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A Pilot Randomized Trial Evaluating Lymphedema Self-Measurement with Bioelectrical Impedance, Self-Care Adherence, and Health Outcomes

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Abstract

Background: Less than half of breast cancer survivors with lymphedema perform self-care as directed. Effective lymphedema self-care is required to obtain acceptable health outcomes. Self-Regulation Theory suggests that objective self-measurement of physiological conditions is necessary to promote self-regulation/self-care. Bioelectric Impedance Spectroscopy (BIS) represents a potential self-measurement method for arm lymphedema. The purpose of this pilot study was to examine the impact of arm self-measurement on daily self-care activities and health outcomes in breast cancer survivors with lymphedema.

Methods and Results: A pilot randomized clinical trial compared outcomes between breast cancer survivors with lymphedema who self-monitored for 3 months and breast cancer survivors with lymphedema who did not self-monitor. Data were collected at baseline, months 1, 2, 3, and 4. Eighty-six women with lymphedema were screened: 62 were eligible, 50 were enrolled, 10 withdrew, and 1 had incomplete data, thus $N = 39$. No between group differences were noted in participant characteristics. The self-monitored group had higher days of garment use ($p = 0.005$) that remained stable after self-monitoring stopped. The median number of days of simple manual lymphatic drainage increased in the intervention group ($p = 0.004$) with a downward trend after self-monitoring ceased.

Conclusions: Objective self-monitoring of arms using BIS is possible. Self-monitoring may positively impact self-care behaviors. Highly symptomatic patients may require coaching or other psychological support to improve their self-care. Studies that combine a cognitive behavioral therapy component along with self-measurement should be considered as potential interventions to impact lymphedema self-care. Other applications of self-monitoring warrant investigation.

Introduction

There are approximately 2.3 million breast cancer survivors (BCS) in the United States.[1] Lymphedema—swelling in the arm, a breast, or chest related to cancer treatment—is a chronic effect of breast cancer treatment for which no cure exists. The current standard treatment for lymphedema onset and swelling exacerbations is a two-phase complete decongestive therapy (CDT).[2] During Phase 1 of professionally administered CDT, patients are treated with manual lymphatic drainage (MLD), compression garments, bandaging, and meticulous skin care. During Phase 2, lifelong self-care consisting of compression garments, self-administered simple-MLD, skin care, and self-monitoring of arm volume and condition is required. This helps maintain the therapeutic gains from Phase 1 and reduces exacerbations of swelling and infection.

Evidence supports that breast cancer treatment-related lymphedema is costly in terms of symptom burden (physical and psychological), economic outlay, and reduced quality of life (QOL).[3,4] Altered sensations in the limb and impaired shoulder mobility are only two examples of physical difficulties BCS with lymphedema experience.[5–7] Psychological distress and depression also occur.[8–10] Comparison of medical costs between BCS with lymphedema and those without reveal significantly higher medical costs within the 2 years

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following breast cancer treatment in the former group ($22,153, $p \leq 0.001$).[4] Higher cost items were outpatient prescription drugs, physical therapy, and lymphedema treatment supplies. QOL studies reflect similar findings (e.g., one study found that lymphedema patients experienced significantly more arm-related problems and scored lower on the FACT-B + 4 subscale ($p < 0.05$) than those without lymphedema).[11]

Effective lymphedema self-care is required to reduce the impact of lymphedema on well-being and disease progression.[12] Previous work by this team has found that less than 50% of BCS with lymphedema complete Phase 2 self-care as directed.[9,13] Contributing factors are the lack of perceived results and feelings of helplessness in managing the condition.[13] To improve outcomes in chronic disease patient populations, such as individuals with diabetes and hypertension, emphasis has been placed on patient education,[14,15] disease monitoring,[16,17] and support for self-care.[15,18] A component of many self-care management programs is objective monitoring of the physiological conditions (e.g., glucose levels, blood pressure). Such monitoring helps patients determine the effectiveness of self-care, set self-care goals, and reinforce continuation of self-care. There is no equivalent standard self-measurement tool for lymphedema patients to use for monitoring their lymphedema.

This team, based upon patients' requests to use single frequency bioimpedance spectroscopy (BIS) for home self-monitoring, previously developed and tested a lymphedema self-monitoring protocol using BIS.[19] The Food and Drug Administration (FDA) has approved a BIS device to measure changes in extracellular fluid associated with lymphedema.[20] This device is small, portable, and gives numerical output (L-Dex readings) informing the patient if extracellular fluid is above normal ranges.[21] Guided by Self-Regulation Theory,[22] a pilot, randomized clinical trial (RCT) was conducted with aims to examine the impact lymphedema self-measurement, using a lymphedema BIS self-monitoring protocol, on 1) self-care adherence (garment use, skin care, simple-MLD) and 2) select health outcomes (symptoms, productivity/activity, self-management/self-efficacy, QOL, treatment days, number of arm infections, and number of antibiotic prescriptions).

Materials and Methods

Participants

Scientific approval for this pilot study was obtained from the Vanderbilt-Ingram Cancer Center Scientific Review Committee, Nashville, TN, USA. Institutional Review Board (IRB) approval was granted by Vanderbilt University prior to commencing study activities. During the informed consent process, all participants were made aware that their monthly self-report forms would be reviewed by a study nurse and that they would be contacted by the nurse if potential warning signs of skin deterioration, infection, or increasing lymphedema were identified.

This community-based study successfully recruited the targeted number of 50 participants from: 1) an existing Vanderbilt University IRB approved registry of breast cancer survivors who have given permission to be contacted for future studies; 2) the Middle Tennessee, USA, region; and 3) flyers posted on national websites (Lymphatic Education and Research Network and National Lymphedema Network). Recruitment took place from August 2011 until August 2012. Inclusion criteria were: 1) a history of breast cancer and diagnosis of lymphedema in one arm only; 2) age 21 or older; 3) ability to stand upright; 4) no conditions that could cause swelling such as pregnancy, congestive heart failure, or liver failure; 5) no open sores on arms or known sensitivity to electrodes; 6) no pacemaker or internal defibrillator; and 7) no use of laxatives or diuretics to lose weight. Exclusion criteria included bilateral arm lymphedema, active cancer, and undergoing chemotherapy or radiation. Participants received token compensation for participation up to a total of $90 for completing the study and all follow up measures.

Design

This pilot RCT tested a previously developed self-measurement protocol.[19] After completion of baseline assessments, participants were randomized (1:1 allocation) into either a BIS self-measurement intervention or standard care control group using a computer-generated, permuted block randomization scheme developed prior to implementation of the study. (Fig. 1). The study principal investigator was blinded to assignments.

Data collection

Data collected during a baseline nurse interview from all participants included self-report demographics, medical history, and lymphedema disease and treatment questionnaires. Additional outcome instruments were completed by participants either with pen and paper or online via the REDCap data capture system and included:

Weekly lymphedema self-care checklist. A 20-item weekly self-report survey of frequency of performed self-care (e.g., days wearing a compression sleeve, days of self-MLD).[13]

Skin assessment. A 20-point yes/no, standardized assessment of skin condition was performed for both the affected and unaffected arms by trained staff who examined the arms at baseline and used as a self-report form by participants during the remainder of the study.[9,13]

Protocol observation checklist. A checklist corresponding to protocol steps was used by staff to document participant's completion of each step.

BIS. Arm measurements were made using a single frequency BIS device manufactured by Impedimed (Mansfield, Australia) that provided output in units of L-Dex, or lymphedema index, scores. An L-Dex reading of greater than 10 is indicative of lymphedema.[21]

BIS measurement log. Date, time, person completing the measurement (lab version only), menstrual status, L-Dex scores and comments (home version only) were recorded.

Perceived Medical Condition Self-Management Scale (PMCSMS). The PMCSMS, an 8-item generic scale that can be adapted to any specific medical condition (e.g., lymphedema), was used to assess perceived ability to complete self-care. Cronbach's alpha of 0.84 has been reported.[23]

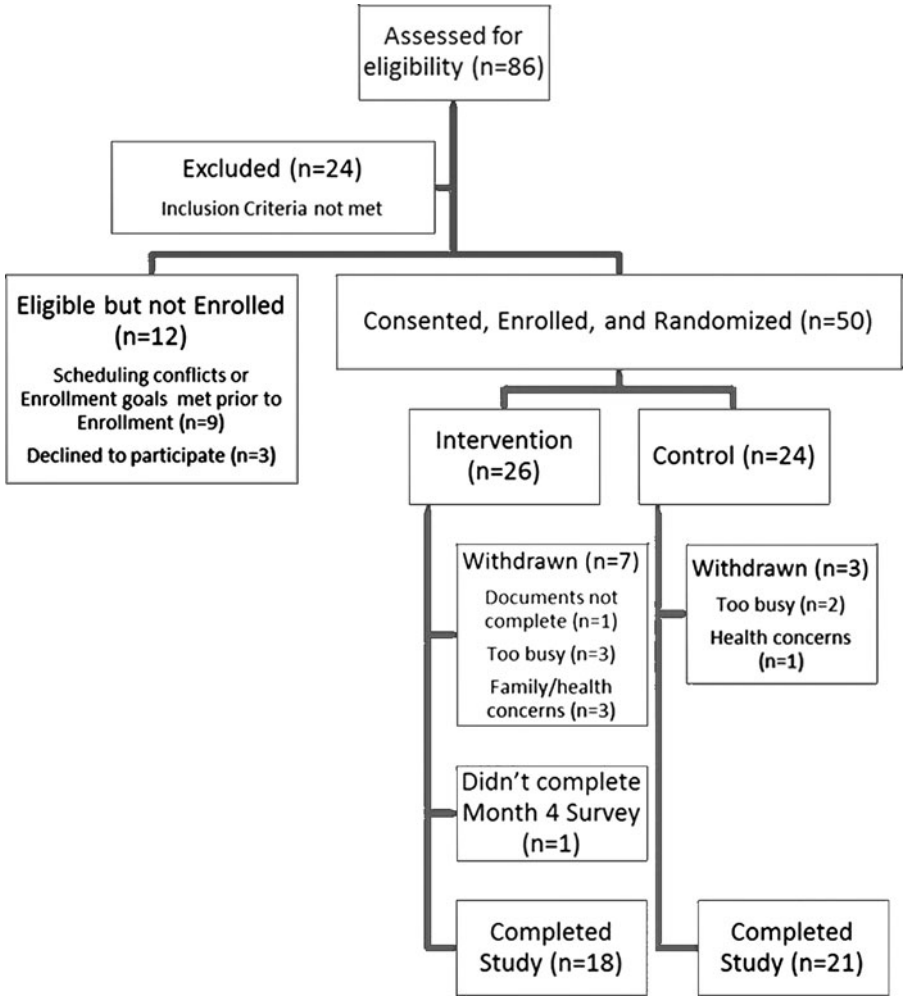

FIG. 1. Consort diagram.

Lymphedema Symptom Intensity and Distress Survey-Arm (LSIDS-A). The 36-item checklist required participants to indicate the presence of a symptom (''yes'' or ''no'') and if ''yes'' rate intensity and associated distress on two separate 10 point scales. In two previous studies, a Cronbach's alpha of 0.95 were noted.[24]

Work Productivity and Activity Impairment (WPAI) Questionnaire. This 9-item questionnaire was used to evaluate lost hours of productivity and reduced activity seven days prior to administration.[25,26] When compared to the SF-36® Health Survey, it correlates with general health scores (r = 0.52), and physical role (r = 0.52).

Upper Limb Lymphedema (ULL-27). This is a 27-item self-report QOL scale specific to arm lymphedema.[27] Cronbach's alphas were 0.92 and 0.93 for the ULL-27 in previous studies.[3,9]

Resource Utilization and Economic Burden Questionnaire (RUEBQ). This 25-item pilot instrument captured self-reported information specific to lymphedema treatment expense and was generated based upon previous work by this team.[4]

Procedures

Intervention group. Participants randomized to this group were taught the self-measurement protocol by study staff. They practiced self-measurement, recording all readings on the BIS Measurement Log. Once participants demonstrated the ability to measure their arms with staff present in the lab, they were knowingly observed through a one-way mirror for ability to follow the protocol unassisted. The Protocol Observation Checklist was used by staff to determine if the participants were able to complete the major steps of the protocol. If problems were noted at any time, additional training and re-assessment took place. Intervention participants who achieved an observation checklist score of 90% were given a copy of the protocol, a BIS Measurement Log, and loaned a BIS device for home use for 3 months. They were instructed to measure their arms every morning, before eating or drinking and after voiding, for 5 days, then once every 3 days for a total of 3 months (approximately 26 total measurements). These participants completed weekly self-care checklists and monthly follow-up questionnaires for 4 months. Study staff called participants the day of their first self-measurement to ensure understanding of the protocol and device use as well as the document completion schedule. Participants were encouraged to call or email staff with any

questions that arose. Study staff picked up the equipment after completion of the third month.

Standard care control group. Reflective of the current standard of lymphedema self-care, participants in this group did not conduct any self-measurement. These participants completed weekly self-care checklists and monthly follow-up questionnaires for 4 months. They were called by study staff the day after their baseline visit to ensure understanding of the document completion schedule. Participants were encouraged to call or email staff with any questions that arose.

Per IRB protocol, self-reported data collected monthly were reviewed by a study nurse to identify potential warning signs of skin deterioration, infection, or increasing lymphedema. Participants were contacted by a study nurse for a phone assessment and therapeutic referrals were made, if needed, should infection be indicated.

Statistical analysis

Statistical analyses were conducted using SPSS (version 21.0) and STATA (version 12). Nominal demographic and study measures were summarized using counts and percentages. Age and education were summarized using mean and standard deviation; however, all of the remaining continuous data distributions were heavily skewed. Therefore, median and 25^{th} to 75^{th} interquartile range were used to describe them. Study group demographic and clinical history variables were compared using Chi-Square Tests of Independence (nominal) and independent *t*-tests (age, education). Differential effectiveness of the study groups was tested specifically by the interaction effect of study group and time of assessment within general linear models using Generalized Estimating Equations (GEE) to account for the lack of independence of observations (repeated assessments). Given a statistically significant interaction effect, contrast terms (representing both between groups and time-related contrasts) were used to determine how the response curves differed between the groups. A Bonferroni-corrected alpha value was used for interpreting these post-hoc contrasts. Otherwise an alpha of 0.05 ($p < 0.05$) was used for determining statistical significance.

Results

Sample characteristics

Eighty-six individuals were screened for the study, 50 individuals enrolled and were randomized. All participants randomized to the intervention group scored $\geq 90\%$ on their observed self-measurement in the laboratory and received a device. A final sample of 39 completed the study with seven withdrawals from the intervention group and three withdrawals from the control group (Fig. 1). Compared to those who completed the study ($N = 39$), those who withdrew ($n = 10$) or did not complete the final set of assessments ($n = 1$) were closer to their last chemotherapy treatment (median = 0.8 years, min = 1, max = 7 vs. median = 5.3 years, min = 1, max = 18; $p = 0.024$), more recently diagnosed with lymphedema (median = 1.2 years, min = 0, max = 8 vs. median = 5.4 years, min = 0, max = 16; $p = 0.040$), reported fewer days per week of keeping skin clean (< 7 days per week: 2 of 11, 18.2% vs. 0 of 39, 0.0%, $p = 0.007$), lower scores on the ULL-27 (median = 74.1, min = 67, max = 80 vs. median = 86.7, min = 39, max = 99; $p = 0.002$), and greater symptom intensity and distress (medians = 1.2 and 1.2, min = 0 and 0, max = 3 and 2 vs. medians = 0.8 and 0.7, min = 0 and 0, max = 4 and 3; $p = 0.021$ and 0.028).

Demographic characteristics of the 39 participants who completed the study are summarized in Table 1. There were no statistically significant differences between the groups in terms of those characteristics. Nor were there demographic differences in those who withdrew and those who remained in the study.

Adverse events

No adverse events related to the study were noted. No referrals for lymphedema treatment were indicated at the time of the monthly reviews of the self-report data and measurement logs.

Aim 1

Summaries of self-care activities at baseline, week 12, and week 16 are shown in Table 2. We hypothesized that compared to participants who are not self-monitoring, those who self-monitor limb volume would report more days of garment use, skin care, and simple-MLD. Our hypothesis was partially supported. Statistically significant ($p = 0.005$) differences in patterns of change were noted in garment usage in favor of the intervention group during the 3 months of self-monitoring. Median days of garment use improved from 2.5 days to 4 days during the 3 months of monitoring and maintained at approximately this level during the 30-day post self-monitoring period (Fig. 2). Statistically significant ($p = 0.004$) differences in patterns of change were also noted in self-MLD in favor of the intervention group during the 3 months of self-monitoring (Table 2). Median days of self-MLD changed from 0 to 1 during the week. This dropped back to baseline levels during the 30-day post self-monitoring period (Fig. 3). No statistically significant group differences were noted in time spent per day doing self-care and number of days of skin care. In the group that received the devices, there were no statistically significant changes in L-Dex values over the course of the study; thus, arm volume remained stable in the intervention group.

Aim 2

We hypothesized that when compared to participants who are not self-monitoring, participants who self-monitor limb volume would have fewer, less distressful, less intense symptoms; better productivity/activity; report higher perceived self-management/self-efficacy and QOL; experience fewer missed days of work, lymphedema treatment days, arm infections; and have a smaller number of antibiotic prescriptions. The overall number of reported symptoms and levels of intensity and distress from symptoms of lymphedema in this study were quite low. As such, there were no statistically significant differences between the groups in the patterns of change in those measures over the course of the study ($p > 0.05$).

Of the cases with baseline and end-of-study employment information, 64.7% (22 of 34) were employed at the time of the study (Intervention: 12 of 17, 70.6%; Control: 10 of 17, 58.8%; $p = 0.473$). No statistically significant group differences or

Table 1. Sample Demographic Characteristics

	Total N = 39 N (%)	*Intervention N = 18* N (%)	*Control N = 21* N (%)	P *value (Likelihood Ratio)*
Race				0.247
White	28 (71.8)	13 (72.2)	15 (71.4)	
African American	9 (23.1)	5 (27.8)	4 (19.0)	
Asian	2 (5.1)	0 (0.0)	2 (9.5)	
Nation of origin				0.262
USA	38 (97.4)	18 (100.0)	20 (95.2)	
Bangladesh	1 (2.6)	0 (0.0)	1 (4.8)	
Marital status				0.963
Married	22 (56.4)	11 (61.1)	11 (52.4)	
Single	11 (28.2)	4 (22.2)	7 (33.3)	
Single, living with partner	2 (5.1)	1 (5.6)	1 (4.8)	
Other	2 (5.1)	1 (5.6)	1 (4.8)	
Widowed	2 (5.1)	1 (5.6)	1 (4.8)	
Employment status				0.263
Employed	26 (66.7)	14 (77.8)	12 (57.1)	
Unemployed	12 (30.8)	4 (22.2)	8 (38.1)	
Other	1 (2.6)	0 (0.0)	1 (4.8)	
Area of residence				0.182
City	29 (76.3)	15 (83.3)	14 (70.0)	
Country	8 (21.1)	2 (11.1)	6 (30.0)	
Other	1 (2.6)	1 (5.6)	0 (0.0)	
Insurance coverage (Primary)				0.076
Private insurance	29 (74.4)	16 (88.9)	13 (61.9)	
Government	8 (20.5)	1 (5.6)	7 (33.3)	
Other	2 (5.1)	1 (5.6)	1 (4.8)	
Insurance coverage (Secondary)	N = 6	N = 2	N = 4	0.105
Annual household income				0.364
≤ 30,000	5 (12.8)	2 (11.1)	3 (14.3)	
30,001–50,000	14 (35.9)	5 (27.8)	9 (42.9)	
Over 50,000	16 (41.0)	10 (55.6)	6 (28.6)	
Do not care to respond	4 (10.3)	1 (5.6)	3 (14.3)	
	Mean (SD)	Mean (SD)	Mean (SD)	
Age	58.2 (8.4)	56.4 (6.2)	59.8 (9.7)	0.207
Highest grade completed	14.8 (2.0)	15.3 (1.9)	14.3 (1.9)	0.095

Table 2. Summaries of Self-care Activities

	Overall Median [IQR] (Min,Max)	*Intervention Median [IQR] (Min,Max)*	*Control Median [IQR] (Min,Max)*
Minutes each day taking care of lymphedema	*N* = 38	*n* = 18	*n* = 20
Baseline	30.0 [10,34] (3,180)	17.5 [5,34] (3,60)	30.0 [10,42] (5,180)
Week 12 (*N* = 37)*	25.0 [11,40] (0,180)	15.0 [7,38] (0,128)	30.0 [16,44] (4,180)
Week 16	25.0 [10,45] (0,120)	15.0 [5,34] (0,76)	30.0 [15,57] (3,120)
Days per week using some type of compression garment	*N* = 39	*n* = 18	*n* = 21
Baseline	3.0 [0,7] (0,7)	2.5 [0,5] (0,7)	5.0 [0,7] (0,7)
Week 12 (*N* = 37)*	4.0 [0,7] (0,7)	4.0 [0,7] (0,7)	2.5 [0,7] (0,7)
Week 16 (*N* = 38)**	3.0 [0,7] (0,7)	3.5 [0,7] (0,7)	0.0 [0,7] (0,7)
Days per week performing Simple MLD			
Baseline	1.0 [0,5] (0,7)	0.0 [0,4] (0,7)	2.0 [0,7] (0,7)
Week 12 (*N* = 37)*	0.0 [0,5] (0,7)	1.0 [0,5] (0,7)	0.0 [0,6] (0,7)
Week 16 (*N* = 38)**	0.0 [0,5] (0,7)	0.0 [0,5] (0,6)	0.0 [0,7] (0,7)
Days per week performing skin care			
Baseline	7.0 [7,7] (2,7)	7.0 [7,7] (2,7)	7.0 [7,7] (7,7)
Week 12 (*N* = 37)*	7.0 [7,7] (3,7)	7.0 [7,7] (3,7)	7.0 [7,7] (4,7)
Week 16 (*N* = 38)**	7.0 [7,7] (0,7)	7.0 [7,7] (0,7)	7.0 [7,7] (5,7)

*Intervention *n* = 17, Control *n* = 20; **Control *n* = 20.

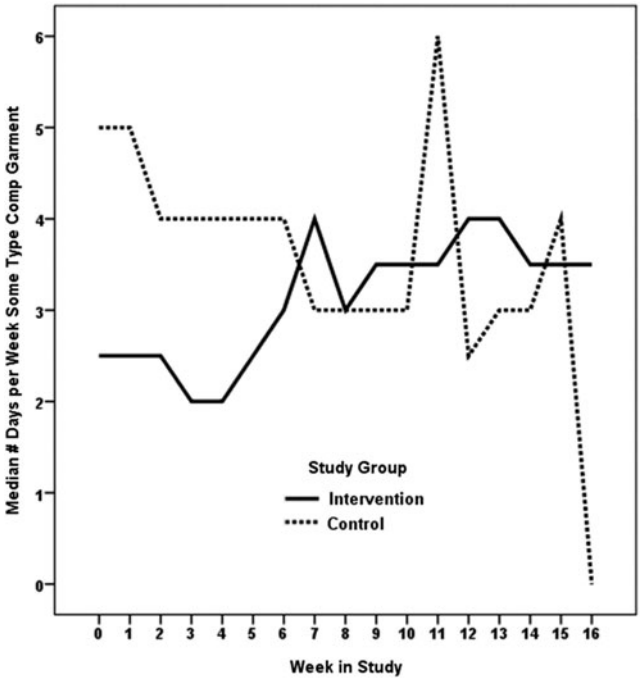

FIG. 2. Compression garment. Wald $X^2_{(df=16)} = 34.37$, $p = 0.005$.

differences between the groups in patterns of change over time were identified in the impact of health on work or non-work activities.

As shown in Table 3, perceived self-management and QOL scores were quite high for participants in this study. There were no statistically significant modifications in those scores throughout the course of the study. Nor were statistically significant differences noted in resource utilization, number of treatment days, number of arm infections, and number of antibiotic prescriptions, all of which were very low (Table 4). No reports of health expenditures related to lymphedema were noted.

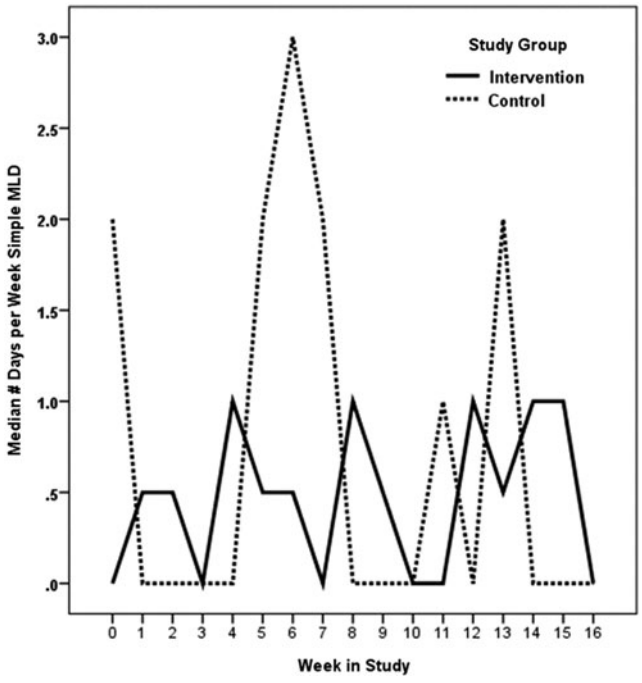

FIG. 3. Self-manual lymphatic drainage. Wald $X^2_{(df=16)} = 35.21$, $p = 0.004$.

Discussion

This is the first known study to test the self-monitoring of lymphedema in the home setting using BIS. As this was a pilot study, findings should be considered in light of its limitations, which include a small sample size, limitation of self-measurement to 3 months, only a 30 day follow-up period, and no end of study BIS measurements for those in the control group. Despite these limitations, several valuable findings were generated.

Self-monitoring with BIS appears to be feasible, as patients willingly monitored their arms as directed and reported no problems with the equipment. There were no noted differences between those who withdrew from the intervention vs. the control groups in terms of demographic characteristics. The device was durable, as there was no equipment failure during the study. Most participants in the intervention expressed a desire to have the device available to them for home use on a consistent basis.

In terms of self-care activities, almost all participants were conducting skin care 7 days a week at baseline and throughout the study. This likely accounts for the lack of change noted in this self-care activity and also suggests that patients are more adherent to skin care than other, more difficult to complete components of Phase 2 CDT, such as self-MLD and donning of compression garments. Improvement in garment use and self-MLD in the intervention group suggests that, as Self-Regulation Theory would support, objective monitoring of lymphedema may enable patients to determine the effectiveness of self-care, set self-care goals, and provide reinforcement for continuation of self-care.[22] Given the findings that there were no statistically significant changes in L-Dex values over the course of the study in the group that received the devices, it is possible that self-monitoring and/or the improvement in self-MLD and compression garment may assist patients in maintaining a stable volume level.

There are some possible explanations for the lack of improvement in several health outcomes, despite statistically significant improvement in self-care. First and foremost, this pilot study was underpowered to detect significant differences in many health outcomes that were examined; however, participants did complete 100% of the outcome measures, establishing that is it feasible to follow such outcomes. Therefore, findings from this study can be used to power larger future studies that evaluate these outcomes. Second, it is possible that the self-care dose (increased garment use and increased self-MLD), despite some improvement, may not have been high enough to facilitate more outcome improvement. Third, a longer observation and follow-up period may be needed. Finally, those who withdrew had significantly poorer reported QOL and a more severe symptom profile compared to those who remained in the study. Thus, those with the greatest room for improvement are not accounted for in these findings. An additional intervention component such as motivational training or coaching, coupled with self-monitoring, may be needed to increase the self-care dose to a level that a broader

Table 3. Perceived Medical Condition Self-Management Scale and Upper Limb Lymphedema

	Overall *Median [IQR] (Min,Max)*	*Intervention* *Median [IQR] (Min,Max)*	*Control* *Median [IQR] (Min,Max)*
PMCSMS Total Score	*N* = 35	*N* = 16	*N* = 19
Baseline	32.0 [28,39] (8,40)	33.0 [29,38] (8,40)	32.0 [25,40] (8,40)
Month 3	32.0 [24,39] (8,40)	32.0 [26,39] (8,40)	32.0 [24,39] (12,40)
Month 4	33.0 [25,38] (12,40)	35.0 [24,38] (16,40)	31.0 [25,40] (12,40)
ULL-27 Overall Score	*N* = 22	*N* = 11	*N* = 11
Baseline	86.3 [81,93] (39,99)	84.4 [82,93] (65,94)	87.4 [77,95] (39,99)
Month 3 (*N* = 19)*	88.2 [83,92] (45,99)	87.4 [80,92] (68,96)	88.5 [74,95] (45,99)
Month 4	87.0 [80,93] (44,100)	86.7 [83,92] (60,94)	90.4 [71,95] (44,100)
ULL-27 Physical	N = 26	*N* = 11	*N* = 15
Baseline	89.3 [85,95] (25,100)	89.3 [86,96] (67,100)	89.3 [80,95] (25,99)
Month 3 (*N* = 23)**	93.3 [82,98] (44,100)	96.0 [86,98] (75,99)	90.0 [82,97] (44,100)
Month 4	92.0 [85,98] (37,100)	90.7 [86,96] (77,100)	92.0 [92,98] (37,100)
ULL-27 Psychological	*N* = 35	*N* = 17	*N* = 18
Baseline	82.9 [71,92] (34,100)	82.9 [71,89] (37,100)	84.3 [68,92] (34,100)
Month 3 (*N* = 34)***	80.0 [70,92] (40,100)	80.0 [71,92] (43,97)	77.1 [70,93] (40,100)
Month 4	80.0 [68,86] (31,100)	80.0 [68,85] (31,100)	78.6 [67,92] (34,100)
ULL-27 Social	*N* = 33	*N* = 16	*N* = 17
Baseline	92.0 [82,100] (48,100)	90.0 [72,99] (56,100)	96.0 [84,100] (48,100)
Month 3 (*N* = 32)****	88.0 [73,99] (32,100)	90.0 [72,92] (52,100)	88.0 [81,100] (32,100)
Month 4	88.0 [76,98] (44,100)	80.0 [73,96] (48,100)	92.0 [82,100] (44,100)

*Intervention *n* = 9, Control *n* = 10; **Intervention *n* = 9, Control *n* = 14; ***Control *n* = 17; ****Control *n* = 16.

clinical relevance is established in those with poor QOL and high symptom burden.

There was little utilization of healthcare resources by either group during the course of this study for either an acute issue, such as cellulitis, or lymphedema therapy by a healthcare professional. It is possible that by asking for participants to report healthcare utilization in the past week only instead of from the time of the last assessment, all utilization patterns may not have been captured. In addition, items included in the RUEBQ may not have accounted for all categories of actual lymphedema-related health care expense; however, the lack of change in work productivity supports that participants in this study as a group did not experience health issues that lead to missed work or extensive medical care.

These findings taken together support that a longer observation and follow-up period may be needed, but this was prohibited due to the pilot nature of the study. A 12-month monitoring period should be considered in future self-monitoring studies, as this would account for potential seasonal variation in lymphedema volume and associated symptoms. Findings from this study support a larger BIS trial

Table 4. Resource Utilization

	Overall *Median [IQR] (Min,Max)*	*Intervention* *Median [IQR] (Min,Max)*	*Control* *Median [IQR] (Min,Max)*
Office visits or hospital admissions	*N* = 37	*N* = 17	*N* = 20
Baseline	0 [0,20] (0,125)	0 [0,20] (0,125)	0 [0,17.5] (0,93)
% no medical care in the past week	68%	65%	70%
Week 12 (N = 36)*	0 [0,20] (0,500)	0 [0,22.5] (0,400)	0 [0,10] (0,500)
% no medical care in the past week	72%	69%	75%
Week 16 (N = 36)**	0 [0,0] (0,2200)	0 [0,0] (0, 85)	0 [0,15] (0, 2200)
% no medical care in the past week	78%	82%	74%
Supplies	*N* = 36	*N* = 18	*N* = 18
Baseline	0 [0,4.5] (0,20)	0 [0,0] (0,20)	0 [0, 5] (0,20)
% no expenses related to medical supplies in the past week	69%	78%	61%
Week 12 (*N* = 35)***	0 [0,7] (0,7000)	0 [0,8] (0,150)	0 [0,4.5] (0,7000)
% no expenses related to medical supplies in the past week	69%	67%	70%
Week 16 (*N* = 37)**	0 [0,0] (0,291)	0 [0,0] (0,291)	0 [0,0] (0, 65)
% no expenses related to medical supplies in the past week	84%	88%	80%

*Intervention *n* = 16, Control *n* = 20; **Intervention *n* = 17, Control *n* = 19; *** Intervention *n* = 15, Control *n* = 20; **** Intervention *n* = 17, Control *n* = 20.

with longer follow-up periods and that compare this method to other self-measurement options.

There are other potential implications from this study beyond those for self-monitoring alone. For example, participants in lymphedema intervention trials could be given devices to self-measure changes in limb status at home over time. This would reduce the need for and cost of researchers to travel to homes to conduct measurements, or, alternatively, for research participants to come to laboratories or clinics for measurements. Additionally, prospective self-monitoring with these devices for breast cancer survivors who are at high risk for lymphedema, such as those with elevated BMI, postoperative wound infections, and axillary dissection, is clearly possible.[28,29] This is critical given findings that early intervention can potentially prevent subclinical swelling from progressing to chronic swelling, and that early identified clinical swelling treated with compression alone produces clinically significant results.[30,31] Such prospective use could lead to early detection of swelling and trigger immediate interventions that could lead to better patient outcomes and less intensive treatment for those developing chronic lymphedema. Theoretically, this could reduce the overall cost of lymphedema after breast cancer treatment to patients and society.

Conclusions

Objective self-monitoring of arms using BIS is possible. Self-monitoring appears to positively impact lymphedema self-care behaviors. However, self-monitoring alone may not be sufficient to promote high levels of self-care activities in highly symptomatic patients, such as those who withdrew from the study and who may require coaching or other forms of psychological support to improve their self-care. Studies that combine a cognitive behavioral therapy component along with self-measurement should be considered as potential interventions to impact lymphedema self-care. Additionally, further studies exploring other potential applications of self-monitoring are indicated.

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