


# Moxibustion as a Therapy for Breast Cancer–Related Lymphedema in Female Adults: A Preliminary Randomized Controlled Trial

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## Abstract

**Objective:** To evaluate the effect of moxibustion on relieving breast cancer–related lymphedema. **Materials and Methods:** A randomized controlled trial was conducted in our institution from March 2016 to March 2017. All patients (N = 48) with cancer-related lymphedema were allocated to 2 groups: a treatment group, in which moxibustion was performed, and a control group, in which pneumatic circulation was performed with compression garments worn every day. Therapeutic efficacy was evaluated by measuring arm circumference (wrist crease, 10 cm proximal to wrist crease, elbow crease, and 10 cm proximal to elbow crease) and determining the Revised Piper Fatigue Scale score and Visual Analog Scale score for swelling before and after treatment. **Results:** All patients were treated for 4 consecutive weeks. Compared with 0 week after treatment, the affected-side arm circumference after 4 weeks' treatment decreased in both treatment and control groups; the difference value in the treatment group was superior to that in the control group. Compared with the controls, moxibustion resulted in a lower Visual Analog Scale score. The Revised Piper Fatigue total scores were improved in both the moxibustion and control group, and there was no significant difference between the 2 groups. Moxibustion reduced the behavioral, sensory, emotional, and cognitive Revised Piper Fatigue scores, but only the behavioral and sensory scores improved in the control group. **Conclusion:** Moxibustion has potential effect on breast cancer–related lymphedema. We present promising preliminary data for larger randomized trials to enable accurate evaluation of moxibustion as a lymphedema treatment.

## Keywords

breast cancer–related lymphedema, BCRL, moxibustion, randomized controlled trial, traditional Chinese medicine, effect observation

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## Introduction

Lymphedema, defined as swelling of the soft tissues caused by accumulation of lymph, is a potential adverse effect of breast cancer surgery and irradiation. Breast cancer–related lymphedema (BCRL), a chronic, disfiguring, disabling condition, is one of the most serious complications of breast cancer treatment. Surgery or radiotherapy can lead to progressive axillary lymphatic reflux dysfunction and accumulation of protein-rich interstitial fluid, resulting in upper limb edema, hypertrophy, and even fibrosis.<sup>1,2</sup> BCRL can occur months or even years after treatment. The reported incidence of BCRL

ranges from 6% to 70%.<sup>3–14</sup> Treatment of BCRL consists of both nonoperative methods (eg, artificial lymphatic drainage,

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multi-layer low-tension bandaging, exercise, wearing an elastic cuff, application of an intermittent pressure pump, and laser treatment) and operative methods.<sup>15,16</sup>

Moxibustion, which involves the application of heat and is a traditional Chinese medicine (TCM) technique used in many countries in Asia, is worthy of more widespread recognition and use. According to TCM theory, moxibustion enhances the blood circulation and relieves swelling and pain. Reports on moxibustion have shown that the local irritation induced by this treatment can regulate the nervous system and improve blood circulation in a lesion.<sup>17</sup> A study on the treatment of BCRL after breast cancer surgery showed that moxibustion achieved better results than routine nursing practices.<sup>18</sup>

We therefore conducted a randomized controlled trial to observe and evaluate the efficacy of moxibustion for treating BCRL. Our results provide a basis for exploring moxibustion as a means of managing lymphedema in patients with breast cancer.

## Materials and Methods

### *Ethical Approval and Informed Consent*

Our institution's ethics committee approved the study protocol (Certificate No. STKTPJ-BZYSY-2017-03). All patients provided written informed consent before enrollment.

### *Patients*

Forty-eight patients were recruited within our institution or after they responded to recruitment notices on the Internet, in newspapers and magazines, or on recruiting posters in nearby public places. The inclusion criteria for this study were female sex; age of 18 to 65 years; pathological diagnosis of breast cancer; a history of surgery with completion of chemotherapy, radiotherapy, or both; circumference of the affected arm  $\geq 2$  cm greater than that of the contralateral arm at baseline<sup>19</sup>; unexplained fatigue; and provision of informed consent for inclusion in the study. The exclusion criteria were the presence of metastases; thrombotic disease, phlebitis, or other vascular disease; lymphangitis or other lymphatic disease; limb skin trauma, ulceration, or skin disease; pregnancy; allergies; and receiving other treatments for lymphedema.

The present study was conducted in our institution from March 2016 to March 2017.

### *Treatment*

All patients were treated for 4 consecutive weeks. Patients in the treatment group underwent moxibustion for 30 minutes every 2 days, whereas those in the control group underwent pneumatic circulation for 30 minutes every 2 days and wore a compression garment every day.

Well-trained doctors performed all treatments and measurements.

### *Moxibustion*

1. The patient was placed in the prone position, and the affected limb was fully exposed.
2. Moxa sticks (1.8 × 20 cm; Nanyang Hanyi Moxa Co Ltd, Nanyang, China) were cut into 5-cm segments, lit, and placed in a moxibustion box (Hanyi, 23 × 16 × 9.2 cm; Nanyang Hanyi Moxa Co).
3. The appropriate treatment points on the affected arm were selected from the following: Binao (LI 14), Shouwuli (LI 13), Waiguan (SJ 5), Jianzhen (SI 9), Shenshu (BL 23), and any Ashi points (an acupuncture point without a specific name or definite location, the site of which is determined by tenderness or other pathological responses; also known as the ouch point). The moxibustion box was then placed on the selected points.
4. The moxa was ignited on the iron gauze, which is in the lower part of the box, and the lid replaced. The aim was for the patient to feel the moxibustion as comfortably warm with no sensation of burning until the skin became moderately erythematous. If the patient reported a sensation of burning, the moxibustion box was opened or the box briefly lifted just above the skin, then put back in place.
5. The moxibustion box was removed after 30 minutes. The whole procedure was performed in accordance with the State Standard of the People's Republic of China—Manipulation of Acupuncture and Moxibustion: Part 1 Moxibustion (GB/T 21709.1-2008).<sup>20</sup>

### *Pneumatic Circulation and Compression Garment*

1. The patient was placed in a sitting position, and the affected limb was fully exposed with the arm and heart at the same level.
2. The patient's arm and shoulder were wrapped in a pneumatic circulation sleeve (LGT-2200W; Guangzhou Longest Science & Technology Co Ltd, Guangzhou, China), and the pneumatic circulation was turned on.
3. After 30 minutes, the sleeve was removed and the pneumatic circulation turned off.

All patients in the control group wore a compression garment every day.

### *Assessment of Outcomes*

The primary outcome of the affected arm circumference was measured with a tape (wrist crease, 10 cm proximal to wrist crease, elbow crease, and 10 cm proximal to elbow crease),<sup>21</sup> and the primary outcome of swelling was quantitated by Visual Analog Scale (VAS) scores.

The secondary outcome of fatigue was quantitated using Revised Piper Fatigue Scale (RPFS) scores.

All outcome measures were assessed at treatment weeks 0, 1, 2, 3, and 4. Well-trained doctors performed all measurements in this study.

### *Determination of Required Study Size*

Because this was a preliminary study, no data with which to determine the required sample size were available. We had identified an intergroup difference in a pilot study. Assuming a dropout rate of 20%, we decided to recruit 48 women for the present study (24 in each group).

### *Randomization*

Randomization was achieved using a simple random sampling method involving generation of a random number table using IBM SPSS 20.0 software (IBM Corp, Armonk, NY). The generated random numbers were sealed in sequentially numbered opaque envelopes with each participant's screening sequence number printed on the outside and the allocated group names inside the envelope. A statistician opened the envelope corresponding to the participant's screening sequence number and assigned the participant to the treatment or control group accordingly. The participants were randomly assigned to the study groups in a ratio of 1:1. It was not possible to blind the patients or treating physicians because of the nature of each treatment. However, both the researcher who evaluated the outcomes and the statistician were blinded to the group allocated and were not involved in any aspect of the treatment.

### *Follow-up*

On completion of the 4-week treatment period, the research staff continued to assess the participants and keep a record of changes in arm circumference, feeling of fatigue, and swelling for a further 1-month follow-up period.

### *Statistical Analysis*

All values are expressed as mean  $\pm$  standard deviation. Significant differences between the groups were statistically analyzed using the independent *t* test or nonparametric test (2 independent samples test). Significant differences before and after the treatment in the same group were analyzed by the paired-samples *t* test or nonparametric test (2 related samples test). Discrete data (eg, surgical method, pathological type, and tumor stage) were compared using the  $\chi^2$  test or an accurate probability method. IBM SPSS 20.0 software was used for statistical analysis. A value of  $P < .05$  was considered to denote statistical significance.

## **Results**

### *Patient Characteristics and Baseline Measurements*

Twenty-four of the 48 patients were allocated to the treatment group and 24 to the control group (Figure 1). The first patient was treated in March 2016 and the last patient in December 2016. Three patients elected to stop treatment (2 in the control group and 1 in the treatment group). There were no significant differences between the 2 groups in age, height, weight, surgical procedure, pathological type, tumor stage, radiotherapy, edema duration, or other assessed variables. There were also no significant differences between the groups in affected arm circumference, VAS swelling score, or RPFS score at baseline (Table 1).

### *Comparison of Arm Circumference on Affected Side*

Moxibustion significantly reduced the affected-side arm circumference. The circumference of the affected arm decreased significantly after treatment in both groups (Table 2). The results in Table 2 and Figure 2 indicate that the mean arm circumference on the affected side did not differ significantly between the 2 groups before treatment, but it decreased progressively in parallel with treatment duration and frequency. Analysis of variance between the 2 groups at different follow-up time points showed that the results were better in the treatment than control group from week 1 of treatment onward (Figure 2).

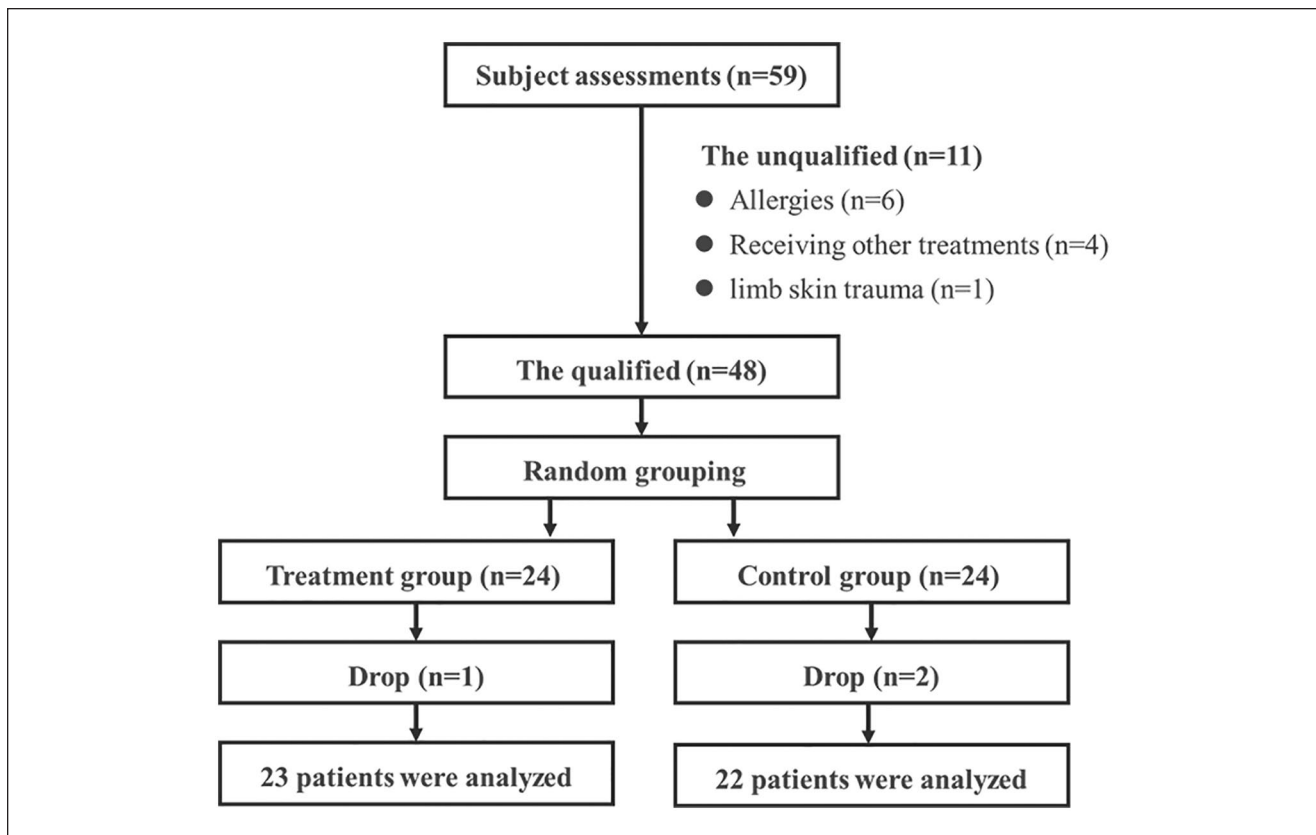
On completion of treatment, the affected-side arm circumference at the wrist crease, 10 cm proximal to the wrist crease, elbow crease, and 10 cm proximal to the elbow crease were compared within groups (before and after treatment) and between groups. The decreased value of the mean circumference after 4 weeks' treatment in the treatment group was significantly superior to the control group (Table 2).

### *Comparison of VAS Swelling Score*

*Moxibustion-Induced Relief of Subjective Sensation of Swelling.* The VAS scores for swelling were better after than before treatment in both groups. Subjective relief of swelling was greater in the treatment group than control group (Table 3).

### *Comparison of RPFS*

*Moxibustion-Induced Reduction in Behavior and Sensory Scores of RPFS.* The total RPFS scores were improved in both groups, with no significant difference between the 2 groups (Table 4 and Figure 3). The behavior, sensory, emotional, and cognitive scores were better after than before treatment in the



**Figure 1.** Flow chart of patient allocation.

treatment group. However, only the behavior and sensory scores improved in the control group (Table 4).

### Safety Assessment

No adverse events such as local burns, bleeding, ecchymosis, or inflammatory reactions occurred during treatment.

### Discussion

In the present study, we found that moxibustion effectively reduces the affected-side arm circumference, relieves subjective symptoms of affected-side arm swelling, and reduces fatigue in patients with BCRL.

According to TCM theory, BCRL is caused by meridian stagnation and retaining of fluid beneath the upper arm skin as a result of surgery- and/or radiotherapy-related injury. Heat can promote fluid circulation in the meridians. Moxibustion has strong heating effects; it smooths the meridians and may therefore promote improvement in lymphedema. Moreover, clinical and experimental studies have shown that moxibustion improves vascular function, repairs damaged tissues and nerves, and reduces expression of inflammatory cytokines and the extent of local tissue microcirculation disorders.<sup>22,23</sup>

Yao et al<sup>21</sup> found that warm acupuncture resulted in a more significant reduction in upper limb arm circumference than did diosmin in patients with lymphedema. The present results are consistent with these findings.

In TCM, the meridians and collaterals are pathways in which Qi and blood are circulated throughout the human body. Acupoints are the specific sites through which the Qi of Zang-Fu organs and meridians are transported to the body surface. In acupuncture and moxibustion treatment, proper techniques are applied on the acupoints to prevent and treat diseases by regulating the functional activities of the body and strengthening body immune resistance.<sup>24</sup> In the present study, we selected acupoints Binao (LI 14), Shouwuli (LI 13), Waiguan (SJ 5), Jianzhen (SI 9), Shenshu (BL 23), and any Ashi points for moxibustion. Binao (LI14), Shouwuli (LI13), Jianzhen (SI9), and Ashi points are local points around the upper arms and have the function of promoting the local blood circulation. Shenshu (BL23) is the Back-Shu point of the kidney. In TCM theory, the kidney regulates the fluid metabolism of the whole body and drains water. The results of the present study showed that moxibustion markedly improved upper arm lymphedema and was more effective than pneumatic circulation and wearing a compression garment. Many researchers have reported

**Table 1.** Demographic Characteristics and Baseline Measurements.

Characteristic	Control Group (n = 24)	Treatment Group (n = 24)	P
<b>Demographics</b>			
Age (years)	58.25 ± 6.19	59.42 ± 7.02	.55
Height (m)	1.61 ± 0.03	1.60 ± 0.03	.52
Weight (kg)	61.95 ± 4.68	59.75 ± 6.32	.18
<b>Surgical methods for treating breast cancer</b>			
Breast conserving surgery (right)	1	0	1.00
Breast cancer modified radical mastectomy (right)	10	10	
Total mastectomy (right)	0	1	
Breast cancer modified radical mastectomy (left)	11	12	
Total mastectomy (left)	2	1	
<b>Pathological type of cancer</b>			
Ductal carcinoma in situ	0	1	1.00
Invasive ductal carcinoma	22	22	
Invasive lobular carcinoma	2	1	
<b>Tumor stages<sup>a</sup></b>			
0	0	0	
I	10	6	.10
II	14	14	
III	0	4	
IV	0	0	
<b>Radiotherapy</b>			
Yes	13	18	.13
No	11	6	
Frequency	25.00 ± 6.45	24.84 ± 7.04	.95
Course of edema (M)	29.42 ± 17.43	30.96 ± 24.39	.80
<b>Affected-side arm circumference (cm)</b>			
Wrist crease	17.97 ± 1.33	17.69 ± 1.53	.50
Proximal 10 cm to wrist elbow	24.60 ± 2.50	24.84 ± 3.17	.78
Elbow crease	29.56 ± 2.69	28.48 ± 2.41	.15
Proximal 10 cm to elbow crease	33.48 ± 3.02	32.146 ± 3.33	.15
Mean circumference of arm	26.40 ± 2.11	25.79 ± 2.24	.33
VAS swelling score	7.17 ± 1.01	7.54 ± 1.14	.23
<b>RPFS</b>			
Behavior dimension	4.92 ± 1.18	5.06 ± 1.08	.67
Emotional dimension	4.50 ± 1.27	4.59 ± 0.86	.79
Sensory dimension	5.20 ± 1.29	5.14 ± 1.04	.86
cognitive dimension	4.45 ± 1.17	4.61 ± 0.80	.58
Total score	4.75 ± 1.04	4.85 ± 0.77	.71

Abbreviations: VAS, Visual Analog Scale; RPFS, Revised Piper Fatigue Scale.

<sup>a</sup>The tumor stages (0, I, II, III, and IV) were applied according to the International Standard TNM Stage method proposed by the American Joint Committee on Cancer.

that moxibustion therapy affects the blood flow in cutaneous tissues and muscles. In previous clinical and experimental studies, moxibustion has been used for various conditions including stroke rehabilitation, rheumatoid arthritis, chronic fatigue syndrome, Crohn's disease, ulcerative colitis, irritable bowel syndrome, and hyperplasia of mammary gland disease. Moxibustion is used to manage these diseases by involving the nervous system, endocrine system, and immune system.<sup>25</sup> The present study tried to explore the beneficial effects of moxibustion on BCRL.

Cancer-related fatigue (CRF) is the most common and devastating symptom associated with tumor or cancer therapy, and few effective interventions are available. A systematic review of 40 studies showed that the reported prevalence of CRF rates ranges from 46% to 96% and that it persists well beyond completion of treatment in at least 25% of patients.<sup>26</sup> In the present study, we found that moxibustion was effective against both BCRL and fatigue. The results in Table 4 show that the total RPFS decreased significantly after treatment in both the moxibustion group and control



**Table 2.** Comparison of Affected-Side Arm Circumference Mean Value at Different Measuring Positions<sup>a</sup>.

	Treatment Group (n = 24)	Control Group (n = 24)	P
Affected-side arm circumference mean value			
0 week after treatment	25.61 ± 2.11	26.70 ± 1.93	.078
4 weeks after treatment	24.48 ± 2.02**	26.09 ± 1.81**###	.005
Difference value <sup>b</sup>	1.13	0.61	
P	.000	.003	
Wrist crease			
0 week after treatment	17.55 ± 1.39	18.07 ± 1.36	.357
4 weeks after treatment	16.93 ± 1.28**	17.66 ± 1.17*#	.018
Difference value <sup>b</sup>	0.62	0.41	
P	.002	.011	
Proximal 10 cm to wrist crease			
0 week after treatment	24.27 ± 2.93	24.86 ± 2.33	.191
4 weeks after treatment	22.95 ± 2.75**	24.02 ± 1.72**#	.012
Difference value <sup>b</sup>	1.32	0.84	
P	.000	.008	
Elbow crease			
0 week after treatment	28.25 ± 2.16	29.91 ± 2.51#	.018
4 weeks after treatment	27.25 ± 1.92**	29.08 ± 2.72**#	.014
Difference value <sup>b</sup>	1.00	0.83	
P	.000	.000	
Proximal 10 cm to elbow crease			
0 week after treatment	32.02 ± 3.35	33.95 ± 2.69#	.039
4 weeks after treatment	30.77 ± 3.11**	33.59 ± 2.73###	.002
Difference value <sup>b</sup>	1.25	0.36	
P	.000	.246	

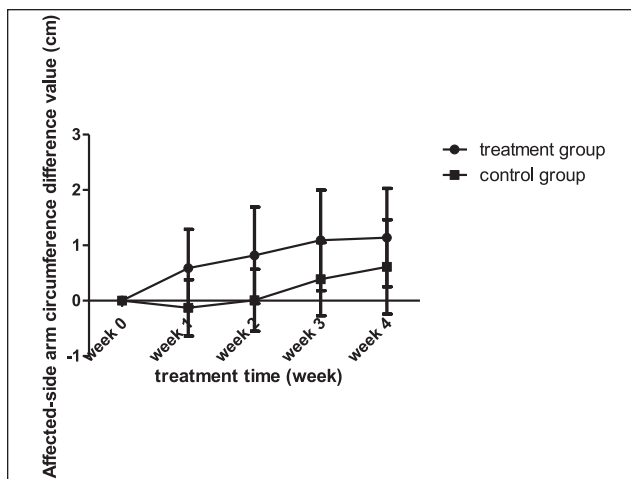
<sup>a</sup>Data are presented as mean ± standard deviation.

<sup>b</sup>Difference value = data of 4 weeks after treatment - 0 weeks after treatment.

\*Compared with 0 weeks after treatment,  $P < .05$ . \*\*Compared with 0 weeks after treatment,  $P < .01$ .

#Compared with treatment group,  $P < .05$ .

###Compared with treatment group,  $P < .01$ .



**Figure 2.** Differences in affected-side arm circumference at various follow-up time points. The lines represent the difference in the affected-side arm circumference at treatment weeks 0, 1, 2, 3, and 4 in the control group (blocks) and treatment group (dots). The difference in the affected-side arm circumference = affected-side arm circumference without treatment - affected-side arm circumference after treatment. Data are reported as mean ± standard deviation.

group, and there was no significant difference between the 2 groups. However, the degree of decrease was greater in the moxibustion group than control group. Additionally, moxibustion reduced the behavior, sensory, emotional, and cognitive aspects of the RPFS, while only on the behavioral and sensory scores improved in the control group. These results suggest that moxibustion may be able to relieve fatigue, which is consistent with the findings of Mao et al,<sup>27</sup> and further establishes that moxibustion can be used to relieve CRF.

When we examined the patients at the end of 4 weeks' treatment, we found that varying degrees of limb swelling had begun to redevelop in some patients. It is well known that BCRL symptoms are chronic and persistent because of impaired lymphatic return. The long-term efficacy of moxibustion is worthy of further study.

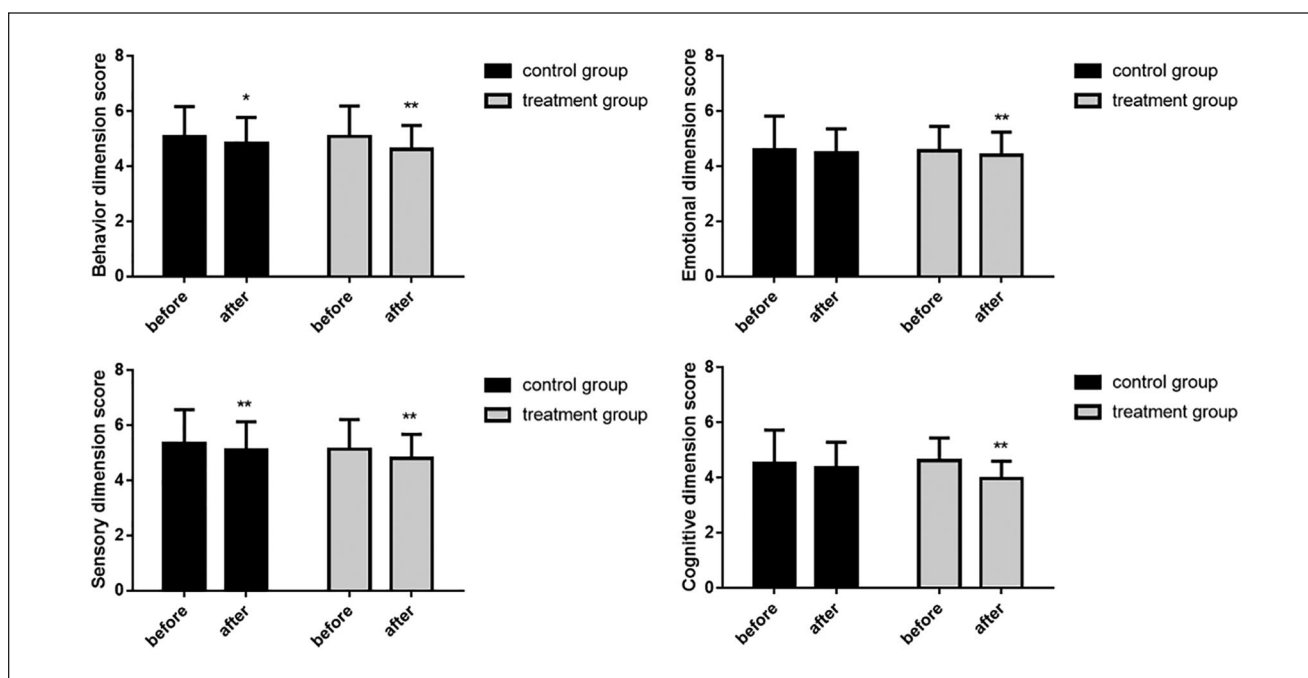
Volume replacement is currently considered the gold standard for evaluating BCRL; however, this method is cumbersome in a busy outpatient practice.<sup>28</sup> Therefore, based on a published report and our clinical situation,<sup>29</sup> we chose 4 points on the arm (wrist crease, 10 cm proximal to wrist crease, elbow crease, and 10 cm proximal to elbow crease) at which to measure the degree of limb swelling.

**Table 4.** Comparison of Revised Piper Fatigue Total Score<sup>a</sup>.

	Treatment Group (n = 24)	Control Group (n = 24)	P
0 week after treatment	4.85 ± 0.79	4.87 ± 0.98	.609
4 weeks after treatment	4.43 ± 0.63**	4.69 ± 0.77**	.085
P	.000	.000	

<sup>a</sup>Data are presented as mean ± standard deviation.

\*\*Compared with 0 weeks after treatment,  $P < .01$ .



**Figure 3.** Comparison of 4 dimensions of the Revised Piper Fatigue Score. Bars represent the score of the behavior dimension, emotional dimension, sensory dimension, and cognitive dimension before and after treatment in the control group (black) and treatment group (gray). Data are reported as mean ± standard deviation. \*Compared with 0 weeks after treatment,  $P < .05$ ; \*\*compared with 0 weeks after treatment,  $P < .01$ .

**Table 3.** Comparison of Visual Analog Scale Scores<sup>a</sup>.

	Treatment Group (n = 24)	Control Group (n = 24)	P
0 week after treatment	7.57 ± 1.16	7.32 ± 0.89	.301
4 weeks after treatment	4.87 ± 0.87**	5.41 ± 0.80**,#	.033
P	.000	.000	

<sup>a</sup>Data are presented as mean ± standard deviation.

\*\*Compared with 0 weeks after treatment,  $P < .01$ .

#Compared with treatment group,  $P < .05$ .

This assessment technique was substantially easier to perform than volume replacement. In this study, moxibustion significantly reduced the circumference of the affected arm. The circumference of the affected arm decreased significantly after treatment in both the treatment and control groups. In the treatment group, the difference in the arm circumference before and after treatment at the affected side, wrist crease, proximal 10 cm to wrist crease, elbow

crease, and proximal 10 cm to elbow crease was 1.13, 0.62, 1.32, 1.00, and 1.25 cm, respectively. In the control group, the difference in the arm circumference before and after treatment at the affected side, wrist crease, proximal 10 cm to wrist crease, elbow crease, and proximal 10 cm to elbow crease was 0.61, 0.41, 0.84, 0.83, and 0.36 cm, respectively. The results showed that the difference value between treatment group and control group at the affected-side arm

circumference was 0.52 cm, with significance. Although there were certain errors in clinical measurement, it is clinically meaningful to treat patients in the same way.

In patients with early BCRL, the limb circumference may not have increased despite a sensation of swelling. Patients who have undergone lymph node excision reportedly feel their arm swelling more than expected from the measured circumference.<sup>19,30,31</sup> We found that although some patients had no measurable change in limb circumference during treatment, their subjective feeling of swelling had improved. Thus, more attention should be paid to subjective feelings of swelling when assessing treatment. We aim to further evaluate the subjective feeling of swelling in a follow-up study. In the present study, we explored the effect of TCM moxibustion on BCRL. However, our study still has some limitations. For instance, the exact mechanism of how moxibustion improves swelling caused by fluid buildup in the lymphatic system was not explored in this research. This study provided experimental evidence for methodological exploration of TCM therapies on BCRL, and the mechanism will be further studied in the future.

Although treating BCRL is challenging, we plan to continue to search for more effective TCM techniques for treating BCRL, such as Chinese herbs (oral administration or external use), moxibustion, and Tui Na. We are also trying to identify treatments that have a long-term effect, induce minimal trauma, and are easy to use. Limitations of this study include that it was not blinded to patients or treating physicians, had a small sample size, and did not include a sham moxibustion group. We will increase sample size and prolong the treatment time in our further study.

## Conclusion

Moxibustion has potential use in the management of BCRL. We have herein presented promising preliminary data for further randomized trials to enable continued evaluation of moxibustion as a BCRL treatment.

## Authors' Note

This trial was registered in the Chinese Clinical Trial Registry (Registration Number ChiCTR-ONR-16009937).

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## Author Contributions

Chunhui Wang wrote the manuscript. Xiaohua Pei conceived and designed the study. Ming Yang and Chunhui Wang contributed to

the collation and treatment of patients. Yingyi Fan contributed to the collation and analysis of the data. All authors read and approved the final manuscript.

## Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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