A Cross-Sectional Study of Chronic Impairments and Activity Limitations in Women at Least Six Months Post-Operative for Breast Cancer: An Exploratory Study.

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ABSTRACT

Objective: The increased survival rate amongst female breast cancer survivors creates a need for an understanding of chronic disability after surgery. The objective of this study is to explore the association between impairments (e.g., pain, mobility, strength) and the personality trait of fear of physical activity, and chronic daily activity limitations for women who had their surgery at least six months prior to the study.

Hypothesis: The study hypothesis is that women with high levels of physical impairments and the personality trait of fear of physical activity will also have higher levels of daily activity limitations six months or more after their breast cancer surgery.

Design: A cross-sectional design.

Outcome Measures: Disabilities of Shoulder, Arm, and Hand (DASH), Visual Analog Scale for Pain (VAS-Pain), Fear Avoidance Belief Questionnaire – Physical Activity (FABQ-PA), and objective measures of shoulder mobility and strength.

Participants: Women who had been diagnosed and undergone surgery for breast cancer, stage 1-3. They must have had their surgery at least six months previously and have completed chemotherapy or radiation therapy. Both English- and French-speaking women from the Ottawa-Gatineau region were eligible.

Results: Data from twelve women were analysed with a mean age of 58.0±8.9 years and post-operative time of 4.0± 2.8 years. DASH scores mean was 12.2 ± 11.38. VAS-Pain (r_s=0.819; p=.001), FABQ-Physical Activity (r_s=0.746; p=.005) were significantly associated with DASH score, whereas non-significant associations were found with supraspinatus strength (r_s = 0.182; p = .572) or infraspinatus strength (r_s=0.553; p=.062) using the Spearman Rho test. Also, no significant relationships were observed between range of

motion (hand-behind-back; p =.366; hand-behind-head; p=.390) and DASH scores using a Kruskal-Wallis test.

Conclusion: The results of this exploratory study suggest that the reported daily activity limitations of women who have had breast cancer surgery may be related to the participant pain perception and/or fear of physical activity.

Keywords: Breast Cancer, Chronic Activity Limitations, Disability, Fear of activity

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INTRODUCTION

An injury or an illness has a wide-ranging impact on people's ability to function in their daily lives. Most notably, this can lead to disability or a severe limitation in functional life. Accurate identification of the factors contributing to disability can assist in the development of a proper rehabilitation program. Disability can occur after any change in health status, including recovery from surgery for breast cancer (BrCa). In Canada, the five-year survival rate for BrCa is 88% (1). This increased life expectancy supports the need for continual evaluation and monitoring for disability after surgery in both the acute and chronic periods.

Disability can affect the overall functional capacity in work and daily activities for a portion of patients who have undergone BrCa surgery. Shoulder mobility limitation was found to significantly prolong cancer survivors' inability to return to regular work activities (2). In Ontario, 20% of women or their caregivers reported a financial burden resulting from not working regular pre-diagnosis hours (3). A loss of income can affect more than just the ill person, and efforts should be made to return to work as soon as possible even with restricted duties. For those BrCa patients in the workforce, 75% reported a loss of productivity, including sick leave and reduced working hours, while the other 25% were able to continue to work with task modifications (4). Financial income changes can add to an already stressful encounter with illness. Canadian women who were working at the time of their BrCa diagnosis did not work during treatment for an average of seven months with a mean loss of 27% of their annual salary. Those who received chemotherapy had an even greater financial loss (5). This time away from work or with less pay can be a stressor during a time of healing when negative factors hit above a person's typical threshold. There are

numerous medical factors to explain why work could remain difficult. Women were less likely to return to their work if it involved manual or intensive labour (6). The inability to resume this type of work could be explained by a loss in physiological function of the upper extremity or general health (i.e., increased fatigue). To identify what factors cause their disability, identification of impairments resulting from BrCa surgery is required. For quality of life and economic reasons, it is important for each patient and society that a normal level of work activity be resumed as soon as feasible after BrCa treatment. Rehabilitation should thus focus on disability after surgical and therapeutic intervention.

LITERATURE REVIEW

INTERNATIONAL CLASSIFICATION OF FUNCTIONING, DISABILITY, AND HEALTH (ICF)

There are several approaches to the assessment and explanation of disability, and this study uses the International Classification of Functioning (ICF), a disability framework created by the World Health Organization (WHO) in 2001. It updated its previous framework, the International Classification of Impairments, Disabilities, and Handicaps (ICIDH).

Historically, disability was examined through a biomedical lens. This approach deemed the disability essentially as an attribute of the individual. In 1980, WHO created its ICIDH model, which used the terms "impairments,""disabilities," and "handicaps" to describe the pathology and function of people with health conditions. This model provided an integrated approach to describing disabilities, but there were concerns were about its linearly fixed sequence where a patient had to experience all levels in the set order and, as well, with the concept that a person and their make-up was responsible for their disability

(7). These concerns contributed to WHO's redesigning its disability model to the current ICF in 2001 (7).

The ICF provides more dynamic movement among the classifications than did the fixed and linear direction of its predecessor. Users of the ICF refer to health conditions and see the patient from a whole-person perspective, describing individuals within their environments. The ICF is composed of two parts. Part 1 includes three domains: the body functions and structures, activities, and participation, with subdomains further breaking down the activities and participation domains. Disability and losses in are termed "impairments," when referring to body functions and structures, "activity limitations," when referring to a person's activities, and "participation restrictions," when referring to their ability to participate in their society. Within this framework, disability occurs when individuals experience losses across all domains (8). For example, an impairment may be the experience of swelling or loss of range of motion. An activity limitation may be the inability to put on a coat, while a participation restriction could be experienced while avoiding interacting with others due to their inability to go outside of their house in winter without a coat. The difference between the latter two examples is that the first is simply the non-completion of a task (activity limitation), whereas the other hinders enjoyment and participation in life (participation restriction) (9). Part 2 of the ICF is "Contextual Factors" and includes two domains: environmental and personal. Both the physical environment and society can create limitations attributed to environmental factors within the ICF, such as inaccessible buildings, poorly designed customer service desks, or non-ergonomic workstations that create barriers to full participation (10). Personal factors, by contrast, are characteristics of people that are not linked or a result of any health conditions, such as perceptions and attitudes. The relationship among all of these domains is individualized to people and their health

conditions. The ICF model does not demand a certain path or process order, and the contribution of each factor to disability can exist independent from any others. This said, management of any one factor may affect one or more of the factors (10). (Figure 1).

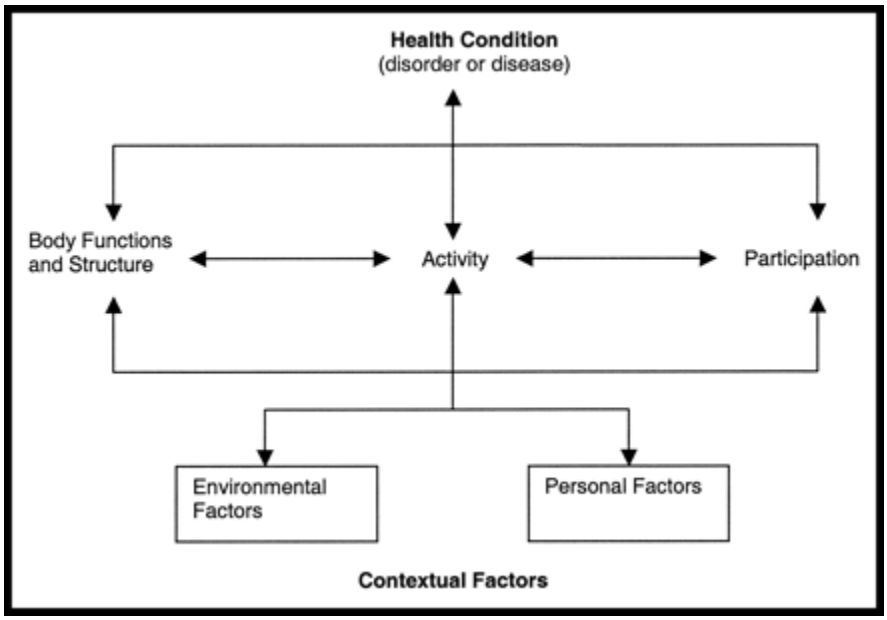

Figure 1- Interactions among the components of ICF. Reprinted with permission from the World Health Organization, July 2013.

The ICF codes elements within domains. The ICF has core sets of codes for common health problems, including the ICF core set for breast cancer (11). The activity limitations and participation restrictions of the core sets were highly associated with disabilities of the arm, shoulder, and hand (DASH) ($r = 0.761$, $p < .001$), as were the body function ($r = 0.669$) and body structure ($r = 0.540$) scores (12). While physiotherapists agreed that the ICF's core set for BrCa was inclusive of the impairments and disability that the physiotherapists encounter, they believed the core set did not include several concepts under the personal and environmental sections of the ICF that would impact on disability, such as a lack of

knowledge of their condition, pain self-management, and coping strategies (13). The inclusion of personal and environmental concepts in the BrCa core set could promote a more biopsychosocial approach to care and ultimately improve disability outcomes.

IMPAIRMENTS AND ACTIVITY LIMITATIONS AFTER BREAST CANCER MEDICAL THERAPY

1. ACTIVITY LIMITATIONS

Problems with the activities of daily living (ADL) can occur at any time after surgery, but a return to normal functional level soon afterward should be expected. However, both at 6 and 12 months, 61.5% and 56.3% of women respectively reported having experienced activity limitations included personal care, lifting, carrying, reaching, and sleeping (14). For example, 49% of women stated that carrying activities were still difficult to perform at twelve months post-op compared with 53% at six months (14). Reaching out above their heads was slightly easier to perform for participants at twelve months (43%) than at six months (53%) (14).

Chronic impairments can result in participation restrictions in life activities. Patients reported being unable to participate in work fully (six months = 16.7% of women; twelve months = 15.6%), home life (32.3% at both six and twelve months), and leisure pursuits (six months = 25%; twelve months = 16.7%) after their surgery (14). This level of disability hampers more than their daily activities, also restricting their ability to reintegrate into society at their pre-surgery level.

2. IMPAIRMENTS

Several common impairments have been found that influence BrCa patients' disability (14-17). Figure 2 outlines possible influences from surgery, radiation, and

systemic therapy on ICF domains. Additionally, ICF elements may be influenced by patients' time in recovery, acute versus chronic phase, and the combination of treatments provided to the patient. Certain impairments and activity limitations have been found to be more prominent after certain treatments. The elements most frequently affected will be discussed separately in the following text.

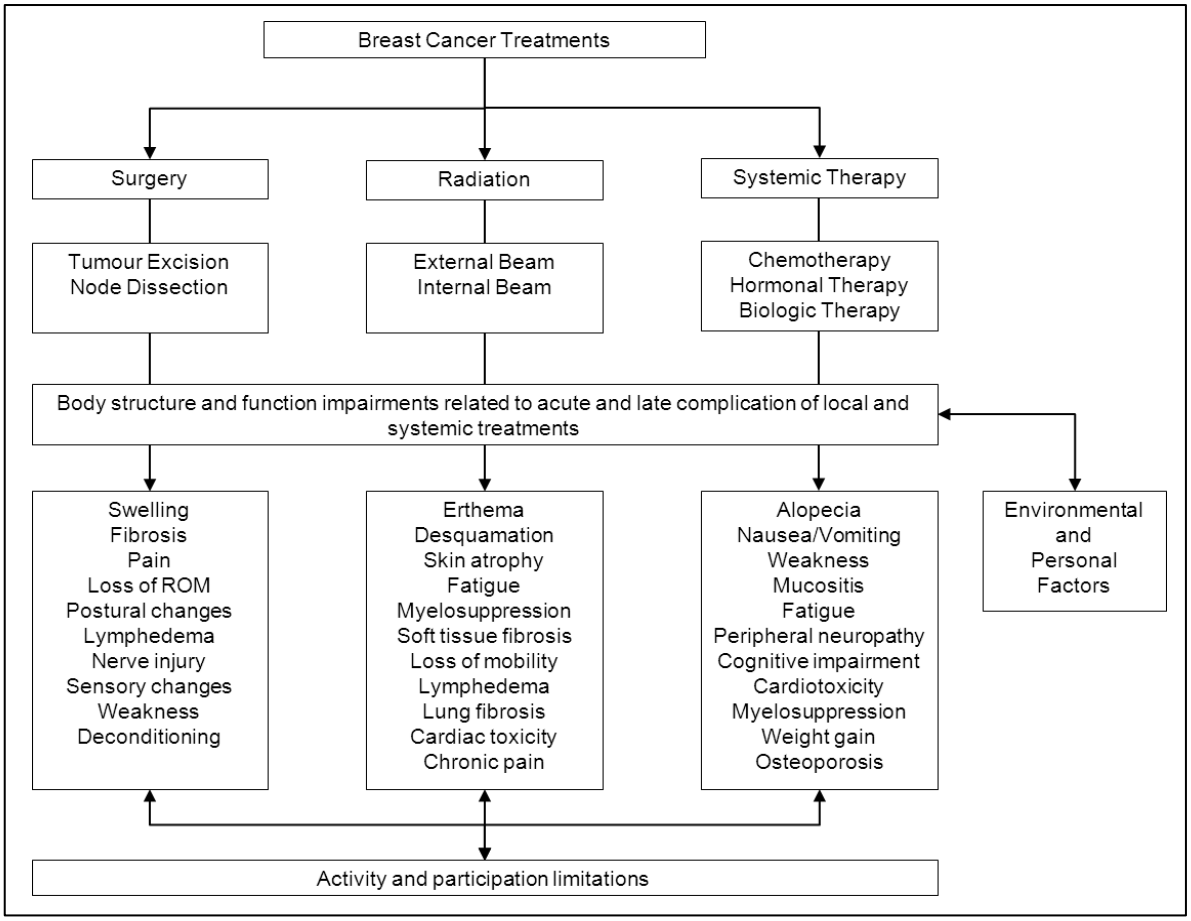

Figure 2 – Body structure and function impairments and activity/participation limitations related to treatment for breast cancer, using the International Classification of Function, Disability, and Health model. Reprinted with permission from Smoot B, Wampler M, Topp KS. Breast cancer treatments and complications: Implications for rehabilitation. Rehabilitation Oncology. 2009; 27(3):17.

2.1 Range of Motion

Range of motion (ROM) at the shoulder contributes to a large proportion of daily activities. In one study, participants included stiffness as occurring the most after surgery and counted it as the third most bothersome symptom (18). Tengrup et al. found that 81% of women who had a breast-conserving technique (BCT) had a loss of shoulder mobility in flexion, extension, and abduction of at least twenty degrees at one-to-two years, post-operative (19). In this study, the timeline of one-to-two years post-surgery is well past the customary post-operative inflammatory period in which complete shoulder ROM recovery would be expected. Many women in the study only reported shoulder impairment for the first time at the one-to-two year mark (16). This is important information for clinicians to prevent missing chronic problems occurring after recovery has been assumed in the earlier months after surgery. In addition, measurements of shoulder mobility taken in the acute phase after surgery did not predict decreased or normal ROM measurements in the chronic phase (20). A woman with typical recovery in the acute phase may still develop immobility later. Continual assessment of shoulder mobility during all stages of BrCa post-operative follow-up is probably needed.

Radiation is often used in conjunction with surgery for breast cancer. The loss of shoulder mobility was greater with women who had had a BCT with radiation treatment (16). Injury from radiation can occur because it increases collagen production leading to increased fibrosis of the soft tissue (21). Radiation can also damage bone, nerve, and muscle and alter the capabilities of the vascular and neural supply. The brachial plexus is particularly vulnerable due to its location in the axilla. Injury to these structures can lead to impairments such as pain and immobility in the shoulder region.

Shoulder dysfunction after receiving radiation treatment can persist for more than 18 months (22). Dysfunction is less perceived subjectively by the patient than by objective measures of mobility loss used by a therapist (16). A discrepancy by some women who did not notice any loss of shoulder mobility versus that found by standardized measurement illustrates that even a small loss of mobility, imperceptible to some, may be the root cause of activity limitations. When assessing activity limitation and participation restrictions, assessors need to remember that impairments must be objectively measured before ruling out any as a contributing factor to disability.

Johansson and colleagues investigated shoulder ROM in women with BrCa who had axillary dissection and grouped them by type of radiation: no radiation, breast-only radiation, and axillary radiation (17). The group that had axillary radiation treatment had a greater loss of shoulder ROM in flexion, external rotation, and abduction 27 months after surgery, although all groups had a significant loss of internal shoulder rotation (17). This residual internal rotation loss can be very problematic because it would limit a woman's ability to reach behind her back, a common movement in everyday activity, such as when putting on a jacket or attaching a bra.

2.2 PAIN

After surgery, pain is expected, but it should also resolve soon afterward as healing progresses through the acute stage. Women who have undergone surgery for BrCa have reported pain lasting longer than the expected time, up to five years post-surgery in some instances (14-15, 19, 23). Tengrup et al. found that 31% of women had pain perceived as moderate to severe at the five-years after surgery (19). Similarly, Rietman et al. found that 60% of women had pain that persisted 2.7 years post-surgery (15). Pain was reported by

68.8% of women one-year after surgery and persisted to five years post-surgery for one-third of the women (24-25). Pain has emerged as a highly persistent impairment that requires evaluation to uncover its cause. Severe pain after six-to-twelve months has passed since surgery has been attributed to axillary edema and numbness (14). Instead of reaching a plateau after surgery or improving with time, pain from the sample continued to worsen even a year after the surgery (14). At this stage in healing, the cause of pain is unknown.

2.3 Strength

Strength of upper extremities is another impairment that can be affected after BrCa surgery. The long thoracic nerve supplies the serratus anterior, and the thoraco-dorsal nerve supplies the latissimus dorsi muscle, both nerves that can be affected by surgery (26). These muscles contribute to the scapula-thoracic joint, which, if affected, could decrease the shoulder's complex stability (27). The medial and lateral pectoral nerves supply the pectoralis minor and major muscles, respectively, which also are at risk during axillary dissection (28). Post-operative women reported that they did not experience arm weakness, though reduced strength was measured in objective testing, especially at 1-2 years and at 4 years post-operative (14). While strength losses may not be detectable to the average person, they could still have an effect on motor control and muscle recruitment during movement in the upper extremity (29). A residual shoulder weakness could increase the stress on other musculoskeletal structures and lead to the development of secondary orthopaedic conditions, such as an impingement syndrome from scapular instability (30). Decreased capacity of a muscle would affect its ability to contribute to mobility, thus potentially limiting the patients' activity.

Shoulder weakness was observed in post-operative BrCa women with shoulder flexion, adduction, and internal rotation strength, while there was no difference with grip strength at six months, one year, and two years post-operative (17). Flexion, adduction, and internal rotation are understandable because the main muscles responsible for these movements, the pectorals and latissimus dorsi, are innervated by nerves that could be damaged during the surgery. However, Rietman et al. found that 40% of BrCa women had a decrease in their grip strength 2.7 years after surgery (15). The difference in these findings could partly be explained by the methodology used to measure arm strength. The former study stated that the dynamometer measurement was taken with no abduction of the shoulder and the elbow bent to 90 degrees; whereas, the body position in the latter study was unstated.

3. Fear of Physical Activity

In healthcare, problems are often examined from a physical limitations point of view. Fear is a personality trait often associated with the flight-or-fight response by the body (31). Fear produces defensive reactions from the body, and anxiety is related to avoidance or preventative reactions; both are often regarded as fear-avoidance, which involves psycho-physiological, behavioural, and cognitive components (32). Research on fear of activity has been conducted on other health problems, most notably chronic musculoskeletal pain, usually in either the neck or back (33). Chronic pain leads to avoidance of activities that can increase pain perception (32). In addition, pain-related fear is related to muscle weakness and decreased physical performance (34-38). Avoidance of physical activity can lead to disuse and de-conditioning, which affects muscle strength, aerobic fitness, and muscle coordination (32). Pain-related beliefs and fear avoidance were significant in establishing disability in those with chronic musculoskeletal pain (39). Catastrophizing, a high degree of disability,

and co-morbidity of musculoskeletal complaints were related to high fear-avoidance scores by those reporting neck-shoulder complaints (40). These are similar impairments that have been found in BrCa survivors. Furthermore, a study including female workers with neck-shoulder pain reported high correlation between disability scores and fear-avoidance models, especially when questioned about work (41). Given the increased survival rates and the incidence of women of a working age with BrCa, the impact of fear avoidance on disability should be studied. To our knowledge, there are no studies that evaluated fear of physical activity in BrCa patients with chronic disability.

4. Relationship between impairments and activity limitations

Improvements in activity limitations and participation restrictions can possibly be achieved by targeting the associated impairments. Several studies have attempted to determine the impairment associated with activity limitations in patients following BrCa surgery. Rietman et al. found that quality of life was affected mostly by pain levels and decreased grip strength (15). Pain accounted for 61% of the individual variation in the disability score, and shoulder mobility (flexion and external rotation) explained 12% (15). At six months post-op, 47% of the individual variation in upper extremity lifting capacity was explained by pain, strength and edema, whereas, 38% of the variance at twelve months was due to strength and pain (14). Pain and shoulder movement restrictions accounted for 32% of the individual variation in activity limitations with regard to carrying at six months, while pain, edema, and age accounted for 46% of the variance by twelve months (14). ADLs were also found to be strongly correlated with shoulder mobility, especially flexion ($r = 0.75$) and abduction ($r = 0.71$) (42). Many ADLs require shoulder movement in flexion, external rotation, and abduction, such as combing one's hair or getting dressed.

Activity limitations are being restricted through several impairments that are noticeable in different activities and movement. A mean of DASH scores of BrCa survivors having received adjuvant therapy was found to be 24/100, indicating mild to moderate disability for this population (43). Hayes, Battistutta, and Newman found modest correlations between upper body impairments ($r = 0.25–0.41$) and the DASH scores, with the strongest relationship between upper-body strength and endurance and hand-grip strength (44). On the DASH, individual activity items found to be correlated ($r > 0.30$) to specific impairments were household chores, gardening, yard-work, making a bed, carrying a shopping bag, carrying 10 lbs, and dressing with a pullover sweater (45). In another study, BrCa participants reported difficulties with three questions in the DASH. In question 17, 8.2% reported difficulty with activities that required "little effort," while 48.5% and 44% reported difficulty in questions 18 and 19 due to the focus on activities involving impact to the arm or freely moving the arm (46). When these three questions were analysed together, a mean score of 4.76 ($SD = 2.23$) was found, which is between "4-severe difficulty" and "5-unable" to perform" (46). These types of activities require the shoulder to absorb impact or to move within a normal range of motion. These are extremely basic activities needed in daily-life situations that women need to be capable of performing after BrCa surgery. The items included in the DASH relate both to impairments and daily activities that are affected by pain, shoulder strength, and mobility. The DASH scores correlated negatively with pain ($r = -0.47$; $p < 0.01$), shoulder abduction ($r = -0.49$; $p < 0.01$), and external rotation ($r = -0.35$; $p < 0.01$) (23). Shoulder abduction, hand-grip strength, and lymphedema and the number of comorbidities were found to explain 46% of the individual variation in the DASH scores in BrCa survivors (47). The DASH scores were also negatively correlated with upper- body

strength (shoulder press and upright row) ($r=-0.26$, $p<0.01$) and grip strength ($r=-0.16$, $p<0.05$) (44).

SUMMARY OF THE LITERATURE

In summary, it is vital to determine which impairments have the strongest relationship with activity limitations in BrCa survivors. To date, there has been little research done using objective measurable outcomes. In much of the existing research, either general questions were asked regarding BrCa patients' function versus using a validated outcome measure, or there were few attempts to determine relationships between the impairment and the activity limitations. For shoulder mobility, most studies have assessed a single plane of motion with goniometric measurement. However, most ADLs use a combination of shoulder planes to be functional. Studying shoulder multi-planar functional movement patterns is closer to ADLs and may detect additional limitations as a result of using a combination of movement simultaneously. As for shoulder strength, there have been limitations in the research concerning the validity of the measurement of this impairment. The few studies that assessed arm strength used a general indicator of upper body strength, such as the chest press test, which evaluates the pectoral muscles that assist in scapular protraction. Scapular protraction has been found to decrease shoulder mobility, thus decreasing rotational strength of the shoulder (48). Furthermore, having strong pectorals may actually be detrimental because these affect other movements of the shoulder (29). It would be more beneficial to evaluate the rotator cuff strength as it is directly involved in upper-extremity mobility and daily activities (42). In addition, there have been no previous studies that have investigated BrCa patients' fear of physical activity. This is an important question to study because health

problems affect the whole person and involve multiple systems at any one time, including cognitive function.

Finally, with the exception of a few small studies, investigations have conducted univariate statistics on their data (16,17,19,43). This statistical approach provides an overview of the potential determinants of the activity impairments in BrCa survivors but would not be as informative as would a study using multivariate statistics, since only multivariate studies can isolate the impact of each factor independently. A multivariate method, such as linear regression, could provide more explanation on the respective contribution of the dependent variable to the individual variation observed of the independent variables. The few studies that did attempt this all had different goals from that of the present study. One study, a similar population used the DASH as its dependent variable but grouped several impairments (lymphedema, grip strength, shoulder abduction mobility, and co-morbidities) together to explain 46% of the individual variation (47). Another study, again with a similar patient population, did not use a shoulder-specific outcome measure as its dependent variable but used the individual acts of lifting, carrying, or reaching and independent variables of pain, weakness, edema, and immobility (14). The individual variation in a chronic disability study was explained by pain (61%), shoulder flexion (9%), and external rotation (3%), although the dependent variable in this study was the Shoulder Disability Questionnaire, a similar outcome measure to the DASH (15). There is, therefore, a need to expand the body of knowledge on disability by combining many of the individual parts of previous works that identify contributors of chronic disability in BrCa survivors.

STUDY OBJECTIVES

The purpose of this study was to assess the relationship between shoulder impairments (pain, mobility, strength), fear of physical activity and persistent activity limitations in women who have had breast cancer surgery at least six months earlier.

It was hypothesized that those with higher levels of impairments and those having a fear-avoidance trait will be more limited in their activities.

METHODS

DESIGN

A cross-sectional design was used to assess the relationship between impairments, the personality trait of fear, and ADLs of women at least 6 months post-breast cancer surgery. The dependent variable was the DASH score for activity limitations. The independent variables were pain, active shoulder mobility, and strength.

PARTICIPANTS

Inclusion Criteria: Women who had surgery for stage 1 to 3 BrCa, with or without axillary dissection, at least 6 months previously were the selected population. Stage 4 was omitted because of the severity of the disease. Either full or partial mastectomy or a lumpectomy were permitted as surgery types. Additional inclusion criteria included having completed chemotherapy or radiation treatment or both treatments, able to understand English or French, living in the Ottawa-Gatineau region, and willing to travel to the study site. Women were eligible if they were still receiving hormonal therapy.

Exclusion criteria: Women were excluded if they had local advanced tumour(s), metastatic disease, other cancer(s), active rheumatologic disease (not including osteoarthritis) affecting the upper extremities, and/or current fractures of the upper extremities. Furthermore, those who had bilateral BrCa surgery whether simultaneously or at different occasions were excluded since it makes it impossible to isolate the impact of a specific impairment on disability.

Recruitment Strategy: Participants were recruited to the study by two methods. The first method was through the Ottawa Cancer Institute where the oncologists identified eligible participants during scheduled follow-up visits. Participants provided an information package by the oncologist consisting of a general information sheet about the study, a consent form, and a copy of the DASH questionnaire to be completed if the participant chose to enrol in the study. Interested participants contacted the investigator for more information through coordinates listed in the information package. The second method for recruitment was a community strategy to find eligible participants. The primary route involved talking to BrCa survivors at the Ottawa-Gatineau Run for the Cure. Secondary routes involved advertising the study to local physicians, physiotherapists, and community support groups for BrCa patients. Additional routes included posting advertisements on community centres' or medical clinics' bulletin boards or in their newsletters. The community-based participants received the same information package as those recruited through the Ottawa Cancer Institute. Participants from the community interested in the study contacted the investigator by telephone for more information. If the participant wanted to continue with the screening, non-medical inclusion and exclusion criteria were reviewed by the investigator. Participants

were simultaneously screened by the investigator with the DASH to guarantee a wide range of DASH scores among participants. A previous study stated that participants with a DASH score between 25–75 reported having some form of disability, while a DASH score below 25 points was considered with limited disability (45). Another study found that people with a DASH score of 20–30 were still able to do their work (49). In contrast, a study found that DASH scores between 23.6 and 26.8 were threshold points for identifying people who were unable to perform their work or other activities (DASH scores > 26.8) and those who could complete their work or other activities (DASH scores < 23.6) (43). Thus, to guarantee that the group representing those with a chronic disability truly had a measurable disability, a DASH score above 30 was chosen to identify the "having activity limitations" group and DASH scores 30 points or below to identify those in the "no activity limitations" group. Clearance for the medical inclusion and exclusion criteria was provided by the participant's physician prior to their enrolment in the study. Once the physician clearance medical form was returned with approval, the investigator called the participant to schedule an appointment for the consent and assessment. (Figures 3 and 4).

The aim of the study was to recruit 59 participants, which would be required to achieve statistical power in the multivariate analysis. This sample size was calculated using G*Power 3.1.2 and a two-tailed linear multiple regression model. As part of the calculation, an alpha error of 0.05, a power of 0.80, and effect size of 0.30 in addition to 6 independent variables were input into the model.

Participation in the study was voluntary. However, participants received $20 as compensation for any expenses, such as parking fees and travel costs, incurred in relation to the evaluation appointment.

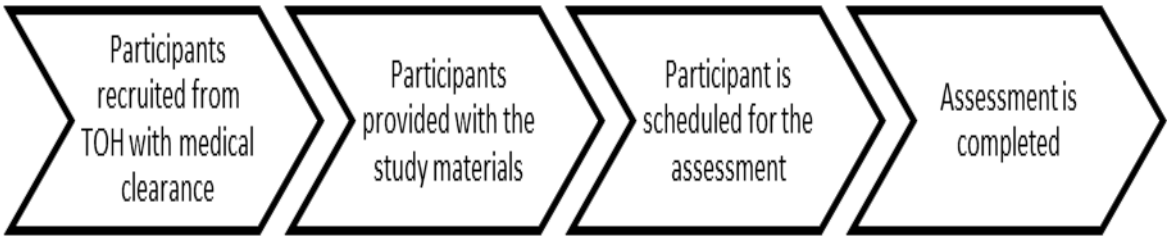

Figure 3 – Patient flow direction for those recruited through oncologists at The Ottawa Hospital. This procedure steers the potential participant to the researcher with medical clearance completed should they choose to participate in the study.

Figure 4 - Patient flow direction for those recruited through community resources such as physiotherapists, flyers, and the Run for the Cure. This procedure requires the participants to seek medical clearance from their physicians. Once the researcher has the medical clearance, the participant is enrolled in the study in the same manner as participants recruited through the hospital.

MATERIALS

Dependant variable: the DASH questionnaire

The primary outcome measure used to assess activity limitation was the disabilities of shoulder, arm, and hand. The DASH is a 30-item questionnaire that evaluates the level of

difficulty in performing tasks, severity of symptoms, and impact on activities of daily living (49). Each item is marked on a 5-point Likert scale. The DASH is scored out of 100, with 0 representing no disability and 100 indicating a high level of disability. The 30 items have been linked to 63 ICF categories (50), supporting the use of the outcome measure to determine activity limitation. The DASH scores had a high test-retest reliability (ICC = 0.96), validity, and responsiveness to small change and was comparable or better to joint-specific measures (51).

Independent variables:

Strength

A standard 12-inch, 2-arm plastic goniometer was used to position the participant in the proper starting position during the strength measurements. A hand-held dynamometer (HHD) was used to evaluate strength in each upper extremity. A Lafayette Manual Muscle Test System, model 01163, by Lafayette Instruments (USA) was selected. The digital Lafayette HHD contains a microprocessor that allows peak isometric muscle force to be measured in kilograms to one decimal place. A curved stirrup was used in all tests for a comfort fit to the upper extremity. This model provided a range of 0–131.1 kg with an accuracy of +/- 1% and a resolution of 0.2 kg in the high range and 0.1 kg in the low range. The timing accuracy, which explains how well the machine can keep time of the 7 seconds that the participant must hold a contraction during strength testing, is +/- 0.03% (52). HHD was compared to a Cybex isokinetic dynamometer for external rotators with intra-rater reliability being $r = 0.780$ ($p < 0.05$) and with reliability demonstrated across two sessions with correlations for both (HHD: $r = 0.986$ and Cybex $r = 0.993$), in addition to having more than 97% of the

common variance due to the measurement techniques (53). Inter-rater ICC values are 0.92 for supraspinatus and 0.82 for external rotation (54).

Fear

The Fear-Avoidance Beliefs Questionnaire (FABQ) was used to assess the participant's fear levels regarding performing physical activity (55). The word "shoulder" was substituted for "low back" in the original questionnaire. This method was used by Mintken et al. (2010), was found to have a high test-retest reliability (0.88-0.98) and was strongly associated with the Shoulder Pain and Disability Index (SPADI) scores (56). For this study, only the sub-score for fear of physical activity will be used (FABQ-PA). The other subscale is fear of work (FABW-W), but was not calculated in this study since the majority of participants were retired.

ROM

A questionnaire assesses the movement using the 0–4 ordinal scale taken from Yang & Lin (2006) (57). The score of "0" indicated full ROM, and "4" represented a severe loss of ROM where the hand did not reach behind the trunk (HBB) or the neck (HBH) (Table 3 & 4). The measurements with the descriptive scale have a strong inter/intra-rater reliability of kappa statistics 0.90/0.80 for "hand behind head" and 0.90/0.90 for "hand behind back" (57).

Pain

A visual analog scale (VAS) was used to measure participant pain perception. Participants marked their average upper-extremity pain perception during the last week on a 100mm line. The timing of their pain was set to match the time period of the DASH

evaluation, which was set at a time period of the last week. One end of the line was marked with "pain as bad as it could be" and the other end was marked with "no pain." A standardized question was printed above the line asking the patient to "Make a vertical line to represent your average level of pain during the last week". A VAS-Pain scale has been validated in a cancer population and had a test-retest reliability of 0.78 (53,58).

EVALUATION PROCEDURE

The data were collected at Glebe Physiotherapy & Sports Injury Clinic in Ottawa, Ontario. A curtained area was used to ensure privacy for the participant. Open-backed gowns were provided to all participants to wear during the evaluation. At the beginning of the assessment, the investigator provided an overview of the proceedings and answered any questions from the participant. The participant gave informed consent by signing a consent form approved by the ethic committees. The investigator also obtained a signed form acknowledging the receipt of the $20 compensation.

The participant answered 3 questionnaires in the first half of the assessment session. A **DASH questionnaire** was completed based on their activity ability of the last week. Although a DASH questionnaire was completed during the screening process, this second DASH questionnaire was used to determine the official DASH scores, as it indicated their functional level at the time the other objective measures were evaluated. The participant also completed the **FABQ** and the **VAS-Pain** questionnaires. This phase of the assessment required approximately 15 minutes and was administered by the investigator.

The second phase of the assessment session was performed by a physiotherapist blinded to the results of the preceding questionnaires. The physiotherapist started with the **active range of motion (AROM)** test, and the participant changed into an open-backed

gown to allow a proper visual of the back.(Appendix E – Photos of test positions). The physiotherapist read standardized instructions for the first movement, "hand-behind-back" (HBB) to the participant but offered no demonstration to the desired movement. The participant, while standing, then moved one arm in the HBB position. The highest place reached by the tip of the index finger signifies the measuring point for the physiotherapist. The participant then repeated the movement with the other arm. Once the physiotherapist recorded the score for both arms on the record sheet, she read the instructions for the second movement, "hand-behind-head" (HBH), to the participant. Again, the movement is performed and recorded for both arms.

The last impairment measure taken was **strength** of the supraspinatus and infraspinatus muscles using the hand-held dynamometer. A "make" test procedure was used in which the patient was asked to build up to a maximal strength in 2 seconds and then maintain this force for an additional 5 seconds (54). The mean of 3 isometric, peak force contraction measurements was used (53). Measurements were taken bilaterally. The testing position for supraspinatus had the participant seated with their arm in scapular elevation (90 degrees of elevation and 30 degrees in front of the coronal plane) (54) and with 45 degrees of humeral external rotation (Full Can position) (59). The physiotherapist read standardized instructions before assisting the participant to achieve the starting position. The physiotherapist verified the position with a goniometer before taking the force measurement. The HHD was placed on the distal forearm just proximal to the wrist crease, and the physiotherapist applied a downward force while the participant maintained their position by exerting force against the hand-held dynamometer (54). One minute of rest was granted between trials, although the participant was allowed a longer time if they felt it was necessary

The testing position for infraspinatus was measured with the arm at 0 degrees abduction, 90 degrees of elbow flexion, and 45 degrees of humeral internal rotation (59). The participant exerted a force into external direction against the hand-held dynamometer. The HHD was placed on the distal forearm just proximal to the wrist crease. The physiotherapist read standardized instructions and then followed the same process as for supraspinatus for the length, frequency, and number of trials. The same method for recording the peak force was used for infraspinatus as used for supraspinatus.

At the completion of the objective measurements, the study session was finished. The participant was thanked for their time.

STATISTICAL ANALYSIS

The results were recorded to a spreadsheet for analysis using SPSS, version 19. Descriptive statistics and frequencies were performed on all data. If the required sample size had been achieved for statistical power, multiple regression between the DASH scores (the dependent variable) and each of the impairments (the independent variables) would have been performed. In this situation, regression analysis would also have been performed on confounding variables such as hand dominance, surgery type, and adjuvant therapy against the DASH. However, the required sample size was not obtained within the time limits of the study, thus non-parametric tests were used to analyze the data. Correlations were calculated using the Spearman Rho test between the DASH scores and the interval data, VAS-Pain, FABQ-PA, and strength. For strength and mobility measurements, the data were recorded to represent the relative difference between the non-affected arms and the affected arm. The ordinal data, i.e., ROM-HBB and ROM-HBH, were analyzed using the Kruskal-Wallis test, again using the relative difference between the non-affected arm and the affected arm. The

confidence interval was 95%, and the level of significance was set at $p < 0.05$ in all statistical tests. All statistical tests were two-tailed.

ETHICAL CONSIDERATIONS

Both the University of Ottawa Health Sciences and Sciences Research Ethics Board and the Ottawa Hospital Research Ethics Board (Appendix A) granted ethical approval for this study. All participants gave written and oral informed consent before participating in the study.

RESULTS

PARTICIPANT DEMOGRAPHICS

Participants were recruited between July and November 2011 from a variety of sources, though the majority either had heard of the study from their oncologist during a follow-up visit or from the study investigator who spoke with participants at The Run for the Cure, a charity race that includes BrCa cancer survivors (Figure 5). There were a large number of potential participants both from the community and referred from the oncologists; however, most participants chose not to proceed with either evaluating their eligibility or with completing the study session. Between July and November 2011, 16 participants completed the study assessment session, but 4 were excluded from the analysis because they had had bilateral surgery. This left the data from 12 participants for statistical analysis. Description of the characteristic of the participants can be found in Table 1. The final group of 12 women had an average age of 58.0 ±8.9 years, from various occupations though half were retired. The mean time since surgery was 4.0± 2.83 years with three-quarters having a

diagnosis of stage 1 or 2 breast cancer. The participants had different types of surgeries, ranging from a lumpectomy to a mastectomy, but the majority were performed on the left side of the chest. Axillary node dissection, chemotherapy, and radiation were each performed on the majority of participants.

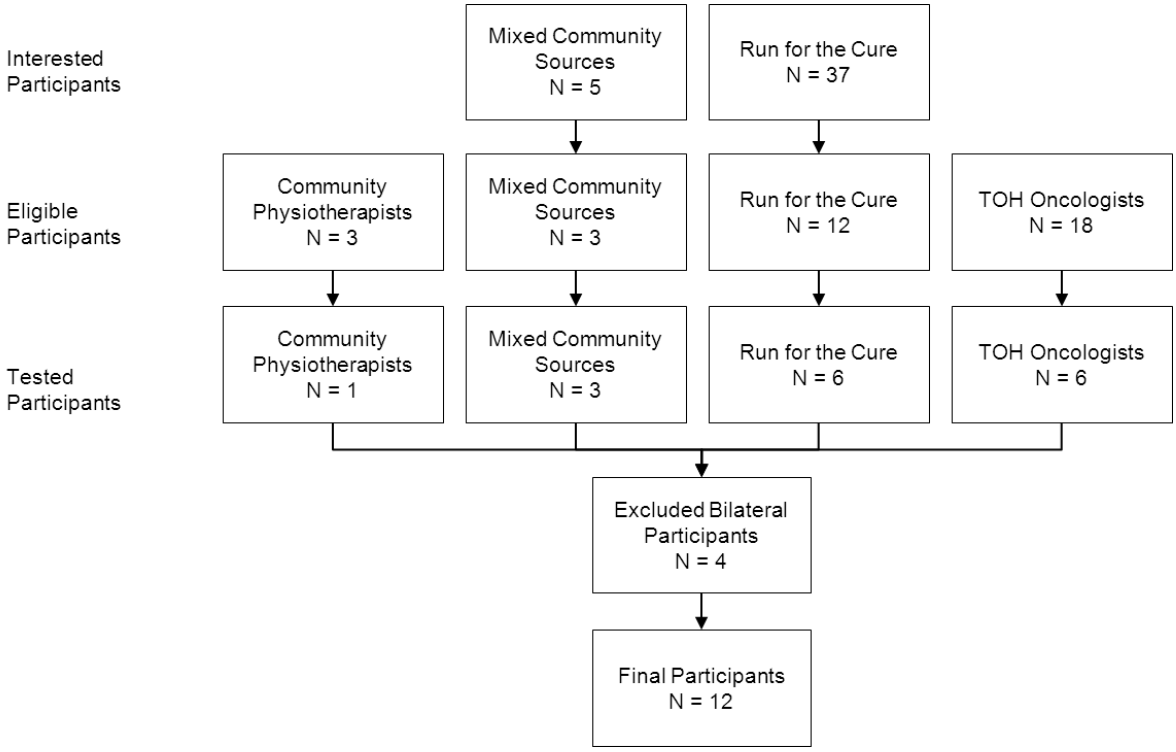

Figure 5- Sources for study recruitment (From left to right: Community Physiotherapists Mixed, Community Sources [Word of mouth, posters, group fitness classes], The Run for the Cure Charity Race, and The Ottawa Hospital Oncologists). From the top row to the bottom row: Row 1= Participants expressing interest in the study; Row 2 = Participants who were eligible for the study. (Note – Not all participants from Row 1 decided to be evaluated for study criteria.) Row 3 = Participants that continued to the study evaluation; Row 4 = Participants who had bilateral surgery were excluded from analysis, and Row 5 is Participants whose data was analysed in the study.

Table 1 - Demographics of Participants (N=12)

	Mean (SD)
Age (at data collection)	58 (8.87)
Surgery (years)	6 (2.83)
	N (%)
Occupation	
Retired	6 (50)
Education	2 (17)
Other (Computer technician, HR Consultant, Project Manager, Physiotherapist)	4 (33)
Dominant Hand	
Right	10 (83)
Left	2 (17)
Cancer Stage	
1	4 (33)
2	5 (42)
3	3 (25)
Surgery	
Lumpectomy	4 (33)
Partial Mastectomy	3 (25)
Mastectomy	5 (42)
Surgical Site	
Right	4 (33)
Left	8 (67)
Surgical Site vs Dominance	
Dominant Side	4 (33)
Non-Dominant Side	8 (67)
Axillary Node Dissection	
Yes	9 (75)
No	3 (25)
Chemotherapy	
Yes	9 (75)
No	3 (25)
Radiation	
Yes	8 (67)
No	4 (33)

Descriptives and Frequencies for Study Variables

The mean, median, mode, range, minimum, and maximum for each of the study variables are presented in Table 2. For the mobility and strength data, the relative difference (RD) was determined, as previously described, from taking the non-affected arm score minus the affected arm score. Frequencies of ordinal data (HBB/HBN) are presented in table 3 and 4.

Table 2 –Study Variables Descriptive Data

Outcome Measure	**Mean**	**Median**	**Mode**	**Min.**	**Max.**	**SD**	**SE**
VAS-Pain (mm)	11.7	3.1	0	0	68	20.66	5.97
FABQ-PA	6.42	1.5	0	0	22	8.45	2.43
HBB - RD	N/A	0	0	-1	1	N/A	N/A
HBH - RD	N/A	0	0	-1	0	N/A	N/A
SSP - RD (kg)	1	1	-1.3	-1.3	3.4	1.59	0.458
ISP - RD (kg)	-0.317	-0.05	0	-2.9	2.5	1.67	0.483
DASH scores	12.2	8.75	0 (smallest)	0	38	11.83	3.41

Legend 1: VAS-Pain = Visual Analog Scale for Pain; FABQ-PA = Fear Avoidance Behaviour Questionnaire for the subgroup of Physical Activity; HBB-RD = the relative difference between arms for hand-behind-back mobility; HBH-RD = the relative difference between arms for hand-behind-head mobility; SSP-RD = the relative difference between arms for the strength of supraspinatus; ISP-RD = the relative difference between arms for the strength of infraspinatus; DASH = the Disabilities of the Arm, Hand, and Shoulder Outcome Measure.

Table 3 – Frequencies of HBB for the affected arm

Score	Description	Frequencies
0	The hand reaches behind the trunk to the opposite scapula or 5cm beneath it in full internal rotation	10
1	The hand almost reaches the opposite scapula, 6-15cm beneath it	2
2	The hand reaches the opposite iliac crest	0
3	The hand reaches the buttock	0
4	Subject cannot move the hand behind the trunk	0

Table 4 – Frequencies of HBH for the affected arm

Score	Description	Frequencies
0	The fingers reach the posterior median line of the neck with the shoulder in full abduction and external rotation without wrist extension	10
1	The fingers reach the median line of the neck but do not have full abduction and/or external rotation	2
2	The fingers reach the median line of the neck, but with compensation by adduction in the horizontal plane or by shoulder elevation	0
3	The fingers touch the neck	0
4	The fingers do not reach the neck	0

RELATIONSHIP BETWEEN DASH SCORES AND THE STUDY VARIABLES

Comparisons and relationships between each of the independent variables and the DASH score were also performed (Table 5). The results indicated that there was a strong positive correlation between pain and DASH scores. The results also indicated that there was a strong positive correlation between fear and DASH scores. For both the supraspinatus muscle and the infraspinatus muscle, the correlation was non-significant with the DASH scores, although infraspinatus was close to significance.

Table 5– Relationship between the Disabilities of the Arm, Shoulder, and Hand Outcome Measure scores and study variables

	r_s	P
Pain	0.819	0.001*
Fear of Physical Activity	0.746	0.005*
Supraspinatus - RD	0.182	0.572
Infraspinatus - RD	0.553	0.062

Legend 2: Supraspinatus-RD = the relative difference between arms for the strength of supraspinatus; Infraspinatus-RD = the relative difference between arms for the strength of infraspinatus.

A Kruskal-Wallis test revealed non-significant relationships between both HBB (p = 0.366), HBH (p = 0.390), and DASH scores.

DISCUSSION

MAJOR FINDINGS OF THE STUDY

The results suggested the presence of a strong relationship between both patient's pain level and fear of activity and activity limitations based on participant DASH outcome measure scores. These finding suggest that women with higher levels of pain and fear reported having higher level of difficulty performing daily activities. However, we found no relationship between ROM and strength with activity limitations reported by the women.

This study found 83.3% of the participants had a score of 0 for both HBB and HBH tests, meaning that the majority of women have a normal shoulder range of motion.

As a group, the participants were relatively young at 58 years old and mostly retired. They reported an average post-operative time of 4 years and diagnostic with Stage 1or 2 breast cancer. Axillary dissection, chemotherapy, and radiation were all heavily reported as adjuvant therapies.

These findings may also have a clinical impact in the rehabilitation for women after breast cancer. It demonstrates the need for increased awareness of the role of chronic pain and fear avoidance in the recovery process from surgery. These personal factors should be incorporated into interventions for women with or at risk of disability. A possible intervention is the use of cognitive behavioural therapy (CBT) and graded exposure techniques for fear of physical activity and fear avoidance-related pain (32). Currently, attention to these personal factors is variable in health professionals' curriculums. Physiotherapists may not be the most appropriate therapists to perform these interventions. It is beneficial to use multi-disciplinary approaches that include occupational therapists or CBT-trained psychologists (60).

IMPORTANCE OF THE FINDINGS

The disability outcome measure (DASH) had a mean of 12.2/100 points, which represents a very low-level of disability where higher scores represent more difficulties with activities. A comparison study found a mean DASH scores for those who had a breast-conserving technique of 19.35/100 while the unaffected control group was 1.16/100 (61). Another found mean disability to be at 32.2 for the DASH in similar patients to this study

(62). A low-level of disability was found in other studies following surgery. Women who had basic standard of care had a mean DASH of 13.7, with 85% of participants falling below 25/100 (63). The DASH score was also low for patients having mastectomies, regardless of hand dominance, over 12 months previously with a range of 10.12-12.97 (64). The DASH score from this study is similar to this finding and could indicate a decreasing DASH score with increased time since the surgery. Had this study achieved full expected participation for power, there would have been participants with higher DASH scores. Unfortunately, due to low recruitment, this level of disability was not found in the present study, which limits the capacity to study the relationship between impairments and disability.

Relationship between range of motion and disability

No significant relationship was found between shoulder ROM and the DASH scores. The level of impairment in our sample of participants was not severe enough to affect either their shoulder ROM or DASH scores. In fact, 83% of our participants had a HBH and/or HBB score of zero, indicating that the shoulder ROM was within normal limits (Tables 3 & 4). This result agreed with shoulder ROM findings for post-mastectomy patients that were insignificant for both dominant and non-dominant affected sides (64). External rotation has been found to be significantly impaired if measured at 90 degrees abduction instead of neutral (61). Our HBH method deducted points if full abduction and external rotation were not achieved. Despite these criteria, our HBH ROM scores were still within normal range for the majority of participants.

There was difficulty directly comparing our results with those of other studies because of variance in measurement methods. Often, a goniometer was used in other studies instead of functional ROM measurement using HBB and HBH tests used in this study.

Occasionally, qualitative methods were used to assess disability. A larger sample size would have permitted a better analysis of loss of mobility in this population.

Relationship between strength and disability

The relative differences for supraspinatus (1.0 kg) and infraspinatus (-0.3 kg) strength show a small difference between the affected and the non-affected arm. Again, the small sample size makes it hard to analyze strength capacity properly. The literature on the effect of surgery and BrCa treatment on strength is mixed. One study reported that 57.6% of patients achieve normal strength on a manual muscle test (65). The non-significant loss of strength is also independent for hand dominance (64). Scaption (full can position) has been found to have a relationship with DASH ($r = -0.56$, $p = 0.003$), but external rotation has not ($r = -0.35$, $p = 0.05$) (66).

There was also no relationship between the DASH scores and the two shoulder strength measures, though a trend was observed for the infraspinatus muscle ($p = .062$) but not for the supraspinatus muscle. However, our small sample size indicated both muscles strength were not related to the DASH scores, and it can be assumed that participants had enough strength to perform their daily activities. This lack of strength impairment limits the capacity to study its relationship with disability. Many studies of BrCa rehabilitation neither investigate nor report shoulder or arm strength measures. Hand-grip strength, instead of shoulder complex muscles measurement, are often used as strength measurements (62). Hand grip was not chosen for this study, as it does not specifically evaluate the muscles of the shoulder complex.

Relationship between pain and disability

There was a positive relationship between pain and the DASH scores of participants. The mean score for pain was 11.7mm, which indicates a low level of pain, but ranged from 0mm to 68mm. The findings would be considered in the low-to-moderate level of pain on a visual pain scale (67). Although the sample size is not large enough for regression analysis, the presence of pain in a moderate level suggests that pain is still a concern after BrCa surgery. Pain during rest can often be different from pain during activity, as evidence shows an escalation from 17mm to 30mm in one study (62). In our study, we did not divide the inquiry of pain into "pain at rest" and "pain with activity" categories. It would be beneficial to make this distinction in their pain. If it was being felt with activity, further questioning could identify potential movement patterns responsible for the pain.

Chronic pain was the second most prevalent symptom behind decreased ROM but the most bothersome symptom to patients (18). Our study was able to demonstrate the relationship between pain and disability. Similar findings were found where moderate pain levels were reported for BrCa patients 8–43 months after surgery, and pain was a predictor to disruptions in recreational activities (68).

Relationship between fear of physical activity and disability

At the beginning of this study, we hypothesized that a fear of activity personality trait would account for a portion of the DASH score variance. However, due to the small sample size, this was not assessed. A relatively small level of fear of physical activity was found with a mean of 6.42/24. At best, these results are comparable to the 9.7±4.2 finding for the FABQ-PA in a non-cancer population with shoulder pain (56). No known studies have evaluated the FABQ in breast cancer survivors.

The personality trait of fear of physical activity had, like pain, a relationship with the DASH. Due to the small sample size in this study and inability to accomplish multivariate analyses, it is impossible to know whether participants' pain perception contributed to their fear avoidance behaviour. In chronic pain literature, the presence and severity of pain have been found to be predictors of pain-related fear, which in turns influences disability (69).

LIMITATIONS OF THE STUDY

There are several limitations to this study. The major one is the small sample size. The number of participants did not allow for a proper analysis of statistics and prevents generalizability to the larger population. A sample size appropriately powered (CI 95%) was determined to be 59, but data from only 12 participants were available. Due to the small sample size, only univariate statistics were performed. This prevented identifying the isolated contribution of each of the impairments to the disability.

Recruitment was another section of the study that would need to be changed in any further attempts. The design of the study was a cross-sectional that is an analysis of the population at the given time. All types of women with varying degrees of abilities should have been included in the recruitment provided they met the other inclusion and exclusion criteria. There was an intention to have an equal number of women who had DASH scores above and below 30 points, but only if the sample size was sufficient. There may have been some confusion with our recruiting sources as to the definition of disability and how to determine whether a woman was a good candidate for the study. In the end, it was very easy to recruit women who fell below 30 pts on the DASH and much harder to recruit women with scores of 31 or higher. With the exception of the physicians, many of the locations for recruitment were related to some form of physical activity, such as the Run for the Cure or

exercise classes for cancer survivors. These types of events may have a higher attendance of women who do not have a high level of disability because they are able to join groups and participate in the community. It would be important for future recruitment to find ways to reach those with a higher level of disability. Possible sources could be through the hospital rehabilitation team, support groups, and local chapters of the Cancer Society. It would also be imperative to have a clear description of which patients physicians could suggest for the study.

The inclusion and exclusion criteria may have decreased the potential recruitment of more women. The largest factor was the requirement to have a physician clear the potential participants for the criteria if they were not referred to the study by their oncologist. In addition, the less severe disease status may have contributed to a less disabled group of participants. Moreover, participation in the study was voluntary, so those who self-selected may have been women who knew they had reasonable function after their surgery.

In 2008, The Ottawa Hospital's Cancer Institute began to have physiotherapists be a part of the psychosocial team for patients living in the greater Ottawa region after their surgery. This new standard of care assisted in identifying and treating BrCa patients in need in the early phase of post-op rehabilitation as well as years afterward if the need persists or arises. Our study sample members had their surgery in 2008, on average, which means a large portion of the participants may have accessed this new rehabilitation program. However, this information was unfortunately not documented in the present study. If they did access this program, they may have received earlier rehabilitation for their disability than those who had surgery earlier than 2008, resulting in less chronic disability and decreasing the possibility to recruit patients with higher levels of disability. .

There were also several study design limitations. This was a cross-sectional exploratory study with the intention of performing regression statistics. This design limited the investigators from defining a cause and effect from the data collected. At most, hypotheses can be generated or relationships can be gleaned from the analyses. Because no definite causality can be established, the clinical usability of the study's results is affected.

There are a few confounding factors that limit the interpretability of the study results. Physical impairment, such as shoulder immobility and arm weakness, becomes more pronounced with increased age. As well, an exploratory sub-analysis of the DASH scores in our sample (results not shown) between dominant vs. non-dominant affected arm did not reveal any significant difference, which seems to suggest that dominance would not be a confounding factor.

A minor limitation was the lack of specific outcome measures for the breast cancer population. The FABQ had two questions that had to be adapted with the substitution of the word of "shoulder" for "back." A specific measure for shoulder disability may improve future results. A recent project may contribute this as the fear of physical activity/exercise scale—breast cancer [FPAX-B] outcome measure has been verified for content validity and is having its other psychometric properties validated (70).

FUTURE RESEARCH

Due to the numerous limitations of this study, several improvements could be made for future study. The most important would be to run a study with an increased sample size and with women who had a greater degree of disability. If these elements were achieved, multi-variate analyses could be conducted. This statistical method could provide an improved isolation of relationships with a multi-variate study.

The findings from this study have also identified possible future areas for research in post-breast cancer rehabilitation. The most promising is the relationship of a fear personality trait to chronic disability in women having undergone BrCa surgery. This is an emerging area in all health practices, and a larger study of BrCa survivors could contribute to the extent that a fear trait could have in recovery.

Future research could also focus on better understanding the causes and consequences of pain in patients undergoing BrCA surgery. In this study, the VAS was chosen to limit the amount of variables, but a subsequent study could focus solely on chronic pain. Rather than using the VAS, an outcome measure that asks about more specific changes in pain at rest and during movement and daily activities could be beneficial. The P4-validated pain outcome measure asks about pain at rest and with activity (71). This may be helpful in determining when people have problems and for establishing a treatment plan.

CONCLUSION

Considering the small sample size in this study, a few minor conclusions can be drawn. One is that pain and fear seem to have a relationship to chronic disability. Upper extremity ROM and strength defined in functional patterns did not seem to have relationships with DASH scores in the same significant manner as did the FABQ-PA and the VAS-Pain. Breast cancer is an extremely common disease in Canada, but escalating survival rates require further evaluation of the components of chronic disability.

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APPENDICES

Appendix A – Ethics Approval & Budget

- Ottawa Hospital Research Ethics Board/University of Ottawa
- Study Budget
- Written documentation from journal publisher for diagram reprint

Appendix B – Outcome Measures Forms

- DASH Questionnaire
- VAS-Pain Line
- FABQ Questionnaire
- Mobility Rank Questionnaire

Appendix C – Patient Package

- Consent Form
- Information Sheet
- Participant Form for payment

Appendix D – Recruitment Materials

- Community Poster
- Investigator Phone Script
- Physician Checklist
- Community Patient Consent for Information
- Recruitment letter to physicians in community

Appendix E – Evaluation Forms

- Physiotherapist's instructions

- Photos of testing positions
- Recording sheet for the Physiotherapist
- Main data collection form for Investigator

Appendix F – Statistical Analysis

- Excel Data Table
- SPSS Output

Appendix A – Ethics Approval

Ottawa Hospital Research Ethics Boards / Conseils d'éthique en recherches
725 Parkdale Avenue, Box 411, Ottawa, Ontario K1Y 4E9 613-798-5555 ext. 14902 Fax: 613-761-4311
http://www.ohri.ca/ohreb

June 13, 2011

[redacted]
School of Rehabilitation Sciences
Roger Guindon Hall
451 Smyth Rd., Rm 3045
Ottawa, ON [redacted]

Dear [redacted]

Re: Protocol # 2011342-01H **The Relationship of Impairments to Chronic Activity Limitations in Women after Breast Cancer**

Protocol approval valid until - August 13, 2011

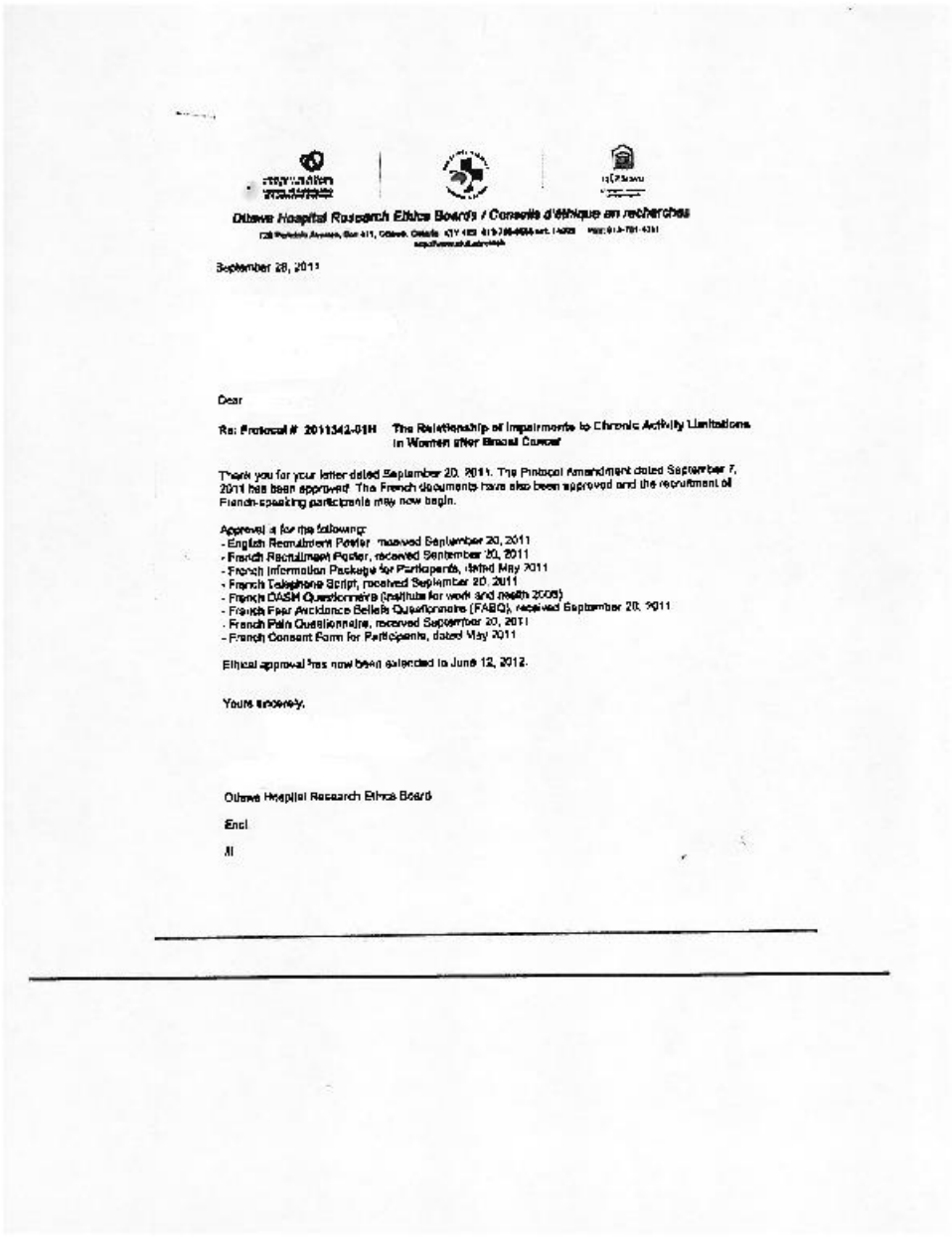
Thank you for your letter received June 7, 2011. I am pleased to inform you that this protocol underwent expedited review by the Ottawa Hospital Research Ethics Board (OHREB) and is approved for two months to begin recruiting English-speaking participants.

Approval is conditional upon the existence of a fully executed agreement between the University of Ottawa, Principal Investigator, and Evaluation Site. Approval is also conditional upon receipt of the University of Ottawa Health Sciences and Sciences REB approval letter. Please submit the approval letter to our attention once received. No changes, amendments or addenda may be made to the protocol or the consent form without the OHREB's review and approval.

Approval is for the following:
- COREB Application
- Protocol Amendment Report dated June 6, 2011
- Thesis Proposal
- English Disabilities of the Arm, Shoulder and Hand (DASH) Questionnaire
- English Fear-Avoidance Beliefs Questionnaire (FABQ)
- English Pain Questionnaire
- English Information Package for Participants (May 2011)
- English Phone Script for Potential Participants
- English Consent Form for Participants, dated May 2011

Upon receipt and review of the French consent, script, information package and questionnaires, approval may be extended for up to one year and the recruitment of French-speaking participants may begin. When submitting French documentation to the OHREB, confirm that it has been translated or approved by [redacted] (email all documentation, except validated questionnaires, to [redacted]

The validation date should be indicated on the bottom of all consent forms and information sheets (see copy attached).



Ottawa Hospital Research Ethics Board / Conseils d'éthique en recherches

September 28, 2011

Dear

Re: Protocol # 2011342-01H The Relationship of Impairments to Chronic Activity Limitations in Women after Breast Cancer

Thank you for your letter dated September 20, 2011. The Protocol Amendment dated September 7, 2011 has been approved. The French documents have also been approved and the recruitment of French-speaking participants may now begin.

Approval is for the following:
- English Recruitment Poster received September 20, 2011
- French Recruitment Poster, received September 20, 2011
- French Information Package for Participants, dated May 2011
- French Telephone Script, received September 20, 2011
- French DASH Questionnaire (Institute for work and health 2006)
- French Fear Avoidance Beliefs Questionnaire (FABQ), received September 20, 2011
- French Pain Questionnaire, received September 20, 2011
- French Consent Form for Participants, dated May 2011

Ethical approval has now been extended to June 12, 2012.

Yours sincerely,

Ottawa Hospital Research Ethics Board

Encl

/l

STUDY BUDGET

ITEM	Description	Costs
Professional Resources **Physiotherapist sessions for measurements**	59 visits @ $45/visit	$2655
Participant Subsidy **Travel, parking**	59 visits x $20	$1180
Equipment **Hand-held dynanometer**	Lafayette 01163	$1000
Administrative Resources	Paper, photocopies,mailings, phone/ fax, secretarial assistance	$150
Total		**$4985**

Recruitment and data collection will be accomplished by a presently enrolled Master's student in Human Kinetics at the University of Ottawa (Vicki Wong).This project will constitute her Master's thesis.Therefore, no funding is required for these human resources.

Appendix A – Editor permission for diagram reprint

Subject:	Re: reprint request
From:	" >
Date:	Mon, 30 April, 2012 11:01 am
To:	
Priority:	Normal
Options:	View Full Header |View Printable Version| Download this as a file| Add to Addressbook

Ms:

As editor of the journal Rehabilitation Oncology, you have my permission to reproduce the figure for your master's thesis. Kindly give credit to the source. Best wishes to you as you complete your degree.

Date:04/29/2012 12:10 PM

Subject:reprint request

Hello,

I am not sure who this would go to, but I would like permission to reproduce a figure from an article in your journal.

I am interested in Figure 1 from:

Smoot B, Wampler M, Topp KS. Breast cancer treatments and complications: implications for rehabilitation. Rehabilitation Oncology. 2009; 27(3),

p.17.

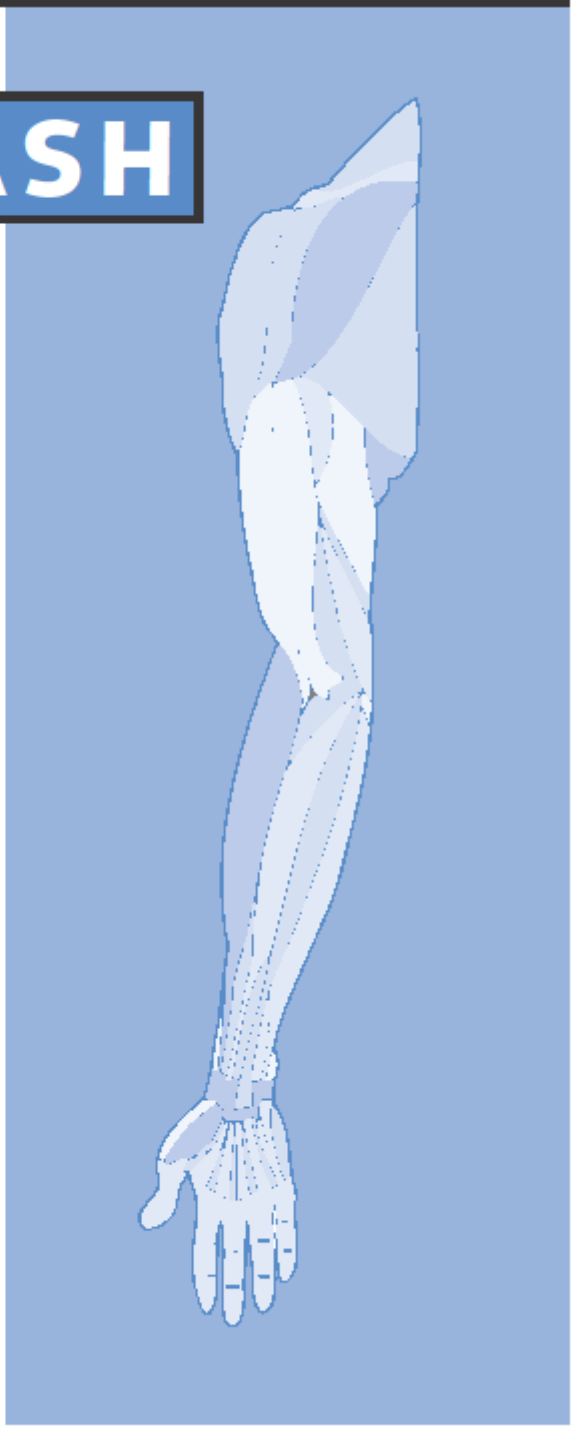
The purpose is to add visual comprehension in the literature section of my masters thesis looking at chronic activity limitations and impairments after breast cancer.

Thank you for your consideration.

Appendix B – DASH Questionnaire

DISABILITIES OF THE ARM, SHOULDER AND HAND

THE DASH



INSTRUCTIONS

This questionnaire asks about your symptoms as well as your ability to perform certain activities.

Please answer *every question*, based on your condition in the last week, by circling the appropriate number.

If you did not have the opportunity to perform an activity in the past week, please make your *best estimate* on which response would be the most accurate.

It doesn't matter which hand or arm you use to perform the activity; please answer based on your ability regardless of how you perform the task.

Disabilities of the Arm, Shoulder and Hand

Please rate your ability to do the following activities in the last week by circling the number below the appropriate response.

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. Open a tight or new jar.	1	2	3	4	5
2. Write.	1	2	3	4	5
3. Turn a key.	1	2	3	4	5
4. Prepare a meal.	1	2	3	4	5
5. Push open a heavy door.	1	2	3	4	5
6. Place an object on a shelf above your head.	1	2	3	4	5
7. Do heavy household chores (e.g., wash walls, wash floors).	1	2	3	4	5
8. Garden or do yard work.	1	2	3	4	5
9. Make a bed.	1	2	3	4	5
10. Carry a shopping bag or briefcase.	1	2	3	4	5
11. Carry a heavy object (over 10 lbs).	1	2	3	4	5
12. Change a lightbulb overhead.	1	2	3	4	5
13. Wash or blow dry your hair.	1	2	3	4	5
14. Wash your back.	1	2	3	4	5
15. Put on a pullover sweater.	1	2	3	4	5
16. Use a knife to cut food.	1	2	3	4	5
17. Recreational activities which require little effort (e.g., cardplaying, knitting, etc.).	1	2	3	4	5
18. Recreational activities in which you take some force or impact through your arm, shoulder or hand (e.g., golf, hammering, tennis, etc.).	1	2	3	4	5
19. Recreational activities in which you move your arm freely (e.g., playing frisbee, badminton, etc.).	1	2	3	4	5
20. Manage transportation needs (getting from one place to another).	1	2	3	4	5
21. Sexual activities.	1	2	3	4	5

Disabilities of the Arm, Shoulder and Hand

	NOT AT ALL	SLIGHTLY	MODERATELY	QUITE A BIT	EXTREMELY
22. During the past week, *to what extent* has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups? *(circle number)*	1	2	3	4	5

	NOT LIMITED AT ALL	SLIGHTLY LIMITED	MODERATELY LIMITED	VERY LIMITED	UNABLE
23. During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem? *(circle number)*	1	2	3	4	5

Please rate the severity of the following symptoms in the last week. *(circle number)*

	NONE	MILD	MODERATE	SEVERE	EXTREME
24. Arm, shoulder or hand pain.	1	2	3	4	5
25. Arm, shoulder or hand pain when you performed any specific activity.	1	2	3	4	5
26. Tingling (pins and needles) in your arm, shoulder or hand.	1	2	3	4	5
27. Weakness in your arm, shoulder or hand.	1	2	3	4	5
28. Stiffness in your arm, shoulder or hand.	1	2	3	4	5

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	SO MUCH DIFFICULTY THAT I CAN'T SLEEP
29. During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand? *(circle number)*	1	2	3	4	5

	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
30. I feel less capable, less confident or less useful because of my arm, shoulder or hand problem. *(circle number)*	1	2	3	4	5

DASH DISABILITY/SYMPTOM SCORE = $\left[\frac{(\text{sum of n responses})}{n} - 1\right] \times 25$, where n is equal to the number of completed responses.

A DASH score may <u>not</u> be calculated if there are greater than 3 missing items.

Appendix B –VAS-Pain Line

Pain Questionnaire

Instructions: Please make a vertical line on the horizontal line to show your average pain for the last week:

No pain _____ Pain as bad as it can be

Appendix B –FABQ Questionnaire

Fear-AvoidanceBeliefs Questionnaire (FABQ)

Instructions: Here are some of the things which other patients have told us about their pain.For each statement please circle the number from 0 to 6 to rate your agreement with 0 = 'Completely Disagree', 3 = 'unsure', and 6 = 'Completely Agree'

Statements:

1. My pain is caused by physical activity.	0	1	2	3	4	5	6
2. Physical activity makes my pain worse.	0	1	2	3	4	5	6
3. Physical activity might harm my shoulder.	0	1	2	3	4	5	6
4. I should not do physical activities which (might) make my pain worse.	0	1	2	3	4	5	6
5. I cannot do physical activities which (might) make my pain worse.	0	1	2	3	4	5	6

The following statements are about how your normal work affects or would affect your shoulder pain:

6. My pain was caused by my work or by an accident at work.	0	1	2	3	4	5	6
7. My work aggravated my pain.	0	1	2	3	4	5	6
8. I have a claim for compensation for my pain.	0	1	2	3	4	5	6
9. My work is too heavy for me.	0	1	2	3	4	5	6
10. My work makes or would make my pain worse.	0	1	2	3	4	5	6
11. My work might harm my shoulder.	0	1	2	3	4	5	6
12. I should not do my normal work with my present pain.	0	1	2	3	4	5	6

13. I cannot do my normal work with my present pain.	0	1	2	3	4	5	6
14. I cannot do my normal work till my pain is treated.	0	1	2	3	4	5	6
15. I do not think that I will be back to my normal work within 3 months.	0	1	2	3	4	5	6
16. I do not think that I will ever be able to go back to that work.	0	1	2	3	4	5	6

Appendix B –Mobility Rank Questionnaire

Descriptive AROM

HBB score: R_____; L_____

0 The hand reaches behind the trunk to the opposite scapula or 5cm beneath it in full internal rotation

1 The hand almost reaches the opposite scapula, 6-15cm beneath it

2 The hand reaches the opposite iliac crest

3 The hand reaches the buttock

4 Subject cannot move the hand behind the trunk

HBH score: R_____; L_____

0 The fingers reach the posterior median line of the neck with the shoulder in full abduction and external rotation without wrist extension

1 The fingers reach the median line of the neck but do not have full abduction and/or external rotation

2 The Fingers reach the median line of the neck, but with compensation by adduction in the horizontal plane or by shoulder elevation

3 The fingers touch the neck

4 The fingers do not reach the neck

Appendix C- Consent Form

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École des sciences de la réadaptation | School of Rehabilitation Sciences

CONSENT FORM FOR PARTICIPANTS

Relationship between activity limitations and impairments:

A cross-sectional study of patients 6 months+post-surgery for breast cancer

Study Leaders: Vicki Wong, PT,Tel:

Dr. StephanePoitras, Tel:

Introduction

You are being asked to participate in this research study because you have been treated for breast cancer in the past, including surgery.

Purpose of the Study

The goal is to find a relationship between problems, like moving your arm, and how easily you do tasks in your daily routine. We are testing women who have had surgery for breast cancer.You must be finished with chemotherapy or radiation. It is alright if you still take hormonal therapy.You cannot be in the study if you have a broken bone, cancer that has spread, a flare-up of joint inflammation, or another type of cancer.

Many other projects do not focus on the long-term problems and the findings may help others avoid these problems in the future.The participants are being asked from the Ottawa Cancer Centre.

Study Procedures

Your role in the study is to provide measurements of how well you can do your daily activities and any symptoms that happen at the same time.You are only being asked to provide this information once.

At the testing session, you will have to answer 3 surveys that will take you approximately 15 minutes. You will also have a physiotherapist measure your mobility and strength.She will ask you to move your arms as far as you can behind your head and behind your back. Next, you will be asked to push as hard as possible against a small machine to measure strength for 7 seconds.There are 6 strength tests for each arm.

Study Duration

The study will be collecting data until fall, 2011, but you are only required to be there for 1 session to have your measurements taken.That session should be finished in an hour.

Possible Side Effects and Risks

If you take part, you may be sore, tired, or thirsty. In rare cases, you may injure a muscle or have swelling in your arm. In extreme cases, there is the possibility of having heart problems, breathing problems, a stroke, or sudden death. These risks are minimal and depend on your current health.The physiotherapist will show you how to do the movements safely before you do them.

Benefits of the Study

You may not receive any direct benefits from your participation in this study.Your participation in this study may allow researchers to plan better and early treatment after breast cancer surgery. This may prevent chronic symptoms, for example pain, after the surgery which may be beneficial to future breast cancer patients.

Withdrawal from the study

You have the right to withdraw from the study at any time without any impact to your current and future care at the OttawaHospital.If you decide to withdraw, you should discuss this with the study investigator before you stop the study.

You may cancel this consent at any time.If you withdraw your consent, the study investigator will no longer use and disclose your personal health information under the consent for this study, unless the study investigator needs to use and disclose some of your personal health information to preserve the scientific integrity.

You have the right to check your study records and request changes if the information is not correct.However, to ensure the scientific integrity of the study, some of your records related to the study may not be available for your review until after the study has been completed.

Compensation

In the event of a research-related injury or illness, you will be provided with appropriate medical treatment/care.You are not waiving your legal rights by agreeing to

participate in this study.The study doctor and the hospital still have their legal and professional responsibilities.

Study Costs

You will not be paid to participate in this research study.You will be provided $20 to cover parking costs and your travel.Income earned as a result of your participation in this study, that is not for reimbursement of study expenses, will be considered taxable income by Revenue Canada.In order to receive payment for your participation in this study, it will be necessary to provide the investigator or their delegate with your Social Insurance Number.The OttawaHospital will then issue a T4A for any amount over $ 500.00, by the end of February of the following year.

Confidentiality

All personal health information will be kept confidential, unless release is required by law.Representatives of the of University of Ottawa,representatives of the Ottawa Hospital Research Ethics Board, as well as the Ottawa Hospital Research Institute, may review your original medical records under the supervision of Dr.StephanePoitras for audit purposes.

The study leader may ask for personal information, for example your name, age, medical background, and phone number. This is to call you and see if you qualify for the study.This information will be kept private. You will not be identifiable in any publications or presentations resulting from this study.No identifying information will leave the OttawaHospital or the University of Ottawa after the evaluation session.All information will be coded with an independent study number that will be written on all your forms instead of your name.

The link between your name and the independent study number will only be accessible by Dr.Poitras and V.Wong.The link and study files will be stored separately and securely.Both files will be kept for a period of 15 years after the study has been completed.All paper records will be stored in a locked file and/or office.All electronic records will be stored on a USB key and protected by a user password and encrypted, again only accessible by Dr.Poitras and V.Wong.At the end of the retention period, all paper records will be disposed of in confidential waste or shredded, and all electronic records will be deleted.

Voluntary Participation

Your participation in this study is voluntary.If you choose not to participate, your decision will not affect the care you receive at this Institution at this time, or in the future.You will not have any penalty or loss of benefits to which you are otherwise entitled to.

Questions about the Study

If you have any questions about this study or if you feel that you have experienced a research-related injury, please contact either Vicki Wong, PT, at or Dr. StephanePoitras at

The Ottawa Hospital Research Ethics Board (OHREB) has reviewed this protocol.The OHREB considers the ethical aspects of all research studies involving human subjects at The Ottawa Hospital.If you have any questions about your rights as a research subject, you may contact the Chairperson of the Ottawa Hospital Research Ethics Board at 613-798-5555, extension 14902.

You may also contact the Protocol Officer for Ethics in Research at the University of Ottawa.The University may be reached by phone at 613-562-5841 or by email at

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CONSENT FORM FOR PARTICIPANTS

Relationship between activity limitations and impairments:

A cross-sectional study of patients 6 months+post-surgery for breast cancer

Study Leaders: Vicki Wong, PT& Dr. StephanePoitras

****

****

Consent to Participate in Research

I understand that I am being asked to participate in a research study chronic symptoms after breast cancer surgery.This study has been explained to me by Vicki Wong, PT.

I have read this *4 page* Patient Information Sheet and Consent Form (or have had this document read to me).All my questions have been answered to my satisfaction.If I decide at a later stage in the study that I would like to withdraw my consent, I may do so at any time.

I voluntarily agree to participate in this study.

A copy of the signed Consent Form will be provided to me.

Signatures

I understand that it is my choice to volunteer for this project. I can decide at any time not to participate for any reason.I was given a copy of this signed consent form to keep.

Participant (print): _____

Participant (signature):_____ Date: _____

Participant Code: _____

Investigator Statement (or Person Explaining the Consent)

I have carefully explained to the research participant the nature of the above research study.To the best of my knowledge, the research participant signing this consent form understands the nature, demands, risks and benefits involved in participating in this study.I acknowledge my responsibility for the care and well being of the above research participant, to respect the rights and wishes of the research participant, and to conduct the study according to applicable Good Clinical Practice guidelines and regulations.

_____

Name of Investigator/Delegate (Please Print)

_____ _____

Signature of Investigator/Delegate Date

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FORMULAIRE DE CONSENTEMENT POUR LES PARTICIPANTS

Relations entre les limitations d'activités et des déficiences :

Une étude transversale des patients 6 mois + post-chirurgie pour un cancer du sein

Chercheurs principaux : Vicki Wong, PT, Tél. :

D[r] Stéphane Poitras, Tél. :

Introduction

Vous êtes invitée à participer à cette étude parce que vous avez été traitée pour un cancer du sein dans le passé, y compris la chirurgie.

But de l'étude

Le but est de trouver une relation entre les problèmes, comme la mobilité de votre bras, et avec quelle facilité vous effectuez des tâches dans votre routine quotidienne. Nous

évaluons les femmes qui ont subi une chirurgie pour un cancer du sein. Vous devez avoir terminé la chimiothérapie ou la radiothérapie. Il est correct si vous devez encore prendre un traitement hormonal. Vous ne pouvez pas être dans l'étude si vous avez un os fracturé, le cancer qui s'est propagé, une poussée d'inflammation des articulations, ou un autre type de cancer.

Peu de projets se penchent sur les problèmes à long terme, et les résultats de cette étude peuvent aider les autres à éviter ces problèmes à l'avenir. Les participants sont invités à partir du Centre de cancérologie d'Ottawa.

Procédures d'études

Votre rôle dans l'étude est de fournir des mesures de la façon dont vous faites vos activités quotidiennes et les symptômes qui se produisent en même temps. Vous êtes seulement invitée à fournir cette information une fois.

Lors de la séance d'évaluation, vous devrez répondre à 3 questionnaires qui vous prendront environ 15 minutes. Un physiothérapeute mesurera également votre mobilité et force. Elle vous demandera de bouger les bras aussi loin que vous pouvez derrière votre tête et derrière votre dos. Ensuite, il vous sera demandé de pousser aussi fort que possible contre une petite machine pour mesurer la force pendant 7 secondes. Il y a 6 tests de force pour chaque bras.

Durée de l'étude

L'étude collectera des données jusqu'à l'automne 2011, mais il vous suffit d'être là pour une séance afin d'avoir vos mesures prises. Cette séance devrait être terminée en une heure.

Effets secondaires possibles et des risques

Si vous participez, vous pourrez être endolorie, fatiguée, ou avoir soif. Dans de rares cas, vous pourriez blesser un muscle ou avoir une enflure du bras. Dans les cas extrêmes, il y a la possibilité d'avoir des problèmes cardiaques, des problèmes respiratoires, un accident vasculaire cérébral, ou une mort subite. Ces risques sont minimes et varieront en fonction de votre état de santé actuel. Le physiothérapeute vous montrera comment faire les mouvements en toute sécurité avant de les faire.

Avantages de l'étude

Vous ne pouvez pas recevoir de bienfaits directs de votre participation à cette étude. Votre participation à cette étude peut permettre aux chercheurs de planifier de meilleurs traitements après la chirurgie du cancer du sein. Cela pourrait prévenir les symptômes chroniques après la chirurgie, par exemple la douleur, et possiblement être bénéfique pour de futurs patients atteints de cancer du sein.

Retrait de l'étude

Vous avez le droit de vous retirer de l'étude à tout moment et sans aucun impact sur vos soins actuels et futurs à L'Hôpital d'Ottawa. Si vous décidez de vous retirer, vous devriez en discuter avec le chercheur avant d'arrêter l'étude.

Vous pouvez annuler ce consentement à tout moment. Si vous retirez votre consentement, le chercheur de l'étude ne pourra plus utiliser et divulguer vos renseignements personnels sur la santé en vertu du consentement pour cette étude, à moins que le chercheur de l'étude doive utiliser et divulguer certains de vos renseignements personnels sur la santé afin de préserver l'intégrité scientifique.

Vous avez le droit de vérifier vos dossiers d'étude et de demander des changements si l'information n'est pas correcte. Toutefois, pour assurer l'intégrité scientifique de l'étude, certains de vos documents relatifs à l'étude peuvent être disponibles pour révision seulement lorsque l'étude sera complétée.

Compensation

Dans le cas d'une blessure liée à la recherche ou de maladie, vous recevrez un traitement médical approprié. Vous ne renoncez pas à vos droits légaux en acceptant de participer à cette étude. Le médecin de l'étude et l'hôpital seront toujours tenus de respecter leurs responsabilités légales et professionnelles.

Frais d'études

Tout revenu résultant de votre participation à cette étude et ne faisant pas partie du remboursement des frais reliés à l'étude sera considéré comme un gain imposable par Revenu Canada. Afin de recevoir votre rémunération pour votre participation à cette étude, vous devrez fournir votre numéro d'assurance sociale au chercheur ou à son délégué. L'Hôpital d'Ottawa vous remettra ensuite un T4A pour tout montant supérieur à 500 $ avant la fin du mois de février de l'année suivante.

Confidentialité

Tous les renseignements personnels sur la santé seront gardés confidentiels, à moins que leur divulgation ne soit exigée par la loi. Des représentants de l'Université d'Ottawa, des représentants du Conseil d'éthique en recherches de L'Hôpital d'Ottawa, ainsi que de l'Institut de recherche de l'Hôpital d'Ottawa, peuvent examiner vos dossiers médicaux originaux sous la supervision du D^{r} Stéphane Poitras, uniquement à des fins de vérification.

Le chercheur principal de l'étude peut demander des informations personnelles, par exemple votre nom, âge, antécédents médicaux, et le numéro de téléphone. C'est pour vous appeler et voir si vous êtes admissible à l'étude. Cette information sera gardée confidentielle. Vous ne serez pas identifiable dans les publications ou présentations issues de cette étude. Aucune information pouvant servir à vous identifier ne sera transmise à l'extérieur de L'Hôpital d'Ottawa ou de l'Université d'Ottawa après la séance d'évaluation. Toutes les informations seront codées avec un numéro d'étude indépendant qui figurera sur tous vos formulaires à la place de votre nom.

Seuls le D[r]Poitras et V. Wong auront accès au lien entre votre nom et le numéro d'étude indépendant. Les fichiers de liens et d'études seront conservés séparément et en toute sécurité. Les deux fichiers seront conservés pendant une période de 15 ans suite à la fin de l'étude. Tous les dossiers papier seront conservés dans un classeur verrouillé et/ou au bureau. Tous les dossiers électroniques seront conservés sur une clé USB et protégés par un mot de passe, à nouveau accessible uniquement au D[r]Poitras et V. Wong. À la fin de la période de rétention, tous les documents papier seront jetés aux rebuts confidentiels ou déchiquetés, et tous les dossiers électroniques seront supprimés.

La participation volontaire

Votre participation à cette étude est volontaire. Si vous choisissez de ne pas participer, votre décision n'influera pas sur les soins que vous recevez à cet établissement à ce moment, ou à l'avenir. Vous n'encourrez aucune pénalité ni perte d'avantages auxquels vous auriez normalement droit.

Questions sur l'étude

Si vous avez des questions sur cette étude ou si vous sentez que vous avez subi une blessure liée à la recherche, veuillez communiquer avec Vicki Wong, PT, au ou D^r^ Stéphane Poitras au.

Le Conseil d'éthique en recherches de L'Hôpital d'Ottawa (CÉRHO) a examiné le présent protocole. Le CÉRHO évalue les aspects éthiques de toutes les études de recherche menées auprès de sujets humains à L'Hôpital d'Ottawa. Si vous avez des questions concernant vos droits en tant que sujet de recherche, vous pouvez communiquer avec le président du Conseil d'éthique en recherches de L'Hôpital d'Ottawa au 613-798-5555, poste 14902.

Vous pouvez également communiquer avec le responsable de la déontologie en recherche à l'Université d'Ottawa. Vous pouvez communiquer avec ce dernier en téléphonant au 613-562-5841 ou par courriel à ethics@uottawa.ca.

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École des sciences de la réadaptation | School of Rehabilitation Sciences

FORMULAIRE DE CONSENTEMENT POUR LES PARTICIPANTS

Relations entre les limitations d'activités et des déficiences :

Une étude transversale des patients 6 mois + post-chirurgie pour un cancer du sein

Chercheurs principaux : Vicki Wong, PT et le D^{r} Stéphane Poitras

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****

Consentement à participer à la recherche

Je comprends que je suis invitée à participer à une étude des symptômes chroniques suite à une chirurgie du cancer du sein. Vicki Wong, PT, m'a fourni les renseignements nécessaires au sujet de cette étude.

J'ai lu cette fiche d'information et formulaire de consentement de 4 pages (ou on m'a lu ce document). On a répondu à toutes mes questions de manière satisfaisante. Si je décidais à un stade ultérieur de l'étude de retirer mon consentement, je pourrai le faire à tout moment.

J'accepte volontairement de participer à cette étude.

On me remettra une copie signée du formulaire de consentement.

Signatures

Je comprends que c'est mon choix de participer à ce projet. Je peux décider à tout moment de ne pas participer pour une raison quelconque. On m'a remis une copie de ce formulaire de consentement signé à conserver.

Participant (en caractères d'imprimerie) : _____

Participant (signature) : _____ Date : _____

Code du participant : _____

Déclaration du chercheur (ou de la personne ayant expliquer la procédure de consentement)

J'ai soigneusement expliqué au participant à la recherche la nature de l'étude ci-dessus. Pour autant que je sache, le participant à la recherche signant ce formulaire de consentement comprend la nature, les exigences, risques et avantages liés à la participation à cette étude. Je reconnais ma responsabilité envers le soin et le bien-être du participant à la recherche ci-dessus, le respect des droits et des souhaits du participant à la recherche, et à le déroulement de l'étude conformément aux lignes directrices et aux règlements relatifs à la bonne pratique clinique.

_____

Nom du chercheur/délégué (en caractères d'imprimerie)

_____ _____

Signature du chercheur/délégué Date

Appendix C – Information Sheet

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INFORMATION PACKAGE FOR PARTICIPANTS

Relationship between activity limitations and impairments:

a cross-sectional study of patients 6 months+post-surgery for breast cancer

Vicki Wong, PT & Dr. StephanePoitras

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This information package is given to patients that may be interested in participating in a research study.The package includes the following:

- A brief information sheet
- A copy of the DASH Questionnaire
- A formal Consent Form for Participants

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BRIEF INFORMATION SHEET

The purpose of the study is to look at what is responsible for limitations in activity after breast cancer surgery.You will be asked a few questions about your health history and the treatment you have received for breast cancer. You will begin by filling in 3 questionnaires. The first is a scale for pain. You mark on line your current level of pain. The second is called the *Fear Avoidance Beliefs Questionnaire.*This asks about how you feel doing your daily activities and your pain. The third is the *Disabilities of the Arm, Shoulder, and Hand questionnaire (DASH).* This one asks about how difficult it is to do your daily activities. These questionnaires should take approximately 15 minutes to complete. You will be allowed to take as long as you would like to finish them.

The second part of the study will be a physical exam done by a physiotherapist.She will take measurements about your how well you are able to move your arms. She will also measure your strength in each arm.These tests should take approximately 20-30 minutes to complete.

For this session, the physiotherapist needs to be able to see the entire shoulder and back area to make accurate measurements.You will need to wear an open-back gown available at the clinic or be in your bra only.The session will be done in a private room.

The session may take up to an hour with time for questions.You may ask questions at any time during your session and withdraw your participation if you are uncomfortable. You may

ask for a break in the evaluation if you need to rest.You will be provided $20 to cover parking costs and your travel.

There are potential risks to participating in the study although they are minimal. Potential risks are muscle soreness, mental & physical fatigue, and arm pain. We expect these to be minimal and short-lasting. If you have any problems remaining after the study, your physician will be contacted and will advise you on further treatment.

The testing sessions are done at Glebe Physiotherapy & Sports Injury Centre. The directions for the clinic are:

Directions to the clinic are available by phone.There is free parking available in front of the clinic.

If you are interested in participating in the study, please answer the questions on the DASH Questionnaire provided in the package.After this is complete, please contact the investigator. She will determine if you qualify for the study during this phone call. She will be asking for the numbers that you circled on the DASH Questionnaire. She can be reached at the following:

Vicki Wong, Physiotherapist, Study Investigator

Telephone:

Email:

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TROUSSE D'INFORMATION POUR LES PARTICIPANTS

Relations entre les limitations d'activités et des déficiences :

une étude transversale des patients 6 mois + post-chirurgie pour un cancer du sein

Vicki Wong, PT et le Dr Stéphane Poitras

****

Cette trousse d'information est remise aux patients qui souhaiteraient participer à une étude.La trousse comprend les éléments suivants :

- Une fiche d'information brève
- Une copie du questionnaire DASH
- Un formulaire de consentement pour les participants

****

FICHE D'INFORMATION BRÈVE

Le but de cette étude est de regarder ce qui engendre des limitations auprès des activités après la chirurgie du cancer du sein. On vous posera quelques questions sur vos antécédents médicaux et le traitement que vous avez reçu pour le cancer du sein. Vous commencerez par remplir 3 questionnaires. Le premier est une échelle de la douleur. Vous indiquerez sur une ligne votre niveau actuel de douleur. Le deuxième est appelé *Questionnaire sur les peurs et croyances*. Il comporte des questions relatives à vos activités quotidiennes et à votre douleur. Le troisième est le *Questionnaire DASH sur les incapacités reliées à une atteinte aux membres supérieurs*. Celui-ci comporte des questions sur la difficulté à effectuer vos activités quotidiennes. Ces questionnaires devraient prendre environ 15 minutes à remplir. Vous bénéficierez de tout le temps nécessaire pour y répondre.

La deuxième partie de l'étude se constituera d'un examen physique effectué par une physiothérapeute. Elle prendra des mesures sur la façon dont vous êtes capable de bouger les bras. Elle mesurera également votre force dans chaque bras. Ces tests devraient prendre environ 20 à 30 minutes.

Pour cette séance, la physiothérapeute doit être en mesure de voir entièrement la zone de l'épaule et le dos pour effectuer des mesures précises. Vous devrez porter une chemise d'hôpital ouverte à l'arrière ou votre soutien-gorge seulement. La séance aura lieu dans une salle privée.

La séance peut prendre jusqu'à une heure, y compris une période pour répondre à vos questions. Vous pouvez poser des questions à tout moment durant votre séance et mettre fin à votre participation si vous êtes inconfortable. Vous pouvez demander une pause au cours de l'évaluation si vous avez besoin de repos.

Il y a des risques potentiels de participer à l'étude, même s'ils sont minimes. Les risques potentiels sont des douleurs musculaires, la fatigue mentale et physique, et une douleur au bras. Nous prévoyons que ceux-ci seront minimes et de courte durée. Si vous avez des problèmes après l'étude, on communiquera avec votre médecin et vous conseillera sur le traitement.

Les séances d'évaluation sont effectuées au GlebePhysiotherapy& Sports Injury Centre.L'adresse de la clinique est :

Les directions à la clinique sont disponibles en ligne ou par téléphone. Un stationnement gratuit est disponible en face de la clinique.

Si vous désirez participer à l'étude, nous vous invitons à répondre aux questions sur le formulaire ci-joint – Questionnaire DASH. Ensuite, veuillez communiquer avec le chercheur le plus tôt possible. Elle déterminera si vous êtes admissible à l'étude lors de cet appel téléphonique. Elle vous demandera les numéros que vous avez encerclés sur le questionnaire DASH. Vous pouvez communiquer avec cette dernière aux coordonnées suivantes :
Vicki Wong, physiothérapeute, chercheuse de l'étude

Téléphone :

Courrier électronique :

Appendix C – Participant Form for Payment

GRANT #601678-160499-2001

I, _____, hereby

acknowledge having

received $20 in cash money as a compensation for my

participation

instudy "The Relationships of Impairments to Chronic Activity Limitations in

Women after Breast Cancer"

led by StephanePoitras in the School of Rehabilitation.

Signatures:

Researcher: ____

Date: ____________________________

Appendix D – Community Poster

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Are you a breast cancer survivor?

We are recruiting participants for a study looking at difficulties doing daily activities after breast cancer surgery.

You would qualify if:

- You had surgery from stage 1 to 3 for breast cancer
- Your surgery was at least 6 months ago
- You have finished chemotherapy and radiation
- Can speak English or French
- Are willing to travel to the evaluation site situated in Ottawa

The exclusion criteria that would prevent you from participating in the study are local advanced tumours, metatastic disease, other cancers, active rheumatological disease, or upper extremity fractures.

You would be required to have a physician sign an eligibility form.You would receive $20 as compensation.

If you are interested, please contact:

Vicki Wong, PT

This study was approved by the Ottawa Hospital Research Ethics Board.

Faculté des sciences de la santé
École des sciences de la réadaptation

Faculty of Health Sciences
School of Rehabilitation Sciences

Êtes-vous une survivante du cancer du sein?

Nous recrutons des participantes pour une étude portant sur les difficultés à faire des activités de tous les jours suite à une chirurgie pour le cancer du sein.

Vous pouvez participer si:

- Vous avez eu une chirurgie pour un cancer du sein de stage 1 à 3
- Votre chirurgie était il y a au moins 6 mois
- Vous avez terminé vos traitements de radiation et chimiothérapie
- Vous parlez français ou anglais
- Vous pouvez vous déplacer jusqu'au site d'évaluation situé à Ottawa

Les critères d'exclusion qui vous empêcheraient de participer à l'étude sont la présence de tumeurs avancées, métastases, autres cancers, maladies rhumatologiques actives ou fractures du membre supérieur.

Vous aurez à faire remplir un formulaire d'éligibilité par un médecin. Vous recevrez une compensation de 20$ pour votre participation.

Si vous êtes intéressées, s.v.p. contacter:

Vicki Wong, Pht

Appendix D – Investigator Phone Script

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Phone Script for Potential Participants

- Thank you for your interest in our study. May I tell you briefly about the study?
- I am looking to see if women have problems like moving their arms after having breast cancer surgery. I am looking specifically for women who had their surgery 6 months ago or more. How long ago was your surgery?
- Great. Would you like to hear about what you would have to do?
- We would set up an appointment for you to come to the clinic.I would go over the study in detail and ask you to sign a consent form if you agree to be in the study.Then you would be asked to fill in 3 questionnaires.These should take about 15 minutes.After that, the physiotherapist will ask you to show how far you can move your arms behind your head and behind your back.She will then see how strong you are.This part of the study should take about 20 minutes.
- Do you think you may want to do this?
- Great. I just want to confirm a few things to make sure you qualify.

- Did you fill in the DASH questionnaire from your doctor?Can you tell me what number you circled for each question that was provided in your package that you received from your physician? Great. You are in the right range for the study.
- May I ask you a few more questions?
- Are you having chemotherapy? Radiation therapy? Hormonal therapy?
- Are you able to come to Glebe Physiotherapy & Sports Injury Centre for the test session?
- Have you been told you have advanced cancer or cancer that has spread to other areas?Have you had other types of cancer?
- Do you have a rheumatologic disease like rheumatoid arthritis or lupus? Are you in a flare-up right now?
- Do you have a broken bone?
- Great it looks like you would qualify for this research study.Do you have any questions?
- Would you like to volunteer for this project?
- When is a convenient time for you to come in? Daytime? Evenings? Weekend?
- Do you need directions to the clinic?
- We will be giving you $20 to cover parking costs and your time.
- Thank you for volunteering and please call me if you have any further questions.
- I will see you in the clinic.
- Good-bye

Script de téléphone pour les participants potentiels

• Je vous remercie de votre intérêt pour notre étude. Puis-je vous parler brièvement de l'étude?

• Je cherche à voir si les femmes ont des problèmes comme le déplacement de leurs bras après avoir été opérées du cancer du sein. Je suis à la recherche spécifiquement de femmes qui ont eu leur chirurgie il y a 6 mois ou plus. Depuis combien de temps avez-vous eu votre chirurgie?

• Excellent. Souhaitez-vous savoir ce que vous auriez à faire?

• Nous prendrions rendez-vous pour venir à la clinique. Je réviserais l'étude en détail et vous demanderais de signer un formulaire de consentement si vous acceptez de participer à l'étude. Ensuite, je vous demanderais de remplir 3 questionnaires. Ceux-ci devraient prendre environ 15 minutes. Après cela, le physiothérapeute vous demandera de montrer dans quelle mesure vous pouvez déplacer vos bras derrière votre tête et derrière votre dos. Elle verra ensuite comment vous êtes fort. Cette partie de l'étude devrait prendre environ 20 minutes.

• Pensez-vous que vous souhaiteriez faire ceci?

• Excellent. Je veux simplement confirmer un certain nombre de choses afin de m'assurer

que vous êtes admissible.

• Avez-vous rempli le questionnaire DASH qui vous a été donné par votre médecin? Pouvez-vous me dire les numéros que vous avez encerclés pour chaque question qui se trouve dans votre trousse reçue de votre médecin? Excellent. Vous êtes dans le bon écart pour l'étude.

• Puis-je vous poser quelques questions supplémentaires?

• Êtes-vous en chimiothérapie? Radiothérapie? Hormonothérapie?

• Êtes-vous capable de venir à *GlebePhysiotherapy& Sports Injury Centre* pour la séance d'évaluation?

• Est-ce qu'on vous a dit que vous avez un cancer avancé ou le cancer qui s'est propagé à d'autres endroits? Avez-vous eu d'autres types de cancer?

• Avez-vous une maladie rhumatologique comme l'arthrite rhumatoïde ou le lupus? Êtes-vous dans une exacerbation à l'heure actuelle?

• Avez-vous un os fracturé?

• Excellent.Il semble que vous soyez admissible pour cette étude. Avez-vous des questions?

• Souhaitez-vous participer à ce projet?

• Quel est le moment idéal pour vous pour venir? Jour? Soirée? Fin de semaine?

• Avez-vous besoin des directions à la clinique?

• Nous allons vous donner 20 $ pour couvrir les frais de stationnement et votre temps.

• Je vous remercie pour votre participation et s'il vous plaît appelez-moi si vous avez d'autres questions.

• Je vais vous voir à la clinique.

• À la prochaine.

Appendix D – Physician Checklist

uOttawa

Relationship between activity limitations and impairments:

A cross-sectional study of patients 6 months+ post-surgery for breast cancer

Dear Physician,

Thank you for helping to recruit participants for this study. Please use the following checklist to verify the eligibility for any potential participants.

INCLUSION CRITERIA

- ❑ Breast cancer stages 1-3
- ❑ Breast cancer surgery at least 6 months ago
- ❑ Finished chemotherapy and radiation (Hormonal therapy is acceptable)
- ❑ English or French speaking
- ❑ Living in Ottawa region, willing to travel to the testing site (Glebe/free parking)

EXCLUSION CRITERIA

- ❑ Local advanced tumor
- ❑ Metatastic disease
- ❑ Other cancers
- ❑ Rheumatological disease
- ❑ Fractures

The patient has **all** inclusion criteria and **no** exclusion criteria.This patient may be eligible for the study. Please give the attached participant information package to the patient.Please complete the following:

Cancer stage: _____

Surgery Type : _____

Adjuvant Therapy : _____

Physician Signature: _____

Please detach this form and return to the research envelope of this project.

For questions, please contact:

Appendix D – Community Patient Consent For Information

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Relationship between activity limitations and impairments:

a cross-sectional study of patients 6 months+post-surgery for breast cancer

Vicki Wong, PT & Dr. StephanePoitras

CONSENT TO RELEASE INFORMATION

This is my consent to release my information required for the completion of the "Physician Checklist' for the purposes of participating in a research study.

Request to Physician:

_____

Phone: _____

Fax: _____

Release to: Vicki Wong, PT

Study Investigator

Ph:

Fax:

Patient's Name: _____

Patient Signature: _____

Date: _____

Appendix D – Recruitment letter tophysicians in the community

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Patient Clearance for Study Participation

September 25, 2011

Re: **Relationship between activity limitations and impairments:**

A cross-sectional study of patients 6 months+post-surgery for breast cancer

Dear Dr. _____,

Your patient, _____, has contacted me to volunteer as a participant in my study about chronic activity limitation after breast cancer.Before be accepted into the study, the medical inclusion and exclusion criteria need to be confirmed.

The study will involve the participant answering 2 questionnaires about their physical activity and daily activities.She will also be asked to give a pain rating for the last week.After finishing these components, a physiotherapist will take 2 objective measures. Mobility will be assessed by having the participant reach behind her head and behind her back.Strength will be measured isometrically testing supraspinatus (elevation) and

infraspinatus (external rotation).These measurements will be taken in both arms for comparison.

I am requesting your assistance in providing this confirmation. I have included the physician checklist for your review.Please mark ‘yes’ or ‘no’ to each of the criteria as well as the type and stage of cancer and any treatment that she has received.

Once completed, please fax the form back to me at. Upon receipt of the checklist, I will be able to schedule the data collection appointment.The goal is to have the data collected by the end of October, 2011, and your patient is eagerly waiting participating in the study.

I thank you for your co-operation in admitting your patient to my study.I have also included our recruitment flyer, should you know of any other women who have been diagnosed with breast cancer.If you require any further information about the study, please contact me at

Yours truly,

Vicki Wong, PT

uOttawa

Relationship between activity limitations and impairments:

A cross-sectional study of patients 6 months+ post-surgery for breast cancer

Dear Physician,

Thank you for helping to recruit participants for this study. Please use the following checklist to verify the eligibility for any potential participants. Please 'checkmark' any criteria that the patient has currently:

INCLUSION CRITERIA

- ❑ Breast cancer stages 1-3
- ❑ Breast cancer surgery at least 6 months ago
- ❑ Finished chemotherapy and radiation (Hormonal therapy is acceptable)
- ❑ English or French speaking
- ❑ Living in Ottawa region, willing to travel to the testing site (Glebe/free parking)

EXCLUSION CRITERIA

- ❑ Local advanced tumor
- ❑ Metatastic disease
- ❑ Other cancers

❑ Active Rheumatological disease

❑ Fractures – current in the upper extremity

The patient has **all** inclusion criteria and **no** exclusion criteria.This patient may be eligible for the study. Please complete the following:

Cancer stage: _____

Surgery Type : _____

Adjuvant Therapy : _____

Physician Signature: _____

For questions, please contact:;

Please fax back to, Attention: Vicki Wong, PT

Appendix E – Physiotherapist's Instructions

Instructions for the Physiotherapist

ROM Testing

Hand-Behind-Back

1. Have the patient change into an open-backed gown or bra-only.
2. Patient is standing for the test.
3. **READ**: This test is to see how well you can move your hand behind your back. Please reach up your back, towards the opposite shoulder blade, as high as you can go comfortably.
4. Choose the appropriate level from the list provided, using the tip of the index finger as the standard marker.
5. Repeat with other arm.

Hand-Behind-Head

1. Have the patient remain in the open-backed gown or bra as above.
2. Patient is standing for the test.
3. **READ**: This test is to see how well you can move your hand behind your head. Please reach for your neck as low along the spine as you can go comfortably.
4. Choose the appropriate level from the list provided, using the tip of the index finger as the standard marker.
5. Repeat with the other arm.

Strength Testing

Full Can Test for Supraspinatus

1. Have the patient sit with her feet supported.
2. Physiotherapist stands to the side of the patient.
3. **READ**: Let me read all of the instructions before you do anything. This is a test to measure the strength of the supraspinatus muscle in your shoulder. You will raise your arm and twist it so your thumb is pointing to the ceiling *(You will have to help position the arm in 90deg flex/abd, approx. 30 deg in coronal plane – Full Can Position).*When I say go, I want you to push up against the machine as I resist you.Try to take 2 seconds to build up to your maximum strength. Then hold that position for 5 seconds.
4. Take 3 measurements on each arm. Allow 1minute between trials.
5. Allow for rest as needed.

Infraspinatus Test – External Rotation

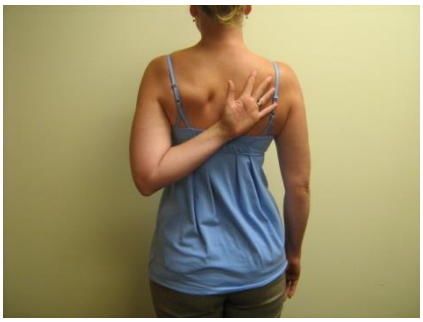
1. Have the patient sit with her feet supported.
2. Physiotherapist stands to the side of the patient.
3. Have a towel between the patient's arm and body to prevent abduction.
4. **READ**: Let me read all of the instructions before you do anything. This is a test to measure the strength of the infraspinatus muscle in your shoulder. Please bend you elbow to 90deg and keep the elbow by your side.Bring the hand toward your stomach. *(You will have to help position the arm in 0deg abd, 90 deg elbow flexion, 45deg IR).*The machine will be placed on your forearm near your wrist.When I say

go, I want you to push up against the machine as I resist you.Try to take 2 seconds to build up to your maximum strength. Then hold that position for 5 seconds.

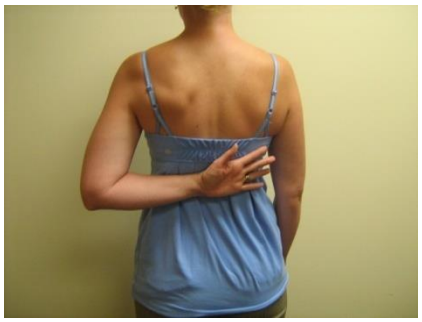
5. Take 3 measurements on each arm. Allow 1 minute between trials.
6. Allow for rest as needed.

Appendix E – Photos of testing positions

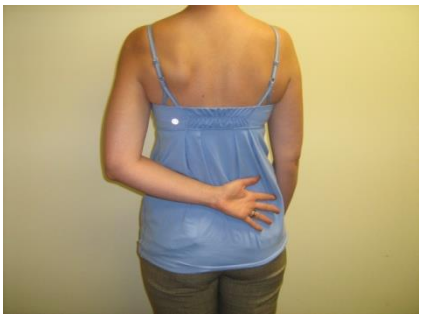
Hand-Behind-Back Mobility Test Position



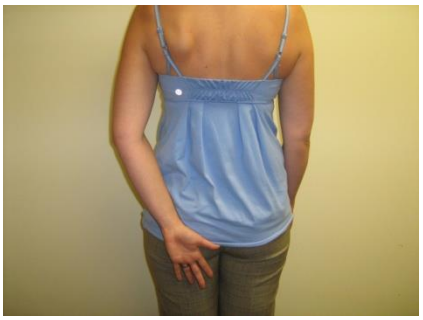
0 = The hand reaches behind the trunk to the opposite scapula or 5cm beneath it in full internal rotation



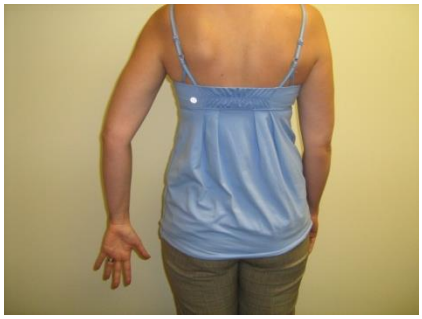
1 = The hand almost reaches the opposite scapula, 6-15cm beneath it



2 = The hand reaches the opposite iliac crest



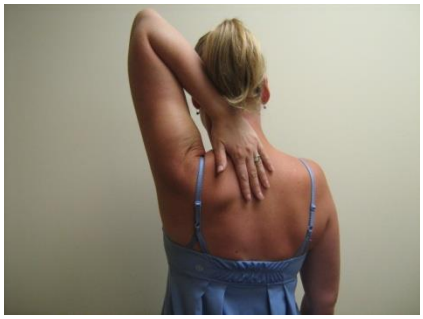
3 = The hand reaches the buttock



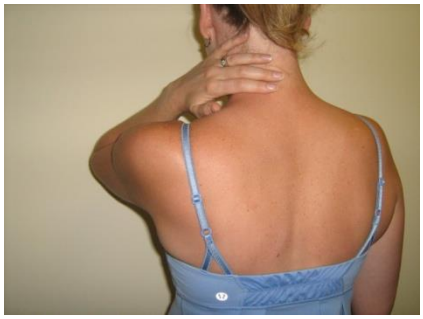
4 = Subject cannot move the hand behind the trunk

Appendix E – Photos of testing positions

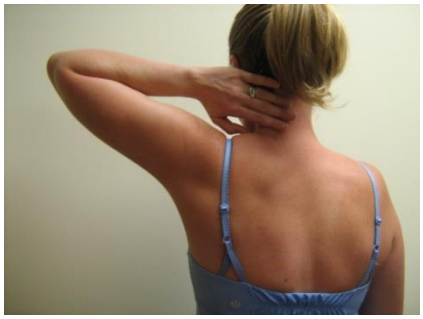
Hand-behind-Head Mobility Test Position



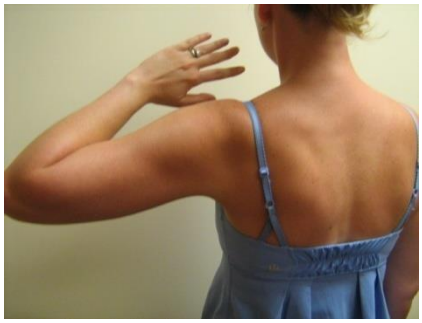
0 = The fingers reach the posterior median line of the neck with the shoulder in full abduction and external rotation without wrist extension



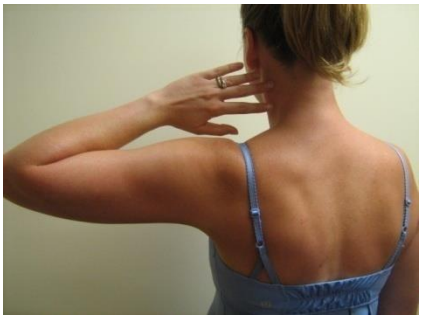
1 = The fingers reach the median line of the neck but do not have full abduction and/or external rotation



2 = The Fingers reach the median line of the neck, but with compensation by adduction in the horizontal plane or by shoulder elevation

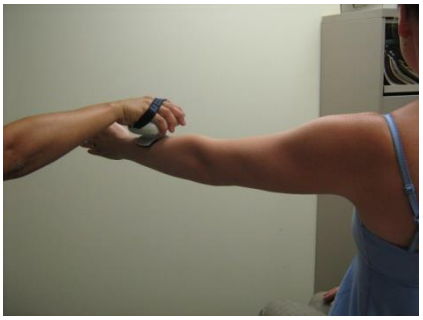


3 = The fingers touch the neck extension

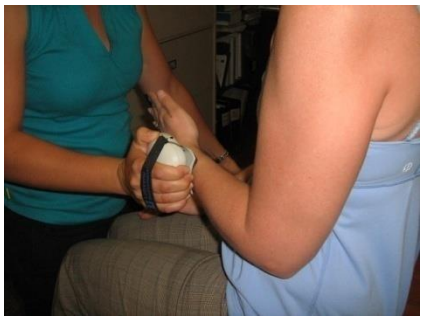


4 = The fingers do not reach the neck

Appendix E – Photos of testing positions



Supraspinatus Strength Test Position



Infraspinatus Strength Test Position

Appendix E – Recording Sheet for the Physiotherapists

Physiotherapist Record Sheet

OBJECTIVE MEASURES:

Descriptive AROM

HBB score: R_____; L_____

0 = The hand reaches behind the trunk to the opposite scapula or 5cm beneath it in full internal rotation

1 = The hand almost reaches the opposite scapula, 6-15cm beneath it

2 = The hand reaches the opposite iliac crest

3 = The hand reaches the buttock

4 = Subject cannot move the hand behind the trunk

HBH score: R_____; L_____

0 = The fingers reach the posterior median line of the neck with the shoulder in fullabduction and external rotation without wrist extension

1 = The fingers reach the median line of the neck but do not have full abduction and/or external rotation

2 = The Fingers reach the median line of the neck, but with compensation by adduction in the horizontal plane or by shoulder elevation

3 = The fingers touch the neck

4 = The fingers do not reach the neck

Strength – Hand-held Dynamometry

Muscle	Trial 1		Trial 2		Trial 3	
	L	R	L	R	L	R
Supraspinatus						
Infrapsinatus						

Appendix E – Main data collection form for Investigator

DATA COLLECTION FORM

Participant Code: _____Date: _____

Dominant Hand:RL Year of birth: _____

Surgery& Date: _____

Cancer Stage:_____

Occupation: _____

Pain Score

VAS measurement (mm):

Fear Avoidance Score

FABQtotal score: _____

Fear-Avoidance beliefs about work (Items 6+7+9+10+11+12+15) = _____

Fear-Avoidance beliefs about physical activity (Items 2+3+4+5) = _____

Function Score

DASH score: _____ (phone)_____ (at appt)

Appendix F – Excel Data Table

Participant Code	Dominant Hand	Year of Birth	Cancer Stage	Surgery Date	Surgery Type	Axillary Node Dissection	Chemo	Radiation	Occupation
2	**L**	**1948**	**2**	**2005**	**R Mastectomy**	**Y**	**Y**	**Y**	**retired**
3	**R**	**1951**	**2**	**2002**	**L Lumpectomy**	**Y**	**Y**	**Y**	**retired**
4	**R**	**1947**	**2**	**2009**	**R Mastectomy**	**N**	**N**	**N**	**retired**
5	**R**	**1963**	**3**	**2008**	**L Mastectomy**	**N**	**Y**	**Y**	**computer technician**
6	**R**	**1953**	**3**	**2010**	**L Mastectomy**	**Y**	**N**	**N**	**PT**
7	**R**	**1937**	**1**	**2004**	**L Partial Mastectomy**	**N**	**N**	**Y**	**retired**
8	**R**	**1961**	**1**	**2011**	**L Partial Mastectomy**	**Y**	**Y**	**Y**	**project manager**

9	**L**	**1953**	**1**	**2008**	**L Mastectomy**	**Y**	**Y**	**N**	**retired**
10	**R**	**1940**	**3**	**2009**	**R Mastectomy**	**Y**	**Y**	**N**	**retired**
12	**R**	**1957**	**1**	**2010**	**R Lumpectomy**	**Y**	**Y**	**Y**	**educator**
15	**R**	**1954**	**2**	**2010**	**L Lumpectomy**	**Y**	**Y**	**Y**	**vice-principal**
16	**R**	**1967**	**2**	**2010**	**L Lumpectomy**	**Y**	**Y**	**Y**	**HR Consultant**

VAS	**FABQ - Work**	**FABQ - Physical Activity**	**DASH - Pre**	**DASH**	**HBB Affected**	**HBB Non-Affected**	**Non A - Affect HBB**	**HBH Affected**	**HBH Non-Affected**	**Non A-Affect HBH**	**SSP Affected**	**SSP Non-Affected**	**RD SSP Non A - Affect**	**ISP Affected**	**ISP Non-Affected**	**RD ISP Non A-Affect**
0	**0**	**3**	**6.7**	**7.5**	**0**	**0**	**0**	**0**	**0**	**0**	**16**	**14.9**	**-1.1**	**14.3**	**16.3**	**2**
2.2	**0**	**0**	**5.8**	**5**	**0**	**0**	**0**	**1**	**0**	**-1**	**15**	**17.2**	**2.2**	**22.3**	**19.9**	**-2.4**
0	**0**	**0**	**N/A**	**3.3**	**0**	**0**	**0**	**0**	**0**	**0**	**8.4**	**9.6**	**1.2**	**14.7**	**13.7**	**-1**
37	**10**	**7**	**N/A**	**20**	**0**	**0**	**0**	**0**	**0**	**0**	**12.6**	**16**	**3.4**	**19.6**	**20.8**	**1.2**
0	**0**	**0**	**N/A**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**11.1**	**10.2**	**-0.9**	**17.7**	**14.8**	**-2.9**

4	**0**	**0**	**N/A**	**1.6**	**0**	**0**	**0**	**0**	**0**	**0**	**7.7**	**8.6**	**0.9**	**4.4**	**4.4**	**0**
6	**3**	**20**	**N/A**	**14.2**	**0**	**1**	**1**	**0**	**0**	**0**	**14.6**	**13.3**	**-1.3**	**17**	**17**	**0**
68	**16**	**22**	**N/A**	**38**	**0**	**0**	**0**	**1**	**0**	**-1**	**4.9**	**7.2**	**2.3**	**5.4**	**7.9**	**2.5**
0	**0**	**0**	**N/A**	**2.5**	**0**	**0**	**0**	**0**	**0**	**0**	**11.1**	**14.3**	**3.2**	**17.9**	**16.2**	**-1.7**
16	**18**	**9**	**20**	**29**	**1**	**0**	**-1**	**0**	**0**	**0**	**6.8**	**7.9**	**1.1**	**5.8**	**4.3**	**-1.5**
2	**4**	**16**	**N/A**	**10**	**0**	**0**	**0**	**0**	**0**	**0**	**4.6**	**5.3**	**0.7**	**6**	**6.1**	**0.1**
5	**0**	**0**	**N/A**	**15.8**	**0**	**0**	**0**	**0**	**0**	**0**	**5.8**	**6.1**	**0.3**	**8.6**	**8.5**	**-0.1**

Appendix F – SPSS Output

```
GET DATA /TYPE=XLSX
/FILE='C:\Users\owner\Desktop\Master Data Sheet.xlsx'
/SHEET=name 'Sheet1'
/CELLRANGE=full
/READNAMES=on
/ASSUMEDSTRWIDTH=32767.
EXECUTE.
DATASET NAME DataSet1 WINDOW=FRONT.
*Descriptives

DATASET ACTIVATE DataSet1.
DESCRIPTIVES VARIABLES=ParticipantCodeYearofBirthCancerStage VAS SurgeryDateFABQWork
FABQPhysicalActivity DASH HBBAffectedHBBNonAffectedNonAAffectHBBHBHAffectedHBHNonAffected
NonAAffectHBHSSPAffectedSSPNonAffectedRDSSPNonAAffectISPAffectedISPNonAffectedRDISPNonAAffect
/STATISTICS=MEAN STDDEV VARIANCE RANGE MIN MAX SEMEAN.
```

Descriptives

Notes

Output Created		20-Feb-2012 20:05:17
Comments		
Input	Active Dataset	DataSet1
	Filter	<none>
	Weight	<none>
	Split File	<none>
	N of Rows in Working Data File	12
Missing Value Handling	Definition of Missing	User defined missing values are treated as missing.
	Cases Used	All non-missing data are used.

Syntax		DESCRIPTIVES VARIABLES=ParticipantCodeYearofBirthCancerStage VAS SurgeryDateFABQWork FABQPhysicalActivity DASH HBBAffectedHBBNonAffectedNonAAffectHBBHBHAffectedHBHNonAffected NonAAffectHBHSSPAffectedSSPNonAffectedRDSSPNonAAffectISPAffectedISP NonAffectedRDISPNonAAffect /STATISTICS=MEAN STDDEV VARIANCE RANGE MIN MAX SEMEAN.
Resources	Processor Time	00 00:00:00.016
	Elapsed Time	00 00:00:00.046

[DataSet1]

Descriptive Statistics

	N	Range	Minimum	Maximum	Mean		Std. Deviation	Variance
	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic
Participant Code	12	14	2	16	8.08	1.305	4.522	20.447
Year of Birth	12	30	1937	1967	1952.58	2.560	8.867	78.629
Cancer Stage	12	2	1	3	1.92	.229	.793	.629
VAS	12	68.0	.0	68.0	11.683	5.9651	20.6636	426.985
Surgery Date	12	9	2002	2011	2008.00	.816	2.828	8.000
FABQ - Work	12	18	0	18	4.25	1.923	6.662	44.386
FABQ - Physical Activity	12	22	0	22	6.42	2.439	8.447	71.356
DASH	12	38.0	.0	38.0	12.242	3.4145	11.8280	139.903
HBB Affected	12	1	0	1	.08	.083	.289	.083
HBB Non-Affected	12	1	0	1	.08	.083	.289	.083
NonA - Affect HBB	12	2	-1	1	.00	.123	.426	.182
HBH Affected	12	1	0	1	.17	.112	.389	.152
HBH Non-Affected	12	0	0	0	.00	.000	.000	.000
NonA-Affect HBH	12	1	-1	0	-.17	.112	.389	.152
SSP Affected	12	11.4	4.6	16.0	9.883	1.1745	4.0685	16.552
SSP Non-Affected	12	11.9	5.3	17.2	10.883	1.1793	4.0852	16.689
RD SSP NonA -Affect	12	4.7	-1.3	3.4	1.000	.4579	1.5863	2.516
ISP Affected	12	17.9	4.4	22.3	12.808	1.8427	6.3833	40.746
ISP Non-Affected	12	16.5	4.3	20.8	12.492	1.7183	5.9523	35.430
RD ISP NonA-Affect	12	5.4	-2.9	2.5	-.317	.4832	1.6738	2.802

Valid N (listwise)	12							

```
*Frequencies

FREQUENCIES VARIABLES=DominantHandCancerStageSurgeryTypeAxillaryNodeDissection Chemo Radiation
Occupation
/ORDER=ANALYSIS.
```

Frequencies

Notes

Output Created		20-Feb-2012 20:05:18
Comments		
Input	Active Dataset	DataSet1
	Filter	<none>
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	Split File	<none>
	N of Rows in Working Data File	12
Missing Value Handling	Definition of Missing	User-defined missing values are treated as missing.
	Cases Used	Statistics are based on all cases with valid data.
Syntax		FREQUENCIES VARIABLES=DominantHandCancerStageSurgeryTypeAxillaryNodeDissection Chemo Radiation Occupation /ORDER=ANALYSIS.
Resources	Processor Time	00 00:00:00.016
	Elapsed Time	00 00:00:00.016

[DataSet1]

Statistics

		Dominant Hand	Cancer Stage	Surgery Type	Axillary Node Dissection	Chemo	Radiation	Occupation
N	Valid	12	12	12	12	12	12	12
	Missing	0	0	0	0	0	0	0

Frequency Table

Dominant Hand

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	L	2	16.7	16.7	16.7
	R	10	83.3	83.3	100.0
	Total	12	100.0	100.0	

Cancer Stage

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	4	33.3	33.3	33.3
	2	5	41.7	41.7	75.0
	3	3	25.0	25.0	100.0
	Total	12	100.0	100.0	

Surgery Type

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	L Lumpectomy	3	25.0	25.0	25.0
	L Mastectomy	2	16.7	16.7	41.7
	L Partial Mastectomy	2	16.7	16.7	58.3
	Lumpectomy & mastectomy	1	8.3	8.3	66.7
	Mastectomy	1	8.3	8.3	75.0
	R Lumpectomy	1	8.3	8.3	83.3
	R Mastectomy	2	16.7	16.7	100.0

Surgery Type

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	L Lumpectomy	3	25.0	25.0	25.0
	L Mastectomy	2	16.7	16.7	41.7
	L Partial Mastectomy	2	16.7	16.7	58.3
	Lumpectomy & mastectomy	1	8.3	8.3	66.7
	Mastectomy	1	8.3	8.3	75.0
	R Lumpectomy	1	8.3	8.3	83.3
	R Mastectomy	2	16.7	16.7	100.0
	Total	12	100.0	100.0	

Axillary Node Dissection

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	N	3	25.0	25.0	25.0
	Y	9	75.0	75.0	100.0
	Total	12	100.0	100.0	

Chemo

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	N	3	25.0	25.0	25.0
	Y	9	75.0	75.0	100.0
	Total	12	100.0	100.0	

Radiation

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	N	4	33.3	33.3	33.3
	Y	8	66.7	66.7	100.0
	Total	12	100.0	100.0	

Occupation

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	computer technician	1	8.3	8.3	8.3
	educator	1	8.3	8.3	16.7
	HR Consultant	1	8.3	8.3	25.0
	project manager	1	8.3	8.3	33.3
	PT	1	8.3	8.3	41.7
	retired	6	50.0	50.0	91.7
	vice-principal	1	8.3	8.3	100.0
	Total	12	100.0	100.0	

```
*Spearmans for Pain & DASH


NONPAR CORR
/VARIABLES=VAS DASH
/PRINT=SPEARMAN TWOTAIL NOSIG
/MISSING=PAIRWISE.
```

Nonparametric Correlations

Notes

Output Created		20-Feb-2012 20:05:18
Comments		
Input	Active Dataset	DataSet1
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Missing Value Handling	Definition of Missing	User-defined missing values are treated as missing.
	Cases Used	Statistics for each pair of variables are based on all the cases with valid data for that pair.
Syntax		NONPAR CORR /VARIABLES=VAS DASH /PRINT=SPEARMAN TWOTAIL NOSIG /MISSING=PAIRWISE.

Resources	Processor Time	00 00:00:00.000
	Elapsed Time	00 00:00:00.021
	Number of Cases Allowed	174762 cases[a]

a. Based on availability of workspace memory

[DataSet1]

Correlations

			VAS	DASH
Spearman rho	VAS	Correlation Coefficient	1.000	.819**
		Sig. (2-tailed)	.	.001
		N	12	12
	DASH	Correlation Coefficient	.819**	1.000
		Sig. (2-tailed)	.001	.
		N	12	12

**. Correlation is significant at the 0.01 level (2-tailed).

```
*Spearmans for FABQ-PA & DASH


NONPAR CORR
/VARIABLES=DASH FABQPhysicalActivity
/PRINT=SPEARMAN TWOTAIL NOSIG
/MISSING=PAIRWISE.
```

Nonparametric Correlations

Notes

Output Created		20-Feb-2012 20:05:19
Comments		
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	Weight	<none>
	Split File	<none>
	N of Rows in Working Data	12
	File	

Missing Value Handling	Definition of Missing	User-defined missing values are treated as missing.
	Cases Used	Statistics for each pair of variables are based on all the cases with valid data for that pair.
Syntax		NONPAR CORR /VARIABLES=DASH FABQPhysicalActivity /PRINT=SPEARMAN TWOTAIL NOSIG /MISSING=PAIRWISE.
Resources	Processor Time	00 00:00:00.015
	Elapsed Time	00 00:00:00.035
	Number of Cases Allowed	174762 cases[a]

a. Based on availability of workspace memory

[DataSet1]

Correlations

			DASH	FABQ - Physical Activity
Spearman rho	DASH	Correlation Coefficient	1.000	.746**

		Sig. (2-tailed)	.	.005
		N	12	12
	FABQ - Physical Activity	Correlation Coefficient	.746**	1.000
		Sig. (2-tailed)	.005	.
		N	12	12

**. Correlation is significant at the 0.01 level (2-tailed).

```
*KW for Affected HBB & DASH

*Nonparametric Tests: Independent Samples.

NPTESTS

/INDEPENDENT TEST (DASH) GROUP (HBBAffected) KRUSKAL_WALLIS(COMPARE=PAIRWISE)

/MISSING SCOPE=ANALYSIS USERMISSING=EXCLUDE

/CRITERIA ALPHA=0.05CILEVEL=95.
```

Nonparametric Tests

Notes

Output Created		20-Feb-2012 20:05:21
Comments		
Input	Active Dataset	DataSet1
	Filter	<none>
	Weight	<none>
	Split File	<none>
	N of Rows in Working Data File	12
Syntax		NPTESTS /INDEPENDENT TEST (DASH) GROUP (HBBAffected) KRUSKAL_WALLIS(COMPARE=PAIRWISE) /MISSING SCOPE=ANALYSIS USERMISSING=EXCLUDE /CRITERIA ALPHA=0.05CILEVEL=95.
Resources	Processor Time	00 00:00:01.170
	Elapsed Time	00 00:00:03.853

[DataSet1]

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of DASH is the same across categories of HBB Affected.	Independent-Samples Kruskal-Wallis Test	.192	Retain the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

```
*KW for Affected HBH & DASH

*Nonparametric Tests: Independent Samples.

NPTESTS

/INDEPENDENT TEST (DASH) GROUP (HBHAffected) KRUSKAL_WALLIS(COMPARE=PAIRWISE)

/MISSING SCOPE=ANALYSIS USERMISSING=EXCLUDE

/CRITERIA ALPHA=0.05CILEVEL=95.
```

Nonparametric Tests

Notes

Output Created		20-Feb-2012 20:05:25
Comments		
Input	Active Dataset	DataSet1
	Filter	<none>
	Weight	<none>
	Split File	<none>
	N of Rows in Working Data File	12
Syntax		NPTESTS /INDEPENDENT TEST (DASH) GROUP (HBHAffected) KRUSKAL_WALLIS(COMPARE=PAIR WISE) /MISSING SCOPE=ANALYSIS USERMISSING=EXCLUDE /CRITERIA ALPHA=0.05CILEVEL=95.
Resources	Processor Time	00 00:00:01.154
	Elapsed Time	00 00:00:00.861

[DataSet1]

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of DASH is the same across categories of HBH Affected.	Independent-Samples Kruskal-Wallis Test	.390	Retain the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

```
*KW for Non-Affected - Affected HBB & DASH

*Nonparametric Tests: Independent Samples.

NPTESTS

/INDEPENDENT TEST (DASH) GROUP (NonAAffectHBB) KRUSKAL_WALLIS(COMPARE=PAIRWISE)

/MISSING SCOPE=ANALYSIS USERMISSING=EXCLUDE

/CRITERIA ALPHA=0.05CILEVEL=95.
```

Nonparametric Tests

Notes

Output Created		20-Feb-2012 20:05:26
Comments		
Input	Active Dataset	DataSet1
	Filter	<none>
	Weight	<none>
	Split File	<none>
	N of Rows in Working Data File	12
Syntax		NPTESTS /INDEPENDENT TEST (DASH) GROUP (NonAAffectHBB) KRUSKAL_WALLIS(COMPARE=PAIR WISE) /MISSING SCOPE=ANALYSIS USERMISSING=EXCLUDE /CRITERIA ALPHA=0.05CILEVEL=95.
Resources	Processor Time	00 00:00:01.107

Notes

Output Created		20-Feb-2012 20:05:26
Comments		
Input	Active Dataset	DataSet1
	Filter	<none>
	Weight	<none>
	Split File	<none>
	N of Rows in Working Data File	12
Syntax		NPTESTS /INDEPENDENT TEST (DASH) GROUP (NonAAffectHBB) KRUSKAL_WALLIS(COMPARE=PAIRWISE) /MISSING SCOPE=ANALYSIS USERMISSING=EXCLUDE /CRITERIA ALPHA=0.05CILEVEL=95.
Resources	Processor Time	00 00:00:01.107
	Elapsed Time	00 00:00:00.889

[DataSet1]

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of DASH is the same across categories of NonA - Affect HBB.	Independent-Samples Kruskal-Wallis Test	.366	Retain the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

```
*KW for Non-Affected - Affected HBH & DASH

*Nonparametric Tests: Independent Samples.

NPTESTS

/INDEPENDENT TEST (DASH) GROUP (NonAAffectHBH) KRUSKAL_WALLIS(COMPARE=PAIRWISE)

/MISSING SCOPE=ANALYSIS USERMISSING=EXCLUDE

/CRITERIA ALPHA=0.05CILEVEL=95.
```

Nonparametric Tests

Notes

Output Created		20-Feb-2012 20:05:27
Comments		
Input	Active Dataset	DataSet1
	Filter	<none>
	Weight	<none>
	Split File	<none>
	N of Rows in Working Data File	12
Syntax		NPTESTS /INDEPENDENT TEST (DASH) GROUP (NonAAffectHBH) KRUSKAL_WALLIS(COMPARE=PAIRWISE) /MISSING SCOPE=ANALYSIS USERMISSING=EXCLUDE /CRITERIA ALPHA=0.05CILEVEL=95.

Resources	Processor Time	00 00:00:00.765
	Elapsed Time	00 00:00:00.809

```
[DataSet1]
```

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of DASH is the same across categories of NonA-Affect HBH.	Independent-Samples Kruskal-Wallis Test	.390	Retain the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

```
*Spearmans for RD Non-Affect - Affected SSP
```

```
NONPAR CORR
/VARIABLES=DASH RDSSPNonAAffect
/PRINT=SPEARMAN TWOTAIL NOSIG
/MISSING=PAIRWISE.
```

Nonparametric Correlations

Notes

Output Created		20-Feb-2012 20:05:28
Comments		
Input	Active Dataset	DataSet1
	Filter	<none>
	Weight	<none>
	Split File	<none>
	N of Rows in Working Data File	12
Missing Value Handling	Definition of Missing	User-defined missing values are treated as missing.

	Cases Used	Statistics for each pair of variables are based on all the cases with valid data for that pair.
Syntax		NONPAR CORR /VARIABLES=DASH RDSSPNonAAffect /PRINT=SPEARMAN TWOTAIL NOSIG /MISSING=PAIRWISE.
Resources	Processor Time	00 00:00:00.015
	Elapsed Time	00 00:00:00.010
	Number of Cases Allowed	174762 cases[a]

a. Based on availability of workspace memory

[DataSet1]

Correlations

			DASH	RD SSP NonA - Affect
Spearman rho	DASH	Correlation Coefficient	1.000	.182
		Sig. (2-tailed)	.	.572
		N	12	12
	RD SSP NonA -Affect	Correlation Coefficient	.182	1.000
		Sig. (2-tailed)	.572	.
		N	12	12

```
*Spearmans for RD Non-Affect - Affected ISP


NONPAR CORR
/VARIABLES=DASH RDISPNonAAffect
/PRINT=SPEARMAN TWOTAIL NOSIG
/MISSING=PAIRWISE.
```

Nonparametric Correlations

Notes

Output Created		20-Feb-2012 20:05:29
Comments		
Input	Active Dataset	DataSet1
	Filter	<none>
	Weight	<none>
	Split File	<none>
	N of Rows in Working Data File	12
Missing Value Handling	Definition of Missing	User-defined missing values are treated as missing.
	Cases Used	Statistics for each pair of variables are based on all the cases with valid data for that pair.
Syntax		NONPAR CORR /VARIABLES=DASH RDISPNonAAffect /PRINT=SPEARMAN TWOTAIL NOSIG /MISSING=PAIRWISE.

Resources	Processor Time	00 00:00:00.000
	Elapsed Time	00 00:00:00.011
	Number of Cases Allowed	174762 cases[a]

a. Based on availability of workspace memory

```
[DataSet1]
```

Correlations

			DASH	RD ISP NonA-Affect
Spearman rho	DASH	Correlation Coefficient	1.000	.553
		Sig. (2-tailed)	.	.062
		N	12	12
	RD ISP NonA-Affect	Correlation Coefficient	.553	1.000
		Sig. (2-tailed)	.062	.
		N	12	12

```
SAVE OUTFILE='C:\Users\owner\Desktop\No Bilat Master Data.sav'
/COMPRESSED.
```