

A PILOT STUDY ON BOWENWORK[®] FOR SYMPTOM MANAGEMENT OF
WOMEN BREAST CANCER SURVIVORS WITH LYMPHEDEMA

by

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DEDICATION

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TABLE OF CONTENTS

LIST OF ILLUSTRATIONS	10
LIST OF TABLES	11
ABSTRACT.....	12
CHAPTER 1 STATEMENT OF THE PROBLEM.....	14
Significance of Lymphedema and the Need to Examine Management Strategies.....	14
Lymphatic System.....	17
Theoretical and Conceptual Framework.....	19
Complex Systems Science.....	20
Fractals.....	22
Catastrophes.....	23
Self-Organization	24
Lymphedema and Complex Systems	25
Symptom Management Theory	27
Symptom Experience	29
Symptom Management Strategies.....	30
Symptom Status Outcomes	31
Complexity Systems Science and Symptom Management Theory.....	32
Bowenwork as a Holistic Symptom Management Strategy	34
Knowledge Gaps about Bowenwork as a Symptom Management Strategy	38
Purpose of Study	39
Significance of Study.....	40
CHAPTER 2 LITERATURE REVIEW	42
Incidence of Lymphedema	42
Symptom Experience Involving Alteration in Sensation and Pain with Lymphedema ..	43
Current Diagnostic and Management for Lymphedema	44
Quality of Life in Women Breast Cancer Survivors with Lymphedema	47
Impairment of Arm Function and Range of Motion Associated with Lymphedema	48
State of the Science of Bowenwork	49
Summary	53
CHAPTER 3 METHODOLOGY	55
Background on Pilot Studies.....	55
Study Design.....	56
Sample.....	57
Inclusion Criteria for Women Breast Cancer Survivors with Lymphedema	57
Exclusion Criteria for Women Breast Cancer Survivors with Lymphedema	58

TABLE OF CONTENTS – *Continued*

Recruitment, Enrollment and Retention	59
Protection of Human Participants.....	61
Informed Consent	61
Confidentiality	62
Risk to Participants.....	62
Certification of Research Team.....	63
Intervention Fidelity	63
Bowenwork Intervention.....	64
Study Procedures and Data Collection	65
Measure for Health-Related Quality of Life	67
Measure for Functional Status	67
Measure for Pain.....	68
Physical Measures.....	69
Data Analysis.....	70
Aim One: Recruitment and Retention	70
Aim Two: Adherence to the Bowenwork Intervention	70
Aim Three: Safety and Comfort Level of the Bowenwork Intervention	71
Aim Four: Effects of Bowenwork on Lymphedema	72
 CHAPTER 4 FINDINGS	 73
Characteristics of Setting and Sample	73
Aim One: Recruitment and Retention Rates.....	74
Aim Two: Adherence to the Bowenwork Intervention	77
Aim Three: Safety and Comfort Level of the Bowenwork Intervention	78
Aim Four: Effects of Bowenwork on Lymphedema Symptoms	80
Summary of Findings	83
 CHAPTER 5 DISCUSSION.....	 85
Characteristics of the Sample	85
Aim One: Recruitment and Retention Rates.....	86
Aim Two: Adherence to the Bowenwork Intervention	87
Aim Three: Safety and Comfort Level of the Bowenwork Intervention	87
Aim Four: Effects of Bowenwork on Lymphedema	88
Limitations of the Study	91
Implications for Nursing Research	92
Conclusion	94

TABLE OF CONTENTS – *Continued*

APPENDIX A: STUDIES EXPLORING THE ALTERATION IN SENSATION AND PAIN	95
APPENDIX B: STUDIES RELEVANT TO CURRENT DIAGNOSTIC AND MANAGEMENT OF LYMPHEDEMA	102
APPENDIX C: STUDIES RELEVANT TO MEASURING QUALITY OF LIFE IN WOMEN WITH LYMPHEDEMA	112
APPENDIX D: STUDIES RELEVANT TO MEASURING IMPAIRMENT IN FUNCTION AND RANGE OF MOTION	119
APPENDIX E: RECRUITMENT FLYER.....	124
APPENDIX F: RECRUITMENT SCRIPT FOR PILOT STUDY ON BOWENWORK	126
APPENDIX G: RECRUITMENT FOR NATIONAL LYMPHEDEMA NETWORK.....	128
APPENDIX H: SCREENING TOOL FOR DETERMINING ELIGIBILITY.....	131
APPENDIX I: INSTITUTIONAL REVIEW BOARD APPROVAL FORMS	134
APPENDIX J: MASTER LIST OF CONTACTS.....	139
APPENDIX K: INFORMED CONSENT.....	141
APPENDIX L: DEMOGRAPHIC INFORMATION OF ENROLLED PARTICIPANTS.....	146
APPENDIX M: LIST OF BEHAVIORAL HEALTH RESOURCES	149
APPENDIX N: VERIFICATION OF TRAINING FORM FOR INSTITUTIONAL REVIEW BOARD	151
APPENDIX O: BOWENWORKER CERTIFICATION CHECK LIST	153
APPENDIX P: BOWENWORK SESSION MOVES	156
APPENDIX Q: ANATOMICAL LOCATION FOR BOWENWORK MOVES	159

TABLE OF CONTENTS – *CONTINUED*

**APPENDIX R: AUTHORIZATION FOR SITE USE FOR BOWENWORKERS
AND REGISTERED COPYRIGHT162**

APPENDIX S: BOWENWORK DOCUMENTATION FORM.....168

**APPENDIX T: BOWENWORKERS DEMONSTRATE SHOULDER
STRETCHING EXERCISES172**

APPENDIX U: QUESTIONNAIRE SF-36.....174

APPENDIX V: QUESTIONNAIRE FACT-B.....179

APPENDIX W: QUESTIONNAIRE BPI.....183

REFERENCES.....186

LIST OF ILLUSTRATIONS

FIGURE 1. Conceptual Model of Symptom Management Theory	29
FIGURE 2. Symptom Management Theory Adapted for Lymphedema	38
FIGURE 3. Flow Chart of Participants Throughout the Study.....	77

LIST OF TABLES

TABLE 1. Principles of Nonlinear Dynamics	22
TABLE 2. Timeframe of Data Collection for Analysis.....	66
TABLE 3. Characteristics of the Study Participants	75
TABLE 4. Recruitment Sources, Responses and Enrollment.....	76
TABLE 5. Safety Evaluations During Intervention Sessions	78
TABLE 6. Comfort Level of Intervention	79
TABLE 7. Length of Bowenwork Sessions.....	80
TABLE 8. Baseline and Post-Intervention Quality of Life, Functional Status and Pain.....	81
TABLE 9. Descriptive Analysis of Pain.....	82
TABLE 10. Descriptive Statistics and ANOVA of Physical Measures	83

ABSTRACT

The objective of this pilot study was to examine the feasibility of using Bowenwork as a complementary intervention for symptom management of breast cancer treatment-related lymphedema in women breast cancer survivors. The aims of the investigation were to 1) determine recruitment and retention rates 2) determine adherence to the intervention, 3) assess the safety and comfort level of the intervention 4) describe the effects of the six week intervention on lymphedema symptoms.

A quasi-experimental, repeated measure design was chosen for this pilot study. Twenty-one community-dwelling women breast cancer survivors were recruited from three cities in Arizona, United States. The intervention was delivered in four consecutive sessions five to ten days apart. Baseline and post-intervention questionnaires were completed by the participants. Quality of life was measured with the SF-36 and the FACT-B questionnaires. The FACT-B was also used to measure functional status. Pain was measured with the Brief Pain Inventory. A paired t-test analysis was performed on the baseline and post intervention data. An ANOVA was performed on repeated physical measures (arm circumference and range of motion).

Ninety-five percent of the women who enrolled completed the study. Adherence to the intervention and home exercises was high, at 100% and 95% respectively. The intervention was evaluated as safe without any reported major changes in medical condition or level of discomfort that required discontinuation from the study. A paired t-test analysis on the scores from SF-36 (mental health) and the FACT-B (quality of life and functional status) improved significantly following the Bowenwork intervention ($p < .05$). An ANOVA revealed a statistical significantly improvement in arm circumference and range of motion ($p < .05$).

Bowenwork was shown to be an effective management strategy that improved mental health, increased quality of life and daily functional status, in addition to reducing arm circumference and increasing range of motion in women breast cancer survivors with lymphedema. A future full-scale study is needed to further explore these findings.

CHAPTER 1 STATEMENT OF THE PROBLEM

Breast cancer is one of the most globally recognized cancers, affecting women of all races, ethnicities, religions, socioeconomic strata and ages (ACS, 2009). Survival rates in the United States are increasing to over two million, particularly in the beginning stages of breast cancer (ACS, 2009). Breast cancer survival is attributed to increased awareness of early detection and improvements in medical and surgical treatments (J. M. Armer, 2005; Gartner et al., 2010). Men diagnosed with breast cancer constitute one percent of this population (NCI, 2011). While men are at risk for breast cancer, women are the focus of this study.

Women breast cancer survivors are susceptible to outcomes that are not desirable and that interfere with their survivorship. The outcomes may be accompanied by worrisome, long-term effects of the disease and adverse treatments that compromise health. Adverse outcomes associated with breast cancer treatment add burdens to this population. Among the most troubling of these burdens is lymphedema. Breast cancer treatment-related lymphedema is a chronic condition that negatively impacts quality of life and creates barriers to daily functions (Ahmed, Prizment, Lazovich, Schmitz, & Folsom, 2008; Ridner, 2005).

Significance of Lymphedema and the Need to Examine Management Strategies

When discussing lymphedema related to breast cancer treatment, lymphedema is generally defined as the chronic swelling of the arm, shoulder or torso (M. R. Fu, Ridner, & Armer, 2009b). It is characterized by a chronic swelling of an extremity and/or inadequate exchange of lymphatic fluid, resulting from mechanical dysfunction or injury (Lacovara & Yoder, 2006). Breast cancer treatment such as surgery, radiation and chemotherapy can be considered such an injury. It can lead to infection, skin changes, alteration in sensation, and

decreased range of motion, strength and function (Ahmed et al., 2008; J. Armer & Fu, 2005).

Stages of lymphedema are mild, moderate and severe; severe is considered irreversible (Norman et al., 2009).

The incidence of lymphedema in breast cancer survivors ranges from 8.1% to 37.2%, with or without a definitive diagnosis (Ahmed et al., 2008). The pattern of incidence is unpredictable, leaving health care providers at a loss when informing women as to when and what to report. The reported rates err on the side of under-reporting, since studies now show that women who lack an understanding and awareness of lymphedema self-report symptoms without clinical diagnosis, reflecting greater incidence and indicating a need for more education and standardization of management (Ahmed et al., 2008; Clough-Gorr, Ganz, & Silliman, 2010). Depending upon the criteria set forth for identifying lymphedema, such as amount of arm swelling and related symptoms, reports indicate that 40% of women will develop lymphedema secondary to breast cancer treatment (J.M. Armer, Stewart, & Shook, 2009; Norman et al., 2009). Those women who are aware of lymphedema fear the development of it and those who are unaware of it experience a delay in treatment which increases adverse effects (Paim, de Paula Lima, Fu, de Paula Lima, & Cassali, 2008). There is no cure for lymphedema, only treatment to temporarily reduce and manage symptoms over time (M. R. Fu et al., 2009b).

Women who experience lymphedema are aware of their health care providers' ignorance and the lack of attention that is given to lymphedema and how it affects them (Ridner, Bonner, Deng, & Sinclair, 2012). Women who are at risk for lymphedema but do not have a diagnosis may not understand the condition and are otherwise unaware of early management and the long term sequelae. Women are confused about current lymphedema treatment and are often given

multiple strategies to manage symptoms that do not necessarily work. These survivors receive conflicting information from health care providers on care of the arm and interpret the advice differently (Lee, Kilbreath, Sullivan, Refshauge, & Beith, 2010). Additional management strategies need to be explored further to help increase the options that are available to them to manage symptoms. These women are left managing their lymphedema with the limited options available from health care providers (Ridner et al., 2012). Women are struggling with insurance providers who lack the awareness of the magnitude of the condition and indicate that it is not worthy of reimbursement for adequate or long-term management (Ridner et al., 2012).

There are a multitude of barriers for women to overcome when experiencing symptoms and challenges of lymphedema. Symptom management is isolated to treatment but may be influenced by many other variables that may or may not support alleviation of symptoms. There are many contributing variables that may serve as barriers or pose threats to treatment, including demographics such as socioeconomic status, age, education, cultural and social beliefs. Women continue to be at risk for lymphedema or for cancer recurrence after a diagnosis of cancer and experience levels of depression, pain and fatigue years after treatment into survivorship (Harrington, Hansen, Moskowitz, Todd, & Feuerstein, 2010). Lymphedema is an adverse outcome that contributes to the symptom burden compounding barriers to improvements in health status.

Types of treatment strategies are expanding beyond allopathic and moving into what is considered complementary or alternative medicine (CAM). A study on cancer survivors' beliefs regarding CAM practices identified that 22% of participants experienced a perceived benefit from CAM treatments (Hooper, Pender, Webb, & McCombe, 2003). Women diagnosed with

breast cancer are open to other forms of symptom management strategies. From a study in which 118 women were diagnosed with breast cancer, 71% percent of the participants believed that there is a connection between their life experiences and their diagnosis (Arman, Backman, Carlsson, & Hamrin, 2006). Other investigators concluded that at least 80% of women diagnosed with breast cancer have used some form of complementary medicine, adding further support to suggesting a holistic approach for this population (Boon, Olatunde, & Zick, 2007).

A greater emphasis on etiology and manifestations of lymphedema is essential when examining management choices for lymphedema. A closer examination of the lymphatic system, the physiological components of lymphedema and the symptom experience is essential to adequately provide management strategies that can improve sequelae of lymphedema and manage symptoms more effectively. Treatment management strategies that focus on alleviating the physiological distress and addressing the psychological aspects of lymphedema can offer women with lymphedema more opportunities. Strategies that have a holistic emphasis are becoming more available and can possibly offer some relief of the distressing symptoms associated with lymphedema (Alem & Salete Costa Gurgel, 2008; Hansen & Taylor-Piliae, 2011; Tidhar & Katz-Leurer, 2010). Lymphedema adversely affects physiological, psychological and mental health, thereby decreasing overall quality of life (Ridner, 2005; Ridner, Dietrich, & Kidd, 2010).

Lymphatic System

The lymphatic system and its function is of primary concern when examining lymphedema of the upper limbs after breast cancer treatment (Hansen, 2010 Unpublished-a). The primary functions of the lymphatic system are to remove interstitial fluid from tissues,

absorb and transport fatty acids and transport immune cells (Margaris & Black, 2012). Under normal conditions, "interstitial proteins and fluid easily enter the lymphatic system through lymphatic vessels securing filaments that are attached to both the endothelial cells in the vessels and the surrounding connective tissue" (Ridner, 2002, p. 1286).

The lymphatic system is a complex system that is dynamic in its interconnectedness between the vascular networks at a cellular level (Margaris & Black, 2012). The very complexity of this system is demonstrated through the increasingly vast channels of networks communicating at a cellular level throughout the body. A delicate balance exists between the blood capillaries, the interstitial space and the lymphatic vessels. The lymphatic system is similar to the venous system, but instead of carrying blood it carries lymphatic fluid, with endothelial cells lining the walls of the vessel (Rockson, 2010). Fluid is present within the cell and outside of the cell. There is a close connection between the structure of the lymph system and venous system. The complex capillary plexuses consist of single layers of thin, flat endothelial cells that lie in the connective tissue spaces in the various regions of the body, within which they are distributed and are submersed by the intercellular tissue fluids (Margaris & Black, 2012). This system not only communicates with the connective tissue but also the fascia and its immense network of channels. The lymphatic vessels are stimulated with sympathetic and parasympathetic nerves and maintain the interstitial balance of fluid in tissues (Power & Brace, 1983). The lymphatic capillaries are present in almost all tissues of the body except the central nervous system and bone, but small interstitial channels continue to communicate with the central spinal fluid and bone marrow (Margaris & Black, 2012). In lymphedema, the lymphatic system no longer functions normally and it begins to fail as a result of the damage.

The damaged system is evident through the physiological changes in the torso, chest and affected arm. Lymphatic channels are compromised during lymphedema, resulting in an insufficient response to arterial pressure and failure of venous return (Fleysher, 2010). The compromise can occur as a result of surgery, chemotherapy, radiation, scarring, obstruction and/or infection, any of which can cause the increased accumulation of fluid in the interstitial space (Hull, 2000; Ridner, 2002). The failure causes the fluid to remain stagnant and trapped within the interstitial space. Lymphedema can also be described as the accumulation of tissue proteins and swelling compounded by inflammation and fibrosis, which results in a failing lymphatic filtering system (Hull, 2000). Fibrotic tissue is common in the areas of the torso, shoulder and upper arm as a result of the surgical procedures, radiation and chemotherapy. Initially, the scarring may present with only minor disturbances, but can become harder and less flexible over time. As fluid accumulates from reduced channels and networks, either acutely or over time, fibrosis accumulation deepens the magnitude of the fluid being trapped within the space and also reduces arm movement.

When the physical symptoms change from mild fluid accumulation to severe, the irreversible fluid accumulation causes physical debilitation. Fluid and fibrosis cause a reduction in arm function, such as range of motion and alteration in sensation (e.g. pain, aching, heaviness, numbness, tingling and prickling). The physical aspects are further compounded by the psychological distress of functional losses without hope for a return to previous health (Ridner et al., 2012). Lymphedema is complex, as is the system it originated from and the symptoms that surround it.

Theoretical and Conceptual Framework

According to the unitary-transformative worldview, humans are constantly and simultaneously interacting with a universal, self-evolving energy system (Wills, 2007). Life forces are dynamic and in constant motion. The uniqueness of each being interacts with the collective consciousness of the whole to create the dynamic state of health and the unique individual perception of life experience. While the symptom experience is unique to each person, it is a result of the collective experience and interaction with their environment, beyond simply the individual's health and illness. Theoretical perspectives that emphasize whole systems could be useful when exploring the effects of complementary methods to reduce severity of symptoms associated with lymphedema (Hansen, 2010 Unpublished-b). The theoretical perspectives guiding this study are twofold 1) complex systems science involving complex systems such as the lymphatic system and 2) Symptom Management Theory and the dynamic relationships within and surrounding human expression of the perceived symptom experience

Complex Systems Science

Complexity science evolved as a result of the inconsistencies or unpredictability of phenomena that could not be explained by traditional methods of scientific discovery (Chaffee & McNeill, 2007). Identification of such phenomena guided inquiry into exploration of dynamical systems and open systems that are nonlinear, as opposed to the standard principles of closed systems and equilibrium (Bentley & Maschner, 2007). Complexity theory focuses on conditions that are dynamic and nonlinear (Chaffee & McNeill, 2007). It is important to understand that complexity theory is not one theory but a combination of theories sharing similar principles (Chaffee & McNeill, 2007). A variety of disciplines have made mentionable contributions to complexity theory, such as chaos theory and physics, control theory and engineering, cybernetics

and mathematics, and general systems theory and biology (A. Ahn et al., 2010).

Reductionist methods of examining complex systems are ineffective because the relationships contributing to the whole are increasingly complex and their parts cannot be separated (Clancy, Effken, & Pesut, 2008). It is the relationship between the parts and interconnectedness among them that characterizes the complexity and adaptability of such systems (Chaffee & McNeill, 2007). Changes that occur in these systems are better conceptualized as nonlinear and dynamic rather than linear. Phenomena can also be examined using complex models, especially when there are multiple factors over space and time (A. Ahn et al., 2010). Nonlinear systems are known for the interaction between their components and the inability to separate them from the whole (Goldberger, 2006). Complexity theory focuses on the whole and explores the relationships of the surrounding parts in respect to the whole (Bell et al., 2002). In addition, it focuses on the relationships that influence outcomes (Sturmberg, 2007). It also attempts to conceptualize, with mathematical models, the discovery of patterns in systems that are more than the sum of their parts (Woehle, 2007). A distinguishable characteristic of this contributing theoretical background is nonlinearity, described as "output does not equal input"; this is also reflective in concepts of nonlinear dynamical systems (NDS) (A. Ahn et al., 2010).

The basic principles of nonlinear systems are worth mentioning when discussing NDS. It is important to emphasize that these principles are not all-inclusive, but chosen based on their relevance to complex systems as stated in Table 1. A brief explanation of the principles of attractors, bifurcations and chaos is necessary to further understand fractals, catastrophes and self-organization. Self-organization will be given a more in-depth explanation to support this theoretical perspective.

Table 1. Principles of Nonlinear Dynamics (Guastello & Liebovitch, 2009)

Attractors	A stable structure in a specified space in which movement could be present or not. The movement is classified by types identified as fixed, limited, toroidal or chaotic.
Bifurcations	A pattern of instability which presents when different dynamics occur simultaneously.
Chaos	A sudden change in the existing state that could include attractors and bifurcations.
Fractals	Repeating patterns of geometric structures such as those seen in trees, roads and people in cities.
Catastrophes	A sudden change in the current state of a system.
Self-organization	A process that occurs when a system appears to be in a disorderly state but actually is efficient.

Fractals

A fractal involves a time component, during which the organism or phenomenon of interest expresses an increase in variability with an alteration in the existing state followed by a reorganization (Guastello & Liebovitch, 2009). These alterations are expressed as identifiable patterns that are only detectable when looking at a phenomenon over time, as they are identified through alterations within the system (Clancy, 2008). Clancy uses the example of the cardiopulmonary system as a dimension of fractals in nature (Clancy, 2008). Initially one can see the general pattern and network of communications within the system. Upon further examination, one sees the intricate patterns of the bronchial tree. These patterns precede the

cardiopulmonary changes; they can predict the pattern that follows. Research is surfacing on complex systems and chronic conditions such as cardiac electrophysiology and diabetes, and how nonlinear perspectives support alternative management options (A. C. Ahn, Tewari, Poon, & Phillips, 2006; Goldberger, 2006). The lymphatic system could be considered another example based upon the complex nature of the system and the vast network of channels and communication networks. Early stages of research have been done on the lymphatic system and mapping the vast channels and communication networks, to better understand the multiple dimensions of this complex system (Margaris & Black, 2012).

Catastrophes

Catastrophes are defined as the sudden changes or critical instabilities in the current state of a system (Guastello & Liebovitch, 2009). They are characterized by a period of variability that opens the possibility of and acceptance of transition or changes in patterns (A. M. Hayes, Laurenceau, Feldman, Strauss, & Cardaciotto, 2007). Such fluctuations are present in observation of behavior during developmental stages, during which they are referred to as intra-individual variability (Van Geert & Van Dijk, 2002). Van Geert and Dijk (2002) discussed how individual patterns of behavior are missed when studying behavior during isolated time periods. They stated that prior to transition into another stage of development, there is a period of variability that allows the host to be open to a change in pattern and movement that could lead to an alternate cycle or period. Therefore, catastrophe has the potential to result in the alleviation of symptoms and transition into a new stage of development. It may be that timing an intervention to the period of openness could be significant in whether the individual can accept alteration into a state of re-organization.

While a physical change within the system may be immediately discernible, the catastrophe may continue to be expressed at any stage of recovery, and in a variety of ways. For example, a breast cancer survivor who has experienced an intervention in the form of a mastectomy will no doubt perceive it as a catastrophe, to some degree. However, the degree of trauma will be individualized in terms of perception, and be influenced by factors of health, environment, and personal characteristics. The catastrophe might even cause the lymphedema as a result of the disruption in the fascia. The perceived trauma in this area may even go unnoticed but is actually a noxious event, symptom, or symptom response. Hence, the degree of symptom experience such as lymphedema may be entwined with and influenced by the perceived trauma of the catastrophic experience. Therefore, interventions that stimulate the movement into another stage of development or cycle may result in alleviation of symptoms such as those surrounding lymphedema. The re-organization has the potential to result in the alleviation of symptoms and transition into a new stage of development.

Self-Organization

Self-organization in a system occurs when a state of order emerges from a state of disorganization (Guastello & Liebovitch, 2009). This development is also reflective in the principles that emphasize the inability to dissect the parts from the whole, because of the dynamic reactions supporting the system. There is a creative adaptation to change in self-organization that is reflective of the characteristics of the system or organism (Guastello & Liebovitch, 2009; Holden, 2005). The system allows for the re-organization as the result of new information that is processed over an integration period allowing for the change to happen. The system has the ability to function as a knowledge or information system. The concept of self-

organization therefore includes the potential for correction of the dysfunctional system, by alleviating symptoms, thereby improving outcomes.

When a given symptom experience improves following an intervention, the concept of re-organization would be considered a possible positive result of the intervention. CAM practices may support re-organization of a condition, and improve the symptom experience, such as those experienced with lymphedema. Self-organization is stimulated and the system is supported to function normally. The individual's response to the intervention must therefore be monitored over sufficient time to allow for that possibility. The actual amount of time may vary according to type of intervention and degree of duration of symptoms.

Lymphedema and Complex Systems

Complexity systems science and NDS provide a theoretical framework for research involving complex systems such as the lymphatic system, and conditions that result from its dysfunction such as lymphedema. Patterns can be present within states of organization that may not be immediately transparent. Nonlinear dynamical systems is engrained in mathematics; it attempts to conceptualize and account for the unanticipated events in a system that cannot be explained using a linear and mechanistic model (Guastello & Liebovitch, 2009). Exploring the lymphatic system through mathematical perspectives and diagramming its vast networks is in the early stages of discovery, and glimpses of its complexity may give us insight into the behavior of this system (Margaris & Black, 2012). Identification of patterns of behavior in complex systems could potentially allow for a better understanding of the complexity of lymphedema and how to improve outcomes.

Systems are considered complex if they exhibit characteristics as a result of the

interconnectedness of their contributing parts (A. Ahn et al., 2010). As systems evolve, so does the complexity of those systems. Systems can be open and characterized by the interconnectedness of the individual parts and the surrounding environment (Sturmberg, 2007). Complex systems are in a state of constant change, in continuous response to the environment and other factors that come into contact with them directly or indirectly. The lymphatic system is a complex system that is constantly responding to its environment. The vast channels of networks are constantly communicating with the surrounding structures. Complex systems are unpredictable and do not necessarily generate similar responses (Clancy et al., 2008). Lymphedema is unpredictable and can present anytime during breast cancer recovery, therefore it exemplifies the unpredictability of the complex system.

Chronic conditions are best examined using a systems approach that allows for the complexity of circumstances, including individual perceptions, surrounding any human condition (A. C. Ahn et al., 2006). Lymphedema is a chronic condition that is progressive and characteristic of such systems. The systems and subsystems within us and around us are influenced by the relationship between the individual parts and the whole (Sturmberg, 2007).

The complexity in human nature and the relational influences surrounding symptom management of chronic illnesses such as lymphedema are evident in this theoretical framework. Traditionally, surgical procedures such as axillary lymph node dissection were considered the main cause of lymphedema. Now there is supporting evidence that less invasive, modified/conservative procedures including sentinel lymph node biopsies and lumpectomies still put women at risk for lymphedema (M. R. Fu, Axelrod, & Haber, 2008). Another inconsistency in the findings relates to age and incidence. One study reports that the incidence of lymphedema

increases with age (Ridner & Dietrich, 2008). Other studies report that advancing age could safeguard against symptoms associated with lymphedema and reduce the risk (Clough-Gorr et al., 2010). In addition, consensus on standardized management is yet to be recognized (Dirican et al., 2010; Omar, Morsey, & Ebid, 2010). The contradictions and unpredictability of lymphedema leave the field open to exploring alternative theories and strategies for managing symptoms and addressing complex phenomena.

States of health and disease in complex systems demonstrate unusual presentations and patterns not consistent with a reductionist understanding of proportional relationships, such as those evidenced through linearity (Goldberger, 2006). The complex nature of lymphedema and its surrounding symptoms may benefit from further exploration through nonlinear models.

While the framework of complexity theory can be used to exploring the unpredictable phenomenon of breast cancer treatment-related lymphedema, a model that emphasizes individual perceptions of symptoms can also be useful. Symptom management strategies that support holistic approaches to alleviating symptoms are also vitally important; introducing new strategies could potentially create alternate pathways for adaptation to the environment and other variables.

Symptom Management Theory

The Symptom Management Model was introduced by the University of California, San Francisco School of Nursing, Symptom Management Faculty Group in 1994 (Larson et al., 1994). Group members recognized a missing link in the management of symptoms of chronic illness. Instead of focusing on a single symptom and the treatment options for alleviation, they suggested expanding the understanding of the perception of symptoms to a general model that would work across disciplines and populations. Larson and colleagues borrowed theories from

nursing models of self-care, psychology, and sociology that focused on sick roles, behaviors and treatment options. However, not any theory captured what they wanted to convey regarding the perceived experience and how this influenced individual responses. Their own theory evolved to identify the importance of the individual perception of the symptom experience, to evaluate management strategies and to identify proposed outcomes (Smith & Liehr, 2008). The revision of the Symptom Management Model to the Symptom Management Theory (SMT) in 2001 was necessary because of the natural evolution of nursing knowledge, which incorporated observations of the inconsistencies or unpredictable nature of the symptom experience (Smith & Liehr, 2008).

The SMT is a theory for addressing practice concerns surrounding chronic conditions and symptom management (Larson et al., 1994). The major assumption of the model is that if symptom management strategies are successful, then the outcomes and the perceived symptom experience will improve. The major concepts of the revised model are symptom experience (perception, evaluation and response), symptom management strategies (who, when, where, how, to whom, how much, and why) and outcomes of symptom status (functional status, emotional status, self-care, costs, mortality, quality of life and morbidity and co-morbidity (Liehr, 2005). The revision supports the person's perception of the symptom and the influence of the experience on the strategies and outcomes as shown in Figure 1. The SMT emphasizes the interrelatedness of the original concepts, as well as the interrelatedness of additional nursing metaparadigm dimensions of person, environment and health. The dimensions support the context of nursing research (Smith & Liehr, 2008). The revised conceptual model operationalizes the concepts and their interrelationships (Dodd et al., 2001). The new conceptual

model for SMT moves toward innovative approaches, in combination with the influences of the nursing science metaparadigm dimensions of person, environment and health. The interconnectedness of variables within concepts alludes to a multidimensional model that is more holistic and moves away from linear perspectives.

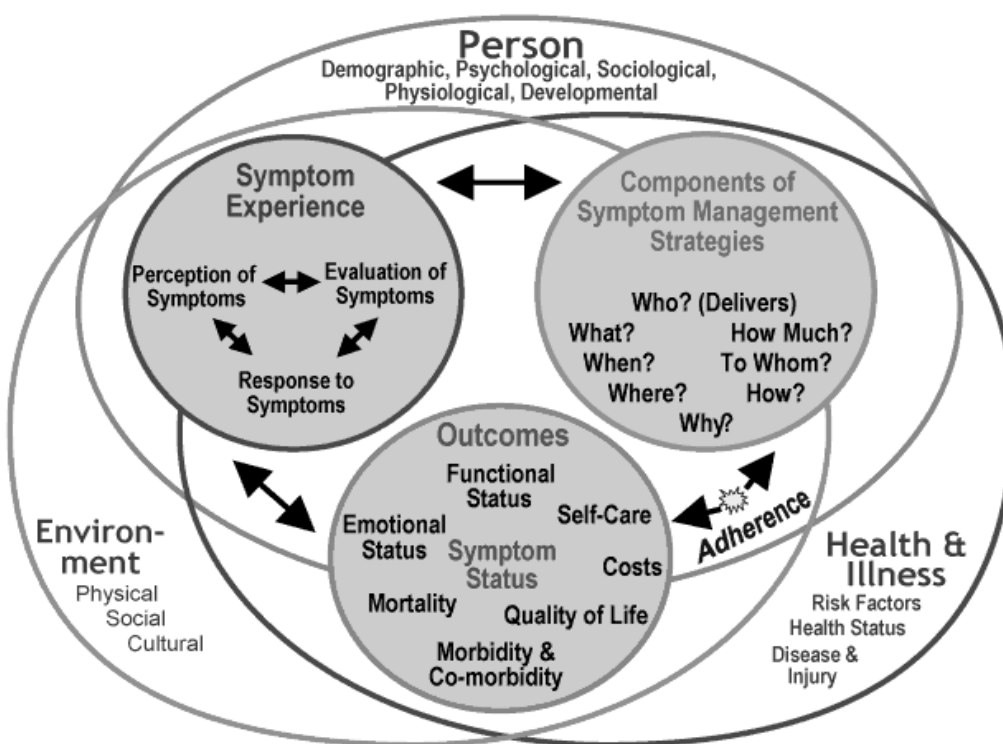


Figure 1. Conceptual Model of Symptom Management Theory (Dodd et al., 2001)

Symptom Experience

Symptom experience is defined as the complex, subjective and perceived evaluation and response to the experience (Dodd et al., 2001). The SMT serves as a framework for exploring a

phenomenon such as lymphedema and the symptoms associated with it. Symptoms may be considered as individual symptoms or as clusters of symptoms. Individual symptoms such as quality of life or cluster symptoms have been reported with lymphedema (Ridner, 2002). Symptoms are complex and dynamic throughout the duration of the experience. Progression of the severity of symptoms requires greater attention, including professional consultation, which may later alter perception. These women perceive their resources as diminishing their experiences (Ridner et al., 2012). Women with lymphedema experience a range of progressive symptoms from physiological to psychological. Physiological symptoms may include edema of the torso, chest and arm, the alteration in arm function through reduced range of motion, increased edema, and sensation ranging from acute pain to constant aches. The psychological symptoms may include the feelings associated with disfigurement, dysfunction and lack of hope for a cure.

Symptom Management Strategies

Symptom management strategies are defined as an intervention that may improve outcomes or counteract negative outcomes with the intent to focus on one or multiple effects (Dodd et al., 2001). The symptom management strategies attempt to alter the symptom experience by identifying supportive methods, while at the same time influencing each other. The strategies are not limited to self-care but can encompass individualized treatments or combinations. Women with lymphedema can benefit from management strategies that offer physiological support as well as psychological support.

The SMT utilizes a complete approach to symptom management (Liehr, 2005). Symptom management is not isolated to treatment, but recognizes many other variables that may

or may not support alleviation of symptoms. The SMT accommodates a holistic approach to symptom management by taking into account the influences of person, environment and health on the perceived symptom experience, management strategy and outcomes. An approach to research that integrates allopathic and complementary methods may work better than a narrow focus (Bell et al., 2002). The SMT offers a more comprehensive approach that allows for more than physiological focused management; it offers a framework that includes psychosocial, emotional and quality of life outcomes. The SMT and its central concepts can support research focusing on symptoms surrounding chronic conditions such as lymphedema and symptom management strategies that embrace the women from a holistic perspective. The SMT implies that symptom experience, management and outcomes are not reducible to $A + B = C$; rather, it is necessary to consider the whole experience. A transition or movement toward improved health or greater order is related to the influencing factors and the related concepts.

Symptom Status Outcomes

Outcomes are the result of the combination of management strategies and the symptom experience. The additional dimension of examining costs during the revision was necessary to emphasize how management influences outcomes and creates additional burdens directly or indirectly on the experience (Dodd et al., 2001). Cost can create unexpected barriers to improvement in outcomes. Research on lymphedema identifies that these women experience a financial burden to manage their lymphedema without the support from health care providers or insurance companies (Ridner et al., 2012). Quality of life and functional status are measureable outcomes for women with lymphedema before and after introducing management strategies.

Once the symptoms of lymphedema progress negatively and it becomes a barrier to daily

function, outcomes such as quality of life and functional status decrease proportionally (Chachaj et al., 2010; Ridner et al., 2010). Perception of symptoms, not their severity alone, affects outcomes negatively (Ridner, 2005), supporting the theoretical underpinnings of this model. Though the SMT lacks the dimension of time and its influence on the symptom experience (Smith & Liehr, 2008), examining the symptom experience over time and identifying patterns consistent with a phenomenon may elicit a deeper understanding of the perceived experience and even potential treatment strategies. Lymphedema may be one such phenomenon, as its associated symptoms are not limited to a physical etiology, but may manifest through the multidimensional influences such as those identified in the SMT.

Complexity System Science and Symptom Management Theory

Examination of complexity theory and nonlinear dynamics reveals a congruency between these perspectives and the SMT. The initial model of the SMT no longer fits what was being observed clinically regarding individual symptom experiences and management options. Outcomes are no longer considered dependent on adherence to management strategies, hence not conducive to the concept of input equals output. The SMT conceptual model emphasizes the continuous movement in multiple directions among all concepts and related dimensions. These dynamic influences are congruent with complexity theory and the principles of complex systems. By examining the relationships among the dimensions of the symptom experience and the strategies to manage the symptoms, one can evaluate the most significant elements in the outcomes. These include phenomena that are influenced by multiple factors. The interconnectedness of the perceived evaluation and response and the additional domains of environment, person and health together transform the model to a multidimensional model with a

multitude of influencing factors. These revisions complement the basic principles of complexity science.

Thus far, the comparison of complexity systems theory and with the SMT has generated results linking these two theoretical perspectives. The general principles or assumptions of complexity theory are: 1) that interconnected, dynamic variables from multiple origins influence the whole 2) that relationships are not linear, and 3) that outcomes are not proportional to input. These principles are consistent throughout the SMT.

Complexity theory and nonlinear dynamics are complementary to holistic approaches. These approaches encompass management and treatments into whole systems that complement the essential nature of complex systems and introduce susceptibility to change. There are many theoretical perspectives that focus on the individual, on communities and even on the global effects of health. Elements linked by these expanding, complex systems and multiple subsystems influence the state of the individual. The uniqueness of how each individual responds to an experience results in a manifestation of symptoms, and continues to play a role during treatment and throughout recovery. Complexity theory is relevant to all these perspectives and supports a framework that accepts a holistic approach when considering all potential influencing variables.

However, the uniqueness of individual and tailored treatments brings up concerns when selecting management strategies. Issues arise within complexity and nonlinear systems research when measuring effects of management that are unique to an individual. If tailored therapy is ignored in favor of standardized treatments or clinical trials, favorable outcomes are substantially reduced because the basic elements of the personalized treatment to support symptom

management are removed. However, when considering the complexity of the lymphatic system and its physiological components, a management strategy that works within the same frame of reference may be beneficial. The SMT model allows for management strategies that influence both physiological responses as well as psychological, regardless if they are individualized or standardized.

The SMT is conducive to the consideration of the unpredictability of a given phenomenon. It provides a structure for measurement that considers the interrelatedness of concepts on perceived symptoms from a broad perspective. The revision of the model suggests a more nonlinear aspect and incorporates alternative input and output options related to any of the concepts; it does not isolate outcomes to management strategies, as the initial model proposed. Since input is not necessarily related proportionally to output, the overlapping of all concepts satisfies this element. Nonlinear dynamics is sensitive to changes in time and the patterns identified during time periods. Variability is recognized in the numerous influences from person, environment and health concepts. Nonlinear dynamics and intra-individual variability can be utilized to examine cross-reference periods of transition and identify critical fluctuations of the symptom experience. The SMT can support research that examines phenomena over time and measures the symptom experience responses to changes in the environment that might have previously been seen as unpredictable, instead of undetectable.

Bowenwork as a Holistic Symptom Management Strategy

Within the realm of complementary options, strategies exist that support allopathic treatments. One such method is Bowenwork, also known as Bowen Technique and Bowen Therapy. The National Center for Complementary and Alternative Methods classifies Bowen

Technique under the category of manipulative/ body-based practices, along with osteopathy and massage (Long & Huntley, 2001). The postulated theory of the mechanism of Bowenwork suggests that through a simple Bowenwork move, golgi and spindle cells in the belly of a muscle are stimulated, along with the surrounding tissue, fascia and fluid, both intra- and extra-cellular (Shapiro, 2004). The move initiates a cascade of reactions, including stimulation of the autonomic nervous system throughout the body and the central nervous system to the brain (Mechner, 2003; Olafimihan & Hall, 2002). A move initiates an energetic impulse into a specific area of the body, similar to the ripple effect of a drop of water on the surface of a pond. This is similar to the effect of acupressure in the stimulation of meridians (Shapiro, 2004). The postulated theory suggests that the energetic impulses stimulate healing pathways to regenerate original states of health prior to insult or trauma, and supports the reduction of stimulated pain receptors (Hansen & Taylor-Piliae, 2011). One of these moves or a combination of moves may stimulate new pathways or restore traumatized ones to reduce the adverse effects of cancer treatment on a compromised complex system.

Bowenwork is a treatment strategy that is congruent with the theoretical framework of this proposed research. The relevance of Bowenwork as a complementary intervention for symptom management is that it is postulated to have self-organizational properties, such as those in the principles of complexity science. The postulated theory of how it stimulates the complex systems such as the lymphatic system and the surrounding physiological structures is consistent with these basic principles. The intervention creates the potential to re-organize through a single Bowenwork move by realigning the fascia's energetic patterns. The system interprets this new information and re-organizes. The intervention may stimulate transition into new knowledge

that in turn, encourages the system to realign existing pathways or even possibly develop new pathways after the event of traumatic breast cancer diagnosis, breast cancer treatment or adverse outcomes such as lymphedema. The lymphedema that follows the event in an unpredictable pattern not only results from the disorganization, but can add to the disorganization.

Lymphedema can affect the individual physiologically, psychologically and emotionally. This complementary management strategy supports the individual physiologically as well as psychologically, and allows the system to reset or return to normal function. Hence, symptom management of lymphedema is one condition among breast cancer survivors that may benefit from Bowenwork.

Bowenwork consists of a series of gentle, specific hand movements over muscles, which stimulate nerve pathways and generate a physical and psychological healing in the body. A Bowenwork treatment consists of multiple combinations of moves over specific areas, the application of which depends upon the symptoms the person is experiencing. The theoretical framework for this research considers the influences of person, health and environment on human perceptions, potential management strategies and outcomes. The literature on Bowenwork supports the use of this treatment for symptom relief in certain populations and not only relies on the physiological response but also supports psychological benefits (Hansen & Taylor-Piliae, 2011). A systematic review on Bowenwork emphasizes several positive outcomes but highlights the need to support outcomes scientifically. (Hansen & Taylor-Piliae, 2011).

The symptom experience is complex and individual perceptions are dynamic throughout the duration of the experience. Initial perception of lymphedema may only involve minimal-to-no attention from a person, while progression of severity of symptoms requires greater attention.

Health care professionals may begin to label symptoms and as they progress, and so influence symptom progression. Once the symptoms associated with lymphedema increase and lymphedema becomes a barrier to daily function, outcomes such as decreased function and decreased quality of life increase proportionally (Chachaj et al., 2010; Ridner et al., 2010). Therefore, the symptom experience, including the individual perception, influences health outcomes, supporting the theoretical underpinnings of the SMT (Ridner, 2005).

The SMT represents the potential influences of demographics, race, religion, social networks, risk factors associated with health, injuries and disabilities on the symptom experience. The literature indicates that lymphedema occurrence may be influenced by these factors. For example, women with lower income, advancing age and co-morbidities experience a higher incidence of lymphedema (Ridner & Dietrich, 2008). In addition, African-American and Chinese-American women have reported a greater severity of symptoms than Caucasian women (M. R. Fu & Rosedale, 2009). These studies exemplify the influencing variables associated with the symptom experience and support the use of SMT as a theoretical framework.

While Bowenwork is recognized as a complementary symptom management strategy, it is also recognized as having a positive effect on the re-organization of many conditions (Hansen & Taylor-Piliae, 2011). Considering the multiple influencing variables affecting breast cancer survivors who develop lymphedema, the theoretical frameworks of nonlinear dynamics and SMT, Bowenwork may be a suitable and plausible intervention to stimulate a re-patterning that would truly be re-organizational in nature. Therefore, by adapting the theoretical models and incorporating lymphedema, a framework can be conceptualized to support the proposed research as shown in Figure 2.

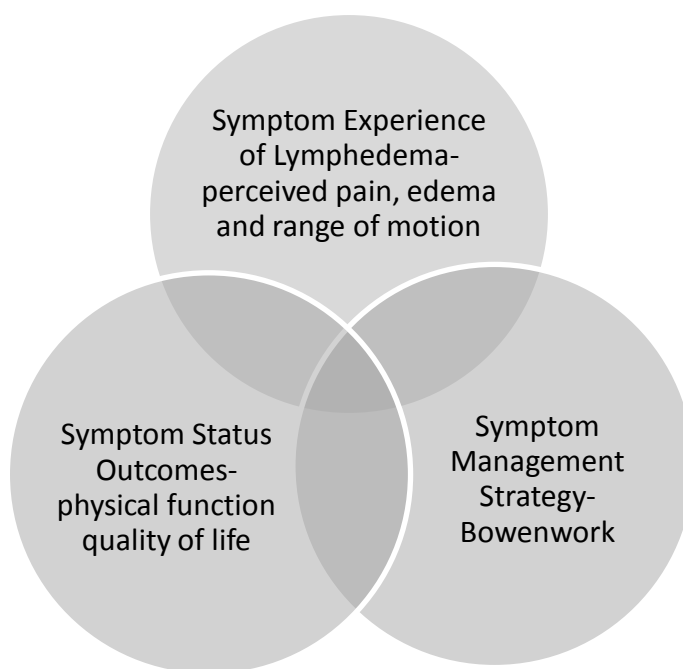


Figure 2. SMT Adapted for Lymphedema

Knowledge Gaps about Bowenwork as a Symptom Management Strategy

Bowenwork is a new symptom management strategy. While it is practiced in over 35 countries (Mechner, 2003), the relative newness of this therapeutic treatment and the lack of scientific evidence supporting the results of the work cause inherent issues with its acceptance as a valid treatment for symptom management. There is a significant gap in the literature supporting the postulated theoretical foundations of Bowenwork, the holistic approach to treating symptoms and the standardization of treatment protocols (Hansen & Taylor-Piliae, 2011).

The research on Bowenwork treatments lacks the evaluation of treatment effects over time. Most of the studies measure an isolated time period, missing valuable information about recovery and potentially missing the identification of pattern recognition discussed earlier with

complex systems. There is a significant gap in researching this complementary practice as a whole system and supporting the treatment as a holistic complementary treatment for symptom management.

Further exploration of Bowenwork and the management of breast cancer-related lymphedema may help to fill the gaps of knowledge about Bowenwork. In addition, Bowenwork could offer an inexpensive, noninvasive, pleasurable symptom management strategy for women who suffer from the chronic effects of lymphedema.

Purpose of Study

The research reported herein constituted a pilot study. Pilot studies are also known as feasibility, preliminary, or trial studies and provide valuable information to researchers prior to full implementation of a larger scale research project, a pilot study was chosen for this project. Since lymphedema is a chronic adverse condition that has no cure and limited management options, it seemed reasonable to implement a pilot study on the innovative, complementary intervention of Bowenwork to provide a foundation for future research in women survivors of breast cancer with lymphedema.

The overall objective of this pilot study was to examine the feasibility of using Bowenwork as a complementary intervention for symptom management of breast cancer treatment-related lymphedema in women breast cancer survivors. The specific aims were to:

- 1) Determine recruitment and retention rates of affected women
- 2) Determine adherence to the Bowenwork intervention
- 3) Assess the safety and comfort level of the Bowenwork intervention
- 4) Describe the effects of a 6-week Bowenwork intervention on lymphedema symptoms

(i.e. quality of life and functional status at baseline and post-intervention, perceived pain, limb circumference and range of motion of the affected arm at baseline, between sessions and post-intervention).

The long-term objective of this study was to explore whether lymphedema-related symptoms among women breast cancer survivors and the chronic negative sequelae associated with breast cancer treatment could be reduced through the implementation of the intervention of Bowenwork.

Significance of Study

There are no studies to date referencing complexity theory and SMT as a supportive theoretical framework for research examining the symptoms surrounding breast cancer-related lymphedema. Symptom perception becomes a key factor when addressing symptom management through nursing. The multiple influencing variables potentially altering the symptom experience must be considered. Historically, nurses have been at the forefront of recognizing inconsistencies and unpredictable patterns associated with the perceived symptom experience. Future research to examine the symptom experience over time and identify patterns consistent with phenomena may elicit a deeper understanding of the expression of symptoms and how to manage them successfully. Complexity science provides additional and innovative support for exploring this phenomenon, while offering a complementary intervention. Research on complementary interventions for symptom management is vital for nurses so they can provide information on safe and effective management strategies.

Findings from this pilot study will support future CAM research for symptom management of breast cancer survivors with lymphedema. Identifying the breast cancer

survivors' awareness and willingness to expand their management options is crucial to future studies offering similar strategies. It can also serve as a preliminary study for future research on exploring the effects of Bowenwork.

CHAPTER 2 LITERATURE REVIEW

This chapter will review the incidence of lymphedema and the symptom experience, including quality of life, functional status, perceived pain and physical arm measurements. In addition, it will review the current literature on treatment options including Bowenwork as a possible complementary intervention.

Incidence of Lymphedema

The alarming statistic of over two million breast cancer survivors in the United States in 2010 has caused intense concern (De Angelis et al., 2009). As of 2006, it was estimated that up to 600,000 survivors may experience lymphedema (Ahmed et al., 2008). The reported incidence of breast cancer-related lymphedema varies depending on definition and diagnostic measures (J. M. Armer, 2005; M. R. Fu, Ridner, & Armer, 2009a; McWayne & Heiney, 2005; Torres Lacomba et al., 2010). With such variations, it is estimated that 40% of women may develop lymphedema secondary to treatment for breast cancer (J.M. Armer et al., 2009; Norman et al., 2009). Even though these discrepancies exist, it is quite clear that once lymphedema is identified, management should be started immediately (Chan, Lui, & So, 2010; Fleyscher, 2010; Torres Lacomba et al., 2010).

An exhaustive search of two electronic databases helped to identify articles on breast cancer-related lymphedema, the related symptoms, and various diagnostic measures and management. Search terms included lymphedema and breast cancer. The first database searched was CINAHL. The limits for the search were breast cancer and lymphedema from inception of database through July 2010. This search produced 26, 385 articles. The second database, PubMed database, had the same limits of breast cancer and lymphedema and publication date

from 2005 through July 2010, in order to focus on the most recent literature. This search generated 1,021 articles. Fifty-one articles were included for review and the remaining articles that were rejected were not research based, not relevant to lymphedema secondary to breast cancer treatment, repeated or duplicate articles, or were not written in English.

Using the SMT concepts (i.e. symptom experience, symptom management strategies, and symptom status outcomes) to guide the literature review, studies were synthesized according to four distinct categories. These categories were: 1) studies exploring the symptom experience including alteration in sensation and pain with lymphedema (see Appendix A for Table); 2) studies relevant to current diagnostic and management of lymphedema (see Appendix B for Table); 3) studies measuring quality of life in women breast cancer survivors with lymphedema (see Appendix C for Table); and 4) studies measuring the impairment of arm function and range of motion associated with lymphedema (see Appendix D for Table).

Symptom Experience Involving Alteration in Sensation and Pain with Lymphedema

Lymphedema affects women physiologically and psychologically. Alteration in sensation, perceived pain, and heaviness are prevalent in women who experience lymphedema, and these symptoms become barriers to their daily life (M. R. Fu & Rosedale, 2009; Gartner et al., 2010; Paim et al., 2008). It also has been identified that women with lymphedema experience a cluster of symptoms that includes altered sensation, decreased body confidence and physical activity, and psychological distress (Ridner, 2002). Despite the advances in treatment, women breast cancer survivors with lymphedema have reported symptoms of pain (Chachaj et al., 2010; Gartner et al., 2010). Pain associated with injury to the intercostalbrachial nerve is common after surgery, with pain continuing to be prevalent in up to 52% of breast cancer

survivors nine years after surgery (Macdonald, Bruce, Scott, Smith, & Chambers, 2005). Pain is associated with psychological and social health and affects quality of life (McWayne & Heiney, 2005; Paim et al., 2008). Women may deal with ongoing and unresolved pain or discomfort to the point of feeling disfigured and isolated from others (M. R. Fu & Rosedale, 2009). Women continue to be at risk for years after the diagnosis and treatment of the cancer, and experience levels of depression, pain and fatigue years into survivorship (Harrington et al., 2010). Lymphedema is an adverse outcome that contributes to the symptom burden and compounding barriers to improvements in health status.

A current review of the literature on lymphedema supports an association between the perceived symptom experience, the degree of symptom progression and outcomes (Gartner et al., 2010; Ridner, 2005; Ridner et al., 2010; Tsauo, Hung, Tsai, & Huang, 2010). Some studies clearly express the importance of managing symptoms physically, mentally and psychologically to support the entire individual, avoiding the isolation of symptoms and treatments that do not support wholeness (Carter, 2002; M. R. Fu et al., 2008; H. Sakuda, Satoh, Sakaguchi, Miyakoshi, & Kataoka, 2010). The literature includes findings associated with the concepts related to perceived symptoms, management strategies and outcomes as those identified in the SMT, but does not necessarily report them within the framework (see Appendix A).

Current Diagnostic and Management for Lymphedema

There are no standardized diagnostic or treatment protocols for lymphedema (M. R. Fu et al., 2009b). Various diagnostic techniques have been available and presented in the literature (see Appendix B). Some diagnostic techniques have been thoroughly examined and recognized in the literature for their accuracy. For example, the use of water displacement and arm

circumference is among the most reliable techniques (Chen, Tsai, & Tsauo, 2008). Water displacement requires the individual to place the lymphatic limb into a special device filled with water, called a volumeter, that measures the amount of water displacement. Simplified water displacement instruments can be a source for measuring the lymphatic-compromised limb, but only in comparison to the unaffected limb (Sagen, Karesen, Skaane, & Risberg, 2009). Other types of measuring instruments that have been tested for accuracy are bioimpedance and spectroscopy (Czerniec et al., 2011; H. Sakuda et al., 2010). Bioimpedance measurements that use spectroscopy measure the amount of intracellular fluid to extracellular fluid in the affected arm, and compare measurements with the unaffected arm (H. Sakuda et al., 2010). In addition to measuring the entire arm, specific arm sections are sometimes measured to capture changes in fluid dispersement (Czerniec et al., 2011). Manual physical arm circumference measurements with a tape measure are also accepted as a valid measuring tool (Torres Lacomba et al., 2010; Tsauo et al., 2010). On average, the standard of a two-centimeter difference in circumference between the affected arm and unaffected arm is acceptable to support a diagnosis of lymphedema (J.M. Armer et al., 2009).

The goal of current lymphedema treatments is to manage symptoms to support a failing system that cannot be restored (M. R. Fu et al., 2009b). As a result of the disturbance in lymphatic drainage, lymphedema sequelae include altered sensation, increased size and shape of arm circumference and impaired range of motion. These treatments focus on moving fluid from the interstitial space back into the venous circulation. Unfortunately, the results are not permanent. The limited treatments that are currently available include physical therapy, decompression, massage and pharmaceutical therapy; these treatments have variable results

(Khan, 2009). While complete decongestive physiotherapy is the most common management for lymphedema, it must still include manual drainage, bandaging, exercise and skin care (J. Armer & Fu, 2005). Manual lymph drainage is a known treatment but lacks comprehensive research to validate its use with lymphedema (A. Williams, 2010). Continued attempts to identify exercise programs and drainage techniques that decrease lymph drainage but do not increase inflammation are proving to be challenging (McClure, McClure, Day, & Brufsky, 2010). Some progress is being reported as to the advantages of exercise and how it may keep inflammation at bay and even improve range of motion (Ahmed, Thomas, Yee, & Schmitz, 2006; Chan et al., 2010). Hyperbaric oxygen therapy is reported to reduce hand edema for approximately 14 months following treatment (Teas et al., 2004). However, this type of treatment is not typical and remains in the experimental stages.

Complementary interventions and practices are becoming more prevalent for women diagnosed with breast cancer (Tarhan et al., 2009). However, there is a definite gap, as they have only been explored minimally with women experiencing lymphedema secondary to breast cancer treatment. McClure and colleagues (2010) reported an improvement with arm flexibility, quality of life and mood after a relaxation intervention. In addition, a systematic review on acupuncture for breast cancer treatment reported improved range of motion of the affected arm with lymphedema (Dos Santos et al., 2010). Women with lymphedema who received acupuncture had a statistically significant improvement in arm abduction and reduced perception of arm heaviness. (Alem & Salete Costa Gurgel, 2008). A study using aqua-lymphatic therapy and relaxation reported statistically significant reduction in arm circumference for the initial post-treatment evaluation; however, the long-term results without clarification on the time period

were not sustained (Tidhar & Katz-Leurer, 2010). Exercise, pneumatic compression devices and laser treatments have been known to improve range of motion and function as well (Chan et al., 2010; Hammond & Mayrovitz, 2009; Omar et al., 2010). The field remains open to exploring other complementary modalities that can support breast cancer survivors with lymphedema.

Quality of Life in Women Breast Cancer Survivors with Lymphedema

Quality of life for breast cancer survivors is gaining more attention as the number of survivors increases and negative outcomes such lymphedema continue to burden this population (see Appendix C). Arm symptoms affect quality of life, and women who experience lymphedema have lower physical and mental health-related quality of life than survivors who are not diagnosed with lymphedema (Ahmed et al., 2008). In addition, a decrease in physical functioning related to arm swelling and lower quality of life further burdens these women (Ridner, 2005). A reduction in quality of life may not be directly related to the increase in arm size itself, but rather the combination of the arm size and the limitations resulting from the lymphedema (Ridner, 2005; Ridner et al., 2010; Tsao et al., 2010). Other contributing factors that reduce the quality of life are the actual diagnosis of breast cancer, lymphedema and increased age (Ahmed et al., 2008; Clough-Gorr et al., 2010). On the other hand, exercise has been shown to increase overall quality of life, even without changes in the physiological condition of the arm (McClure et al., 2010; McKenzie & Kalda, 2003) (M. R. Fu et al., 2009b). Unfortunately, the symptoms associated with lymphedema extend beyond physiology and include the unexpected sensation of disconnection from self and the feeling of being less than whole (M. R. Fu & Rosedale, 2009). These women are faced with perpetual discomfort, unexpected confrontation, loss of pre-lymphedema self, and feeling handicapped (M. R. Fu &

Rosedale, 2009). The perceived symptom experience and the symptom status outcomes such as quality of life are compounded by the many influencing variables of the effects of lymphedema.

Impairment of Arm Function and Range of Motion Associated with Lymphedema

Impairment in arm function and range of motion add to the burdens of women with lymphedema (see Appendix D). Impaired function is the inability to perform an expected physical movements or activity. When discussing breast cancer-related lymphedema, the impairment in function is associated with the affected arm and hand. These survivors often suffer physically from impaired range of motion as well as the altered sensation, various degrees of swelling, heaviness and pain (Gartner et al., 2010). Decreased range of motion of the affected arm is a major contributing component to reduction in daily functional status for women suffering from lymphedema after breast cancer treatment (J.M. Armer et al., 2009; Bani et al., 2007; Ridner, 2005; Teas et al., 2004). This alteration in range of motion is the result of scarring, adhesions and increased weight of the limb secondary to the surgery, radiation and the swelling of the arm. Breast cancer survivors who develop lymphedema also may not experience an impairment in function initially, but will deteriorate if progression continues into later stages (Bani et al., 2007; Dirican et al., 2010; Hammond & Mayrovitz, 2009). Breast cancer survivors without lymphedema may also experience an alteration in function and range of motion (Smoot et al., 2010).

Management options available for improving the range of motion are limited and usually given secondary management to the existing edema (see Appendix D). Improvement in the identification of risk factors predisposing women to development of lymphedema, such as increase in body mass index, are being reported in the literature (Helyer, Varnic, Leong, &

McCready, 2009; Ridner & Dietrich, 2008; Swenson, Nissen, Leach, & Post-White, 2009; Vignes, Porcher, Arrault, & Dupuy, 2010). However, as previously mentioned, the reduction in range of motion is not directly associated with the amount of swelling, but also the extent of invasive procedures. Research is limited that identifies holistic treatment options for successful management of symptoms associated with the reduction of range of motion (see Appendix D). However, the literature indicates substantial improvement in functional status with Bowenwork, especially with shoulder range of motion (Carter, 2002; Cheung et al., 2006; Potter, 2002). A study focusing on the holistic approach as well as the physiological etiology could potentially ameliorate the physical and the psychological effects and lymphedema and improve outcomes. Since Bowenwork is a CAM therapy that has been clinically noted for its effectiveness in patients suffering from lymphedema, a closer look at Bowenwork and the science behind the theoretical mechanism is prudent in considering it as a management strategy for lymphedema.

State of the Science of Bowenwork

Bowenwork is a complementary therapy that supports mind, body, and spirit through physical, mental and psychological pathways (Olafimihan & Hall, 2002). It originated in Australia in the 1950's by Thomas Bowen (1916-1982) and was first introduced into the United States in 1989 by Oswald and Elaine Rentsch (Mechner, 2003). In comparison to other forms of complementary modalities, Bowenwork has yet to be recognized by the scientific community because of the lack of scientific evidence (Hansen & Taylor-Piliae, 2011). However, there is a growing compilation of published work giving favorable reviews on the observed results of Bowenwork for alleviating acute and chronic symptoms associated with altered states of health (Hansen & Taylor-Piliae, 2011).

A Bowenwork treatment consists of a series of moves on the surface of the skin, gentle enough to avoid introducing discomfort, but firm enough to displace the skin and surrounding tissue by approximately one inch. A certified Bowenworker performs the moves on a client while they are usually in a supine and prone position. Clients may perform some moves on themselves during an acute injury, but the treatments are typically done by the Bowenworker in a clinic setting. There are standard moves for general stabilization of health and the overall system, and specific moves intended to treat specific and acute ailments. The treatments often are individualized, as many complementary treatments are, to meet the specific needs of the person and address either one or multiple issues. One aspect of treatments consists of required, two-minute pauses between sets of moves to allow for integration of moves throughout the body (Amato, 2001; Mechner, 2003; Olafimihan & Hall, 2002). A treatment can last from 30 minutes to two hours.

The theory about Bowenwork's mechanism is derived from observations in clinical practice. To date, there is no scientific evidence published in the literature to substantiate the theory. There are a few publications from a variety of health care providers that have similar theories about what is happening at a physiological level (Amato, 2001; Olafimihan & Hall, 2002; Shapiro, 2004). Findings from most of the published research studies to date (n=8) showed favorable outcomes for pain relief, fewer migraine headaches, and improved shoulder mobility (Carter, 2001, 2002; Dicker, 2001, 2005; Hansen & Taylor-Piliae, 2011; Long, Huntley, & Ernst, 2001; Potter, 2002; Stephens, 2006). Bowenwork is effective for management of pain, with substantial results reported on pain reduction in health conditions ranging from

frozen shoulder and sciatica to chronic conditions such as back pain and lymphedema (Carter, 2001, 2002; Dicker, 2001; Lund, 1999; Stiles, 2003).

A literature review on the published works of Bowenwork revealed the need for utilizing standardized tools and statistical analysis. The studies reviewed had varying degrees of methodological problems, including type of sampling technique, incomplete description of the study sample and procedures, and the lack of standardized measurement tools (Dicker, 2001, 2005; Marr, Lambon, & Baker, 2008; Potter, 2002). Only a few studies utilized standardized measurement tools to assess health-related outcomes such as joint range of motion, hamstring flexibility, and mobility (Carter, 2002; Marr et al., 2008; Potter, 2002; H. Williams, 2008). This lack of attention to methods discredits the results in the medical scientific community. Marr et al. (2008) conducted a randomized clinical trial on 116 community dwelling healthy volunteers and reported a statistically significant improvement in hamstring flexibility, using an electrogoniometer. The study lacked adequate descriptive data, though reported a significant result (t -test, $p < 0.01$), and failed to mention the second group (Marr et al., 2008). Therefore, the study quality was low when compared to other published work (Hansen & Taylor-Piliae, 2011). Even though better methodology is advised, the amount of improvement documented on outcomes cannot go unrecognized.

The one systematic review done on Bowenwork revealed that 53% of the studies reported that Bowenwork was effective for pain reduction, and 33% reported that it improved mobility (Hansen & Taylor-Piliae, 2011). Bowenwork has also been used to treat conditions of migraines, asthma, temporomandibular joint pain, colic in babies, coccyx injuries, infertility, breast tenderness, concussions, fibromyalgia, and sciatica (Amato, 2001; Dicker, 2005; Mechner,

2003). Complexity science is useful when trying to explain the theoretical mechanism for how these outcomes improve clinically. The physiological improvement of range of motion is experienced when existing or alternate patterns may be stimulated through Bowenwork. In addition, the perceived experience of reduction of pain may be the result of re-organization mentally and emotionally.

Only one case study to date has explored the effects of Bowenwork on lymphedema (Lund, 1999). Lund reported the effects of treatment for lymphedema, not only for cancer treatment-related lymphedema, but also inherited forms of lymphedema. This study lacked adequate descriptive data and statistically significant results. However, arm measurements were consistently taken before and after treatment. A measurable reduction in edema was recorded, either through weight or garment size, with greater incidence in the lower extremities, and improvements were noted in the mobility of the arm.

Further studies may be able to examine breast cancer survivors' perception of their symptoms, involvement and commitment to treatment strategies with Bowenwork. Since adherence to treatment by women with lymphedema is low, which is often attributed to time-consuming procedures that are difficult to perform when function is limited (J. M. Armer, 2005), Bowenwork may offer a more manageable therapy; it is simple and requires minimal to no supplemental management by the individual.

Concerns about the safety and comfort of complementary interventions are vital when considering a newer complementary management strategy. The literature reviewed does reference the procedures and client responses, indicating satisfaction with the procedures both physically and mentally (Carter, 2001, 2002; Mechner, 2003). However, the studies lack the

required documentation of physiological and mental responses from the entire sample (Hansen & Taylor-Piliae, 2011).

The science of Bowenwork merits further investigation with improved research methods. Even though the recent review produced a substantial amount of written information on findings with Bowenwork, it is evident that science requires more intense research to support and validate health-related outcomes (Hansen & Taylor-Piliae, 2011). The scholarly discussions on Bowenwork and the growing literature indicate that it is worth investigating the outcomes associated with this work. Through the scientific exploration of Bowenwork, the science behind its mechanisms will become more clearly understood (Hansen & Taylor-Piliae, 2011).

Summary

The phenomenon of lymphedema related to breast cancer treatment is difficult to predict and even understand (M. R. Fu et al., 2009b). Studies indicate that many women experience some degree of lymphatic system damage as a result of treatment, yet not all women develop lymphedema (J.M. Armer et al., 2009; M. R. Fu et al., 2009b). It is quite clear that the degree of surgical interventions, axillary lymph node dissection, sentinel lymph node biopsy, chemotherapy and radiation affects the incidence of lymphedema and the degree of symptoms (Helyer et al., 2009; Khan, 2009; McClure et al., 2010). Current symptom management strategies that are available are limited. However, research is continuing to identify complementary options.

Even though research does embrace the concepts of SMT, there are gaps when using a theoretical framework that includes the symptom experience and the complexity of individual. The literature review provides an opportunity to introduce a new management strategy that

considers the interconnectedness of multiple concepts on outcomes.

CHAPTER 3 METHODOLOGY

The purpose of this pilot study among women breast cancer survivors with lymphedema was to 1) determine recruitment and retention rates, 2) determine adherence to a Bowenwork intervention, 3) assess the safety and comfort level of the Bowenwork intervention, and 4) examine the effects of a Bowenwork intervention on lymphedema symptoms (i.e. quality of life, functional status, perceived pain, limb circumference and range of motion of the affected arm). This chapter will describe the methods for this pilot study including the design, sample, eligibility criteria, recruitment strategies, enrollment, the Bowenwork intervention, study measures and data analysis.

A pilot study is instrumental in working through the logistical steps of a study, and can address methodological concerns of recruitment and retention issues, procedures and protocols, and measuring outcomes (Van Teijlingen & Hundley, 2002). The pilot study can test any aspect of the larger study that could potentially cause failure in a larger study; in effect, the pilot can potentially maximize its success (Van Teijlingen & Hundley, 2002). Selected components are subjected to testing on a smaller level to determine their feasibility. Even though some pilot studies are merely smaller versions of the larger research project, the specific aims usually have a different focus (Lancaster, Dodd, & Williamson, 2004). As such, this pilot study explored the effects of Bowenwork on lymphedema symptoms among women breast cancer survivors; it will not be powered to find statistically significant results.

Background on Pilot Studies

The overall purpose of pilot studies, including this study, is to first test the feasibility of a larger study. Pilot studies are an efficient way to proceed with future CAM research. Pilot

studies are categorized into either internal or external types (Lancaster et al., 2004). External pilot studies are conducted independently prior to the main study, whereas internal pilot studies are conducted concomitantly with the main study (Lancaster et al., 2004). External pilot studies are conducted to determine feasibility. This study was an external pilot study, examining the effects of Bowenwork as a symptom management strategy for lymphedema among women with breast cancer. An external pilot study provides the best information possible to support further investigation of the intervention and allowing for testing of the methods and procedures so that any aspect of feasibility can be determined. Strategies to reach into multiple communities can easily be identified and evaluated during pilot studies (Vickers, Rusch, Malhotra, Downey, & Cassileth, 2006). Multiple pilots report such limitations, such as randomization procedures which allow the researcher to make improvements to the full study (Darnall, Aickin, & Zwickey, 2010; Esch, Duckstein, Welke, & Braun, 2007). Methodological concerns for performing pilot studies encompassed recruitment and retention issues, procedures and protocols, and measuring outcomes (Van Teijlingen & Hundley, 2002)

Study Design

The study design was a quasi-experimental, repeated measure design. There was no control group or random assignment. For this pilot study, it was decided to only have one group receiving the six-week long intervention of Bowenwork, consisting of four Bowenwork treatments approximately five to ten days apart. Each participant served as his or own control and received study assessments prior to, during, and following the intervention.

Sample

A convenience sample of women breast cancer survivors with unilateral treatment-related lymphedema was targeted for enrollment. A total of twenty-eight women were recruited to participate in this study. For pilot studies that have objectives related to feasibility, such as this one, sample size is less of a concern. However, some guidance is available on sample sizes for randomized control trials specifically for pilot studies (Hertzog, 2008). The ranges were in this report based on actual studies, and it was estimated that 10-40 participants per group offered sufficient information (Hertzog, 2008). This sample size was achievable because, in the United States, 261,000 women were diagnosed with breast cancer in 2010, indicating 2.5 million survivors (ACS, 2009). Similarly, in 2007, the Arizona Department of Health reported that breast cancer incidence increased from 100.7/100,000 to 106.9/100,000, and projected that there would be 10,000 women breast cancer survivors in Arizona by 2011. Based on the current calculated incidence of lymphedema in the U.S. it was estimated that four thousand of these Arizona breast cancer survivors experienced some degree of lymphedema (Ahmed et al., 2008).

Inclusion Criteria for Women Breast Cancer Survivors with Lymphedema

- Over 18 years of age
- Diagnosis of any stage of breast cancer and completion of treatment including:
 - Sentinel lymph node biopsy
 - Lumpectomy
 - Partial mastectomy
 - Segmental mastectomy /radical mastectomy
 - Axillary lymph node dissection

- Intravenous chemotherapy
- Radiation
- Post-treatment for breast cancer without a specified time frame
- Unilateral arm lymphedema with or without a diagnosis (if no diagnosis, at least two centimeters increase in arm circumference, based on comparison with unaffected arm)
- Continuation of current treatment such as hormone therapy (such as tamoxifen, aromatase inhibitors) and targeted therapy (such as monoclonal abs, Herceptin, T-K inhibitors) was acceptable
- Usual care for lymphedema such as compression therapy, manual lymph drainage, and the use of arm sleeves was acceptable

Exclusion Criteria for Women Breast Cancer Survivors with Lymphedema

- Currently receiving surgery, radiation, or intravenous chemotherapy treatment for primary breast cancer, recurring breast cancer, or metastatic disease
- Currently receiving treatment for any other type of cancer
- Bilateral lymphedema
- Current hospitalization for acute care
- Physical limitations requiring bed rest and/or inability to stand without assistance
- Pregnancy

Selection of the exclusion criteria was specifically identified to support the integrity of the study. Participants were not allowed to enroll unless they finished active treatment. Active treatment for breast cancer, adjunct cancer treatments, or acute hospitalization which may have involved pain medications would have influenced the results of the study. Women with bilateral

lymphedema were excluded to keep the sample characteristic as homogeneous as possible. Women who were debilitated and not able to perform the at-home exercises, which included standing, were excluded from the study. Since the effects of Bowenwork on pregnant women were not reported in the literature, these women were excluded, as well.

The study participants were allowed to continue with their usual care for lymphedema. However, they were asked to avoid any other complementary modalities including acupuncture, acupressure, aquatic therapy, relaxation therapy, ice, heat, magnets, electrical stimulation and Reiki. These modalities would have interfered with the effects of Bowenwork and contaminated the results. Participants were able to ask the PI any questions about other CAM practices that might have been influential. If they were already receiving one of these therapies and would not stop the therapy during the pilot, then they were considered ineligible for the study.

Recruitment, Enrollment and Retention

Recruitment and retention play a major role in all studies, and are essential for study success. Without study participants, the study cannot progress nor can effects be measured (Shadish, Cook, & Campbell, 2002). Recruitment issues surface when there are limited sites and resources such as support groups, local and national organizations. This pilot study focused on recruitment and retention of 20 participants. Enrollment was defined as the percentage of total participants who signed consent. Retention was defined as the percent of participants who completed the intervention, which included the baseline questionnaire and final follow-up appointment. The PI was responsible for the recruitment and study enrollment. The participants were recruited from several sources, including four breast cancer support groups in Arizona (University of Arizona Cancer Center and Arizona Oncology in Tucson, Flagstaff Medical

Center in Flagstaff, and Virginia G. Piper Cancer Center in Scottsdale). Recruitment was also conducted through the Beat Cancer Boot Camp organization in Tucson. Flyers for the study were handed out during all the group meetings (see Appendix E for flyer).

The PI gave presentations at four support group meetings and screened all participants. Potential participants were instructed to contact the PI for further information (Appendix H). The PI used a standardized recruitment script (see Appendix F for script). Further recruitment was done via the internet through a community cancer survivor resource program called, LinkIN! Community Cancer Connections. The website offered a link to the information on the flyer and email contact information for the PI. These centers, clinic and electronic resource served as the setting for supplying initial information to the PI on potential participants and data collection. Finally, recruitment occurred locally in Tucson, Scottsdale and Flagstaff and through the website newsletter at the National Lymphedema Network (see Appendix G for website posting). In general, patients had completed their treatment after six months. These women continued to be seen by their oncologist and surgeon for follow-up assessments, plus diagnostic and laboratory testing. They were screened for the study once active treatment was completed.

Interested participants were instructed to contact the PI for further information either by telephone or email, and they were interviewed by the PI either in person or by telephone to determine eligibility. The screening tool included the inclusion and exclusion criteria and the participant's commitment to the six-week intervention (see Appendix H for screening tool).

Retention was essential for achievement of the desired sample size of 20 women for the duration of the study. Evaluation of retention was important to determine. Drop-outs during the

study would have caused impeded implementation of a future larger study. Retention was tracked through the duration of the intervention.

Protection of Human Participants

Approval to conduct this research study was obtained by the Institutional Review Board (IRB) of the University of Arizona, prior to implementation of the study (see Appendix I for IRB approval form).

Informed Consent

The PI informed potential participants about the purpose and nature of the questions, and then asked them to provide verbal consent to continue the conversation. The PI provided potential participants with the opportunity to decline participation, refuse to answer any questions, and ask questions. Informed consent was given either in person or over the telephone, after the PI read the entire consent to each potential participant (see Appendix K for copy of consent). Once the participant agreed, the PI signed the consent form to validate the process. The consent process was approved by the University of Arizona Institutional Review Board (IRB). As instructed by the IRB, the signature of the participant was not necessary on this consent, as data were de-identified. The participant's last name was not recorded on any forms. The participants were given a copy of the consent if they requested a copy. The consents were stored at the PI's home office in a locked file cabinet. The PI collected the demographic information from each participant and stored the data in the participant's file (see Appendix L for demographic form). Demographic items addressed age, gender, marital status, educational level, employment status, income, ethnicity, and self-reported breast cancer and lymphedema

information. The demographic information was labeled with the participant code and kept in the locked file cabinet at the PI's home.

Confidentiality

Once the participants were determined to be eligible for the study, they were given an identification code. The code included the first three letters of their first name followed by a number. The numerical order began with one and ended with 23. As part of the screening review, the PI had telephone numbers and addresses for contact information. The screening forms were kept in a locked file cabinet at the University of Arizona, College of Nursing. A master coded list of all screened women and consented participants were kept in the PI's home computer that was passcode protected (see Appendix J for master list form).

Risks to Participants

There were minimal risks for participating study, but the PI informed participants that they could discontinue participation for any reason at any time during the study. Safety was determined by the reporting of changes in condition of health and adverse events (Turner et al., 2011). Safety and comfort level of the Bowenwork intervention was assessed by recording each participant's personal response to each Bowenwork session, including any changes in current medical condition, and supplemented by observations made by the Bowenworker (see section on Intervention Fidelity). The Bowenwork moves did not penetrate the surface of the skin. Recognizing that some areas of the body may be sensitive to even the light touch of Bowenwork, the PI reassured the participants that they could discontinue the study at any time in the event of discomfort or unpleasant feelings. Occasionally, Bowenwork is known to generate a physiological and/or psychological response such as nausea, dizziness or tears as a result of

stimulation in damaged areas. Participants were encouraged to discuss how they felt with the Bowenworker and determine their comfort level for continuation. The Bowenworkers documented any observed or subjective responses from the participants during and after the procedure. The participants were also asked if they experienced any changes in their condition that would interfere with them continuing with the study to monitor safety of the intervention. The PI provided Bowenworkers with a list of medical and psychological resources to offer to the participants, if indicated (see Appendix M for resource list).

Certification of Research Team

All persons who assisted with the study were required to complete the Collaborative Institute Training Initiative (CITI) training prior to participation (see Appendix N for verification of training form). These persons included Bowenworkers that were hired by the PI to assist with the data collection. Each Bowenworker received a policy and procedure manual with all forms. The PI was available via phone or in person.

Intervention Fidelity

Four different Bowenworkers provided the intervention for this study. These Bowenworkers were chosen to participate in the study based on their completion of standardized testing modules through Module Ten from the national Bowenwork Academy USA. The Bowenworkers were not responsible for recruitment. To ensure fidelity of the assessments and intervention, a specialized group instructional session was held with all of the Bowenworkers and the PI. To ensure consistency in delivering the intervention and precision in obtaining the physical measurements, the PI developed a certification check sheet for delivery of the

intervention and measurements. All Bowenworkers were required to be certified by the PI on the study techniques to deliver the intervention prior to initiation of study (see Appendix O for certification form). This certification was necessary for interrater reliability. The Bowenworkers performed all moves on each other, while the PI observed for accuracy and consistency between them to ensure that all of them were performing the same moves in the same fashion. In addition, the PI taught all Bowenworkers identical measuring techniques for arm and ankle circumferences with a tape measure, and shoulder range of motion with the goniometer. The PI purchased and gave identical tape measurers and goniometers to all of the Bowenworkers. The Bowenworkers were allowed to keep the tape measurer and goniometer at the end of the study.

Bowenwork Intervention

Each participant received four Bowenwork treatments approximately five to ten days apart, for a four week period. There were intervention protocols for each of the four treatments with each participant receiving the same sequence of moves during each session (see Appendix P for list of moves). Participants were asked to wear comfortable lightweight clothing; they were not asked to remove any garments during the intervention. Bowenwork moves were performed over light clothing or directly on the surface of the exposed skin. The Bowenwork intervention involved noninvasive moves done by the hands, using just enough gentle pressure to stimulate the structure they were intended to affect (i.e. nerve, tendon, muscle and fluid), with enough sensitivity to avoid discomfort. Each participant received the same treatment during each session. Even though individualized treatments are more common with CAM practices, including Bowenwork, these protocols were followed to facilitate the measurement of outcomes and intervention fidelity. Each of the moves was specifically chosen by the PI based on

anatomical location and the postulated theory of Bowenwork (see Appendix Q for anatomical location and rationale). For example, session three included moves on the neck to “milk” or drains the lymphatic channels behind the sternocleidomastoid muscle along the trachea to the clavicle. The basic purpose of these moves was to normalize muscle tension and fascial connections from the shoulder to the torso and stimulate neural pathways.

Each Bowenworker delivered the intervention during office hours at his or her individual clinics or the designated cancer center, after permission to use the facility was obtained by the PI (see Appendix R for authorization letters). Authorization to use the registered copyright of Bowenwork was obtained for future publications (see Appendix R for authorization letters). The Bowenworkers documented each session on the forms provided for each session (see Appendix S for documentation form). Each Bowenworker obtained physical measurements (arm and ankle circumference and range of motion for the affected limb) and performed the intervention. Ankle circumference was added to measure a potential systemic response to treatment. The form included documentation on all sessions including specific intervention moves, participant responses and completion of requested exercises and questionnaires. Each participant received instructions and specific exercises for shoulder range of motion between the second, third, and fourth sessions and the final evaluation period. The exercises were gentle stretching movements performed at least three times prior to the next session and were easily done at home. The participants were also given written instructions to help remind them how to perform the exercises (see Appendix T for exercise instructions).

Study Procedures and Data Collection

The PI mailed or delivered in person a baseline self-report questionnaire for participants to complete and to bring with them to their first Bowenwork session. The questionnaire measured quality of life, functional status, and pain. A post-intervention questionnaire was given to the participants by the Bowenworker after their fourth Bowenwork session to be completed and returned when they returned for their last physical measurements at the fifth appointment. The PI reviewed all forms for accuracy and completeness at the time of data collection. The questionnaires were either mailed to the PI or picked up from the Bowenworkers' offices by the PI. Baseline information, physical measurements, Bowenwork sessions, and final evaluation timeframes are shown in Table 2.

Table 2. Timeframe of Data Collection for Analysis

Baseline Information	Bowenwork session 1	Bowenwork session 2	Bowenwork session 3	Bowenwork session 4	Post assessment Appointment 5
Demographics	ROM	ROM	ROM	ROM	ROM
Questionnaire	Shoulder	shoulder	shoulder	shoulder	shoulder
SF-36	Arm/ankle	Arm/ankle	Arm/ankle	Arm/ankle	Arm/ankle
FACT-B					
BPI	circumference	circumference	circumference	circumference	circumference
					Questionnaire
					SF-36 FACT-B BPI

Measure for Health-Related Quality of Life

Health-related QOL was measured using the *Medical Outcomes Short Form Health Survey* (SF-36). This survey is a 36-item, self-administered instrument for assessing health-related quality of life that takes approximately 15 minutes to complete (see Appendix U for SF-36 questionnaire). It includes the domains of physical functioning limitations due to health, role limitations due to emotional problems, energy/fatigue, emotional well-being, social functioning, bodily pain and general health. This scale is scored using a code for answers and ratings and each concept given a score of 0-100; a higher score indicates a higher quality of life (J. Ware, Snow, & Kosinski, 1993). The SF-36 measures two main composite scores: perceived physical and mental health. In addition, the SF-36 has eight subscales: physical functioning (PF), role physical (RP), bodily pain (BP), general health (GH), vitality, (VT), social functioning (SF), role emotion (RE) and mental health (MH).

The subscales were not evaluated in this study due to study design and sample size. However, the physical composite summary (PCS) and mental composite summary (MCS) were sufficient to examine the effect of the intervention for this pilot study. The PCS measure was a combination of specific questions in the subscales for PF, RP and BP. The reported re-test reliability of this measure ranged from 0.74 to 0.98 (J. Ware et al., 1993). The MCS measure was a combination of specific questions in the subscales for GH, VT, and SF. All of the scales were first coded and given a summary score (J. E. Ware, Jr. & Sherbourne, 1992). Once the coding was completed a higher score was indicative a higher quality of life.

Measure for Functional Status

Functional status was measured using the *Functional Assessment of Cancer Therapy-Breast* (FACT-B) index. This index is a 37-item, self-administered questionnaire that takes approximately 25 minutes to complete (see Appendix V for FACT-B questionnaire). It is specific to breast cancer patients and includes six domains: physical well-being, social/family well-being, emotional well-being, functional well-being, relationship with doctor, and additional concerns. Items are scored on a five-point Likert scale with responses ranging from zero (not at all) to four (very much). All of the questions were specifically written to generate a positive response and if necessary answers can be recoded for scoring (Webster, Cella, & Yost, 2003). Scoring for this measure is based on the summation of scores for each individual measure, with a higher score indicating a good response (Webster et al., 2003). The subscales for physical well-being (PWB), emotional well-being (EWB), and additional breast concerns (BAC) were all recoded into the positive direction, reflecting a high score as positive. The overall functional status score was calculated by a summation of each of the five subscales. The physical and functional well-being (PFWB) was determined by an aggregate score of PWB, FWB and BAC and used for reporting any changes in functional status (Brady et al., 1997). Internal consistency was reported to be 0.90 with supporting evidence of validity by measuring sensitivity to change ($p=.006$) and the significant correlation with other measures for quality of life. (Brady et al., 1997).

Measure for Pain

Pain was measured using *The Brief Pain Inventory* (short form), which is a self-administered questionnaire that contain nine items and takes approximately 15 minutes to complete (see Appendix W for PBI questionnaire). It measures the amount of pain during daily

activities. Pain responses were measured on a numeric scale ranging from zero(no pain) to ten (“as bad as you can imagine”) and included the nature of pain and amount of information provided to evaluate pain (Daut, Cleeland, & Flanery, 1983). The BPI also measured with additional items the severity of pain and the interference of pain. The BPI was scored using the comparison of the means of the pain items, the severity items, and the interference items. No psychometrics was available for this measure.

Physical Measures

Range of motion and arm and ankle circumference data were collected prior to implementation of the intervention each week and one week following the last intervention session, for a total of 5 times. The affected limb of each study participant was assessed in two ways. First, the Bowenworker assessed range of motion (ROM) of the affected arm using a goniometer. All Bowenworkers received a JAMAR EZ-Read goniometer and were certified to use it (see Appendix O for certification form). The Bowenworkers measured both abduction and forward flexion for range of motion. These two assessments were chosen to evaluate any reduction in fluid based on movement of lymphatic fluid and softening of adhesions from breast cancer treatment. Second, the Bowenworker obtained arm and ankle circumference measurements of the affected side using a Sammons Preston retractable tape measure (see Appendix O for certification form).

All the physical measures that were done by the Bowenworkers were done in the same fashion. They were instructed on the precision of anatomical locations for each measurement. Each measurement had specific guidelines to follow prior to documentation. The certification process ensured their understanding by a required return demonstration (Appendix O).

Data Analysis

Descriptive statistics for all variables were calculated (i.e. mean, standard deviation, frequencies and percentages). Paired t-test was performed to compare the differences from baseline and post-intervention for quality of life (SF-36, functional status (FACT-B) and pain (BPI). Analysis of variance (ANOVA) was performed to compare physical measurements (range of motion and arm and ankle circumference) overtime (sessions one through post intervention). The α level for significance was set at <0.05 . All data were entered using a double-entry technique and analyzed using the Predictive and Analytical Software program (PASW 18.0).

Aim One: Recruitment and Retention

Recruitment was evaluated by tracking the number of total contacts, the type of referrals, and the enrollment of participants. Enrollment was determined if the participant consented to participate. Retention was evaluated by tracking the participants who enrolled in the study through the completion of the study. Retention period was from signing of the consent to submitting the baseline questionnaire and getting their final physical measurements. Recruitment and retention rates were reported as frequencies and percentages. Descriptive statistics were calculated for all variables and included mean, percentile and sum.

Aim Two: Adherence to the Bowenwork Intervention

Adherence for this pilot study was defined as the completion of all the Bowenwork interventions during the required time period, and adherence with home exercises during specified time periods. The certified Bowenworkers gave minimal exercises for supplemental management; these were performed following the standardized treatment protocols for shoulder

symptoms. The exercises consisted of gentle range of motion movements done at home to support and enhance the received treatment. The adherence rate was determined by tracking and recording the number of Bowenwork sessions offered and the number actually attended by the participants, and compliance with performing the instructed arm exercises after required sessions. Descriptive statistics were calculated for all variables, including mean, standard deviation, frequency, percentile, and sum.

Aim Three: Safety and Comfort Level of the Bowenwork Intervention

Safety was defined for this pilot study as the percentage of total reports of change in medical conditions that caused a drop-out in the study or resulted in harm. Even though it was recognized that due to the noninvasiveness of the Bowenwork technique and the gentle amount of pressure, harm is unlikely, clear documentation was prudent for future studies. The safety and comfort level of the Bowenwork intervention was determined by an ongoing assessment during the Bowenwork sessions. Any changes in medical conditions were documented at the beginning of each session. Changes were reported to the PI to determine the significance of the change and if continuation was safe and appropriate. The participants were able to discontinue participation at any time during the study. If any significant changes had been reported that would have interfered with the continuation of the intervention, the PI would have discontinued them from the study. A subjective assessment of the participant's comfort level was assessed during the sessions. Each participant was asked if she was comfortable and if she experienced any nausea or tearfulness. Descriptive statistics were calculated for all variables, including mean, standard deviation, frequency, percentile, and sum.

Aim Four: Effects of the Bowenwork on Lymphedema

The effects of the Bowenwork intervention on lymphedema symptoms were determined by measuring the quality of life, functional status, perceived pain and physical measurements of the affected arm. The paired *t*-test was used to examine the difference in mean scores between the baseline scores and post intervention scores for quality of life (SF-36), and functional status (FACT-B) and perceived pain (BPI). By using this test, not only was the difference between the means determined but also the measure of variability between the pre- and post-intervention evaluation of scales.

Repeated measurements of data were collected for physical measurements (range of motion and arm and ankle circumference). These data analyzed using the analysis of variance (ANOVA). The initial measurements were taken prior to the first Bowenwork session and served as the baseline. Measurements were taken on the arm circumference and range of motion of the affected arm. In addition, the ankle circumference was taken on the same side. The ankle measurement was taken to assess a potential systemic effect. The arm measurements were taken in centimeters, in three distinct locations. The arm measurements that were taken included the upper arm, lower arm and wrist. The shoulder range of motion was documented in degrees with the standardized measurement tool of the goniometer for both abduction and forward flexion. The final measurements were taken during the fifth appointment approximately five to ten days after the fourth Bowenwork session and served as the post-intervention evaluation.

CHAPTER 4 FINDINGS

The purpose of this pilot study was to 1) determine recruitment and retention rates 2) determine adherence to a Bowenwork intervention, consisting of four Bowenwork treatments; 3) assess the safety and comfort level of the Bowenwork intervention and 4) examine the effects of a Bowenwork intervention on lymphedema symptoms (i.e. quality of life, functional status, perceived pain, and range of motion and limb circumferences of the affected side).

Characteristics of Settings and Sample

Data collection occurred in Tucson, Scottsdale, Flagstaff, and Prescott, Arizona. The Tucson, Flagstaff and Prescott group received the intervention at one of four locations consisting of private Bowenwork practices in an office setting. The seven participants who were seen at the Virginia G. Piper Cancer Center in Scottsdale received the intervention in the location using transportable massage tables. The Bowenwork sessions were performed in a quiet place, free from public access and free of any interruptions.

Twenty-one women breast cancer survivors with unilateral lymphedema were recruited into the study. One woman who enrolled dropped out and never completed the initial baseline evaluation or started the intervention. The characteristics of the remaining women (n=20) who enrolled and completed the baseline evaluation and completed the intervention were listed in Table 3. The mean age of the sample was 60.8 years. Participants were predominantly Caucasian (95%), married (55%), financially well off (40%), and well educated (100%). The type of breast cancer treatment was self-reported by the participants. The majority of the women reported receiving chemotherapy (80%) or radiation (75%) or a radical mastectomy (65%). The

majority of the women had received either a lymph node biopsy or axillary lymph node dissection (65%).

Aim One: Recruitment and Retention Rates

Twenty-eight women were recruited from various sources as shown in Table 4. Eighteen women were recruited from Tucson and 10 received their intervention in Tucson. Eight women were recruited from Scottsdale; seven received their Bowenwork intervention at the Virginia G. Piper Cancer Center and one in Prescott. Two women were recruited from Flagstaff and received their intervention in Flagstaff.

Table 3. Characteristics of the Study Participants

Description	Range	Mean	SD	Total	Percentage
Age	48-76	60.8 yrs.	8.1 yrs.	(n)	(%)
Ethnicity					95
Caucasian				19	5
Latina/Hispanic/Mexican				1	
Annual Family Income					
>75,000				8	40
<\$15,000				4	20
\$16,000-24,999				3	15
50,000-74,000				2	10
25,000-34,999				1	5
35,000-49,000				1	5
Time Post Breast Cancer Treatment					
1 year or less				79	35
1-3 years				6	30
>10 years				5	25
3-5 years				1	5
5-6 years				1	5
Type of Breast Cancer Treatment					
chemotherapy				16	80
radiation				15	75
radical mastectomy				13	65
Sentinel lymph biopsy				7	35
axillary lymph dissection				6	30
lumpectomy				4	20
partial mastectomy				3	15
hormone therapy				3	15
targeted therapy				3	15
segmental mastectomy				1	5
				0	0
Marital Status					
Married				11	55
Single				5	25
Divorced				2	10
Widowed				1	5
Separated				1	5
Highest Education					
College				13	65
Graduate				5	25
Junior College				2	10

Table 4. Recruitment Sources, Responses and Enrollment

Source	Number of referrals (n)	Enrolled into study (n)	Conversion referral ratio (%)
Flyer	5	3	60
Support Group	9	9	100
Meetings			
Nurse Case Manager	2	2	100
Oncologist	5	3	60
Radiologist Oncologist	2	1	50
Occupational Therapist	4	2	50
Friend	1	1	100
Total	28	21	75

A total of 28 women were screened for eligibility shown in Figure 3. Of the 21 women who were enrolled in the study, twenty continued on to receive the intervention and completed all sessions. One woman dropped out of the study before completion of the baseline questionnaire or start of the intervention. Ninety-five percent of the women who enrolled were retained and completed the intervention.

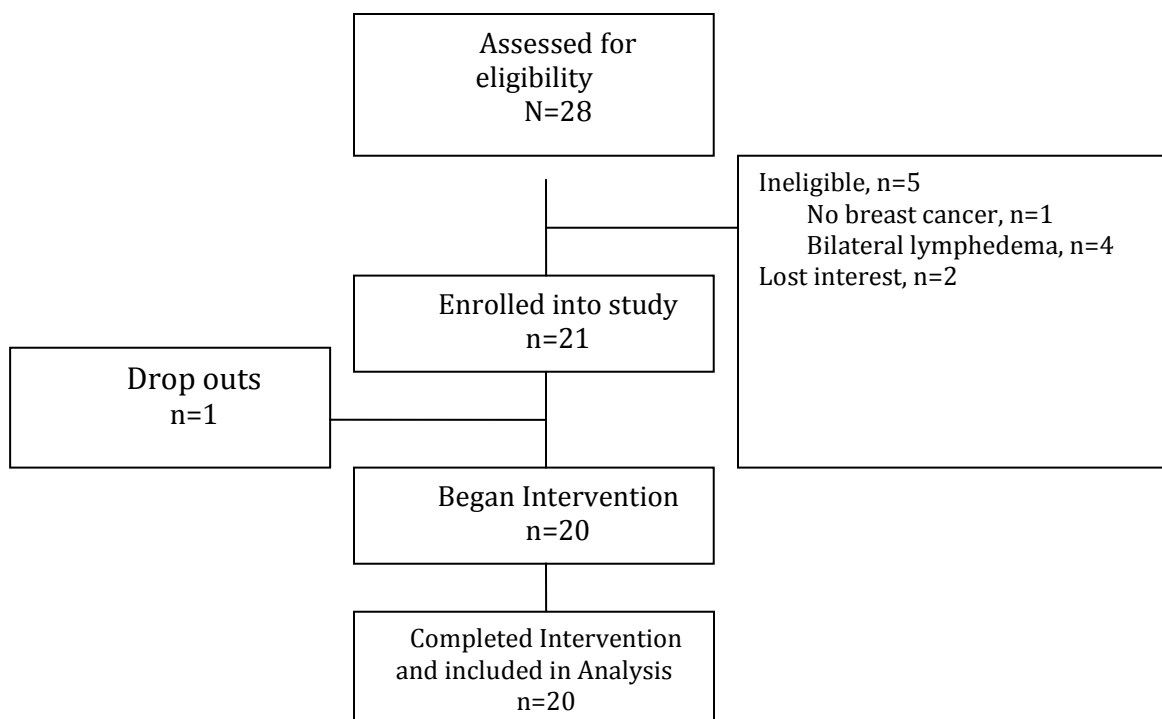


Figure 3. Flow Chart of Participants Throughout the Study. Recruitment and enrollment took place between June 2011 and September 2011. Data was collected through October 2011.

Aim Two: Adherence to the Bowenwork Intervention

Adherence to the Bowenwork interventions was determined by two factors. One, that the participant received four sessions at least five to ten days apart. Second, that the participant followed the instructions to perform home exercises between sessions two and three, three and four, and session four and final evaluation, and then returned questionnaires and received final measurements. The 20 participants who continued on with the study after enrollment were all compliant with adhering to scheduling and receiving four sessions, in addition to the fifth follow-

up appointment for evaluation. There was 100% adherence to receiving all of the required Bowenwork interventions.

The adherence to performing home exercises was acceptable. Nineteen out of 20 participants (95%) reported adherence between session two and three. Eighteen out of 20 participants (90%) reported adherence between session three and four. Twenty out of 20 participants (100%) reported adherence between session four and the final evaluation period. Adherence to the intervention and home exercises was high at 100% and 95%, respectively.

Aim Three: Safety and Comfort Level of the Bowenwork Intervention

The ongoing assessment of the safety of the intervention indicated that the intervention was safe. Safety was determined by a reported major change in medical condition shown in

Table 5. Safety Evaluations During Intervention Sessions

Assessment period	Session 2 n=20	Session 3 n=20	Session 4 n=20	Final evaluation period n=20
Report of minor changes in medical condition	2	2	4	0
Identified major changes in condition	0	0	0	0

The 20 participants received 80 sessions in total included in the evaluation. The participants reported a low percentage of discomfort during the intervention. The range of percentages from session one to session four was 25% to 35%. Eight sessions reported minor changes in condition documented at the beginning of the Bowenwork sessions. One percent (8/80) of those who received the intervention elicited a response that required evaluation for continuation of the

intervention. For example, one of the participants reported changes that had to do with her thyroid medication. Another reported major migraine headaches that were being evaluated prior to the start of the study. One participant reported a new development in her breast cancer recovery after an annual mammogram. She was offered the choice to drop out of the study, but decided to continue and complete the study. She was through the intervention prior to any decision on further treatment.

Comfort level was determined by asking participants if they were comfortable and if they experienced any nausea, dizziness or tearfulness shown in Table 6.

Table 6. Comfort Level of Intervention

Assessment period	Session 1 n=20	Session 2 n=20	Session 3 n=20	Session 4 n=20
Discomfort*	6	5	5	7

*physical discomfort, nausea, dizziness or tearfulness

Some participants reported unusual sensations or feelings they described as an electrical (n=2) or tingling sensation (n=3) after the moves and an increase in tenderness (n=1) or pain (n = 1). Some participants experienced familiar ailments of discomfort, such as their previously experienced back (n=2), arm (n=1) or hip (n=1) discomfort. Some participants also experienced tearfulness (n=3), lightheadedness (n=1) or nausea (n=1). After session four, unpleasant feelings decreased for back pain (n=1) and electrical or tingling sensations (n=2). Over 15% (13/80) reported a generalized feeling of relaxation during the intervention. An increase in sensations or

emotional release of tears was recognized by session four. The intervention never introduced pain or discomfort that caused any participants to discontinue or drop out of the study.

Each session was delivered with an expectation of lasting approximately 45 minutes to one hour. The average time for each session was 53 minutes shown in Table 7. Participants were allowed time between moves within sessions to integrate moves and allow for normalcy to return prior to continuing with the session if necessary. The average time between sessions was seven days, with a range from five to ten days.

Table 7. Length of Bowenwork Sessions

Session	Mean Minutes	SD
One	46.65	21.43
Two	54.54	16.96
Three	55.45	13.07
Four	56.75	11.95

Aim Four: Effects of Bowenwork on Lymphedema Symptoms

The effects of Bowenwork on lymphedema symptoms were evaluated through quality of life, functional status, perceived pain and physical measurements of arm range of motion and circumference. A paired t-test was performed to compare the baseline and post-intervention evaluation of quality of life (SF-36), quality of life and functional status (FACT-B) and perceived severity and interference of pain (PBI) shown in Table 8.

Table 8. Baseline and Post-Intervention Quality of Life, Functional Status and Pain

Scale	Baseline Mean/SD		Post Intervention Mean/SD		Paired t-test <i>t(df)</i>	<i>p</i>-value
PCS	42.31	8.18	43.10	9.44	-.58(19)	.57
MCS	44.97	10.22	49.74	12.00	-3.10(19)	.006
FACT-B	97.15	20.94	102.9	18.81	-3.38(19)	.003
PFWB	61.60	15.17	65.10	12.28	-2.35(19)	.030
BPI						
Severity	2.36	1.79	2.31	1.49	.21(19)	.838
Interference	2.68	2.34	2.28	1.89	1.06(19)	.303

PCS=physical composite summary, MCS, mental composite summary, FACT-B=functional assessment of cancer treatment-breast, PFWB= physical functional well-being, BPI=brief pain inventory

There was not a statistically significant difference between pain severity and pain interference from baseline to post-intervention from the beginning of the study to the end. A pre and post comparison of the twenty-one words chosen to describe pain revealed that 14(66%) of the descriptive symptoms increased shown in Table 9.

Table 9. Descriptive Analysis of Pain

Descriptors	Baseline/Post-Evaluation n(%)		Descriptor	Baseline/Post-Evaluation n(%)	
Aching	12(57)-	13(61)*	Penetrating	3(14)	4(19)*
Tender	8(38)-	9(43) *	Dull	2(10)	4(19)*
Numb	6(28)	8(38) *	Squeezing	1(5)	3(14)*
Deep	5(24)-	6(28) *	Radiating	3(14)	3(14)
Prickling	6(28)-	7(33) *	Miserable	3(14)	3(14)
Burning	7(33)	6(28)	Shooting	3(14)	3(14)
Tiring	4(19)	6(28)	Stabbing	2(10)	3(14)*
Nagging	6(28)	5(24)	Gnawing	0	3(14)*
Sharp	4(19)	5(24) *	Unbearable	0	1(5) *
Throbbing	5(24)	5(24)	Cramping	2(10)	2(10)
Exhausting	3(14)	4(19) *			

*= an increase in descriptive symptom

Physical measurements were analyzed by measuring the arm circumference in three locations and the abduction and forward flexion motion of the shoulder of the affected arm. In addition, the ankle circumference was measured on the affected side. The descriptive statistics for the arm measurements revealed a small reduction in arm edema in centimeters and a notable increase in range of motion measured in degrees shown in Table 10. The ANOVA was performed because of the multiple measurements taken during five separate time periods; session one, session two, session three, session four, and final post-intervention evaluation shown in Table 10. Physical measurements of the shoulder range of motion testing (abduction and

forward flexion) and upper and lower arm circumference were significantly improved following the Bowenwork intervention ($p < .05$).

Table 10. Descriptive Statistics and ANOVA of Physical Measures

Measure	SES1 Mean/SD	SES2 Mean/SD	SES3 Mean/SD	SES4 Mean/SD	SES5 Mean/SD	Change from Baseline Mean/SD	Univariate Repeated measures F(df)	p	eta ²
Upper arm	34.47/4.82	33.83/4.32	33.65/4.09	33.56/4.26	33.42/4.02	1.05/.80	5.57(4.00)	.001	0.23
Lower arm	24.24/2.92	23.51/2.43	23.68/2.78	23.75/2.86	23.33/2.73	0.91/.19	3.55(4.00)	0.01	0.16
Wrist	16.75/1.41	16.47/1.13	16.50/1.23	16.42/1.22	14.40/1.19	2.35/.22	1.95(2.41*)	0.15	0.09
Ankle	22.82/2.03	22.86/1.99	22.51/1.83	22.34/1.74	22.52/1.93	0.3/.10	1.98(2.39*)	0.14	0.10
ROM <i>abd</i>	123.9/32.35	141.2/27.68	138.5/27.62	145.7/26.46	144.5/26.55	20.6/5.8	5.44(2.47*)	0.01	0.22
ROM <i>ff</i>	123.7/23.56	131.4/21.79	136.1/21.13	136.9/21.91	141.1/20.86	17.4/2.7	5.60(2.71*)	0.00	0.22

SES=session, *=Greenhouse-Geisser correction, eta²=partial eta squared, abd=abduction, ff=forward flexion

Summary of Findings

The specific aims were all addressed during the study period. The goals identified for recruitment and retention were achieved with this population at the specified geographical location. The safety and comfort level of the Bowenwork intervention was documented and reported with each session. There were no major changes in medical conditions or levels of discomfort that caused harm or interfered with completion of the study. The participants demonstrated an interest and completed the study with a high adherence rate to the requested protocols. There was a statistically significant improvement in mental health, quality of life and functional status. In addition, there were statistically significant findings for a reduction in upper and lower arm circumference and an increase in arm forward flexion and abduction. While promising, these results examining the effects of Bowenwork intervention on lymphedema

symptoms must be interpreted cautiously due to the small sample size and the fact that this study was not powered to detect statically significant results.

CHAPTER 5 DISCUSSION

This final chapter will review the findings from the pilot study on Bowenwork and symptom management for women breast cancer survivors with lymphedema. The specific aims were 1) determine recruitment and retention rates 2) determine adherence to a Bowenwork intervention, consisting of four Bowenwork treatments 3) assess the safety and comfort level of the Bowenwork intervention and 4) examine the effects of a Bowenwork intervention on lymphedema symptoms (i.e. quality of life, functional status, perceived pain physical measurements of arm circumference and range of motion). Also described in this chapter are the strengths, limitations, and implications for future nursing research involving symptom management for chronic conditions while using Bowenwork as a complementary intervention.

Characteristics of the Sample

The women who were recruited and retained were college graduates (100%), Caucasian (95% with mean age 60.8 years.) and had an annual income of \$50,000 or more (55%). Though these findings may reflect the recruitment locations, they limit generalizability. The Arizona Department of Health Services reported that in the counties where the participants resided, there was a higher annual incidence of breast cancer in white, non-Hispanic women (8,490) compared to Hispanic, African-American, Asian and other (1,913) as of 2011 (ADHS, 2012). Other studies have reported that African American and Asian women have a greater severity of symptoms (M. R. Fu & Rosedale, 2009). In addition, other studies have reported that women with lower income and comorbidities have experienced a higher incidence of lymphedema (Cheville, Almoza, Courmier, & Basford, 2010; Ridner & Dietrich, 2008). The study sample lacked cultural diversity and a wider range of ages.

The majority of the women reported receiving chemotherapy, radiation, a radical mastectomy, and either, or combination of, a lymph node biopsy or axillary lymph node dissection. This was typical treatment for women who were at risk for developing lymphedema (Norman et al., 2009; Shih et al., 2009; Torres Lacomba et al., 2010). About one-third of participants did not report having a sentinel lymph node biopsy or axillary lymph node dissection; yet they still developed lymphedema. This phenomenon has not reported in the literature. This finding does support the theoretical framework for the unpredictability of lymphedema as a chronic condition, but it also was recognized that self-reporting could have produced erroneous results.

Aim One: Recruitment and Retention Rates

Recruitment from the three metropolitan settings generated a 75% enrollment rate. A sample size of twenty breast cancer survivors with lymphedema was achieved in four months. Breast cancer support groups were an effective recruitment strategy reflected in the nine referrals that enrolled and completed the study. Recruitment in the Tucson support groups was stressed, due to competing complementary therapies that the breast cancer survivors were involved in at the cancer centers. Reiki was offered and practiced at two of the Tucson locations interfering with the commitment to only practice one form of complementary therapy during the study.

Physician support was important for recruitment and was evident by the type of referrals. Community oncologist and oncology radiologist were interested in the study and willing to refer as soon as the lymphedema was identified, even if this was during current treatment.

Recruitment was limited to women who had completed breast cancer treatment. Women would

benefit from earlier recruitment during early stages of lymphedema (Chan et al., 2010; Fleysheer, 2010; Torres Lacomba et al., 2010).

Aim Two: Adherence to the Bowenwork Intervention

Adherence to the Bowenwork intervention was high. The women in the study were highly motivated to participate in a study that offered a low risk intervention to help improve their lymphedema. The high motivation was reflected in the 100% adherence to the Bowenwork sessions. These results contradicted published findings where adherence to treatment was low in women breast cancer survivors with lymphedema (J. M. Armer, 2005). Barriers to adherence included cost and difficulty with performing procedures alone. The recommended home exercises for the study were cost effective, very short, and easily done at home. Adherence for performing home exercises was high (90-100%). Further exploration is needed to evaluate why adherence was so high, especially if using the SMT that emphasizes the influences of person, environment and health. For example, SMT recognized influencing factors such as age or culture that was not diverse in this study that could also be a barrier to adherence for symptom management strategies.

Aim Three: Safety and Comfort Level of the Bowenwork Intervention

The Bowenwork intervention was safe. There were no major changes in medical condition reported. Participants reported sensations that were uncomfortable but never necessitated stopping the intervention or dropping out of the study. These subjective responses consisted of such feelings they described as electrical sensations, previously experienced pain, or increased tearfulness.

When considering the comfort level of the intervention, timing and dosage requires further consideration. Timing and dose of the intervention was a potential issue with the increase in subjective descriptors surrounding the sessions. The exact dose and time frame was purposeful to support consistency throughout the study. However, complimentary therapies are commonly tailored to meet the needs of the individual (Manheimer & Berman, 2006). It is not uncommon for timing and dosage to be adjusted during treatments for some complementary therapies; Bowenwork is no exception. Taking into consideration that lymphedema can be acute if recently diagnosed, or chronic as in this study, increasing the time between treatments and lowering the dose may benefit this condition when in the chronic stages. Chronic conditions may benefit from a greater time period between treatments and a lower dose allowing for a more gradual integration of realigned patterns or self-organization to occur during or following the intervention.

Aim Four: Effects of Bowenwork on Lymphedema

The effects of Bowenwork were examined during this study. However, this pilot study examining the effects of Bowenwork intervention on lymphedema symptoms must be interpreted cautiously, due to the small sample size and the fact that this was not powered to detect statistically significant results. Nevertheless, it was evident that the results of the statistical analysis on the data collected were promising. The instruments used for measuring quality of life and functional status did not present any difficulty for the participants. All of the summary scores for the SF-36 and FACT-B collectively increased from baseline to post evaluation which indicated a better quality of life and functional status post intervention. Considering the documented validity of these instruments and the consistent use of them in research, they were a

satisfactory choice for the pilot study. The findings in this pilot study were consistent with the literature supporting a proportional relationship between physical function and quality of life in breast cancer survivors with lymphedema (Ridner, 2005; Ridner et al., 2010; Tsao et al., 2010).

The BPI instrument presented some difficulties that were identified after completion of the study. Further examination of instruments for measuring pain, may be necessary for future studies. The data collected from the BPI needed additional review. The participants were asked to select from a list of descriptors their pain experience before and after the study intervention. The participants were not asked to only evaluate their symptoms surrounding their lymphedema and included an entire report of overall physical pain. These results were interpreted cautiously when evaluating the response to the intervention because they were not isolated to lymphedema.

The postulated theory of Bowenwork suggests that a single move can cause a vibrational wave from the surface of the skin reaching deep into the fascia and nervous system. (Hansen & Taylor-Piliae, 2011; Marr et al., 2008; Shapiro, 2004). Participants in this study experienced an increased perception of pain and uncomfortable feelings accompanied by tearfulness and dizziness. This aggravation of symptoms may have resulted from Bowenwork, i.e. from the release of tension and softening of the tissue. The tissue was softened and relaxed and the actual line of tension and trauma became more obvious to the participant. The body normalized after a Bowenwork move, and the participants experienced an increase in symptoms that may have otherwise been masked through chronic compensation mechanisms. Bowenwork may demonstrate such reorganizational properties that stimulate exacerbation of symptoms, or an aggravation, evidenced by the increase in perceived pain following the intervention time period. In addition, the introduction of treatment may cause this window that may trigger realignment of

patterns of healing. The literature supported early intervention as soon as the lymphedema was identified (Chan et al., 2010; Fleysheer, 2010; Torres Lacomba et al., 2010). The participants in this study were already through treatment and even progressed into further advanced stages of lymphedema. Establishing realignment or alternate pathways as soon as possible and supporting the whole person, to lessen the impact of trauma, would be a logical approach while implementing earlier timing of the intervention. An intervention that may stimulate pathways and promote re-patterning, such as the proposed intervention of Bowenwork, may support symptom management for the acute as well as chronic stage of lymphedema. This period of normalization through an aggravation of symptoms requires more exploration.

The analysis of the physical measurements identified a statistically significant change in arm circumference and range of motion. The mean arm circumference reduction ranged from 0.03 to 1.05 centimeters. Clinical significance of this finding is individualized to each the participants and their importance of 0.03 centimeters or 1.05 centimeters.

The increase in shoulder range of motion was both clinically and statistically significant. The mean range for increase in shoulder range of motion was 17.4 to 20.6 degrees. This outcome supports the theoretical mechanism of Bowenwork in that the surrounding tissue and adhesions may have been softened causing the increase in range of motion.

The patterns that follow as a result of the disorganization may be measured physically and the reorganization that occurs may be measured mentally and emotionally. The measurement of outcomes, such as quality of life, functional status, perceived pain and physical measures served this purpose. Based on the postulated theory of Bowenwork and how tissues soften, and the re-patterning and self-organizational principles of complexity systems science,

Bowenwork may be a suitable complement for conventional therapy for reduction of unpleasant symptoms that are not easily managed alone.

Limitations to the Study

There were some recognized limitations to the study that can potentially affect the validity of the research. Limitations included selection bias, measurement bias, intervention bias and proficiency bias. Selection bias was observed because recruitment did not reach a diverse population such as Latina/Hispanic/Mexican, African American and Asian women. Additional recruitment strategies are needed in order to reach additional areas such as rural areas and communities. Emphasis was not given to support groups in rural areas and activities not typical in metropolitan areas, such as clinics, church groups, and ethnic centers. In addition, women under 40 years old did not enroll in this pilot study, which further limits generalizability of the findings to older women with breast cancer experiencing lymphedema symptoms.

Measurement bias was identified with one of the study instruments, BPI. The results of the BPI must be interpreted with caution in regard to pain related to lymphedema. Participants were not instructed to isolate their comments to those relating to pain or discomfort of the lymphedema. Participants commented on any pain regardless of its origin. Modification of the measure to instruct participants to distinguish between pains associated with lymphedema and other ailments could eliminate this bias, or selection of another instrument.

Even though there was no control group, a possible intervention bias could have been a factor for this study. Specifically proficiency bias, because the Scottsdale group received treatment in slightly different environment. The center was not able to provide a private practice office like setting, rather, the intervention occurred in an isolated, uninterrupted

education/conference room. The intervention setting was not identical to all of the participants potentially interfering with validity.

Participants were allowed to continue with any standard treatments for lymphedema that they were actively implementing before enrollment of the study. Interference of these extraneous variables was not taken into consideration during the analysis. In addition, self-management of home exercises was not monitored and timing was not regulated which could further compromise the integrity of the study results.

Implications for Nursing Research

Symptom management is an integral part of nursing care whether it involves direct patient care or the facilitation of care. Breast cancer survivorship is continuing to increase. Symptom management of treatment effects with burdensome unwanted outcomes is a reality that challenges these women. Symptom management of lymphedema is among one condition that may benefit from a complementary modality such as Bowenwork. Future aspects of this study might explore further the expression of symptoms such as perceived pain. In addition, more examination of the timing of the intervention might provide insight into assessing the effectiveness of the results, such as is indicated by recognition of intra-individual patterns. Another reason a study over a longer period of time, may be more beneficial, is related to the inherent properties of the lymphatic system and the slower transfer of fluid from one compartment to the next. The lymphatic fluid accumulates slowly and advanced stages are considered irreversible, the improvement in mobility and softening of adhesions may provide alternate pathways for fluid exchange that can only be measured over longer time periods. Research on lymphedema and symptom management over a longer time period may benefit

women breast cancer survivors as well as examine long term results of Bowenwork. Future research on Bowenwork will enhance our understanding of how it works, and what types of conditions are likely to respond to this treatment. A longitudinal study to evaluate lasting or even irreversible effects will provide valuable information into complex systems and re-organizational principles over time. A future larger full scale study would benefit from implementing the intervention over a longer time period, which is congruent with the theoretical framework.

Even though this quasi-experimental design was sufficient for a pilot study, a larger a randomized clinical trial would provide greater insight into Bowenwork as a symptom management strategy for lymphedema. A previously reported randomized trial including women breast cancer survivors with lymphedema used the unaffected arm as the control (Dirican et al., 2010).

Nursing research of symptom management that offers a complementary intervention may be a potential avenue for supporting individuals with chronic illnesses. Patients with chronic conditions continue to be overburdened with managing their symptoms such as the women with lymphedema. Bowenwork is one such intervention for symptom management that is a safe and an effective holistic treatment that may support mental health as well as physiological well-being. Nursing research exploring complementary interventions provides resources that educate patients on potential health care options. Individuals, such as women breast cancer survivors, need accurate information on the effectiveness, usefulness and safety of potential management strategies to support or even improve health outcomes. Complementary intervention can support these goals to improve health in a cost effective and safe environment.

Conclusion

This pilot study demonstrated the feasibility of offering a complementary management strategy to women breast cancer survivors with lymphedema. Community health care providers were receptive to offering Bowenwork as a symptom management strategy to support unwanted outcomes associated with breast cancer treatment, such as lymphedema. Bowenwork is a safe intervention that may result in an improvement in mental health and physiological functioning. These findings supported the possibility of a larger full scale study to examine the effects holistically. Future exploration of complex systems, such as the lymphatic system, will help us improve symptom management strategies for complex system failure. Offering a holistic management strategy for symptom management of chronic complex conditions may reduce unpleasant symptoms and improve quality of life.

APPENDIX A

STUDIES EXPLORAING THE ALTERATION IN SENSATION AND PAIN

Studies Exploring the Symptom Experience for Alteration Sensation and Pain

Author	Design and Setting	Purpose/Aim	Sample size, age	Measure	Findings	Conclusion
(J. Armer & Fu, 2005)	Descriptive exploratory cross-sectional, Women BC survivors from Midwestern cancer center US	Explore the age difference in LE occurrence and self-reported symptoms	N=102, mean age=59, 95% Caucasian	Anthropometric measurements arm, LBCQ(self-reported)	LE is higher in women <60 at 41% as compared to 30% and six subjective symptoms reported more in the younger age group (numbness now and past year, tenderness past year, aching now and past year, increased temperature in arm	Younger women may have increased risk and experience more LE related symptoms
(Ahmed et al., 2006)	RCT, BC survivors from greater Minneapolis metropolitan area, MN US	Examine the effects supervised upper and lower body weight training on the incidence and symptoms of LE in BC survivors	N=23, mean age=52.3 Control=23, mean age=51.7	Physical arm measurements, validated self-reported survey tool, The Baecke Questionnaire (physical activity)	None of the intervention group participants experienced a change in arm circumference or self-reported diagnosis or symptoms change	A six month intervention of exercise resistance does not increase risk or exacerbate symptoms of LE

APPENDIX A (continued)

Author	Design	Purpose/Aim	Sample size, age	Measure	Findings	Conclusion
(Norman et al., 2009)	Prospective, BC survivors from Philadelphia and Delaware County US	Examine the incidence, degree, time course, treatment, and symptoms of lymphedema in breast cancer survivors	N=238	Questionnaire developed for study, informal interviews, Memorial Symptom Assessment scale(symptoms of LE)	LE occurs in 42% of women after five years, Women with mild to moderate LE were three times more likely to develop moderate to severe LE	Incidence of LE initially is mild and subtle differences in symptoms can reflect early signs of LE
(M. R. Fu et al., 2008)	Cross-sectional, BC survivors NYC US	Explore the effect of providing lymphedema information on breast cancer survivor's symptoms and practice of risk-reduction behaviors	N=136, mean age 54, 74% white, 13% Asian, 9% African-American, 4% Hispanic	Demographic and medical information interview tool, LBCQ, LRRB checklist	Fifty-seven percent reported receiving LE information, participants experienced average of three LE symptoms with only 18% symptom free	Education reduces risk of LE development

APPENDIX A (continued)

Author	Design	Purpose/Aim	Sample size, age	Measure	Findings	Conclusion
(Paim et al., 2008)	Cross-sectional descriptive correlational study, Outpatient clinic in Belo Horizonte, Brazil	Investigate postlymphadenectomy complications after ALND and SLNB and explore the associative relationship between the complications and quality of life	N= 96, (48 ALND and 48 SLNB) mean did not differ between groups with age=53.5±11.6	Goniometer Short form McGill Pain questionnaire	QOL significantly correlates with pain	Further studies necessary to identify interventions to promote QOL
(M. R. Fu & Rosedale, 2009)	Descriptive phenomenological study	Explore and describe breast cancer survivors' lymphedema-related symptom experiences	N=34, mean age=55	Informal interviews	Themes revealed, living with perpetual discomfort, confronting the unexpected, confronting the unexpected, losing pre-lymphedema being, handicapped	Symptom distress is evident and more research is needed to enhance current treatment

APPENIX A (continued)

Author	Design	Purpose/Aim	Sample size, age	Measure	Findings	Conclusion
(J.M. Armer et al., 2009)	Prospective repeated measure pre and post treatment, Midwest university hospital in	Compare three measurement techniques to quantify LE occurrence up to 30 months post treatment	N=211, mean age=57, 30%ALND	(A)- Two cm circumference change at any measured location (B) 200ml perometry LVC of the affected arm (C) 10% perometry LVC of the affected arm(D) self-report of limb heaviness and swelling LBCQ- evaluate symptom	Incidence of LE ranges form 41-91% after 30 months post treatment with 2cm circumference changes indicating the greatest change and self-reported symptoms the lowest	The two cm measurement generates the greatest indication of development of LE

APPENDIX A (continued)

Author	Design	Purpose/Aim	Sample size, age	Measure	Findings	Conclusion
(Chachaj et al., 2010)	Cross-sectional Women post BC surgery oncology center in Poland	Identify factors associated with worse physical and emotional functioning of breast cancer survivors with upper extremity lymphedema	N=117 (with lymphedema) Control=211 (without LE)	Demographic data and health related questionnaires, WHO-DAS II (disability), Eortc QLQ-C30 and Eortc QLQ-BR23 (QOL, function and symptoms), GHQ-30(psychological distress)	Women with lymphedema are more disabled and report greater pain and limitations	Higher DAS scores, higher GHQ scores, lower QOL scores were associated with pain in the upper limb operated breast, history of hand edema, dermatolymphangitis and chemotherapy

APPENDIX A (continued)

Author	Design	Purpose/Aim	Sample size, age	Measure	Findings	Conclusion
(Gartner et al., 2010)	Cross-sectional, Post breast cancer treatment in US	Examine the impact of BC treatment on perceived swelling/sensation of heaviness and on function	N=3253, age range=18-69	Questionnaire developed for study after two pilot studies	Perceived pain/sensation varied from 13-65%, associated factors were age, ALND and radiation but not type of surgery or chemotherapy, giving up activities was associated with pain and swelling/heaviness, young age, ALND, chemotherapy, time elapsed since surgery and dominant side.	One to three years after breast cancer surgery 13-65% patients report LE, 11-44% report functional impairment----the variance in numbers are reflective of the individualized treatments and procedures and differences in age

LE=lymphedema, BC=breast cancer, BCRL=breast cancer related lymphedema, BIS=Bio impedance spectroscopy, DASH=Disability of Arm, Shoulder and Hand scale, ROM=range of motion, UBS=upper body strength, ALND=axillary lymph node dissection, QOL=quality of life, LSCS=lymphedema self-care survey, ICF=international classification of functioning, disability and health model, BMI=body mass index, EORTC= European Organization for Research and Treatment, HRQOL=health related quality of life, LVC=limb volume change, LBCQ= lymphedema breast cancer questionnaire, FACT=functional assessment of cancer therapy, LLLT=low level laser therapy, BIS= bio impedance spectroscopy, , SNLD=sentinel lymph node dissection, WHO-DAS=World Health Organization Disability Assessment Schedule, LBCQ=Lymphedema and Breast Cancer questionnaire, LRRB= Lymphedema Risk-Reduction Behavior checklist

APPENDIX B

STUDIES RELEVANT TO CURRENT DIAGNOSTIC AND
MANAGEMENT OF LYMPHEDEMA

Studies Relevant to Current Diagnostic and Management of Lymphedema

Author	Design and Setting	Purpose/Aim	Sample size, age,	Measure	Findings	Conclusions
(Teas et al., 2004)	Experimental, Post-menopausal women who were on average 9 years post BC treatment	Explore the effects of hyperbaric oxygen therapy on BC treatment-related LE	N=17, mean age=58±5.7	Circumferential arm measurements by Certified LE therapist, standard plethysmography water cylinder	38% reduction in hand LE that was independent of body weight and this reduction persisted 14.2 months	Further studies are needed to explore the effects of hyperbaric oxygen therapy on BC treatment-related LE
(Chen et al., 2008)	Cross-sectional Women BC survivors who underwent surgery and developed LE in US	Investigate the reliabilities, and define the limits for clinical change indicative of clinical improvement	N=14, mean age 63.8±7.8 (water displacement and tissue tonometry) N=17, mean age=57.6±9.9	Water displacement with volumeter, physical circumference measurement, tonometry(tissue resistance)	All measures had fair to excellent reliability with tonometry the greatest variation	Water displacement and arm circumference most reliable techniques for assessing LE

APPENDIX B: (continued)

Author	Design and Setting	Purpose/Aim	Sample size, age,	Measure	Findings	Conclusions
(S. C. Hayes, Reul-Hirche, & Turner, 2009)	RCT, women post BC treatment six months who developed LE unilateral, Australia	Investigate the effects of participating in a supervised mixed type exercise program on LE status	N=16, age=59±7 Control=16, age 60±11	BIS and perometry to measure LE	No differences was reported between groups, however, two women in the exercise group had complete resolution of LE	Exercise does not increase LE
(Helyer et al., 2009)	Prospective enrollment, Women from tertiary care center after diagnosis of BC Ontario, Canada	Determine predictors of arm LE after SLND with and without ALND	N=137	Physical measurements of arm circumference	LE development was related to the BMI >30	Consider preoperative counseling on BMI reduction to decrease risk of LE

APPENDIX B (continued)

Author	Design and Setting	Purpose/Aim	Sample size, age	Measure	Findings	Conclusions
(Sagen et al., 2009)	Validity Design, Women 6 years after BC treatment with ALND chosen from a RCT on BC LE in Norway	Evaluate concurrent and construct validity for SWDI	N=23, mean age=64±11	SWDI measure arm volumes and arm LE, computed tomography for comparison and accuracy	SWDI is a valid measure for arm volume in LE	Only to be used as a measure for LE as comparison to nonLE volume validity decreases
(Swenson et al., 2009)	Multisite case-control study women post BC treatment from clinic in Minneapolis US	Identify risk factors for LE after breast cancer surgery	N=94 (with LE) N=94(without LE)	Measure of Arm Symptom Survey(risk of LE)	Women who develop LE have a greater BMI, have received axillary radiation, mastectomy and chemotherapy.	Weight training is a modifiable risk factor for decreasing incidence of LE and axillary radiation, mastectomy and active cancer are predictive of LE

APPENDIX B (continued)

Author	Design and Setting	Purpose/Aim	Sample size, age	Measure	Findings	Conclusions
(Avraham et al., 2010)	Prospective group from Memorial Sloan-Kettering Cancer Center, NY, US (Post BC treatment with ALND)	Determine the impact of immediate tissue expander breast reconstruction on the risk of developing LE	N= 168, mean age=45 Control=130(no reconstruction), mean age=61	LBCQ (subjective symptoms), Physical measurements of arm circumference,	Lower rate of LE was reported in the group who had SNLB/ALND who underwent reconstruction surgery tissue expansion	Reconstruction surgery with tissue expanders does not increase the risk of LE
(Czerniec et al., 2011)	Cross-sectional Women post BC treatment with and without LE Australia	Determine if BIS could detect localized LE of the arm and to compare BIS measurements with perometry	N=29, age=60±8.1 Control=11(without LE), age=53.5±6.8	Physical measurements of arm using BIS vs. Perometry	Both instruments adequately measure LE, however BIS is more sensitive to mild LE	BIS can be used a reliable measure of LE because of its specificity for extracellular fluid

APPENDIX B (continued)

Author	Design and Setting	Purpose/Aim	Sample size, age	Measure	Findings	Conclusions
(H. Sakuda, Satoh, M., Sakaguchi, M., Miyakoshi, Y., Kataoka, T., 2010)	Mixed-Cross-sectional, Female BC patients post-surgery with a comparison to healthy adult women in Japan	Determine physiological characteristics of women with LE based on fluid content in fingers as a predictive index	N=39, age=55.0±6.35 Control=45, age=54.2±6.95	Bio impedance spectrometer with a four electrode method(fluid level) Tape measurer Interviews	Comparison of limbs can indicate increased levels of fluid and be used as a predictive index for LE	Physiological markers are evident for detection of LE but more research on psychological and/or holistic perspective should not be under recognized per the authors
(Torres Lacomba et al., 2010)	RCT, Women post breast cancer surgery in Spain	Determine the effectiveness of early physiotherapy in reducing the risk of secondary lymphoedema after surgery for breast cancer	N= 60, mean age 52.9 (early physiotherapy and education) Control=60, mean age 53.9, (education only) 100%ALND	Physical-manual arm measurements	7% women developed LE in the intervention group as compared to 25% in the control group	Early physiotherapy is effective in decreasing incidence of LE for up to one year after surgery

APPENDIX B (continued)

Author	Design and Setting	Purpose/Aim	Sample size, age	Measure	Findings	Conclusions
(Vignes et al., 2010)	Longitudinal, Consecutive women on lymphology unit France	Evaluate LE volume during maintenance phase and to identify factors that influence volume status	N=682, mean age 62	Physical measurement of arm circumference	Initial reports of a decrease in arm volume after decongestive therapy, at 1,2 and 4 year intervals risk of treatment fails	Maintenance therapy for LE is at risk for failure and associated with age, higher weight and body mass index, while bandages and sleeves had good results
(Carter, 2002)	Qualitative descriptive, Women after BC treatment one year post urban community Midwest US	Explore women's experience with LE	N=10, age range=36-75	Interviews	Continuation with life evident	Expansion of research is necessary to prevent and treat LE, they experience depression, anxiety and impairments related to their intimate, work and social relationships

APPENDIX B (continued)

Author	Design and Setting	Purpose/Aim	Sample size, age	Measure	Findings	Conclusions
(M.R. Fu, 2005)	Cross-sectional, descriptive phenomenological method, BC survivors post treatment month post diagnosis LE,	Describe the experience of managing LE in BC survivors	N=12, mean age=59, 83%white, 17%african-american	Semi-structured interviews	Major intentions identified were, keeping in mind the LE from getting worse, get ready to live with LE, integrate the care of LE into daily life.	Increases awareness for practitioners to consider the intentions of the individual when planning care
(Ridner & Dietrich, 2008)	Cross-sectional descriptive, Community based BC survivors in US	Compare the self-reported conditions and medication usage between women with LE and those without LE	N=64, mean age=59.6 Control=64, mean age=55.7	Demographic questionnaire, Breast cancer history and treatment form, Lymphedema history and treatment form, health and medication	Women with LE experience more comorbid conditions	Comorbid conditions influence the development of LE and have statistically difference in BMI, orthopedic issues, and certain medications

Appendix B (continued)

Author	Design and Setting	Purpose/Aim	Sample size, age	Measure	Findings	Conclusions
(Shih et al., 2009)	Cross-sectional, women 2 years post BC treatment from the 1997-2003 Medstat MarketScan Health and Productivity Management(HPM) database US	Estimate the economic burden of breast cancer-related LE among working-age women, and associated risk factors	N=180 (with LE), mean age=48.9 Control=1697(without LE), mean age=48.8	Logistic regression model	ALND and chemotherapy were a high predictor of LE, women with LE had significantly higher medical costs with outpatient care, especially mental health services, diagnostic imaging accounting for this increase cost	Women with LE had a greater incidence of infection and higher medical costs further suggesting more education and risk identification is necessary
(Lee et al., 2010)	Cross-sectional survey, women with BC from Sidney, Australia 6-15	Describe women's experience receiving advice about arm care	N=175, mean age not reported	Survey developed for study	Women reported inadequate and conflicting advice, lack of	Upper limb impairments are problematic and concerns are not taken seriously

APPENDIX B (continued)

Author	Design and Setting	Purpose/Aim	Purpose/Aim	Measure	Findings	Conclusions
	months after surgery	and exercise after breast cancer treatment			acknowledgement of concerns of upper limb impairment, fears of LE,	

LE=lymphedema, BC=breast cancer, BCRL=breast cancer related lymphedema, BDI=Beck Depression Index, SF-36= Medical Outcomes study short form, BIS=Bio impedance spectroscopy, DASH=Disability of Arm, Shoulder and Hand scale, ROM=range of motion, UBS=upper body strength, ALND=axillary lymph node dissection, QOL=quality of life, LSCS=lymphedema self-care survey, POMS-SF=Profile of mood states-short form, LSIDS-A, US=United States, ICF=international classification of functioning, disability and health model, BMI=body mass index, VAS=visual analogue scale, EORTC= European Organization for Research and Treatment, HRQOL=health related quality of life, LVC=limb volume change, LBCQ= lymphedema breast cancer questionnaire, FACT=functional assessment of cancer therapy, LLLT=low level laser therapy, BIS= bio impedance spectroscopy, POSAS=Patient and Observer Scar Assessment Scale, SWDI=simplified water displacement instrument, SNLD=sentinel lymph node dissection, WHO-DAS=World Health Organization Disability Assessment Schedule, LBCQ=Lymphedema and Breast Cancer questionnaire, LRRB= Lymphedema Risk-Reduction Behavior checklist, WCLS- Wesley Clinic Lymphedema Scale, CESD=Center for Epidemiologic Studies of Depression,

APPENDIX C

STUDIES RELEVANT TO MEASURING QUALITY OF LIFE IN

WOMEN WITH LYMPHEDEMA

Studies Measuring Quality of Life in Women Breast Cancer Survivors with Lymphedema

Author	Design	Purpose/Aim	Sample size, age	Measure	Findings	Conclusion
(McKenzie & Kalda, 2003)	RCT, BC survivors 6 months post treatment who developed unilateral LE	Examine the effect of a progressive body exercise program on LE secondary to BC treatment	N=7 Control=7	Physical measurements and SF-36 (QOL)	No changes were found in arm circumference, QOL domains for physical functioning, general health, vitality for the exercise group	Participation in upper body exercise caused no changes in LE but did show an increase in QOL
(Ridner, 2005)	Cross- sectional mixed method, BC survivors	Compare quality of life and symptoms between BC survivors with those who have undergone	N= 64(with LE), mean age=58, 91%caucasian, 9%african-american Control=64(without LE), mean age=55,	FACTB(QOL) WCLS(LE specific scale for past 2 weeks), lymphometer(measure extracellular fluid, symptom checklist, CESD(depression)	Poorer QOL reported with LE and symptom cluster (alteration in limb sensation, loss of function	Current treatment for LE does not address the multiple concerns associated

APPENDIX C (continued)

Author	Design	Purpose/Aim	Sample size, age	Measure	Findings	Conclusion
	from metropolitan area and surrounding rural counties in the southeastern US	treatment for chronic LE and those who do not have LE	89%caucasian, 7%african-american		confidence in body, decreased physical activity, fatigue, and psychological distress.	with the symptoms experienced Greater perception influence of arm size than volume
(Ahmed et al., 2008)	Data collection from previous cohort, Iowa Women's Health Study	Examine the impact of LE or related arm symptoms on HRQOL in BC survivors	N=104(diagnosed with LE) N=475(reported symptoms of LE but no diagnosis) N=708(no diagnosis or symptoms,Cohort=1,287 defined for analysis based on LE survey	SF-36	8.1% self-reported diagnosed LE, 37% self-reported arm symptoms, Knowledge of LE was low among those not diagnosed with	HRQOL was low for those diagnosed and self-reported symptoms of LE Those with no diagnosis had a lower physical and mental QOL

APPENDIX C (continued)

Author	Design	Purpose/Aim	Sample size, age	Measure	Findings	Conclusion
(S. C. Hayes, Janda, Cornish, Battistutta, & Newman, 2008)	RCT Population based sample of Australian women 6 to 18 months post treatment for invasive BC	Determine prevalence and incidence of LE in US	N=287, mean age=55, lymph node dissection=86.7%	BIS - LE, DASH- (Upper body symptoms and functions) FACT- (QOL)	33% with lymphedema, 34-62% report high UBS regardless of LE status, or axilla node dissection, treatment related complications increased odds of developing LE Symptoms=pain, stiffness, weakness, tingling, poor ROM, numbness	LE is a health concern that warrants greater attention and it is evident more emphasis on early detection and prevention is necessary

APPENDIX C: (continued)

Author	Design	Purpose/Aim	Sample size, age	Measure	Findings	Conclusion
(Clough-Gorr et al., 2010)	Longitudinal study, data collection from tumor registries Los Angeles, Minnesota, North Carolina, Rhode Island seven years post BC treatment	Evaluating predictors specific to symptoms of persistent lymphedema in older BC survivors.	N=400, mean age not reported because of various ranges	Telephone interviews, 3,6,27,39,51,63,75,87 months after surgery	Older BC survivors experience persistent symptoms surrounding QOL, physical functioning and mental health	Identification of risk factors may lead to preventive and therapeutic measures to maintain health over long periods of time.
(McClure et al., 2010)	RCT, women from outpatient clinics in Pittsburgh US	Examine the effects of an exercise and relaxation program on BCRL	N=10, mean age=56.5±3.9 Control=11, mean age=62.2±2.3	ImpediMed(bioelectrical impedance analysis extracellular fluid), goniometer (ROM), BDI-II (mood), SF-36(QOL)	Treatment group reported improvements in bioimpedance, arm flexibility, QOL, mood and weight loss	Improvements in physical and emotional symptoms of LE can be treated

APPENDIX C (continued)

Author	Design	Purpose/Aim	Sample size, age	Measure	Findings	Conclusion
(Ridner et al., 2010)	Cross-sectional, breast cancer registry in US	Examine BC treatment-related LE self-care education, self-care practices, perceived self-care barriers and exploring associations among self-care education, practices, symptoms and QOL	N=51	LSCS(self-care and education) POMS-SF, LISIDS-A(physical, psychological or situational symptoms), Skin checklist(self-evaluation of skin and arm symptoms), Upper limb lymphedema-27(QOL)	Identification of barriers to self-care and those with more symptoms spent more time on self-care activities with a poorer QOL	The depth of understanding LE and supporting those who are affected needs greater attention from multiple disciplines

APPENDIX C: (continued)

Author	Design	Purpose/Aim	Sample size, age	Measure	Findings	Conclusion
(Tsauo et al., 2010)	Descriptive Taiwanese women post breast cancer treatment	Determine if the ICF with clinical data can predict health related QOL	N=61	Physical arm measurements, VAS score (11 arm symptoms), DASH(upper extremity function), EORTIC QLO-C30, EORTIC QLO-BR23 questionnaires(HRQOL)	ICF model accounted for 20.5% to 55.6% variance of each domain of HRQOL with activity and upper extremity function the greatest predictor HRQOL	Arm symptoms correlated with upper extremity function more than volume indicating treatment of symptoms are equally important as treatment for LE

LE=lymphedema, BC=breast cancer, BCRL=breast cancer related lymphedema, BDI=Beck Depression Index, SF-36= Medical Outcomes study short form
 BIS=Bioimpedance spectroscopy, DASH=Disability of Arm, Shoulder and Hand scale, ROM=range of motion, UBS=upper body strength, ALND=axillary lymph node dissection, QOL=quality of life, LSCS=lymphedema self-care survey, POMS-SF=Profile of mood states-short form, LSIDS-A, US=United States, ICF=international classification of functioning, disability and health model, BMI=body mass index, VAS=visual analogue scale, EORTC= European Organization for Research and Treatment, HRQOL=health related quality of life, LVC=limb volume change, LBCQ= lymphedema breast cancer questionnaire, FACT=functional assessment of cancer therapy , LLLT=low level laser therapy, BIS= bioimpedance spectroscopy, POSAS=Patient and Observer Scar Assessment Scale, SWDI=simplified water displacement instrument, SNLD=sentinel lymph node dissection, WHO-DAS=World Health Organization Disability Assessment Schedule, LBCQ=Lymphedema and Breast Cancer questionnaire, LRRB= Lymphedema Risk-Reduction Behavior checklist, WCLS- Wesley Clinic Lymphedema Scale, CESD=Center for Epidemiologic Studies of Depression

APPENDIX D

STUDIES RELEVANT TO MEASURING IMPAIRMENT IN FUNCTION AND
RANGE OF MOTION

Studies Relevant to Measuring Impairment in Function and Range of Motion

Author	Design and Setting	Purpose/Aim	Sample size, age	Measure	Findings	Conclusion
(Bani et al., 2007)	Longitudinal, women BC survivors from outpatient clinic in Franconia Germany	Evaluate self-reported incidences of LE in BC survivors and the effect of providing the patients with information about LE on the extent to which lymph-drainage massage services and compression garments were used	N=742, mean age without LE= 53.1±11.3, mean age with LE=53.0±10.0	Questionnaire	Thirty-two percent reported having LE, Radiation was a significant risk factor for LE. Pain, parasthesia and functional limitation were associated with occurrence of LE. One predictor associated with lymph-drainage massage was provision of information	Self-reported assessments are feasible

APPENDIX D (continued)

Author	Design and Setting	Purpose/Aim	Sample size, age	Measure	Findings	Conclusion
(Hammond & Mayrovitz, 2009)	Case study, women diagnosed with LE with both arm and trunk edema at home in Florida US	Report clinical outcomes , observations, subjective impressions post home pneumatic compression device	N=5, age range=44-66	Physical measurements of trunk circumference, perometer for arm circumference, informal interviews	Reduced arm ,trunk swelling, fibrotic tissue softening, pain reduction, improved ROM and flexibility after 2 months	In home treatment for LE is feasible with the use of a programmable pneumatic device
(Chan et al., 2010)	Quantitative Review	Review the effectiveness of exercise programs on shoulder mobility and LE after ALND	N=six studies reviewed	Systematic review	Early exercise intervention does not prevent LE but it does improve the ROM and deceases deterioration of shoulder.	Education to women with LE is crucial for improving function of shoulder when LE is present

APPENDIX D (continued)

Author	Design and Setting	Purpose/Aim	Sample size, age	Measure	Findings	Conclusion
(Dirican et al., 2010)	Cross-sectional LE patients currently enrolled in LE program clinic, Pittsburg, US	Review short-term experience with LLLT in the treatment of LE	N=17, mean age=51.8	Physical measurements of arm circumference, pain score per pain diagram 10/10, goniometer(ROM), POSAS (scar mobility, ROM)	Reduction of limb circumference, pain, increased ROM and scar mobility reported	LLT in conjunction with standard LE treatment.
(Smoot et al., 2010)	Cross-sectional Post breast cancer treatment in US	Compare upper extremity impairment and activity between women with and without lymphedema after BC treatment	N=144, mean age=56.3, ALND=75%	Standardized Purdue Pegboard, Finger Tapper Test, dynameters, goniometer (ROM), Semmes-Weinstein monofilaments(tactile sensitivity), DASH(upper limb symptoms and function)	The LE group had more lymph nodes removed, more upper arm symptoms, greater limitations, both groups experienced less strength, less ROM	Women with and without LE post BC treatment experience limitations, those with LE experience more pain, decrease ROM and strength

APPENDIX D: (continued)

Author	Design and Setting	Purpose/Aim	Sample size, age	Measure	Findings
(Omar et al., 2010)	RCT, Women post breast cancer surgery in Cairo, Egypt	Evaluate the effect of LLLT on limb volume, shoulder mobility, and hand strength	N=25, age=57.6±3.33 Control=25, age=53.36±3.56	Physical measurement of arm circumference, Portable hand Jamar Dynamometer (grip strength), goniometer (ROM)	Decrease in arm volume reported in both groups with a greater trend in the treatment group, in addition to statistically significant improvement in ROM and hand grip in the intervention group.

LE=lymphedema, BC=breast cancer, BCRL=breast cancer related lymphedema, BDI=Beck Depression Index, SF-36= Medical Outcomes study short form
 BIS=Bio impedance spectroscopy, DASH=Disability of Arm, Shoulder and Hand scale, ROM=range of motion, UBS=upper body strength, ALND=axillary lymph node dissection, QOL=quality of life, LSCS=lymphedema self-care survey, POMS-SF=Profile of mood states-short form, LSIDS-A, US=United States, ICF=international classification of functioning, disability and health model, BMI=body mass index, VAS=visual analogue scale, EORTC= European Organization for Research and Treatment, HRQOL=health related quality of life, LVC=limb volume change, LBCQ= lymphedema breast cancer questionnaire, FACT=functional assessment of cancer therapy, LLLT=low level laser therapy, BIS= bio impedance spectroscopy, POSAS=Patient and Observer Scar Assessment Scale, SWDI=simplified water displacement instrument, SNLD=sentinel lymph node dissection, WHO-DAS=World Health Organization Disability Assessment Schedule, LBCQ=Lymphedema and Breast Cancer questionnaire, LRRB= Lymphedema Risk-Reduction Behavior checklist, WCLS- Wesley Clinic Lymphedema Scale, CESD=Center for Epidemiologic Studies of Depression,

APPENDIX E
RECRUITMENT FLYER

Recruitment Flyer

Invitation to Participate in a Research Study on Breast Cancer Survivors with Lymphedema

Call to determine your eligibility

Lymphedema is the chronic swelling of the arm caused by the Breast Cancer treatment

This is a preliminary study to determine feasibility of a complementary therapy called, "Bowenwork" a gentle form of touch therapy to stimulate healing and enhance the flow of lymph fluid.



This Pilot study has been approved by the Institutional Review Board of the University of Arizona

- * Four Bowenwork® treatments at no cost to you
- * Two Tucson locations and one Flagstaff

**If interested
Contact
Christine Hansen
520-240-4600**

Christine Hansen
520-240-4600

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APPENDIX F

RECRUITMENT SCRIPT FOR PILOT STUDY ON BOWENWORK

Recruitment Script for Pilot Study on Bowenwork

Hello, my name is *Christine Hansen*. I am an RN and a 4th year graduate student at the University of Arizona, College of Nursing. I am currently working on my dissertation involving a complementary intervention called Bowenwork for the symptoms surrounding the type of lymphedema caused from breast cancer treatment. The treatment is a gentle form of touch therapy that stimulates the central nervous system by touching the skin to promote healing and relieve uncomfortable symptoms. This study will be the first step for this type of research. I will be looking at how many women want to be involved in the study. I will be looking at the safety and comfort surrounding Bowenwork and how it effects the symptoms including range of motion, arm size, pain and quality of life.

There is very minimal risk for being in the study with Bowenwork . A treatment consists of moves on the surface of the skin, gentle enough to never cause pain, but firm enough to move the skin about one inch. It is done while you are lying down on your stomach and back on a comfortable surface.

You will not be paid to be in the study

If you volunteer as a participant in this study, you will be asked to commit to the 8 week period of receiving six Bowenwork treatments and some additional stretching exercises at home. You will be responsible for your own transportation to and from the Bowenworker's office in (Tucson or Flagstaff). All of the information you share will be kept confidential.

You will also be asked to complete a packet of questionnaires at the beginning and end of the study. Each Bowenwork session will take approximately one hour. The Bowenworker will take measurements of your arm movement and size at the beginning of each session and some additional questions about how you are feeling when you arrive and during the treatment. At the end of the eight week session, you will be given a packet of questionnaires to take home and bring with you to the final follow up appointment with the Bowenworker. You will not receive any more treatments, however, the Bowenworker will take the final measurements and collect the questionnaires at this time.

I would like to assure you that this study has been reviewed and received approval from the University Institutional Review Board for your safety. However, the final decision about participation is yours and you can discontinue at any time during the study.

If you are interested in participating you will be asked a series of screening questions to determine eligibility. Some of these questions may be personal in nature, such as type of treatment you received for breast cancer. You may refuse to answer any questions. After it is determined you are able to participate, you will be given a consent explaining the study in more detail.

Do you have any questions about the study?

If you have any questions later you can call me at 520-240-4600 or email me at chanson@nursing.arizona.edu. Thank you for your interest and time.

APPENDIX G

RECRUITMENT FOR NATIONAL LYMPHEDEMA NETWORK

Recruitment for National Lymphedema Network

Title: A Pilot Study on Bowenwork for Symptom Management of Women Breast Cancer Survivors with Lymphedema

- **Researcher and affiliation:** Christine Hansen, BSN, RN, PhD Candidate, University of Arizona, College of Nursing
- **Enrollment is Open**
- The overall purpose of this study is to examine Bowenwork among women breast cancer survivors with lymphedema. In addition, the study will determine the number of participants who are recruited and complete participation in the study, assess the safety and comfort level of Bowenwork and measure improvement of lymphedema in terms of quality of life, pain and physical measurements.

Am I Eligible? You are eligible to participate if:

- You have a diagnosis for any stage of breast cancer and you have completed breast cancer treatment
- You have completed breast cancer treatment more at least six months ago
- You have lymphedema of one arm with or without a diagnosis of lymphedema
- You are over 18 years of age
- You are not pregnant
- You can read and understand English

What can you expect?

You will receive four Bowenwork treatments over an eight week period at no cost to you. A Bowenwork treatment consists of a series of moves on the surface of the skin gentle enough to never introduce discomfort but, firm enough to move the skin and surrounding tissue by approximately one inch. Bowenwork is performed by a certified Bowenworker and takes approximately 45 minutes.

Before starting the treatments, you will be asked to complete three questionnaires. The answers will give us information about your current quality of life, physical functioning and level of pain or discomfort. During each treatment, your arm circumference and range of motion will be taken. You will be asked during the treatment if you feel comfortable and safe. After the last treatment you will be asked to complete and return the same questionnaire and allow the final arm measurements to be taken the following week. At this point, you will have completed the study.

Location of the study:

Two Private clinics in Tucson, AZ

5300 E. Erickson Dr. Suite 104, Tucson AZ, 85712

6993 N. Oracle Rd., Tucson, AZ 85704

One private clinic in Flagstaff, AZ

2104 N. Third Street, Flagstaff AZ 86004

MORE INFO contact Christine Hansen at chansen@nursing.arizona.edu or call 520-240-4600

APPENDIX H
SCREENNG TOOL FOR DETERMINING ELIGIBILITY

Screening Tool for Determining Eligibility

Date of screening		
Date of Breast Cancer Diagnosis		
Name		
Address		
Telephone number		
Have you completed treatment for breast cancer including, surgery, radiation, IV chemotherapy?	Yes	No (Exclude)
Are you at least 6 months post treatment for breast cancer?	Yes	No (Exclude)
Are you currently receiving any more treatment? Explain	Yes (Explain)	No
Are you pregnant?	Yes (Exclude)	No
Have you been diagnosed with Lymphedema?	Yes	No
Do you have lymphedema in both arms?	Yes (Exclude)	
Have you ever been told you have lymphedema?	Yes	No
Do you feel you have lymphedema?	Yes	No
Are you currently being treated for lymphedema and how?	Yes (Explain)	No
Are you doing anything else for your lymphedema on your own?	Yes (Explain)	No

Are you currently on bed rest or unable to stand on your own?	Yes (Exclude)	No
Are you pregnant?	Yes (Exclude)	No
Do you use any Complementary/Alternative treatments?	Yes (Explain)	No
Do you take any medication for your lymphedema?	Yes (Explain)	No
Do you take any herbal therapy?	Yes (Explain)	No
Are you willing to refrain from other complementary/alternative modalities during the intervention period?	Yes	No (Exclude)
Are you willing to commit to the baseline evaluations procedures, 8 week intervention and 1 post week evaluations for a total of 9 weeks?	Yes	No (Exclude)
Are you willing to continue your current treatment and refrain from introducing any new treatments until after the intervention is completed?	Yes	No (Exclude)
Do you read and write English?	Yes	No (Exclude)
Will you be in Tucson for the next 10 weeks?	Yes	No
Are you currently being treated for an acute condition that would interfere with the 10 week study?	Yes (Exclude)	No
Are you currently receiving treatment for another type of cancer?	Yes (Exclude)	No
Eligible	Yes	No
	ID Assignment	

APPENDIX I

INSTITUTIONAL REVIEW BOARD APPROVAL FORMS



Human Subjects
Protection Program

1618 E. Helen St.
P.O. Box 245137
Tucson, AZ 85724-5137
Tel: (520) 626-6721
<http://ocr.vpr.arizona.edu/irb>

HSPP Correspondence Form

Date: 05/16/11

Investigator: Christine Hansen, RN, BSN, Ph.D.

Department: Nursing

Advisor: Ruth Taylor-Piliae, Ph.D., RN

Project No./Title: 11-0372-04 A Pilot Study on Bowenwork for Symptom Management of Women Breast Cancer Survivors

Current Period of Approval: 05/16/11 – 05/15/12

Submit the "FORM: Continuing Review Progress Report" no later than 45 days prior to the end of the approval period listed above.

IRB Committee Information

IRB4 – IRB00005448

Expedited Review – New Project

FWA Number: FWA00004218

Documents Reviewed Concurrently	Status
F200: Application for Human Research Form (revised 05/12/11)	Appr
Consenting Instruments: Subject's Consent Form (version 05/11/11)	Appr
VOTF (version 05/06/11)	Appr
Site Authorizations: From the private practices of Geoffrey Kearney, Teresa Peterson, Nancy Brownell-Howe	Ack
Recruitment Materials: Recruitment Flyer and Script	Appr
Data Collection Instruments: Bowenworker Certification Checklist	Appr
Screening tool for eligibility	Appr
Demographic Characteristics of Bowenwork Study Participants	Appr
Intervention Documentation Form for Bowenworkers	Appr
Questionnaires: Quality of Life, Functional Status, Brief Pain Inventory	Appr
Master List	Appr
Grant Application (dated 04/12/11)	Ack
Other (define): Bowenworker Policy and Procedure Manual	Appr
CV for PI	Ack

Determination

Approved as submitted effective 05/16/11

Comments

PHI Authorization Form not required. No Protected Health Information (PHI) is being collected in this study.

Regulatory Determination(s)

- **Criteria for Approval has been met (45 CFR 46.111):** The criteria for approval listed in 45 CFR 46.111 have been met (or if previously met, have not changed) in that (1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. (2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility. (3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly

Reminders: No changes to a project may be made prior to IRB approval except to eliminate apparent immediate hazard to subjects.

Christine Hansen, RN

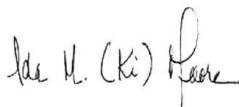
11-0372-04

Page 2

05/16/11

cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. (4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116. (5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117. (6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. (7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. (b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

- **Eligible for Expedite Approval (45 CFR §46.110):** Identification of the subjects or their responses (or the remaining procedures involving identification of subjects or their responses) will **NOT** reasonably place them at risk of criminal or civil liability or be damaging to the their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- **Expedite Approval (45 CFR 46.110 Category 4):** Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing.
- **Expedite Approval (45 CFR 46.110 Category 7):** Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
- **Waiver of Documentation of Informed Consent (45 CFR 46.117(c)(2)):** the research involves no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context (**these procedures are also one clinically and are being performed in private practices by trained professionals. The information gathered from subjects in this study would be obtained normally by Bowenworkers in their normal practice. All personal information obtained will be self disclosed by the subjects**).



05/16/11

Ida M. (Ki) Moore, DNSc
Co-Chair, IRB4 Committee
UA Institutional Review Board
IMM/deg

Date

cc: Unit Reviewer

-
- No changes to a project may be made prior to IRB approval except to eliminate apparent immediate hazard to subjects.



Human Subjects
Protection Program

1618 E. Helen St.
P.O. Box 245137
Tucson, AZ 85724-5137
Tel: (520) 626-6721
<http://orcr.vpr.arizona.edu/irb>

HSPP Correspondence Form

Date: 08/05/11

Investigator: Christine Hansen, RN, Ph.D. Candidate

Department: Nursing

Advisor: Ruth Taylor-Piliae, Ph.D.

Project No./Title: 11-0372-04 A Pilot Study on Bowenwork for Symptom Management of Women Breast Cancer Survivors

Current Period of Approval: 05/16/11 – 05/15/12

Submit the "FORM: Continuing Review Progress Report" no later than 45 days prior to the end of the approval period listed above.

IRB Committee Information

IRB4 – IRB00005448

Expedited Review – Modification

FWA Number: FWA00004218

Documents Reviewed Concurrently

F213: Modification of Approved Human Research Form (signed 07/31/11)

Research Site Authorization: Virginia C. Piper Cancer Center (dated 07/28/11)

Other: Revised F200 Application (received 08/02/11)

Description of Submission

- **Protocol changes:** Expanding recruitment and research sites to Phoenix and surrounding communities, through the Lymphedema support group affiliated with Virginia C. Piper Cancer Center Clinic
- **Additional research and recruitment site:** Virginia C. Piper Cancer Center in Scottsdale, AZ

Determination

- **Approved** as submitted effective 08/05/11

Requirements

For any future sites:

- **Research Site Authorization Requirement:** Clearance from official authorities for sites where research is to be conducted must be obtained prior to performance of this study at those sites. Evidence of this must be submitted to the HSPP office.
- **Recruitment Site Authorization Requirement:** Before posting any flyers/advertisements on private bulletin boards OR University of Arizona bulletin boards outside of the Principal Investigator's home department OR physically recruiting from any location, written site authorization must be obtained. Please retain this authorization in your research records.

Regulatory Determination(s)

- **Criteria for Approval has been met (45 CFR 46.111):** The criteria for approval listed in 45 CFR §46.111 have been met (or if previously met, have not changed).
- **Modification Eligible for Expedite Review (45 CFR 46.110):** The modification(s) do not affect the design of the research AND the modification(s) add no more than minimal risk to subjects.

Brenda J. Wittman

08/05/11

Brenda J. Wittman, M.D., MPH
Co-Chair, IRB4 Committee
UA Institutional Review Board
BJW/deg

Date

Reminders: No changes to a project may be made prior to IRB approval except to eliminate apparent immediate hazard to subjects.

Arizona's First University – Since 1885

T106: HSPP Correspondence Form
Form version: 08/01/2011



APPENDIX J
MASTER LIST OF CONTACTS

Master List of Contacts

[illegible]

APPENDIX K
INFORMED CONSENT

T502a – Consent Form

APPROVED BY UNIVERSITY OF AZ IRB
 THIS STAMP MUST APPEAR ON ALL
 DOCUMENTS USED TO CONSENT SUBJECTS.
 DATE: 05/16/11 EXPIRATION: 05/15/12

The University of Arizona Consent to Participate in Research

Study Title: A Pilot Study on Bowenwork® for Symptom Management of Women Breast Cancer Survivors with Lymphedema

Principal Investigator: Christine Hansen, BSN, RN, PhD candidate,
University of Arizona, College of Nursing

Sponsor: None

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

You may or may not benefit as a result of participating in this study. Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious, depending on the nature of the research.

1. Why is this study being done?

The overall purpose of this study is to examine Bowenwork® among women breast cancer survivors with lymphedema. In addition, the study will determine recruitment and retention rates, assess the safety and comfort level of Bowenwork® and measure symptom improvement through quality of life, pain and physical measurements

2. How many people will take part in this study?

We plan to enroll 20 women.

3. What will happen if I take part in this study?

If you agree to be in the study, the following will occur:

- a) At the start of the study, you will provide information about your medical history related to your breast cancer diagnosis and treatment, current medical history, medications and treatment, and demographic information such as age, ethnicity, educational background, employment status, marital status, and income. This will take approximately 20 minutes.
- b) You will answer questions about your quality of life, pain, and how you function physically every day; before you receive the four Bowenwork® treatments. This will take approximately 45 minutes to one hour to complete.

- c) Your arm and ankle measurements will be taken with a tape measure, and your shoulder flexibility will be measured with a special ruler that measures angles. This will be done before each Bowenwork® treatment and at the end of the study. This will take 10 minutes.
- d) You will receive four Bowenwork® sessions approximately 5-10 days apart over an eight week period. A Bowenwork® move consists of a series of moves on the surface of the skin or over a light weight cotton material such as a t-shirt. All moves for this study that are done below the neck on the torso will be done over light clothing, such as a short sleeved t-shirt, to maintain a comfortable environment. The moves are gentle enough to never introduce discomfort, but it is recognized that participants may be sensitive in certain areas related to breast cancer treatment and lymphedema. The moves will include areas of the head, neck, chest (including the breast) and lower back. The Bowenworker will document the physical measurements of arm range of motion and the arm and ankle measurements before each session. You will also be asked how you feel during and after each treatment. The entire Bowenwork® session will take approximately one hour. You will be asked to do gentle shoulder stretching exercises at home between the second and fourth treatment.
- e) At the end of the study, you will be asked to answer the same questions about your quality of life, pain, and how you function physically every day.

4. How long will I be in the study?

The study will take approximately 10 weeks.

5. Can I stop being in the study?

Your participation is voluntary. You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The University of Arizona. If you are a student or employee at the University of Arizona, your decision will not affect your grades or employment status. If you withdraw from the study or are no longer eligible to participate, the data that was already collected cannot be withdrawn and will be used in the analysis.

6. What risks, side effects or discomforts can I expect from being in the study?

There are minimal risks for being in this study. The Bowenwork® moves do not penetrate the surface of the skin. It is recognized that some areas of the body may be sensitive to even the light touch of Bowenwork® and at any time you feel discomfort or unpleasant feelings you may discontinue participation. Occasionally, a personal response may generate feelings such as nausea, dizziness or tears; and may occur as the result of

stimulation in damaged areas. You are encouraged to discuss how you feel with the Bowenworker and determine your comfort for continuation.

7. What benefits can I expect from being in the study?

You will receive four Bowenwork® treatments at no cost to you, and the results of your physical evaluation before and after the study.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies
- The University of Arizona Institutional Review Board or Office of Responsible Research Practices
- Dissertation Committee- Dr. Ruth Taylor-Piliae, Dr. Lois Loesch, and Dr. Mary Koithan

10. What are the costs of taking part in this study?

There are no costs for participating in the study, other than your time and commitment to complete the study.

11. Will I be paid for taking part in this study?

You will not be paid to be in the study.

12. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should seek treatment. The University of Arizona has no funds set aside for the payment of treatment expenses for this study.

13. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The University of Arizona reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact: **Christine Hansen, BSN, RN, PhD candidate, 520-240-4600**

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Protection Program at 520-626-6721 or online at <http://ocr.vpr.arizona.edu/irb>.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact: **Christine Hansen, BSN, RN, PhD candidate, 520-240-4600**.

Thank you for your time,

Christine Hansen

APPENDIX L
DEMOGRAPHIC INFORMATION OF ENROLLED PARTICIPANTS

Demographic Information of Enrolled Participants

Name/ID participant
Age
Which of the ethnic groups best describes you? American Indian/Alaskan native Asian/Asian-American Black/African American Latina/Latino/Hispanic/Mexican Native Hawaiian/Pacific Islander Middle Eastern Whit European-American Other-
What is your total yearly household family income? <15,999 16,000-24,999 25,000-34,999 35,000-49,999 50,000-74,999 >75,000 Including yourself, how many people do you support?
Diagnosis of Lymphedema Yes No
Diagnosis of breast cancer-date How long post treatment (surgery, radiation, chemotherapy intravenously?) One year or less One to three years Three to five years Five to ten years

Greater ten years
Surgical and medical procedures (select all that apply) Sentinel Lymph Node Biopsy Lumpectomy Partial Mastectomy Segmental Mastectomy Radical Mastectomy Axillary lymph node dissection Chemotherapy Radiation Hormone therapy (for example Tamoxifen, Aromatase inhibitors Targeted therapy (for example monoclonal abs, Herceptin, T-K inhibitors, etc.)
Marital Status at time of diagnosis Married Divorced Widowed Single
Marital Status currently Married Divorced Widowed Single
Education Elementary school or below High school Junior college or vocational College Graduate school
Employment status at time of diagnosis Employed Unemployed
Employment status currently Employed Unemployed

APPENDIX M
LIST OF BEHAVIORAL HEALTH RESOURCES

List of Behavioral Health Resources

1. University Medical Center, a 350 bed acute care hospital located at 1501 N Campbell Ave, Tucson, Arizona 85724, Operator: (520) 694-0111, Physician Appointments: telephone: (520) 694-8888.
2. Behavioral Health Services in Pima County, Community Partnership in Southern AZ: 520-318-6946, or 1-800-771-9889.
3. COPE Community Services, a private nonprofit community service and behavioral health organization with a holistic emphasis, located at 82 S. Stone Ave, Tucson AZ, 85701: 520-792-3293
4. SAMHC Behavioral Health Services provides crisis intervention, mental health screening, referral and linkages to other mental health services. Located at 2502 N. Dodge Blvd., Suite 190, Tucson, AZ, 85716: 520-622-6000.
5. Flagstaff Medical Center, a 271 bed acute care hospital located at 1200 N. Beaver St., Flagstaff, AZ 86001: 928-779-3366; Cancer Center at the medical center: 928 773-226, Behavioral Health Services at the medical center: 928-213-6300.

APPENDIX N

VERIFICATION OF TRAINING FORM FOR INSTITUTIONAL REVIEW BOARD

Use to list all current Key Personnel				
IRB Project No.:	11-0372-04			
Protocol Name:	A Pilot study on Bowenwork® for Symptom Management of Women Breast Cancer Survivors with Lymphedema			
Investigator:	Christine Hansen, BSN, RN, Doctoral Candidate			
Investigator's Contact Information:	520-240-4600 chansen@nursing.arizona.edu PO BOX 32655 Tucson, Arizona 85751-2655			
Alternate Contact:	Ruth Taylor-Piliae, PhD, RN (Dissertation Chair)			
Alternate Contact's Information:	rtaylor@nursing.arizona.edu; 520-626-4881			
PI Attestation: (SAVAHCS Studies only)	I confirm that the below staff members are qualified and have been properly trained to perform consenting procedures under my supervision in this study.			
	PI Signature:	Date:		
Name	Research Role	Department & Institution	Consent r	Training Date
Christine Hansen, RN BSN, PhD candidate	Primary Investigator	University of Arizona, College of Nursing	☐ No ☒ Yes	2/3/2010
Ruth Taylor-Piliae, PhD, RN	Dissertation Chair	University of Arizona, College of Nursing	☒ No ☐ Yes	Refresher 08/10/2009
Lois Loescher PhD, RN	Dissertation Committee member	University of Arizona, College of Nursing	☒ No ☐ Yes	01/04/2011
Mary Koithan PhD, RN	Dissertation Committee member	University of Arizona, College of Nursing	☒ No ☐ Yes	12/28/2010
Teresa Peterson, Certified Bowenworker	Bowenworker, Research Assistant		☐ No ☒ Yes	3/7/2011
Geoffrey Kearney, Certified Bowenworker	Bowenworker, Research Assistant		☐ No ☒ Yes	4/5/2011
Nancy Howe, Certified Bowenworker	Bowenworker, Research Assistant		☐ No ☒ Yes	4/6/2011
Alexia Monroe, Certified Bowenworker	Bowenworker		☒ No ☐ Yes	5/15/2011

APPENDIX O
BOWENWORKER CERTIFICATION CHECK LIST

Bowenworker Certification Check List

Name	Date and Signature
Instruction and Observation	
CITI Certification for Research	
<u>Session One</u> Lower Back 1,2,3,4 Upper back Kidney Neck 1,2,3,4,5,6	
<u>Session Two</u> Instruct participant in arm circling exercises before session Lower Back 1,2 Upper Back 1,2,3,4,5,6,7,8 Neck 1,2,3,4,5,6,7,8 Upper Respiratory/Temperomandibular Joint (TMJ) Shoulder (in sitting position) Begin arm exercises at home following day	
<u>Session Three</u> Lower Back 1,2,3,&4 Upper Back 1,2,3,4,5,6,7,8 Respiratory Lower back 11&12 Neck (modified moves 7&8 done more inferiorly ½ inch) Upper Respiratory/TMJ Shoulder (in sitting position) Continue with home arm exercises	
<u>Session Four</u> Lower Back 1,2,3,4,5,6,7,8 Upper Back 1,2,3,4,5,6,7,8 Chest replace with East if breast implants Neck 1,2,3,4,5,6 Sternal Additional move forearm	
<u>Limb Circumference</u> Lymphedema Assessments with Tape pressure touching skin with no pulling on tape. Upper Arm: Measure distance from tip of humerus / clavicle junction to head of radius at elbow. Divide in half and place tape at this location. Record measurement. Lower Arm: Measure length of radius. Divide in half and place tape at this location. Record measurement.	

Wrist: Place tape at the bend of the wrist. Record measurement. Ankle: Place tape 1" superior to center of both malleoli. Record measurement <u>Goniometer</u> Abduction: Stand posterior to subject. Place center of goniometer at junction of scapula and humerus head. Hold goniometer so that the clear leg is vertical. Ask subject to abduct slowly with palm anterior, stopping at first restriction. Point measurement leg of goniometer directly at the head of the radius at elbow. Record measurement. Forward Flexion: Stand at side of subject. Place center of goniometer at joint between head of humerus and lateral border of scapula, superior to axilla. Hold goniometer so that clear leg is vertical. Point measurement leg at head of radius at elbow. Record measurement.	
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APPENDIX P
BOWENWORK SESSION MOVES

Bowenwork Session Moves

Session #1

Lower Back 1,2,3,&4

Upper Back

Kidney,

Neck 1,2,3,4,5,6

Session #2

Instruct participant in arm circling exercises before session

Lower Back 1&2

Upper Back 1,2,3,4,5,6,7,8,

Neck 1,2,3,4,5,6,7,8,

Upper Respiratory/Temperomandibular Joint (TMJ),

Shoulder(in sitting position)

Begin arm exercises at home following day

Session #3

Lower Back 1,2,3,&4

Upper Back 1,2,3,4,5,6,7,8

Respiratory

Lower back 11&12

Neck(modified moves 7&8 done more inferiorly ½ inch)

Upper Respiratory/TMJ

Shoulder (in sitting position)

Continue with home arm exercises

Session #4

Lower Back 1,2,3,4,5,6,7,8

Upper Back 1,2,3,4,5,6,7,8

Chest or East

Neck 1,2,3,4,5,6

Sternal

Additional move forearm

APPENDIX Q

ANATOMICAL LOCATION FOR BOWENWORK MOVES

Anatomical Involvement for Bowenwork Moves

<u>Specific Bowenwork Move</u>	<u>Anatomical Involvement in Chosen Procedures</u>
Low Back	Erector spinae, gluteus maximus, medius and minimus, hamstrings, common peroneal nerve (branch of the sciatic) iliotibial tract, vastus lateralis Purpose: to initiate parasympathetic nervous system response, normalize tension in the gluteals and hamstrings thereby allowing any torque in the hips to untwist
Upper Back	Erector spinae, rhomboideus major and minor, levator scapula, latissimus dorsi Purpose: to add to parasympathetic response through the central nervous system, soften tight upper back muscles, allow thoracic area to soften, deepen breathing, address fascial connections to shoulder
Kidney	Movement through erector spinae and latissimus dorsi, through lumbar area inferior to 12 th rib Purpose: to address potential lymph congestion in the area
Neck	Posterior and middle scalenus, semispinalis capitus, occipital lymph nodes, trapezius Purpose: to relax neck, initiate lymph drainage, address fascia connections with shoulder
Respiratory / Gall Bladder	Erector spinae, rectus abdominus, diaphragm, linea alba, vagus nerve, falciform ligament, lateral obliques Purpose: to facilitate lymph drainage in the thorax and removal, relax muscles in the chest
Upper Respiratory / TMJ	Mylohyoid, lymph nodes along trachea, behind sternocleidomastoid (SCM) and superior to clavicle, and jugular foramen (junction of occiput and temporal bones), cranial nerves IX, X, and XI (glossopharyngeal, vagus, and spinal accessory nerves), neurovascular bundle at attachment of mandible anterior to ear Purpose: to initiate lymph drainage, free potential adhesions in the trachea lymph drainage area, relax

	SCM muscle, stimulate lymph drainage and blood flow, affect autonomic nervous system, address cartilage in TMJ
Shoulder (seated) position	Posterior, middle and anterior deltoid, triceps, axillary nerve, brachial plexus Purpose: to free shoulder restrictions
	Arm circling exercise – gentle circular arm ROM Purpose: to free facial restriction and move lymph
Knee 1-4A	Vastus lateralis, retinacular ligaments, vastus medialis, gastrocnemius, Achilles tendon, tibial nerve Purpose: Stimulate lymph drainage in the pelvis and lower body
Chest or East	lymph nodes of the axilla and breast, pectoralis major Purpose: to initiate lymphatic drainage of chest and upper arm area

APPENDIX R

AUTHORIZATION FOR SITE USE FOR BOWENWORKERS
AND REGISTERED COPYRIGHT

Authorization for Site Use for Bowenworkers and Registered Copyright

March 31, 2011

Study Title: *A Pilot study on Bowenwork® for Symptom Management of Women Breast Cancer Survivors with Lymphedema*

Primary Investigator
Christine Hansen, RN, BSN, PhD Candidate, University of Arizona
PO BOX 32655
Tucson, AZ 85751-2655

Dear Christine

I am pleased to inform you that I am willing to commit to the responsibilities of the Bowenworker, in your pilot study of Bowenwork® for symptom management for women breast cancer survivors with lymphedema. With you as the Primary Investigator, overseeing the entire project and responsible for recruitment, data management and data analysis, I realize my responsibility is crucial to the success of this project. My responsibilities are as follows:

- Take an online CITI (Collaborative Institutional Training Initiative) course on the Ethics of study on human subjects, prior to participating in the study.
- Schedule four intervention appointments within the study protocol time frame for each participant.
- Collect questionnaires at first appointment that participants will have completed prior to the appointment and the first Bowenwork® session.
- Collect and document data on study forms at the onset of each appointment
- Deliver the Bowenwork® intervention as per protocol for each of the sessions
- Complete the documentation at the end of each intervention session
- At end of fourth session, give participants final questionnaire to complete at home
- Schedule a fifth session one week later of approximately 15 minutes for final measurements and to collect final questionnaire from participants.
- Assist with returning all collected data to the Primary Investigator

I am also authorizing the use of my office located at 5300 E. Erickson Dr. Ste. 104 Tucson, AZ 85712 for the use of delivering the Bowenwork® to the enrolled participants.

Sincerely,

Geoffrey Kearney



March 31, 2011

Study Title: *A Pilot study on Bowenwork® for Symptom Management of Women Breast Cancer Survivors with Lymphedema*

Primary Investigator

Christine Hansen, RN, BSN, PhD Candidate, University of Arizona
PO BOX 32655
Tucson, AZ 85751-2655

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- At end of fourth session, give participants final questionnaire to complete at home
- Schedule a fifth session one week later of approximately 15 minutes for final measurements and to collect final questionnaire from participants.
- Assist with returning all collected data to the Primary Investigator

I am also authorizing the use of my office located at 2104 N. Third Street, Flagstaff, AZ for the use of delivering the Bowenwork® to the enrolled participants.

Sincerely,



Teresa O. Peterson

March 31, 2011

Study Title: *A Pilot study on Bowenwork® for Symptom Management of Women Breast Cancer Survivors with Lymphedema*

Primary Investigator

Christine Hansen, RN, BSN, PhD Candidate, University of Arizona
PO BOX 32655
Tucson, AZ 85751-2655

Dear Christine

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- Deliver the Bowenwork® intervention as per protocol for each of the sessions
- Complete the documentation at the end of each intervention session
- At end of fourth session, give participants final questionnaire to complete at home
- Schedule a fifth session one week later of approximately 15 minutes for final measurements and to collect final questionnaire from participants.
- Assist with returning all collected data to the Primary Investigator

I am also authorizing the use of my office located at **6993 N. Oracle Rd., Tucson, AZ 85704**, for the use of delivering the Bowenwork® to the enrolled participants.

Sincerely,



Nancy Brownell-Howe



August 21, 2011

Christine Hansen, BSN, RN
Doctoral Student
University of Arizona
College of Nursing
1305 N. Martin, P.O. Box 210203
Tucson, AZ 85721-0203

Dear Christine,

I, Alexia L. Monroe, authorize you to use Creekside Center in Prescott, AZ, for the purpose of conducting your research study with breast cancer survivors. I am happy to support your efforts in every way that I can.

You may use my electronic signature, below, as verification of this agreement.

Sincerely,

Alexia L. Monroe, Proprietor (Electronic Signature)

Creekside Center
337 N. Rush St.
Prescott, AZ 86301

December 21, 2011

Ms. Christine Hansen
PO Box 32655
Tucson, AZ 85651

Dear Ms. Hansen:

Bowenwork Academy USA grants to Christine Hansen authorization to use the registered copyright for Bowenwork (Bowenwork®) in your dissertation work and on any associated publications.

Feel free to give me a call if you have any questions or if I can be of further assistance.

Kind regards
BOWENWORK ACADEMY USA

A handwritten signature in cursive script that reads "N. Sue Rutter". The signature is written in black ink and is positioned above the printed name.

N. Sue Rutter
Bowenwork Admin

APPENDIX S
BOWENWORK DOCUMENTATION FORM

Bowenwork Documentation Form

Session 1 Date		
Any changes in condition or medical treatment since the study started?	Yes (Explain and contact PI)	No (Continue with treatment)
Did the participant drive themselves?	Yes	No
Did the participant complete the survey prior to appointment?	Yes	No Assisted with completion? Yes/no If no unable to continue with intervention
What arm is affected?(circle)	Right	Left
Limb Circumference A= Upper Arm B= Lower Arm C= Wrist D= Ankle	A= B= C= D=	A= B= C= D=
Degree of range of motion with goniometer		
Bowenwork intervention moves completed (list)		
How long was the treatment?		
Subject Questions: a. Did you feel uncomfortable during the treatment?	Yes (Explain)	No
b. Did you experience any nausea, dizziness, or tearfulness?	Yes (Explain)	No
Other comments (Bowenworker)		
Other comments (Subject)		
Study ID/Acrostic Session 2 Date		
Any changes in condition or medical treatment since the study started?	Yes (Explain and contact PI)	No (Continue with treatment)
Did the participant drive themselves?	Yes	No
What arm is affected?(circle)	Right	Left

Limb Circumference A= Upper Arm B= Lower Arm C= Wrist D= Ankle	A= B= C= D=	A= B= C= D=
Degree of range of motion with goniometer		
Bowenwork intervention moves completed (list)		
How long was the treatment?		
Did the participant receive shoulder exercise instruction and handout?	Yes	No (Explain)
Subject Questions: a. Did you feel uncomfortable during the treatment?	Yes (Explain)	No
b. Did you experience any nausea, dizziness, or tearfulness?	Yes (Explain)	No
Other comments (Bowenworker)		
Other comments (Subject)		
Study ID/Acrostic Session 3 Date		
Any changes in condition or medical treatment since the study started?	Yes (Explain and contact PI)	No (Continue with treatment)
Did the participant drive themselves?	Yes	No
Did the participant perform the expected shoulder exercises between sessions?	Yes	No (Explain)
What arm is affected?(circle)	Right	Left
Limb Circumference A= Upper Arm B= Lower Arm C= Wrist D= Ankle	A= B= C= D=	A= B= C= D=
Degree of range of motion with goniometer		
Bowenwork intervention moves completed (list)		
How long was the treatment?		
Subject Questions:	Yes	No

a. Did you feel uncomfortable during the treatment?	(Explain)	
b. Did you experience any nausea, dizziness, or tearfulness?	Yes (Explain)	No
Other comments (Bowenworker)		
Other comments (Subject)		
Study ID/Acrostic Session 4 Date		
Any changes in condition or medical treatment since the study started?	Yes (Explain and contact PI)	No (Continue with treatment)
Did the participant drive themselves?	Yes	No
Did the participant perform the expected shoulder exercises between sessions?	Yes	No(Explain)
What arm is affected?(circle)	Right	Left
Limb Circumference A= Upper Arm B= Lower Arm C= Wrist D= Ankle	A= B= C= D=	A= B= C= D=
Degree of range of motion with goniometer		
Bowenwork intervention moves completed (list)		
How long was the treatment?		
Subject Questions: a. Did you feel uncomfortable during the treatment?	Yes (Explain)	No
b. Did you experience any nausea, dizziness, or tearfulness?	Yes (Explain)	No
Other comments (Bowenworker)		
Other comments (Subject)		
Did the participant receive the final questionnaire packet?	Yes	No

APPENDIX T

BOWENWORKERS DEMONSTRATE SHOULDER STRETCHING EXERCISES

Bowenworkers Demonstrate Shoulder Stretching Exercises

Purpose- To increase mobility, reduce swelling and soften stiffness.

You can begin the exercises the day after your Bowenwork treatment

Directions- In a standing position, start with the arm without lymphedema. Circle the arm in a slow windmill action, keeping the arm straight; let your arm drop for a moment between circles so each on is a separate movement. Do six circles in one direction, than, with the same arm, do six in the other direction. Do arm circles in the eight instructed by Bowenworker. The first four positions are done with the arm in front of you and remaining four positions with the arm toward the back of you. Exercises should be at least three times between your next Bowenwork sessions. No pain is allowed. We want your brain to remember moving your shoulder without pain. The size and shape of your circles will be determined by your comfortable range of motion.

APPENDIX U
QUESTIONNAIRE SF-36

SF-36 QUESTIONNAIRE

#ID: _____

Date: _____

Please answer the 36 questions of the **Health Survey** completely, honestly, and without interruptions.

GENERAL HEALTH:

In general, would you say your health is:

☐ Excellent ☐ Very Good ☐ Good ☐ Fair ☐ Poor

Compared to one year ago, how would you rate your health in general now?

☐ Much better now than one year ago
☐ Somewhat better now than one year ago
☐ About the same
☐ Somewhat worse now than one year ago
☐ Much worse than one year ago

LIMITATIONS OF ACTIVITIES:

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.

☐ Yes, Limited a Lot ☐ Yes, Limited a Little ☐ No, Not Limited at all

Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf

☐ Yes, Limited a Lot ☐ Yes, Limited a Little ☐ No, Not Limited at all

Lifting or carrying groceries

☐ Yes, Limited a Lot ☐ Yes, Limited a Little ☐ No, Not Limited at all

Climbing several flights of stairs

☐ Yes, Limited a Lot ☐ Yes, Limited a Little ☐ No, Not Limited at all

Climbing one flight of stairs

☐ Yes, Limited a Lot ☐ Yes, Limited a Little ☐ No, Not Limited at all

Bending, kneeling, or stooping

☐ Yes, Limited a Lot ☐ Yes, Limited a Little ☐ No, Not Limited at all

Walking more than a mile

☐ Yes, Limited a Lot ☐ Yes, Limited a Little ☐ No, Not Limited at all

Walking several blocks

☐ Yes, Limited a Lot ☐ Yes, Limited a Little ☐ No, Not Limited at all

Walking one block

☐ Yes, Limited a Lot ☐ Yes, Limited a Little ☐ No, Not Limited at all

Bathing or dressing yourself☐ Yes, Limited a Lot☐ Yes, Limited a Little☐ No, Not Limited at all**PHYSICAL HEALTH PROBLEMS:**

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

Cut down the amount of time you spent on work or other activities☐ Yes☐ No**Accomplished less than you would like**☐ Yes☐ No**Were limited in the kind of work or other activities**☐ Yes☐ No**Had difficulty performing the work or other activities (for example, it took extra effort)**☐ Yes☐ No**EMOTIONAL HEALTH PROBLEMS:**

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

Cut down the amount of time you spent on work or other activities☐ Yes☐ No**Accomplished less than you would like**☐ Yes☐ No**Didn't do work or other activities as carefully as usual**☐ Yes☐ No**SOCIAL ACTIVITIES:**

Emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

☐ Not at all☐ Slightly☐ Moderately☐ Severe☐ Very Severe**PAIN:**

How much bodily pain have you had during the past 4 weeks ?

☐ None☐ Very Mild☐ Mild☐ Moderate☐ Severe☐ Very Severe

During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

☐ Not at all☐ A little bit☐ Moderately☐ Quite a bit☐ Extremely

ENERGY AND EMOTIONS:

These questions are about how you feel and how things have been with you during the last 4 weeks. For each question, please give the answer that comes closest to the way you have been feeling.

Did you feel full of pep?

- ☐ All of the time
☐ Most of the time
☐ A good Bit of the Time
☐ Some of the time
☐ A little bit of the time
☐ None of the Time

Have you been a very nervous person?

- ☐ All of the time
☐ Most of the time
☐ A good Bit of the Time
☐ Some of the time
☐ A little bit of the time
☐ None of the Time

Have you felt so down in the dumps that nothing could cheer you up?

- ☐ All of the time
☐ Most of the time
☐ A good Bit of the Time
☐ Some of the time
☐ A little bit of the time
☐ None of the Time

Have you felt calm and peaceful?

- ☐ All of the time
☐ Most of the time
☐ A good Bit of the Time
☐ Some of the time
☐ A little bit of the time
☐ None of the Time

Did you have a lot of energy?

- ☐ All of the time
☐ Most of the time
☐ A good Bit of the Time
☐ Some of the time
☐ A little bit of the time
☐ None of the Time

Have you felt downhearted and blue?

- ☐ All of the time
☐ Most of the time
☐ A good Bit of the Time
☐ Some of the time
☐ A little bit of the time
☐ None of the Time

Did you feel worn out?

- ☐ All of the time
☐ Most of the time
☐ A good Bit of the Time
☐ Some of the time
☐ A little bit of the time
☐ None of the Time

Have you been a happy person?

- ☐ All of the time
☐ Most of the time
☐ A good Bit of the Time
☐ Some of the time
☐ A little bit of the time
☐ None of the Time

Did you feel tired?

- ☐ All of the time
☐ Most of the time
☐ A good Bit of the Time
☐ Some of the time
☐ A little bit of the time
☐ None of the Time

SOCIAL ACTIVITIES:

During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

- ☐ All of the time
☐ Most of the time
☐ Some of the time
☐ A little bit of the time
☐ None of the Time

APPENDIX V
QUESTIONNAIRE FACT-B

FACT-B (Version 4)

US English 3/19/03
Copyright 1987, 1997 Page 1 of 3

ID _____

Below is a list of statements that other people with your illness have said are important.
By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

PHYSICAL WELL-BEING

	Not at all	A little bit	Somewhat	Quite a bit	Very much
GP1 I have a lack of energy	0	1	2	3	4
GP2 I have nausea	0	1	2	3	4
GP3 Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4 I have pain	0	1	2	3	4
GP5 I am bothered by side effects of treatment	0	1	2	3	4
GP6 I feel ill	0	1	2	3	4
GP7 I am forced to spend time in bed	0	1	2	3	4

SOCIAL/FAMILY WELL-BEING

	Not at all	A little bit	Somewhat	Quite a bit	Very much
GS1 I feel close to my friends	0	1	2	3	4
GS2 I get emotional support from my family	0	1	2	3	4
GS3 I get support from my friends	0	1	2	3	4
GS4 My family has accepted my illness	0	1	2	3	4
GS5 I am satisfied with family communication about my illness	0	1	2	3	4
GS6 I feel close to my partner (or the person who is my main support)	0	1	2	3	4
Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box and go to the next section.	0	1	2	3	4
Q1 GS7 I am satisfied with my sex life					

EMOTIONAL WELL-BEING

	Not at all	A little bit	Somewhat	Quite a bit	Very much
GE1 I feel sad	0	1	2	3	4
GE2 I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3 I am losing hope in the fight against my illness	0	1	2	3	4
GE4 I feel nervous	0	1	2	3	4
GE5 I worry about dying	0	1	2	3	4
GE6 I worry that my condition will get worse	0	1	2	3	4

FUNCTIONAL WELL

	Not at all	A little bit	Somewhat	Quite a bit	Very much
GF1 I am able to work (include work at home)	0	1	2	3	4
GF2 My work (include work at home) is fulfilling	0	1	2	3	4
GF3 I am able to enjoy life	0	1	2	3	4
GF4 I have accepted my illness	0	1	2	3	4
GF5 I am sleeping well	0	1	2	3	4
GF6 I am enjoying the things I usually do for fun	0	1	2	3	4
GF7 I am content with the quality of my life right now					

ADDITIONAL CONCERNS

	Not at all	A little bit	Somewhat	Quite a bit	Very much
B1 I have been short of breath	0	1	2	3	4
B2 I am self-conscious about the way I dress	0	1	2	3	4
B3 One or both of my arms are swollen or tender	0	1	2	3	4
B4 I feel sexually attractive	0	1	2	3	4
B5 I am bothered by hair loss	0	1	2	3	4
B6 I worry that other members of my	0	1	2	3	4

family might someday get the same illness I have					
B7 I worry about the effect of stress on my illness	0	1	2	3	4
B8 I am bothered by a change in weight	0	1	2	3	4
B9 I am able to feel like a woman	0	1	2	3	4
P2 I have certain parts of my body where I experience significant pain	0	1	2	3	4

APPENDIX W
QUESTIONNAIRE BPI

BRIEF PAIN INVENTORY

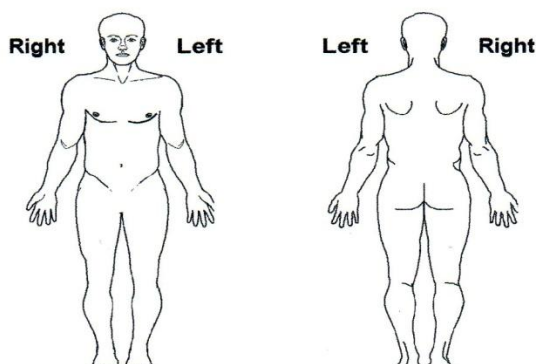
Date ____/____/____ Time: ____

ID#: _____

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

1. Yes 2. No

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



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

0 1 2 3 4 5 6 7 8 9 10
No Pain Pain as bad as you can imagine

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

0 1 2 3 4 5 6 7 8 9 10
No Pain Pain as bad as you can imagine

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

0 1 2 3 4 5 6 7 8 9 10
No Pain Pain as bad as you can imagine

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

0 1 2 3 4 5 6 7 8 9 10
No Pain Pain as bad as you can imagine

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

- 8) In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that shows how much **RELIEF** you have received.

0% 10 20 30 40 50 60 70 80 90 100%
No relief Complete relief

- 9) Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

A. General activity

0 1 2 3 4 5 6 7 8 9 10
Does not interfere Completely interferes

B. Mood

0 1 2 3 4 5 6 7 8 9 10
Does not interfere Completely interferes

C. Walking ability

0 1 2 3 4 5 6 7 8 9 10
Does not interfere Completely interferes

D. Normal work (includes both work outside the home and housework)

0 1 2 3 4 5 6 7 8 9 10
Does not interfere Completely interferes

E. Relations with other people

0 1 2 3 4 5 6 7 8 9 10
Does not interfere Completely interferes

F. Sleep

0 1 2 3 4 5 6 7 8 9 10
Does not interfere Completely interferes

G. Enjoyment of life

0 1 2 3 4 5 6 7 8 9 10
Does not interfere Completely interferes

In addition to completing the Brief Pain Inventory, to help your doctor better manage your pain, please tell us:

What does the pain feel like? Circle those words that describe your pain.

aching	throbbing	shooting
stabbing	gnawing	pricking
sharp	tender	burning
exhausting	tiring	penetrating
nagging	numb	miserable
unbearable	dull	radiating
squeezing	cramping	deep

How long have you had this pain? (Circle one)

less than a week	1 to 2 weeks
2 to 4 weeks	more than a month

What kinds of things make your pain feel better (for example, heat, medicine, rest)?

What kinds of things make your pain worse (for example, walking, standing, lifting)?

Do you have any other symptoms? Circle any that apply:

nausea	vomiting
constipation	diarrhea
lack of appetite	indigestion
difficulty sleeping	feeling drowsy
nightmares	dizziness
tiredness	itching
urinary problems	sweating
weakness	headaches

Talking About Your Pain

It's important to remember that each person's pain is different. The pain that you experience can't be compared to another person's pain. ONLY YOU know how and when you hurt, and how the pain affects your life.

It is important to describe what you are feeling to those who are trained to help you. Don't be embarrassed to talk to your doctor, nurse, or pharmacist. They need to know as much as possible about your pain in order to develop the best plan to control it. The questions on this form can help you describe your pain.

Why Is Pain Relief So Important?

Proper treatment for pain is not only a matter of comfort. Unrelieved pain can lead to nausea, loss of sleep, depression, loss of appetite, weakness, and other problems. Pain can also affect your life at home and at work. Relieving your pain means that you can continue to do the day-to-day things that are important to you.

Most Pain Can Be Controlled

It is important to know that most pain CAN be relieved. Your doctor will work with you to find the treatment that may be best for your pain.

The key to effective pain control is to take the RIGHT AMOUNT, of the RIGHT MEDICINE, at the RIGHT TIME. You should take your pain medicine on a regular schedule, as your doctor, nurse, or pharmacist tells you. Don't wait until the pain becomes severe. Pain is easier to control when it is mild than when it has reached full force.

If your pain medicine wears off too soon, is not relieving the pain, or causes problems with side effects, you should call your doctor because you may need to have your treatment plan changed.

Comments: Write down any questions or information you need to share with your doctor, nurse, or pharmacist about your pain.

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