**Research Scholars Initiative**

Randomized Controlled Trial of the Breast Cancer Recovery Program for Women With Breast Cancer–Related Lymphedema


**KEY WORDS**

- breast neoplasms
- exercise
- lymphedema
- relaxation

Evidence-based exercise and relaxation recommendations for people with breast cancer–related lymphedema (BCRL) are needed. We report a randomized controlled study of one program, designed to achieve synergistic improvements in physical and emotional BCRL symptoms. People in the treatment group received an exercise and relaxation program, The Breast Cancer Recovery Program (N = 16). The control participants (N = 16) continued with health professionals’ recommendations. Participants were tested at entry, 2.5 weeks, 5 weeks, and 3 months. Treatment group participants, compared with control participants, demonstrated significant treatment effects for improved bioimpedance z, arm flexibility, quality of life, mood at 3 months, and weight loss. Adherence was high for this safe and effective program, which improved lymphedema physical and emotional symptoms.


Breast cancer–related lymphedema (BCRL) is a blockage in the one-way lymphatic transport system from physical trauma to the affected area caused by surgery or radiation. This blockage leads to mechanical insufficiency, chronic inflammation, and an imbalance in tissue pressures (Pain & Purushotham, 2000), as described in Starlings Law of Capillaries (Board & Harlow, 2002). Reports of the incidence of BCRL cluster around 20% (Box, Reul-Hirche, Bullock-Saxton, & Furnival, 2002a; Petrek & Heelan, 1998).

Symptom progression over time without continual management (Casley-Smith, 1995) highlights the need for high-quality, long-term therapeutic programs for patients with BCRL. The high degree of physical morbidity, including swelling and loss of limb flexibility, may lead to fibrosis (Boris, Weindorf, & Lasinski, 1997), stasis (Brennan, DePompolo, & Garden, 1996), and bouts of infection (Peturk & Heelan, 1998). The high degree of emotional symptoms leading to an array of psychological morbidities has been well established, with more severe emotional symptoms seen compared with those with a primary breast cancer diagnosis (Passik & McDonald, 1998) or the general population (Tobin, Lacey, Meyer, & Mortimer, 1993). Psychological morbidities appear to continue even after completion of active lymphedema treatment and are unrelated to the severity of the swollen limb (Ridner, 2005).

Attempts to identify an appropriate program of exercise that encourages drainage from the affected tissue through alternate lymphatic pathways but does not result in increased swelling from increased blood flow into the affected tissue has...
been a challenge. There has been no evidence-based, baseline standard of care program of exercise for patients with BCRL. Thus, the therapist is left to make a recommendation for exercise only on the basis of the evaluation of the current patient and previous recommendations for patients with similar presentations. Studies evaluating exercise have reported either initial significant increased swelling in the affected arm in patients with BCRL (Johansson, Tibe, Weibull, & Newton, 2005; McKenzie & Kalda, 2003), no statistically significant change in affected-side swelling in breast cancer survivors (Harris & Niesen-Vertommen, 2000; Sandel et al., 2005; Turner, Hayes, & Reul-Hirche, 2004), or increases in bilateral arm swelling in breast cancer survivors (Lane, Jespersen, & McKenzie, 2005). Only one non-randomized gentle exercise/deep diaphragmatic breathing (DDB) study reported swelling reduction (Moseley, Pillar, & Carati, 2005). We found no studies in the literature evaluating therapeutic effects of DDB for BCRL.

We evaluated whether treatment group (TG) participants with BCRL completing the Breast Cancer Recovery Program (BCRP), compared with control group (CG) participants, demonstrated decreased swelling, as measured by bioimpedance and arm girth; desired weight loss; and improved active range of motion (AROM), mood, quality of life (QoL), and high adherence. We evaluated whether a Circle of Healing synergistic, feed-forward strategy through exercise and emotional outcomes based on the immune system’s role in healing would result in joint physical and emotional outcomes. The Circle of Healing concept was developed by Marjorie McClure for the Breast Cancer Recovery Program (see McClure & Brusky, 2009).

Method

Experimental Design

This study used a randomized controlled design. Participants who met study criteria in the initial screening were entered sequentially into either TG or CG using a randomization matrix for groups of eight with four in each TG and CG. Each participant opened a randomized, sealed, sequentially numbered envelope informing him or her of group status, and both participant and screener signed and dated the opened letter. After 8 participants entered the study, initial testing and program sessions were initiated for that group. Table 1 provides the timing of TG and testing for both groups. Each group of 8 participants was scheduled for testing within a 2-day period. The same therapist performed all participant testing and was unaware of participant group status. This therapist was trained and tested in the use of the testing instruments by a licensed occupational therapist specializing in this field. Data from the initial testing were monitored and discussed with the tester to ensure that measurements were properly obtained; formal testing, however, was not carried out. CG participants were instructed to continue with the lymphedema instructions from their medical team. The TG participants completed the exercise program daily either at home or during the required 1-hr biweekly group sessions for 5 weeks followed by 3 months continuation of the daily exercise and relaxation program.

The independent variables were group status (treatment or control) and assessment time points for the study. The dependent variables with accompanying instruments were arm swelling (bioimpedance z, L-Dex, and arm girth), weight change (lb), AROM (goniometer), mood (Beck Depression Inventory—II; BDI), QoL (SF–36, Version II), and program adherence (internally generated questionnaire). In this study, we used degree of swelling as a dependent variable because it is the primary method used to diagnose and monitor lymphedema progression by the lymphedema medical community. The AROM variable was used because it is important in determining the functional level of independence of the patient within daily activities. We used weight change because weight is a primary determinant of the progression of lymphedema. We used QoL and mood variables because they report on the emotional status of the patient and are important to good program adherence. We evaluated adherence because lymphedema progresses in intensity and grade without adherence to treatment.

Assessment Tools

Lymphedema swelling was assessed using two methods: (1) an ImpediMed (Penkenna, Queensland, Australia) IMP™ XCA bioelectrical impedance analysis system and (2) truncated cone girth measurements, which report volume. Bioimpedance measures the amount of extracellular fluid in an arm by reporting the level of resistance to a low-frequency electrical current. The resistance is related to the amount of

<table>
<thead>
<tr>
<th>Table 1. Participation Schedule</th>
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<tr>
<td>Group</td>
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<tr>
<td>-------</td>
</tr>
<tr>
<td>TG</td>
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<tr>
<td>CG</td>
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</tbody>
</table>

Note. T = outcome measure tests; sessions = 1-hr Breast Cancer Recovery Program exercise-relaxation sessions; TG = treatment group; CG = control group.
extracellular fluid, including lymph, because low-frequency currents travel outside cells through extracellular fluid. The XCA, which is a modification of a multifrequency bioelectrical impedance instrument, is the only U.S. Food and Drug Administration–cleared device for the clinical assessment of lymphedema in the arm (Impedimed, 2008). L-Dex values, which incorporate bioimpedance measurements, compare affected to unaffected arms, taking into account arm dominance. Truncated cone volumes calculated from arm-girth measurements report percentage of swelling of affected compared with unaffected area (Casley-Smith & Casley-Smith, 1997). Although both techniques have been used in detecting lymphedema, multifrequency bioelectrical impedance measures have been reported to be a more sensitive measure of lymphedema than manual girth measurements (Cornish, Bunce, Ward, Jones, & Thomas, 1996).

Participants were weighed with a medical scale at each testing timepoint (Table 1). Shoulder AROM measurements were obtained using a standard, two-armed goniometer described by Scott and Trombly (1983). Mood was assessed using the BDI, a 21-question self-report inventory used to measure mood and depression (Beck, Steer, & Brown, 1996). The BDI has been shown to have a high test–retest reliability (Pearson r = .93) and a high internal consistency (α = .01; Beck, Steer, Ball, & Ranieri, 1996). QoL was evaluated using the 36-question, self-report SF–36 Health Survey–II (Ware, Kosinski, & Gandek, 2000). The SF–36 measures eight domains of health: physical functioning, role limitations caused by physical health problems, bodily pain, general health, vitality, social functioning, role limitations caused by emotional problems, and mental health. The results from 14 studies demonstrated reliability coefficients equal to or exceeding .80 with the exception of social functioning (.76), and the validity of the SF–36 is well established (Ware et al., 2000).

Exercise adherence was assessed at the end of the 5-week program and 3-month follow-up using a self-report adherence tool specifically designed for this study, which asks the number of times per week the participant (1) exercised, (2) practiced relaxation techniques, and (3) used affected arm compression. The adherence questions given at 5 weeks sampled all sessions, including the 2.5-week test period. Participants reported exercise and relaxation adherence in the range of 0 to 14 times per week. Compression adherence was characterized as low if wraps were worn <50% of time or high if worn ≥50% of the time.

**Procedures**

The TG participants attended 10 biweekly, 1-hr sessions for 5 weeks (see Table 1), followed by a 3-month self-monitored home program period. Each structured session included participation in the video “From Lymphedema Onto Wellness” (FLOW; McClure & Bittman, 2003). Also during each session, verbal instructions with accompanying written educational material were highlighted in topics related to lymphedema, coping techniques, and relaxation techniques, including hands-on practice in DDB, progressive muscle relaxation, and facial massage. Each session concluded with a question-and-answer component and group discussion. TG participants were instructed to complete the FLOW video and relaxation techniques at home daily.

The FLOW video is a 17-min demonstrated exercise and relaxation program for clinic, hospital, or home use that incorporates low-to-moderate intensity, muscle shortening, gravity-resistive arm flexibility exercises together with DDB, supplemented by imagery, natural scenery with flowing water, and background music. The exercises visually resemble tai chi or qigong but correspond to verbal directives and relaxation imagery cues. The exercises can be done in seated, standing, or supine positions with adaptations. Lymphogenesis and increased flow in alternative, healthy lymphatic routes away from the affected area are sought by contracting area muscles underlying alternative lymphatic routes. This approach is consistent with literature reports that recommend isotonic, not isometric, exercise with muscle shortening for increased lymph flow (Pain & Purushotham, 2000).

The FLOW exercises and DDB follow a proximal to distal sequence, as in manual lymphatic drainage (Földi, Földi, & Clodius, 1989), and are designed to encourage flow in alternate lymphatic pathways. Gravity-resistive arm movements using concentric muscle-shortening motions out away from the body in work positions of shoulder flexion (SP), abduction (AB), and external rotation (ER) correspond with the inhaling breath. Arm positions in the work phase that are reported to have the greatest limitation in flexibility after breast cancer surgery (Box, Reul-Hirche, Bullock-Saxton, & Furnival, 2002b) have the greatest number of repetitions in the video. Work positions are alternated with rest positions with arms close to the body to encourage alterations in total tissue pressure. Arm movements back toward body midline, including internal rotation (IR), correspond to the slowed exhaling breath and an emphasis on relaxation.

**Participants**

This study was approved by the University of Pittsburgh institutional review board. Participants were female outpatients from the local community recruited through advertisements placed in local hospitals and outpatient clinics and at breast cancer survivor events. Female patients ages 21 to 80 who demonstrated Stage I or II unilateral BCRL with ≥10% increased affected arm size compared with the unaffected arm were eligible for the study. Exclusion criteria included bilateral extremity lymphedema; breast cancer surgery ≤3
months previous; arthritis limiting self-care independence; pregnancy; current use of diuretics; or traditional lymphedema treatment contraindications, such as cellulitis, cardiac or kidney impairment, and metastatic disease. The sample size for this study was estimated from the effect size that exercise might have on the reduction of lymphedema reported in a study by Casley-Smith and Casley-Smith (1994), who reported that between complex physical therapy treatment courses, participants who performed the prescribed written exercises experienced a reduction in swelling (mean of percentage difference in Final Volume – Initial Volume) of −15.3%, standard error = 2.3% (N = 24). Those who did not perform the exercises had a reduction of swelling (mean % difference) of −1.8%, standard error = 1.2% (N = 51; p = .0001). Assuming that the standard error values given by Casley-Smith and Casley-Smith (1994) are standard error of the mean, the standard deviations would be 11.26 and 8.57, respectively, for those who did exercises and those who did not comply. Using a two-sample t-test power analysis, a sample size of N = 16 for each group would give a high power (95.8%) for obtaining a true difference between the two study groups at a Type 1 error level of .05.

Statistical Analysis

Analysis of percentage of swelling taken at entry indicated that not all participants met study criteria for 10% swelling. Therefore, the primary statistical analysis was conducted on participants (TG, N = 10; CG, N = 11) who had percentage of swelling ≥10% or an L-Dex score ≥10 to maximize treatment effects for improving arm lymphedema. Details of the exclusion of participants from the primary analysis are given in the Results section. Data were initially analyzed by examining means of outcome measures plotted with 95% confidence error bars for both groups at entry (baseline, Time Point 1), 2.5 weeks (Time Point 2), 5 weeks (Time Point 3), and 3-month follow-up (Time Point 4). Because baseline values of the TG and CG were different, comparison of TG and CG were performed using differences from baseline (i.e., Dif1 = measures obtained at baseline [Mb] – measures at Time Point 2 [M2]; Dif2 = Mb – M3; Dif3 = Mb – M4). P values ≤.05 are considered significant.

Plots of the means of Dif1, Dif2, and Dif3 with 95% confidence error bars for the two cohorts were plotted with the same scale to examine the effect of treatment. A repeated-measures mixed-model analysis implemented in SAS Version 9.1 (SAS Institute, Inc., Cary, NC) was used to test the significance of the effect of treatment on outcome measures. The main effect terms were treatment and difference time point with an unstructured covariance matrix. In the case of BDI, the main treatment effect indicated a trend (p = .12). Plots of the mean differences showed an increasing trend toward improvement. The treatment effects at Dif2 and Dif3 were tested using univariate tests (contrasts in the SAS mixed model), which are reported in the Results section for BDI. Multiple comparison corrections were not done. To examine the effect of adherence with compression (high or low) on physical outcome measures, compression adherence was added as a covariate in the statistical model, including treatment and difference time point.

Results

Participant Characteristics

Forty-nine participants provided voluntary written consent and underwent preliminary screening to determine whether they met study criteria. Thirty-two participants successfully completed the preliminary screening and were randomly assigned into four groups of 4 TG and 4 CG participants. Participant characteristics are provided in Table 2. Of the 32 participants entered into the study, 11 were not included in the primary statistical analysis because of the following concerns: triple bypass after baseline testing (1 CG participant), metastatic breast cancer (1 TG participant), participants who did not continue past 2.5 weeks (3 TG participants), and L-Dex scores and percentage swelling <10 (2 TG participants, 4 CG participants). Participant characteristics (age, weight change, body mass index, length of lymphedema, length of breast cancer diagnosis, and lymph nodes removed) were not significantly different for participants in the primary analysis compared with those not included in the primary analysis (data not shown). No adverse reactions were reported in this study.

Bioimpedance $z$ Measure

Bioimpedance $z$ mean differences of the affected arm of TG participants, compared with CG participants, showed a significant positive main effect for treatment ($F[1, 19] = 4.43, p = .049$; Figure 1).

Effect of Compression Adherence on Bioimpedance Measures

Compression adherence (high or low) was included as a covariate in the repeated-measures mixed model. Compression adherence was not significant in the model, and the main effect for treatment remained significant ($F[1, 19] = 4.09, p = .057$). The effect of adherence on bioimpedance measures is shown in Figure 2. Participants who complied with compression (high) in both TG and CG demonstrated graphs for TG compared with CG (Figure 2) similar to those of Figure 1. The low compression adherence TG participants (1 participant at Dif1 and Dif2 and 2 participants at Dif3)
### Table 2. Characteristics of Breast Cancer–Related Lymphedema Participants

<table>
<thead>
<tr>
<th></th>
<th>Participants Entered Into the Study</th>
<th>Participants Included in the Primary Analysis</th>
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<tbody>
<tr>
<td></td>
<td>TG ((n = 16))</td>
<td>CG ((n = 16))</td>
</tr>
<tr>
<td>Age (years)(^a)</td>
<td>57.0 ± 2.9 (30.7; 78.0)</td>
<td>59.7 ± 2.1 (42.2; 78.7)</td>
</tr>
<tr>
<td>Weight (lbs)(^a)</td>
<td>174.6 ± 10.0 (110; 285)</td>
<td>197.3 ± 13.2 (148; 328)</td>
</tr>
<tr>
<td>BMI(^a)</td>
<td>29.8 ± 1.6 (20; 48.8)</td>
<td>33.7 ± 2.3 (24.5; 54.3)</td>
</tr>
<tr>
<td>Stage of lymphedema</td>
<td>3 Stage I</td>
<td>5 Stage I</td>
</tr>
<tr>
<td></td>
<td>13 Stage II</td>
<td>11 Stage II</td>
</tr>
<tr>
<td>Length of lymphedema (months)(^b)</td>
<td>53.3 ± 13.8 (3; 222)</td>
<td>45.7 ± 14.4 (2; 228)</td>
</tr>
<tr>
<td>Length of breast cancer diagnosis (months)(^b)</td>
<td>66.1 ± 14.5 (5; 228)</td>
<td>79.2 ± 18.2 (14; 228)</td>
</tr>
<tr>
<td>Type of surgery</td>
<td>10 M; 6 L</td>
<td>4 M; 12 L</td>
</tr>
<tr>
<td>Nodes removed(^d)</td>
<td>18.2 ± 7.3 (8; 30)</td>
<td>13.4 ± 6.3 (2; 25)</td>
</tr>
<tr>
<td>Chemotherapy</td>
<td>1 N; 15 Y</td>
<td>6 N; 10 Y</td>
</tr>
<tr>
<td>Radiation</td>
<td>7 N; 9 Y</td>
<td>3 N; 13 Y</td>
</tr>
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</table>

\(^a\)Mean ± standard error of the mean; range (low; high).

\(^b\)BMI = body mass index; M = mastectomy; L = lumpectomy; TG = treatment group; CG = control group; N = no; Y = yes.

\(^d\)Note. Differences from initial test values are calculated by Dif1 = measures obtained at baseline (Mb) – measures at Time Point 2 (2.5 weeks); Dif2 = Mb – measures at Time Point 3 (5 weeks); and Dif3 = Mb – measures at Time Point 4 (3-month follow-up). 95% confidence error bars are shown.

**Figure 1.** Impedance z measure average differences in the affected arm of the treatment group (TG) participants compared with control group (CG) participants. Differences from initial test values are calculated by Dif1 = measures obtained at baseline (Mb) – measures at Time Point 2 (2.5 weeks); Dif2 = Mb – measures at Time Point 3 (5 weeks); and Dif3 = Mb – measures at Time Point 4 (3-month follow-up). 95% confidence error bars are shown.
appear to be outliers. The significant treatment effect of the exercise–relaxation program on bioimpedance z was not dependent on compression adherence.

**L-Dex Bioimpedance Scores**

L-Dex mean differences of TG participants improved over time, whereas those of CG participants did not (Figure 3). Although statistical analysis of L-Dex differences did not show a significant treatment effect \( p = .19 \), Figure 3 shows improvement in L-Dex scores of TG participants compared with CG participants at 3-month follow-up (L-Dex difference = 6.2, \( p = .10 \)).

**Volume Measurements**

Mean differences in volume of the affected arm obtained by the truncated cone method represented as differences from baseline values showed a reduction in swelling throughout the program \((223 \pm 41 \text{ mL at 5 weeks})\) for TG participants; however, there was not a significant treatment effect.

**Weight**

There was a significant positive treatment main effect for weight loss for TG participants compared with CG participants \((F[1, 19] = 5.00, p = .038)\). Weight loss at 5 weeks \((3.5 \pm 5.0 \text{ lb})\) in the TG was maintained at 3-month follow-up.

**AROM**

Total shoulder AROM (TotalSH) of the affected arm (Carette et al., 2003) was obtained by summing the work positions of SF, AB, and ER. Percentage of TotalSH was calculated compared with the sum of unimpaired values (TotalSH 440°; SF 180°; AB 180°; ER 80°; Scott & Trombly, 1983). Percentage improvement in TotalSH showed a significant positive treatment main effect \((F[1, 16] = 5.41, p = .034)\) for TG participants compared with CG participants (Figure 4).

IR was analyzed separately from positions of TotalSH, because IR is moving toward a position of rest and is involved in the relaxation component of the program and the exhaling breath. Percentage improvement differences in IR rest positions showed a significant positive treatment effect \((F[1, 18] = 6.23, p = .022)\) for TG participants compared with CG participants.

Individual AROM scores were examined by using a 20% reduction in AROM from unimpaired values as a criterion of impairment in AROM. The distribution of participants demonstrating impairments in AROM at baseline and
Figure 3. Mean LDex differences in treatment group (TG) participants compared with control group (CG) participants. See Figure 1 legend for calculation of difference points. 95% confidence error bars are shown.

Figure 4. Mean total shoulder active range of motion (AROM) score differences in the affected arm of the treatment group (TG) participants compared with control group (CG) participants. See Figure 1 legend for calculation of difference points. 95% confidence error bars are shown.
improvement of TG participants with AROM impairments at 5 weeks and 3-month follow-up compared with CG participants are shown in Table 3.

**Mood**

Differences in mood assessed by BDI scores showed a significant positive treatment effect for TG participants compared with CG participants at 5 weeks ($F[1, 19] = 3.95, p = .03$) and 3-month follow-up ($F[1, 19] = 6.90, p = .017$; Figure 5).

**QoL**

Significant treatment main effects in QoL assessed by the SF–36 Health Survey–II were observed in norm-based physical function ($F[1, 18] = 6.73, p = .02$) and general health ($F[1, 19] = 5.66, p = .03$) areas. Also, vitality showed a significant positive treatment effect at 5 weeks ($F[1, 19] = 2.96, p = .05$) for TG participants compared with CG participants.

**Relationship of Mood and QoL With Bioimpedance z Measures**

Bivariate plots illustrate the relationships between average bioimpedance $z$ measures and QoL (physical function, Figure 6; general health and vitality not shown) and mood (BDI not shown). The plot that shows improvements in both bioimpedance $z$ and physical function is highlighted. Significantly more TG participants compared with CG participants had improvement in average bioimpedance $z$ measures accompanied by improvement in average difference scores of mood (BDI, $N = 20, \chi^2 = 4.23, p = .04$) and QoL (physical function, $N = 19, \chi^2 = 6.54, p = .011$; general health, $N = 20, \chi^2 = 5.50, p = .019$; and vitality, $N = 20, \chi^2 = 5.05, p = .025$). (All $df = 1$ for the $\chi^2$ calculations.)

**Adherence**

Because explicit exercise–relaxation instructions were not determined for CG participants, a comparison of exercise–relaxation adherence between TG and CG participants could not be made. Adherence scores representing the number of times TG participants practiced exercise (E) and relaxation (R) techniques during a 7-day week demonstrated excellent adherence at 5 weeks ($E = 7.9 \pm 1.6, R = 8.7 \pm 1.7$) and good adherence reported at 3-month follow-up ($E = 5.3 \pm 1.0, R = 5.4 \pm 1.1$).

**Discussion**

The results of this study demonstrate that the BCRP provides a significant treatment effect in decreasing extracellular fluid in the affected arm, weight loss, improving shoulder AROM, mood, and QoL. Adherence in the treatment group was high. The improvement in L-Dex measures of lymphedema during the study was encouraging, with a 3-month follow-up of 6.2 L-Dex units. Significantly more TG participants with improvement in decreased extracellular fluid did improve in mood and QoL than CG participants, as demonstrated by the bivariate plots, possibly indicating a synergistic, feed-forward Circle of Healing effect in TG participants.

**Reduction of Extracellular Fluid**

No evidence-based, baseline standard of care for exercise for people with BCRL has been developed, probably because of the complication of cardiac activity during exercise, which increases the tissue pressure in the affected arm. Thus, the significant reduction of extracellular fluid in TG participants, as measured by bioimpedance, is an important finding of this study.

**Weight Loss**

The TG showed a significant main effect of weight loss compared with the CG at 5 weeks, which continued during the 3-month follow-up. This finding may be related to improved mood, self-efficacy, or educational information.

### Table 3. Summary of AROM Improvement in Participants With AROM Impairment

<table>
<thead>
<tr>
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<th>5 Weeks</th>
<th>3-Month Follow-Up</th>
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<tbody>
<tr>
<td></td>
<td>AROM Impaired$^a$ TG</td>
<td>AROM Impaired CG</td>
</tr>
<tr>
<td></td>
<td>Mean % Improvement ± SEM</td>
<td>n</td>
</tr>
<tr>
<td>SF</td>
<td>3</td>
<td>25.18 ± 5.61</td>
</tr>
<tr>
<td>SA</td>
<td>3</td>
<td>15.37 ± 0.81</td>
</tr>
<tr>
<td>ER</td>
<td>3</td>
<td>32.92 ± 12.81</td>
</tr>
<tr>
<td>IR</td>
<td>7</td>
<td>27.75 ± 10.63</td>
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*Note. AROM = active range of motion; TG = treatment group; CG = control group; SF = shoulder flexion; SA = shoulder abduction; ER = external rotation; IR = internal rotation; SEM = standard error of the mean; n = number of participants impaired.

$^a$AROM was considered impaired if AROM was 20% less than expected value.

$^b$Mean % improvement was from baseline values.
Figure 5. Beck Depression Inventory (BDI) score mean differences in treatment group (TG) participants compared with control group (CG) participants. See Figure 1 legend for calculation of difference points. 95% confidence error bars are shown.

Figure 6. Bivariate plot of average bioimpedance $z$ differences versus average quality-of-life (QoL) physical function (PF) score differences. Averages were calculated by using measures at the three difference timepoints. Highlighted quadrant indicates improvement in average differences of both measures.

Note. TG = treatment group; CG = control group.
gained during the program. This result is encouraging because a high incidence of unwanted weight gain has been seen after breast cancer surgery and chemotherapy treatment (Goodwin et al., 1999). Obesity has been linked to the development of lymphedema (Werner et al., 1991) and upper-extremity symptoms (Westrup, Lash, Thwin, & Silliman, 2006). Weight gain in breast cancer patients has been seen consistently in people with low exercise levels. Conversely, exercise has been linked to successful weight stability (Werner et al., 1991).

**Range of Motion**

The TG, compared with the CG, demonstrated a significant positive treatment effect in total shoulder AROM work positions, flexion, abduction, and external rotation. Internal rotation (moving toward a position of rest) also gave a significant positive treatment effect. Limited shoulder flexibility is reportedly one of the most serious emotional concerns of people undergoing breast cancer surgery (Kuehn et al., 2000), and its consequences persist even 20 years after surgery (Kornblith et al., 2003). Reductions in SA, SF, and ER were found after axillary radiotherapy (Johansson, Ingvar, Albertsson, & Ekdahl, 2001).

**Mood and QoL**

BDL and QoL scores showed significant positive treatment effects for TG compared with CG participants. It is surprising that the therapeutic application of DDB relaxation techniques appears not to be used by many people with BCRL, even with the growing number of studies linking their positive emotional components to immune system benefits.

**Relationship of Mood and QoL With Bioimpedance Measures**

Bivariate scatter plots indicate that TG participants who showed improvement in mood and QoL also showed improvement in bioimpedance $z$ (Figure 6), reinforcing the proposed BCRP Circle of Healing concept. Relaxation techniques, including DDB, may have helped to lower levels of stress, which in turn could have positive effects on the immune system to provide healing effects on lymphedema.

**Adherence**

TG participants showed excellent adherence to the exercise and relaxation regimen during the 5-week program and good adherence at 3-month follow-up. Good lymphedema treatment outcomes have been shown to be significantly related to good adherence (Boris et al., 1997), yet achieving exercise adherence for people with BCRL appears to present more barriers than for primary breast cancer patients (Passik & McDonald, 1998). A successful, standardized program with established efficacy should promote adherence. Adherence with compression was not a significant main effect when included as a covariant in the mixed-model analysis of $z$ scores; participants most compliant with compression did not show the most improvement in bioimpedance $z$ scores.

**Implications of the Circle of Healing Strategy**

This program is based on the premise that a Circle of Healing (Figure 7) may result in improvements in feed-forward loops in areas of exercise, physical and emotional status, and immune functioning in people with BCRL. In this Circle of Healing, progress made in one area of the healing circle may encourage more progress along the feed-forward loop in other areas. This healing loop is seen as self-perpetuating and self-motivating because people with BCRL who have devastating physical and psychological morbidity and who are desperate to regain a sense of health and completeness find relief and self-efficacy when they benefit from an initial success in one area, motivating them to achieve continued progress. Although each area may have a positive effect on the status of lymphedema, the continuation of progress may have an even higher motivating effect on continued adherence and improvement in lymphedema.

The rationale for the BCRP feed-forward Circle of Healing concept (Figure 7) is derived from the knowledge base of lymphatic system physiology in areas of exercise, DDB, mood and QoL, and immune function. We explore the healing loop areas by first choosing the area of exercise, although we could begin at any point on the circle of healing.

More than 100 studies have reported universal and multifactorial benefits of exercise for cancer patients (Young-McCaughan & Arzola, 2007), including a biopsychosocial mechanism thought to improve an ability to cope with cancer diagnosis (Pinto & Maruyama, 1999). Exercise has been shown to enhance macrophage action (Woods, Davis, Smith, & Nieman, 1999) and improve lymph flow (Lane, Dolan, Worsley, & McKenzie, 2007), in part by skeletal muscle movement (Mazzoni, Skalak, & Schmid-Schonbein, 1990). Moderate, not high-intensity, exercise has been shown to result in a dosage-related increase in enhanced oxidative burst immune activity (killing pathogens once engulfed; Nieman, 1997), although by contrast, lack of motion leads to greatly decreased lymph flow (Foldi, 1977). This program may be tapping into the ability to enhance oxidative burst immune activity to kill pathogens by keeping the intensity at the low to moderate levels. The video’s low-to-moderate intensity is used to establish an acceptable exercise baseline, but it has the potential for increased intensities, such as the addition of weights (not evaluated in this study). The 17-min duration of exercise is thought to result in the greatest
amount of lymph flow in the shortest amount of time that would fit into a person’s busy daily schedule and fit within the U.S. insurance reimbursement of one unit of therapeutic exercise treatment time. Also, a 15-min exercise duration has been shown to result in the highest amount of lymph flow (five times higher than at rest; Coates, O’Brodovich, & Goeree, 1993).

DDB is a recommended component of the Casley-Smith and Vodder lymphedema treatment approaches (Brennan & Miller, 1998; Casley-Smith & Casley-Smith, 1997) because of its ability to facilitate lymph flow during respiration (Brennan et al., 1996). Exercise with DDB has been reported to decrease arm volume in one noncontrolled study (Moseley et al., 2005). DDB may be an important exercise component involved in the success of the BCRP because of its role in clearing the proximal trunk so excess fluid from the affected arm can then be drained.

The next area of the Circle of Healing involves the effect of exercise to result in emotional benefits. Exercise and depression are inversely related and apparently can be extrapolated to include people with mild to moderate depression, even in the absence of cardiovascular benefits (LaFontaine et al., 1992). Exercise has been shown to provide emotional benefits in specific QoL areas for breast cancer (Courneya et al., 2003) and people with BCRL. Historically, DDB and relaxation techniques have been a significant component of the mind, body, and spirit exercises of yoga, tai chi, and qigong, and several studies have identified the efficacy of these techniques for initiating improvements in emotional areas and immune function (Cohen et al., 2006; Ryu et al., 1995). The slow, graceful exercise in the BCRP, with DDB, is designed to work as a relaxation technique to improve emotional states. Other exercise programs that do not incorporate exercise for relaxation may not be able to achieve these emotional gains as easily.

The next area of this proposed healing loop involves the effect of emotional states and stress on the immune system. More than 300 studies have shown that psychological stress is capable of a dose-related modification of the immune system. Behavior and stress are postulated to enter the body through sympathetic fibers descending from the brain into bone marrow, thymus, spleen, and lymph nodes (Segerstrom & Miller, 2004). Lowering stress through the relaxation techniques of the BCRP may have the added potential of strengthening the immune system.

The final area completing this healing loop involves the immune system’s effect on the lymphatic system. It is reported that extrinsic and intrinsic interactions within the central nervous system, exercise, and mood affect the strength of the immune system (Webster, Tonelli, & Sternberg, 2002). Immune function has been shown experimentally in the skin of lymphedematous limbs to be suppressed in both the afferent and the efferent loops (Mallon, Powell, Mortimer, & Ryan, 1997). In turn, the interactive immune system’s response to environmental events helps it regulate the central nervous system (Segerstrom & Miller, 2004) as it lyases large,
macromolecule proteins, which are involved in the worsening of lymphedema symptoms. In addition, the immune system provides a protective factor from infection (Petrek & Heelan, 1998), a major concern for people with BCRL. A healthier physiological state within the affected lymphedema-tous area may improve lymphatic function and physical and emotional BCRL symptoms for the mind, body, and spirit. The BCRP, which is designed to promote the healing loop to work in a feed-forward strategy, resulted in physical and emotional symptom improvements. Programs that do not address both physical and emotional areas of healing may not result in as high of a degree of symptom improvement.

Future studies could be conducted with an increased number of participants to evaluate effects that did not reach significance because of the low number of participants. Also, the addition of graduated weights to the program, the role of DDB in achieving positive study outcomes, the program’s role in preventing lymphedema postsurgery, and the use of this program for hospice and other cancer or health diagnoses could be explored. Future studies could evaluate individual components of the BCRP to evaluate which had the most significant outcome results.

Conclusions

The results of this controlled, randomized, evidence-based study support the BCRP as a standardized program of exercise and relaxation showing improvements in physical and emotional BCRL symptoms. For the primary benefit of people with BCRL and, secondarily, for insurance reimbursement issues, an evidence-based program that improves BCRL physical and emotional symptoms and that is easy to implement in the clinic and home setting, is cost-effective, is flexible to daily schedule changes, and promotes good adherence should be valuable. ▲

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References


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