Effects of Health Belief Model based nursing interventions offered at home visits on lymphedema prevention in women with breast cancer: A randomized controlled trial

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Backround

Secondary lymphedema is one of the most severe complications resulting from damage to lymphatic drainage due to breast cancer treatment. Many women suffer from lymphedema after breast cancer treatment. Due to the lack of standard diagnostic criteria for the incidence of lymphedema varies from less than 5% to more than 50%. In a recent meta-analysis, it has been found to be 21.4%.

The primary risk factors of lymphedema are lymph node involvement and axillary lymph node dissection. The other risk factors are radiotherapy, adjuvant chemotherapy, early postoperative swelling, body mass index, advanced age, insufficient physical activity, infections in the affected arm and injuries. A study performed axillary dissection in women with breast cancer and found that 13.4% of the women not receiving radiotherapy and 42.4% of the women receiving radiotherapy had lymphedema.

Lymphedema reduces the quality of life due to physical and psychosocial disorders it creates. Women with lymphedema have physical problems such as restricted movements, retraction, weakness, pain and swelling on the affected breast and arm, difficulty in maintaining daily life activities and psychological problems like low self-confidence, disappointment, sadness and fear due to the appearance of lymphedema.

It has been reported that the yearly cost of treatment (visits to therapists and compression garment) per person is $977 for lymphedema, $277 for subclinical lymphedema, higher than $1400 for moderate and severe lymphedema. Effective management of lymphedema on the affected arm could reduce negative effects of lymphedema and resultant high treatment costs.

Nurses believed that risk reduction (95%) and self-management (68%) were the responsibility of nursing while 69% felt that management of lymphedema was the responsibility of a different discipline, such as lymphedema therapy. The patient-centered educational and behavioral program delivered by trained nurses is effective to enhance lymphedema risk reduction. Lewis and Morgan emphasized that cooperation with public health nurses improves

patient care outcomes and costs associated with lymphedema management. At this point, the literature suggested that nurses should inform individuals about the risk of lymphedema after breast cancer.

It has been shown in the literature that women are not aware of lymphedema before its development, are unable to recognize its symptoms and can not take sufficient preventive measures. Similar to the aims of the present study, Zhou et al. examined effects of a comprehensive Health Belief Model (HBM) based nursing care program on the quality of life, lymphedema and other complications after breast surgery in their randomized controlled study on women in 2016.

The conceptional framework most frequently used to explain health behavior and to help patients to acquire this behavior is HBM. The model describes what motivates people to exhibit or not exhibit health behavior and especially what conditions are effective at this behaviors. The results of the present study, using HBM, will contribute to determination of beliefs and attitudes likely to create problems with adoption of behavior preventing lymphedema and selection of nursing interventions performed to manage the condition. Chronicity of lymphedema, likely to appear in the long-term, and its potential to affect the quality of life indicate that individuals with breast surgery have home care needs.

Study Protocol

Aims

The aim of this study was to examine effects of HBM based nursing interventions offered at home visits on lymphedema development in women undergoing breast surgery.

Study design and setting

The study had a single-blind, randomized controlled experimental design. To avoid bias, the participants were not told whether they were in the experimental or the control group. The conceptual structure of the study is given in Figure. This randomized clinical trial was based on

the guidelines proposed by the Consolidated Standard of Reporting Trials – CONSORT 2010. The study was conducted at homes of patients receiving treatment for breast cancer at a hospital and living in Samsun, a city in northern part of Turkey , between May 2016 and April 2017.

Inclusion criteria

The study population included individuals receiving radiotherapy after breast surgery. Inclusion criteria were diagnosis of primary breast cancer and having stage I, II and III, having axillary dissection, not having the diagnosis of lymphedema, receiving radiotherapy, volunteering to participate in the study, age over 18 years and female and residing in the city.

Non-inclusion criteria and exclusion criteria

Exclusion criteria were diagnosis of bilateral breast cancer, open wound or infection in the upper extremities, musculoskeletal disorders preventing movements of the upper extremities, ongoing adjuvant systemic chemotherapy.

Randomization

An intervention group and a control group were formed by using the research randomizer software. The program used random numbers to select participants and randomly assign them to the experimental or control group (100 participants were assigned to each group). Homogeneity test showed no significant difference between the measures of the groups in Table 1 (p>.05).

Blinding of data collectors and the statistician was implemented in this randomized blinded study. Another researcher who did not know the group assignments coded the data in the computer. After statistical analysis was conducted and the research report was written, the assistant researcher explained the codes for the experimental and control group. Therefore, blinding of data collectors, statistical analysis, and report writing was provided.

Study outcomes

Personal Information Questionnaire;The questionnaire, developed by the researchers, is composed of 17 questions about sociodemographic characteristics, diagnosis and treatment of breast cancer, behavior of lymphedema prevention.

Quick-Disabilities of the Arm, Shoulder and Hand Score;Q-DASH is used to determine severities of disabilities in the upper extremities and benefits gained from treatment. It was adapted…by Duger et al. and its cronbach's alpha was reported to be .91. It is a five-point likert scale and includes 11 questions. The score zero indicates lack of a disability and 100 the most severe disability.

Strategies Used by Patients to Promote Health;SUPPH is a self-report scale created by Lev and Owen to evaluate self-efficacy of individuals in development of health promotion strategies. It was adapted by Akın and its Cronbach's alpha was reported to be .92. The scale consists of 29 items. The subscale stress reduction includes the items 1-10, making decision the items 11-13, positive attitude the items 14. Each item is scored from one to five:one corresponds to very little and five very much. The lowest and the highest scores for the scale are 29 and 145 respectively. Higher scores show higher levels of self-efficacy in self-care behavior 29.

European Organization for Research and Treatment of Cancer Quality of Life Scale for Breast Cancer 23;EORTC QLQ-BR23 was developed from European Organization for Research and Treatment of Cancer Quality of Life Scale 30 by EORTC to measure the quality of life in individuals with breast cancer. It was adapted Turkish by Demirci et al. The scale is composed of 23 items, a four-point scale and has two scales named FS and SS. Cronbach's alpha was reported to be .88 for the FS .66 for the SS. The FS has the subscales body image (items 39,40,41,42), sexual functions (items 44,45), sexual satisfaction (item 46), worry about the future (item 43). The SS has the subscales side effects of systematic treatment (items 31,32,33,34,36,37,38), breast symptoms (items 50,51,52,53), arm symptoms (items 47,48,49), worry about hair loss (item 35). The lowest and the highest scores for each scale are zero and

100 respectfully. Higher scores for the FS show a higher quality of life and higher scores for the SS indicate a poorer quality of life.

To calculate scores for the FS and the SS, the total score for the items of each scale is divided by the total number of items and the following formulae are used:FS={1-((((total score for the items)/number of items)-1)/range)}x100 and SS={(((total score for the items)/number of items)-1)/range}x100. The highest and lowest score for the items are four and one and the difference between them, that is, three, refers to range.

Arm Circumference Measurement Form;The form was made on four different sites on both arms:at the dorsum of the hand, the wrist, and 10cm below and above of the elbow. The difference more than 2cm between circumferences of the arms was considered as significant in terms of lymphedema.

Protocol

Oral informed consent was obtained from the eligible women at the initial interviews on the phone. The women who agreed to participate in the study were assigned to the groups according to the research randomizer software. The women assigned to experimental and control groups were planned first home visit and obtained written informed consent was obtained at this visits. At the Intervention group; the researcher made pretest (baseline measurements) before the nursing interventions at the first home visit. The researcher offered education and guide about prevention of lymphedema after the baseline measurements at the first home visit. Second and third home visits were made three and six months after the first visit. At the second and the third home visits, the measurements were repeated, and the nursing interventions were maintained in the direction of the patients' individual needs.

At the control group; the researcher administered the pretests at first home visit. The measurements were repeated in the third and sixth months after the first home visit. The

reseacher also given at the end of the sixth month, all of the nursing interventions, given to the intervention group, for the control group.

Intervention

Education Material;Breast Cancer Related Lymphedema Education Guide, prepared in light of the literature and revised in accordance with three experts opinions, was used at home visits. The content of the guide was directed towards supporting seriousness and sensitivity of the participants about lymphedema and created by taking account of HBM.

Home Visits;At the first home visits to the intervention group, the researcher met the participants and their families, explained the aim of the study and administered the pretests. The guide was introduced, and health education was given. Arm exercises used to prevent lymphedema were demonstrated and measurement of the arm circumference was taught. Follow-up forms were introduced and from the women were asked to do exercises as daily, make measurements as weekly, and record them in the forms day to day regularly. The arm measurements made by the researcher were included into the analysis. The participants and their families were encouraged to phone and receive counseling about things which they needed. Each home visit lasted 45 minutes on average. Three and six months after the first visit, the patients were phoned and made an appointment. At the second and the third home visits, the measurements were repeated, and the nursing interventions were maintained in the direction of the patients' individual needs (repeate of education, exercises and arm circumference measurement, control of follow-up forms).

At the first home visits in the control group, the researcher was introduced herself, explained the study and administered the pretests. The measurements were repeated in the third and sixth months after the first home visit. The womens in the control group were not told about the nursing interventions, given to the intervention group, during the study period in order to

avoid bias. At the end of the sixth month, education and guide about prevention of lymphedema were offered to this group.

Reminders; In the intervention group was sent a message reminding behavior preventing lymphedema every week.

Sample size calculation

Before initiation of the study, to achieve 80% power, 95% confidence interval and 0.05 error range, a power analysis was made with G-power software and the sample size was found to be 14 were in each groups. However, a higher number of participants was planned to be included into the study:37 formed the intervention group, 35 formed the control group. At the end of the study, a post-hoc power analysis was made by using primary outcome variables. The post-hoc power analysis score was .98 for Q-DASH, .94 for SUPPH, .67 for the function scale (FS) and .80 for the symptom scale (SS) in EORTC QLQ-BR23.

Study budget

The study was supported by The Scientific and Technological Research Council of Turkey 1002-Short Term Funding Program (number:215S656).

Hypotheses of the study

1. Extremity function restrictions will be lower in the intervention group than in the control group.

2. Self-efficacy levels will be higher in the intervention group than in the control group.

3. Functions improving the quality of life will be higher in the intervention group than in the control group.

4. There will be fewer symptoms reducing the quality of life in the intervention group than in the control group.

5. The incidence of lymphedema will be lower in the intervention group than in the control group.

6. The mean cost of the intervention group at home visits, will be lower than in the control group.

Statistical analysis plan

Data obtained in this study were analyzed with SPSS 21.0. Multifactorial variance analysis of repeated measures was used to compare the groups in terms of dependent variables, the significance test of difference between two means to compare pretest and posttest measures, one-way variance analysis of repeated measures to compare intragroup pretest and posttest measures and t-test for dependent groups with Bonferroni correction to perform further analysis of the difference between the mean scores of the groups. Intention-to-treat (ITT) analysis was utilized to eliminate effects of dropouts from the study, to maintain randomization. To prevent bias the database were analyzed by a statistician who was independent of the study.

Costs of treatments likely to be given for lymphedema in the intervention group and the control group due to the potential incidence of this condition and HBM based nursing interventions to be offered at home visits were made. The costs of the nursing interventions included time spent by the researcher at home visits, transportation for these visits, reminders on the phone, education material and tape measure. The cost of treatment for lymphedema included costs of medical treatment of an individual with stage I/II lymphedema in upper extremities in hospital. It was based on opinions of three experts. To calculate the costs from the perspective of Social Security Institution, prices of services and materials reported in Health Services Bulletin issued in Mar 2017 were taken. The expenses directly made by the patients were determined by the mean value of prices obtained from three national firms.
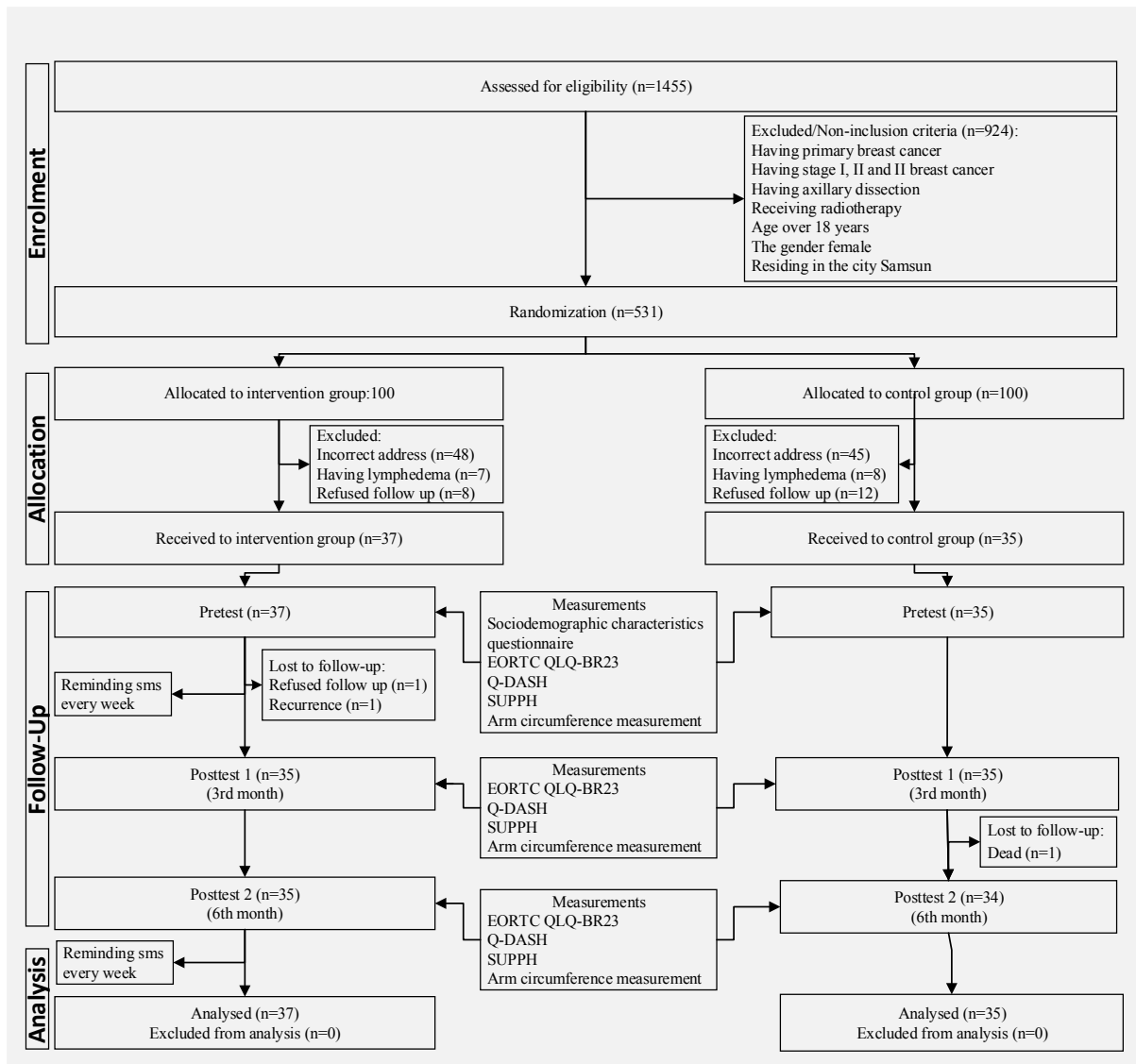
Ethical aspects

Ethical approval was obtained from DEU Noninterventional Clinical Research Committee (Protocol number: 2014/08-19; approval number: 248; date: 4 April 2013 970-GOA) and State Hospitals Directorate. Oral informed consent was obtained from the women at the initial

interviews on the phone and written informed consent was obtained at the first home visits. At the end of the study, nursing interventions about prevention of lymphedema were offered to the control group.

In the current study, the HBM based nursing interventions offered at home visits decreased perceived barriers to lymphedema management, increased perceived benefits and improved self-efficacy in positive health behavior.

The cost of treatment for lymphedema in the intervention group was four times as low as that in the control group, which confirmed the sixth hypothesis. The finding indicated that follow-up of women having breast surgery through home visits is a cost-effective practice. Programs conducted in cooperation with public health nurses improve patient care outcomes and reduce costs for lymphedema. Sixty-seven percent of the women mention the presence of a financial burden of breast cancer treatment and 80% of the women point out to the cost of treatment for lymphedema. Treatment of breast cancer costs $14.887-23.167 in patients developing lymphedema after breast surgery than those without lymphedema and this complication increases indirect costs due to loss of work force.

Enrolment	Assessed for eligibility (n=1455)

Excluded/Non-inclusion criteria (n=924):
Having primary breast cancer
Having stage I, II and II breast cancer
Having axillary dissection
Receiving radiotherapy
Age over 18 years
The gender female
Residing in the city Samsun

Randomization (n=531)

Allocation

Allocated to intervention group:100

Excluded:
Incorrect address (n=48)
Having lymphedema (n=7)
Refused follow up (n=8)

Received to intervention group (n=37)

Allocated to control group (n=100)

Excluded:
Incorrect address (n=45)
Having lymphedema (n=8)
Refused follow up (n=12)

Received to control group (n=35)

Follow-Up

Pretest (n=37)

Reminding sms every week

Lost to follow-up:
Refused follow up (n=1)
Recurrence (n=1)

Measurements
Sociodemographic characteristics questionnaire
EORTC QLQ-BR23
Q-DASH
SUPPH
Arm circumference measurement

Pretest (n=35)

Posttest 1 (n=35)
(3rd month)

Measurements
EORTC QLQ-BR23
Q-DASH
SUPPH
Arm circumference measurement

Posttest 1 (n=35)
(3rd month)

Lost to follow-up:
Dead (n=1)

Posttest 2 (n=35)
(6th month)

Reminding sms every week

Measurements
EORTC QLQ-BR23
Q-DASH
SUPPH
Arm circumference measurement

Posttest 2 (n=34)
(6th month)

Analysis

Analysed (n=37)
Excluded from analysis (n=0)

Analysed (n=35)
Excluded from analysis (n=0)

Abbreviations: EORTC QLQ-BR23, European Organization for Research and Treatment of Cancer Quality of Life Scale for Breast Cancer 23; SUPPH, Strategies Used by Patients to Promote Health; Q-DASH, Quick-Disabilities of the Arm, Shoulder and Hand Score.

FIGURE Consort flowchart