

A 10 MINUTE SELF-CARE PROGRAM MAY REDUCE BREAST CANCER-RELATED LYMPHEDEMA: A SIX-MONTH PROSPECTIVE LONGITUDINAL COMPARATIVE STUDY

Y. Arinaga, F. Sato, N. Piller, T. Kakamu, K. Kikuchi, T. Ohtake,
A. Sakuyama, F. Yotsumoto, T. Hori, N. Sato

Department of Nursing (YA), Nagasaki University School of Biomedical Sciences, Nagasaki, Japan; Division of Oncology, Department of Nursing (FS,NS), and Department of Dermatology (KK), Tohoku University Graduate School of Medicine, Sendai, Japan; Department of Surgery (NP), Flinders University School of Medicine, Adelaide, Australia; Department of Hygiene & Preventive Medicine (TK) and Division of Breast Surgery, Department of Surgery (TO), Fukushima Medical University, Fukushima, Japan; Kato Breast Surgery Clinic (AS), Kusatsu, Japan; Departments of Surgery (FY) and Palliative Medicine (TH), Shiga Medical Centre for Adults, Moriyama, Japan

ABSTRACT

Patients with breast cancer-related lymphedema (BCRL) need a life-long self-care program that they can adhere to enable them to manage their lymphedema. The objective of this study was to assess the effectiveness of a holistic BCRL self-care program that patients could easily adhere to and comply with. A prospective, longitudinal, comparative study between affected arms and unaffected arms in unilateral breast cancer patients was implemented over a six-month period. Both the lymphedematous and unaffected arms of 23 patients with unilateral BCRL were followed and measured. The daily 10-minute holistic BCRL self-care program consisted of modified Japanese raijo taiso (Japanese radio calisthenics), a gentle arm exercise combined with deep breathing, skin moisturizing care using a traditional lymphatic drainage technique, and basic self-care education. Arm and edema volume, relative volume change, resistance of the skin to compression (fibrosis), lymphedema-related symptoms, skin condition, and self-care were assessed. At the end of

six-months the volume of all limb segments and resistance of the tissues to compression at all measurement points of the affected arm were significantly reduced. On the unaffected side, only the volume of the forearm and the whole arm was significantly reduced and fibrosis significantly reduced only in the forearm. There was no significant difference in edema volume and relative volume change. Lymphedema-related symptoms significantly improved. Perceived adherence, effectiveness, burden, score and average time for self-care significantly increased. Our results demonstrate that this 10-minute self-care program may improve BCRL and its self-care.

Keywords: Breast cancer, lymphedema, self-care, exercise, skin care, *raijo taiso*, aromatherapy, arm volume, nursing

To prevent onset or worsening of BCRL, life-long self-care is necessary for patients at risk. In Japan, patients are taught self-care based on phase 2 complex decongestive therapy (CDT) including skin care, full-body exercise, compression, and self-lymphatic

drainage (SLD), which is likely to effectively control lymphedema (1). They are also generally taught to perform SLD without the use of cream or oil, although previous studies have suggested that lymphatic drainage with cream or aroma oil can reduce limb volume (2,3). Apart from SLD, patients are also required to apply skin moisturizer. SLD itself is a complicated technique and takes more than 20 min per day (4). Maintaining healthy skin is crucial for these patients as many suffer from skin problems (5) including dry skin, fibrosis, wounds, and cellulitis.

In Japan, 20.6% of patients with lymphedema experience cellulitis, and 53.3% have recurrences (6). This is a slightly higher incidence of cellulitis compared to other countries (7,8), which suggests that skin care is not well practiced in Japan (9). Although exercise programs for lymphedema have become more common in recent times, patients still tend to keep their arms immobile because they find it the most comfortable option (10) and there is a lack of detailed clear information and instruction. This further highlights the need for proper education in exercise training.

Generally, adherence to self-care may not always be optimal (11), and the actual amount of self-care performed is unknown (1). In fact, most patients tend to not take any preventative action against lymphedema (12,13). The non-adherence to self-care may be due to the time-consuming factor of the current self-care practice (4)), and it causes skin problems such as dry skin, fibrosis, inflammation and infections. Sherman and Koelmeyer suggests that greater belief in lymphedema controllability, self-efficacy, perceived consequences, and perceived self-regulatory ability may improve patients' adherence to lymphedema risk management (14,15). In doing this, it is important that patients are not overwhelmed by the self-care practice prior to the start of any program or course.

The objective of this study was to develop a safe, simple, effective, and feasible BCRL self-care program that is likely to have a high

compliance and to assess the effectiveness of this program over a six-month period.

We, therefore, developed a 10-min holistic BCRL self-care program that is simple and feasible for BCRL patients. The evaluation of this program after three months was described previously and results showed effectiveness in controlling BCRL over the short time period (16). In that study, significant difference was shown in the whole arm, upper arm, forearm in only affected side, but not in unaffected side over time in 3 months with ANOVA. Fibrosis was also significantly reduced in forearm and breast in the affected side, but also in unaffected forearm. In addition, BMI, symptoms such as arm discomfort, numbness, sensory alternation, swelling, heaviness, and skin condition were significantly reduced during the study even though it was a short period. We undertook further analysis to extend the evaluation of the effectiveness of the program on BCRL after six months.

METHODS

Study Design

The development of the 10 min holistic self-care program for BCRL patients (BCRL self-care program) and its evaluation of short term effectiveness after a week, 1 month and 3 months has previously been published (16). This study extends the results to 6 months for a more realistic and better follow up. The program consisted of 1) Japanese *rajio taiso* (17), a national health exercise developed by Japan Post Insurance Co., Ltd., which is broadcast on TV and radio several times a day by the Japan Broadcasting Corporation, 2) gentle arm exercises combined with deep breathing (18), 3) skin moisturizing care with grapefruit essential oil and sweet almond massage oil using a traditional lymphatic drainage technique (aromatherapy drainage), and 4) 1 min of central lymphatic drainage around the subclavian vein before aromatherapy drainage.

The prospective longitudinal comparative

study between affected arms and unaffected arms in unilateral breast cancer patients was implemented from May 2012 to February 2014.

This study (UMIN000007616) was approved by the Ethics Committee of Tohoku University Hospital, Fukushima Medical University, and other participating hospitals.

Participants

Patients were recruited from four institutions in the Kansai and Tohoku regions of Japan. Based on results from a prior study on yoga (19) and since there was only one similar existing study protocol available when we started, we estimated that 13-19 participants with alpha at 0.05 and power at 80% were adequate for this study. However, we considered up to a 30% attrition rate and decided to recruit 25 patients.

Eligibility criteria included: age over 20 years; at least grade 1 unilateral breast cancer treatment-related lymphedema assessed by Common Terminology Criteria for Adverse Events (CTCAE) v4.0 (20); six months since active treatment; ECOG PS0-2; and able to respond to questionnaires and perform self-care. Patients with acute inflammation on the affected arm, cancer recurrence, an allergy to aromatherapy, atopic dermatitis, and pregnant or attempting conception were excluded.

Intervention

We introduced the holistic BCRL self-care program consisting of Japanese *rajio taiso* (17), a gentle arm exercise combined with deep breathing (18), central lymphatic drainage around the subclavian vein, and skin-moisturizing care using SLD techniques with a 0.5% grapefruit oil and sweet almond massage oil, which we called aromatherapy drainage. This was also part of the basic self-care education for the patient.

Rajio taiso is an aerobic rhythmic exercise that uses muscles throughout the body and stimulates blood circulation and flexibility. The Japanese often practice this

three min exercise at schools or offices as a warm-up for sports or at work to prevent injury. In our study, patients were told to practice each movement at half the speed of the original movements to avoid centrifugal force. These movements should allow fluid from the limbs to flow into the central region.

A gentle arm exercise combined with deep breathing (18), central lymphatic drainage, and aromatherapy drainage were respectively scheduled before, during, and immediately after bathing to make this program a habit in daily life.

Central lymphatic drainage is used for clearing the fluid from around the shoulder or upper body. Lymphatic drainage is slow, with associated lymphangion contraction rates of 6-10 beats per minute. To reduce the risk of complication, we simplified the technique to very slowly stroking each area once toward the thoracic duct. In aromatherapy drainage, grapefruit essential oil was used as the smell was preferred by Japanese and effectiveness for edema was expected (21,22). Grapefruit oil was diluted to 0.5% in sweet almond oil to minimize the risk of skin reaction. At the initial meeting, we applied massage oil on the patient's arms and observed the skin for allergic reactions. The massage oil was applied simultaneously with lymphatic drainage. The drainage technique was also simplified, stroking the shoulder toward the thoracic duct first, then the upper arm toward the shoulder, followed by the forearm toward the upper arm, and finally the hand toward the thoracic duct. The investigator then gave the feedback of the measurement with advice on risk minimization for each patient. In addition, a follow-up was also conducted by phone at one week, two months, four months, and five months to check for adverse effects or if any difficulty was experienced using the program. The patients participated in this self-care program for a period of six months. Measurements as indicated in the next section were taken at baseline, one month, three months, and six months.

Measurements

Arm volume

We measured forearm and upper arm volume using Taylor's method (23) and hand volume by water displacement. Together, these combined for total arm volume. Taylor's method was used to calculate the volume from a circumferential measurement around anatomic landmarks. The mid-ulnar styloid, the olecranon, and the 50% point between them make up the volume of the forearm. The olecranon, the acromion, and the 50% and 65% points make up the volume of the upper arm. The circumferences were measured by weighted tape measure. The arm volume was calculated using the software 'upper arm lymphedema follow-up system' (IGM Co., Ltd, Tokyo, Japan).

Edema volume

The segment and whole limb volume difference between both arms was used to give an estimate of the edema volume.

Relative Volume Change (RVC) (24)

As Japanese women tend to have smaller arm volume (25), it is difficult to detect larger amounts of edema volume such as 200 ml in the international standard. However, RVC can detect smaller changes in the affected arms from the baseline. RVC is calculated by the formula:

$$\left\{ \frac{(\text{Affected arm volume after intervention}) - (\text{Unaffected arm volume before intervention})}{(\text{Unaffected arm volume after intervention}) - (\text{Affected arm volume before intervention})} \right\} - 1$$

Resistance of the skin to compression (fibrosis)

The degree of fibrosis on the forearm, upper arm, and breast were measured using a pressure measuring device (Tonometer; Biomedical Engineering, Flinders Medical Centre, Adelaide, Australia) (26). Higher

numbers might indicate a higher degree of fibrosis.

Lymphedema-related symptoms

The symptom score items were produced using the lymphedema quality of life tool (LYMQOL) (27), upper limb lymphedema 27 questionnaire (ULL-27) (28), and advice from professionals and researchers after face validity was examined by breast cancer specialists, dermatologists, and breast cancer researchers. Arm discomfort, numbness, sensory alternation, pain, pins and needles, tiredness, swelling, heaviness, tightness, and feeling hot were self-reported by a seven-point (-3 to 3) semantic differential (SD) scale. Higher scores indicate worse symptoms. In the case that the affected and unaffected arms were the same, a score of 0 was given. If the affected arm was worse, a score of 1-3 was given. If the affected arm was better, a score of -1 to -3 was given.

Skin condition

A self-rated score on the SD scale (-3 to 3 points) was also given for comparing the skin condition of both arms as well as lymphedema-related symptoms.

Difficulty in activity of daily living (ADL), social activity, and psychological activity

A self-reported 0-4-point SD scale was used. A score of 0 indicated 'no difficulty', whereas 4 indicated 'quite difficult'. A higher score indicates more difficulty.

Self-care

Perceived adherence for self-care (0-4 points), effectiveness for self-care (0-4 points), and burden for self-care (0-4 points) using the SD score and the average time spent on daily lymphedema self-care were self-reported.

Patients completed a 14-item self-care checklist, examining common lymphedema

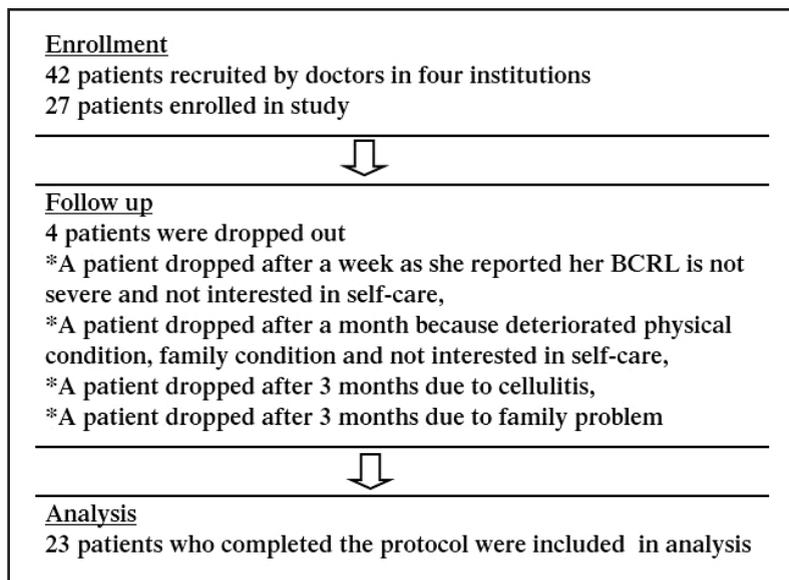


Fig 1. Participant flow during study

risk minimization strategies on a weekly basis with a free response section in which they could comment on their lymphedema and self-care. The self-care score was an overall total of the points from the checklist (0-14 points).

Demographic and clinical data at baseline

Age, BMI, type of surgery, months since surgery, type of adjuvant therapy, months since lymphedema was perceived, CTCAE grade in the edema limb (20), history of cellulitis, current lymphedema treatment, and history of self-care education were included in the demographic and clinical data at baseline.

Statistical analyses

Patients who completed the six-month program were included in the analysis. All analyses were conducted using analytical software (IBM SPSS Statistics 21.0; IBM, USA 2012).

Descriptive statistics for demographic and clinical data at baseline variables included counts and percentages for binary variables and medians and ranges of 25% and 75% quartiles for continuous variables.

Baseline arm volume between the arms was assessed using the Mann-Whitney U test. The Wilcoxon signed-rank test compared to baseline data was applied for change between two time points, before intervention and after 6 months. All p values were two sided with the level of significance set to 0.05. Effect size $>.50$ indicated large, $>.30$ indicated medium, and $<.30$ indicated a small effect size using the formula $(r)=|Z|/\sqrt{N}$.

RESULTS

Demographic and Clinical Data at Baseline

From the 42 patients who registered, 27 participated, with four dropping out during the study (Fig. 1). A total of 23 patients were included in the final assessment of this study. Reasons for patient dropout were listed in Fig. 1.

TABLE 1
Demographic and Clinical Characteristics at Baseline

	N=23				
	Median	min	max	n	%
Age	61	29	71		
BMI	23.1	19.3	31.1		
Type of surgery					
Breast conserving therapy				15	65.2
Mastectomy				8	34.8
Axillary lymph nodes dissection				19	82.6
Sentinel lymph node biopsy				4	17.4
Months since surgery	49	12	144		
Type of adjuvant therapy					
Chemotherapy				18	78.3
Radiation therapy				20	87.0
Target therapy				3	13.0
Endocrinotherapy				14	60.9
Months since onset of BCRL	17.00	1	132		
CTCAE (Edema limbs)					
Grade 1				14	60.9
Grade 2				9	39.1
Grade 3				0	0.0
Edema Volume (%)					
Hand	0.00	-7.8	24.3		
Forearm	3.60	-11.90	30.30		
Upper arm	3.20	-15.30	20.10		
Upper limb	3.50	-11.90	21.80		
History of cellulitis					
0				21	91.3
>3				2	8.7
History of self-care education				15	65.2
Self-care practice					
Avoidance of pressure				22	95.7
Referral to professional if needed				20	87.0
Avoidance of injury				19	82.6
Hygiene				19	82.6
Avoidance of heavy lifting				18	78.3
Sunscreen				17	73.9
Maintaining weight				17	73.9
Arm elevation				15	65.2
Avoidance of temperature extremes				14	60.9
Monitoring skin condition				13	56.5
Proper use of compression as needed				13	56.5
Self-lymphatic drainage				9	39.1
Skin moisturizing care				8	34.8
Exercise				8	34.8
Self-care Score (0-14 points)	11.00	1.0	14.0		
Average time for daily self-care (minutes)	3.00	0.0	40.0		
Perceived adherence for self-care	1.00	0.0	4.0		
Perceived effectiveness for self-care	1.00	0.0	4.0		
Perceived burden for self-care	0.00	0.0	2.0		

Demographic and clinical data at baseline variables included counts and percentages for binary variables and medians, and ranges for continuous variables.

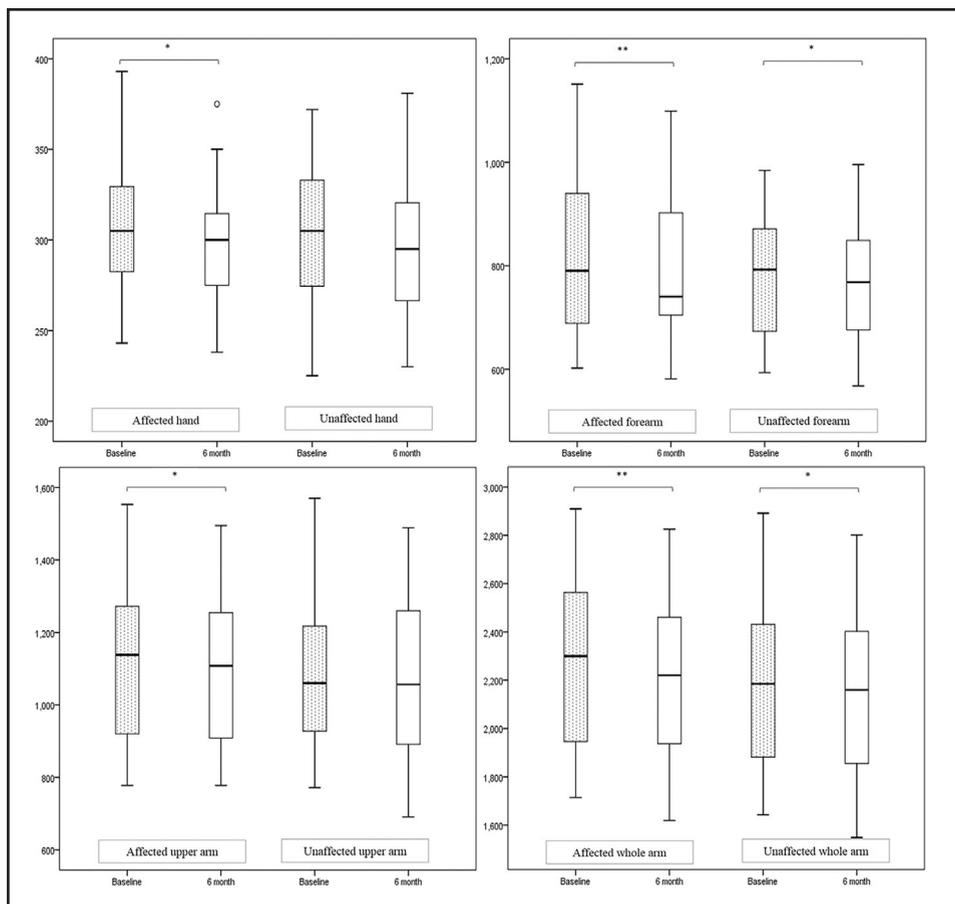


Fig 2. Change in affected and unaffected arm volume. Wilcoxon signed rank test compared to baseline data. All p values are two sided; the level of significance was set to 0.05. * $p \leq 0.05$ ** $p \leq 0.01$

Table 1 displays demographic and clinical characteristics at baseline. Most patients were CTCAE grade 1 (60.9%) or 2 (39.1%). Fourteen patients had a whole arm edema volume less than 5%. They were classified as grade 1 as a result of anatomical changes between arms and complaints from the patients. Two patients (8.7%) had cellulitis on more than three occasions. 65.2% answered they received self-care education before. The lowest compliances in the self-care program were SLD (39.1%), skin care (34.8%), and exercise (34.8%). The time for self-care ranged from 0-40 min (median of 3 min), with 34.8% reporting that they had no time for self-care, and 78.3% spending less than 10 min.

Effectiveness of the Holistic BCRL Self-care Program

The distribution between arm volumes showed no significant difference at baseline. The change in arm volume, determined as the primary outcome, is shown in Fig. 2. After six months, a significant volume reduction was observed in the affected hands ($p = 0.04$, $r = .43$), forearms ($p = 0.01$, $r = .57$), upper arms ($p = 0.02$, $r = .47$), and whole arms ($p = 0.01$, $r = .55$), with medium to large-effect sizes. Unaffected forearms ($p = 0.03$, $r = .45$) and whole arms ($p = 0.03$, $r = .44$) also showed a significant volume reduction, and the effect sizes of both were medium.

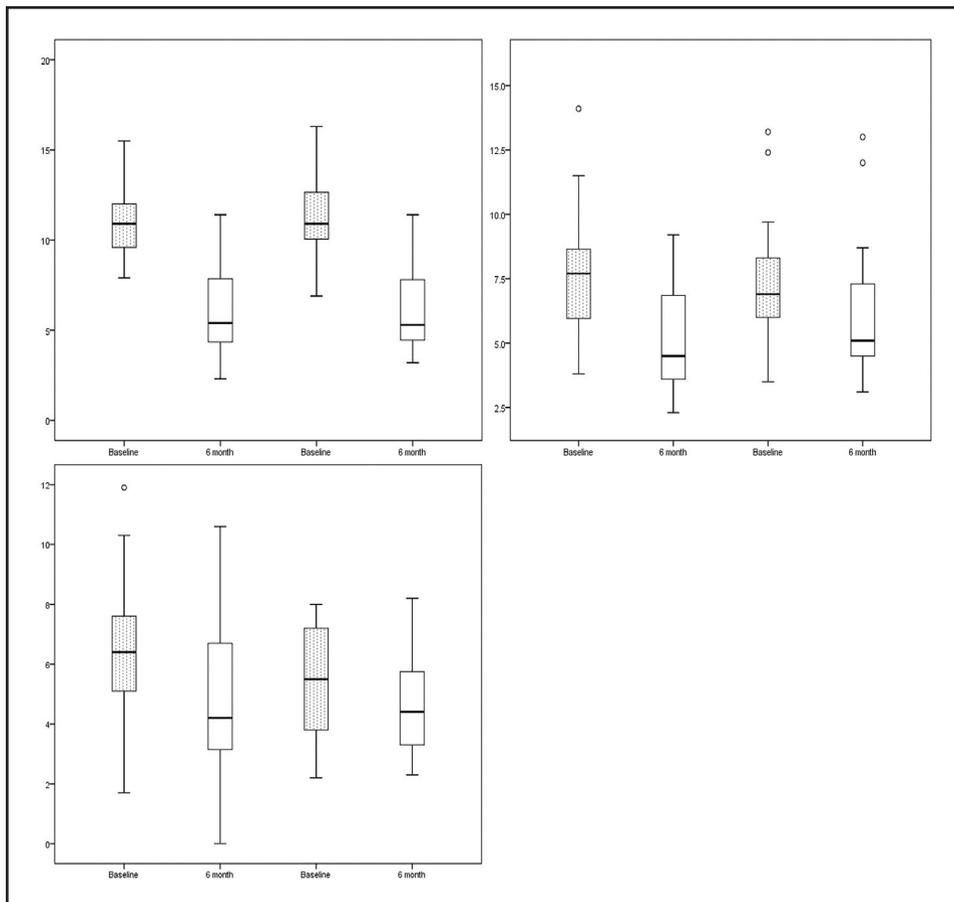


Fig 3. Resistance of the skin to compression (fibrosis). Wilcoxon signed rank test compared to baseline data. All *p* values are two sided; the level of significance was set to 0.05. * $p \leq 0.05$ ** $p \leq 0.01$

Resistance of the skin to compression (Fig. 3) significantly declined in both forearms. All measured areas in the affected side significantly declined.

Although the median of forearm, upper arm, and whole arm in relative edema volume and hand, forearm, upper arm, and whole arm in RVC were reduced after 6 months, there was no significant difference between the baseline and the endpoint (Table 2). A significant decline in BMI was seen at the three-month follow-up (16) but not at six months. With lymphedema-related symptoms (Table 3), discomfort ($p = 0.00$, $r = .62$), sensory alteration ($p = 0.02$, $r = .45$), swelling ($p = 0.02$, $r = .51$), and heaviness

($p = 0.05$, $r = .42$) showed significant improvement after six months. There was no significant difference in skin condition.

Difficulty in ADL, social activity, and psychological activity did not change. There were significant increments in perceived adherence, perceived effectiveness and perceived burden for self-care, self-care score and self-care time (Table 4). Skin reaction to massage oil occurred in three patients after the second or later use. Two patients felt skin irritation without redness, and one patient's skin showed mild redness. Application of massage oil was stopped and changed to moisturizer.

TABLE 2
Change in Relative Edema Volume (REV) and
Relative Volume Change (RVC)

						N=23	
		Median	Q1	Q3	<i>r value</i> ^{a)}	<i>p value</i> ^{b)}	
REV hand							
	Baseline	0.00	-3.30	7.10			
	6 months	1.40	-4.90	5.00	-0.26	0.223	
REV forearm							
	Baseline	3.60	-4.10	6.30			
	6 months	2.10	-4.30	13.30	-0.18	0.393	
REV upper arm							
	Baseline	3.20	-6.00	10.50			
	6 months	1.30	-9.30	8.70	-0.21	0.318	
REV whole arm							
	Baseline	3.50	-4.70	7.50			
	6 months	3.40	-5.40	4.90	-0.25	0.244	
RVC hand							
	Baseline	0.00	0.00	0.00			
	6 months	-1.90	-4.40	2.10	-0.22	0.301	
RVC forearm							
	Baseline	0.00	0.00	0.00			
	6 months	-1.10	-3.80	2.00	-0.19	0.381	
RVC upper arm							
	Baseline	0.00	0.00	0.00			
	6 months	-1.10	-4.00	2.40	-0.20	0.349	
RVC whole arm							
	Baseline	0.00	0.00	0.00			
	6 months	-0.60	-3.60	1.10	-0.25	0.25	

a) Effect size (r) = $|Z|/\sqrt{N}$
b) Wilcoxon signed rank test compared to baseline data. All p-values are two

DISCUSSION

The ideal study design is a randomized allocation of patients to each group with pair matching to reduce heterogeneity between groups. However, such matching of patients is difficult because there are too many variables affecting lymphedema including body composition (fat, muscle, and bone), arm volume, lifestyle, skin types, and a range of associated clinical conditions involving the cardiovascular system. Confounders as well as the Hawthorne effect could be avoided by using this study design. The difference of body composition between the affected and unaffected arm could be the extracellular fluid (ECF) / intracellular fluid (ICF) ratio. Thus, if only the affected arm volume was

reduced after six months, we could assume that it was excess fluid that was reduced. Furthermore, ignoring progressive lymphedema in the control group would become an ethical issue.

All segments of the affected arm volume declined significantly at the end of study. Unaffected arm volume also significantly decreased but only in the forearm and whole arm. The effect size was greater in the affected arm with significant reduction, suggesting improvement of lymphedema. As the difference between the arms was only lymphedema (fluid and fibrosis) and muscle and fats were likely to remain the same between both arms over this time period, it is assumed that the changes are due to fluid removal from the affected arm. This self-care

TABLE 3
Changes in Lymphedema-Related Symptoms and Skin Condition

		N=23				
		Median	Q1	Q3	r value ^{a)}	p value ^{b)}
Arm discomfort	Baseline	1.00	0.00	2.00		
	6 months	1.00	0.00	1.00	.62	.00**
Numbness	Baseline	0.00	0.00	1.00		
	6 months	0.00	0.00	1.00	.38	.10
Sensory alternation	Baseline	1.00	0.00	2.00		
	6 months	0.00	0.00	1.00	.45	.02*
Pain	Baseline	0.00	0.00	1.00		
	6 months	0.00	0.00	0.00	.21	.38
Pins & needles	Baseline	0.00	0.00	1.00		
	6 months	0.00	0.00	1.00	.00	1.00
Tiredness	Baseline	1.00	0.00	2.00		
	6 months	0.00	0.00	1.00	.33	.16
Swelling	Baseline	1.00	0.00	2.00		
	6 months	0.00	0.00	1.00	.51	.02*
Heaviness	Baseline	1.00	0.00	2.00		
	6 months	0.00	0.00	1.00	.42	.05*
Tightness	Baseline	0.00	0.00	1.00		
	6 months	0.00	0.00	1.00	.09	.73
Feeling of heat	Baseline	0.00	0.00	0.00		
	6 months	0.00	0.00	0.00	.00	1.00
Perceived skin condition	Baseline	0.00	0.00	1.00		
	6 months	0.00	0.00	0.00	.36	.13

a) Effect size(r)=|Z|/√ N|
b) Wilcoxon signed rank test compared to baseline data. All p-values are two sided; the level of significance was set to 0.05. * p≤0.05 ** p≤0.01

program may have increased muscle and reduced symptoms due to the removal of fluid earlier (16). An improved lymphatic system with muscle, increased external transport using exercise, deep breathing, and SLD may have stimulated the lymphatic drainage in the upper body. However, these hypotheses require further research using other reliable objective parameters such as ECF / ICF.

At baseline, the median value of resistance of the skin to compression was higher in the affected side. Reductions in resistance of the skin to compression indicate an improvement in skin fibrosis (5), which also occurred in the unaffected side. However, the softened skin was more apparent in the affected side. This could possibly mean that characteristics of this holistic program improved the lymphatic

system of whole upper body (particularly the affected side) by fluid removal.

Edema volume and RVC showed no significant difference. This could be a result of the small sample size. Some patients showed reduced affected arm volume even though the volume at baseline was smaller than the unaffected side. Although edema volume is often used as a diagnostic item in current practice, a difference of >2 cm, >10%, or >200 ml between arms is difficult to obtain in smaller arms such as occurs in Japanese women. In addition, reduction of edema volume is not associated with quality of life (29). Thus, assessment should not be solely based on edema volume. We need to assess lymphedema by carefully listening to the patient and examining small changes between both arms. It is noted that no significant

TABLE 4
Changes in Self-Care

		Media	Q1	Q3	rvalue ^{a)}	N=23 p
Perceived adherence for self-care	Baseline	1.00	0.00	2.00	.55	.01**
	6 months	2.00	2.00	3.00		
Perceived effectiveness for self-	Baseline	1.00	0.00	2.00	.64	.00**
	6 months	2.00	2.00	3.00		
Perceived burden for self-care	Baseline	0.00	0.00	2.00	.54	.01**
	6 months	1.00	1.00	2.00		
Self-care score	Baseline	11.00	9.00	13.0	.82	.00**
	6 months	14.00	14.0	14.0		
Average time for daily self-	Baseline	3.00	0.00	10.0	.53	.01**
	6 months	10.00	10.0	15.0		

a) Effect size(r)=|Z|/√ N|
b) Wilcoxon signed rank test compared to baseline data. All p-values are two sided; the level of significance was set to 0.05. * p≤0.05 ** p≤0.01

change in edema volume was seen over the 6 months and this could indicated some level of prevention although the follow up needs to be extended for further evaluation of prevention.

Because there is no reliable or validated BCRL specific symptom scale in Japan, we used an original questionnaire with a semantic differential scale. As this scale is only validated for face validity, the interpretation of the results has to be considered.

On the other hand, arm discomfort and swelling were immediately palliated after the program (16), which lasted until the end of the study. Symptom palliation could have started before an objective change was observed, even a week after program introduction. The previous and current results may indicate that this program has both immediate and long lasting effectiveness. No patient experienced skin reaction on the first use of massage oil. Although 6 patients experienced mild skin symptoms from the application of the oil over time during the study and changed to a moisturizer, the effect of this would be small as it was in a preliminary study (not published). Therefore,

those patients are still included in final analysis. In lymphedema, as skin can easily be irritated, patients need to be informed of the reasons for using skin care. The improvement of self-reported skin condition was not shown in this study, thus a more valid and objective parameter for skin assessment such as the transepidermal water loss is required.

Three out of four patients with a history of recurring cellulitis of more than three times at baseline had a recurrence of acute inflammation. This indicated a difficulty in controlling cellulitis recurrence. However, the patients without a history of cellulitis did not experience such an event during the study, and the prevalence rate was lower than that in the previous report on patients in Japan (6).

The time for self-care and self-care score progressed immediately after implementation of the program(16). The significant increase in burden can be related with the increased time for self-care, because the median time was three min at baseline. Perceived adherence and effectiveness increased, which indicated that the patients were confident in their self-care even though there was

increased burden. According to Prochaska et al (30), people can maintain a change of behavior if a routine can be continued for six months. In addition, a greater belief in lymphedema controllability and self-efficacy may improve patients' adherence (15) and may keep the continuity of self-care. To reinforce patients' motivation, nurses need to keep in contact with patients to motivate them for self-care, perhaps every month for a minimum of six months. Furthermore, patients have their reasons to discontinue self-care, despite recognizing its need, with a feeling of guilt for their non-compliance (31). Therefore, it is critical to listen to and understand the reasons why patients do not complete the program and help them (32).

Because this program is simple and uses a familiar method for Japanese, nurses will feel more confident educating patients using the program rather than teaching more complex methods such as SLD.

Limitation and Future Research

There were limitations in this study. The sample size was enough to detect significant change in arm volume, but not for the other measured parameters. A larger sample size is needed in future research. Furthermore, the comparison between the intervention group and the control group would have been ideal as a study design, therefore, an effort for RCT should be made in future study. Additionally, longer follow up is required to see the feasibility of this program as being "life-long self-care" and for prevention assessment. The measurement tools including questionnaire of symptoms and self-care we used in this study need to be validated. More reliable and validated objective outcome measures such as bioimpedance and trans-epidermal water loss as a parameter for skin barrier function will likely be used in future research.

CONCLUSION

A significant volume reduction was observed in each segment in both the affected and unaffected arms after 6 months. Skin tissue was also more softened in each affected site but softening was also noticed in the unaffected sites. Improvement of the whole upper body may have been due to the holistic BCRL self-care program including full body exercises to stimulate the lymphatic system in the whole body. Lymphedema related symptoms including arm discomfort, sensory alternation, swelling, and heaviness were also significantly improved. In addition, the adherence of self-care improved and the patients seemed to be confident in the program. The 10-min holistic BCRL self-care program seems effective in palliating BCRL and improving self-care adherence.

List of Abbreviations

BCRL: Breast cancer treatment related lymphedema; CDT: Complex decongestive therapy; SLD: Self-lymphatic drainage; CTCAE: Common Terminology Criteria for Adverse Events; RVC: Relative volume change; LYMQOL: lymphedema quality of life; ULL-27: upper limb lymphedema 27; SD: semantic differential; ADL: activity of daily living; BMI: body mass index; ECF: extracellular fluid; ICF: intracellular fluid

Trial registration: UMIN Clinical Trials Registry (UMIN-CTR) UMIN000007616

ACKNOWLEDGMENT

Authors' contributions: YA was responsible for every part of this work including the design of study, the data collection, analysis and interpretation of the data, and preparation and critical revision of this manuscript. FS, TK, KK, and NP contributed to the design of the study, analysis and interpretation of the data, and critical revision of this manuscript. TO, AS, FY, TH, and NS provided valuable suggestions for this study. All the authors have read

and approved the final version of the manuscript.

We would like to express our deepest gratitude to the participants, Dr Makoto Kato, Dr Yoshio Moriguchi, Professor Eiko Kashiwagura, the staff at cooperated institutions including Fukushima Medical University, Tohoku University, Flinders Medical center, Kato Breast Clinic, Shiga Medical center for Adults, Kyoto city hospital, NPO Re-vid, IGM Co. Ltd, and Emeritus Professor Ian Maddocks. This work was supported by JSPS KAKENHI (grant no. 25463419), the Sagawa foundation for promotion of cancer research, and Australian prime minister's education assistance for Japan.

We thank Roy Stuart Cameron who provided medical writing services on behalf of Freecom.

REFERENCES

- Ridner, SH, MR Fu, A Wanchai, et al: Self-management of lymphedema: a systematic review of the literature from 2004 to 2011. *Nursing Research* 61 (2012), 291-299.
- Barclay, J, J Vestey, A Lambert, et al: Reducing the symptoms of lymphoedema: Is there a role for aromatherapy? *Eur. J. Oncol. Nurs.* 10 (2006), 140-149.
- Kirshbaum, M: Using massage in the relief of lymphoedema. *Prof. Nurse.* 11 (1996), 230-232.
- Armer, JM, CW Brooks, BR Stewart: Limitations of self-care in reducing the risk of lymphedema: Supportive-educative systems. *Nurs. Sci. Q.* 24 (2011), 57-63.
- Bernas, M: Assessment and risk reduction in lymphedema. *Semin. Oncol. Nurs.* 29 (2013), 12-19.
- Kitamura, K, K Akazawa: Nyuganjyutsugono rinpahusyuni kansuru tashisetsujittaichousato kongonokadai. *Ann. Vasc. Dis.* 50 (2011), 715-720.
- Shih, YC, Y Xu, JN Cormier, et al: Incidence, treatment costs, and complications of lymphedema after breast cancer among women of working age: A 2-year follow-up study. *J. Clin. Oncol.* 27 (2009), 2007-2014.
- Indelicato, DJ, SR Grobmyer, H Newlin, et al: Delayed Breast cellulitis: an evolving complication of breast conservation. *Int. J. Radiat. Oncol. Biol. Phys.* 66 (2006), 1339-1346.
- Nishimura, H, Y Katano, A Hasegawa, et al: Nyuganjyutsugo no linpafushuyobou ni okeru self-care no jittai to sidouhyouka no kousatsu. *Niigata Cancer Center hospital Kangobu Kangokenkyu.* (2011), 7-14.
- Ryan, T: The skin as a barrier: what does it mean when it fails when lymphoedema is present? *J. Lymphoedema* 8 (2013), 6.
- Brown, JC, AL Cheville, JC Tchou, et al: Prescription and adherence to lymphedema self-care modalities among women with breast cancer-related lymphedema. *Supportive Care in Cancer* (2013), 1-9.
- Armer, J, M Whitman: The problem of lymphedema following breast cancer treatment: Prevalence, symptoms, and self-management. *Lymphology* 35(Suppl) (2002), 153-159.
- Radina, E, J Armer, D Daunt, et al: Self-reported management of breast cancer-related lymphoedema. *J. Lymphoedema* 2 (2007), 12-21.
- Sherman, KA, L Koelmeyer: Psychosocial predictors of adherence to lymphedema risk minimization guidelines among women with breast cancer. *Psychooncology* 22 (2013), 1120-1126.
- Sherman, KA, L Koelmeyer: Psychosocial predictors of adherence to lymphedema risk minimization guidelines among women with breast cancer. *Psychooncology* (2012).
- Arinaga, Y, F Sato, N Sato, et al: The effectiveness of reducing affected arm volume by self-care program in patients with breast cancer treatment-related lymphoedema. *J Jpn. Acad. Nurs. Sci.* 35 (2015), 10-17.
- JapanPostInsurance: Rajio Taiso Douga Eizou (Rajio Taiso Movies): 2013. http://www.jp-life.japanpost.jp/aboutus/csr/radio/abt_c_sr_rdo_movie.html.
- Moseley, A, N Piller, C Carati: The effect of gentle arm exercise and deep breathing on secondary arm lymphedema. *Lymphology* 38 (2005), 136-145.
- Loudon, A, T Barnett, N Piller, et al: The effect of yoga on women with secondary arm lymphoedema from breast cancer treatment: *BMC Complement Altern Med.* 12 (2012), 66.
- JCOG: Common Terminology Criteria for Adverse Events (Ctcae), Version 4.0: Common Terminology Criteria for Adverse Events (CTCAE), Version 4.0. 2013. (2009), http://www.jcog.jp/doctor/tool/CTCAEv4J_20111217.pdf.
- Haruta, H: Mechanism of improvement of edema by the essential oil *lavandula angustifolia*: *J. Jpn. Soc. Aromatherapy* 5 (2006).
- Haze, S, K Sakai, Y Gozu, et al: Grapefruit Oil attenuates adipogenesis in cultured

- subcutaneous adipocytes. *Planta Med.* 76 (2010), 950-955.
23. Taylor, R, UW Jayasinghe, L Koelmeyer, et al: Reliability and validity of arm volume measurements for assessment of lymphedema. *Phys. Ther.* 86 (2006), 205-214.
 24. Ancukiewicz, M, TA Russell, J O'Toole, et al: Standardized method for quantification of developing lymphedema in patients treated for breast cancer. *Int. J. Radiat. Oncol. Biol. Phys.* 79 (2011), 1436-1443.
 25. OECD: Health at a Glance 2011: 2014.(2011), <http://www.oecd.org/els/health-systems/49105858.pdf>.
 26. Moseley, A, N Piller: Reliability of bioimpedance spectroscopy and tonometry after breast conserving cancer treatment. *Lymphat. Res. Biol.* 6 (2008), 85-87.
 27. Keeley, VL, S Crooks, J Locke, et al: A quality of life measure for limb lymphoedema (Lymqol): *J. Lymphoedema* 5 (2010).
 28. Launois, R, A Mègnigbèto, K Pocquet, et al: A specific quality of life scale in upper limb lymphedema: The Ull-27 questionnaire. *Lymphology* 35 (Suppl) (2002), 181-187.
 29. Sitzia, J, L Sobrido: Measurement of health-related quality of life of patients receiving conservative treatment for limb lymphoedema using the Nottingham Health Profile. *Qual. Life Res.* 6 (1997), 373-384.
 30. Prochaska, JO, WF Velicer: The trans-theoretical model of health behavior change. *Am. J. Health Promot.* 12 (1997), 38-48.
 31. Dart, L: Non-Compliance? It's easy for you to say... *J. Lymphoedema* 7 (2012), 8-10.
 32. Piller, N: We need to help patients to help themselves. *J. Lymphoedema* 7 (2012), 6.

Yoko Arinaga, R,N, PhD
Associate Professor, Department of Nursing
Nagasaki University School
of Biomedical Sciences
1-7-1 Sakamoto,
Nagasaki 852-8520, Japan
Telephone: +81-95-819-7900
Fax: +81-95-819-7907
E-mail: arinaga@nagasaki-u.ac.jp