EFFECTS OF PILATES EXERCISES ON SHOULDER RANGE OF MOTION, PAIN, MOOD
AND UPPER EXTREMITY FUNCTION IN WOMEN LIVING WITH BREAST CANCER:
A PILOT STUDY

by

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ABSTRACT

Effects of Pilates Exercises on Shoulder Range of Motion, Pain, Mood, and Upper Extremity Function in Women Living with Breast Cancer: A Pilot Study

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Background and Purpose: Our purpose was to examine the effects of Pilates exercises on shoulder range of motion (ROM), pain, mood, and upper extremity (UE) function in women who had been treated for breast cancer.

Participants: Participants were four women who had undergone axillary dissection and radiation therapy for Stage I-III breast cancer. Methods: A non-concurrent, multiple baseline, single subject research design was used to examine the effects of Pilates exercises on the four outcomes. Results: Visual analyses of the data suggest a moderate functional relationship between the implementation of the Pilates program and improved shoulder abduction and external rotation ROM. Statistically significant improvement in shoulder internal and external rotation on the affected UE was shown for the participant with metastatic disease. The improving baselines seen for pain, mood and UE function data make it impossible to assess Pilates’ effects. No adverse events were experienced.

Discussion and Conclusion: Pilates may be an effective, enjoyable and safe exercise option for women recovering from breast cancer treatments; however further research is needed.
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LIST OF ABBREVIATIONS

QOL  Quality of life
UE   Upper extremity
ROM  Range of motion
SSRD Single subject research design
BPI  Brief Pain Inventory – Short Form
WHO  World Health Organization
POMS Profile of Mood States
UEFQ Upper extremity function questionnaire
IT   Instructor trainer (for Pilates exercise)
Rho ($r_h$) Inter-rater correlation coefficient
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CO-AUTHORSHIP STATEMENT

Chapter 1 represents a review of the literature relating to the thesis. It is co-authored with Susan R. Harris, Joseph M. Lucyshyn and Donna L. MacIntyre.

My contributions to this chapter include:

- refining the research question and designing the literature search strategy, with the assistance of my co-authors
- conducting the literature search and selecting relevant data
- synthesizing the findings
- preparing the initial draft of the chapter, and incorporating co-author suggestions into subsequent versions

Chapter 2 represents a manuscript to be submitted to the journal *Physical Therapy*, and is co-authored with Susan R. Harris, Joseph M. Lucyshyn and Donna L. MacIntyre.

My contributions to this manuscript include:

- coordinating the research design, under the direction of my co-authors
- coordinating recruitment and data collection
- administering the intervention
- preparing the initial draft of the manuscript and incorporating co-author suggestions into subsequent versions

I am the primary author and identified as the corresponding author for journal submission for the manuscript presented in chapter 2.

Chapter 3 is a summary chapter, and not intended to be a manuscript for submission.
1.1 Introduction

The goal of rehabilitation is to restore independence and self-sufficiency with a focus on quality of life (QOL), a multidimensional concept involving physical, psychological, emotional, social and spiritual well-being. Functional and emotional well-being are the strongest predictors of overall QOL for women and functional QOL is often the least possessed but most important QOL dimension underlying overall life satisfaction. The diagnosis and treatment of breast cancer can have profoundly negative impacts on quality of life, making rehabilitative interventions that impact physical and psychological functioning, resulting in improved QOL, necessary.

Conventional forms of exercise/physical therapy as well as dance therapy have been investigated as interventions to enhance various aspects of QOL in women living with breast cancer, both during and after cancer treatment. Complementary forms of exercise, such as Pilates, yoga and Feldenkrais, have received little research attention as part of cancer rehabilitation. Complementary therapies are those that improve quality of life; address issues of the body, mind and spirit; and help to manage symptoms. Up to 80% of women living with breast cancer use complementary and alternative therapies.

1.2 Literature Review

Systematic searches of PUBMED, MEDLINE, CANCERLIT and CINAHL (1983-May 2006) revealed no studies involving the effects of Pilates exercise on women living with breast cancer. Keywords used were breast cancer, breast neoplasm, Pilates, radiation, axillary dissection and rehabilitation.

Axillary dissection and radiation are common in the management of breast cancer. Axillary surgery and irradiation are predictive factors for developing reduced shoulder mobility in the affected upper extremity (UE). This physical complication has been reported to last up to 11 years after initial treatment. In Kwan and colleagues' survey of women 2-7 years post diagnosis and treatment, 49.9% experienced at least one UE problem, including one or more of the following: arm or hand swelling, shoulder or arm stiffness and lymphedema. At 2 years post surgery, Johansson and colleagues found that none of their sample of women (n=96) living with breast cancer had regained pre-treatment shoulder internal rotation range of motion (ROM). Another study found significant restriction of shoulder ROM in 14.1% of women who were 6-96 months post breast conserving therapy or mastectomy, including axillary dissection. The mean restriction was 21° for abduction and 12° for flexion, compared to the contralateral shoulder. Sneeuw and colleagues' study of women 2-11 years post treatment (mean
of approximately 4 years) revealed that 14% had a limitation in arm movement that the participants rated as moderate to severe. Voogd et al\textsuperscript{38} examined the results of a treatment-specific questionnaire given to women who had axillary dissection an average of 4.2 years prior to the study. Twenty-six percent of patients in the study reported a difference in arm circumference of 2 cm or more (which can be indicative of lymphedema), or a difference in shoulder abduction of 20° or more between their affected and unaffected UEs. Voogd et al found that the differences in arm circumference of 2 cm or more and the limitation of shoulder abduction of 20° or more were strong indicators for the presence of severe physical complaints, limitations in everyday life and psychosocial problems for women who had axillary lymph node dissection for breast cancer.\textsuperscript{38, p.79} Ernst et al\textsuperscript{39} found a difference of more than 20° in shoulder abduction, extension or flexion in 12% of patients post axillary dissection. Fifty-two percent of the patients studied were 6-12 months post axillary dissection, and 48% had undergone surgery more than five years before the study. Clearly not all women regain full shoulder motion.

It has been suggested that post-operative exercise programs could prevent the shoulder stiffness and decreased ROM that often follow axillary surgery and radiation.\textsuperscript{31} Exercise may also decrease the pain and discomfort associated with fibrosis secondary to treatment.\textsuperscript{40} Limited evidence suggests that women who have had axillary dissection can safely engage in UE exercise without developing lymphedema.\textsuperscript{16,41,42} Patients who have been treated with radiotherapy may benefit from more intensive physiotherapy of longer duration.\textsuperscript{43} Supervised exercise programs appear to optimize shoulder ROM recovery.\textsuperscript{37}

Chronic pain of variable severity is another common side-effect of axillary dissection \textsuperscript{21,29,34,36,39,44-46} that can negatively impact mood and QOL.\textsuperscript{47} Post treatment pain can persist from 6 months to 8 years after surgery.\textsuperscript{32,44} At 1-year post-treatment, 23%\textsuperscript{45} to 30.4%\textsuperscript{26} of participants reported intermittent or mild pain. Hladiuk and colleagues\textsuperscript{37} studied women 18 months post-treatment for breast cancer; 28% reported pain on shoulder movement and 11% of those reported the pain to be moderate or severe. Up to 10% of women have reported pain at rest.\textsuperscript{28} Sneeuw et al\textsuperscript{34} found that 27% of women treated for early stage breast cancer were still experiencing pain, rated as moderate to severe, 2-11 years after treatment. Polinsky\textsuperscript{48} surveyed women from 16 months to 32 years after their original surgery for breast cancer. Pain in the axilla was reported by 33%, 31% reported pain at the site of the scar and 39% reported pain in the arm. In Kuehn et al's\textsuperscript{32} sample of women 6-96 months post treatment, 23% reported permanent pain or disturbed sleep due to pain. The nature, duration and severity of post treatment pain are not yet clearly understood. Pain in subcutaneous tissues, inter-costal muscles or ribs may result from radiation fibrosis.\textsuperscript{40}
Breast pain may be caused by fibrosis following radiotherapy along with surgical scarring.\textsuperscript{33} Pain can be the result of inter-costobrachial nerve damage.\textsuperscript{29} Lymphedema may also cause pain.\textsuperscript{49} Incisional pain, posterior cervical pain, shoulder girdle pain and muscle spasm in the neck and shoulder region can also occur after treatment.\textsuperscript{50}

Anxiety, depression and anger,\textsuperscript{40,48} as well as depreciation of self, somatic distress and poor body image,\textsuperscript{48} are common psychological sequelae of breast cancer which can also last more than one year following diagnosis.\textsuperscript{40,48,51} At times, these sequelae continue despite improvements in physical function.\textsuperscript{52} Emotional well-being (i.e. mood) is a significant predictor of QOL.\textsuperscript{26} The number of axillary lymph nodes dissected has been positively associated with pain and surgery-related pain has been positively associated with emotional distress.\textsuperscript{53}

Exercise can decrease feelings of anxiety,\textsuperscript{5-7,11} depression,\textsuperscript{5,54} anger,\textsuperscript{54} stress,\textsuperscript{54} and lead to improvements in self-esteem,\textsuperscript{12,56} self-efficacy,\textsuperscript{57} vigor\textsuperscript{12,58} and satisfaction with life.\textsuperscript{52} Exercise may also have a cathartic effect.\textsuperscript{57} Conventional exercise has been shown to be safe and effective for decreasing physical and psychological symptoms and improving QOL in cancer patients.\textsuperscript{9,14,15,18-20,57} The type of exercise that has the greatest benefit for minimizing psychological sequelae is not clear. It appears, however, that exercise need not be aerobic to improve mood.\textsuperscript{54}

Compared to women who have not had breast cancer, long-term breast cancer survivors tend to have poorer functional status.\textsuperscript{29} For women with Stage I-II breast cancer, functional QOL has been shown to have the strongest relationship to overall satisfaction with life.\textsuperscript{3} Reduced shoulder ROM after axillary surgery and irradiation has been correlated with lack of functional ability.\textsuperscript{29} At 1-year post treatment, Shimozuma and colleagues\textsuperscript{26} reported that 22.8\% of women had difficulty performing household chores. Post-treatment shoulder stiffness significantly influenced daily activities in 14\% of study participants.\textsuperscript{35} At 18 months after wide local excision and axillary irradiation, Sugden and colleagues\textsuperscript{29} reported that 24\% of participants had difficulty fastening bras, 72\% had difficulty doing up a back zipper, 25\% had difficulty touching the ipsilateral scapula, 39\% had difficulty reaching overhead and 57\% had difficulty carrying 5 kg of groceries with the ipsilateral arm. While appropriate exercise can improve UE function,\textsuperscript{60} there is evidence that supervised exercise may be more effective than self-directed exercise.\textsuperscript{61}
1.3 Pilates/Intervention

Developed in the early 1900s and originally called "Contrology", Pilates is a mind-body exercise approach based on Eastern theories of body-mind-spirit interaction combined with Western theories of biomechanics, motor learning and core stability. In this case "spirit" encompasses the whole person, including their emotional well-being. Mind-body exercise is physical exercise executed with an inwardly directed, non-judgmental focus and specific attention to breathing and proprioception. Although the mind-body interaction of the Pilates approach is perceived as alternative within Western medicine, it is foundational for most Eastern medical practices. Support is growing for use of Eastern exercise, in the form of yoga, Tai chi and Qi Gong in rehabilitation settings.

During a Pilates session, intense mental effort is focused on activating specific muscles or muscle groups in a prescribed functional sequence, throughout a full ROM at a controlled speed. Quality, precision and control of movement are emphasized. Repetitions rarely exceed 10 and resistance is usually in the form of body weight or springs. Proponents of the Pilates method claim that regular Pilates practice results in relaxation and control of the mind, enhanced body and self-awareness, improved core stability, better coordination, more ideal posture, greater joint ROM, uniform muscle development and decreased stress.

Despite the fact that Pilates exercise has been recommended in injury prevention and rehabilitation for ballet, groin, and foot and ankle injuries, literature searches reveal a dearth of Pilates studies involving patients. Initially, Pilates research focused primarily on dancers, examining issues of posture and alignment. For example, McLain et al examined the effects of eight weeks of Reformer (a Pilates machine) instruction on 1) supine jump height and 2) pelvic alignment (while standing and performing jumps) in university dance students (n=14). The experimental group attended 1.5 hours of supervised Reformer workouts per week, as well as 1 hour of unsupervised Reformer workouts per week. The control group (n=10) did not undergo any Reformer instruction. While a significant improvement was found in jump height for each group from pre-test to post-test, there was no significant difference in the amount of improvement between the groups. Pelvic alignment deteriorated for the experimental group and improved for the control group from pre to post test. The researchers concluded that the Reformer protocol used in this study did not improve pelvic alignment while performing a standing jump for university dance students.

Self and colleagues studied the range of knee motion and the amount of caudally directed force applied by dancers (n=10, all were members of a professional ballet company) during demi-plié movements in first and fifth
positions. McMillan et al\textsuperscript{82} investigated the effects of Pilates-based exercises on dancers' dynamic posture. Participants were 10 ballet dancers (15-19 years of age) who were divided into experimental (n=5) and control (n=5) groups. The control group did not receive any Pilates-based training. The experimental group attended 23 one-hour, private Pilates sessions over the course of 14 weeks. In addition, they were given a home (mat-based) exercise program to perform daily. When compared to the controls, the participants in the experimental group were found to be more stable in the upper body region while performing a grand plié movement. Based on this, the researchers suggested that Pilates-based exercises may improve dynamic body control.

More recently, Petrofsky et al\textsuperscript{85} compared the effects of Pilates exercises performed with a resistive device (the “Zone Pilates Sculpter”) to commercial weight lifting equipment in healthy participants (n=6) between 18 and 30 years of age. The researchers were interested in comparing muscle use (based on electromyogram) during both forms of exercise. Their results showed that the Pilates exercises studied yielded minimal muscle activity in the abdominal and paraspinal muscles when compared to exercise on commercial weight lifting equipment; the Pilates exercises performed with the resistive device provided a more efficient workout than the commercial weight lifting equipment because multiple muscle groups were exercised simultaneously; and the Pilates resistive device restricted adverse movement at the joints, making exercise smoother and safer.

Herrington and Davies\textsuperscript{86} evaluated the effects of Pilates exercises and abdominal curls on the ability of asymptomatic participants (n= 36) to contract their transversus abdominis (TrA). The 36 participants were divided into a Pilates exercise group (n=12), an abdominal curl group (n=12) and a control group (n=12). Participants in both the Pilates and abdominal curl groups attended a minimum of 25 classes in the 6 months leading up to the study. The ability to engage the TrA was determined using a Stabilizer pressure biofeedback unit while the participants performed an abdominal hollowing exercise and a lumbo pelvic stability test (both supine). The results suggested that the Pilates-trained participants could contract their transversus abdominis muscle and maintain better lumbo-pelvic control than the participants who performed regular abdominal curl exercises or no abdominal exercises.

Segal et al\textsuperscript{87} assessed the effects of Pilates training on flexibility, body composition and health status in a sample of 47 adults (45 women, 2 men). Participants attended a one-hour Pilates group mat class at a community athletic club once a week for eight weeks. The researchers concluded that Pilates training may result in improved flexibility (as measured by fingertip to floor distance) but its effects on body composition and health status were
more limited and may be difficult to establish. Current knowledge supports principles of core stabilization central to
the Pilates approach.  

1.4 Study Design

Study aims were evaluated using a non-concurrent, multiple baseline, single subject research design (SSRD). SSD is well suited to rehabilitative settings and useful in the early stages of hypothesis generation. SSD is designed to allow the therapist to isolate variables directly contributing to changes in performance. Portney & Watkins proposed that single subject research can be the source of “empirical hypotheses that lead to new avenues of study and to the discovery of clinical implications that would not otherwise have been seen or shared”. The underlying principle for single subject evaluation is that no two individuals are alike. When compared to group research, SSRD is often easier to incorporate into clinical settings and is appropriate for studying small populations. SSRD has been used previously in rehabilitation research. Many articles are available to the reader interested in a more in-depth exploration of SSRD methodology and its associated strengths and weaknesses.

SSRD is characterized by systematic, repeated measurement of a target behavior through both baseline and intervention phases in which each participant serves as his/her own control. This allows comparisons to be made before, during and after an intervention within each participant. At least two independent baselines are required to demonstrate a functional relationship (i.e. an effect) between intervention and behavior change. Multiple baseline designs rule out threats to internal validity, including history, maturation, testing effects and regression toward the mean. Generalizability improves as findings are replicated across subsequent studies with different participants and different researchers. The multiple baseline design is considered one of the strongest SSRD in terms of methodologic rigor and generalizability.
1.5 Conceptual Framework for Pilates

In 1945, Joseph Pilates, founder of the Pilates method, authored a manuscript entitled “Return to Life through Contrology.” The following passages from this manuscript provided the conceptual framework on which the hypotheses of this study were based:

1) “It (Pilates) was conceived to limber and stretch muscles and ligaments so that your body will be as supple as that of a cat”. [This statement was assessed as it related to shoulder ROM.]

2) “Contrology develops the body uniformly, corrects wrong postures, restores physical vitality, invigorates the mind and elevates the spirit”. [This assumption was evaluated as it related to improved mood.]

3) “Contrology exercises build a sturdy body and sound mind fitted to perform every daily task with ease and perfection as well as to provide tremendous reserve energy for sports, recreation and emergencies”. [This statement was examined as it related to upper extremity function.]

4) “If you faithfully perform your Contrology exercises regularly only 4 times a week for just 3 months... you will find your body development approaching the ideal, accompanied by renewed mental vigor and spiritual enhancement”. [This statement provided the parameters for frequency of exercise sessions and length of intervention.]

1.6 Study Aim/Objective

The objective of this pilot study was to examine the effects of Pilates exercise on shoulder ROM, pain, mood and UE function in women who had undergone axillary dissection and radiation therapy for the treatment of Stages I-III breast cancer.

1.7 Study Hypothesis

We hypothesized that a Pilates exercise program would increase shoulder ROM, decrease pain, enhance mood and improve UE function in women who are at least six months post-treatment for breast cancer.
1.8 References


Chapter 2

2.1 INTRODUCTION

Rehabilitation aims to restore independence and self-sufficiency while focusing on quality of life (QOL). Functional QOL is often the least possessed but most important QOL dimension underlying overall life satisfaction. Diagnosis and treatment of breast cancer can have profoundly negative impacts on QOL, making rehabilitative interventions that affect physical and psychological functioning important.

Rehabilitation researchers have studied the effects of conventional forms of exercise/physical therapy and dance therapy in enhancing QOL of women living with breast cancer, both during and after treatment. Despite increasing popularity, the complementary form of exercise known as Pilates, has received no research attention as part of breast cancer rehabilitation. Complementary therapies are directed at improving QOL; addressing issues of the body, mind and spirit; and helping to manage symptoms. Up to 80% of women living with breast cancer use complementary and alternative therapies.

2.2 LITERATURE REVIEW

Systematic searches of PUBMED, MEDLINE, CANCERLIT and CINAHL (1983-May 2006) revealed no studies that had examined the effects of Pilates exercise on women living with breast cancer. Keywords used were breast cancer, breast neoplasm, Pilates, radiation, axillary dissection and rehabilitation.

Axillary dissection and radiation are common in the management of breast cancer, and contribute to reduced shoulder mobility in the affected upper extremity (UE), which can last up to 8 years after initial treatment. Post-operative exercise programs may prevent the shoulder stiffness and decreased range of motion (ROM) that often follow axillary surgery and radiation. Limited evidence suggests that women who have had axillary dissection can safely engage in UE exercise without developing lymphedema. Supervised exercise programs appear to optimize shoulder ROM recovery.

Chronic pain is another common side effect of axillary dissection that can negatively impact mood and QOL, and can persist from 6 months to 8 years after surgery. The potential causes of post breast cancer treatment pain are many. Pain may result from radiation fibrosis, surgical scarring or inter-costobrachial nerve damage, to name a few.
Anxiety, depression and anger, as well as poor body image, are common psychological sequelae of breast cancer which can also last more than a year after diagnosis.\textsuperscript{18} These sequelae may continue despite improvements in physical function.\textsuperscript{19} Emotional well-being (i.e. mood) is a significant predictor of QOL.\textsuperscript{1} The number of axillary lymph nodes dissected has been directly related to pain and surgery-related pain has been associated with emotional distress.\textsuperscript{16}

Exercise can decrease feelings of anxiety,\textsuperscript{5} depression,\textsuperscript{20} anger,\textsuperscript{20} and can lead to improved self-esteem,\textsuperscript{7} self-concept,\textsuperscript{20} vigor\textsuperscript{6} and satisfaction with life.\textsuperscript{19} Conventional exercise has been shown to be safe and effective in decreasing physical and psychological symptoms and improving QOL in cancer patients.\textsuperscript{2-4,9} Although the type of exercise that is most beneficial in minimizing psychological sequelae is unclear, exercise need not be aerobic to improve mood.\textsuperscript{20}

Long-term breast cancer survivors tend to have poorer functional status than women who have not had breast cancer\textsuperscript{21} with functional QOL having been shown to have the strongest relationship to overall satisfaction with life.\textsuperscript{1} Reduced shoulder ROM after axillary surgery and radiation has been correlated with lack of functional ability.\textsuperscript{17} While appropriate exercise can improve UE function, supervised exercise may be more effective than self-directed exercise.\textsuperscript{22}

Developed in the early 1900s and originally called “Contrology”, Pilates is a mind-body exercise approach based on Eastern theories of body-mind-spirit interaction combined with Western theories of biomechanics, motor learning and core stability.\textsuperscript{23,24} “Spirit” encompasses the whole person, including emotional well-being.\textsuperscript{25} Mind-body exercise is physical exercise executed with an inwardly directed, non-judgmental focus and specific attention to breathing and proprioception.\textsuperscript{26}

During a Pilates session, mental effort is focused on activating specific muscles in a functional sequence, at controlled speeds. Quality, precision and control of movement are emphasized. Repetitions rarely exceed 10 and resistance is usually in the form of body weight or springs. Proponents of Pilates claim that regular practice results in relaxation and control of the mind, enhanced body and self-awareness, improved core stability, better coordination, more ideal posture, greater joint ROM, uniform muscle development and decreased stress.\textsuperscript{24,27}

Studies have examined the effects of Pilates on aspects of dance performance,\textsuperscript{28-32} muscle use,\textsuperscript{33} and flexibility.\textsuperscript{34} Pilates exercise has been recommended in injury prevention and rehabilitation for ballet,\textsuperscript{35} groin,\textsuperscript{36} and foot and ankle\textsuperscript{37} injuries, yet the literature is scant on Pilates studies involving other types of patients.
2.3 STUDY OBJECTIVE

The objective of this pilot study was to examine the effects of Pilates exercise on shoulder ROM, pain, mood and UE function in women who had undergone axillary dissection and radiation therapy for the treatment of Stage I-III breast cancer.

We hypothesized that the Pilates exercise program would increase shoulder ROM, decrease pain, enhance mood and improve UE function in women who are at least six months post-treatment for breast cancer. The data for ROM, level of pain, mood and UE function were not expected to change until a few weeks into the Pilates intervention. We expected that the degree of improvement would vary, based on individual differences.

2.4 METHODS

2.4.1 Study Design

Study aims were evaluated using a non-concurrent, multiple baseline, single subject research design (SSRD). SSD is well suited to rehabilitative settings and useful in early stages of hypothesis generation. SSD allows the investigator to isolate variables directly contributing to changes in performance. The underlying principle for single subject evaluation is that no two individuals are alike. When compared to group research, SSDs are often easier to incorporate into clinical settings and are appropriate for studying small samples.

SSRD is characterized by systematic, repeated measurement of a target behavior through both baseline and intervention phases in which each participant serves as his/her own control, allowing comparisons to be made before, during and after an intervention within each participant. At least two separate baselines (i.e. in this case, two separate participants) are required to demonstrate a therapeutic relationship between intervention and behavior change.

Data were collected across four participants to enhance generalizability. To control for history and maturation, participants entered the intervention phase at staggered intervals. Participants were randomly assigned to baselines of 3, 5, 7 or 9 sessions of repeated measures observation. Baselines of varying lengths were used to establish the pre-intervention rate of performance and serve as a basis for comparison after intervention was introduced, thus strengthening the evidence that intervention effects were not caused by extraneous variables to which all participants were exposed.
Phase changes were made based on shoulder ROM data. Intervention was introduced at the pre-selected time (i.e., after 3, 5, 7 or 9 data collections sessions) if the ROM baselines demonstrated stability.\textsuperscript{38} If a baseline failed to exhibit stability, it was extended until stability was achieved or until the intervention had to begin for reasons of social validity. To examine the effects of the independent variable on the dependent variables over time (i.e. the "durability" of the intervention effects), follow up data were collected approximately four weeks after completion of the intervention.

2.4.2 Participants

To recruit participants, an article was published in the provincial breast cancer newsletter; posters (Appendix 1) advertising the study were distributed to local cancer support groups and posted in the provincial cancer center and community centers around the city; email messages were sent to local breast cancer dragon boat teams; and announcements were made at local breast cancer forums. Thirty-four women responded to the ads over the course of nine months. Thirteen women could not participate because they did not meet the inclusion criteria and 17 could not participate for "other" reasons (time, location etc).

Participants (n = 4) were volunteers who had undergone axillary dissection and completed radiation therapy for Stages I-III breast cancer. To be eligible to participate, women had to be at least six months post axillary dissection and radiation therapy for Stages I-III breast cancer and demonstrate restricted shoulder ROM secondary to breast cancer treatment. Restricted ROM was defined as a difference of $\geq 10^\circ$ between the surgical and the nonsurgical UE.\textsuperscript{13} Women who were actively undergoing chemotherapy; had a history of bilateral breast cancer; were attending regular physical therapy, chiropractic, massage therapy or psychological counseling; had previous shoulder injuries or health problems other than cancer and related side-effects were excluded. Demographic data for age, education, marital status, hand dominance, affected side, diagnosis, treatments and current physical activities were collected (Tables 2.1 and 2.2). Signed informed consent (Appendix 2) was acquired from all participants; the study was approved by the Clinical Research Ethics Board at the University of British Columbia (Appendix 3).
2.4.3 Setting

The Pilates exercise and data collection sessions took place at Meridian Pilates Studio in Vancouver, BC. Meridian Pilates is typical of many community-based Pilates studios in existence today. The home exercise sessions took place in the participants’ homes.

2.5 REPEATED MEASURES

2.5.1 Shoulder ROM

Shoulder ROM was defined as the range through which the participant could move the shoulder while maintaining a neutral thorax. Measurements were taken with the same plastic, 12-inch universal goniometer while the participant lay supine on a plinth-like platform (a Pilates Cadillac table). Standardized procedures outlined by Clarkson\(^41\) were used for all assessments, and the unit of measurement was ROM in degrees. Active shoulder flexion, abduction, internal and external rotation were measured bilaterally. The unaffected UE was measured for comparative purposes. Internal and external rotation measurements were taken with the shoulder in 90° of abduction and a folded hand towel under the humerus. The unaffected (i.e. non-surgical) side was measured first. The rater took three consecutive measurements in each range; the average of the three trials was used as the final score. Higher scores indicate greater ROM.

2.5.2 Level of Pain

Pain was assessed using the Brief Pain Inventory Short-Form (BPI),\(^42\) suitable for evaluating pain over time.\(^10\) Developed as part of a World Health Organization collaborative project for use with cancer patients, the BPI was designed to provide information on the intensity of pain and the degree to which it interferes with function and various aspects of QOL. The BPI consists of 15 items, including pain drawings (front and back views of a human figure on which the participant is asked to shade the areas of pain) and 7 pain interference questions (e.g. participant is asked to rate how much their pain has interfered with their general activity over the past 24 hours) (Appendix 4). The BPI items are rated on an 11-point scale with lower scores indicating less pain. The test is self-administered, taking approximately 10 minutes to complete and has demonstrated respectable test-retest item correlations over short intervals.\(^42\)
2.5.3 Mood State

Mood was assessed using the self-administered Profile of Mood States Scale-Short Form (POMS),\textsuperscript{43} which rates a variety of mood states (e.g. anxiety, depression, anger, vigor, fatigue, confusion) using a 30-item adjective checklist rated on a 5-point Likert scale (Appendix 5). The score for total mood disturbance is calculated by summing the scores of the 6 POMS factors and then subtracting that score from the Vigor subscale. A lower score indicates less mood disturbance. The short form of the POMS was selected to enhance adherence, given the need for repeated measures in this study. Test-retest reliability estimates range from 0.65 for the Vigor subscale to 0.74 for the Depression subscale.\textsuperscript{43} Acceptable concurrent validity ($r = 0.80; p < 0.01$) was demonstrated when the Tension-Anxiety section of the POMS was compared to the Taylor Manifest Anxiety Scale.\textsuperscript{43}

2.5.4 Upper Extremity Functioning

A 12-item questionnaire was used to assess functional status of the affected UE (Appendix 6). Tasks require a combination of movements through a variety of shoulder ranges and are activities that most women would perform daily. Each item is scored on a 10-point Likert scale from “no difficulty with the task” to “completely unable to do the task”. This questionnaire has been used in studies of women living with breast cancer\textsuperscript{15} and was modified from that used by Wingate\textsuperscript{8} and designed specifically to assess UE function of women with breast cancer. As suggested by Box et al,\textsuperscript{15} the scale was expanded from 5 to 10 points to enhance sensitivity. Lower scores indicate improved UE function.

2.5.5 UE Circumference

Circumference measures of both UEs, at anatomical landmarks suggested in published clinical practice guidelines,\textsuperscript{44} were collected weekly to monitor for the potential development of lymphedema. These data served only as a safety guide. If a difference of $\geq 2$ cm was noted at any landmark, the participant would have been referred to their oncologist, and to a physical therapist, for in-depth assessments. Although we initially recommended that participants wear compression sleeves on their affected UEs during the Pilates sessions (as a prophylactic measure), none found the sleeves to be comfortable. All four participants provided letters signed by their oncologists, stating that they did not have to wear compression sleeves during the Pilates sessions.
2.5.6 Social Validity Questionnaire

At the end of the intervention, a social validity questionnaire (Appendix 7) was given to the participants to assess the acceptability and viability of the Pilates exercise program. The questionnaire was divided into three sections. The first section asked participants to rate the importance of the project goals. The second section asked the participants to rate the acceptability of the strategies used in the study. Responses in sections one and two were rated on a 10-point Likert scale. The third section consisted of five open-ended questions that asked participants to comment on things such as positive and negative effects of the program and whether the Pilates program offered them benefits that other, more conventional forms of exercise, had not. The Likert scale scores were averaged across participants to give an overall social validity rating. The information garnered from this questionnaire will be used to develop community-based Pilates programs for women recovering from breast cancer treatments.

2.6 PROCEDURES

2.6.1 Pilates Intervention

The same certified Pilates instructor conducted most of the Pilates sessions. When the instructor was unable to teach, another certified instructor from the same studio led the participants through their exercise program. Participants attended hour-long exercise sessions, 3X/week for 12 weeks (Appendix 8) and were also given a Pilates exercise program to perform at home 1X/week for 12 weeks (Appendix 9). Pilates exercises were based on those taught by Stott Pilates. Participants began with pre-Pilates exercises and individualized stretches, and progressed to level beginner and, when appropriate, level intermediate exercises. Progression was based on an assessment of the participant's "working level", i.e., the level at which the participant could be safely "in their body", making appropriate neuromuscular connections while still being challenged. Peak Pilates manufactured the equipment used in this study.3

3 Peak Pilates 5555 Central Ave. - Suite 200 - Boulder, CO 80301
Local: (303) 998-1531 Toll Free: 1-800-925-3674 Fax: 303.473.9142
2.6.2 Data Collection

A trained rater collected all baseline and intervention data at the Pilates studio where the intervention took place. Measures were collected in the same order, at the same time of day, on the same day of the week. Data for shoulder ROM were collected 2X/week during baseline and intervention phases. Data for pain, mood and UE function were collected 1X/week during both baseline and intervention phases. Follow-up data were collected on the same day of the week and time of day as during baseline and intervention phases.

2.6.3 Inter-rater Agreement

A licensed physical therapist trained the raters in this study. During the training session, a woman who had been treated with axillary dissection and radiation for breast cancer served as the person to be measured while the physical therapist guided the two raters through the shoulder ROM measurement procedures outlined by Clarkson. The two raters repeated the procedure five more times, without the guidance of the physical therapist, using two different women living with breast cancer as participants (on four occasions) and a woman who had not been treated for breast cancer (on one occasion). The criteria for allowing a rater to conduct experimental measurement were: participation in the physical therapist-led training session; participation in the five additional training measurement sessions; an understanding of the need for, and demonstration of, the systematic, standardized approach to shoulder range of motion measurement.

Inter-rater agreement sessions were conducted for 20% of all shoulder ROM data collection sessions, balanced across study phases. To account for lack of rater blinding, a trained outside rater, blind to the phase of the study as well as to the study hypothesis, served as the second rater for inter-rater agreement sessions. Differences of \( \leq 7^\circ \) were considered acceptable inter-rater variability. Percent agreement was calculated by dividing the number of agreements by the sum of agreements plus disagreements and multiplying by 100%. Percent agreement for the inter-rater agreement sessions was 74%.

Currently, no standards exist as to what constitutes satisfactory inter-rater agreement for active shoulder ROM in women treated for breast cancer. The inter-rater agreement for shoulder ROM in this study was somewhat below the acceptable standard of 80%, despite a standardized measurement protocol and trained raters. This suggests that shoulder ROM in this population may be more variable than in non-patient populations. A study of patients with
shoulder dysfunction conducted by Hayes et al\textsuperscript{46} supports our findings. Hayes and colleagues investigated inter-rater reliability for shoulder flexion, abduction, and external rotation in patients with rotator cuff repair (n=6), adhesive capsulitis (n=1) and scapulothoracic fusion (n=1). Their inter-rater correlation coefficients (\(r\_s\)) were: flexion = 0.69, abduction = 0.69, external rotation = 0.64. It has been suggested that correlation coefficients from 0.40 - 0.75 equal fair to good reliability.\textsuperscript{46} Shoulder ROM reliability in women treated for breast cancer needs further study.

### 2.6.4 Observer Drift

The rater and co-investigator periodically reviewed procedures for ROM measurement and questionnaire administration over the course of the study to prevent observer drift.

### 2.6.5 Treatment Integrity

Treatment integrity refers to the degree to which treatments are implemented as intended. To ensure that the Pilates instructor was adhering to the study protocol, a Pilates instructor trainer (IT) monitored one session for each participant. The IT was provided with a sheet outlining the Pilates exercises to be performed. Requirements were that the basic choreography and Pilates principles be adhered to, with flexibility allowed for the images and visualizations used with each participant. In all four cases, the IT confirmed that the Pilates instructor was adhering to protocol. Additionally, the participants could not miss more than 15\% (i.e. 5) of the supervised Pilates sessions for the intervention to be considered “complete”. No limit was set as to how many home exercise sessions the participants could miss. The instructor standardized and documented the exercises performed during each Pilates exercise session using SOAP notes. The SOAP acronym stands for “Subjective” (what the participant reported that day), “Objective” (what the Pilates instructor noticed during the participant’s session), “Action” (which exercises where performed) and “Plan” (what to do in the next session).
2.6.6 Treatment Adherence

A series of 10 guidelines were followed to promote treatment adherence (Appendix 10). In addition, an adherence history questionnaire (Appendix 11) was given to the participants prior to initiating the study. The questionnaire asked about the participants’ expectations of the intervention, their goals for the intervention, their perceptions of risks and benefits of the intervention, and life circumstances that might affect adherence. Potential solutions to adherence barriers were discussed prior to initiating the study.

2.7 DATA ANALYSIS

Graphed data were visually analyzed using standard rules of evidence for single subject data. Levels, trends and variability within and across phases were determined and analyzed for all repeated measures for all participants, and comparison of data paths across participants was made. Level is defined as changes in magnitude of the data, conveyed by changes in the mean level for each phase (i.e. average rate of performance across two or more phases). Defined as the direction of change within a phase, an accelerating trend is one that progresses in an upward direction, whereas a decelerating trend progresses downward. Trends for all data paths were determined using the Microsoft Excel program (“linear regression” option). To aid in the visual analysis of trend, the baseline trend lines were extended into the intervention and follow up phases. The number of data points above and below the extended trend lines, across the phases, were compared to aid in determining whether or not the intervention had an effect. Variability refers to the amount of fluctuation of data points in a series.

Statistical analysis was conducted using ITSACORR, an interrupted time-series analysis software program. ITSACORR uses an omnibus F-test to determine statistical significance of overall change in intercept and slope between baseline and intervention phases with ≥5 data points and controls for autocorrelation. ITSACORR was selected over the more commonly used C-statistic, as there has been some suggestion that the C-statistic fails to maintain an acceptable risk of type I error. ITSACORR has been used to assess treatment effects in published SSRD studies. ITSACORR analyses were performed only on data sets in which all participants had baseline phases consisting of ≥5 data points.
2.8 RESULTS

Throughout presentation of the results, "unaffected" refers to the non-surgical and non-irradiated UE, and "affected" refers to the surgical and irradiated UE. For shoulder ROM, an accelerating trend indicates increasing range and a decelerating trend indicates decreasing range. A decelerating trend for level of pain, mood state and UE functioning indicates improvement.

2.8.1 Visual Analysis

2.8.1.1 Unaffected Shoulder Flexion Range of Motion (Figure 2.1)

Participant 1 showed a stable baseline, with an average shoulder flexion range of 142° (range: 138-147°). Following intervention, a gradual improvement was observed across the 3 months of treatment. ROM increased to an average of 146° (range: 140-154°). Shoulder flexion at one month post intervention (144°) fell below the last data point (153°) in the intervention phase, and 2° below the mean for the intervention phase.

During baseline, Participant 2 showed an accelerating trend (increasing range) with an average shoulder flexion ROM of 168° (range: 165-170°). While the intervention phase showed no trend, ROM increased to an average of 172° (range: 168-174°) across the 3 months of treatment. The one-month follow up data point (170°) fell below the last data point (172°) in the intervention phase, and 2 degrees below the intervention mean.

During baseline, Participant 3 demonstrated a decelerating trend (decreasing range) with an average shoulder flexion ROM of 165° (range: 162-168°). While the data path for the intervention phase showed no trend, the average ROM increased to 167° (range: 161-174°). The one-month follow up data point (167°) was the same as both the last data point in the intervention phase and the mean for the intervention phase.

Participant 4 showed an unstable baseline with a steep accelerating trend, indicating that ROM was increasing prior to the introduction of the intervention. The average baseline shoulder flexion ROM was 163° (range: 152-171°). During intervention, the data showed less variability and a slightly accelerating trend. The average intervention ROM was 175° (range: 170-181°). The one-month follow up data point (176°) was one degree above the average of the intervention phase (175°), and the same as the last two data points in the intervention phase.
2.8.1.2 Affected Shoulder Flexion Range of Motion (Figure 2.1)

During baseline, Participant 1 showed a decelerating trend, with an average shoulder flexion range of 127° (range: 123-133°). Following intervention, a gradual improvement was observed across the 3 month treatment. ROM increased to a mean of 137° (range: 130-149°). The one-month follow up data point (142°) was 4° above the last data point (138°) in the intervention phase, and 5° above the mean (137°) for the intervention phase.

For Participant 2, the average range of shoulder flexion increased from baseline to intervention. The baseline trend was one of decreasing ROM, with the average range being 150° (range: 146-153°). Over the course of the 3-month intervention, ROM gradually improved to an average level of 154° (range: 143-161°). The one-month follow up data point (158°) was 2° below the last data point (160°) in the intervention phase, and 4° above the mean (154°) for the intervention phase.

Participant 3 showed a stable baseline with no trend and an average shoulder flexion range of 154° (range: 153-156°). The intervention data showed a slightly decelerating trend and the average ROM decreased to 153° (range: 147-159°). The one-month follow up data point (154°) was 2° above the last data point (152°) in the intervention phase, and 1° above the mean (153°) for the intervention phase.

Participant 4 demonstrated an unstable baseline with a steep accelerating trend and an average ROM of 153° (range: 137-167°). Following intervention, ROM continued to increase, at a less dramatic rate, to an average of 170° (range: 162-174°). The one-month follow up data point (172°) was 2° above the intervention mean, and the same as the last data point in the intervention phase.

2.8.1.3 Unaffected Shoulder Abduction Range of Motion (Figure 2.2)

During baseline, Participant 1 showed a decelerating trend with an average range of 115° (range: 111-119°). Following intervention, the average ROM gradually increased to 121° (range: 110-130°). The one-month follow up data point (124°) fell 6° below the last data point during the intervention phase (130°), and 3° above the mean for the intervention phase (121°).

During baseline, Participant 2 showed a decelerating trend with an average ROM of 140° (range: 130-160°). A trend of increasing range was seen during intervention. The average shoulder ROM remained unchanged from baseline (140°), but the range varied (132-152°). The one-month follow up data point (144°) was 2° above the last data point (142°) in the intervention phase, and 4° above the mean (140°) for the intervention phase.
During baseline, the data for Participant 3 exhibited a decelerating trend with an average ROM of 134° (range: 130-145°). During the intervention phase, the data exhibited an accelerating trend and the average ROM increased to 138° (range: 122-146°). The one-month follow up data point (144°) was 6° above the last data point (138°) in the intervention phase, and 6° above the mean (138°) for the intervention phase.

During baseline, the data for Participant 4 exhibited a steep accelerating trend. The average baseline ROM was 131° (range: 111-144°). During intervention, ROM continued to increase gradually, reaching an average level of 143° (range: 131-154°). The one-month follow up data point (142°) was 3° below the last data point in the intervention phase (145°), and 1° below the intervention mean (143°).

2.8.1.4 Affected Shoulder Abduction Range of Motion (Figure 2.2)

Participant 1 showed a stable baseline with an average shoulder abduction range of 85° (range: 80-89°). Following intervention, a gradual improvement was observed across the 3 months of treatment. ROM increased to an average of 90° (range: 76-105°). The one-month follow up data point (105°) was 5° above the last data point in the intervention phase (100°), and 15° degrees above the mean (90°) for the intervention phase.

For Participant 2, the average range of shoulder abduction increased from baseline to intervention. The baseline mean was 92° (range: 86-96°), and the intervention mean was 110° (range: 92-126°). No trend was shown during baseline, and an accelerating trend was demonstrated during intervention. The one-month follow up data point (116°) was 4° below the last data point (120°) in the intervention phase, and 6° above the intervention mean (110°).

During baseline, Participant 3 demonstrated a steep decelerating trend, and an average shoulder abduction ROM of 106° (range: 94-116°). During intervention, the data showed an accelerating trend with an average of 104° (range: 91-117°). The one-month follow up data point (115°) was 2° below the last data point (117°) in the intervention phase, and 11° above the intervention mean (104°).

During baseline, Participant 4 demonstrated a steep accelerating trend with an average range of 107° (93-122°). During intervention, the trend continued to accelerate with ROM reaching an average of 131° (range: 113-141°). The one-month follow up data point (132°) was 1° above the intervention mean (131°) and 3° below the last data point in the intervention phase (135°).
2.8.1.5 Unaffected Shoulder Internal Rotation Range of Motion (Figure 2.3)

During baseline, Participant 1 showed no trend and an average shoulder internal rotation range of 55° (range: 46-61°). During intervention, the average ROM gradually increased to 60° (range: 55-67°) and the data continued to show no trend. The one-month follow up data point (60°) was 5° above the last data point (55°) in the intervention phase, and the same as the mean (60°) for the intervention phase.

During baseline, Participant 2 demonstrated a trend toward decreasing range. The baseline average ROM was 67° (range: 64-75°). While the average ROM during intervention (64°, with a range of 57 to 70°) was less than in baseline, the trend changed to one that was accelerating, indicating increasing range. The one-month follow up data point (61°) was 5° below the last data point (66°) in the intervention phase, and 3° above the mean (64°) for the intervention phase.

During baseline, Participant 3 demonstrated a decelerating trend with an average shoulder internal rotation ROM of 36° (range: 33-41°). During intervention, the baseline demonstrated an accelerating trend and the average shoulder range increased to 38° (range: 32-42°). The one-month follow up data point (43°) was 3° above the last data point (40°) in the intervention phase, and 5° above the mean (38°) for the intervention phase.

During baseline, Participant 4 demonstrated a slightly decelerating trend with an average ROM of 59° (range: 51-65°). During intervention, ROM continued to show a slightly decelerating trend. The average ROM during intervention decreased to 54° (range: 49-60°). The one-month follow up data point (46°) was 8° below the mean of the intervention phase and 6° below the last data point in the intervention phase.

2.8.1.6 Affected Shoulder Internal Rotation Range of Motion (Figure 2.3)

For Participant 1, the baseline showed no trend, while the intervention demonstrated a slightly accelerating trend. There was no change in mean level from baseline to intervention (both were 66°), with the intervention phase showing greater range (62-72°) than the baseline phase (63-69°). The one-month follow up data point (67°) was 3° above the last data point (64°) in the intervention phase, and 1° above the intervention mean (66°).

The average shoulder internal rotation ROM decreased (by 1°) from baseline to intervention for Participant 2. The baseline mean was 56° (range: 52-63°) and the intervention mean was 55° (range: 48-63°). The baseline data demonstrated a decelerating trend. During intervention, an accelerating trend was shown. The one-month follow up (59°) was above the last data point (57°) in the intervention phase, and 4° above the intervention mean (55°).
Participant 3 showed a baseline with a decelerating trend, and an average shoulder internal rotation ROM of 44° (range: 40-48°). During the intervention phase, the average ROM decreased to 43° (range: 38-49°), yet the data were stable with a slightly accelerating trend. The one-month follow up (46°) was the same as the last data point (46°) in the intervention phase, and 3° above the intervention mean (43°).

During baseline, Participant 4 demonstrated a slightly decelerating trend with an average ROM of 48° (range: 43-56°). While the data exhibited a slightly accelerating trend during intervention, the average ROM decreased to 46° (range: 41-51°). The one-month follow up data point (49°) was 3° above the intervention mean (46°) and 1° below the last data point in the intervention phase (50°).

2.8.1.7 Unaffected Shoulder External Rotation Range of Motion (Figure 2.4)

Participant 1 demonstrated a baseline with no trend and an average shoulder external rotation of 67° (range: 57-77°). A gradual improvement was seen during the intervention phase, with the intervention mean increasing to 81° (range: 73-94°). The one-month follow up data point (85°) was 2° above the last data point (83°) in the intervention phase, and 4° above the mean (81°) for the intervention phase.

During baseline, Participant 2 showed an accelerating trend with an average shoulder external rotation of 92° (range: 85-97°). Although the average ROM increased to 96° (range: 89-102°) during intervention, the trend changed to a decelerating one. The one-month follow up data point (97°) was 5° above the last data point (92°) in the intervention phase, and 1° above the mean (96°) for the intervention phase.

Participant 3 showed a trend toward decreasing ROM. The average shoulder external ROM during baseline was 80° (range: 69-101°). During intervention, an accelerating trend was evidenced. The average shoulder external rotation during intervention was 82° (range: 70-93°). The one-month follow up data point (81°) was 8° below the last data point (89°) in the intervention phase, and 1° above the mean (80°) for the intervention phase.

Participant 4 exhibited an unstable baseline with no trend and an average ROM of 75° (range: 61-89°). During intervention, the data exhibited an accelerating trend and ROM increased to an average of 93° (range: 71-106°). The one-month follow up data point (99°) was 6° above the intervention mean and 2° below the last data point in the intervention phase.
2.8.1.8 Affected Shoulder External Rotation Range of Motion (Figure 2.4)

Participant 1 demonstrated no trend during baseline, with an average shoulder external rotation ROM of 22° (range: 19-26°). Following intervention, a gradual improvement was observed across the 3 month treatment and ROM increased to an average of 40° (range: 25-52°). The one-month follow up data point (53°) was 10° above the last data point (43°) in the intervention phase, and 13° above the intervention mean (40°).

For Participant 2, the average shoulder external rotation ROM increased from baseline to intervention. No trend was shown during baseline and the mean ROM was 62° (range: 57-68°). During intervention, an accelerating trend was evidenced with an average ROM of 74° (range: 56-83°). The one-month follow up data point (76°) was 6° below the last data point (82°) in the intervention phase, and 2° above the intervention mean (74°).

Participant 3 showed a baseline with an accelerating trend and an average shoulder external rotation ROM of 71° (range: 65-77°). During intervention, an accelerating trend was with an average of 74° (range: 64-86°). The one-month follow up data point (81°) was 5° below the last data point (86°) in the intervention phase, and 7° above the intervention mean (74°).

Participant 4 showed an accelerating trend and an average ROM of 67° (range: 55-80°). During intervention, the trend continued to accelerate and the average ROM increased to 90° (range: 72-101°). The one-month follow up data point (97°) was 7° above the intervention mean (90°) and the same as the last data point in the intervention phase.

2.8.1.9 Overall Summary of Shoulder Range of Motion Results

2.8.1.9.1 Unaffected UE

For the unaffected UE, all four participants experienced an improvement in average level from baseline to intervention for shoulder flexion and external rotation. Participants 1, 3 and 4 improved in level from baseline to intervention for shoulder abduction, and Participants 1 and 3 improved in average level for shoulder internal rotation. The average level did not change from baseline to intervention for Participant 2 in shoulder abduction, and deteriorated for Participants 2 and 4 in shoulder internal rotation. A change in trend, from a stable or deteriorating to an improving trend, was seen in: Participant 1 for shoulder flexion; Participants 1 and 3 for shoulder abduction; Participants 2 and 3 for shoulder internal rotation; and Participants 1, 3 and 4 for shoulder external rotation. Participant 2 showed a change from a deteriorating trend to a stable trend for shoulder abduction. An improving
trend in baseline, followed by an improving or stable trend during intervention, was seen for Participants 2 and 4 for shoulder flexion, and Participant 4 for shoulder abduction.

For Participants 1 and 3, the majority of the shoulder flexion intervention data points were above the baseline trend lines (Figure 2.5). For Participant 2, almost all of the data points were either below the baseline trend line or on the baseline trend line. All of Participant 4's intervention data points were below the baseline trend line.

For shoulder abduction, the majority of the intervention data points for Participants 1, 2 and 3 were above the baseline trend lines (Figure 2.6). All but one of the intervention data points for Participant 4 were below the baseline trend line.

For shoulder internal rotation, the majority of the intervention data points for all participants were above the baseline trend lines (Figure 2.7).

For shoulder external rotation, the majority of intervention data points were above the baseline trend lines for Participants 1, 3 and 4 (Figure 2.8). For Participant 2, the majority of intervention data points were below the baseline trend line.

2.8.1.9.2 Affected UE

All participants improved in average level from baseline to intervention for shoulder external rotation, and Participants 1, 2 and 4 improved in shoulder flexion and abduction. The average level of shoulder flexion (by 1°) and shoulder abduction (by 2°) deteriorated for Participant 3 from baseline to intervention. None of the participants showed improvement in average level from baseline to intervention for shoulder internal rotation: Participant 1 showed no change; Participants 2 and 3 showed levels that deteriorated by 1°; and Participant 4 showed an average level that deteriorated by 2°. A change in trend, from a stable or deteriorating to an improving trend, was seen in: Participants 1 and 2 for shoulder flexion; Participants 1, 2, and 3 for shoulder abduction; Participants 1, 2, and 3 for shoulder internal rotation; and Participants 1 and 2 for shoulder external rotation. An improving trend in baseline, followed by an improving or stable trend during intervention was seen for Participant 4 in shoulder flexion, abduction and external rotation, as well as Participant 3 for shoulder external rotation.

For shoulder flexion, all but one of the intervention data points for Participants 1 and 2 were above the baseline trend lines (Figure 2.5). The majority of intervention data points for Participant 3 and all of the data points for Participant 4 fell below the baseline trend lines.
For shoulder abduction, the majority of the intervention data points for Participants 1, 2 and 3 were above the baseline trend lines (Figure 2.6). All of the intervention data points for Participant 4 were below the baseline trend line.

For shoulder internal rotation, the majority of the intervention data points for Participants 1, 2 and 3 were above the baseline trend lines (Figure 2.7).

For shoulder external rotation, the majority intervention data points were above the baseline trend lines for Participants 1, 2 and 4 (Figure 2.8). For Participant 3, all of the intervention data points were below the baseline trend line.

2.8.1.10 Level of Pain (Figures 2.9 and 2.10)

During baseline, Participant 1 showed a decelerating trend, indicating that level of pain was decreasing prior to the introduction of the intervention. The average level of pain for the baseline phase was 22 (range: 2-55). Following intervention, the average level of pain continued to decrease to an average of 11 (range: 0-29). The follow up data point (0) fell below the last data point in the intervention phase (2), and well below the mean (11) for the intervention.

The average level of pain increased from baseline to intervention for Participant 2. The baseline phase demonstrated a decelerating trend (indicating a level of pain that was decreasing) and an average score of 4 (range: 2-7). The intervention phase also demonstrated a decelerating trend, although the slope of the trend line was not as steep as in baseline, and the average score increased to 5 (range: 0-18). The one-month follow up data point (3) was the same as the last data point in the intervention phase (3) and 2 points below the mean (5) for the intervention phase.

During baseline, Participant 3 showed a decelerating trend, indicating that level of pain was decreasing prior to the introduction of the intervention. The average level of pain score during baseline was 2 (range: 0-5). During intervention, the data exhibited no trend and the average level of pain score decreased to 0 (i.e. all intervention scores were 0). The one-month follow up data point (0) was the same as the last data point in the intervention phase (0) and the mean (0) for the intervention phase.

Participant 4 exhibited a decelerating trend during baseline, indicating that level of pain was decreasing prior to the introduction of the intervention. The average level of pain score during baseline was 5 (range: 0-17).
During intervention, all data points were 0, indicating that Participant 4 had no pain. No pain was reported at the one-month follow up.

At the end of the intervention, the majority of the intervention data points were above the baseline trend lines for all participants.

2.8.1.11 Mood State (Figures 2.11 and 2.12)

For Participant 1, the mean level of mood disturbance decreased from baseline to intervention, indicating improvement in overall mood. The baseline mean was 7 (range: -11 to 33), and the intervention mean was -2 (range: -12 to 10). The baseline phase demonstrated a trend of improving mood. This trend continued into the intervention phase, but the slope of the trend line was not as steep as in baseline. The follow up data point (-11) was slightly above (indicating more mood disturbance) the last data point in the intervention phase (-12), but well below (by 9 data points) the intervention mean (-2).

For Participant 2, the average level of mood disturbance decreased from baseline to intervention, indicating improvement in overall mood. The baseline phase demonstrated a decelerating trend, with an average mood disturbance score of 0.6 (range: -8 to 5). The intervention phase also demonstrated a decelerating trend, but the slope of the trend line was not as steep as in the baseline. During intervention, the average mood disturbance score decreased to -3 (range: -7 to 3). The one-month follow up data point (2) was above (indicating greater mood disturbance) the last data point in the intervention phase (-7), and above (by 5 data points) the intervention mean (-3).

During baseline, Participant 3 reported an average mood disturbance score of -3 (range: -2 to -4). During intervention, the data demonstrated greater variability and an accelerating trend (indicating deteriorating mood). The average mood disturbance score during intervention was -5 (range: -13 to 3). The one-month follow up data point (-13) was below (indicating less mood disturbance) the last data point in the intervention phase (-4), and below (by 8 data points) the intervention mean (-5).

Participant 4 showed an improving mood state during baseline. The data showed a decelerating trend with an average score of 14 (range: 5 to 23). During intervention, mood state continued to improve, as evidenced by the decelerating trend and the lower average mood score of 9 (range: -12 to 9). By the one-month follow up data collection session, mood state had deteriorated, reaching a score of 19.
For Participants 1, 2 and 4, the majority (all but 2) of the intervention data points were above the baseline trend lines, while all of the data points for Participant 3 were below.

2.8.1.12 Upper Extremity Functioning (Figures 2.13 and 2.14)

During baseline, Participant 1 demonstrated a decelerating trend, indicating improving UE functioning prior to the introduction of the Pilates exercise program. The baseline average was 54 (range: 37-63). Following intervention, UE functioning continued to improve, reaching an average of 27 (range: 15-41). At follow up, UE functioning had deteriorated slightly (by 7 points) when compared to the mean of the last 3 data points in the intervention phase (17).

For Participant 2, the baseline data exhibited a stable trend, with an average UE functioning score of 24 (range: 21-28). During intervention, the trend changed to one of slightly decreasing function, with an average score of 22 (range: 19-26). The follow up data point (30) was 9° above the last data point in the intervention phase (21) and 1 point above the mean for the intervention phase (22).

During baseline, Participant 3 showed a decelerating (improving function) baseline with an average UE functioning score of 25 (range: 23-27). During intervention, the data demonstrated a decelerating trend with an average score of 26 (range: 22-41). The follow up data point (29) was 3 points above both the last data point in the intervention phase (26) and the mean for the intervention phase (26).

Participant 4 showed a trend toward improving UE functioning during the baseline phase. The average score during baseline was 16 (range: 11-23). The level of functioning was stable during intervention, showing an average of 12 (range 11-13). At follow up, the level of functioning remained unchanged from that seen during intervention.

For Participant 1, all but one of the intervention data points were above the baseline trend line. Approximately half of the intervention data points were above and approximately half were below the baseline trend line for Participant 2. For Participants 3 and 4, all of the intervention data points were above the baseline trend lines.

Note: In order to compare the data paths across all four participants, the questionnaire was scored out of 110 instead of 120. The question relating to “zipping up a back fastening dress” was omitted from the data analysis for all participants, due to missing data for Participant 1.
2.8.2 Statistical Analysis

Shoulder ROM data were analyzed using the ITSACORR program. The results are presented in Table 2.3. Statistical significance was set at \( p < .05 \) for all tests. The only analyses that indicated statistically significant change were those for Participant 3’s affected UE shoulder internal (\( p = 0.028 \)) and external rotation (\( p = 0.049 \)) ROM. Participant 1 approached significant improvement in shoulder abduction (\( p = 0.123 \)) and external rotation (\( p = 0.115 \)) on the affected UE.

2.8.3 Treatment Adherence

Adherence for the supervised exercise sessions for Participants 1 to 4 was 86%, 89%, 94%, 89%, respectively. To monitor adherence for the home exercise sessions, participants were asked at the beginning of each week during the intervention: “How many of the home program exercises did you complete last week?” Adherence for the home exercise sessions for Participants 1 to 4 was 100%, 100%, 33% and 92%, respectively.

2.8.4 Social Validity Questionnaire

Participants were asked to rate questionnaire items on a 10-point Likert scale. The Likert scales ranged from 1 (either: not satisfied, not acceptable or not important, depending on the questionnaire item) to 10 (either: completely satisfied, completely acceptable, very important, depending on the questionnaire item). The average social validity scores across items for participants 1 to 4 were: 8.8/10, 7.2/10, 9.5/10 and 8.6/10 respectively. The average score across participants was 8.6/10. The questionnaire items rated on a Likert scale are summarized in Table 2.4. Participant responses to the social validity questionnaire items that were not rated on a Likert scale are summarized in Table 2.5.
2.9 DISCUSSION

2.9.1 Summary of Results

2.9.1.1 Shoulder ROM

When all participants and unaffected UE ranges are considered, 13/16 comparisons showed an increase in level from baseline to intervention, and 8/16 comparisons demonstrated improvement in trend (from stable or deteriorating in baseline, to improving during intervention). On the unaffected UE, 7/16 comparisons showed improvement in both average level and trend (from stable or deteriorating to improving) from baseline to intervention. More specifically: Participant 1 showed improvement in both level and trend for shoulder flexion, abduction and external rotation; Participant 3 showed improvement in both level and trend for shoulder abduction, internal rotation and external rotation; and Participant 4 showed improvement in both level and trend for shoulder external rotation.

When all participants and affected UE ranges are considered, 10/16 comparisons showed improvement in level from baseline to intervention, and 10/16 exhibited improvement in trend (from stable or deteriorating in baseline, to improving during intervention). On the affected UE, 6/16 comparisons showed improvement in both level and trend: shoulder flexion, abduction and external rotation for Participants 1 and 2.

Overall, there was a modest functional relationship between the implementation of the Pilates program and improvement in shoulder external rotation and abduction.

Visual analyses suggest that Participant 1 showed the strongest association between implementation of the Pilates intervention and improved shoulder ROM. Average shoulder flexion ROM increased by 4°, abduction by 6°, and external rotation by 14° on the unaffected UE from baseline to intervention. On average, from baseline to intervention, shoulder flexion ROM increased by 10°, abduction by 5° and external rotation by 18° on the affected UE. It is worth noting that Participant 1 was only six months post radiation treatment when she joined the study. Participant 1 was also the oldest (71 years) of the participants; showed the highest overall scores for pain, disturbed mood and difficulty with tasks listed on the UE function questionnaire; and demonstrated the most impaired shoulder ROM on the affected side in flexion, abduction and external rotation when compared to the other three participants, despite the fact that she was the only one of the group that did not have a mastectomy. Participant 1 may also have been the most motivated of the group. From a social validity perspective, Participant 1 rated her satisfaction with the study outcomes as 10/10 (indicating "completely satisfied") and added: "I notice all sorts of
changes in my body and really felt the benefit of the exercises, so much that I'll continue with exercises on my own” and “I think that it (the Pilates exercise program) has positive effects beyond the goals of increased mobility and lessened pain in my affected arm/shoulder. I feel my posture is better, I feel taller, my core strengthened, I've lost inches on my thighs and I have more confidence about my ability to commit to a program”. After completing the study, Participant 1 continued with supervised and home Pilates sessions and reported increasing benefit from the exercise program.

One month after completing the intervention, Participant 2 was diagnosed with metastatic cancer to the patellae and skull. Given this, it is reasonable to assume that she was living with metastatic cancer while taking part in the Pilates intervention. Even with metastatic cancer, Participant 2 was able to show improvement in both level and trend for shoulder flexion, abduction and external rotation on the affected UE.

While Participant 3 was the only participant to show statistically significant change in shoulder ROM for internal and external rotation on the affected UE, visual analysis suggests that, of the participants under study, she may have experienced the least change due to the Pilates program. When compared to the other participants, her changes in level from baseline to intervention across all ranges were the smallest of the sample and, in 3 instances (flexion, abduction and internal rotation on the affected UE), average ROM actually decreased from baseline to intervention. Participant 3 did, however, experience an increase in both level and trend for shoulder abduction, internal rotation and external rotation ROM on the unaffected UE, and scored a 10/10 (indicating “completely satisfied”) when asked how satisfied she was with the study outcomes. When asked to comment on the study outcomes, she replied: “I noticed improved function, in terms of greater strength and mobility. I found both the stretching and resistance exercises extremely helpful in improving my range of motion and strength.”

2.9.2 Summary of Secondary Dependent Measures

2.9.2.1 Level of Pain

Except for Participant 1, the others did not report high levels of pain at the study outset. Participants 1, 3, and 4 demonstrated a decrease in average level of pain from baseline to intervention (decreases of 2-11 points), with Participant 1 showing the greatest decrease (11 points). Level of pain for Participant 2 increased by 1 point from baseline to intervention. The increase in Participant 2’s pain scores during the intervention can likely be attributed to what she thought was the aggravation of a longstanding knee injury, but was later diagnosed as patellar metastases.
The fact that all participants demonstrated trends toward decreasing pain during baseline makes it difficult to conclude that the Pilates exercise program was responsible for the decrease seen in level of pain over the course of the study.

### 2.9.2.2 Mood State

All participants showed a decrease in average level of mood disturbance from baseline to intervention. However, the improving mood exhibited by Participants 1, 2 and 4 during baseline makes it difficult to conclude that improvement during intervention was due to the Pilates exercises. The improving mood could have been due to factors unrelated to participation in the study or could have resulted from anticipating positive effects from the upcoming Pilates intervention. At the one-month follow up, Participant 4 showed a dramatic increase in mood disturbance, when compared to the level exhibited during the last part of the intervention phase. She reported feeling “almost a sense of grief” at the loss of the regular Pilates sessions.

Two factors make one contemplate whether the POMS was the best choice of instrument to measure mood in this study. First, the POMS asked participants to rate various aspects of their mood “during the past week including today” and was completed prior to the Pilates exercise sessions. Participants reported feeling very relaxed and calm after the Pilates sessions, suggesting that the exercise program may have had a transient effect on mood that the POMS was unable to detect. For example, when asked to comment on the effects of the Pilates exercise program, Participant 3 replied: “Pilates was great for my mood - I really enjoyed the sessions and felt very relaxed afterwards.” Secondly, one item on the social validity questionnaire asked participants to comment on the instruments used to measure change in the study. Participants 1 and 2 felt that the POMS was insensitive, ineffective and inappropriate as a dependent measure. Although Participants 1 and 2 did not endorse the use of the POMS, the researchers are of the opinion that the effects of Pilates on mood are still worthy of study. Participant 2 provides support for this theory, in her statement that she would recommend the Pilates program to other women living with breast cancer for “both the physical and psychological benefits.”

### 2.9.2.3 Upper Extremity Functioning

While Participants 1, 2, and 4 demonstrated changes in average level from baseline to intervention that were consistent with improving UE functioning, Participants 1 and 4 also exhibited trends indicative of improving
function during baseline, making it difficult to conclude that improvement during intervention was due to the Pilates exercises. Participant 3 showed an average level that deteriorated by 1 point from baseline to intervention. This deterioration may be due to the fact that the day on which she reported the most difficulty with UE functioning (the first day of the intervention phase), she was also getting over a bad sinus infection, sore throat, cough and had been bed-ridden for the days leading up to the Pilates session. When her data for day 1 of the intervention phase are ignored, the average level of performance for the baseline phase is the same as for the intervention phase.

2.9.3 Theories as to Why Modest Results Occurred

The modest results seen in this study may be due to the Pilates exercise selection and the length of the intervention. The selection of a three month intervention was based the conceptual framework outlined in Joseph Pilates' book "Return to Life Through Contrology", in which he states: "If you faithfully perform your Contrology exercises regularly only 4 times a week for just 3 months... you will find your body development approaching the ideal, accompanied by renewed mental vigor and spiritual enhancement". Because the participants in this study were from a patient population, three of them were over 50 years of age and two of them had metastatic disease, the exercises that Joseph Pilates outlined in his book would not have been appropriate beginning exercises and they were not the exercises selected for the study. It is also possible that the participants in question might have needed more than a three month intervention in order to show dramatic change in ROM. The Pilates program included several exercises that required movement into shoulder abduction and external rotation, which might explain why they were the ranges most affected across participants. Only one of the exercises used in the intervention required notable internal rotation. This, along with postural issues that would likely require more than a three-month exercise intervention to correct, may partially explain why visual analyses suggest that internal rotation ROM appeared to have been less affected by the exercise program. Additionally, the Pilates program was a generic "whole body" program that did not target the UE specifically. An individualized, UE-specific program may have resulted in a more significant improvement in shoulder ROM. It is also possible that the intensity of the Pilates exercise program was too low to elicit statistically significant changes in shoulder ROM. Lastly, the cancer metastases diagnosed in Participant 2 one month after completion of the intervention may explain the lack of improvement seen in her pain and UE functioning scores over the course of the intervention.
2.9.4 Contributions to the Literature

This study is: 1) the first demonstration of an experimental effect of Pilates on shoulder ROM; 2) the first documentation of the high social validity of a Pilates intervention; 3) provides documentation of the safety of Pilates exercises for women living with breast cancer, when performed under the direction of a certified Pilates instructor in a community based Pilates studio; 4) provides documentation on the effects of Pilates on multiple measures (ROM, pain, mood and UE function); 5) demonstrates the use of a SSRD that was feasible in a clinical setting (i.e. community based Pilates studio). The results of this pilot study also add to the literature relating to exercise for patients with metastatic breast disease, as two of the participants experienced metastases. Participant 3 was treated with surgery and radiation for metastases to the brain 1.5 years prior to joining the study and, as mentioned earlier, Participant 2 was diagnosed with metastases in both patellae and the skull one month after completing the intervention, and was likely living with metastatic disease while involved in the study. Both women successfully completed the intervention and reported feeling benefit from it. Additionally, Pilates is increasingly sought out as a form of post-rehabilitation exercise for which there is little scientific support. This study will add to the limited data on to Pilates and patient populations.

2.9.5 Implications of the Study

None of the participants experienced any adverse events and none developed lymphedema over the course of the intervention. Results of this study suggest that community-based Pilates programs may be safe options for women living with breast cancer. Physical therapists should encourage interested clients to seek out Pilates instructors who have levels of training consistent with the guidelines established by the Pilates Method Alliance, as well as some knowledge of breast cancer treatments and related cautions. Group Pilates classes are not an appropriate starting point for anyone from a patient population. Women living with breast cancer should begin with private Pilates sessions, in order to ensure that they are performing the exercises safely, and work their way up to joining group classes. When discussing post-rehabilitation exercise options with breast cancer clients, it is important for physical therapists should be aware that Pilates is unlikely to have an aerobic conditioning effect, and should serve as an adjunct to aerobic exercise. Because of its low intensity nature and its focus on neuromuscular repatterning, Pilates would be a sensible starting point from which women could gradually return to their regular activities after breast cancer treatments.
Rehabilitation interventions of any kind are unlikely to have an impact on impairments if they are not important, viable and acceptable to the consumer. The participants in this study stated that they would recommend the Pilates program to other women living with breast cancer, indicating that they found the program acceptable. Pilates exercise may benefit women living with breast cancer in a variety of ways that were not examined in this pilot study. For example, when asked if the exercise program had positive or negative effects beyond what had been measured, Participant 4 responded: “I learned so much. Breathing deeply was wonderful. I learned to overcome my fear, trust my body and movement. I was shocked at how much I could do after a month or so. I feel connected to my body in a way I never did before. I think the numb areas from surgery have felt more connected - almost sensation returned.” When compared to conventional exercise, Pilates may provide different benefits. When asked what the Pilates exercise program offered that other, more conventional forms of exercise did not, Participant 2 answered: “To realize that ‘doing it right’ is better, more subtle and more challenging than the ‘no pain, no gain’ thesis. To experience such an infinite variety of ways of moving and thinking was wonderful.” Although the participants in this study found the intervention to be acceptable, it is unlikely that at an average rate of $50-75/hour, many women could afford to attend one-on-one Pilates sessions three times a week for three months, as was the case in this study.

In terms of study design, a concurrent multiple baseline would have been a stronger choice, as there has been some suggestion that the non-concurrent multiple baseline SSRD used in this study does not control for history as a threat to internal validity. The non-concurrent multiple baseline was selected because: it was not known whether the Pilates intervention would have any effect on the primary dependent measure, shoulder ROM; if shoulder ROM did show change after the implementation of the intervention, it was expected to happen gradually, resulting in participants having to remain in baseline for lengthy periods of time; and it was important to complete the study in a time frame befitting a master’s thesis. A longer follow up period would have allowed the researchers to determine how long the improved ROM (where applicable) would last in the absence of a thrice-weekly, supervised Pilates program.
2.9.6 Limitations

There are several limitations to this study. Testing effects may have threatened internal validity, as evidenced by improving ROM during several of the baselines. The baseline data that showed trends consistent with improving ROM, pain, mood or function make it difficult to effectively assess the intervention's effects. Based on these pilot data, it would appear that three baseline data collection sessions are not sufficient to establish “stable” ROM data for shoulder flexion, abduction, internal and external rotation. The fact that the baseline phases had to be extended for two participants (1 and 4) lacked social validity, as the participants were anxious to begin the intervention and found the data collection sessions tedious and boring. Because the rater worked at the Pilates studio where the intervention took place, it was impossible to keep her blind to the study hypothesis, or to the study phase. We accounted for this limitation, however, by using a blind outside rater for inter-rater agreement sessions. Although this was intended to be a pilot study, the small number of participants limits generalizability. Finally, it may be difficult to measure the exercise dose, as it may have differed slightly from participant to participant for a variety of reasons, i.e. the time required to explain and refine the exercises depended on the individual, participants’ energy levels differed (e.g. Participant 3 attended the Pilates sessions after lunch, a time of day when she reported feeling the most “sleepy”), actual time spent exercising per session may have differed (e.g. Participant 3 often started late and had to leave early), and adherence to the home exercise program differed (e.g. Participants 2 and 3 did not complete all the home exercise sessions). In cases where participants did experience improvement in shoulder ROM, it was impossible to determine whether it was due to the Pilates program on the whole, or to specific exercises in the program.

2.9.7 Suggestions for Future Research

Larger studies that compare Pilates exercises to conventional weight training or physical therapy exercise programs would be worth studying, as would studies that involve interventions of longer duration and the more sensitive outcome measures. Because breast cancer treatments are individualized and few women receive exactly the same treatments, individualized Pilates programs could be compared to the generic Pilates program given to the participants in this study. Group Pilates classes could also be compared to one-on-one Pilates sessions to help understand the associated costs and benefits of each. Additionally, as there are no standard definitions of what constitutes “reduced shoulder mobility” or “acceptable inter-rater and intra-rater shoulder ROM reliability” after breast
cancer treatments, research aimed at developing such definitions would be of value. Standard definitions would allow for more accurate comparisons of study results.

2.9.8 Conclusion

Not every woman who undergoes treatment for breast cancer will develop impaired shoulder ROM but, for those who do, appropriate interventions are necessary. Most of the reduction in shoulder mobility may develop within the first two years after treatment, making early identification of women prone to developing this impairment important. More people are engaging in Pilates as a form of post-rehabilitation exercise therapy, yet few patient-based studies have been conducted. Data suggest that the Pilates program, had a modest effect on shoulder abduction and external rotation. The participants in this pilot study perceived the Pilates exercise to be enjoyable and the program beneficial and did not experience any adverse events. While further study is needed, preliminary data suggest that Pilates could be an effective, enjoyable and safe and exercise option for women after breast cancer treatments.
Table 2.1 Participant Background Information

<table>
<thead>
<tr>
<th>Participant</th>
<th>Age</th>
<th>Highest Level of Education Completed</th>
<th>Marital Status</th>
<th>Dominant Arm/Hand</th>
<th>Other Activities - Current</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>71</td>
<td>University</td>
<td>Widowed</td>
<td>Right</td>
<td>Walking</td>
</tr>
<tr>
<td>2</td>
<td>66</td>
<td>University</td>
<td>Married</td>
<td>Right</td>
<td>Walking</td>
</tr>
<tr>
<td>3</td>
<td>38</td>
<td>University</td>
<td>Married</td>
<td>Right</td>
<td>Walking/Running</td>
</tr>
<tr>
<td>4</td>
<td>51</td>
<td>University</td>
<td>Divorced</td>
<td>Right</td>
<td>Walking/Running</td>
</tr>
</tbody>
</table>

Table 2.2 Participant Treatment Information

<table>
<thead>
<tr>
<th>Participant</th>
<th>Diagnosis</th>
<th>Year of Diagnosis</th>
<th>Stage</th>
<th>Affected Side</th>
<th># Nodes Dissected</th>
<th># Nodes Involved</th>
<th>Surgery</th>
<th>Radiation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Invasive ductal carcinoma</td>
<td>2002</td>
<td>III</td>
<td>Left</td>
<td>17</td>
<td>0</td>
<td>Lumpectomy</td>
<td>(L)breast</td>
</tr>
<tr>
<td>2</td>
<td>Invasive ductal carcinoma</td>
<td>2002</td>
<td>II</td>
<td>Right</td>
<td>18</td>
<td>2</td>
<td>Complete right breast mastectomy</td>
<td>(R)mid-axilla</td>
</tr>
<tr>
<td>3</td>
<td>Invasive ductal carcinoma</td>
<td>2001</td>
<td>III</td>
<td>Left</td>
<td>6</td>
<td>6</td>
<td>Bilateral mastectomy</td>
<td>(L)chest wall</td>
</tr>
<tr>
<td>4</td>
<td>Invasive lobular carcinoma</td>
<td>2003</td>
<td>I</td>
<td>Left</td>
<td>16</td>
<td>0</td>
<td>Bilateral mastectomy, reconstruction</td>
<td>(L)chest wall</td>
</tr>
</tbody>
</table>
Table 2.3 ITSACORR Shoulder Range of Motion Results

<table>
<thead>
<tr>
<th>Participant</th>
<th>UNAFFECTED</th>
<th>AFFECTED</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Flexion</td>
<td>F(2, 24) = 0.050  ( p = 0.951 )</td>
</tr>
<tr>
<td></td>
<td>Abduction</td>
<td>F(2, 24) = 1.234  ( p = 0.309 )</td>
</tr>
<tr>
<td></td>
<td>Int. Rotation</td>
<td>F(2, 24) = 0.864  ( p = 0.434 )</td>
</tr>
<tr>
<td></td>
<td>Ext. Rotation</td>
<td>F(2, 24) = 1.011  ( p = 0.379 )</td>
</tr>
<tr>
<td>2</td>
<td>Flexion</td>
<td>F(2, 26) = 1.909  ( p = 0.169 )</td>
</tr>
<tr>
<td></td>
<td>Abduction</td>
<td>F(2, 26) = 0.872  ( p = 0.430 )</td>
</tr>
<tr>
<td></td>
<td>Int. Rotation</td>
<td>F(2, 26) = 1.499  ( p = 0.242 )</td>
</tr>
<tr>
<td></td>
<td>Ext. Rotation</td>
<td>F(2, 26) = 1.584  ( p = 0.224 )</td>
</tr>
<tr>
<td>3</td>
<td>Flexion</td>
<td>F(2, 20) = 1.204  ( p = 0.321 )</td>
</tr>
<tr>
<td></td>
<td>Abduction</td>
<td>F(2, 20) = 0.459  ( p = 0.638 )</td>
</tr>
<tr>
<td></td>
<td>Int. Rotation</td>
<td>F(2, 20) = 0.504  ( p = 0.612 )</td>
</tr>
<tr>
<td></td>
<td>Ext. Rotation</td>
<td>F(2, 20) = 0.450  ( p = 0.644 )</td>
</tr>
<tr>
<td>4</td>
<td>Flexion</td>
<td>F(2, 24) = 0.555  ( p = 0.581 )</td>
</tr>
<tr>
<td></td>
<td>Abduction</td>
<td>F(2, 24) = 1.482  ( p = 0.247 )</td>
</tr>
<tr>
<td></td>
<td>Int. Rotation</td>
<td>F(2, 24) = 0.028  ( p = 0.972 )</td>
</tr>
<tr>
<td></td>
<td>Ext. Rotation</td>
<td>F(2, 24) = 1.360  ( p = 0.276 )</td>
</tr>
</tbody>
</table>

Note: “Int. Rotation” = internal rotation, “Ext. Rotation” = external rotation
Table 2.4 Social Validity Questionnaire: Summary of Items Rated on 10-point Likert Scale

<table>
<thead>
<tr>
<th></th>
<th>Participant</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>How important are the following project goals to you:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Improved shoulder ROM</td>
<td></td>
<td>8</td>
<td>8</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Decreased level of pain</td>
<td></td>
<td>9</td>
<td>4</td>
<td>10</td>
<td>3</td>
</tr>
<tr>
<td>Improved mood state</td>
<td></td>
<td>8</td>
<td>4</td>
<td>7</td>
<td>10</td>
</tr>
<tr>
<td>Improved upper extremity functioning</td>
<td></td>
<td>8</td>
<td>8</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Strategies Used</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How satisfied are you with the Pilates exercise program</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Study Outcomes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How satisfied are you with study outcomes</td>
<td>10</td>
<td>9</td>
<td>10</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Total social validity rating (/60)</td>
<td></td>
<td>53</td>
<td>43</td>
<td>57</td>
<td>53</td>
</tr>
</tbody>
</table>

Note: For the project goals section of the questionnaire, the scale ranged from 1 (not important) to 10 (very important). For the strategies used section of the questionnaire, the scale ranged from 1 (not acceptable) to 10 (completely acceptable). For the study outcomes section of the questionnaire, the scale ranged from 1 (not satisfied) to 10 (completely satisfied).
<table>
<thead>
<tr>
<th>Social Validity Questionnaire Item</th>
<th>Participant 1</th>
<th>Participant 2</th>
<th>Participant 3</th>
<th>Participant 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>In your opinion, were the instruments used to measure change in this study sensitive, effective and appropriate?</td>
<td>All but the POMS - a client's mood is subject to many intervening factors.</td>
<td>I found the questionnaires boring and repetitive. Improved mood and decreased pain are hard to quantify and fluctuations are likely caused by factors outside of this study.</td>
<td>I thought the POMS was a bit silly - there are too many options. For example, what is the difference between &quot;full of pep&quot;, &quot;energetic&quot; and &quot;lively&quot;?</td>
<td>Yes</td>
</tr>
<tr>
<td>Did this exercise program have positive or negative effects beyond what has been measured? If so, please list them.</td>
<td>Yes, I think that it has positive effects beyond the goals of increased mobility and lessened pain in my affected arm/shoulder. I feel my posture is better, I feel taller, my core strengthened, I've lost inches on my thighs and I have more confidence about my ability to commit to a program.</td>
<td>Positive: the interaction with the researchers, the feeling of personal warmth and connection was the best aspect of the program. Getting to learn how to reprogram my mind as well as my body was fascinating - I hope it lasts a long time.</td>
<td>NA</td>
<td>I learned so much! Breathing deeply was wonderful. I learned to overcome my fear, trust my body and movement. I was shocked at how much I could do after a month or so. I feel connected to my body in a way I never did before.</td>
</tr>
<tr>
<td>What, if anything, did this Pilates exercise program offer you that other, more conventional forms of exercise, have not?</td>
<td>1) a focus on a weak area 2) a structure that was consistently guided 3) a chance to try a new way of exercising 4) improved posture and a strengthened core 5) improved balance and flexibility in toes and ankles</td>
<td>To realize that &quot;doing it right&quot; is better, more subtle and more challenging than the &quot;no pain, no gain&quot; thesis. To experience such an infinite variety of ways of moving and thinking was wonderful.</td>
<td>1) stretches and exercises that were tailored perfectly to my needs 2) felt secure knowing that the instructor was ensuring that I performed each exercise in a safe and correct manner - other exercise programs focus less on anatomically correct movement</td>
<td>Focus, relaxation, balance, connection - at a very deep level I was able to feel my body. It felt like I was light, flexible, limber - like the Tin Man after he got oil.</td>
</tr>
<tr>
<td>Social Validity Questionnaire Item</td>
<td>Participant 1</td>
<td>Participant 2</td>
<td>Participant 3</td>
<td>Participant 4</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>---------------</td>
<td>---------------</td>
<td>---------------</td>
<td>---------------</td>
</tr>
<tr>
<td>What did you enjoy the most about this exercise program? What was the most significant benefit?</td>
<td>1) the consistent one-on-one sessions 2) liked having a chance to voice my concerns and being asked how I was doing and listened to before every session</td>
<td>NA</td>
<td>1) the many stretching exercises 2) instructor's touch and explanations were fantastic and allowed me to get full benefits of each exercise</td>
<td>Poise, posture, confidence, peace. It really expanded my mind as far as what is possible. I'm so proud of myself and so grateful for the opportunity to enjoy my body again.</td>
</tr>
<tr>
<td>What did you enjoy the least about this exercise program?</td>
<td>It took a long time and a lot of patience before I could see any real benefits.</td>
<td>Trying to make the home exercise segment as rewarding as the studio sessions. Having someone watch and cue you is great - I'll have to learn to do that now for myself.</td>
<td>The frequency of the exercise sessions - it was difficult at times to fit in 3 sessions a week.</td>
<td>I feel like I need to say something, so I'll say &quot;parking&quot; - mostly because I was so thrilled with all of it.</td>
</tr>
<tr>
<td>Would you recommend a Pilates exercise program to other women who have limited shoulder range of motion secondary to breast cancer treatments? Why or why not?</td>
<td>Yes, I would, but I would explain two things: 1) they would need to be patient 2) the improvement might not be as dramatic as they would hope for...but I would assure them that if they worked at it they would be happy with the results.</td>
<td>Yes, definitely, for both the physical and psychological benefits.</td>
<td>Yes - for the reasons already mentioned and because the program has given me a good understanding of how my bones and muscles work, and how to do activities to maintain my strength and mobility.</td>
<td>Absolutely. I think I would serve many rehab situations also.</td>
</tr>
</tbody>
</table>
Figure 2.1 Shoulder flexion: mean level lines and trend lines for each phase.

The figures above are organized from shortest to longest baseline for ease of interpretation.
Figure 2.2 Shoulder abduction: mean level lines and trend lines for each phase.

The figures above are organized from shortest to longest baseline for ease of interpretation.
Figure 2.3 Shoulder internal rotation: mean level lines and trend lines for each phase.

The figures above are organized from shortest to longest baseline for ease of interpretation.
Figure 2.4 Shoulder external rotation: mean level lines and trend lines for each phase.

The figures above are organized from shortest to longest baseline for ease of interpretation.
Figure 2.5 Shoulder flexion: baseline trend line extended into intervention and follow up.

The figures above are organized from shortest to longest baseline for ease of interpretation.
Figure 2.6 Shoulder abduction: baseline trend line extended into intervention and follow up.

The figures above are organized from shortest to longest baseline for ease of interpretation.
Figure 2.7 Shoulder internal rotation: baseline trend line extended into intervention and follow up.

The figures above are organized from shortest to longest baseline for ease of interpretation.
Figure 2.8 Shoulder external rotation: baseline trend line extended into intervention and follow up.

The figures above are organized from shortest to longest baseline for ease of interpretation.
Figure 2.9 Brief Pain Inventory: mean level lines and trend lines for each phase.

The figures above are organized from shortest to longest baseline for ease of interpretation.
Figure 2.10 Brief Pain Inventory: baseline trend line extended into intervention and follow up.

The figures above are organized from shortest to longest baseline for ease of interpretation.
Figure 2.11 Profile of Mood States: mean level lines and trend lines for each phase.

The figures above are organized from shortest to longest baseline for ease of interpretation.
Figure 2.12 Profile of Mood States: baseline trend line extended into intervention and follow up.

The figures above are organized from shortest to longest baseline for ease of interpretation.
Figure 2.13 Upper Extremity Function Questionnaire: mean level lines and trend lines for each phase.

The figures above are organized from shortest to longest baseline for ease of interpretation.
Figure 2.14 Upper Extremity Function Questionnaire: baseline trend line extended into intervention and follow up.

The figures above are organized from shortest to longest baseline for ease of interpretation.
2.10 REFERENCES


Chapter 3

3.1 Primary Findings

As the data in Chapter 2 demonstrate, there was a modest functional relationship between implementation of the Pilates intervention and increased shoulder abduction and external rotation ROM.

When all participants and affected UE ranges of motion were considered, 10/16 comparisons showed improvement in level from baseline to intervention, and 10/16 exhibited improvement in trend (from stable or deteriorating in baseline, to improving during intervention). On the affected UE, 6/16 comparisons showed improvement in both level and trend: shoulder flexion, abduction and external rotation for Participants 1 and 2. ITSACORR results showed a significant change in shoulder internal ROM ($p = 0.028$) and external rotation ROM ($p = 0.049$) on the affected UE for Participant 3.

Visual analyses suggest that Participant 1 showed the strongest association between implementation of the Pilates intervention and improved shoulder ROM. It is worth noting that Participant 1 was only six months post radiation treatment when she joined the study. Participant 1 was also: the oldest (71 years) of the sample; did not have a mastectomy; showed the highest overall scores for pain, disturbed mood and difficulty with tasks listed on the UE function questionnaire; and demonstrated the most impaired shoulder ROM on the affected side in flexion, abduction and external rotation when compared to the other three participants. For the reasons listed above, Participant 1 may also have been the most motivated of the group. After completing the study, she continued with supervised and home Pilates sessions and reported increasing benefit from the exercise program.

One month after completing the intervention, Participant 2 was diagnosed with cancer that had metastasized to the patellae and skull. Even with metastatic cancer, Participant 2 showed an improvement in both level and trend for shoulder flexion, abduction and external rotation ROM on the affected UE.

While Participant 3 was the only participant to show statistically significant change in shoulder ROM for internal and external rotation on the affected UE, visual analysis suggests that, of the women under study, she may have experienced the least change due to the Pilates program. Despite this, Participant 3 rated a 10/10 (indicating "completely satisfied") when asked how satisfied she was with the study outcomes. When asked to comment on the study outcomes, she replied: "I noticed improved function, in terms of greater strength and mobility. I found both
the stretching and resistance exercises extremely helpful in improving my range of motion and strength”, suggesting that the program resulted in change that was of clinical importance to her.

The International Classification of Functioning, Disability and Health framework defines impairments as “problems in body functions or structure”, activity as “the execution of a task or action by an individual” and participation as “involvement in a life situation”. Despite their common impairment of reduced shoulder ROM, the participants in this study appeared to be living well with their conditions even at the study’s outset, suggesting that impairment may not always result in activity limitation. Rietman et al also reported that the impairments of the arm found in their study of women living with breast cancer did not result in a high state of disability. They did, however, caution that due to the small number of patients studied, their study may have a lack of sufficient power.

As the data in Chapter 2 demonstrate, during the baseline phase, none of the participants (with the exception of data from Participant 1’s first day of the study) showed comparatively high scores (i.e. the maximum possible score for each test) on the BPI, the POMS or the UEFQ, indicating that their impairments of reduced shoulder ROM, and where applicable, pain and impaired mood, were not excessively limiting their activities or participation. Over the course of the study, Participants 1 and 4 improved their ability to perform activities (as demonstrated by improved UEFQ scores), and did not report substantial participation restrictions (as demonstrated by scores for the “nominated hobby” and “nominated activity” on the UEFQ). The increase in Participant 2’s BPI and UEFQ scores (indicating worsening conditions) over the course of the intervention were largely the result of the aggravation of what she reported as “a longstanding knee problem”, later diagnosed as metastases to the patellae.

3.2 Status of Relevant Working Hypotheses

In Chapter 1, it was hypothesized that a 3-month Pilates exercise program would improve shoulder ROM, decrease pain, enhance mood and ameliorate UE function in women who had been treated with axillary dissection and radiation for the treatment of Stages I-III breast cancer.

3.2.1 Shoulder ROM

Shoulder ROM was the primary dependent measure in this study. While our inclusion criteria required a difference of at least 10° between UEs, three participants (1, 2, 3) had differences between extremities of over 20° in abduction (range: 29-64°) and external rotation (range: 25-54°) at intake. The literature suggests a wide variety of
patterns for post-treatment shoulder ROM impairment, suggesting that the response to treatment likely varies among individuals. For example, Box et al's findings suggest that shoulder external rotation ROM is not adversely affected by breast cancer surgery or radiotherapy, while Kuehn et al's assessment of 396 patients (retrospectively using a self-report questionnaire and a clinical examination) found a mean abduction restriction of 21°, and no restriction for external rotation on the affected UE. Voogd et al found that 10% (n = 33) of women who had undergone axillary lymph node dissection (range: 0.3 - 28 years before the study) demonstrated a difference of more than 20° in shoulder abduction between the affected and unaffected UEs. While the women in Voogd et al's study were treated with radiation, none had radiation to the axilla. It has been suggested that severe abduction impairment may occur more often in women who are treated with mastectomies. Two of three participants in our study who demonstrated abduction impairment had also undergone mastectomies.

Visual analyses of shoulder flexion and abduction data in this study indicated improved ROM from baseline to intervention, particularly for the affected UE in Participants 1, 2 and 4, while all participants showed improvement in shoulder external rotation ROM on the affected side. Participants may have tried harder and paid more attention to how they were using the affected UE during the exercise sessions. Additionally, there was simply more room for improvement on the affected UE for the participants.

Visual analysis suggested that shoulder internal rotation ROM was the least affected and shoulder external rotation and abduction ROM were the most affected, by the Pilates program. Several of the Pilates exercises in the study required movement into shoulder abduction and external rotation, while only one required notable internal rotation. Additionally, the participants entered the study with baseline postural issues that would likely require more than a three-month exercise intervention to correct. Other authors have reported similar findings relating to shoulder internal rotation ROM. Johansson et al studied women who had undergone axillary dissection with mastectomy (n=26) or segmental resection (n=35) for breast cancer. The women were also treated with breast radiotherapy (n=16), breast and axillary radiotherapy (n=19) or no radiotherapy (n=26). The women were given a daily home exercise program that included five repetitions of active shoulder flexion, abduction, internal and external rotation, three times a day for six months. No data were provided regarding patient adherence to the exercise program. At two years post-treatment, none of the women had regained their pre-treatment internal rotation ROM, with the women who had received radiotherapy to the breast and axilla faring the worst. Internal rotation was the range most affected by the
treatments, with women who had been treated with both radiotherapy to the breast and axilla showing the most impairment in all ranges measured.

3.2.2 Level of Pain

Except for Participant 1, the others did not report high levels of pain at the study outset. When the BPI scores are examined, each participant demonstrated a decrease in pain from baseline to the end of the intervention (total decreases of 2-53 points), with Participant 1 showing the greatest decrease. At follow-up, Participant 1’s pain had continued to decrease. Of note, Participant 1 continued to do her Pilates home program exercises two to three times a week during the follow-up period, while none of the other participants did. The increase in Participant 2’s pain scores during the intervention could be attributed to the aggravation of a longstanding knee injury, and perhaps to the later-diagnosed patellar metastases.

3.2.3 Mood State

The improving mood exhibited by Participants 1, 2 and 4 during baseline makes it difficult to conclude that improvement during intervention was due to the Pilates exercises. The improving mood could have been due to factors unrelated to participation in the study or could have resulted from anticipating positive effects from the upcoming Pilates intervention. Two factors make one ponder whether the POMS was the best choice of instruments to measure mood in this study. First, the POMS asked participants to rate various aspects of their mood “during the past week including today” and was completed prior to the Pilates exercise sessions. Participants reported feeling very relaxed and calm after the Pilates sessions, suggesting that the exercise program may have had a transient effect on mood that was unable to be detected by the POMS. Secondly, one item on the social validity questionnaire asked participants to comment on the instruments used to measure change in the study. Participants 1 and 2 felt that the POMS was insensitive, ineffective and inappropriate as a dependent measure.

3.3 Limitations

There are several limitations to this study. Testing effects may have threatened internal validity, as evidenced by the improving ROM during several participants’ baselines. The baseline data that showed trends consistent with improving ROM, pain, mood or function make it difficult to effectively assess the intervention’s effects. Based on
these pilot data, it would appear that three baseline data collection sessions are not sufficient to establish "stable" ROM data in shoulder flexion, abduction, internal and external rotation. The fact that the baseline phases had to be extended for two participants (1 and 4) lacked social validity, as the participants were anxious to begin the intervention and found the data collection sessions tedious and boring. Because the rater worked at the Pilates studio where the intervention took place, it was impossible to keep her blind to the study hypothesis, or to the study phase. We accounted for this limitation, however, by using a blind outside observer for inter-observer agreement sessions. The small number of participants limits generalizability, although this was intended to be a pilot study.

It is also possible that the intensity of the Pilates exercise program was too low to elicit statistically significant changes. Finally, it may be difficult to measure the exercise dose, as it may have differed slightly from participant to participant for a variety of reasons, i.e. the time required to explain and refine the exercises differed, depending on the individual participants’ energy levels (e.g. Participant 3 attended the Pilates sessions after lunch, a time of day when she reported feeling the most “sleepy”), actual time spent exercising per session may have differed (e.g. Participant 3 often started late and had to leave early), and adherence to the home exercise program differed (e.g. Participants 2 and 3 did not complete all the home exercise sessions).

3.4 Strengths

Strengths of this study included variability in participant ages (38-71 years), stages of cancer (I-III at diagnosis, with one case of metastatic disease at the study outset), time since initial diagnosis (2.5 - 5 years), and surgical procedures (lumpectomy, right mastectomy, bilateral mastectomy, bilateral mastectomy with reconstruction). The intervention took place in a community-based Pilates studio with a program typical of what a “regular” Pilates client would receive, supporting the ecological validity of the results.

3.5 Metastatic Disease

The successful completion of the intervention by Participant 3, who had been treated with surgery and radiation for metastases to the brain 1.5 years prior to joining the study, is important because of the lack of scientific information on the effects of exercise for women with metastatic disease. Literature searches on exercise and metastatic cancer revealed only: one program description; three case studies; a feasibility study; and a randomized controlled, longitudinal trial that reported on exercise interventions for patients with advanced and
progressive cancer. In all cases, patients improved their physical performance and QOL without experiencing adverse events. It is interesting to note that Participant 3, the participant with metastatic disease, was the only participant who demonstrated statistically significant change in shoulder internal and external ROM on the affected UE. If the guidelines and precautions for exercise during and after cancer treatment\(^\text{15}\) are adhered to, individual differences are considered, exercise programs are of low to medium intensity and performed under the supervision of an oncologist, patients with metastatic breast cancer should be able to undertake exercise studies without risking undue harm.

### 3.6 Inter-rater Agreement

Currently, no standards exist as to what constitutes satisfactory inter-rater agreement for active shoulder ROM in women treated for breast cancer. In Chapter 2 we stated that the inter-rater agreement for shoulder ROM was 74%. This is somewhat below the acceptable standard of 80%, despite the use of a standardized measurement protocol and trained raters. This suggests that shoulder ROM in this population may be more variable than in non-patient populations. A study of patients with shoulder dysfunction conducted by Hayes et al\(^\text{16}\) supports our findings. Hayes and colleagues investigated inter-rater reliability for shoulder flexion, abduction, and external rotation in patients with rotator cuff repair (n=6), adhesive capsulitis (n=1) and scapulothoracic fusion (n=1). Their inter-rater correlation coefficients \(r_s\) were: flexion = 0.69, abduction = 0.69, external rotation = 0.64. It has been suggested that correlation coefficients from 0.40 - 0.75 equal fair to good reliability.\(^\text{16}\) Shoulder ROM reliability in women treated for breast cancer needs further study.

### 3.7 Adherence

Generally, high levels of participant adherence were seen in this study, particularly for the supervised exercise sessions (86% - 94%). The reasons given for missing the studio exercise sessions included illness, lack of child care and issues related to work. Michebaum and Turk\(^\text{17}\) suggested that low to moderate intensity exercise programs (of which Pilates is one) tend to have greater adherence rates. Higher education levels and support for exercise from family and friends are also associated with increased participation in planned exercise.\(^\text{18}\) The participants in this study were university-educated and most (n=3) could enlist support from family and friends.
The theory of planned behavior proposes that the intention to perform a behavior is partially determined by the attitude toward the behavior. All participants in this pilot study believed that the Pilates exercises would increase shoulder ROM, decrease pain, and improve mood and UE function. The one-on-one nature of the exercise program may have made the relationship between the participants and the instructor more personal, leading them to be more accountable and less likely to miss the exercise sessions.

3.8 Clinically Meaningful Change

The authors are not aware of any research that has defined clinically significant change for active shoulder ROM, the BPI, the POMS or the UEFQ. Because the results of the UEFQ represent the participants’ opinions regarding their ability to perform activities of daily living and participate in self-selected hobbies and activities, they could be analogous to the participants’ sense of whether or not clinically meaningful change resulted from the Pilates intervention. Participant 1 changed the most dramatically in UEFQ scores with a 46-point decrease from the first baseline data point to the last intervention data point. Participant 4 showed a decrease of 10 points, Participant 2 a decrease of one point and Participant 3 showed no change. When the final data points during the intervention phase are compared to the follow-up data points, Participants 1, 2 and 3’s UE function scores had increased by nine, nine and three points respectively, indicating increasing activity limitation in the absence of the supervised Pilates exercises. Participant 4 showed no change.

Clinically significant change has been described as a “return to normal functioning” that would render the patient’s level of functioning consistent with that of well-functioning people. Functional shoulder ROM is 160° flexion, 145° abduction and 80° internal and external rotation. Although we did not hypothesize that participants would attain functional ROM, three achieved functional external rotation ROM in the affected shoulder. None, however, attained functional shoulder abduction or internal rotation ROM on the affected UE. Data for functional shoulder flexion ROM show no consistent patterns across participants.

3.9 Social Validity

Experts in single subject research design have suggested the importance of assessing the social validity of study results. Rehabilitation interventions are unlikely to have an impact on impairments if the interventions are not viable and acceptable to the consumer/patient. When participants in this study were asked if they would recommend
the Pilates program to other women living with breast cancer, all four responded “yes”, indicating that they found the program acceptable. Participant 2 stated that she would recommend the Pilates program to other women living with breast cancer for “both the physical and psychological benefits.”

When asked to rate (on a 10-point Likert scale) how satisfied they were with the study outcomes, three participants responded “completely satisfied” (10/10) and one responded “almost completely satisfied” (9/10). Participant 1 stated: “I notice all sorts of changes in my body and really felt the benefit of the exercises, so much that I’ll continue with exercises on my own” and “I think that it (the Pilates exercise program) has positive effects beyond the goals of increased mobility and lessened pain in my affected arm/shoulder. I feel my posture is better, I feel taller, my core strengthened, I’ve lost inches on my thighs and I have more confidence about my ability to commit to a program”. After completing the study, Participant 1 continued with supervised and home Pilates sessions and reported increasing benefit from the exercise program.

When asked if the exercise program had positive or negative effects beyond what had been measured, Participant 4 responded: “I learned so much. Breathing deeply was wonderful. I learned to overcome my fear, trust my body and movement. I was shocked at how much I could do after a month or so. I feel connected to my body in a way I never did before. I think the numb areas from surgery have felt more connected - almost sensation returned.”

When asked what the Pilates exercise program offered that other, more conventional forms of exercise did not, Participant 2 answered: “To realize that ‘doing it right’ is better, more subtle and more challenging than the ‘no pain, no gain’ thesis. To experience such an infinite variety of ways of moving and thinking was wonderful.”

3.10 Evaluation of Current Knowledge

Current knowledge suggests that women living with breast cancer are not meeting physical activity recommendations for the adult population and that they decrease their levels of physical activity by 2 hours per week after a breast cancer diagnosis. Holmes et al. found that physical activity, while beneficial to women with Stage I and II disease, appeared to have particular benefit for women with Stage III disease. Walking 3-5 hours a week at an average pace provided the maximal benefit in reducing mortality from breast disease. Little evidence was found for increased benefits of more exercise, suggesting that vigorous activity may be less beneficial than moderate activity for women with breast cancer. Pilates exercise is classified as being low to moderate in intensity. As the number of safe
exercise options for women living with breast cancer increases, so might the likelihood that these women will engage in regular physical activity, thereby reducing their impairments and increasing their ability to perform their activities, as well as their level of participation. This thesis research suggests that complementary forms of exercise, such as Pilates, may also have a place in breast cancer rehabilitation.

3.11 Suggestions for Future Research

Larger studies that compare Pilates exercises to conventional weight training or physical therapy exercise programs would be worth studying, as would studies that involve interventions of longer duration and the use of more sensitive outcome measures. Additionally, as there are no standard definitions of what constitutes “reduced shoulder mobility” or “acceptable inter-rater and intra-rater shoulder ROM reliability” after breast cancer treatments, research aimed at developing such definitions would be of value. Standard definitions would allow for more accurate comparisons of study results.

3.12 Conclusion

As the literature review in Chapter 1 suggest, not every woman who undergoes treatment for breast cancer will develop impaired shoulder ROM but, for those who do, appropriate interventions are necessary. Most of the reduction in shoulder mobility may develop within the first two years after treatment, making early identification of women prone to developing this impairment important. More people are engaging in Pilates as a form of post-rehabilitation exercise therapy, yet few patient-based studies have been conducted. Data suggest that the Pilates program, had a modest effect on shoulder abduction and external rotation. The participants in this pilot study perceived the Pilates exercise to be enjoyable and the program beneficial and did not experience any adverse events. While further study is needed, preliminary data suggest that Pilates could be an effective, enjoyable and safe and exercise option for women after breast cancer treatments.
3.13 References


Effects of Pilates Exercises on Shoulder Range of Motion, Pain, Mood and Upper Extremity Function in Women Living with Breast Cancer: A Pilot Study

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School of Rehabilitation Sciences, UBC

STUDY FUNDED BY:
Canadian Breast Cancer Research Alliance

You have been invited to participate in this study because you had axillary dissection and radiation for stages I or II breast cancer at least one year ago. As a result, you have restricted range of motion in your shoulder.

Four women who have had axillary dissection and radiation for stages I or II breast cancer will be invited to participate in this study. The study will take place at Meridian Pilates Studio in Vancouver, BC.

PURPOSE
The purpose of this study is to examine the effects of a rehabilitative Pilates exercise program on shoulder motion, pain, mood and arm function in women who have had axillary dissection (removal of lymph nodes under the arm) and radiation therapy for stages I or II breast cancer.

INDIVIDUALS WHO ARE ELIGIBLE
Women who are at least one-year post axillary dissection and radiation therapy for stages I or II breast cancer, who have restricted shoulder movement (i.e. a difference of 10 degrees or more between the surgical and non-surgical arm) secondary to breast cancer treatment.

INDIVIDUALS WHO ARE NOT ELIGIBLE
Those individuals who do not meet the above stated criteria as well as women who are actively undergoing chemotherapy treatment or attending regular physiotherapy, chiropractic or massage therapy or psychological counseling; women who have previous shoulder injuries or health problems other than cancer and related side-effects will be excluded from the study.

Version 6, Oct. 10, 2005
TEST PROTOCOL
The order of testing will be: active shoulder motion on both sides, Brief Pain Inventory, Profile of Mood States – Short Form and Upper Extremity Function questionnaire. You will also be asked to keep a daily diary of your physical activities. Active shoulder motion tests will include flexion (lifting your arm in front of you), abduction (lifting your arm to the side), internal rotation (elbow bent at 90 degrees, arm lifted away from side so that elbow is in line with shoulder, palm facing forward, rotate arm forward toward floor) and external rotation (elbow bent at 90 degrees, arm lifted away from side so that elbow is in line with shoulder, palm facing forward, rotate arm backward toward floor).

PILATES EXERCISES
Pilates is a mind-body exercise approach based on Eastern theories of body-mind-spirit interaction combined with Western theories of biomechanics, motor learning (how your body produces movement), and core stability (strengthening of the muscles of the torso). The proponents of this approach claim that regular Pilates practice results in relaxation and control of the mind, enhanced body and self-awareness, improved core stability, better coordination, more ideal posture, greater joint motion, uniform muscle development and decreased stress.

A certified Pilates instructor will conduct all exercise sessions. Sessions will involve the use of Pilates specific exercise equipment. Exercise programs will be individualized to suit your specific needs.

You will wear exercise attire during the sessions. Form fitting clothing such as leggings and tank tops are most beneficial as they allow the instructor to have a better sense of body positioning. You will wear a compression garment on your affected arm during the exercise sessions.

You may refuse to perform any movements or tests that the investigator requests.

TEST PROCEDURES
Shoulder Motion
You will lie on a hard surface (i.e. table, portable massage bed, mat on the floor) while the investigator uses a 12-inch goniometer (plastic device used to measure range of movement of the arm) to measure flexion (lifting your arm in front of you), abduction (lifting your arm to the side), internal rotation (turning your straight arm so that your palm faces backward) and external rotation (turning your straight arm so that your palm faces forward) for both of your shoulders.

Pain – Brief Pain Inventory (BPI)
The BPI is a questionnaire that consists of 15 items, including pain drawing and 7 pain interference questions, rated on a 11-point scale. The BPI provides information on the intensity and the degree to which pain interferes with function.
Profile of Mood States Short Form (POMS SF)
The POMS-SF is a questionnaire that rates a variety of mood states (including anxiety, depression, anger, vigor, fatigue and confusion) using a 30-item adjective checklist. Each item is rated on a 5-point scale. The test provides a score for total mood disturbance.

Upper Extremity Function Questionnaire (UEFQ)
The UEFQ is a questionnaire that will be used to rate the degree of difficulty with which you can perform tasks that involve your arms. For each task, you will rate the degree of difficulty on a 10-point scale that ranges from “no difficulty” with the task to “completely unable to do” the task.

TIME COMMITMENT
You will attend 3 private (i.e. one on one) Pilates sessions every week for 12 weeks at Meridian Pilates Studio in Vancouver, BC. Each studio based exercise session will last for 55 minutes. For the same 12 weeks that you are attending the studio based Pilates sessions, you will be given an additional 30-minute Pilates exercise program to perform on your own (at home) once a week.

You will be randomly assigned (i.e. the number will be picked out of an envelope) to 3, 5, 7, or 9 baseline data collection sessions. These sessions will establish your pre-Pilates exercise function. These sessions will take place either in your home or at Meridian Pilates Studio and will include measurements of shoulder motion, pain, mood and upper extremity function. Once the exercise sessions begin, the same measurements will take place twice a week for 12 weeks. Of the two weekly data collection sessions, the first should take approximately 10 minutes and the second should take approximately 25 minutes. The first data collection session will take place early in the week (i.e. Monday), and the second will take place at the end of the week (i.e. Friday). If those days are not convenient, an alternate schedule can be arranged.

Should you choose not to participate in this study, or if you do not meet the inclusion criteria, we will refer you to exercise professionals who specialize in breast cancer rehabilitation. If we are aware of any researchers who are recruiting women living with breast cancer to participate in their studies, we will provide you with the appropriate contact information.

MONETARY COMPENSATION
There is no monetary compensation for participation in this study. If you do not have one already, a compression sleeve (an elastic stocking worn on the affected arm during exercise, thought to decrease the chance of developing lymphedema) will be provided for you, providing you obtain a physician’s prescription for it.

RISKS AND BENEFITS
You may experience some muscle soreness secondary to the exercise program. This is common and should subside within 48-72 hours of the exercise session.
There is a theoretical risk that you could develop lymphedema (swelling) in your affected arm due to your participation in this study, however this risk is thought to be minimal. Recent research has shown that women living with breast cancer can engage in vigorous upper extremity exercise without increasing their risk of developing lymphedema. Pilates, a much gentler form of exercise that focuses on the whole body, is not expected to contribute to the development of lymphedema. In the unlikely event that you should develop lymphedema, you will be referred to a qualified physiotherapist for treatment.

The benefits of this research is that it will lead to a better understanding of whether or not Pilates exercise can contribute to the physical and psychological rehabilitation of women who have undergone axillary dissection and radiation for stages I or II breast cancer.

The investigator will cover the cost of the private Pilates sessions.

CONFIDENTIALITY
Your confidentiality will be respected. No information that discloses your identity will be released or published without your specific consent to the disclosure. However, research records and medical records identifying you may be inspected in the presence of the principal investigator or his or her designate by representative of the UBC Research Ethics Board or by Health Canada for the purpose of monitoring the research. However, no records which identify you by name or initials will be allowed to leave the investigator’s offices.

CONTACT
Any questions that you have, have been answered to your satisfaction by the investigator(s). You understand that if you have any further questions or desire more information with respect to the study, or if you experience any adverse effects, you should contact Dr. Susan Harris or any of the investigators. If you have any concerns about your treatment or rights as a research subject you may contact the “Research Subject Information Line” office at UBC (604-822-8598).
CONSENT
I have read the above comments and wish to proceed with the evaluation. I understand that participation in this study is entirely voluntary and that I may refuse to participate or I may withdraw without any consequences to my continuing medical care. I understand that I do not waive my legal rights by signing this consent form.

I have received a copy of this consent form.

1. Name ____________________________ Date ______________
Signature ____________________________________________

2. Witness __________________________ Date ______________
Signature ____________________________________________

3. Investigator ______________________ Date ______________
Signature ____________________________________________
Appendix 4

Brief Pain Inventory – Short Form

Brief Pain Inventory (Short Form)©

Study ID#________________________________________ Hospital#________________________________________

Do not write above this line

Date: __/__/____

Time: ______________________

Name: ________________________ Last ________________________ First ________________________ Middle Initial

1) Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?

1. yes  2. no

2) On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.

3) Please rate your pain by circling the one number that best describes your pain at its WORST in the past 24 hours.

0  1  2  3  4  5  6  7  8  9  10

No pain

Pain as bad as you can imagine

83
4) Please rate your pain by circling the one number that best describes your pain at its LEAST in the past 24 hours.

<table>
<thead>
<tr>
<th>No pain</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain as bad as you can imagine</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
<td>10</td>
<td>10</td>
</tr>
</tbody>
</table>

5) Please rate your pain by circling the one number that best describes your pain on the AVERAGE.

<table>
<thead>
<tr>
<th>No pain</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain as bad as you can imagine</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
<td>10</td>
<td>10</td>
</tr>
</tbody>
</table>

6) Please rate your pain by circling the one number that tells how much pain you have RIGHT NOW.

<table>
<thead>
<tr>
<th>No pain</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain as bad as you can imagine</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
<td>10</td>
<td>10</td>
</tr>
</tbody>
</table>

7) What treatments or medications are you receiving for your pain?

8) In the past 24 hours, how much RELIEF have pain treatments or medications provided? Please circle the one percentage that most shows how much.

<table>
<thead>
<tr>
<th>No relief</th>
<th>0%</th>
<th>10%</th>
<th>20%</th>
<th>30%</th>
<th>40%</th>
<th>50%</th>
<th>60%</th>
<th>70%</th>
<th>80%</th>
<th>90%</th>
<th>100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete relief</td>
<td>100%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

9) Circle the one number that describes how, during the past 24 hours, PAIN HAS INTERFERED with your:

A. General Activity:

<table>
<thead>
<tr>
<th>Does not interfere</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completely interferes</td>
<td>10</td>
<td>9</td>
<td>8</td>
<td>7</td>
<td>6</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

B. Mood

<table>
<thead>
<tr>
<th>Does not interfere</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completely interferes</td>
<td>10</td>
<td>9</td>
<td>8</td>
<td>7</td>
<td>6</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>C. Walking ability</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does not interfere</td>
<td>Completely interferes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>D. Normal work (includes both work outside the home and housework)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
</tr>
<tr>
<td>Does not interfere</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>E. Relations with other people</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
</tr>
<tr>
<td>Does not interfere</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>F. Sleep</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
</tr>
<tr>
<td>Does not interfere</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>G. Enjoyment of life</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
</tr>
<tr>
<td>Does not interfere</td>
</tr>
</tbody>
</table>

Used with permission. May be duplicated and used in clinical practice. Source: Dr. Charles Cleeland, Anderson Cancer Center, Pain Research Group, 1100 Holcombe, Houston, TX 77030.
Appendix 5
Profile of Mood States – Short Form

<table>
<thead>
<tr>
<th>NAME</th>
<th>DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEX: Male ☐ Female ☐ Identification No.</td>
<td></td>
</tr>
</tbody>
</table>

Below is a list of words that describe feelings people have. Please read each one carefully. Then fill in ONE circle under the answer to the right which best describes HOW YOU HAVE BEEN FEELING DURING THE PAST WEEK INCLUDING TODAY.

The numbers refer to these phrases.
- ☐ = Not at all
- ☐ = A little
- ☐ = Moderately
- ☐ = Quite a bit
- ☐ = Extremely

| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

MAKE SURE YOU HAVE ANSWERED EVERY ITEM.

SHORT FORM

| A | C | D | F | T | V |

## Upper Extremity Function Questionnaire

*Please circle the number which best describes your ability to perform the task in question today.
*(range from 1 = no difficulty with the task to 10 = completely unable to do the task)*

1. **Scratching/washing the top of your opposite shoulder blade**

<table>
<thead>
<tr>
<th>No difficulty</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>Completely Unable to do</th>
</tr>
</thead>
</table>

2. **Reaching overhead (i.e. to a cupboard)**

<table>
<thead>
<tr>
<th>No difficulty</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>Completely Unable to do</th>
</tr>
</thead>
</table>

3. **Driving a car for greater than 15 minutes**

<table>
<thead>
<tr>
<th>No difficulty</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>Completely Unable to do</th>
</tr>
</thead>
</table>

4. **Pulling a shirt on/off over your head**

<table>
<thead>
<tr>
<th>No difficulty</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>Completely Unable to do</th>
</tr>
</thead>
</table>

5. **Brushing or combing your hair/fixing your wig or head scarf**

<table>
<thead>
<tr>
<th>No difficulty</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>Completely Unable to do</th>
</tr>
</thead>
</table>

6. **Doing up a back fastening bra**

<table>
<thead>
<tr>
<th>No difficulty</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>Completely Unable to do</th>
</tr>
</thead>
</table>
7. Zipping up a back fastening dress

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>No difficulty</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Completely Unable to do</td>
</tr>
</tbody>
</table>

8. Wiping down a table top or bench

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>No difficulty</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Completely Unable to do</td>
</tr>
</tbody>
</table>

9. Making a double bed

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>No difficulty</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Completely Unable to do</td>
</tr>
</tbody>
</table>

10. Pushing a full supermarket trolley with two hands

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>No difficulty</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Completely Unable to do</td>
</tr>
</tbody>
</table>

11. Nominated sport/recreational activity

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>No difficulty</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Completely Unable to do</td>
</tr>
</tbody>
</table>

(Sport/Activity: ____________________________)

12. Nominated hobby

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
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<th>4</th>
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<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>No difficulty</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Completely Unable to do</td>
</tr>
</tbody>
</table>

(Hobby: ____________________________)

Questionnaire modified from:
Appendix 7
Social Validity Questionnaire

Please read each question carefully. Your feedback will help us to improve future programs.

Project Goals

A. Please rate how important the following project goals are to you:

1. Improved shoulder range of motion:

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not important</td>
<td>Very Important</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. Decreased pain:

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not important</td>
<td>Very Important</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. Improved mood:

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not important</td>
<td>Very Important</td>
<td></td>
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<td></td>
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<td></td>
</tr>
</tbody>
</table>

4. Improved upper extremity function:

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not important</td>
<td>Very Important</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

B. Have you experienced any post breast cancer treatment problems, other than the four listed above, that you would like to address? If so, what are they?

Comments/suggestions regarding project goals:

Strategies Used

C. In your opinion, how acceptable were the following:

1. The Pilates exercise program

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
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<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not acceptable</td>
<td>Completely acceptable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. The private exercise sessions (when compared to possible group classes)

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not acceptable</td>
<td>Completely acceptable</td>
<td></td>
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</tr>
</tbody>
</table>

3. The setting (Meridian Pilates Studio)

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
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<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not acceptable</td>
<td>Completely acceptable</td>
<td></td>
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<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. The length of the baseline phase
5. The frequency of the data collection sessions
Not acceptable

6. The length of the intervention (i.e. the Pilates program) phase
Not acceptable

7. The frequency of the studio exercise sessions (3x/week)
Not acceptable

8. The frequency of the home exercise sessions (1x/week)
Not acceptable

Comments/suggestions regarding the acceptability of the strategies used in the study:
D. In your opinion, were the instruments used to measure change in this study (goniometer, Brief Pain Inventory, Profile of Mood States and Upper Extremity Function Questionnaire) sensitive, effective and appropriate? If not, please explain.

Study Outcomes
E. Overall, how satisfied are you with the study outcomes?
Not satisfied

Comments regarding overall satisfaction with study outcomes:
F. Did this exercise program have positive or negative effects beyond what has been measured? If so, please list them.

G. What, if anything, did this Pilates exercise program offer you that other, more conventional forms of exercise, have not?

H. What did you enjoy the most about participating in this exercise program? What was the most significant benefit? (Please make a distinction between the exercise program and the entire study (i.e. do not consider all of the data collection sessions when you answer this).

I. What did you enjoy the least about participating in this exercise program? (Please make a distinction between the exercise program and the entire study (i.e. do not consider all of the data collection sessions when you answer this).

J. Would you recommend a Pilates exercise program to other women who have limited shoulder range of motion secondary to breast cancer treatments? Why or why not?

Thank you!
Appendix 8

Pilates Studio Program

<table>
<thead>
<tr>
<th>Exercise</th>
<th>Progression/Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Barrels</strong></td>
<td>Over ½ foam roll, then full foam roll</td>
</tr>
<tr>
<td>Pectoral stretch over 2 arc barrels</td>
<td>With instructor assist</td>
</tr>
<tr>
<td>Spine corrector side stretch</td>
<td></td>
</tr>
<tr>
<td><strong>Cadillac</strong></td>
<td>Arms crossed on bar</td>
</tr>
<tr>
<td>Roll down</td>
<td>Single arm pull</td>
</tr>
<tr>
<td>Latissimus dorsi pull</td>
<td></td>
</tr>
<tr>
<td><strong>Reformer</strong></td>
<td>On mat first</td>
</tr>
<tr>
<td>Footwork</td>
<td>Or on cadillac</td>
</tr>
<tr>
<td>Abdominal preparation/100</td>
<td>Or on cadillac</td>
</tr>
<tr>
<td>Mid-back series</td>
<td>Start sitting on long box, progress to without box</td>
</tr>
<tr>
<td>Bend and stretch</td>
<td>once able to sit comfortably</td>
</tr>
<tr>
<td>Back rowing preparation</td>
<td></td>
</tr>
<tr>
<td><strong>Front rowing preparation</strong></td>
<td>Straight arm pull</td>
</tr>
<tr>
<td>Short box</td>
<td>Round back, straight back</td>
</tr>
<tr>
<td>Knee stretches</td>
<td>Round back, straight back</td>
</tr>
<tr>
<td>Running</td>
<td></td>
</tr>
<tr>
<td><strong>Mat</strong></td>
<td>Preparation</td>
</tr>
<tr>
<td>Swan</td>
<td>Seated</td>
</tr>
<tr>
<td><strong>Theraband</strong></td>
<td>Seated, elbow at 90°</td>
</tr>
<tr>
<td>Mid-back pull</td>
<td></td>
</tr>
<tr>
<td>Shoulder external rotation</td>
<td></td>
</tr>
</tbody>
</table>

B For more information on the Pilates exercises, please consult the Stott Pilates Reformer and Cadillac Manuals. Stott Pilates | 2200 Yonge Street, Suite 500, Toronto, Ontario M4S 2C6 (ph)1-800-910-0001

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Appendix 9

Pilates Home Program

First month

Seated breathing
Anterior pelvic floor and transverse abdominals isolation
Knee folds
Barbie arms
Spinal rotation/rib opener
Shell stretch
Hip rolls
Wall roll down

Second month

Change Barbie arms to arm circles
Change spinal rotation to “around the clock”

Add:
Small weight and arm circles to wall roll down
Spine twist seated
Mid-back Theraband pull

Third month

Add:
Abdominal preparation/100
Seated shoulder external rotation with Theraband
Baby swan

C For more information on the Pilates exercises, please consult the Stott Pilates Matwork Manual.
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Appendix 10

Treatment Adherence Guidelines (Michenbaum & Turk 1987, p.244)

1) anticipate non-adherence
2) consider the prescribed self-care regimen from the patient’s perspective
3) foster a collaborative relationship based on negotiation
4) be patient oriented
5) customize treatment
6) enlist family support
7) provide a system of continuity and accessibility
8) make use of other health care providers and personnel as well as community resources
9) repeat everything
10) don’t give up
Appendix 11

Treatment Adherence Questionnaire

1) What is your adherence history? For example; have you been able to stick with your “new year’s resolutions” in the past; have you been able to commit to previous exercise programs; when you decide to undertake a new activity are you able to fulfill your commitment to yourself?

2) What are your expectations regarding:
   a. The intervention (Pilates)
   b. The goals of intervention (increase shoulder range of motion, decrease pain, improve mood and upper extremity function)
   c. The risks vs the benefits of the intervention
   d. Your sense of self-efficacy
   e. Can you identify any life circumstances that might affect your adherence

3) To what extent do you believe that you will be able to perform the exercise program:
   a. at the studio
   b. at home

4) Do you believe that doing your exercises will lead to increased ROM, decreased pain, improved mood and upper extremity function?

5) How important is achieving this goal to you?

6) What barriers can you foresee?

7) What can you do to make adherence easier?

8) What problems can you anticipate?

9) Can you enlist family support (spouse, children etc)?