

Original Article

LYMPH-V: A wearable arm volume measurement device and mobile application for the prevention and early detection of breast cancer-related lymphedema: A study protocol

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ARTICLE INFO

Received 28 October 2024

Accepted 17 February 2025

Available online at:

<http://npt.tums.ac.ir>

Keywords:

breast neoplasms;
lymphedema;
early diagnosis;
mobile application;
wearable electronic devices;
self-management

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DOI: 10.18502/npt.v12i3.18975

ABSTRACT

Background & Aim: Early detection of lymphedema is crucial to prevent progression to advanced stages that impair the quality of life in breast cancer survivors. This study aims to develop and evaluate LYMPH-V, a wearable arm volume measurement device and mobile application designed for the prevention and early detection of breast cancer-related lymphedema.

Methods & Materials: The study consists of two phases. In the first phase, the LYMPH-V wearable device and a supportive mobile application will be developed. The app will feature five core components: exercise modules, educational content, coping strategies, arm volume measurement/recording, and personalized reminders. Content will be created based on current guidelines and expert opinions. In the second phase, the effectiveness of the intervention will be assessed through a pilot randomized controlled trial, a reproducibility study, and usability evaluations. The device uses stretch sensors to monitor arm volume, and the mobile app provides alerts if measurements suggest early signs of lymphedema. Data will be stored securely and shared with healthcare professionals upon user approval.

Results: Expected outcomes include high usability, strong agreement with manual measurements, and improved capacity for at-home lymphedema monitoring and prevention.

Conclusion: LYMPH-V offers a promising digital solution that empowers survivors and healthcare providers through home-based arm volume tracking. This approach may facilitate early intervention, reduce healthcare burden, and enhance quality of life for breast cancer survivors.

Introduction

Cancer is a prevalent and significant global health concern. According to the World Health Organization's (WHO) international cancer surveillance report (GLOBOCAN 2022), it is estimated that 20 million individuals worldwide were diagnosed with cancer and 9.7 million died due to cancer in 2022 (1). Breast cancer represents the second most prevalent type of cancer globally. The GLOBOCAN 2022 data indicates that breast cancer was the second most prevalent type of cancer in 2022, with 2.3 million new cases (1).

In the treatment of patients with stage I and II breast cancer, half of the patients undergo breast-conserving surgery with adjuvant chemotherapy, while 34% of patients undergo mastectomy without radiotherapy or chemotherapy. In patients with stage III breast cancer, 65% undergo mastectomy, with the majority of these patients receiving adjuvant chemotherapy after surgery. Mastectomy is even more commonly used in young patients (under 40 years of age) and in patients with large or aggressive tumours. The preference for

Please cite this article as: Toygar I, Bağçıvan G, Arıkan Dönmez A, Bilek F, Dönmez Ç.F, Borman P, et al. LYMPH-V: A wearable arm volume measurement device and mobile application for the prevention and early detection of breast cancer-related lymphedema: A study protocol. *Nursing Practice Today*. 2025; 12(3):259-74.



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mastectomy in early-stage breast cancer patients increased from less than 2% in 1998 to 28-30% between 2010 and 2012 (2).

In addition to the increase in cancer incidence, survival rates for many cancers, particularly colorectal and breast cancer, are increasing rapidly around the world (3). Among the reasons for the increase in survival rates are the use of more effective treatments with early diagnosis, thanks to advanced diagnostic methods and new treatment approaches (2, 4). According to the GLOBOCAN 2020 report, the total number of people living within 5 years of a cancer diagnosis is estimated to be 50.6 million worldwide. In the United States of America (USA), there were 16.9 million cancer survivors in 2019, and this number is projected to exceed 22.2 million by 2030 (4). In the UK, the number of cancer survivors is expected to exceed 4 million by 2030 (3). According to Miller et al. (2022), 4 million (42%) of the total 9.7 million women who survived cancer in the USA in 2022 were breast cancer survivors (2).

Breast cancer is a cancer with low mortality and high survival compared to other cancers, where early diagnosis and treatment options are available. For this reason, breast cancer survivors represent a significant proportion of cancer survivors worldwide. It is predicted that the number of breast cancer survivors will gradually increase with (1) the increasing incidence of breast cancer in the world, (2) improved methods of diagnosis and treatment of breast cancer, and (3) changes in patients' preferred methods of breast cancer treatment (2, 5).

Although cancer curation refers to the complete disappearance of the tumour and the absence of recurrence, it should not be overlooked that various co-morbidities and complications may also be present. Fu et al (2015) reported that 73.8% of breast cancer survivors had at least one or more comorbidities (6). One of the most common problems experienced by breast cancer survivors is lymphoedema. The incidence of breast cancer-related lymphoedema varies from 3% to 36.7% (7). Another study by Carreira et al (2021) reported that in addition to lymphoedema, the risk of anxiety, depression, fatigue, sleep

disturbance, pain, and sexual dysfunction was significantly increased in breast cancer survivors (8).

The risk of developing lymphoedema in individuals who have undergone surgical treatment sentinel lymph node biopsy (SLNB) or radiotherapy, for breast cancer persists throughout their lifetime (9, 10). Lymphoedema can result in a number of physical and psychological difficulties, including decreased mobility and function, deformity, decreased range of motion, loss of muscle strength, impairment in activities of daily living, and emotional distress. These challenges can significantly impact the quality of life of breast cancer survivors (7,11). When the psychological effects of lymphoedema are examined, it has been reported that women may experience a decline in self-confidence due to a deterioration in body image, which can lead to negative emotions such as anxiety, frustration, sadness, and anger (9). Anbari et al. (2021) reported that breast cancer-related lymphoedema negatively affects the quality of life of the individual, not only during diagnosis but also throughout the rest of life (12). Furthermore, breast cancer-related lymphoedema and its treatment negatively affect individuals' return to work and may lead to labour force losses (13). The direct cost of lymphoedema is reported to range from 2,306 to 2,574 USD per patient per year. The indirect cost is estimated to be between 3,325 and 5,545 USD per year (14).

Lymphoedema is a health problem that is challenging to treat after clinical signs and symptoms (7,11). Therefore, it is very important to prevent lymphoedema or to detect it before clinical manifestations. The main components in the prevention of lymphoedema are the reduction of risk factors, education of survivors, and physiotherapy (15, 16, 17). The recommendations of an expert panel consisting of multidisciplinary members for the prevention of lymphoedema are as follows; establishing a surveillance plan, performing baseline arm circumference measurements (ipsilateral and contralateral), maintaining healthy weight/BMI levels of survivors, educating survivors during pre- and postoperative hospital visits, performing

resistance and aerobic exercises, and applying therapeutic lymphangiogenesis methods (18, 19).

In the prevention of lymphoedema, health education is a crucial component for survivors to adhere to the necessary practices to remove risk factors and protect the extremity. Choi et al. (2015) reported that the level of knowledge and awareness of lymphedema in breast cancer patients was low (20). In a study conducted in Turkey, it was reported that 80.5% of patients who developed breast cancer-related lymphedema did not receive information or education about lymphedema (21). Lu et al. (2015) reported that patient education initiated in the first week after surgery and subsequent physiotherapy were effective in reducing the risk of developing breast cancer-related lymphedema (17). Lu et al. (2015) reported that patient education initiated in the first week after surgery and subsequent physiotherapy were effective in reducing the risk of developing breast cancer-related lymphedema (17). A systematic review by Perdomo et al. (2023) found that the effectiveness of patient education for breast cancer-related lymphedema is enhanced by the repetition of education and the variation in the depth of the content (22).

The prevention of breast cancer-related lymphoedema has been a topic of interest since the past, with exercise being included in the prevention of this condition or as a part of treatment (23). A systematic review by Hayes and colleagues (2022) reported that different types of exercise (resistance exercises and aerobic exercises) are effective in preventing cancer-related lymphedema (24). The systematic review revealed that exercise yielded positive outcomes in pain, heaviness, firmness, quality of life, aerobic capacity, upper extremity strength, lower extremity strength, fatigue, weight, body mass index, and body fat ratio (24). Wu et al. (2021) reported that complex decongestion treatment and exercise in the early period were effective in reducing the incidence of lymphedema, improving quality of life, and reducing fatigue (25). Wanchai and Armer (2019) reported that weight lifting or resistance exercises are effective methods in the prevention or treatment

of lymphoedema (26). In a consensus on exercise practices for cancer survivors, it is recommended that resistance exercises be employed at a strong evidence level for the prevention of lymphedema in breast cancer survivors (27).

A study examining the challenges encountered in the prevention of lymphoedema in Turkey revealed that a significant proportion of breast cancer survivors failed to implement and maintain recommendations (28). Additionally, the study highlighted that survivors' inadequate level of knowledge constituted an important obstacle (28). Another result of this study is that coping is an important component in the prevention of lymphoedema, and that survivors require social support. In the study conducted by Cal and Bahar (2016) in Turkey, it was reported that the interaction of survivors with other survivors made them more motivated to implement interventions to prevent lymphedema (28). In a study conducted by Ouyang et al. (2021), it was reported that approximately half of breast cancer survivors ceased attending hospital visits within the first five years (29). Additionally, it was found that breast cancer survivors and their caregivers exhibited positive attitudes and a willingness to utilise online health information systems and mobile applications (30). In a systematic review conducted by Dahlke and colleagues, a taxonomy was developed according to Abraham and Michie's theories and existing applications developed for breast cancer survivors were evaluated. The review concluded that current practices are insufficient to provide the necessary components for behaviour change (31).

Despite educational and exercise interventions, the incidence of breast cancer-related lymphoedema remains high. Therefore, early detection of lymphoedema is also crucial in cases where it cannot be prevented. The preclinical stage is the only stage where lymphedema can be treated. Soran et al. (2014) reported that only 4.4% of patients with preclinical lymphedema who were detected and treated at an early stage developed clinical lymphedema (32). However, the methods used in the early diagnosis of lymphedema are not

suitable for use in the home or work environment of survivors (33). The most commonly used methods for early diagnosis of lymphedema are currently upper arm volume measurement, bioelectric impedance spectroscopy, indocyanine green lymphography, tissue dielectric contrast, serum biomarkers and shear wave elastography (33). However, all of these measurements require hospitalisation. In breast cancer survivors, hospital admission decreases by approximately 50% in the first five years (29). Therefore, there is a need for portable methods that breast cancer survivors can use at home. Non-invasive methods that can be used at home and do not require high-tech equipment are extremity (upper arm) circumference measurement, evaluation of tissue resistance and water overflow test. The upper arm circumference measurement entails measuring the circumference of the same area of the arm by taking measurements from a fixed site, such as a bone (e.g. 5 cm below the upper end of the humerus). While it is not possible to make comparisons between different patients in this method, it allows for the monitoring of changes in the patient over time (34). Additionally, arm volume can be calculated by measuring the arm circumference at regular intervals. This method is one of the most frequently employed in arm volume calculation (35). Tonometry is another method that offers the possibility of measurement at the patients' home. It is reported that the reliability of tonometer measurements is low (36). Although the water overflow test does not require advanced technology, it requires large equipment, and this limits its portability (33, 36). Bioelectric impedance spectroscopy, optical imaging + infrared + motion sensor integrated system, ultrasound, power-sensitive sensors, and sensors that measure skin fluid density are recommended for home use by breast cancer survivors. However, of these, systems such as bioelectric impedance spectroscopy, optical imaging + infrared + motion sensor integrated system and ultrasound have limited portability and their use is complicated for survivors. Furthermore, only sensors that can measure

skin fluid density are wearable. However, the specificity of these sensors for lymphedema is limited (37). One of the most common forms of lymphedema detection is limb circumference measurement (33). Volume calculation for the arm can also be made by means of limb circumference measurement (35). Two types of sensors are commonly used to measure limb circumference: pressure/force-sensitive sensors and elastic strain sensors. Pressure-sensitive sensors are unable to determine the direction of pressure/force due to their structure, which can result in inaccurate readings when used under clothing. Strain sensors, on the other hand, have been used to determine the movements of people for years. It offers a safe use in many areas, especially in sports, health and physiotherapy (38). However, the use of strain sensors in the field of lymphoedema is very limited. In the literature, except for the effectiveness of lymphedema treatment, only one study has been used to determine the relationship between movement and lymphedema (37). The objective is to develop a device that, through stretch sensors, monitors arm volume and alerts users via the mobile app about any changes that may indicate the onset of lymphedema.

Methods

The study includes several processes to develop the device and mobile application and to evaluate their effectiveness. The protocol of these studies is presented in line with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines (39, 40). Clinical trial registration number of the study is NCT06507033 and registered on 12 November 2024.

Study design and settings

The phases of the study include two qualitative studies, a pilot randomised controlled study, and a reproducibility study. The study flow is presented in Figure 1.

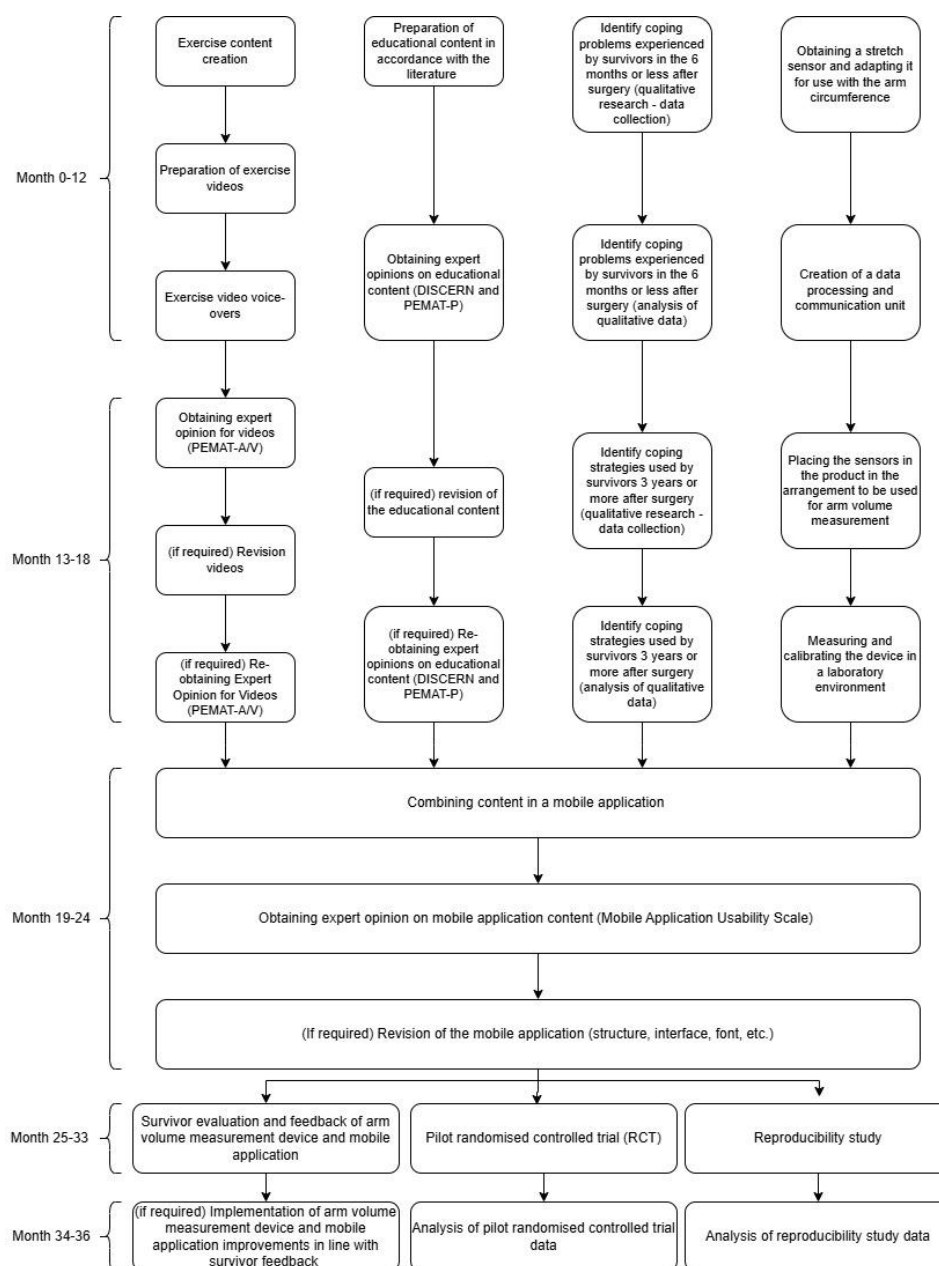


Figure 1. Study the flow and time periods of study

All of the abovementioned studies will be conducted at two university hospitals in Turkey, Hacettepe University Hospital and Koç University Hospital.

Study sample

Samples were calculated for each study as listed below.

Qualitative Studies: When determining the sample, the literature reports that interviewing twelve (12) people is sufficient in qualitative studies aimed at understanding the common perceptions and

experiences of a group. Furthermore, it is reported in the literature that sampling can be terminated at the point where there is no new input from the sampling unit, i.e. at the saturation point, and that the saturation point is usually reached with twelve participants (41, 42). Therefore, it is estimated that the sample in the qualitative part of this study will be saturated with 12 participants. Both qualitative studies will be carried out with 12 participants.

Pilot Randomized Controlled Trial: Power analysis was used to determine the minimum required number of participants in the pilot randomized controlled trial. Cocks

and Torgerson (2013) reported that at least 9% of the sample calculated for the randomized controlled trial should be included in the pilot randomized controlled trial (43). For this study, the sample for the randomized controlled trial was determined first. Then 9% of this sample was included in the pilot randomized controlled trial. As there was no similar study in the literature, the estimated effect size was used. In this power analysis, the hypothesis test was an independent groups t-test, type 1 error was 0.05, power was 0.80, and effect size was 0.50. The minimum number of patients required for the randomized controlled trial was set at 128, 64 in each group. For the pilot randomized controlled trial, it was calculated that the sample should consist of a total of 14 individuals, 7 in each group, which is 9% of the sample.

Reproducibility study: The calculation of the sample size for the reproducibility study is based on the central limit theorem. According to the central limit theorem, the sample mean of independent and identically distributed random variables converges to the normal distribution as n increases. Therefore, the sample size must reach a certain threshold for the normal distribution to obtain. Generally, when $n \geq 30$, the transition from the Student t distribution to the normal distribution is acceptable (44). Therefore, in order to use the normal distribution approach in the analyses, the sample size was set at 30 in the repeatability assessment.

Inclusion and exclusion criteria

The inclusion and exclusion criteria were determined for each of the four studies.

First Qualitative Study: Patients with the following characteristics will be included in the study: (i) consent to participate in the study, (ii) breast surgery including lymph node dissection within the last 6 months, (iii) 18 years of age or older, (iv) ability to communicate in Turkish, (v) no diagnosed psychiatric disorder (based on electronic medical records), (vi) no cognitive impairment (based on electronic medical records).

Second Qualitative Study: The inclusion criteria for the second qualitative study will be identical to those of the first qualitative study. However, only those who have survived breast cancer for at least three years will be included, rather than those who have survived for six months or less. Additionally, the State and Trait Anxiety Scale will be employed to assess the anxiety status of individuals to be included in the second qualitative study and to exclude those with high levels of anxiety. This measure is used to assess an individual's state and trait anxiety. The scale was first developed by Spielberger et al. (1964), and after the adaptation and standardization of the inventory into Turkish by Oner and Le Compte in 1974-1977, the inventory was used in studies with young and adult Turkish groups (45, 46). Scores between 20 and 80 are obtained from the instrument for measuring state and trait anxiety levels, with high scores indicating increased levels of anxiety (46). Individuals with a score of 50 and above, which is the mean score from either of these two measurement tools, are excluded from the second qualitative study.

Pilot Randomized Controlled Study: Patients with the following characteristics will be included in the study (i) Agree to participate in the study (ii) Breast surgery, including lymph node dissection within the last six months (iii) To be 18 years of age or older, (iv) To be able to communicate in Turkish, (V) Use of a smartphone with an Android operating system, (vi) No cognitive impairment (based on electronic patient records).

Reproducibility Study: Patients with the following characteristics will be included in the study (i) consenting to participate in the study, (ii) having undergone breast surgery including lymph node dissection within the last 6 months, (iii) being 18 years of age or older, (iv) being able to communicate in Turkish, (v) having no cognitive impairment (based on electronic medical records).

Development of mobile application

The content of the mobile application to be developed will include the arm volume measurement and monitoring panel, as well as

exercise instructions and videos, components involved in the education of survivors, and methods and suggestions used by previous survivors to cope. The data collected via mobile application will be shared with the healthcare team upon the patient's approval. In the event of an increase in arm volume that could be considered risky, the mobile application will notify the patient and request their approval to send an email or SMS to the relevant healthcare professionals. Due to the legal regulations on data privacy, patients' approval for data sharing is required. The data will be stored in a cloud service.

1) Creation and evaluation exercise videos

Recommendations from international guidelines will be considered in the development of exercise content. As a result of a consensus to develop an exercise guide for cancer survivors, resistance exercises are recommended for the prevention of lymphedema in breast cancer survivors (27). For resistance exercises, it is recommended to start with low resistance and gradually increase (start low, progress slowly) two or three times a week (27). Elastic bands (TheraBand) with different resistance levels are provided for survivors to do exercises at home. Survivors are encouraged to perform shoulder (flexion, extension, abduction, adduction, internal rotation and external rotation), elbow (flexion and extension) and wrist (flexion, extension, supination and pronation) exercises against resistance.

Resistance training is performed under the supervision of a physiotherapist using a general progressive programme focusing on large muscle groups, two to three times a week, following the principle of 'start low, progress slowly' (47, 48). Exercises are performed 3 times per week in two sets of 8-12 repetitions (48, 49). The use of compression garments during physical activity and exercise is recommended (50). Therefore, all participants in the study (both experimental and control groups) will be provided with compression garments during resistance exercise. The compression garment will be provided by the researchers from the

wrist to the shoulder. All applications will be performed by the researchers and videotaped, with explanatory voice-overs added to each video. The video recordings will be made in a studio with green box technology and the voice-overs will be done by professional voice actors in a sound studio. This will provide individuals with both guidance and exemplary practice.

In determining the resistance levels to be used by survivors, the maximum strength in one repetition will be assessed and 50-80% of this strength will be used. The Patient Education Materials Assessment Tool - Audio/Visual (PEMAT-A/V) will be used to assess the content of the exercise videos. The PEMAT-A/V is used to assess materials that contain an audio and a visual component, such as a video or multimedia material. Multimedia materials may include a combination of text, audio, still images, animation, video or interactive content.

The PEMAT-A/V consists of 13 items measuring comprehensibility and 4 items measuring applicability, with a Cronbach's alpha of 0.76. This value is 0.77 for comprehensibility (items 1, 3-5, 8-14 and 18-19) and 0.74 for applicability (items 20-22 and 25) (51). The validity and reliability of the measurement tool in our country was carried out by Paylan Akkoç (2020) (52). In this study, if the comprehensibility and applicability scores of the practice videos are 80% and above, it will be considered successful. In addition, there will be a panel in the mobile application where survivors can communicate with their physiotherapist if they have any questions.

2) Creation and evaluation of educational content

In preparing the educational content to be applied to breast cancer survivors, the topics will be determined by considering the American Cancer Society recommendations for breast cancer survivors, the Oncology Nursing Society (ONS) guide for the prevention of cancer-related lymphedema, the recommendations of the International Lymphedema Framework, and other

international guidelines, and other international guidelines (53, 54, 55). The developed educational content will be submitted to expert opinion and feedback will be received. The DISCERN measurement tool and the Patient Education Materials Assessment Tool - Print (PEMAT-P) will be used in these feedbacks. The DISCERN (Quality Criteria for Consumer Health Information) measurement tool was used. DISCERN was developed by Charnock et al. (1999) and translated into Turkish by Gökdoğan et al. (2003) (56, 57).

The scale is a 15-item scale and a total score of 15 indicates that the quality of the content of the application is low, while a score of 75 indicates that the quality of the information is high. PEMAT-P consists of 17 items measuring comprehensibility and 7 items measuring applicability. PEMAT-P is used to evaluate printed materials such as booklets and brochures, as well as electronic file types (doc, docx, pdf) and health education to be implemented through websites. The measurement tool was developed by Shoemaker et al. (2014) and culturally adapted in Turkey by Orgun and Paylan Akkoç (2020).

The measurement tool is reported to be highly valid and reliable in terms of structure, scope and internal consistency (51, 52). In this study, it is expected that the comprehensibility and applicability of the training content will be above 80%, in line with the expert opinions obtained with PEMAT-P for the training content. The mobile application will also include a panel where survivors can communicate with their physician, nurse and physiotherapist if they have any questions.

3) Supporting the coping mechanisms

A sub-heading will be included in the mobile application to support survivors' coping mechanisms. The content to be included in this sub-heading will be determined at the end of two qualitative studies. The first qualitative study aims to identify the coping problems of people who have survived breast cancer for less than 6 months. The second qualitative study will

determine the coping methods used by people who have survived breast cancer for more than 3 years and have not developed lymphedema, and the data obtained at the end of the second qualitative study will be presented in this sub-heading of the mobile application.

4) Reminder and arm volume measurement panels

The reminder module in the mobile application will provide patients with reminders under three headings: measurement, hospital appointment and exercise. The patient will be able to choose on which days these reminders will be sent. On the measurement panel, when the patient is wearing the armband, there will be two buttons for the right and left arm and a button to view past measurements. The volume is calculated for each compartment using the formula reported in the literature by the arm circumference measurement system located at 5 cm intervals in the device, and the sum of these volumes gives the total arm volume. The cylinder formula used to measure total arm volume is shown below. The formula was published by Podleska et al. in 2014 (58).

$$V = \frac{h \times \pi}{3} \times \left\{ \left(\frac{\text{Arm Circumference 1}}{2\pi} \right) \times \left(\frac{\text{Arm Circumference 1}}{2\pi} \right) + \left(\frac{\text{Arm Circumference 1}}{2\pi} \right) \times \left(\frac{\text{Arm Circumference 2}}{2\pi} \right) + \left(\frac{\text{Arm Circumference 2}}{2\pi} \right) \times \left(\frac{\text{Arm Circumference 2}}{2\pi} \right) \right\}$$

In the formula, V is the volume of each segment and h is the distance between two measurements. This formula is used to calculate the volume of the area between two measurement sites. By calculating and summing the volume between all sensors, the total limb volume will be calculated. This calculation will also allow the patient to be informed in which part of the arm the

increase is located. The measurements obtained here will be recorded in the mobile application and compared with the initial measurement and the percentage increase will be evaluated. Ochalek and Gradalski (2023) reported that a 2% increase in arm circumference or a 5% increase in arm volume in any area of the arm may be an indicator of preclinical (subclinical) lymphedema and should be considered as a 'red flag' (59). In this project, a 2% increase in arm circumference or a 5% increase in total

arm volume in any measurement area will send a notification to the patient and the healthcare team (relevant physician, nurse and physiotherapist).

The mobile application will also include exercise reminders for survivors on specific days of the week. The reminders will be sent to individuals as notifications. The draft content of the mobile application to be developed in the research is shown in Figure 2.

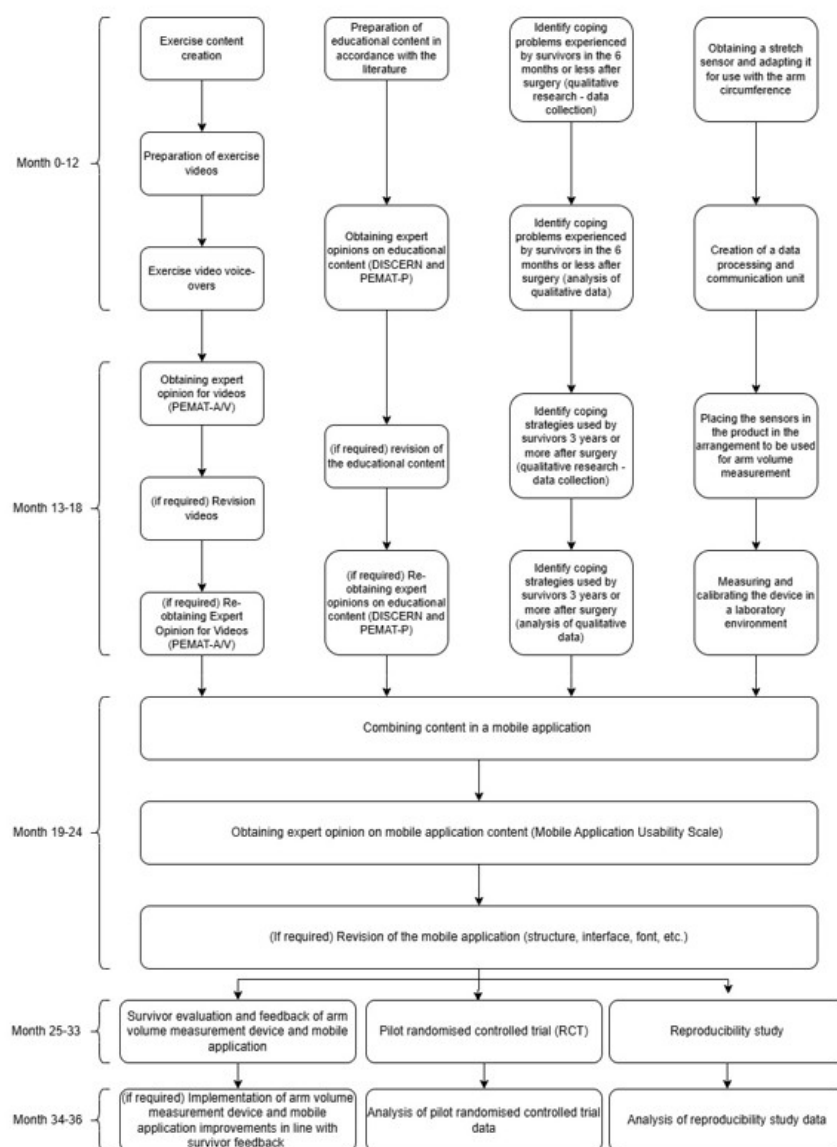


Figure 2. Draft content for mobile application

5) Mobile application content evaluation

After the components to be included in the mobile application have been prepared, all the components will be combined in the mobile application. The components to be included in the mobile application are (1) exercise, (2) training, (3) coping experiences and strategies, (4) arm volume measurement and tracking panel, and (5) reminder panel. To evaluate the usability of the mobile application, the mobile application usability scale is used, which was developed by Hoehle and Vankatesh (2015) and adapted to the Turkish society by Güler in 2019 (60, 61).

The scale is a 7-point Likert-type measurement tool and consists of a total of 40 questions. There are 10 factors in the scale, each of which consists of 4 questions. This measurement tool evaluates basic features such as the colours used in the mobile application, writing styles, font sizes, transitivity and management of the application (61). In this research, a score between 4 and 28 can be obtained for each factor, and scores above 20 will be considered successful. In addition, the tendency to continue to use (mobile application) scale and the brand addiction scale (for mobile applications) developed by Hoehle and Vankatesh (2015) and adapted by Çetin (2019) for the Turkish society are also used in the evaluation of the mobile application (60, 61). Both scales are seven-point Likert-type scales with high scores indicating positive attitudes (61).

The tendency to continue using scale consists of six items and scores between 6 and 42 can be obtained (60, 61). In this study, a score of 30 or more is considered successful for the tendency to continue to use scale. The brand addiction scale consists of five items and the scores that can be obtained vary between 5-35 (60, 61). In this research, scores of 25 and above are considered successful.

Pilot randomized controlled study

It is anticipated that four of the armbands can be developed within the project budget. It is anticipated that the armband can be tested on two or three patients after sterilisation

within the project period and therefore it has been decided to conduct a pilot randomised controlled trial as part of this study. Computer-assisted simple randomisation will be used in this study.

This pilot randomised controlled trial will involve breast cancer survivors who have undergone axillary lymph node dissection and have not developed lymphoedema. Participants will be asked to take measurements with the product at least one day per week.

Dependent variables: Disability of Arm, Shoulder and Hand (DASH) score, Adult Quality of Life in Cancer Survivors Scale score, Positive Affectivity, Negative Affectivity Scale (PANAS) score.

Independent variables: Whether participants were in the experimental or control group.

Reproducibility study

The aim of this research, known as reproducibility, is to assess whether different measurement tools provide consistent measurements (62). This study aims to compare the arm volume measurement method to be developed with the manual cylindrical limb measurement method previously used in the literature. In both methods, arm volume is determined by measuring the arm circumference at 5 cm intervals. In the manual method, these measurements are performed manually and the calculation is performed manually or with a pre-prepared Excel file (35).

This research will demonstrate the usability of the device developed by the application of the two methods by the same researcher instead of the current method of manual cylindrical limb measurement. The individuals who will participate in this study will consist of individuals who have not developed lymphedema and who will present to the appropriate outpatient clinic.

For the reproducibility study, the socio-demographic data collection form and the chart where the measurements will be recorded will be used. Measurements are taken consecutively on the same day by the same observer. This is to avoid changes over time and inter-observer bias.

Statistical analysis

Evaluation of quantitative studies

IBM SPSS 26.0 software will be used to analyze quantitative data. Number, percentage, mean, standard deviation, median, minimum and maximum values will be used for descriptive information. In the randomized controlled pilot study, the normal distribution of the data will be examined primarily in the assessment of the difference between the groups. Kolmogorov-Smirnov and Shapiro-Wilk tests will be used to examine the normal distribution of the data. The Kolmogorov-Smirnov (K-S) test and the Shapiro-Wilk (S-W) test are two commonly employed methods for assessing normality, each with specific strengths. The S-W test is highly sensitive and effective for small to medium sample sizes, rendering it an optimal choice for detecting deviations from normality.

In contrast, the K-S test, while less sensitive, is better suited for larger datasets and offers flexibility in comparing the data to any theoretical distribution, thereby providing complementary insights when used in conjunction with the S-W test. In cases where the data are normally distributed, the independent groups t-test is used to assess the statistically significant difference between groups, and the Mann-Whitney U test is used in cases where the data are not normally distributed. For multiple group comparisons, one-way analysis of variance (ANOVA) was used when the data were normally distributed, and Kruskal-Wallis analysis was used when the data were not normally distributed. In the case of a statistically significant difference, Cohen's criteria will be used to calculate the effect size of this difference. Power analysis will be performed using G-Power 3.9.1 software. Bland-Altman analysis will be used as a hypothesis test in the evaluation of the reproducibility study. In addition, interclass correlation (ICC) will be used to assess the agreement between the two measurement methods. The statistical significance level will be accepted as $p < 0.05$.

Analysis of qualitative studies

Thematic analysis will be used for both qualitative studies. All audio recordings,

including semi-structured interviews, will be analyzed using the thematic analysis method developed by Braun and Clarke (2006) (63). The six stages of Braun and Clarke's analysis (1. recognition (familiarity with the data), 2. creating initial codes, 3. searching for themes, 4. reviewing themes, 5. identifying and naming themes, 6. writing the report) will be used to analyze the data (64). This thematic analysis involves in-depth recording to consolidate codes and themes. These will be reviewed and refined by researchers experienced in qualitative research to arrive at final themes and sub-themes. The themes will reflect the data collection questions and will be identified and coded accordingly. NVivo 11.0 software will be used to facilitate data management and to systematically code transcriptions into themes and sub-themes. Coding will be carried out independently by at least two researchers to increase the reliability and validity of the study. Coding will be deductive and will be included in the final report. In addition, the COREQ list (List of criteria for reporting qualitative research) will be used, which is designed to help qualitatively designed research to be conducted according to appropriate criteria (65).

Ethical consideration

The study was approved by the Medical Research Ethics Committee of Üsküdar University with approval number 2023/10 dated 13.12.2023. All principles of the Helsinki Declaration will be followed throughout the study. Informed consent will include detailed information on study participation, potential risks, expected benefits, and privacy measures implemented to protect participant data. The data collected in this study will be used solely for the purposes of scientific reporting, and in accordance with the formal authorizations and ethical committee approval, the participants' informations will be blinded in these reports.

Timetable of the study

The timetable of the study is presented in Figure 3 in accordance with SPIRIT guidelines (39, 40).



	STUDY PERIOD					
	Enrolment	Allocation	Post-allocation			Close-out
TIMEPOINT	-t ₁	0	t ₁ 1st month	t ₂	t ₃ 3rd month	t _x
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
Allocation		X				
INTERVENTIONS:						
Use of the device and mobile application						
Control group						
ASSESSMENTS:						
Disability of Arm, Shoulder and Hand - DASH		X				X
Quality of Life in Adult Cancer Survivors		X				X
Positive Affectivity, Negative Affectivity Scale		X				X

Figure 3. Timetable for the pilot randomized controlled trial in accordance with SPIRIT guidelines

Results

Potential outcome metrics for the pilot RCT in the protocol will include:

The compliance rates are as follows: The objective is to evaluate the extent to which participants adhere to the intervention as outlined in the protocol. The ease of use of the intervention is also a factor that must be taken into account. The user-friendliness of the intervention is evaluated through participant-reported outcomes, interviews, or usability questionnaires. Feasibility metrics include: Such factors as recruitment and retention rates, adherence to study timelines, and logistical challenges encountered during implementation must also be considered. The acceptability of the intervention is determined by the extent to which participants find it satisfactory and appropriate.

The evaluation of satisfaction surveys and qualitative feedback allows for the assessment of participants' overall perception of the intervention.

Discussion

The present study protocol outlines a pilot randomised controlled trial, the objective of which is to evaluate the feasibility and acceptability of the intervention for the prevention of breast cancer-related lymphedema. By facilitating at-home monitoring with early warning features, LYMPH-V empowers patients to be active in their own care management and may help lower healthcare system burdens as well as long-term outcomes.

However, certain predicted problems deserve attention. Maintenance of usage of the

wearable device and the smartphone application can be hampered by personal motivation, technical issues, or lack of familiarity with technology. Moreover, because this was a small sample pilot study, generalizability of the results is limited. Larger and more representative samples are needed in future research to confirm the effectiveness and scalability of the intervention.

In spite of these constraints, LYMPH-V has the potential to reshape the self-management and early detection of lymphedema in survivors of breast cancer and potentially in other patient populations with chronic oedema. Its flexible nature and multi-disciplinary approach can be used as a model for the development of future digital health devices in other related fields. These findings point to the importance of the integration of wearable technology and mobile apps in longer-term cancer pathways of care and highlight the need for ongoing research in this exciting field.

Conclusion

The projected outcomes demonstrate the feasibility and potential effectiveness of the intervention for breast cancer-related lymphedema, and suggest its adaptability to other forms of cancer-related lymphedema, including those associated with gynaecological or head and neck cancers. Moreover, the principles of personalised care and continuous monitoring embedded in this intervention could be extended to manage other chronic conditions involving oedema, mobility restrictions, or vascular health. Further research could explore these adaptations to broaden the intervention's utility across diverse patient populations and clinical contexts.

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