2010

Utilising a Combined Exercise and Counselling Program to Examine the Relationship Between Emotional Self-Efficacy and Physiological Improvements in Breast Cancer Survivors

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Publication Details

Buchan, J. K. (2010). Utilising a Combined Exercise and Counselling Program to Examine the Relationship Between Emotional Self-Efficacy and Physiological Improvements in Breast Cancer Survivors (Master of Health Sciences). University of Notre Dame Australia.
http://researchonline.nd.edu.au/theses/45

Methodology

Subject Characteristics

Twenty-one women between the ages of 30 and 75 years volunteered and were eligible for participation in this study. Participants were initially recruited from oncology specialists, Cancer Council WA and cancer support groups operating in Perth. Additional recruitment was then done using informational fliers distributed to local breast care clinics and via word of mouth from other program participants and involved staff.

Inclusion criteria for participation were:

- Female with confirmed diagnosis of Stage I, II or III invasive breast cancer;
- Between the ages of 30 and 75 years;
- Completed with all planned surgery, chemotherapy and/or radiation therapy;
- Participants receiving adjuvant hormonal therapy or trastuzumab (Herceptin) were still eligible.
- Apparently healthy, based on PAR-Q and physician approval;
- Not currently involved in a structured exercise or diet program.

Criteria for exclusion from the study included:

- Acute or chronic bone, joint, or muscular abnormalities that would compromise ability to participate in the exercise rehabilitation program;
- Metastatic disease;
- Immune deficiency that would compromise the participant's ability to participate in the exercise testing;
- Unable to understand written or verbal English.

No inclusion or exclusion criteria were included related to mental health. Upon referral to the program, participants contacted the program director to determine preliminary study eligibility. This eligibility was based on meeting the inclusion criteria outlined above and being able to commit to the program attendance requirements. Any individual deemed ineligible following this phone call was given information on other gym-based exercise programs and local services. Those individuals meeting eligibility criteria were then mailed a package including: a

consent form, clearance form to be signed by an oncologist or personal GP, medical history, pre-evaluation guidelines, Physical Activity Readiness Questionnaire (PAR-Q) and four questionnaires used to establish a baseline psychological level (Appendix A). The questionnaires utilised were the Stanford Emotional Self-Efficacy Scale-Cancer to measure emotional self-efficacy, the Piper Fatigue Scale to assess fatigue levels, the Beck Depression Inventory (BDI) to determine depression level and the Functional Assessment of Cancer Therapy-Breast (FACT-B) to assess quality of life. Once participants had completed the questionnaires and obtained approval from their oncologist or GP, a facility visit was scheduled to ensure eligibility and, if appropriate, conduct a baseline physiological assessment and group randomisation.

Study Design

This study utilised a randomised four-group design consisting of an exercise-only group (Ex, n=5), a counselling-only group (C, n=5), a combination exercise and counselling group (ExC, n=5) and a delayed treatment usual care control group (UsC, n=6). Participants were randomised to each group on a rolling enrolment basis, for a total of twenty-one participants in the study. Each group had eight weeks in their allocated group of either counselling-only, exercise-only, exercise and counselling, or usual care. After these 8 weeks, all participants spent the remaining 12 weeks undertaking both exercise and counselling, regardless of their initial group assignment. This resulted in a total intervention time of twenty weeks (Figure 2).

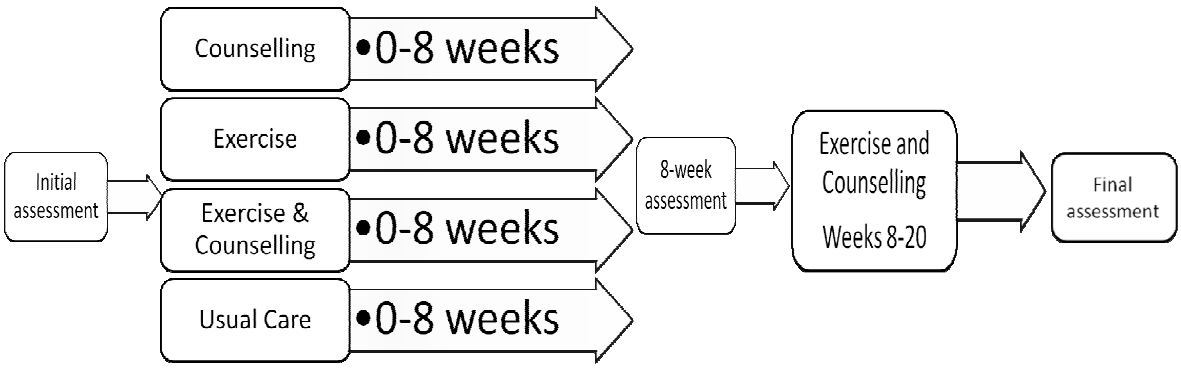

Figure 2. 20-week group allocation

This design was chosen for ethical and retainment reasons. By having eight weeks of group-specific treatment, it was possible to have a control group and assess the treatment-specific benefits of counselling separately, exercise separately, and the two modalities combined. Enrolling all participants in exercise and counselling during their remaining 12 weeks prevented any participants not initially in the exercise and counselling group from feeling mislead. In other words, participants interested in the program believed they were going to receive both exercise and counselling, so it was deemed important to offer this opportunity during the second half of the program to maintain participant interest and trust.

Assessment

General fitness and psychological assessments were conducted on all participants prior to commencing the intervention program, at the eight-week mark and upon completion of the five-month intervention. These assessments included obtaining measurements of the dependent variables (emotional self-efficacy, body composition, cardiorespiratory endurance, strength, and flexibility), along with other physiological and psychological parameters monitored for additional research purposes outside of this study. All assessments were conducted at the Institute of Health and Rehabilitation Research on the campus of the University of Notre Dame-Australia in Fremantle, Western Australia. Ethical approval for all testing procedures was obtained from the university's Human Research Ethics Committee.

Procedures

Psychological assessment. Subjects completed the first of three psychological assessments prior to visiting the study facility and meeting the program coordinators (Appendix B). This was done in an attempt to minimise the impact of seeing the facility and meeting the researcher on obtaining a baseline psychological state. Evaluation was done via mail, with each participant receiving a packet of questionnaires after an initial phone conversation with the program director to confirm eligibility. Psychological parameters assessed included the dependent variable of emotional self-efficacy, along with three other parameters:

1) Emotional self-efficacy (Stanford Emotional Self-Efficacy Scale-Cancer)

2) Depression (Beck Depression Inventory)
3) Fatigue (revised Piper Fatigue Scale)
4) Overall quality of life (Functional Assessment of Cancer Treatment-Breast)

The Stanford Emotional Self-Efficacy Scale-Cancer (SESES-C) was utilised to assess emotional self-efficacy (Giese-Davis et al., 2004). This 15-item scale assesses a patient's confidence in three domains: communicating emotions in relationships, focusing on the present moment and confronting death and dying. It uses a Likert-type scale from 0-100, in increments of 10, ranging from 'not at all confident' to 'completely confident'. Total score is determined by calculating the mean response across all 15 items. Validity for use in the cancer population was assessed and supported with three studies, examining scale structure, concurrent and predictive validity and generalisability (Giese-Davis et al., 2004). Test-retest reliability over a three-month period has also been demonstrated (r=0.80-0.95) for both the subscales and total score (Giese-Davis et al., 2002).

Depression levels were measured with the Beck Depression Inventory (BDI) (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961), which asks 21 questions assessing varying aspects of depression. Each question has four to five statements of increasing severity, and scores for each item range from zero to three. Total scores fall between 0 and 26, with a higher score corresponding to a higher degree of depression. Studies have found this is a suitable tool for assessing depression in general practice, when health professionals may not be of a psychology background (Salkind, 1969).

To assess fatigue, the revised Piper Fatigue Scale was used (Piper, Dibble, Dodd, Weiss, Slaughter, & Paul, 1998). There are four subscales to this questionnaire, each assessing a different component of fatigue: behavioural subscale, affective subscale, sensory subscale, and cognitive and mood subscale. The patient is presented with 22 questions in total, and the average score represents the total fatigue score. Each question is answered by the patient circling a number best describing their current status, with the Likert scale ranging from 0 (none) to 10 (a great deal) of fatigue

(Piper et al., 1998). A higher overall average score corresponds with a greater level of fatigue. This assessment tool has a standardised Cronbach alpha of 0.97 and subscale reliability ranging from 0.92-0.96 (Piper et al., 1998; Hsieh, Sprod, Hydock, Carter, Hayward, & Schneider, 2008).

The Functional Assessment of Cancer Therapy-Breast (FACT-B) was utilised to assess participant quality of life (Cella et al., 1993; Brady et al., 1997). This instrument is composed of 44 items and consists of the FACT- General (FACT-G) plus the Breast Cancer Subscale (BCS), which assesses issues specific to quality of life in breast cancer. Studies with breast cancer patients have concluded this tool is suitable for use in clinical practice, with sufficient test-retest reliability, a high alpha coefficient (alpha =0.90) and subscale alpha coefficients ranging from 0.63 to 0.86 (Brady et al., 1997).

A reassessment was then conducted at the eight-week mark of a participant's program by issuing the questionnaires at the session prior to their mid-program physiological assessment and collecting them on testing day. A final assessment was done at the completion of the overall five-month intervention, with participants being issued the questionnaires at the session prior to their final day and returning them upon attending the last session.

Physiological assessment. Upon entry into the study, all participants underwent a baseline physiological assessment prior to commencing the program (Appendix C). This battery of tests measured the following parameters:

1) Resting vitals (resting heart rate-RHR, blood pressure-BP, and pulse oximetry for determination of haemoglobin saturation
2) Height, weight, and Body Mass Index (BMI)
3) Body circumferences
4) Body composition (skinfolds)
5) Cardiorespiratory endurance ($\dot{V}O_{2max}$)
6) Muscular strength (YMCA Bench Press and 1-RM Leg Press
7) Flexibility (Sit-and-reach)

These assessments were also completed at the eight-week mark of each participant's program, and following completion of the full five-month intervention. The protocol used for each of these assessments is presented in the following sections.

Resting vitals, height and weight. Upon the participant's arrival, each was instructed to relax in a chair while answering questions pertaining to cancer treatment history, other medical conditions and history, and exercise history. Resting heart rate and haemoglobin saturation were then determined utilising a Nonin Onyx pulse oximeter (Minnesota, USA), and a 3M™ Littman stethoscope (Minnesota, USA) and blood pressure cuff were used to gain a resting blood pressure. Following the obtainment of resting vitals, participants were instructed to remove their shoes in order to obtain a height and weight measurement using a wall-mounted stadiometer for height and an A&D Weighing scale (California, USA). These two values were then used to calculate the participant's BMI utilising the equation: weight (kg)/height^2 (m^2).

Body circumferences and skinfolds. After measuring resting vitals, body circumferences and skinfold measurements were taken. Circumferences were obtained at the following sites:

1) Gluteus-most prominent part of the gluteal region
2) Waist-smallest part of the torso, above the umbilicus and below the xyphoid process
3) Abdominal-level with the umbilicus
4) Upper arm (both)-widest part of the arm between the elbow and shoulder
5) Lower arm (both)-widest part of the arm between the wrist and elbow
6) Thigh (both)-widest part of the leg between the knee and groin

A seven-site skinfold measurement was then done to determine percent body fat. The seven sites used were: triceps, chest, subscapular, midaxilla, abdomen, suprailiac, and thigh (Jackson, Pollock, & Ward, 1980). All measurements were taken on the side of the unaffected breast. Due to a double mastectomy, a three-site

skinfold measurement was conducted on one of the women to determine percent body fat, using the triceps, suprailiac, and thigh. For both the seven- and three-site tests, each site was measured in a rotational order until two measurements were obtained for each site. Any areas with consecutive measurements more than 2 mm apart were measured for a third time (American College of Sports Medicine [ACSM], 2006). After obtaining an average for each site, the sum of the sites was plugged into an equation devised by Jackson and colleagues to determine body density (1980). This value for body density was then used in an age-specific equation developed by Heyward and Wagner to calculate percent body fat (2004).

Care was taken to ensure skinfold measurements were a reliable reflection of participant body fat. Whenever possible, the same researcher conducted measurements for the participant's three assessments. This was done in an attempt to minimise the amount of between-technician error, which has been found to be greatest for measurements of the abdomen and thigh (Lohman, Pollock, Slaughter, Brandon, & Boileau, 1984). When care is taken to minimise measurement error, skinfold measurements have been demonstrated to produce similar values for subcutaneous fat as those found by magnetic resonance imaging (Hayes, Sowood, Belyavin, Cohen, & Smith, 1988).

Cardiorespiratory endurance. Cardiorespiratory endurance was assessed using the Modified Bruce Treadmill Protocol, a multistage, variable speed and elevation treadmill test used to estimate $\dot{V}O_{2max}$. The test begins with a 3-minute warm-up stage of 0% incline and 2.74 kph speed, with speed, incline or both then increased every 3 minutes (Lerman, Bruce, Sivarajan, Pettet, & Trimble, 1976). Testing stops when the participant reaches 75% of their maximum heart rate ([220-age] x 0.75) or requests to stop. A F4 Polar Heart Rate Monitor (Kempele, Finland) was used to monitor each participant's heart rate during testing.

The Modified Bruce protocol was chosen to assess cardiorespiratory endurance due to the population being tested. Participants tended to be higher risk for physical and deconditioned, so the use of a maximal exercise test such as the Bruce protocol was deemed unsafe. A study by McInnis and Balady (1994) found similar physiological

responses in heart rate and blood pressure when comparing the Bruce and the Modified Bruce protocols. When using submaximal exercise tests to predict $\dot{V}O_{2max}$, research has shown values tend to be underestimated for untrained, inactive individuals (Heyward, 2006). Additionally, the Modified Bruce protocol's reliance on an age-predicted heart rate maximum may result in a 10-15% error in $\dot{V}O_{2max}$ prediction (Heyward, 2006, p. 67). Despite these limitations, submaximal tests can still provide a relative idea of baseline fitness while not increasing the risk to the participant.

Muscular strength. The YMCA Bench Press test was utilised to estimate upper-body muscular strength (Golding, 1989). Participants were positioned supine on a flat bench and given a 35-lb (15.9 kg) bar. They then performed as many repetitions as possible at a set cadence of 30 repetitions per minute, with pace established using a metronome. Testing was stopped when the participant could no longer maintain the exercise cadence or chose to stop (Kim, Mayhew, & Peterson, 2002). Due to its attempt to control for repetition duration and posture alignment, ACSM views this test as having high reliability (2006).

A 1-RM leg press test was utilised to assess lower-body dynamic strength. Using a seated leg press set at a 45-degree angle, the participant was fitted on the machine and allowed to warm up by completing five repetitions at 40 to 60% of their estimated 1-RM. A one-minute rest was then given, during which the participant was instructed to stretch the muscle group. This was followed by three to five repetitions of the leg press at 60 to 80% of the estimated 1-RM. Weight was then increased, and a 1-RM lift was attempted. If successful, the woman was given a three-minute rest before attempting the next weight increment. This procedure was repeated until a 1-RM value was obtained. All attempts were made to achieve this weight within three to five trials (Heyward, 2006). Precautions were made to ensure testing was done as safely as possible. The researcher ensured each participant had an adequate warm-up before attempting the 1-RM lift and closely monitored the lift to ensure correct technique and breathing. When properly administered, the 1-RM leg press provides a valid measure of lower-body strength (ACSM, 2006).

A handgrip dynamometer was utilised to assess static grip strength. The grip was adjusted to a position comfortable for the individual. The participant was then made to stand erect, with the arm straight and slightly abducted, shoulder adducted and neutrally rotated, forearm in the neutral position and wrist in slight extension (Canadian Society for Exercise Physiology [CSEP], 2003). Once positioned, the woman used on brief maximal contraction to squeeze the handgrip, avoiding any extraneous body movement. Two trials were conducted with each hand, and the highest score was recorded as static strength.

Flexibility. To assess flexibility, the standard box sit-and-reach test was used (ACSM, 2006). Participants completed this following the muscular endurance and strength assessments to minimise the risk of muscle pulls potentially resulting from attempting to stretch cold muscles. The test utilised a sit-and-reach box with the toe line at 23 centimetres (Heyward, 2000). The test was completed barefoot, with the participant instructed to sit on the floor, knees extended and soles of the feet against the outside edges of the box. Keeping knees fully extended, arms evenly stretched in front and hands parallel with palms down, the woman slowly moved a marker along the top of the box, head down, as far as possible. This hold was maintained for two seconds, with the score corresponding to the distance the marker was moved with both hands. Three trials were completed, and the furthest distance was recorded. This test has been suggested to be a good measure of hamstring flexibility, but limited in assessing lower back flexibility (Jackson & Baker, 1986; ACSM 2006).

Interventions

Counselling protocol. Women randomised into the counselling-only or exercise and counselling combination group attended a weekly one-on-one counselling session for approximately 45 to 60 minutes for the 5-month duration of the program. Those placed into the exercise-only or usual care group began counselling after their first 8 weeks were over, at which point all groups began both exercise and counselling for the remaining 12 weeks. Session frequency was determined over the course of the study on a needs-based schedule discussed between the counsellor and participant. Sessions were completed on the same day as one of the exercise sessions if the participant was in the combination group. All

sessions were conducted by a Master of Counselling student trained and supervised by an accredited psychologist.

The general aim of the counselling sessions were to form relationships, let the participants have a voice, and learn how to do so outside of the counselling sessions, and aid the women in exploring what they have been through and where to go from there. Though specific issues and events discussed were kept confidential between the counsellor and participant, a few key themes were relevant for most participants. Sessions primarily focused on relationship issues, working on ways of verbalising thoughts and concerns with family and friends and taking back some control in situations. Other topics of discussion were stress management, searching for the positive, dealing with issues of the past, and embracing changes and positive risk-taking.

Exercise protocol. Participants in the exercise-only group and exercise and counselling combination group were instructed to attend one to three weekly sessions lasting for approximately one hour, for a five-month period at the rehabilitation centre anytime during open clinic hours on Monday, Wednesday and Friday mornings. All sessions were overseen by an accredited exercise physiologist, and also by qualified personal trainers responsible for providing direct supervision of participants. Each exercise session consisted of flexibility, resistance training and an aerobic component, lasting for at least 20 minutes, as recommended by ACSM for special and elderly populations (2006). Each session began with an aerobic warm-up and workout, utilising a treadmill, seated bicycle, upright bicycle or crosstrainer (Appendix D). Initial cardiorespiratory activity length and intensity was customised for each participant based on the results of their baseline testing, and time was progressed until 20 to 30 minutes of activity could be comfortably achieved. Interval training, utilising changes in speed, resistance or incline, was incorporated as participants progressed in the aerobic component. Resistance and balance training was then undertaken for approximately 20 to 30 minutes, and each session ended with a 5- to 10-minute cool-down utilising a light cardiorespiratory component and whole-body static stretching. For the resistance training component, 8 to 12 different exercises were incorporated into the session, with participants performing 1 to 2 sets

of 8 to 20 repetitions, depending on the exercise and the individual participant's baseline results and progression. Programs were updated weekly to include more repetitions, sets, weight increase or new exercise as the participant advanced in the program. To perform the various resistance exercises, free weights, weight machines, therabands and own body weight were utilised, depending on the exercise. Undertaken exercises targeted all major muscle groups, with a trainer carefully monitoring performance to ensure correct form and control. Balance tasks were also performed, utilising single-leg standing before progression to single- and double-leg balance tasks on a BOSU ball.

A home-based program was also devised and implemented using an earlier program created by Sandy Hayes and Elizabeth Eakin as a guideline (2006). Participants attended at least one session at the clinic each week, and then completed the remaining sessions at home using a theraband, fitball and available cardiorespiratory equipment. Each participant was shown the home program during her initial exercise session, and was then given ways to advance this program as she progressed. Women were also able to use this program if they went on holiday during their time in the intervention. A weekly home exercise log and home program exercise booklet was given to each participant to ensure correct adherence and provide guidance (Appendix D).

Usual care control group. Women enrolled in the usual care group completed the initial physiological and psychological assessment and were then encouraged to maintain their normal daily activities during the eight weeks they were in the usual care group. Additionally, the participants were instructed not to enrol in any structured physical activity or counselling programs for those two months. Each woman was then contacted during week seven of her involvement in the study and scheduled for her mid-program assessment, during which she completed the same physiological and psychological tests done at baseline. The participant was then enrolled in both exercise and counselling for the remaining 12 weeks of the intervention.

Adherence

Adherence to exercise was monitored for each participant. The number of counselling sessions was on a needs-based schedule based on both the clinician's recommendation and the participant's willingness, so specific attendance figures were not recorded. Instead, adherence was measured as whether or not the participant attended counselling until she was "graduated" by the counsellor. With exercise, attendance was recorded for each session, with home-based sessions monitored by checking the exercise log completed by the participant. Reasons for any missed sessions were tracked as well. Women who went on holiday during program duration were given a home-based program and daily log to minimise missed sessions. Participant dropout and reasoning was also recorded.

Statistical Analysis

Statistical analysis was completed using the Statistical Package for the Social Sciences (SPSS) version 17.0 software (SPSS Inc., Chicago, IL). Due to the small sample size, nonparametric testing was utilised for data analysis. Baseline descriptive statistics were compared using the Kruskal Wallis test and asymptotic significance values for continuous variables and Fisher's Exact test values from Chi-Square crosstabs with two-tailed exact significance results for categorical variables. Between-group analyses comparing Δ8wk, Δ12wk, and Δ20wk values were completed utilising Kruskal Wallis testing and asymptotic significance values, with no adjustments made for baseline variation. Within-group comparisons were made using Wilcoxon Signed Ranks test from baseline to 8 weeks, 8 weeks to 12 weeks, and baseline to 20 weeks, looking at 2-tailed exact significance values. Spearman Rho correlation was performed to examine the relationship between emotional self-efficacy and both adherence and physiological and psychological changes over the 20 weeks. Median and range were reported for relevant analyses due to the use of nonparametric tests, though mean and standard error values were included as well. Discrepancies between the median and mean values are addressed by presenting information on individual scores that may have impacted the groups' values. The significance level for all comparisons was set at $p=0.05$. To examine if any groups experienced a clinically significant change in the main variable of interest, emotional self-efficacy, from baseline to the end of the 20-week intervention, Jacob Cohen's suggestion of using an effect size of 0.50 was utilised (1988).

CHAPTER 4