid with its discriminatory ability to distinguish patients with and without lymphedema.

High quality information regarding effective self-care strategies for lymphedema symptom management is key for patient-centered care. Participants in our usability and feasibility studies rated the usability high in terms of

Table 7 Usability testing: summary of themes from qualitative data (n=30) 30 (100%) participants provided qualitative evaluation of The-Optimal-Lymph-Flow Health IT system

Themes	Representative quotes
Empowerment	I am so happy that I came for the study. It empowers me, any breast cancer patients should come; The website is empowering for the women who want to prevent lymphedema, as well as for those who already have lymphedema; It is a fabulous program. Women will love it. I learned so much about risk reduction. The videos are fabulous to show how to exercise & I love the why I need to do the exercise. This will be a great asset to patients; I liked the clarity of the explanations & the simplicity of using the website. The website is empowering for the women who want to prevent lymphedema, as well as for those who already have lymphedema
High quality information	High quality information. Easy to understand, details included in each section are clear to read and view; Excellent explanation of lymphedema-best I've seen; The system is excellent when I compare to the time years ago when I had breast cancer and was given Xerox copies of exercises to do; Lymphatic system, lymphedema and self-care are explained very clearly. It did not create panic but clearly stated why it is important to do the lymphatic exercises; Very well rounded/comprehensive approach to helping in reducing the risk of lymphedema; Love the self-care tips; Looked at many lectures on lymphedema but none as clear as this system; The option to read along, or just listen, while watching the videos. Great idea! Invaluable information. Great videos!—pictures and movies help me understand both the lymphatic system and the lymphatic exercises; Simple language provided clear understanding. The information was effective…very much so. The diagrams & process guides provided understanding & learning on a higher level; Very effective exercises; Love the information about what, when and how to recover and managing symptoms
Loving avatar simulation videos	I like the exercises!!! After I finished learning the exercises by following the videos, my pain and soreness were much better; Videos are very helpful in teaching how to do the exercises. It is nice that I can go back and watch it again & again. I am glad that patients can have it at home. I love the contents & hope patients can get it sooner. I enjoyed the videos a lot; I love the videos that show the anatomy & fluid flow & deep breathing. I also love the lymphatic system video; The videos of how to perform the lymphatic exercises were very easy to follow; Videos are excellent-you could do as you watched; Love the avatar videos. You can follow the videos and do the exercises

quality of information. All the participants agreed that the information provided by TOLF regarding lymphedema symptom management is clear, easy to understand, high quality, and empowering. Easy access to high quality health information for lymphedema symptom management is essential for patient-centered care to achieve health equity. Participants loved the fact that patients can access TOLF at anytime and anywhere and learn about lymphedema, symptoms, and self-care strategies at their own pace. As our participants commented, "*portable*", "*patients can have this at their fingertips*", "*self-paced; can repeat & review particular sections.*"

TOLF was designed to enhance fidelity, transparency, and reproducibility of intervention delivery for lymphedema symptom management by providing a novel training system using avatar simulation videos to assist breast cancer survivors in building self-care skills based on the request from breast cancer survivors in our prior research that used face-to-face, nurse-delivery model of intervention for lymphedema symptom management (26). These videos provide visual demonstration of how lymph fluid drains in the lymphatic system when performing lymphatic exercises. Participants in our usability and feasibility studies loved avatar simulation videos that help them to understand lymphatic system and learn daily lymphatic exercises. As our participants remarked, "*I love the videos that show the anatomy & fluid flow & deep breathing. I also love the lymphatic system video.*" Avatar simulation videos hosted by TOLF was able to train our participants do the daily lymphatic exercises, as our

Table 8 Pilot feasibility testing: demographic and clinical characteristics of participants (N=20)

Variables	Data
Age at study (years), median (mean ± SD) (range)	55.0 (55.9±11.7) (34.0–77.0)
Years since breast cancer treatment, median (mean ± SD) (range)	4.0 (4.3±2.6) (2.0–10.5)
No. of lymph nodes removed, median (mean ± SD) (range)	2.0 (5.7±7.9) (0–30.0)
Body weight (pounds), mean ± SD (range)	
Before intervention	155.8±36.9 (104.7–278.6)
12 weeks after intervention	154.9±36.1 (102.9–279.9)
Body mass index (BMI), mean ± SD (range)	
Before intervention	26.6±5.6 (17.7–46.1)
12 weeks after intervention	26.4±5.5 (17.1–45.5)
Highest level of education [%]	
Less than high school	1 [5]
High school	2 [10]
Associate's degree	2 [10]
Partial college	3 [15]
Bachelor's degree	8 [40]
Master's degree	3 [15]
Professional degree	1 [5]
Marital status [%]	
Married	13 [65]
Partnered	1 [5]
Divorced/separated	3 [15]
Widowed	2 [10]
Single or never partnered	1 [5]
Ethnicity [%]	
Asian	2 [10]
African American or black	2 [10]
White	13 [65]
Hispanic/Latino	2 [10]
Other: Arabic	1 [5]
Employment status [%]	
Unemployed	7 [35]
Employed	13 [65]
Perceived household income [%]	
Comfortable: have more than enough to make ends	11 [55]
Have enough to make ends meet	8 [40]
Do not have enough to make ends meet	1 [5]
Surgery [%]	
Mastectomy	9 [45]
Lumpectomy	11 [55]
Breast reconstruction	11 [55]
Radiotherapy [%]	
No	4 [20]
Yes	16 [80]
Adjuvant chemotherapy [%]	
No	7 [35]
Yes	13 [65]
Diagnosed/treated for lymphedema [%]	
No	15 [75]
Yes	5 [25]

Table 9 Pilot feasibility testing: quantitative evaluation of The-Optimal-Lymph-Flow program (N=20)

Variables	Yes [%]	No [%]
Self-care behaviors		
Have you been performing the set of lymphatic exercises to promote lymph flow every day?	18 [90]	2 [10]
Have you been performing the set of limb mobility exercises every day?	18 [90]	2 [10]
Have you been performing Large Muscle Exercises?	Daily: 12 [60]	8 [40]
	2–3 times a week: 5 [25]	3 [15]
Have you been eating nutrition-balanced and portion-appropriate diet?	Daily: 12 [60]	8 [40]
	2–3 times a week: 5 [25]	3 [15]
The-Optimal-Lymph-Flow Program…		
Helped me to manage pain, and other symptoms	20 [100]	0 [0]
Helped me to reduce my fear and anxiety of having pain and other symptoms	15 [75]	5 [25]
Helped me to develop a plan to manage pain, and other symptoms	18 [90]	2 [10]
Helped me to understand how to reduce my risk of lymphedema	20 [100]	0 [0]
Helped me to reduce my fear and anxiety of developing lymphedema	18 [90]	2 [10]
Helped me to develop a plan to reduce my risk of lymphedema	18 [90]	2 [10]
Created injury or discomfort to me	0 [0]	20 [100]

Table 10 Pilot feasibility testing: qualitative evaluation of The-Optimal-Lymph-Flow program (N=20)

Themes	Representative quotes
Skills building	It made me realize that I can manage the loss of strength in my right arm and may be able to manage the numbness and tingling. I will be able to help myself; Being on this study allowed me to do something for myself, really take care of myself and focus on being healthy; It helped me realize that I had excess fluid. My arms got lighter each time I did the exercises. My arms began to feel less heavy. It noticed it in my clothes as well; It helps me to understand more about all my symptoms, and how to manage them with the exercises
Perceived ease	This is a very easy study and the videos helped to complete the exercise; I can repeat & review particular sections whenever and wherever I want; I like the fact that I can go to the site at any time even when I travel; The (lymphatic) exercise were easy and could be completed anywhere. According to my measurements there was a decrease in fluid. That was good news; The exercises were easy to do and remember. If I noticed my arm was more stiff than usual, I would do the exercises more and they helped; It is not about whether I can do it (self-care) or I feel I can do it. The breathing and pumping exercises (daily lymphatic exercise) are easily to do and I feel better after doing them. So, I do it every day
Perceived effectiveness	I personally feel the exercise helped with the pain; The exercises made my arm feel a lot better; The exercise really helped increase my range of motion and was effective for decreasing my pain. I do the exercises every day; The exercises definitely helped reduce pain and increase mobility; The (lymphatic) exercise really helped increase my range of motion and was effective for decreasing my pain. I do the exercises every day; The (lymphatic) exercise made my arm feel a lot better
Psychological benefits: fear and anxiety relief	It afforded me the opportunity to feel better about myself. I was actually doing something to alleviate the anxiety about having symptoms and now I feel more in control of managing my physical and mental state
Enjoy doing the exercises	I enjoyed the exercises! The exercises that I have been doing in this study helped me to gain strength and mobility in the affected limb even after I stopped physical therapy. I also found the exercises fun and enjoyable
Loving avatar videos	It was helpful to have an animated model of the exercises, rather than a sheet with merely pictures of the exercises; I love to follow the daily videos to do the exercises

Summary of themes from qualitative data: 100% of 20 participants who completed the study provided unanimous highly positive qualitative feedback.

participants remarked, "*I like the (lymphatic) exercises!!! After I finished learning the exercises by following the videos, my pain and soreness were much better.*" Findings of our usability and feasibility studies demonstrate that TOLF is able to enhance the patients' self-care skill building given that patients can review the self-care strategies on their own schedule and pace virtually anytime and anywhere.

The ease of accessing and navigating TOLF is enormously important to enhance patients' engagement in using the system. All our participants in the usability and feasibility rated the use of TOLF very easy. The use of user manual that lists the tasks to explore the system for technical skill training enhances the perceived ease for our participants to use the system.

Limitations

Our participants in this usability and feasibility studies represented general breast cancer survivor population in terms of age, education, and ethnicity in the study institute. Yet, our participants had relatively high education level and were familiar with internet use. Further testing of TOLF is needed for breast cancer survivors with less education level or limited experience of using internet. In addition, randomized clinical trial was not used for the feasibility testing. It is important to note that the percentage of 58.6% participants in the psychometric testing were diagnosed with lymphedema, this was higher than current literature of 20–40% (1,2). This sample characteristics reflect the findings of prior research on breast cancer survivors that patients with lymphedema were more eager and motivated to participate in research on lymphedema related issues (1,2,13-17).

Conclusions

Findings of psychometric testing on the ability of TOLF system to collect health, clinical, research data support the reliability and validity of electronic instruments administered by TOLF system. Findings of testing on TOLF system have provided evidence for breast cancer survivor's acceptance, usability and feasibility of TOLF system to enhance self-care strategies for lymphedema symptom management. TOLF provides a much-needed mHealth system for advancing the science of self-care for lymphedema symptom management and a foundation for transformation of healthcare from reactive and hospital-centered to preventive, proactive, evidence-based, patient-centered and focused on well-being rather than disease.

Acknowledgements

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Ethical Statement: Institutional Review Board approvals for the usability testing (IRB #14-10208), psychometric evaluation (HS#10-0251) and pilot feasibility testing (s15-00221) were obtained from the institute of the researchers in the metropolitan area of New York. Written informed consent was obtained from all patients in the usability and feasibility studies. For the psychometric evaluation study, the completion of the study served as the participants' consent. We followed the guidelines to protect human subject set forth by the Institutional Review Board and successful recruitment procedures used in our prior studies.

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