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EVALUATION OF A MIND-BODY WEB SITE BY WOMEN WITH BREAST CANCER

by

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A doctoral thesis submitted in partial fulfillment of the requirements
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ABSTRACT

Despite having access to volumes of information, women newly diagnosed with breast cancer report a moderate level of distress related to their diagnosis, treatment, life expectancy, threat to current roles, and life-changing surgery and treatment choices. Web sites designed to teach people strategies to reduce distress are readily available online. The online format may be useful and practical for women who can access the site at their convenience, learn the components of the interventions at their own pace, and practice the strategies in the comfort of their home.

The purpose of this study was to evaluate an online Mind-Body web site (<http://www.preparingforyoursurgery.com>) designed to reduce distress related to surgery for its usability, practicality, and appropriateness for women newly diagnosed with breast cancer. Results of this study will be used to either adopt use of the web site into standard of care at our cancer center or explore development of a similar web site to meet the needs of women newly diagnosed with breast cancer.

Women recently diagnosed with breast cancer, who had breast cancer surgery in the past 60 days, were asked to evaluate an online Mind-Body web site and then respond to an online questionnaire measuring the web site usability, practicality, and appropriateness.

Thirty-one women evaluated the web site and completed the online survey. The majority of women agreed the web site is useful, practical, appropriate, and would recommend to others. There was no significant relationship between age, income, level of education, frequency of Internet use, or experience with Mind-Body techniques and women who agreed the web site is useful, appropriate, or practical compared to women who were neutral or disagreed the web site

is useful, appropriate, or practical. The results of this study suggest the web site could be introduced to women newly diagnosed with breast cancer at our cancer center regardless of age, income, education, frequency of Internet use, or experience with Mind-Body techniques.

The research project is dedicated to the women who graciously gave of their time to provide valuable information to ease the distress of those who follow.

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CHAPTER ONE: INTRODUCTION

The American Cancer Society (2011) predicts that in 2012, over 288,130 women would be diagnosed with breast cancer in the United States. In 2011, in the state of Florida, 14,080 women were diagnosed with breast cancer (American Cancer Society [ACS], 2011) and 558 of those women received treatment at MD Anderson Cancer Center Orlando (MD Anderson Orlando Annual Report, 2011). With mortality rates for breast cancer on the decline since 1990 (ACS, 2011), treatment goals have expanded beyond state-of-the-art comprehensive treatment to integrating strategies to minimize psychological side effects associated with cancer, such as distress.

Cancer-related distress is defined as “a multifactorial unpleasant emotional experience of a psychological (cognitive, behavioral, emotional), social and/or spiritual nature that may interfere with the ability to cope effectively with cancer, its physical symptoms and its treatment” (The National Comprehensive Cancer Network, 2008, p. 6). Women rate their distress prior to breast cancer surgery at the moderate level (Von Ah & Kang, 2007). Distress in women newly diagnosed with breast cancer arises from many aspects of diagnosis. The emotional impact of facing a potentially life-limiting illness, experiencing body image changes, and exploring their life’s purpose can result in distress (Schneider, Fletcher, & Snider, 2008). Personal and family issues, such as dealing with threats to their varied roles in life, also result in distress (Waldrop, O’Connor & Trabold, 2011). In addition, making decisions concerning breast surgery options has been reported as a major source of distress for women newly diagnosed with breast cancer (Wise, Han, Shaw, McTavish & Gustafson, 2008). Facing daunting decisions in a short period of time, women are required to co-exist with distress and uncertainty for several weeks until the comprehensive treatment plan is finalized.

In general, distress is prevalent in people with cancer and can lead to significant symptoms; however, if interventions for distress are used there can be improvements in quality of life. While the level of distress varies from person to person, up to 100% of women report experiencing distress at diagnosis and during the initial phases of treatment (Preyde, Chevalier, Hatton-Bauer, & Barksey, 2010, Montgomery et al., 2003). Women newly diagnosed with breast cancer report experiencing distress related to insomnia, anxiety, situational depression, fear, appetite changes, and relationship strain (Waldrop et al., 2011). Additionally, pre-surgery distress contributes to post-surgery discomfort, fatigue, and pain (Montgomery & Bovbjerg, 2004). Effectively managing distress can improve decision making capabilities, enhance coping with a life-threatening disease, and improve quality of life (Institute of Medicine [IOM], 2004).

Due to the prevalence of distress and the profound benefits in managing it well, several national organizations stress the importance of conducting research to identify effective strategies for managing distress. Organizations such as the National Cancer Institute, American Public Health Association, American Society for Preventive Oncology, Society of Behavioral Medicine, and American Cancer Society support and encourage research on distress (Stefanek, Andrykowski, Lerman, Manne, & Glanz, 2009). In addition, the Institute of Medicine (2004) supports the use of evidenced-based interventions in community practice, and the Oncology Nursing Society (ONS, 2011) is calling for research that improves distress through interventions. Therefore, in order to address distress in people with cancer and find effective ways to teach distress reduction strategies, this research project will evaluate an online Mind-Body web site designed to reduce distress for its usability, practicality, and appropriateness for women newly diagnosed with breast cancer.

Background

Personnel at a community cancer center in central Florida recognize the prevalence of distress, brought about by the complexity of decision making in a short time frame for women newly diagnosed with breast cancer. Therefore, the personnel at the cancer center would like to incorporate or develop evidence-based, low-cost, practical interventions to manage distress while respecting the time limitations of patients and staff. Mind-Body interventions such as meditation, guided imagery, positive affirmations, and breathing techniques could be an effective approach as they have been shown to decrease distress in cancer patients (Herman, Craig & Caspi, 2005). An online Mind-Body intervention could potentially meet the needs of women newly diagnosed with breast cancer without additional financial burden to the patient or the need to reallocate resources of the cancer center. Learning more about how women perceive interventions to lower distress in the time period prior to surgery will help target strategies to meet their needs. The first step in this process will be to have women evaluate the usability, practicality, and appropriateness of an online Mind-Body intervention that could potentially be recommended by providers at the cancer center to help women newly diagnosed with breast cancer manage distress prior to and after surgery.

Problem

Current strategies to address distress at our cancer center include patient education on the disease process and its treatment, medications for anxiety and depression, counseling for groups and individuals, and Mind-Body educational classes offered at the cancer center. Staff time and written material are allocated for education on breast cancer and its treatment on every office visit. However, offering educational information on breast cancer is not enough because women

newly diagnosed with breast cancer also experience distress from not knowing their personal outcome even if their informational needs have been met (Preyde et al., 2010).

Often, women newly diagnosed with breast cancer who expresses distress to their physician are given medication and referred to counseling. However, these strategies have limitations. Prescription anti-anxiety medications can effectively diminish acute distress, but the medications can have a variety of side effects including dizziness, sedation, unsteady gait, depression, and delirium and can interact with other medications, resulting in serious events (Micromedix, 2012). These pharmacologic approaches to address the symptoms of anxiety work quickly but have a short duration of response (Micromedix, 2012). Conversely, medications for depression can require weeks to achieve therapeutic levels (Micromedix, 2012), and therefore, are not immediately helpful in the preoperative setting. In addition, women are often reluctant to take medication even if it could reduce anxiety due to the side effects of the medications (Brenes et al., 2005).

Non-pharmacologic approaches for distress are available at the cancer center and in the community and include counseling, support groups, and Mind-Body interventions. Research suggests that individual counseling (Koopman et al., 2002) and support groups have successfully decreased distress in women with breast cancer during or after treatment (Montazeri et al., 2001). Mind-Body interventions like meditation are widely accepted and used by patients and the medical profession for holistic health and wellness in health prevention, treatment, and recovery (Horowitz, 2010). In addition, relaxation techniques like guided imagery, inspirational music, yoga, meditation, and breath work are also used by people with cancer during and after treatment (Boyce, 2007). Current Mind-Body interventions at our center are designed as classes requiring return visits to the cancer center. These classes can be just one session or are scheduled once a

week over several weeks and are only offered a few times a year. Classes at MD Anderson Orlando vary but often include Yoga, Acupressure for Symptom Management, Creative Arts Workshops, Energy Medicine and the Daily Energy Routine, Seven Spiritual Exercises, and Walking the Labyrinth. Unfortunately, this schedule of class offerings may be impractical for someone facing surgery in two weeks due to the competing time demands of appointments with physician specialists and medical testing.

Introducing Mind-Body interventions right after diagnosis may offer women distinct benefits (Preyde et al., 2010). Research has shown that if distress is not effectively managed, it can continue at high levels even a year later at rates of up to 40% (Waldrop, et. al, 2011). This residual distress can lead to significant health issues including anxiety, depression, fatigue, difficulty sleeping, loss of self-esteem, pain, cognitive impairment, and weight gain (Brem & Kumar, 2011). Delivering easy to access Mind-Body interventions early in the treatment trajectory may be able to prevent health issues in women with breast cancer by effectively managing distress.

Currently, over 80% of women newly diagnosed with breast cancer use the Internet to find general informational about breast cancer and breast cancer treatment (Setoyama, Yamazaki & Nakayama, 2011). Education programs, tailored to educating women on breast cancer in general as well as specific ways to manage treatment related side effects, which are offered on an Internet web site, have been shown to be effective for increasing knowledge of breast cancer and its treatment (Shaw et al., 2007). In addition, strategies to reduce distress are also appearing online and may be useful and practical for women who could access the site at their convenience, learn the components of the interventions at their own pace, and practice the strategies in the comfort of their home.

Objective

The purpose of this study is to evaluate an online Mind-Body web site designed to reduce distress for its usability, practicality, and appropriateness for women newly diagnosed with breast cancer. Results of this study will be used to either adopt use of the web site into standard of care at our cancer center or explore development of a similar web site to meet the pre-surgery needs of women newly diagnosed with breast cancer.

Research Questions

Research question 1: Do women with breast cancer perceive the Mind-Body intervention as useful based on the Perceived Health Web Site Usability Questionnaire (PHWSUQ)?

Research question 2: Do women with breast cancer perceive an online Mind-Body intervention to be practical and appropriate for reducing pre-surgical distress?

Definitions

For this study, terms are defined as follows:

Table 1: Definitions

Term	Conceptual Definition
Mind-Body techniques	A form of self-care based on the understanding that our beliefs and attitude affect biological functioning and that what we do with our physical body can modify mental, psychological and physical functioning (Gordon, 2008). See examples below.
Breathing technique	Mind-Body techniques that use focusing on the breath to invoke the relaxation response.
Centering and grounding	Mind-Body technique used to quiet one’s thoughts and invoke the relaxation response.
Guided imagery	Mind-Body technique directing use of the imagination to activate a healing response (Gordon, 2008).
Healing goals	Mind-Body technique using positive affirmations before and after surgery.
Usability	“Extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of the user” (International Organization for Standardization, 1998, p. 2).

Assumptions

For the purposes of this research, the following assumptions are made:

1. Patients will provide authentic feedback concerning the web site.
2. Patients can navigate the website without professional assistance.

Study Importance

Distress in women newly diagnosed with breast cancer is prevalent, and current strategies to meet the needs of these women in the time period prior to surgery are inadequate. Information is needed to determine the usability, practicality, and appropriateness of an online Mind-Body intervention designed to reduce distress prior to surgery. Women may be able to learn evidenced based distress reduction techniques via an Internet web site that they may not otherwise have the opportunity to access in the time period prior to breast cancer surgery. Information obtained from this research will contribute to a body of knowledge for use when adopting or designing online Mind-Body intervention strategies. In addition, if women's perceptions of an online Mind-Body intervention are favorable, women could potentially access the web site resource repeatedly along their entire cancer journey to facilitate optimal wellness.

CHAPTER TWO: LITERATURE REVIEW

Introduction

The goal of this chapter is to provide information on the growth of Internet access and use by people to obtain health-related information and information about managing symptoms or side effects using traditional and non-traditional methods. This literature review will support the use of Mind-Body interventions delivered over the Internet. The challenges of Internet use in healthcare and evaluating the usability of an Internet web site will be discussed.

Three searches were conducted using the Psych-INFO, CINAHL, and Medline databases. All three searches were limited to articles written in English, adult populations, and published from 2002 to 2012. The key words “online” or “web site” or “Internet” or “virtual” were combined with pertinent terms for each of the three searches. The first search used the key words and added the term “patient health education,” and 811 articles were returned. Many of the articles pertained to educating healthcare providers on patient education or discussed the process of setting up an online patient education program. Nine pertinent research articles that were similar to this research project were incorporated into the review.

The second search used the first search’s key words and added the term “patient health intervention,” and 484 articles were returned. A number of articles also discussed educating healthcare providers on patient education. Twenty-seven research articles that were similar to this project were included.

The third search used the first search’s key terms and added the terms “Mind-Body” or “meditation” or “guided imagery” or “biofeedback” or “positive affirmations” or “breathing technique” and “intervention” and 84 articles were returned. When the 84 articles were reviewed, only 13 articles directly applied to Internet Mind-Body interventions; the majority

pertained to Mind-Body interventions that were face-to-face programs. Of the 13 articles included in this review, four articles describe Internet support groups led by a moderator, and nine articles describe self-directed Internet interventions.

The following paragraphs will highlight the results of the literature review. The first section will discuss the expansive use of the Internet followed by the use of the Internet in healthcare focusing on the Internet providing health information its impact on health behaviors both in physical and mental health. This section will close with a summary of studies regarding online Mind-Body interventions that are utilized on the <http://www.preparingforyoursurgery.com> web site. The final section describes the importance and challenges of determining if web sites are usable, practical and appropriate by the target audience.

Internet Growth and Use

The impact of the Internet on healthcare in America has been recorded by the Pew Internet and American Life Project since the 1990s (Fox, 2012). The number of Americans accessing the Internet has climbed steadily from 15% of the population in 1995, to almost 78% of Americans in 2011 (Fox, 2011). In addition, the expansion of Internet access through the use of cell phones has changed the demographics of people who routinely access the Internet (FOX, 2012). While users of the Internet used to be limited to those who could afford a home computer, people in lower socioeconomic groups and minority ethnic groups now have access to the Internet and are the consumers with the most rapid growth of Internet use (FOX, 2012).

Over the last 15 years, the Internet has emerged as the primary source for obtaining information on any topic (Sechrest, 2010). People find the Internet convenient and widely available, which leads to improved efficiency of information access (Sechrest, 2010). The Internet has become a “Self-serve just in time” entity (Sechrest, 2010, p. 2568). People have

embraced the Internet for many activities including banking, travel planning, searching for real estate, shopping, and stock market trading, among others (Sechrest, 2010). In February 2012, consumers were asked what they used the Internet for—finding health-related information ranked third behind using email (1) and use of a search engine (2) (Zickuhr, 2012).

Traditionally, healthcare has lagged behind other industries in embracing the Internet and the opportunities it provides for improving health-related services (Sechrest, 2010). Originally, healthcare web sites were limited to giving information in text without engaging the consumer. For example, hospital web sites gave information about their staff and services, pharmaceutical companies provided text information about their medications, and organizations like the American Cancer Society's web site posted information in a bulletin board type format. Even when physician office web sites became interactive, opportunities were often limited to completing health information forms, making appointments, obtaining test results, and/or paying a bill (Walters, Barnard, & Paris, 2006). While the Internet provided information-based web sites and the ability for patients to use it for the practical purposes of completing tasks such as appointments, it did not improve patient outcomes (Sechrest, 2010). Recently, the health care industry has learned that high-quality, engaging web sites result in satisfied customers and improved health outcomes (Sechrest, 2010). Although the healthcare industry has made improvements in Internet offerings, it continues to explore how to improve patient outcomes and patient satisfaction via the Internet.

Internet Use in Healthcare

The Internet can potentially improve participants' outcomes and patient satisfaction scores by providing information and improving health behaviors by providing a venue for education and interventions related to health. The Internet can engage the consumer through its

ease of use, convenience, flexibility, and visual and auditory learning opportunities (Anderson & Klemm, 2008, Sechrest, 2010).

Internet Provides Health Information

Several studies have examined the benefit of providing healthcare information online. For example, Loiselle, Edgar, Batist, Lu, and Lauzier, (2010) found that providing information about breast cancer and its treatment via Internet web sites and a CD-ROM could maintain quality of life in women newly diagnosed with breast cancer. In this randomized study, women received either a one-hour class on how to access and navigate reputable Internet web sites and were given an educational CD-ROM on the disease process, nutrition, psychosocial care, and community support services (N=120), or they received the standard of care, which was written information about the disease process, nutrition, and supportive services (N=85) (Loiselle et al., 2010). Women in the intervention group not only showed higher satisfaction with health information at both 8 and 20 weeks, when compared to the control group; they also had better functional quality of life scores (Loiselle et al., 2010).

Other studies have also shown the Internet to be superior in providing consumers with health education when compared to traditional written materials. This has been demonstrated in web sites designed to inform women about the importance of mammograms (Lin & Effken, 2010) and skin protection to prevent melanoma (Marble, Loescher, Lim, & Hiscox, 2010). Albada, van Dulmen, Lindout, Bensing, and Ausems (2012) also demonstrated this in a randomized study designed to examine the effects of online, tailored information on genetic counseling for women with breast cancer (N=101). Women who used the web site had a better idea of what to expect, less unrealistic expectations, increased knowledge of heredity's impact on

breast cancer, and lower information needs when they met with the genetic counselor compared to a control group given only written information (Albada et al., 2012).

Internet Impacts on Health Behaviors

Several researchers have demonstrated that not only can information provided via the Internet improve knowledge, but it can also impact health behaviors. For example, Yardley (2010) conducted a randomized controlled trial evaluating the impact of an Internet site that explained self-care of minor acute respiratory symptoms in adults (N= 332). After using the site, participants who accessed the web site not only showed higher scores regarding understanding their illness, they were more likely to be doing self-care behaviors for their illness and less likely to contact a doctor for their current symptoms than the control group, which did not access the web site.

Mevisen (2011) was also able to demonstrate improved health behaviors through the use of an online educational web site, which specifically promoted condom use, to decrease sexually transmitted infections (STI). In this randomized controlled trial, young adults who viewed the online educational web site on STIs (N=171) were compared to a control group given only written information on the same topic. The group who viewed the web site had more accurate perceptions of susceptibility to STI, was more likely to go for STI-testing, and was more likely to use condoms than the control group at the three-month follow-up period.

Lin and Effken (2010) showed improvement in health behavior by tailoring an Internet intervention for women in pre-contemplation stage concerning obtaining a mammogram. Women (N=181) were randomized to receive either a brochure about the benefits of obtaining a mammogram or an Internet intervention designed to increase knowledge and change perceptions through the use of personal testimonies of cancer survivors (Lin & Effken, 2010). The group

that accessed the Internet intervention had significantly improved perceptions of mammography and they reported increased intention to obtain a mammogram than the group who received the brochure (Lin, 2010).

In a randomized trial, Ritterband (2009) adapted an established face-to face intervention for insomnia to an Internet intervention. Participants were randomized to a wait list control group or the Internet intervention group that asynchronously completed a six session sleep program consisting of behavioral, educational, and cognitive techniques for insomnia. Participants were asked to keep a daily sleep diary from which weekly suggestions for sleep were generated via a computer based algorithm. Ritterband (2009) found the majority of the Internet intervention group upon completion of the nine-week program no longer met the clinical criteria for insomnia, while the control group had no change in their symptoms (Ritterband, 2009). Participants' improvement in sleep was sustained on the six-month follow-up survey (Ritterband, 2009).

Finally, Wangberg (2011) was able to show improvement in health behavior by engaging participants with an interactive web site on smoking cessation. Participants were randomized to a standard general information web site on smoking cessation (N=999) or a web site intervention for smoking cessation. The web site intervention tailored educational information by asking participants questions that assessed their educational needs for smoking cessation. After answering questions on the web site, they were provided tailored information and emailed tailored information on smoking cessation (N=982). At one month, the group with tailored information and emails had a significantly higher smoking abstinence rate than the group with general information (Wangberg, 2011).

These studies reflect the benefit of the Internet in providing information and improving health behavior for people across the health continuum from prevention to survivorship and from a broad topic like respiratory symptoms to specific issues like insomnia. The benefit of the Internet on physical health will be expanded upon in the next section.

Online Physical Health Interventions

In addition to providing information and improving health behaviors, online interventions have been shown to be effective in training people to self-manage chronic conditions such as diabetes (Hess et al., 2007), hypertension (Green et al., 2008), obesity (vanGenugten et al., 2012, McTigue et al., 2011), and chronic low back pain (Carpenter et al., 2012). For example, Solomon (2012) compared access to a 1) health information only web site or 2) an interactive health information web site that taught self-management of their physical health. Adults (N=201) with a variety of chronic health conditions were randomized to one of the two web sites for 12 weeks. Both groups benefitted from using an online web site, however, participants who had access to the interactive site, which taught self-management of their disease process by increasing knowledge, self-care management of the disease and self-efficacy, had significant improvements in managing their physical health by engaging in activities such as exercise (Solomon, 2012).

Carpenter (2012) randomized people with chronic back pain to an interactive online intervention that teaches self-management skills or a wait list control group. Participants (N=141) completed a wellness workbook online over a 3-week period. Participants showed significant improvement in pain, less disability, decreased disabling attitudes, and increased self-efficacy for pain control and mood when compared to the control group (Carpenter, 2012). The

control group then experienced the interactive self-management skills web site and had similar results to the initial intervention group.

These studies demonstrate that providing information on the Internet can be a powerful tool, and interactive sites are more effective in improving participant's health outcomes by teaching self-management skills and not just offering information.

Online Mental Health Interventions

Not only have Internet interventions demonstrated effectiveness in helping people manage physical conditions; they have also shown effectiveness in helping people manage mental health issues also. Internet interventions have demonstrated improved outcomes in mental health disorders including decreasing anxiety (Gun, Titov, & Andrews, 2011), decreasing depression (Roberston et al., 2007; Clarke et al., 2009), decreasing college student stress (Chiauzzi et al., 2008), and decreasing traumatic stress (Mouthaan et al., 2011).

Internet preventive interventions initiated when symptoms first appear may be able to actually prevent a mental health disorder. For example, early intervention with stress management training can prevent the development of Post-Traumatic Stress Disorder (PTSD) (Barak & Grohol, 2011). Jacobi, Volker, Trockel, & Taylor, 2012) also demonstrated that treating symptoms prior to development of a disorder can be effective. In a randomized trial, women (N=126) with symptoms of disordered eating who did not meet the criteria for an eating disorder were assigned to Internet-based eight-week moderated program or wait list control who did not receive any intervention (Jacobi et al., , 2012). The intervention used a cognitive-behavioral program (targeting weight and shape concerns, negative body image and low self-esteem) combined with an asynchronous moderated discussion group (Jacobi et al., 2012). The intervention group had significant improvements in eating attitudes and health eating behavior

and reduction in symptoms of disordered eating directly after the intervention, which was maintained at six-month follow-up (Jacobi et al., 2012). An online prevention program was able to demonstrate improved attitudes and behaviors in participants over the wait list control group.

Early intervention may also be effective in women facing a stressful event such as breast cancer surgery to avoid mental health diagnosis such as ineffective coping or depression. An Internet intervention for women with depression was able to show moderate improvement in depression scores, which is similar to face-to-face sessions (Clarke, 2009). Insurance holders were randomized to an Internet self-guided interactive cognitive behavioral skills training program (N=83) or a control group (N=77). The self-guided interactive cognitive and behavioral intervention was used by participants at their own pace and at any time over the 32 weeks of the study (Clarke, 2009). The Internet intervention had an education section offering information about depression, a place to journal thoughts and feelings, and interactive section that presented tools to use for depression such as replacing negative thoughts with neutral or positive thoughts. The goal of the online intervention was to reach women in the convenience of their own home, therefore, reaching women that might not otherwise have access to an intervention for depression (Clarke, 2009).

Several researchers have also use online interventions to reduce stress in general and targeted populations. For example, Dayang (2011) created and evaluated a web site for the general population that contained two sections: one section provided information on stress, and the second section provided stress reduction therapy using a virtual environment with music or guided imagery plus peaceful images. Sexton, Byrd, O'Donohue, and Jacobs (2010) also evaluated stress reduction in women with infertility using a web site providing information and teaching skill based stress management techniques. Women were randomized to the intervention

group (N=21) and given access to the password protected web site or wait list control group who did not have access to the web site until after completion of the study. The Internet intervention group had significant reduction in stress scores while the control group stress scores increased. No further data was collected from the wait control group once they had access to the intervention.

Winzelberg (2003) also studied the use of a professional moderator with a 12-week Internet intervention designed to motivate breast cancer survivors to express their emotions in a supportive group environment. Women diagnosed with breast cancer in the past 32 months (N=72) were randomized to web-based asynchronous semi-structured support group, which was moderated by a psychotherapist or a wait list control group (Winzelberg, 2003). The moderator introduced and facilitated discussion on a new topic related to breast cancer each week (Winzelberg, 2003). Participants shared their thoughts concerning the weekly topic, read personal stories of other participants, posted comments on others stories, and kept a private personal journal. Upon completion, participant scores on depression, perceived stress, and cancer-related trauma measures were reduced compared to the wait list control group (Winzelberg, 2003).

Online Mind-Body Interventions

While some of the prior studies also used intervention that might have a component of a Mind-Body Strategy, this section will specifically outline online Mind-Body interventions that are either facilitated by a moderator or are entirely self-directed by the user/client. Both formats have demonstrated significant improvement in physical and mental health in a variety of studies.

Online Mind-Body interventions that are led by a moderator have shown benefit in patients with arthritis, depression, and breast cancer. In a randomized trial, Lorig (2008) tested a

moderator-led intervention in 855 people with rheumatoid arthritis, osteoarthritis, or fibromyalgia. A moderator led a weekly discussion and over saw the content of postings by participants. Weekly discussions included exercise routines, relaxation, visualization, distraction, self-talk, management of negative emotions, medications, communication with physicians, healthy eating, fatigue, action planning, and how to solve arthritis-related problems (Lorig 2008). Participants were randomized to asynchronously log in to participate in the weekly discussions for six weeks or to a control group receiving usual care. The moderator-led intervention group had significant improvements in pain, global health, distress, and level of activity at 6 and 12 months compared to the control group (Lorig 2008).

Thompson (2010) studied a moderator-led intervention for people diagnosed with depression (N= 53). Participants (N= 40) were randomized using a stratified crossover design to one of four groups. During the first eight weeks, two groups received one of two interventions. One group of 10 met weekly at the same time to increase knowledge of depression and Cognitive Based Therapy (CBT) (Thompson, 2010). Mind-Body techniques that were introduced and practiced included progressive relaxation, mindfulness breathing and meditation (Thompson, 2010). The second group of 10 viewed the material on the web site at a time of their covering the same information using video instruction with moderator initiating and monitoring discussion postings. The other two groups served as the control group (N=20). Then, during weeks 9-16, the control groups crossed over to receive the intervention in the same way as the first two groups, and the intervention groups crossed over to observation (Thompson, 2010). Both of the moderated interventions demonstrated significant improvement in knowledge of depression, skills to help manage depression, self-efficacy, and significant decrease in depressive symptoms over the control group (Thompson, 2010). The participants who were initially on the wait list

then received the intervention and did not have as dramatic a reduction in depressive symptoms as those who received the intervention first (Thompson, 2010).

A moderator was also used for an Internet intervention tailored to breast cancer survivors (Owen, 2005). Women (N=62) were randomized to either an asynchronous online intervention group for 12 weeks or a wait list control group. The Mind-Body component included instruction in techniques for stress reduction including deep breathing, progressive muscle relaxation, and meditation. Additional components of the intervention included a discussion board, self-guided training on symptom management, and six structured coping-skills training exercises on communication, coping styles, relationships, stress management, assertiveness training, and structured problem-solving (Owen, 2005). The moderator corresponded with the intervention group by email to encourage weekly discussions and manage discussion postings on specific topics each week (Owen, 2005). The wait list control group did not receive any intervention. Women in the intervention group showed improvement in emotional well-being and quality of life compared to the control group, and participants in the intervention group, who had lowest health scores initially, had the greatest improvement.

Internet interventions without the benefit of a moderator have been found to be useful in improving outcomes as well. Self-directed Internet interventions that were adapted from successful face-to-face group interventions have been effective to manage stress and control irritable bowel symptoms and chronic pain. For example, Ljotsson (2010) randomized participants (N=85) with irritable bowel syndrome (IBS) to a wait list control group or a 10-week intervention group, which included instruction in Mindfulness - a Mind-Body technique that incorporates the principles of meditation and being in present thought instead of analyzing the past or worrying about the future. The intervention group used an established text self-help

manual, which was released one module per week with weekly homework assignments and a discussion forum. The intervention also included education on how emotions and symptoms are related and how to managing avoidance behaviors and practice of using techniques in specific situations (Ljotsson, 2010). Participants reported reduction in weekly symptoms and improved quality of life at completion and three months later (Ljotsson, 2010). Long term response to the 10-week intervention was demonstrated by persistent reduction in weekly symptoms and improved quality of life when participants were surveyed one year later (Ljotsson, 2011). Frequency of use of the Mind-Body techniques was not collected on the follow-up study.

A self-directed online intervention for stress reduction was tested by Williams, Hagerty, Brasington, Clem, & Williams (2010) in military personnel. A convenience sample of 142 sailors evaluated the Internet delivery of a stress management intervention (Stress Gym) adapted from a face-to-face group intervention. Stress gym contained nine modules designed to: increase awareness of stress in interpersonal relationships, increase awareness of stress-related specific health issues, and alert participants to maladaptive responses to stress (Williams et al., 2010). One module included specific Mind-Body strategies (deep breathing, creating a visualization, and use of positive statements) (Williams et al., 2010). Participants' stress scores significantly decreased from baseline to post web site use, and there was also a positive correlation between number of modules completed and a decrease in stress scores (Williams et al., 2010). Although the impact of the Mind-Body module on outcomes is not known, this study demonstrates the success of an integrative stress reduction education program, which includes Mind-Body techniques.

Another self-directed online intervention for self-management of chronic pain was studied by Berman (2009). Adults with chronic pain (N=78) were randomized to wait list

control group who did not receive an intervention or an Internet intervention used once a week for six weeks completing six Mind-Body modules, which included: abdominal breathing, relaxation, writing about positive experiences, writing about difficult experiences, creative visual expression, and positive thinking (Berman, 2009). Participants in both groups had similar pain scores at the end of the intervention; however, participants in the intervention group had significant increase in use of self-care techniques and improved ability to manage pain with non-medical strategies (Berman, 2009).

In a randomized trial, sleep hygiene behavior was enhanced by people participating in an online intervention that taught the Mind-Body technique of self-hypnosis (Farrell-Carnahan, 2010). Cancer survivors (N=28) were randomized to an intervention group that used four weeks of self-hypnosis recordings at bedtime accessed via the Internet or a waitlist control group. The self-hypnosis intervention reported benefit in sleep, fatigue, mood, and quality of life compared to the wait list control (Farrell-Carnahan, 2010).

Finally, Litz (2007) compared two types of Internet interventions to treat PTSD. People who worked for the Department of Defense (N=45), who met the criteria for PTSD, were randomized to one of two groups for an eight-week intervention comparing two interventions: (1) a supportive counseling group, which consisted of use of a web site with educational information and an online journal where participants were asked to write daily on non-traumatic concerns and daily hassles or (2) a web site, which taught self-management skills including stress reduction techniques, self-monitoring for stress triggers and practice with exposure to triggers. The Mind-Body techniques of abdominal breathing and progressive muscle relaxation were presented and then reinforced in homework assignments. This web site also had an online journal however; participants were given structured writing assignments about their traumatic

experiences instead of only writing neutral daily concerns. The self-management intervention group, which included Mind-Body techniques, was found to have significant decrease in PTSD and depression symptoms and in less time than the supportive counseling group. At three- and six-month follow-ups, participants in self-management Internet intervention had higher functioning scores.

In summary, multiple studies have shown the success of online interventions to improve health outcomes in physical health and mental health. In addition, Mind-Body interventions have been used successfully as an individual intervention or integrated into comprehensive programs to improve physical and mental health. Adapting face-to-face programs to online interventions have been found to be successful in improving health outcomes for cancer survivors, people with chronic pain, IBS, PTSD, and depression. However, it is not known if Mind-Body interventions will be helpful in the hectic and stressful time from breast cancer diagnosis to breast cancer surgery. Research on online interventions for reducing distress in women with breast cancer is limited to women on treatment and in survivorship. Studies have shown online interventions are effective and women are receptive to them; however whether women perceive online interventions as useful, appropriate, and practical is not known.

Satisfaction with Online Interventions

The importance of participant satisfaction with online interventions and challenges with Internet delivery of interventions is explored in the following paragraphs. Internet education is an attractive option for delivering healthcare information to consumers and healthcare interventions to those who cannot access face-to-face interventions (Barak & Grohol, 2011). Internet interventions are well received especially by those who live in remote places, find it difficult to schedule face-to-face sessions, and those who are individualistic and prefer to work

independently (Barak, & Grohol, 2011). Internet interventions allow for rapid and effective treatment in groups that might otherwise have not have access to the intervention due to travel and time constraints (Litz, 2007). For example, people with Melanoma preferred accessing the information via the Internet because it was familiar, easy to use, convenient, and had the options of visual and auditory learning (Marble, 2010).

Several studies suggest that web sites are useable, practical, or appropriate by users in the general population for health education on specific topics such as respiratory illness (Yardley, 2010), obesity (Mc Tigue, 2011), and sexually transmitted infections (Hightow-Weidman, 2011), and Mind-Body techniques (Dayang, 2011; Willimas et al., 2010). Web sites teaching Mind-Body techniques have been well received by participants with chronic pain (Lorig, 2008; Berman, 2009), depression (Thompson, 2010), breast cancer (Owen, 2005; Farrell-Carnahan, 2010), irritable bowel syndrome (Ljotsson, 2010), and post-traumatic stress disorder (Litz, 2007). Specifically, Williams et al. (2010) found that users rated an Internet-based self-help stress management intervention incorporating Mind-Body techniques positively on usability, content appropriateness, and overall satisfaction (Williams et al., 2010). Berman (2009) looked at the practicality of an Internet intervention for adults (N=41) with chronic pain, which included instruction in Mind-Body techniques. Participants rated the web site as helpful or very helpful and liked the variety of choices and access to the information at their convenience (Berman, 2009).

Usability of an Online Intervention

Beyond satisfaction, a broader evaluation of an online intervention is to determine a web site's usability. Web site usability is described in Human-Computer interaction circles as having five attributes; it's easy to learn, it's efficient to use, it's easy to remember, it causes few errors,

and it's pleasant to use (Nielsen, 1995). This definition builds on a body of research that studies how people perceive and process information through learning, the use of memory, and attention (Head, 1999). Research on usability focuses on how users think about a site, how they interact with it, and how they retain the information provided (Head, 1999). Usability also examines the utility and functionality of the web site to determine if it is valued by the target population (Rubin, 2003). Often, emphasis on implementation of web sites has focused on functionality, which is defined as how well the site is programmed rather than utility, which is the user being able to interact with the web site to meet his or her needs (Kay, 2005). Therefore, web sites should be evaluated by the target participants for their usability in order to meet the needs of the users instead of evaluated by software analysts to determine if they function correctly. Usability testing has successfully been utilized to build health education web sites including sites for nutrition (Zimmerman et al., 2003), cancer resource information (Tweddle et al., 2000) and sunscreen use for cancer prevention (Armstrong, 2010). For example, Dayang (2011) evaluated the usability of a web site for stress management, which provided text information on stress and a section using a virtual environment with music or guided imagery plus peaceful images. Usability scores were favorable and intention to use in the future was high (Dayang, 2011). Some researchers have specifically looked at user satisfaction, which is a subscale of usability. For example, Gun (2011) looked at satisfaction of adults with an online treatment intervention for anxiety and depression by visitors to a web site on anxiety and depression. Of 1,543 consumers who completed a questionnaire, consumers with mild to moderate symptoms of anxiety or depression were satisfied with online interventions (Gun, 2011). Previous users of Internet interventions had significantly greater satisfaction with online interventions (Gun, 2011).

Wakefield (2011) also found patients preferred Internet education when compared to the same information provided on paper. Wakefield (2011) asked men to evaluate a paper version of a decision aid, which uses age and family history to determine their risk of developing prostate cancer and help them decide whether or not to proceed with prostate cancer screening (N=22). Wakefield (2011) then asked them to evaluate an Internet version of the decision aid. The men significantly preferred the Internet version over the paper version (Wakefield et al., 2011).

This research supports the use of online interventions, but further research is needed to determine the usability, practicality, and appropriateness of specific web sites for specific populations at specific time periods along the health continuum.

Challenges

Despite the success of Internet health education web sites and health-related interventions in research, challenges have been identified and include engaging the target population and preventing attrition. Use rates of online interventions can be less than 10% even if offered for free in programs such as weight loss and smoking cessation (Bennett & Glasgow, 2009).

Wanner (2009) randomized participants from the general population (N=1369) to an interactive web site intervention group designed to engage the participant or a control group that had access to a web site with general education on the health benefits of physical activity. The participants in the interactive web site received recommendations tailored to the individual's current level of physical activity based on the participants input. The participants who were in the intervention group, with strategies to engage them, had an increase in their physical activity (Wanner, 2009).

Attrition rates for Internet interventions vary widely and are similar to attrition rates in face-to-face interventions. The attrition rates in Internet interventions have been reported as high as 30% in Post-Traumatic Stress Disorder (Litz, 2007) and as low as 4% in an Internet

intervention for adults in the general population who suffer from insomnia (Ritterband, 2009). Other researchers such as Van Genugten (2012) saw significant attrition after only two weeks in a weight reduction intervention. In an Internet intervention for diabetes for self-management, Glasgow (2011) found use rates dropped significantly after six weeks. Smoking cessation and weight loss programs have limited success not only in Internet interventions but in face-to-face and telephone interventions as well.

This study tried to address the challenges of engagement and attrition by offering several types of Mind-Body techniques that can be completed in less than an hour. Women with breast cancer are more likely than people with other disease processes to access the Internet for breast cancer information and management (Setoyama et al., 2011); therefore they may be receptive to an online intervention. However, it is not known if women newly diagnosed with breast cancer would perceive an online Mind-Body intervention as usable, practical, or appropriate in the time period from diagnosis to surgical intervention.

Summary

The Internet provides an opportunity to intervene quickly and effectively to improve health outcomes. Internet interventions have had similar outcomes when compared to face-to-face, phone, and group programs (Ritterband, 2010). Studies show the Internet is able to reach populations that might not otherwise have their needs met (Anderson & Klemm, 2008; Litz, 2007). The literature shows that the Internet is useful and effective at improving knowledge, changing health behaviors, helping people manage illness, and reducing distress in people with and without cancer. Some Internet-based mental health interventions have been found to be acceptable, useful, and feasible in a variety of participants and types of interventions to improve outcomes in a variety of disorders. Success in stress reduction and early intervention via self-

directed Internet sites supports the exploration of using the Internet for helping women newly diagnosed with breast cancer reduce distress.

The goal of this thesis project is to have women who are newly diagnosed with breast cancer to evaluate an Internet-based Mind-Body intervention “Preparing for Your Surgery.” Studies have shown that healthcare consumers prefer the Internet format for education and interventions; however, the extent to which women newly diagnosed with breast cancer will find a Mind-Body Internet intervention useful, practical, and appropriate is not currently known.

CHAPTER THREE: METHOD

Design

This project was a non-experimental, descriptive research design to evaluate the usability, practicality, and appropriateness of a web-based resource to reduce distress for newly diagnosed breast cancer patients. Women who have had breast cancer surgery in the past 60 days were invited to evaluate the web site and then respond to an online questionnaire measuring usability, practicality, and appropriateness. Characteristics of the women who respond to the survey were obtained.

Intervention

An Internet search was conducted by the principal investigator to find a web site designed for individuals facing surgery that teaches several Mind-Body techniques, is based on evidenced based research, can be completed in less than an hour, and is available to the public without cost. The Internet web site www.preparingforyoursurgery.com (see Appendix A) met all of the desired criteria. The web site provides instruction on Mind-Body interventions that can be used by women to reduce distress before and after initial surgery for newly diagnosed breast cancer. The goal of the web site is to teach Mind-Body techniques to people scheduled for surgery that are easy to learn and help patients manage distress (fear, worry, and anxiety) and help promote faster healing with less discomfort. The web site was developed by a master's-prepared clinical nurse specialist with expertise in Mind-Body interventions. Permission to use the web site for this research project and permission to use the screenshots were obtained (see Appendix B). The web site is divided into six sections. Table 2 contains the components of each section.

Table 2: Components of Web Site

<i>Sections on Web site</i>	<i>Components of each section</i>
Home	– Welcome page
	–
Introduction to web site	– Benefits of Mind-Body Techniques <ul style="list-style-type: none"> ○ List of research articles
	– How it works
	–
Before Surgery	– Introduction
	– Self Assessment
	– Learn Relaxation Techniques <ul style="list-style-type: none"> ○ Nutrition and Surgery ○ Breath work ○ Centering & Grounding ○ Guided Imagery ○ Biofeedback
	– Healing Goals
	–
After Surgery	– Introduction
	– 7-Day Schedule
	–
Healing Results	– Testimonials
	–
Relaxation Resources	– Books and CD's
	– Biofeedback Tools

The web site explains how the techniques can be used once or twice a day or more often as needed for a brief period. In the after surgery section, women can print a handout that lists each technique as a visual reminder to use the techniques in the first 7 days after surgery. The web site includes an audio button on each page which allows those accessing the web site to have the text read to them. The breath work stress management technique has video instruction. In addition, each technique can be downloaded to the individual's portable electronic device. The web site also has links to other reputable web sites providing more information on select topics. The web site is accessible on demand, allowing participants to proceed with any module that is of interest to them and women can proceed with the intervention at their own pace. By

calculating the length of the audio on each page, it is estimated to take 45-60 minutes to navigate through the web site.

Sample Description

Participant Characteristics

A convenience sample was used. Women who had a lumpectomy or mastectomy for breast cancer in the past 60 days and presented as a new or a returning patient to MD Anderson Cancer Center Orlando Medical Oncology Department or Radiation Oncology Department were approached and invited to join the study until target numbers were accrued. Inclusion criteria consisted of female, 18 years of age or older, status post breast surgery for cancer, Stage 0 through Stage III, and ability to navigate the Internet. Exclusion criteria included recurrent breast cancer, diagnosed with any other cancer in the past five years except skin cancer, currently under the care of a psychiatrist, requires language interpreter for medical office visits, or legal consents are signed by someone other than the patient.

Sample Size, Power, and Precision

A power analysis was calculated to reduce the risk of a Type II error. The risk of a Type I error was established as .05, the power was .80, the effect size was estimated based on previous studies with PHWSUQ as modest. A sample of 30 women newly diagnosed with breast cancer status post breast cancer surgery was needed for this study. Assuming a potential attrition rate of 25%, the target sample size was 40 women to achieve a final sample size of 30 participants. The attrition rate of women who signed consent yet did not complete the survey was over 50% in the first two months of the study. Therefore, the protocol and consent were reapproved by the IRB to allow up to 100 women to enroll in the study in order to obtain at least 30 completed surveys.

Setting

The study was conducted at MD Anderson Cancer Center Orlando. In 2011, this cancer center treated over 550 patients with breast cancer. The majority of these women underwent breast cancer surgery. Patients are cared for by board-certified medical and radiation oncologists who follow the National Comprehensive Cancer Network guidelines for management of breast cancer patients.

Ethical Considerations

This study was reviewed and approved by the Nursing Research Council at Orlando Health. Institutional Review Board approval was obtained from MD Anderson Cancer Center Orlando and University of Central Florida (UCF) (Appendix C). The human subjects' permission letter was obtained from Institutional Review Board at UCF (Appendix D). Potential participants had equal access to their healthcare team whether or not they participated in the study. Participants provided written consent (Appendix E).

Procedures

Recruitment

A convenience sample of women who were newly diagnosed with breast cancer who met criteria were invited to participate in the study.

Steps

1. The principal investigator (PI) completed the Screening Spreadsheet, which contained the eligibility criteria for the study (Appendix F) from a list of patients scheduled for an appointment with a medical oncologist or radiation oncologist who are part of the Breast Cancer Specialty section. The list was generated by the PI from the computer-based

scheduling software. The PI completed the Screening Spreadsheet based on information in the patient's electronic medical record including the physician visit notes, pathology reports, and radiology reports. If a patient did not meet eligibility criteria, the exclusion reason was noted on the screening spreadsheet. The screening spreadsheet was kept in a password-protected laptop computer and hard copies, which were kept in a locked cabinet.

2. If the patient met the eligibility criteria to participate in the trial and the treating physician gave permission, the patient was approached by the PI at the conclusion of her visit with the medical or radiation oncologist. The PI explained the study, answered all questions, and asked if she would like to participate. If they say yes, the IRB-approved consent was signed by the patient. If they say no, they were thanked for their time reassured that their care will not be affected by opting not to participate. Participants who are offered participation but declined were asked the reason they declined. The responses to the decline question were entered on the screening spreadsheet.
3. After consent was signed, the participant was assigned a study number. The PI gave participants a written handout (Appendix G) on instructions for evaluating the web site, and accessing the Web site Evaluation Questionnaire via Survey Monkey once they had completed using the web site. They were given a worksheet for keeping track of the amount of time they spent on the site, whether they used the audio buttons and a place to make notations as they navigated through the web site (Appendix H). Participants were encouraged to call the PI if they had any problems using the web site or the questionnaire.

4. Participants were asked to access and evaluate the site within two weeks. A personal email reminder (Appendix I) was sent individually to each participant by the PI 7 and 14 days after signing consent to remind them to access the web site and complete the web site evaluation questionnaire (Appendix J).
5. The protocol was amended for the last 15 participants allowing the principal investigator to call the participant one time 7-14 days after signing consent in addition to the email reminder.

General Considerations

No monetary incentives were given. The PI did not know who had completed the “Web site Evaluation Questionnaire.” The email address log was kept on a password-protected laptop computer in a locked cabinet and was destroyed at the conclusion of their participation. Patients’ signed consents are kept in a locked cabinet at the cancer center.

Instruments

The “Web site Evaluation Questionnaire” had three parts (Appendix I). Questions on the survey consisted of open and closed ended questions including free text responses and a list of responses to choose from on a Likert-scale. Directions for answering the questions included the statement that participants were required to enter a response before proceeding with the next question. However, some personal questions that may be sensitive to some women, for example income, have a “do not care to respond” choice.

Part one included participants’ personal information. Questions included the following: age, ethnicity, socioeconomic status, level of education, type of surgery, how they accessed the Mind-Body web site, how many years they accessed Internet, frequency of general Internet

access, frequency of Internet use for health information, current training in Mind-Body techniques, and current use of Mind-Body techniques. Questions in part one were created by the PI with expert review by committee members.

The second part of the survey included the PHWSUQ developed by Nahm and colleagues (2006). The 12-item instrument asked participants to respond on a Likert-scale. It contains three subscales, which define usability (satisfaction, ease-of-use, and usefulness). The first 6 items measure satisfaction on a Likert-scale from 1 (very unsatisfied) to 7 (very satisfied), the next 3 items measure ease-of-use on a Likert-scale 1 (strongly disagree) to 7 (strongly agree), and the last 3 items measure usefulness on a Likert-scale 1 (strongly disagree) to 7 (strongly agree). In Nahm's research with older adults (N=10), the coefficient alpha of the overall scale was .90-.92, satisfaction subscale .88-.93, ease-of-use .84-.90 and usefulness .64-.84 (Nahm, 2006). These values reflect the PHWSUQ is internally consistent as coefficient alpha results range from .70 to 1.00 with higher values reflecting the scale is reliably measuring the critical attribute (Polit & Beck, 2008).

The third part of the survey included questions designed to measure the appropriateness and practicality of the web site for women facing breast cancer surgery. The questions asked women to respond to three questions with a Likert-scale from 1 (strongly disagree) to 7 (strongly agree). The participants were asked to input the number of minutes they spent on each page of the web site as recorded on their worksheet. The survey concluded with three open-ended qualitative questions with free text response asking what the participants found useful on the Mind-Body web site, what they did not find useful on the Mind-Body web site, and any additional comments on the web site. The questions on the third part of the survey were developed by the PI with evaluation by expert panel of the thesis committee.

Data Analysis

The sample is described with the following statistics. The sample's age, time spent on the Mind-Body web site, and time spent on each page of the Mind-Body web site are described as a mean and a range. Categorical responses are reported as a percentage for the following questions; ethnicity, socioeconomic status, level of education, type of surgery, how they accessed the Internet web site, how long they have used the Internet, frequency of Internet use, frequency of Internet use for health information, training in Mind-Body techniques, and use of Mind-Body techniques. The data were analyzed using SPSS 21.0 statistical package.

The primary research questions and data analyses plan:

- Research question 1: Do women with breast cancer perceive the Mind-Body intervention as useful based on the PHWSUQ? Usability of the web site was evaluated by calculating a mean for the overall score and for each subscale (satisfaction, ease-of-use and usefulness). The mean was converted to 100 to allow comparison across subscales with different numbers of items.
- Research question 2: Do women with breast cancer perceive an online Mind-Body intervention to be practical and appropriate for reducing pre-surgical distress? The mean score of each question was calculated. The mean was converted to 100 to allow for comparison.

The results include mean score, range, and standard deviation for 1) range and standard deviation of the total PHWSUQ; 2) each of the three PHWSUQ subscales: PHWSUQ satisfaction, PHWSUQ ease of use, and PHWSUQ usefulness; 3) the question on practicality; 4) the question on appropriateness; and 5) the question on would recommend.

Due to the small sample size select variables (age, income, education, minutes spent evaluating site, whether they tried Mind-Body techniques in the past or used the techniques after surgery) were divided into two to three categories. Women were also divided into two groups based on their responses to each of the following statements: site was useful, practical, appropriate, or would recommend. Group one for each statement agreed to strongly agreed. Group two for each statement was neutral or disagreed. Then crosstabulation was calculated for each selected categorical variable with group one and group two for each statement (web site is useful, appropriate, practical, and would recommend) chi square was considered significant if <0.05 .

Responses to the open-ended questions were evaluated using content analysis to identify themes. A procedure similar to that described by Johnson and LaMontagne (1993) was used. Two Mind-Body experts,(the first expert was the principal investigator; the second was a Nurse Practitioner with additional training in Mind-Body medicine) independently sorted each response into themes. Then, the two Mind-Body experts met to reach consensus on themes. Then, they independently sorted the responses based on the final themes. For the last step, they reached consensus on the responses contained under the final themes.

Summary

The goal of this project was for women newly diagnosed with breast cancer to evaluate the usefulness, appropriateness, and practicality of a Mind-Body web site. Data from this project will be presented to the MD Anderson Orlando Breast Cancer Committee to determine future action plans and research.

CHAPTER FOUR: RESULTS

Introduction

The results are presented in this chapter, starting with sample characteristics, followed by the research questions, which are then followed by other questions about navigating the web site and when to introduce the web site to women with breast cancer. The chapter concludes with participant free text responses.

From September 2012 through January 2013, 75 women who met screening criteria were approached by the principal investigator for participation in the study. Figure 1 depicts the follow of participants through the study. Sixty-five women signed consent for this study; 35 initiated the online survey; and 31 completed the survey. Of the 10 women who were offered the study and declined, 6 women stated they did not use the Internet or only used the Internet for email; and 4 women stated they were overwhelmed and did not want to take on another task. Of the first 24 women who signed consent, only eight women completed the survey. In attempt to increase survey completion, the protocol was modified to include a phone number on the consent form so the principal investigator could call the participant 7-14 days after study enrollment. The revised protocol and consent were utilized for the last two months of enrollment.

It is not known why 30 women who signed consent did not initiate the survey or why 4 women answered only the first 14 questions. The protocol did not permit contacting those who did not initiate or complete the survey to determine their reason for non-completion. However, one participant who signed consent emailed the principal investigator explaining she had multiple medical issues and did not have the energy to evaluate the web site. Crosstabulation for chi square was performed to compare the four women who only completed the initial 14 questions to the 31 women who completed the entire survey. There was no statistically

significant difference between those who completed only the first 14 questions and the women who completed the survey for age, ethnicity, race, type of surgery, household income, level of education, frequency of internet access or experience with Mind-Body techniques.

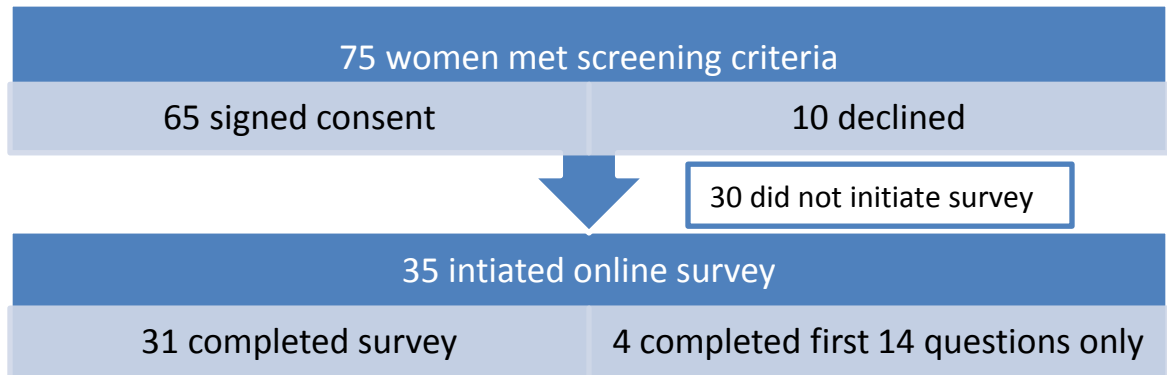


Figure 1. Flow of study sample.

Sample Characteristics

Characteristics of the 31 women who completed the survey are shown in Table 3. The age range was 38 to 82 with a mean (SD) age of 58 (11) years. The majority of women in the study were white (96.8%) and not Hispanic (87.1 %). The surgical procedures women had experienced were lumpectomy (51.6%) and mastectomy (48.4%). Of those who had mastectomy, less than half had reconstruction (46.6%). Women typically had an income of \$75,000 annual income or less; however, 11 women chose not to respond. Two women did not respond to the education question. Twenty-nine of the participants had higher than a high school education with the majority (58.1%) having an associate degree or higher.

Table 3: Demographic Data of Participants

Variable	Sample: N=31
	Response Frequency N (%) or Mean (SD)
Age	
Mean (SD)	58 (11)
Ethnicity	
Hispanic or Latino	4 (12.9%)
Not Hispanic or Latino	27 (87.1%)
Race	
Black or African American	1 (3.2%)
White	30 (96.8%)
Type of Surgery	
Lumpectomy	16 (51.6%)
Mastectomy	15 (48.4%)
Reconstruction	
Yes	7 (46.6%)
No	8 (53.4%)
Household Income Per Year	
Less than \$50,000	7 (22.6%)
\$50,000 to \$75,000	6 (19.4%)
\$75,001 to \$100,000	1 (3.2%)
More than \$100,000	6 (19.4%)
Do not care to respond	11 (35.5%)
Highest Level of Education	
High school	9 (29.0%)
Trade school	2 (6.5%)
Associate degree	8 (25.8%)
Bachelor degree	8 (25.8%)
Graduate degree	2 (6.5%)
Did not respond	2 (6.5%)

All women in the sample had more than three years of experience with the Internet. The number of hours women typically accessed the Internet in one week varied from more than 14 hours (38.7%), 8-14 hours (25.8%), 1-7 hours (32.3%) to less than one hour (3.2%). The majority of women (74.2%) spent less than 6 hours per month accessing the Internet for health-related information. Women accessed the study's web site by desktop at home (48.4%), laptop (29%), iPad (14.3%), desktop at work (3.2%), and desktop at library (3.2%). None of the participants used a smart phone to access the web site. See Table 4 for detailed information on characteristics of Internet use.

Table 4: Characteristics of Internet use

Variable	Frequency (%) (N=31)
How Did You Access the Web site?	
Desktop at home	15(48.4)
Desktop at work	1 (3.2)
Computer at library	1 (3.2)
Lap top computer	9 (29.0)
iPad	5 (14.3)
Smart phone	0 (0)
When Did You First Start Using the Internet?	
More than three years ago	31 (100)
How Often Do You Access The Internet in a Week?	
Less than one hour	1 (3.2)
1-7 hours	10(32.3)
8-14 hours	8(25.8)
>14 hours	12(38.7)
Hours in the Past Month on Internet Health Information	
None	1 (3.2)
1-2 hours	15 (48.4)
3-6 hours	7 (22.6)
7-10 hours	3 (9.7)
11 or more hours	5 (16.1)

The majority of participants were familiar with most of the techniques taught on the web site. Participants were most familiar with breath work (80.6%), followed by guided imagery (54.8%), biofeedback (51.6%), and healing goals (51.6%); however, less than 50% of the women were familiar with centering and grounding (32.3%). Participants had limited training in the

Mind-Body techniques taught on the web site. Participants had the most training in breath work (16.1%), followed by guided imagery (9.7%), biofeedback (3.5%), centering and grounding (3.5%), and healing goals (3.5%). A summary of participants' familiarity, training, and use of Mind-Body techniques are in Table 5.

Table 5: Mind-Body Technique Characteristics

Techniques on Web Site	Breath work	Centering and Grounding	Guided Imagery	Biofeed-back	Healing goals
Had you heard of the techniques?	25 (80.6)	10 (32.3)	17 (54.8)	16 (51.6)	15 (48.4)
Had you tried the techniques?	23 (74.2)	11 (35.5)	9 (29.0)	1 (3.2)	9 (29.0)
Did you have any training in the techniques?	5 (16.1)	2 (6.5)	3 (9.7)	2 (6.5)	2 (6.5)
Did you use any of the techniques before surgery or in the first 7 days after your surgery?	12 (38.7)	4 (12.9)	4 (12.9)	1 (3.2)	9 (29.0)

Usefulness of the Web Site

The majority of women who evaluated the web site agreed it was useful. The mean (SD) score on the PHWS instrument was 67.9 (12.80) out of a possible high score of 84, or 80.83 when the score is converted to out of 100. The mean scores on the survey were “converted to out of 100” to facilitate comparison with subscales and responses to the questions on appropriateness of the web site, practicality of the web site, and whether women would recommend the site to others. A mean positive response (greater than neutral) converted out of 100 would be = to/or > 58. The total score of the 12 questions on the PHWSUQ ranged from 36 to 84 (the maximum

possible score). In addition, the majority of women rated the web site as positive (greater than neutral) on all three subscales of the PHWSUQ. On the subscales, the ease of use subscale had the highest score 84.48 (mean converted out of 100), followed by the satisfaction subscale with 81.73 (mean converted out of 100), and then usefulness subscale was 71.42 (mean converted out of 100). Table 6 summarizes the results for the PHWSUQ.

The PHWSUQ was found to be a reliable scale for this population with an alpha coefficient of .875. These results are similar to its reliability in other samples .90-.92 (Nahm, 2006) and .85 (Atack, 2011).

Table 6: Summary of the Perceived Web Site Usability Questionnaire

Dimension (Range)	Mean (SD)	Mean Converted/100
Satisfaction (7-42)	34.32 (9.90)	81.71
Ease of use (11-21)	18.58 (2.73)	84.48
Usefulness (5-21)	15.00 (4.44)	71.42
Total (36-84)	67.90 (12.80)	80.83

Is the Web Site Practical and Appropriate?

The majority of women agreed the web site is practical. The mean (SD) score was 5.94 (1.29) or 84.86 (mean converted out of 100); the range of responses was from 3 to 7.

The majority of women agreed the web site was appropriate. The mean (SD) score was 6.23(1.06) out of 7 (strongly agree) or 89.00 (mean converted out of 100). The range of responses was from neutral (4) to strongly agree (7).

The majority of women agreed they would recommend the web site. The mean (SD) score was 5.77 (1.71) or 82.43 (mean converted out of 100). The range of responses varied from strongly disagree (1) to strongly agree (7).

Free text responses explained why women would recommend the web site; however, free text responses did not provide specific reasons for the selection of strongly disagree to the *would recommend* site to others statement. Table 7 summarizes the responses to the questions is the web site practicality, appropriateness, and if women would recommend it to others.

Table 7: Responses to "Practical, Appropriate and Would Recommend" Scale

Question	Range	Mean (SD)	Mean Converted/100
It is practical to use this web site in the time period from breast biopsy to breast surgery.	3-7	5.94 (1.29)	84.86
This web site is appropriate for women facing breast cancer surgery.	4-7	6.23 (1.06)	89.00
I would recommend this web site to someone who is facing breast cancer surgery.	1-7	5.77 (1.71)	82.43

Comparisons Between Groups

Crosstabulation analysis for chi-square was performed to determine if there was a significant relationship between select variables and the group of women who agreed the web site was useful, practical, appropriate, and would recommend compared to the group of women who responded neutral or disagree. The following variables were selected for comparison.

First to determine if age, income, or education had a relationship, each response was recoded into two or three categories. Age was divided into three categories: less than 50 years of age, 51 to 64 years of age and 65 years of age or older. Income was divided into women who have a household income less than \$75,000 and women whose income is or greater than \$75,000.

Education was divided into three categories: women who have a high school education, women who have trade school or an associate degree, and women who have a Bachelor's degree or higher.

Second, to evaluate if Internet experience was a factor, the responses to the following topics were divided into two groups. Frequency of Internet access was divided into women who access the Internet less than eight hours per week and women who access the Internet greater than eight hours per week. Frequency of looking on the Internet for health information was divided into women who look less than 7 hours per month and women who look greater than 7 hours per month. The number of minutes women spent evaluating the web site was divided into women who spent 60 minutes or less and women who spent more than 60 minutes.

Subsequently, to determine if previous experience with Mind-Body techniques had a significant relationship the following areas were divided into two groups. Women who stated they had tried at least one Mind-Body technique in the past were placed in one group and women who had no previous experience with any of the techniques were placed in another group. Women who stated they tried at least one Mind-Body technique prior to or in the first 7 days of their surgery were placed in one group and women who did not use any of the techniques were placed in a second group.

Finally, women were divided into two groups based on their response to each area of interest (useful, practical, appropriate, and would recommend to others). One group consists of women who responded agree to strongly agree, the second group consists of women who responded neutral to strongly disagree for each area of interest.

Crosstabulation for chi square for each categorical variable above compared to the women who agreed with each area of interest versus those who were neutral or disagreed for

each area of interest was performed. There were no statistically significant relationships found. See Table 8. Age, income, education, frequency of Internet use, and experience with Mind-Body techniques did not significantly impact on whether women agreed the web site is useful, practical, appropriate, or would recommend to others compared to those who responded neutral to disagree. Only two of the comparisons approached statistical significance and both pertained to the “Would recommend” question. Income approached significance at $p=0.058$ and frequency of seeking health information on the Internet $p=0.076$.

Table 8: Categorical Variables of Women who Agree compared to Women who are Neutral or Disagree

Categorical variables	Total sample N(%)	Useful		Appropriate		Practical		Recommend	
		Neutral or disagree N(%)	Agree N(%)	Neutral or disagree N(%)	Agree N(%)	Neutral or disagree N(%)	Agree N(%)	Neutral or disagree N(%)	Agree N(%)
Age									
38-50	9(29)	0	9(100)	1(11)	8(89)	2(22)	7(78)	3(33)	6(77)
51-64	14(46)	3(21)	11(79)	3(21)	11(79)	4(29)	10(71)	3(21)	11(79)
...65-82	8(26)	1(13)	7(87)	0	8(100)	0	8(100)	1(12)	7(88)
		p=0.326		p=0.347		p=0.255		p=0.585	
Household income *									
...< \$75,00	13(42)	1(8)	12(92)	3(23)	10(77)	3(23)	10(77)	5(38)	8(62)
> \$75,000	7(23)	0	7(100)	0	7(100)	1(14)	6(86)	0	7
		p=0.452		p=0.168		p=0.639		p=0.058	
Education *									
High school	9(31)	0	9	1(11)	8(89)	1(11)	8(89)	2(22)	7(78)
...Trade or Associate Degree	10(32)	1(10)	9(90)	2(20)	8(80)	2(20)	8(80)	3(30)	7(70)
...Bachelors or higher	10(32)	1(10)	9(90)	0	10(100)	2(20)	8(80)	2(20)	8(80)
		p=0.617		p=0.339		p=0.842		p=0.861	
Frequency of internet access									
< or = 8 hours per week	11(36)	2(18)	9(82)	2(18)	9(82)	2(18)	9(82)	3(27)	8(73)
...> or = 8 hours per week	20(64)	2(10)	18(90)	2(10)	18(90)	4(20)	16(80)	4(20)	16(80)
		p=0.516		p=0.516		p=0.902		p=0.430	
Frequency of health info on internet									
< 7 hours per month	23(74)	4(17)	19(83)	4(17)	19(83)	6(26)	17(74)	7(30)	16(70)
> or = to 7 hours per month	8(26)	0	8(100)	0	8(100)	0	8(100)	0	8(100)
		p=0.206		p=0.206		p=0.108		p=0.076	

Categorical variables	Total sample N(%)	Useful		Appropriate		Practical		Recommend	
		Neutral or disagree N(%)	Agree N(%)	Neutral or disagree N(%)	Agree N(%)	Neutral or disagree N(%)	Agree N(%)	Neutral or disagree N(%)	Agree N(%)
Minutes spent evaluating									
< or = to 60 minutes	9(29)	2(22)	7(78)	1(11)	8(88)	2(22)	7(77)	2(22)	7(78)
> 60 minutes	22(71)	2(9)	20(91)	2(10)	19(90)	4(19)	17(81)	5(24)	16(76)
		p=0.144		p=0.894		p=0.842		p=0.925	
Tried Mind-Body techniques in past									
At least one technique	26(84)	3(12)	23(88)	6(12)	20(88)	3(12)	23(88)	6(23)	20(77)
...Had not tried techniques	5(16)	1(25)	3(75)	1(20)	4(80)	1(20)	4(80)	1(20)	4(80)
		p= 0.605		p=0.605		p=0.605		p=0.880	
Used Mind-Body techniques prior to or 7-days after surgery									
...At least one technique	14(45)	2(14)	12(86)	2(14)	12(86)	3(21)	11(79)	3(21)	11(79)
... Did not use techniques	17(55)	2(13)	15(87)	2(12)	15(88)	3(18)	14(82)	4(24)	13(76)
		p=0.835		p=0.835		p=0.791		p=0.889	

* N does not equal 31, some women selected “Do not care to respond.”

Navigation of Web Site by Participants

The mean (SD) self-reported evaluation time for the web site's 18 pages was 78.20 (35.07) minutes, with a range of 40 to 225 minutes. When the average time women spent on each individual page was evaluated, women spent the most time on pages teaching the techniques like breath work (6 min), centering and grounding (6 min), biofeedback (6 min), and guided imagery (10 min) and less time on pages providing general information like introduction to before surgery (3 min) and after surgery (3 min). Participants were more likely to use audio buttons on pages that taught the techniques rather than pages that were strictly informational. Table 9 details time spent on each page and use of the audio button.

The video on the site that taught breathing techniques was evaluated by 22 of the participants. Fifteen (48.4%) participants found the video very helpful, and 5(16.1%) participants found it did not add to the content or 3(9.7%) participants chose the video was not helpful, and 8 (25.8%) did not view the video. Table 10 summarizes participants' responses to the breathing technique video.

Table 9: Number of Minutes/Use of Audio per Web Page

Web Page	Minutes Mean (SD)	Use of Audio Button N (%)	
		Yes	No
Introduction to Web site	3.96 (3.17)	11 (35.5)	18 (58.1)
Benefits of Mind-Body	4.41 (2.10)	16 (51.6)	14 (45.2)
How It Works	5.14 (2.07)	17 (54.8)	12 (38.7)
Before Surgery	3.64 (2.93)	9 (29)	20 (64.5)
Introduction to Before Surgery	3.07 (1.18)	8 (25.8)	21 (67.7)
Self-Assessment	5.00 (2.29)	18 (58.1)	12 (38.7)
Learn Relaxation	5.04 (2.96)	14 (45.2)	15 (48.8)
Techniques	4.09 (4.25)	13 (41.9)	12 (38.7)
Breath Work	5.76 (3.39)	22 (71)	8 (25.8)
Centering and Grounding	5.79 (3.13)	23 (74.2)	7 (25.8)
Guided Imagery	9.55 (6.29)	22 (71)	8 (25.8)
Biofeedback	6.00 (3.64)	21 (67.7)	9 (29)
Healing Goals	4.79 (2.67)	11 (35.5)	18 (58.1)
After Surgery	3.41 (2.18)	7 (22.6)	21 (67.7)
Introduction to After Surgery	2.93 (1.12)	6 (19.4)	23 (74.2)
7-Day Schedule	3.57 (2.90)	6 (19.4)	23 (74.2)
Healing Results	4.64 (2.91)	15 (48.4)	15 (48.4)
Relaxation Resources	3.63 (3.00)	7 (22.6)	22 (75.9)
Total Minutes Spent on Web site	78.2 (35.07)		

N does not always = 31 so not all sums will = 100

Table 10: Thoughts about the Video Teaching Breathing Techniques

Responses	Frequency N (%)
Video was very helpful	15 (48.4)
Video did not add to the text information.	5 (16.1)
Video was not helpful.	3 (9.7)
I did not view video	8 (25.8)

When to Introduce Web Site?

In anticipation of introducing the web site to women who seek treatment for breast cancer care at our center, participants were asked the best time to be introduced to the web site. The majority of participants chose the surgeon’s consultation (74.2%), followed by the medical oncologist’s consultation (22.6%). Only one participant chose pre-op testing department. See Table 11 for a complete summary of responses.

Table 11: When to Introduce Web Site

When is the Best Time to Introduce the web site to Women?	Frequency N (%)
From the surgery team at the appointment planning surgery.	23 (74.2)
From the medical oncology team at first appointment.	7 (22.6)
From the pre-op testing department.	1 (3.2)

Participants’ Comments

The free text responses were analyzed to further explore the findings in the quantitative data. Twenty-five of the 31 women who completed the survey expressed their thoughts about the web site in the free text responses. The free text responses reinforced the usefulness of the web site.

Themes in response to the question, “What is Most Useful on this Web site?” included: not all aspects of the web site are useful, information on the web site was helpful, preferences for certain techniques, preferences for certain aspects of the web site, applications of the information on the web site beyond surgery, liked option of audio and video, and other. The first theme not all aspects of the web site are useful was stated by one participant “I would utilize some of the information but not all.” The second theme information on the web site is useful or very useful was noted by five participants without further detail. Techniques women stated were useful included breath work by eight women, centering and grounding by four women, guided imagery by four women, biofeedback by three women, and healing statements by one woman. Aspects of the web site women stated were useful include the resources by three women, the seven-day schedule by two women, the post surgery assessment form, the patient testimonials, and the research section. Another theme was how the techniques on the web site can help beyond the time period before and after surgery. Women suggested the techniques could be useful for overall health, blood pressure reduction, dental work, and everyday stress. The last theme pertained to the audio and video aspects of the web site. Three women stated they liked both the audio and the video; three other women specifically mentioned they like the video; two other women stated they liked the audio as it made it “easier to follow.” The themes and the participants’ responses are found in Table 12.

Table 12: Free Text Responses to “What Is Most Useful on this Web Site?”

What is Most Useful on this Web Site?	
Themes	Illustrative quotes
Not all aspects useful	-“There is something useful for any woman facing this. I would utilize some of the information, but not all.”
Information was helpful	-“I found the techniques very helpful; the information provided will help people keep focused on their goal of healing.” -“I think the web site is very helpful and well explained.” -“How to reduce stress was very helpful.” -“Very useful and instructive to prepare you for surgery.”
Preferences for certain techniques	-“The breathing techniques I found to be the most helpful.” -“I know it has helped with centering and grounding.” -“The guided imagery is very calming.” -“Biofeedback was interesting, as my hands did get warmer.”
Applications beyond surgery	-“Learning how to better their stress levels to obtain better overall health.” -“I struggle sometimes from high blood pressure, so these were very instrumental in helping teach myself to relax.” -“Came in handy when undergoing dental work.” -“The breath work portion was the most useful to me as I feel anyone can use it anywhere and at any time.” -“This is a practical approach to relieve every day stress.” -“Combat stress” -“Provides basic information and provides support”
Audio and video	-“I liked the fact there was video and audio.” -“The breathing video was excellent.” -“The audio portions were easier to follow.”
Other	-“You can access it from home in a more controlled environment.”

Although the number of participants who responded to the question “What was not useful on the web site?” was small, their responses offer themes to be considered when using this web site. Some women stated specific techniques were not useful. Women also suggested that the usefulness of the web site may be influenced by the end user. Other women reported technical challenges

limited usefulness of the web site. Women offered suggestions for improvement of the web site to make it more useful. Eight participants reinforced the web site was useful. Table 13 lists the themes and their responses.

Table 13: Responses to “What is Not Useful on this Web Site?”

What is Not Useful on this Web Site?	
Themes	Illustrative quotes
Specific techniques not useful	<ul style="list-style-type: none"> -“I do not think the 7-day schedule is helpful.” -“Healing goals I’m personally not sure I would give a statement to surgeon/anesthesiologist but there are others that would benefit from having this done.” -“Guided imagery gives me the giggles. Don’t like healing goals pain is pain not discomfort.”
Usefulness may be influenced by end user	<ul style="list-style-type: none"> -“May not be useful to patients who are not willing to learn and cannot adjust to use techniques that are crucial to healing.” -“I didn’t find after surgery section useful. It was easy for me to recover.” -“The woman’s accent was irritating.”
Technical challenges to usefulness of web site	<ul style="list-style-type: none"> -“The video didn’t show, couldn’t find it. To me video would have been much more interesting. “ -“Sometimes the audio was slow.”
Reinforced was useful	<ul style="list-style-type: none"> -“I thought that all the information was helpful, even in helping me with future surgeries.” -“All could be used by many people.” -“I did not find anything that wasn't useful”
Suggestions for improvement	<ul style="list-style-type: none"> -“I like to obtain personal experiences. It helps with one's own recovery or surgery knowing what others have experienced.” -“The video would have been more effective if there was one person breathing as to show proper technique and to demonstrate and the other narrating.” Trying to breath with the video was counterproductive.” -“Some of the audio tutorials were long in length and harder to concentrate.” -“I thought there was too much introduction, meaning I think they could have gotten right to the point or right to the techniques.” -“Person on audio hard to understand on self-assessment.”

Themes in response to the question, “Any Comments on the Web site You Would like to Share?” include information on the web site being useful for everyday use, affirming the web site is helpful for surgery, suggestions for improving the web site, and hesitancy to use all suggestions on the web site. Table 14 lists the themes and their free text responses.

Table 14: Responses to “Any Comments on the Web site You Would Like to Share?”

Any Comments on the Web site You Would Like to Share?	
Themes	Illustrative quotes
Helpful for surgery	<ul style="list-style-type: none"> -“I have shared and I am going to continue sharing this web site with anyone I know who will be having surgery in the future. I think this is very helpful.” -“Very complete and helpful. Wish I had it before my surgery!” -“As a medical person, I might recommend the web site to patients before surgery, emphasizing the ability to personalize the choice of techniques.” -“I feel it would be helpful to patients who have the motive to overcome the disease and strengthen their will to survive.” -“Very practical and for self-learning for the self-healing techniques.”
Useful for everyday use	<ul style="list-style-type: none"> -“This site is helpful to many that are facing surgery as well as help in daily life of all. Good overall help for stress reduction, not just preparation for surgery.” -“Would be very useful and calming before surgery, and also just for everyday use. I am glad I saw it.”
Suggestions for improvement	<ul style="list-style-type: none"> -“Better quality with the audio, need someone to pronounce the words more clearly.” -“They need to change the color of the lavender print on the site, as it was difficult to read.” -“How it works page under introduction was more technical. Guided imagery was a little long but easy to follow.” -“Other than make it shorter and more concise--too much intro.”
Hesitancy to use all suggestions on web site	<ul style="list-style-type: none"> -“I feel my surgeon would have felt I was stupid if I stated my "Healing Statements" before surgery.” -“The only thing would be to let the patient know not to stress over not being able to keep to a schedule. To use this as a tool not a have to.”

Summary

This chapter provided findings from the study. The qualitative and quantitative data suggest women in this study found the web site to be useful, practical, and appropriate for women newly diagnosed with breast cancer. Discussion of findings follows in Chapter 5.

CHAPTER FIVE: DISCUSSION

The majority of women in the study agreed the web site www.preparingforyoursurgery.com is useful, practical, appropriate, and would recommend the web site to women newly diagnosed with breast cancer. In addition, findings from this study suggest the web site could be introduced to women newly diagnosed with breast cancer who present to our cancer center regardless of age, income, education, frequency of Internet use, or experience with Mind-Body techniques.

Thirty one women who were status/post breast cancer surgery evaluated the web site www.preparingforyoursurgery.com and completed the PHWSUQ. The mean PHWSUQ score of the web site was 81.3 out of 100. These findings indicate the majority of respondents rated the web site as useful. On the three subscales of the PHWSUQ, the Ease of Use subscale mean score (82.64/100) and Satisfaction subscale mean score (84.48/100) were higher than the Usefulness subscale (71.24/100). The total score on the PHWSUQ of www.preparingforyoursurgery.com was similar to another health education web site evaluated with PHWSUQ by Attack, Luke, and Chien (2008) who found a mean total PHWSUQ score of 86.5 out of 100 for the web site they evaluated.

In this study, the free text responses also supported usefulness of the web site, some women did have complaints; however, it may not be possible to find a web site that is satisfactory to everyone. This is supported by Berman et al. (2008) who found participants favored some techniques over other techniques when they evaluated a different Mind-Body web site, which taught techniques for chronic pain. In addition in Kang et al. (2011) study, women with breast cancer, who attended an eight-week integrated cognitive behavioral stress management intervention, preferred some Mind-Body techniques more than others.

The majority of women in this study who evaluated the web site agreed with the statements the web site is practical (85/100) and appropriate (89/100) for women newly diagnosed with breast cancer. Women were very supportive of the site and stated the ability to be able to access the site at home contributed to their desire to use it. Women not only found the information on the site appropriate for women with breast cancer but also some believed the information was appropriate for any women facing a stressful situation. These findings support adopting the web site into clinical practice at our cancer center.

The majority of women in this study reported they would recommend (82/100) this web site to women newly diagnosed with breast cancer. This is similar to findings by Kim and Chang (2006) who report a significant positive correlation between perception of usability and recommendation of health-related web sites. Even if women recommend the web site, personal preferences need to be taken into consideration when reinforcing use of the web site and the information it contains when interacting with women at various time points along the treatment continuum.

There were no significant differences between the group of women who agreed the Web site was useful, practical, appropriate, or would recommend it to others, and the group of women who were neutral or disagreed related to select demographic variables. The women who completed the survey ranged in age from young adults to the elderly (38 to 82 years). Despite this wide age range, age did not influence whether or not they found the web site useful, practical, appropriate, or would recommend to others. These findings are similar to findings by Williams et al. (2010) and McDowell et al. (2010) who found age, income, and education did not significantly impact use of

online health education web sites. This suggests the web site could be used with women in our cancer center regardless of age, income, or educational background.

Experience with Mind-Body techniques did not significantly influence whether women rated the web site as useful, practical, appropriate, and whether they would recommend it to others. These findings similar to Berman et al. (2008) who found women with and without Mind-Body experience found a different web site teaching Mind-Body techniques for chronic pain useful. These results suggest the web site would be useful to women who have no previous experience with these techniques, as well as those who have tried or used Mind-Body techniques in the past.

Considering all the women in the study had recently undergone breast cancer surgery, only a few reported having training in Mind-Body techniques. Participants expressing familiarity but limited training in the techniques suggest the www.preparingforyoursurgery.com web site may be able to meet an unmet need by providing training in Mind-Body techniques. As these results suggest the women in this study are not currently utilizing other training formats to obtain training in these techniques. Web site training allows flexibility and convenience that may not otherwise be available to women in the time period from diagnosis to surgery. This web site is available without cost, which offers an advantage over classes that may be available in the community and expands the number of women who will be able to access the information. It is noteworthy that in free text responses, women found the techniques taught on the web site to be useful beyond the circumstance of surgery. Further investigation is warranted to determine, if learning the techniques on the web site at diagnosis, could lower women's stress levels throughout their cancer journey.

The research findings raise the question of whether providing structure for the use of the Mind-Body techniques may increase utilization of the techniques prior to and in the first seven days

after surgery. Less than half of participants who were familiar with the techniques reported using them in the first seven days after surgery. The observation that women knew of the techniques yet did not use them suggests opportunities to remind women of these Mind-Body practices and encourage use of these techniques prior to or during the first week after surgery. Two respondents suggested that the printout from the web site, which is designed to help patients plan use of the techniques in the first seven days after surgery, may be a useful tool; however, two other women stated they did not like the 7-day schedule. Berman et al. (2008) also had 2 participants out of 43, who evaluated different Mind-Body web site teaching techniques to manage chronic pain, who did not like the worksheets on the web site. Regardless, the use of a “schedule” may be beneficial to some women. Sensitivity to how women individualize their use of the web site is important when nurses discuss the web site with women. Nurses could encourage women to explore what reminders would work well for them with one option being the 7-day schedule worksheet found on the web site or setting an alarm on their cell phone or selecting a reminder such as after every meal to help them utilize the Mind-Body technique throughout the day.

Limitations

The findings of this study should be interpreted with caution due to limitations related to the sample, attrition, and the questionnaire itself. A major limitation of this study is the small sample size, and the homogeneity of participants. Underrepresented groups include Hispanics, races other than Caucasian, inexperienced Internet users, income less than \$50,000 per year, and women with less than a high school diploma. Women who were felt to be highly anxious by the treating physician were excluded from participation in the study. Women who met screening criteria; however, were felt to be “too anxious” for participation by the treating physician, were not

approached for participation in the study. This selection bias resulted in women, who were felt to be highly anxious, being excluded from participation. This study was limited to women who presented to a central Florida cancer center and required use of the English language; therefore, the generalizability of the results is limited to a similar population.

Attrition is another limitation. Less than one half of the women who enrolled in the study completed the questionnaire (48%). This attrition rate is similar to completion rates of Internet research reported by Bennett and Glasgow (2009) of 40% to 50%. These researchers suggest that participants' interest, although initially enthusiastic, simply wanes (Bennett & Glasgow, 2009). The women in this study were also healing up from surgery and starting on treatment with chemotherapy, radiation therapy or oral medications. Their ability to cope with the diagnosis and treatment plan may have impacted attrition. In future studies, attrition can be addressed by requesting permission to telephone the participant as a reminder to complete the survey in addition to an email reminder. Another suggestion to minimize attrition would be to hold focus groups with computers available where women could evaluate the web site and complete the survey in one sitting. Incentives such as a gift card or a coupon for valet parking at the cancer center could have increased completion rates.

The questionnaire, which used SurveyMonkey® as its platform, had limitations as well. Three people completed only the first 14 questions of the online questionnaire. The reason for this is unknown, but it is suspected that participants did not know they needed to advance to another page. An improvement in the questionnaire would have been to eliminate the need to click the Next button after answering the first 14 questions and putting all of the questions on one continuous page.

Implications for Nursing Practice

Web sites can potentially improve participants' outcomes and patient satisfaction scores by providing information and improving health behaviors in a cost-effective, convenient format reaching populations that might not otherwise have their needs met. The findings of this study suggest nurses can introduce www.preparingforyoursurgery.com web site to women newly diagnosed with breast cancer regardless of age, income, education, frequency of Internet use, or familiarity with Mind-Body techniques. At the preoperative visit, nurses could provide the web site address for women to use at their convenience. Nurses from surgical oncology, medical oncology, the infusion center and radiation oncology who have subsequent contact with the women in person or via the telephone could reinforce use of the web site and the information it contains. If distress is assessed at an office visit the web site could be recommended by the nurse.

Nurses will need to be sensitive to a woman's individual preferences and use of the information the web site provides emphasizing it is a tool to customize for their use. Nurses being a trusted source of information can be instrumental in increasing patients' use of online health information (Xiao, 2012). Nurses introducing this web site could result in stress reduction for women in the time period from diagnosis to one week after surgery and other areas of their lives as well. Since results of this study support the use of www.preparingforyoursurgery.com in women newly diagnosed with breast cancer, integrating the web site into our cancer center is an important next step for nursing practice.

Recommendations for Further Research

The next step in research would be a randomized intervention study to evaluate how use of <http://www.preparingforyoursurgery.com> by women newly diagnosed with breast cancer impacts

on distress. Outcome measures that could be of interest to researchers include distress, insomnia, anxiety, situational depression, appetite changes, relationship strain, fatigue, and pain. A component of the study could also be longitudinal, examining the use of the techniques and information on the web site in the first year after diagnosis, to measure the impact of the web site over time.

Additional research in specific populations of women with breast cancer would be beneficial. Studies that include stratified sampling by race and ethnicity would assist in obtaining perspectives of use of the web site from Hispanics and specific ethnic groups. A study specifically designed to obtain the perspectives of women with limited Internet experience may provide knowledge of how to support women using this web site prior to and after breast cancer surgery. A possible research design and setting for women with limited Internet experience may be a computer lab with technical assistance available. This would allow women to be introduced to the Mind-Body techniques so they could practice them at home. In addition, evaluating the web site with women with less than a high school diploma is also needed to determine if they find the web site useful, practical, and appropriate. Efficacy studies related to distress could also follow.

Future studies could also include both men and women who undergo surgery for any tumor type at our cancer center. This would allow larger sample sizes and allow comparisons between women who undergo breast cancer surgery to other populations such as women who undergo gynecologic cancer surgery or colon cancer surgery. Research studies with larger sample sizes could also explore which aspects of the web site have the most benefit and how frequency of using Mind-Body techniques impacts outcomes. Larger studies could examine how the web site augments participants' baseline Mind-Body practices and Mind-Body opportunities currently

available at the cancer center. Future studies could evaluate attrition by including a structured telephone interview to determine why the participants did not complete the survey.

Conclusions

Over 500 women will be treated by our cancer center annually for breast cancer. Cancer-related distress is estimated to affect the majority of these women and the period from breast biopsy to breast cancer surgery can be an especially distressing time. This research study was the first step in evaluating a web site that offers women the opportunity to learn a variety of Mind-Body techniques from the convenience of their home to help reduce distress. The majority of women who participated in this study rated the web site as useful, practical, and appropriate and would recommend the web site to women newly diagnosed with breast cancer. This study also suggests the web site could be introduced to women newly diagnosed with breast cancer without restriction due to age, income, education, frequency of Internet use, or experience with Mind-Body techniques. Online resources provide women an opportunity to explore a variety of Mind-Body techniques to manage distress at diagnosis and during treatment. The use of online resources is a cost-effective and convenient way for women to learn Mind-Body techniques that may not otherwise have exposure to. More research is needed to evaluate if this, and other online resources, have a beneficial impact on outcomes in women with breast cancer and other patient populations.

APPENDIX A: PREPARING FOR SURGERY WEB SITE SCREEN SHOTS

Preparing for Surgery

LEARN MIND-BODY TECHNIQUES FOR SURGERY AND RECOVERY

HOME

INTRODUCTION

BEFORE SURGERY

AFTER SURGERY

HEALING RESULTS

RELAXATION RESOURCES

Intro

Self Assessment

Learn Relaxation Techniques

Healing Goals



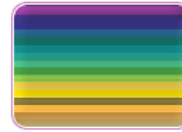
Breathwork



Centering & Grounding



Guided Imagery



Biofeedback

Some of the techniques I will share with you today can be practiced on your own and this will give you a sense of control - not just for preparing for surgery but even after surgery when you are back to your usual activities. Stress is a normal part of life - and it's not a bad thing but we have to learn to cope and learn how to manage it.

The foundation of any stress management program is breathwork. There is no right or wrong way to breathe - but I will teach you how to breathe more efficiently. I'm going to demonstrate the technique later and then we'll do it together.

I have some simple techniques you can use so that you can slowly and gradually bring this into your life without worrying about whether you can do it or not. For instance, meditation. One of the techniques I'm going to teach you is an introduction to meditation, where you focus for a short time, a minute or two minutes or less.

We'll go over each of the techniques that you can do for yourself: breathing, imagery, simple biofeedback. There are also techniques that a healthcare practitioner can do for you that will help you manage the anxiety of going through surgery or a medical procedure. These include practices like massage, acupuncture, gentle yoga and energy healing such as Reiki. Another possible way to maximize your healing process is the use of nutrition for healing before and after surgery.

[Nutrition and Surgery](#) →

Preparing for Surgery

LEARN MIND-BODY TECHNIQUES FOR SURGERY AND RECOVERY

HOME

INTRODUCTION

BEFORE SURGERY

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HEALING RESULTS

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Healing Goals

As we have seen, research and patients' direct reports of their experience show that relaxation practices can have a positive impact before and after surgery. To help this type of training become a regular part of pre-surgical preparation we are offering this free online course developed over the past 8 years by Aurora Ocampo, clinical nurse specialist at Beth Israel Medical Center in New York City. In this way, anyone with access to a computer can get these benefits. We are grateful to the Balm Foundation for making this possible.

Let's begin with Ms. Ocampo's work with patients before surgery which combines helpful information and direct relaxation practice.

Reducing stress and boosting your healing

What we really want before surgery is to trigger the release of healing hormones like endorphins and serotonins that will assist you in healing in a normal time frame or healing faster. Endorphins are known to be your body's natural pain killer so they also help you cope better with your pain. And as studies show, being physically, emotionally and mentally prepared for surgery through relaxation practices may also help prevent many complications that can delay your healing.

Learning how to manage your anxiety really is the foundation and success of these practices. When you're anxious and your stress level is way up, your body releases a hormone called cortisol that can alter white blood cell function, compromise your immune system and create a more open environment to infection. In preparing for surgery you want to be in an optimal level of wellness so that you prevent any complications.

These techniques work to support your body's ability to mend, to decrease complications and to shorten the recovery period. By healing faster or at a normal rate, you're able to go back to your activities of daily living, go back to work, go back to enjoyable recreation a little faster, and not delayed.



Each mind/body technique has the ability to impact more than one system in the body at the same time. That is why they provide multiple benefits to support healing.

[Listen To This Material](#) 

(Adjust your computer volume as needed)

On a physical level:

By decreasing stress, you can change the way your body functions. The brain responds to what we focus on mentally and what we imagine with our senses *as if it were actually happening*. A 2008 study published in the journal *Science* has shown that when we call up a memory, the same neurons in our brain fire that were firing during the actual experience (Gelbard-Sagiv, 2008). This shows that images in the mind are almost as real to the body as actual events.

When we send the brain relaxation messages, they are passed on to the body's endocrine, immune and autonomic nervous systems. The brain translates these messages into biochemical actions that help the body rebalance to a less stressful state. Together, these systems can help decrease muscle tension and pain, reduce anxiety, and lower your blood pressure and heart rate. When that happens, your body is better equipped to handle the stress of surgery and to recover more quickly.



On an emotional level:

It is quite normal to experience a range of feelings about your upcoming surgery, including high levels of stress and anxiety. Learning how to relax can help you manage these feelings and cope better. This is because having a greater sense of control over your thoughts, feelings and reactions is empowering and helps further reduce your anxiety. This is important - because studies show a direct relationship between anxiety and pain, particularly on the 2nd post-operative day (Nelson, 1998).

On a mental level:

Relaxation techniques can help distract you from pain and anxious thoughts. They help shift your attention to a more positive and calm state of mind. The mind now focuses on new positive thoughts and pushes the negative information aside to the background - that is the shift. This new information is immediately sent by your brain to your body, and now your body responds to this positive calming input. As you begin to practice these techniques, you will increasingly ease into that shift naturally and you will feel how your mind and body welcome it.

When should I start to practice and for how long?

As soon as you find out you are going to have surgery, you can begin to prepare yourself by practicing the relaxation techniques. We now know that practicing for even two to three days can have a positive impact on your recovery. Of course the longer you practice the easier it will be to create a relaxation response, but any time you reduce your anxiety level, the better the surgical outcome will be.

APPENDIX B: PERMISSION TO USE WEB SITE AND SCREEN SHOTS

September 27, 2011

Dear Laura:

I've spoken with Aurora Ocampo, the clinical nurse specialist who developed the program here at Beth Israel, and we are both interested (I am director of online education at the Center and created the site).

We have forwarded your request to our Director of Research to get his input. As soon as we've heard back we'll let you know. I do know, however, that we have not done any research yet on using this web site with patients. We'll be interested in hearing more of your ideas as well.

Best,

Marsha J. Handel, MLS

Director, Informatics and Online Education

Department of Integrative Medicine

Continuum Center for Health and Healing

Beth Israel Medical Center

646 935-2246

October 4, 2011

Hi Laura:

I spoke with our research director and he is very supportive about your using our online program as part of your research.

If there is any way we can be helpful just let us know. Please keep us in the loop as things progress.

Our best,

Marsha

March 3, 2013

Thanks Laura for letting us know how your project is progressing. We are very interested in learning the results of your study.

Yes, please feel free to use 3 screen shots of the site in your thesis and poster presentations.

Acknowledgment:

This grant-funded online course is based on the work of Aurora Ocampo, MS, RN, CS, Clinical Nurse Specialist at the Continuum Center for Health and Healing. Her work as a holistic nurse is informed by extensive expertise in Reiki, Clinical Imagery, Clinical Aromatherapy, Biofeedback and Therapeutic Touch. The web site was developed by Marsha J. Handel, MLS, Director of Informatics and Online Education at the Continuum Center for Health and Healing, Beth Israel Medical Center, New York.

Thanks much,

Marsha

Director, Informatics and Online Education

Department of Integrative Medicine

Continuum Center for Health and Healing

Beth Israel Medical Center

646 935-2246

APPENDIX C: IRB APPROVAL LETTERS



1414 Kuhl Ave.
Orlando, FL 32806
321.843.7000
orlandohealth.com

MDACCO FWA # 00000131
ORMC/APMC FWA # 00000384

DATE: August 17, 2012

TO: Laura Beck, ARNP
FROM: MD Anderson Cancer Center Orlando IRB

PROJECT TITLE: [354042-1] Evaluation of a Mind-Body Website by Women with Breast Cancer
REFERENCE #: 12.047.08
SUBMISSION TYPE: New Project

ACTION: APPROVED
APPROVAL DATE: August 17, 2012
EXPIRATION DATE: August 16, 2013
REVIEW TYPE: Expedited Review

REVIEW CATEGORY: Minimal Risk

Thank you for your submission of New Project materials for this project. The following items were received:

- Advertisement - Advertisement form (UPDATED: 06/30/2012)
- Confidentiality/Non-Disclosure - MaryLou Sole (UPDATED: 08/14/2012)
- Conflict of Interest - Declaration - Victoria Loerzel (UPDATED: 08/14/2012)
- Conflict of Interest - Declaration - Beck (UPDATED: 08/14/2012)
- Consent Form - Revised consent form 8/16/12 (UPDATED: 08/16/2012)
- Data Collection - Appendix IV Website evaluation questionnaire (UPDATED: 07/4/2012)
- Data Collection - Appendix I Screening spreadsheet (UPDATED: 07/4/2012)
- Letter - Nurse Research Council Approval (UPDATED: 07/29/2012)
- Letter - Support MD Anderson Cheryl and Jayne (UPDATED: 07/6/2012)
- Letter - UCF permission to move forward with project (UPDATED: 07/2/2012)
- Letter - Email reminder to evaluate website and complete survey (UPDATED: 06/30/2012)
- Orlando Health - IRB Application - Orlando Health - IRB Application (UPDATED: 07/29/2012)
- Other - Appendix III Participant worksheet for evaluating website (UPDATED: 06/30/2012)
- Other - Appendix II Instructions for evaluating the website (UPDATED: 06/30/2012)
- Proposal - Website Proposal (UPDATED: 07/29/2012)

The MD Anderson Cancer Center Orlando IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a project design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on the applicable federal regulation. The MD Anderson Cancer Center Orlando IRB is organized and operates in compliance with DHHS regulations as described in 45 CFR part 46, i.e. The Common Rule, FDA regulations as described in 21 CFR Parts 50 and 56, and guidelines resulting from the International Conference on Harmonisation (ICH) E-6 Good Clinical Practice guidelines as appropriate.

In addition, the MD Anderson Cancer Center Orlando IRB operates in compliance with portions of the Health Insurance of Portability Act of 1996 (HIPAA Privacy Rule) that apply to research, as described in 45 CFR Parts 160 and 164 as appropriate.

Please remember that informed consent is a process beginning with a description of the project and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the project via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All UNANTICIPATED PROBLEMS involving risks to subjects or others (UPIRSOs) and SERIOUS and UNEXPECTED adverse events must be reported promptly to this committee. Please use the appropriate reporting forms for this procedure. All FDA and sponsor reporting requirements should also be followed.

All NON-COMPLIANCE issues or COMPLAINTS regarding this project must be reported promptly to this committee.

This project has been determined to be a Minimal Risk project. Based on the risks, this project requires continuing review by this committee on an annual basis. Please use the appropriate forms for this procedure. Your documentation for continuing review must be received with sufficient time for review and continued approval before the expiration date of August 16, 2013.

Please note that all research records must be retained for a minimum of three years after the completion of the project.

If you have any questions, please contact David Flory at 321 843-1412 or david.flory@orlandohealth.com. Please include your project title and reference number in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within MD Anderson Cancer Center Orlando IRB's records.

Orlando Health Facilities: * ARNOLD PALMER HOSPITAL FOR CHILDREN * SOUTH SEMINOLE HOSPITAL
* M. D. ANDERSON CANCER CENTER, ORLANDO * WINNIE PALMER HOSPITAL FOR WOMEN & BABIES
* SOUTH LAKE HOSPITAL * DR. P. PHILLIPS HOSPITAL * ORLANDO REGIONAL MEDICAL CENTER



1414 Kuhl Ave.
Orlando, FL 32806
321.843.7000
orlandohealth.com

MDACCO/ORMC/APMC
FWA # 00000384

DATE: December 19, 2012

TO: Laura Beck, ARNP
FROM: MD Anderson Cancer Center Orlando IRB

PROJECT TITLE: [354042-3] Evaluation of a Mind-Body Website by Women with Breast Cancer
REFERENCE #: 12.047.08
SUBMISSION TYPE: Amendment/Modification

ACTION: APPROVED - Revised Consent Form
EFFECTIVE DATE: December 11, 2012
EXPIRATION DATE: August 16, 2013

Thank you for your submission of Amendment/Modification materials for this project. The following items were received:

- Amendment/Modification - Request to call participants and increase number of participants (UPDATED: 12/9/2012)
- Consent Form - Revised with phone call reminder (UPDATED: 10/28/2012)
- Protocol - Revised with phone call reminder (UPDATED: 10/31/2012)

The MD Anderson Cancer Center Orlando IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a project design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

Please remember that informed consent is a process beginning with a description of the project and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the project via a dialogue between the researcher and research participant. Federal regulations require that each participant receives a copy of the consent document.

The MD Anderson Cancer Center Orlando IRB has APPROVED your submission and requires the following:

- Re-consent research participants receiving the research treatment/intervention **and** those in follow up.
- Re-consent only research participants that are receiving treatment and/or research intervention.
- Re-consent **all** enrolled research participants **and** inform those that have completed their participation via letter. Submit letter template for IRB approval.
- Re-consenting of research participants not required.

—

If you have any questions, please contact David Flory at 321 843-1412 or david.flory@orlandohealth.com. Please include your project title and reference number in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within MD Anderson Cancer Center Orlando IRB's records.

Orlando Health Facilities: * ARNOLD PALMER HOSPITAL FOR CHILDREN * SOUTH SEMINOLE HOSPITAL
* M. D. ANDERSON CANCER CENTER ORLANDO * WINNIE PALMER HOSPITAL FOR WOMEN & BABIES
* SOUTH LAKE HOSPITAL * DR. P. PHILLIPS HOSPITAL * ORLANDO REGIONAL MEDICAL CENTER

APPENDIX D: IRB HUMAN SUBJECTS PERMISSION LETTER



University of Central Florida Institutional Review Board
Office of Research & Commercialization
12201 Research Parkway, Suite 501
Orlando, Florida 32826-3246
Telephone: 407-823-2901, 407-882-2901 or 407-882-2276
www.research.ucf.edu/compliance/irb.html

From : **UCF Institutional Review Board**
FWA00000351, IRB00001138

To : **Laura M. Beck**

Date : **August 21, 2012**

IRB Number: **SBE-12-08566**

Study Title: **Evaluation of a Mind-Body Website by Women with Breast Cancer**

Dear Researcher:

The research protocol noted above was reviewed by the University of Central Florida IRB Designated reviewer on 8/21/2012. The UCF IRB accepts the MD Anderson Cancer Center's Institutional Review Board review and approval of this study for the protection of human subjects in research. **The expiration date will be the date assigned by the MD Anderson Cancer Center, Orlando, Institutional Review Board and the consent process will be the process approved by that IRB.**

This project may move forward as described in the protocol. It is understood that the MD Anderson Cancer Center, Orlando, IRB is the IRB of Record for this study, but local issues involving the UCF population should be brought to the attention of the UCF IRB as well for local oversight, if needed.

All data, including signed consent forms if applicable, must be retained in a locked file cabinet for a minimum of three years (six if HIPAA applies) past the completion of this research. Any links to the identification of participants should be maintained on a password-protected computer if electronic information is used. Additional requirements may be imposed by your funding agency, your department, or other entities. Access to data is limited to authorized individuals listed as key study personnel.

Failure to provide a continuing review report for renewal of the study to the MD Anderson Cancer Center, Orlando, IRB could lead to study suspension, a loss of funding and/or publication possibilities, or a report of noncompliance to sponsors or funding agencies. If this study is funded by any branch of the Department of Health and Human Services (DHHS), an Office for Human Research Protections (OHRP) IRB Authorization form must be signed by the signatory officials of both institutions and a copy of the form must be kept on file at the IRB office of both institutions.

On behalf of Sophia Dziegielewski, Ph.D., L.C.S.W., UCF IRB Chair, this letter is signed by:

Signature applied by Joanne Muratori on 02/20/2013 08:44:40 AM EST

A handwritten signature in cursive script that reads "Joanne Muratori".

IRB Coordinator

APPENDIX E: INFORMED CONSENT

Participant's Name: _____ Date: _____

Sponsor: None

Principal Investigator: Laura Beck, MS, ARNP-BC

Sub-Investigators: Victoria Loerzel, PhD, RN, OCN

Mary Lou Sole, PhD, RN, CCNS, CNL, FAAN, FCCM

MD Anderson Cancer Center Orlando
1400 South Orange Ave, MP# 780
Orlando, FL 32806

INFORMED CONSENT FOR CLINICAL RESEARCH

You are being asked to take part in a research study at MD Anderson Cancer Center Orlando (MD Anderson-Orlando) because you have newly diagnosed breast cancer.

Research studies include only people who choose to take part. This consent form explains why the study is being done, what will happen during the study, and what your role will be if you choose to take part. This form also describes the possible risks of taking part in the study. After reviewing this information, you will be asked if you want to take part. Feel free to talk to your friends and loved ones, and your personal doctor, before you decide. You will be asked to sign this form only if you choose to take part.

1. PURPOSE OF THE STUDY

The purpose of this study is to gain knowledge of women's perceptions related to using a website that offers instruction in Mind-Body techniques to use prior to breast cancer surgery to decrease distress.

2. EXPERIMENTAL DRUG /TREATMENT /DEVICE

Women newly diagnosed with breast cancer will evaluate a Mind-Body website <http://www.preparingforyoursurgery.com> for its fit in everyday practice.

3. LENGTH OF PARTICIPATION

This research study may last up to 1 year; however, your participation will last from one to 2 hours.

4. NUMBER OF PARTICIPANTS

There will be about _50_ participants in this study at 2 centers in the United States/ Europe/worldwide. MD Anderson-Orlando is approved to enroll up to 50 participants.

5. STUDY PROCEDURES

If you agree to participate in the study, you will be given written instructions and a worksheet. You will be asked to spend 30-45 minutes evaluating the website "<http://www.preparingforyoursurgery.com>" at a time and place that you choose. The worksheet provided will guide you as you evaluate the website. The information you record on the worksheet will be used to answer an online questionnaire. After you have evaluated each page of the website, you will be asked to complete an online questionnaire. The online questionnaire will ask about your thoughts of the website and about yourself. It will take 20-30 minutes to complete the online questionnaire. You can complete the questionnaire at a place and time that you choose. The principal investigator will email you a reminder 7 days and 14 days after you sign this consent.

6. RISKS/SIDE EFFECTS

There are no known risks to participants who participate in this study. It is possible that reviewing the website or completing the questionnaire may make you uncomfortable. You will be able to end the website evaluation or completion of the questionnaire if you are uncomfortable.

RESEARCH RELATED INJURY

You will be referred to the Mental Health Counselors at MDACCO if you feel you have been upset by participating in this study. You may also stop the study at any time. There are no funds available for injury related to this study.

7. INSTITUTIONAL REVIEW BOARD

An institutional review board (IRB) is a group of scientists and non-scientists who assure in advance and by periodic review that appropriate steps are taken to protect the rights, safety, and well-being of all research participants. The IRB does this by reviewing research protocols and related materials.

For more information about your rights as a research participant, you may call the Institutional Review Board manager at 321 843-1412 or 800 648-3818 ext. 8431412.

9. BENEFIT

There may be no benefit to you if you participate in this study. However, findings from this study are important to determine if a Mind-Body website is usable, practical and appropriate for women newly diagnosed with breast cancer. Information obtained from this research will be used to determine if this website will be recommended at the cancer center. You may learn Mind-Body techniques that potentially could help you on your cancer journey.

10. ALTERNATE PROCEDURES OR TREATMENT

This is not a treatment study; therefore, there are no alternatives to this study or alternate procedures. You may just decide not to participate.

11. VOLUNTARY PARTICIPATION

You do not have to take part in this study if you do not want to. You may get care from a doctor of your choice if you do not participate in this study. The quality of your care will not change if you choose not to be part of this study, or if you stop being part of the study. You will not lose your usual medical or legal benefits if you choose not to participate in this study or if you stop participating in this study.

12. STOPPING THE STUDY EARLY

The principal investigator may stop your participation in the study without your consent. You may decide not to complete the study. The IRB can stop the study.

13. NEW FINDINGS

You will be told about any new findings or changes in this study that might affect your health or willingness to remain in this study.

14. COSTS

There is no cost to you for participating in this study

15. PAYMENT

There is no compensation for participating in this research study.

16. FINANCIAL DISCLOSURE

The principal investigator and the sub-investigators are not receiving any funds for this study.

17a. CONFIDENTIALITY OF RECORDS

Laura Beck will collect and keep all data related to this study. She will remove all identifiers from all surveys or forms, and replace these with a numbered code. A list linking the names to number codes will be kept in a password-protected file on a password-protected computer. Any hardcopies will be kept in a locked cabinet at MD Anderson Cancer Center Orlando. While other study personnel may have access to your de-identified data, access to your private information will be limited to Laura Beck. IRB members from MDACCO and/or UCF might review the name-number code list and consent forms for the purposes of auditing the study procedures only.

The confidentiality of your medical records will be carefully protected, but absolute confidentiality cannot be guaranteed.

17b. AUTHORIZATION TO USE OR DISCLOSE PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH

Federal Privacy Regulations, including the Health Insurance Portability and Accountability Act (HIPAA), provide safeguards for privacy and security of health information that may identify you. You will be given a copy of the Notice of Privacy Practices, which describes the

MD Anderson-Orlando privacy practices. In certain circumstances, PHI about you may be used or disclosed for research purposes.

What PHI Is Collected in the Study?

Your PHI is information that could be used to find out who you are. It includes information in your existing medical records and information created or collected during the study.

The following PHI may be collected during your involvement with this study:

Name
Medical record number
E-mail address

Who May Use or Disclose Your PHI?

The following individuals/organizations may use or disclose your PHI for this study:

Study investigator and the study investigator's team
MD Anderson-Orlando Institutional Review Board
Orlando Health, Inc.
Nursing Research Council at Orlando Health, Inc.

To Whom May Your PHI Be Disclosed?

As part of the study, the study doctor and the study doctor's team may disclose the results of study related tests and procedures that may identify you to the following:

UCF Institutional Review Board
Office for Human Research Protection (OHRP)
MD Anderson-Orlando Institutional Review Board
Orlando Health, Inc.

In addition to the list of individuals and organizations to which your PHI may be disclosed, others that are not currently known may receive the information. If information from your records is given to any of these people, they might give it to someone else. If this happens, the information will no longer be protected. Whomever MD Anderson-Orlando gives the information to is supposed to protect it, but MD Anderson-Orlando cannot always keep that person from giving it to someone else. Your PHI may no longer be protected by HIPAA once it is disclosed by your study doctor to these other parties.

By agreeing to take part in this study and signing this informed consent document, you authorize MD Anderson-Orlando to use and disclose your PHI for research related to this study. Only the least information necessary for this purpose will be used, and may be sent by mail, fax or by verbal communication. Portions of your medical information may be sent electronically through the Internet, but will be protected to keep confidentiality.

There is no expiration date for the use of your health information for this study. It may be used until all follow-up procedures and all research and data analyses have been completed, and all sponsor and federal regulatory agency requirements for verification of data have been met. You agree to allow your health information to be used for future re-analysis of the data to verify the accuracy of the results of this study. The MD Anderson-Orlando Office of Clinical Trials will destroy (shred or permanently destroy) your records after the length of time specified by MD Anderson-Orlando policy, local, state, and federal regulations, and sponsor guidelines, whichever is longest.

More facts about confidentiality of and access to your medical records while taking part in this study:

- If your study doctor wishes to use your identifiable information for other purposes than this study, she must get your consent for that purpose.

- You may withdraw your consent to use your PHI by making a request in writing to the study doctor of this study, but continued use and release of already-gathered information may occur as necessary in analyses and reporting of important events. Examples of these events may include your withdrawal from the study, adverse event reports to the FDA to monitor the safety of participants, or federal regulatory agency audits.
- If you withdraw your consent to use your health information, neither MD Anderson-Orlando nor your study doctor will release future information to the sponsor or anyone else.
- If you withdraw your consent to use and release your health information, you will also withdraw from the study because this information is a requirement of the study.
- Your study doctor may discuss other research projects with you if she thinks the other projects relate to your condition. However, your health information cannot be released to another study doctor or sponsor to ask you to enroll in another study.
- You have the right to inspect (look over) and obtain a copy of your health information that is kept for research purposes for as long as this information is held by your study doctor or Orlando Health, Inc. However, to ensure the integrity of the research, you will not be able to review some of the study information until the end of the study.

Please initial your choice Yes or No to the statement(s) below. If you have any questions, please talk to your study investigator.

1. *I agree that my study investigator or someone he or she chooses may contact me in the future to ask me to take part in more research.*

Yes _____ No _____

2. *I agree to have the principal investigator contact me by the email address provided below:*

3. I agree to have the principal investigator call me at the following phone number 7-14 days after signing below.

18. SIGNATURES

My signature means that I consent and authorize Laura Beck and her assistants, including MD Anderson-Orlando, Orlando Health, Inc., their employees, and their agents, to enroll me in this study and to perform upon me the procedures described in this document. If any unforeseen conditions arise in the course of the study calling in her judgment for procedures in addition to or different from those outlined in this study, I further request and authorize her to do whatever she deems advisable.

I AM MAKING A DECISION TO TAKE PART IN THIS STUDY. I HAVE READ ALL OF THE ABOVE, ASKED QUESTIONS, RECEIVED ANSWERS ABOUT AREAS I DID NOT UNDERSTAND, AND WILLINGLY GIVE MY CONSENT TO TAKE PART IN THIS STUDY. UPON SIGNING THIS FORM, I WILL GET A COPY OF THIS CONSENT.

_____ Print Name of Participant

_____ Signature of Participant

_____ Date / Time

Signature of Witness Date

I have defined and fully explained the study as described in this consent form to the participant.

____ Laura M Beck, ARNP-BC _____
Print Name of Study Investigator

Signature of Study Investigator Date

APPENDIX F: SCREENING SPREAD SHEET

Screening Spreadsheet

Name	MRN#	Female	Over 18	Stage 0-III	Computer access	English	Able to Consent	Psychiatrist	Cancer Hx	Eligible N= No	Appt Date/ Time

If response is no to column 3-8 or yes to 9-10 may not be eligible.

APPENDIX G: INSTRUCTIONS FOR EVALUATING THE WEB SITE

Plan 30-45 minutes to complete the evaluation of the web site.

Please read the directions below prior to evaluating the web site.

1. Please evaluate the web site “<http://www.preparingforyoursurgery.com>” and complete the online survey within 2 weeks.
2. Please use the table to record the time you spent in each page of the web site.
3. Please record your thoughts about the web site on the table provided as you go through each section of the web site.
4. Information from the table will be used when completing the online survey about the web site. Be sure to try the audio and video options. For this project, you do not need to use the links to other sites but feel free to explore them if you would like.
5. After completing the evaluation please take the survey at [https://www.surveymonkey.com/s/web sitequestions](https://www.surveymonkey.com/s/web%20sitequestions)

If you have any questions please contact:

Laura Beck, Principal Investigator at 321-841-7055.

APPENDIX H: PARTICIPANT WORKSHEET FOR WEB SITE EVALUATION

Web site Pages	Number of Minutes Spent on Each Page of the Web site	Thoughts On Satisfaction, Ease Of Use, Usefulness, Practical, Appropriate
1. Introduction		
Benefits		
How it Works		
2. Before Surgery		
Introduction		
Self-Assessment		
Learn Relaxation Techniques		
Breath Work		
Centering and Grounding		
Guided Imagery		
Biofeedback		
Healing Goals		
3. After Surgery		
Introduction		
7-day Schedule		
4. Healing Results		
5. Relaxation Resources		

APPENDIX I: EMAIL LETTER

Dear participant,

This is a reminder to evaluate the web site <http://www.preparingforyoursurgery.com> and complete the online survey at [https://www.surveymonkey.com/s/web sitequestions](https://www.surveymonkey.com/s/web%20sitequestions). If you have already completed the survey please ignore this email. If you have not yet completed the survey please evaluate the web site and complete the survey this week.

If you have any questions please respond to this email or call Laura Beck principal investigator at 321-841-7055. Thank you for your time.

Sincerely,

Laura Beck

APPENDIX J: WEB SITE EVALUATION QUESTIONNAIRE

Welcome

Welcome to the survey. Please answer all questions. It should take you 20 minutes to complete the survey. Please have your worksheet available to complete the questions. This survey is anonymous, the data is pooled and no one will see your individual response. Thank you for your time and opinions on the Mind-Body website. If you have any questions please do not hesitate to call Laura Beck at 321-841-7055.

*1. What is your age?

*2. What ethnicity do you consider yourself to be?

- Hispanic or Latino
- Not Hispanic or Latino

*3. What race do you consider yourself to be ?

- American Indian/Alaska Native
- Asian
- Native Hawaiian or Other Pacific Islander
- Black or African American
- White
- Other

Other (please specify)

*4. What type of surgery did you have? Please select all that apply.

- Lumpectomy
- Mastectomy
- Reconstruction

*5. What is your household income per year?

- Less than \$50,000
- \$50,000 to \$75,000
- \$75,001 to \$100,000
- more than \$100,000
- Do not care to respond.

6. What is the highest level of education you have completed?

- Less than high school diploma
- High school diploma
- Completed trade school
- Associate degree
- Bachelors degree
- Graduate degree

***7. How did you access the website preparingforyoursurgery.com?**

- Desk top computer at home
- Desk top computer at cancer center library
- Lap top computer
- I-pad
- Tablet
- Smart phone

Other (please specify)

***8. When did you first start using the internet?**

- Less than one year
- One to Two years
- Two to Three years
- More than three years

***9. How often do you access the internet in a normal week?**

- less than one hour per week
- 1-7 hours per week
- 8-14 hours per week
- more than 14 hours per week

***10. How many hours in the past month did you look on the internet for health related information?**

- Did not look on internet for health information
- 1-2 hours
- 3-6 hours
- 7-10 hours
- 11 or more hours

***11. Before you evaluated the website, had you heard of any of the following techniques?**

	Yes	No
Breath work	<input type="checkbox"/>	<input type="checkbox"/>
Centering and Grounding	<input type="checkbox"/>	<input type="checkbox"/>
Guided Imagery	<input type="checkbox"/>	<input type="checkbox"/>
Biofeedback	<input type="checkbox"/>	<input type="checkbox"/>
Healing goals (positive statements)	<input type="checkbox"/>	<input type="checkbox"/>

***12. Before you evaluated the website, had you tried any of the following techniques?**

	Yes	No
Breath work	<input type="checkbox"/>	<input type="checkbox"/>
Centering and Grounding	<input type="checkbox"/>	<input type="checkbox"/>
Guided Imagery	<input type="checkbox"/>	<input type="checkbox"/>
Biofeedback	<input type="checkbox"/>	<input type="checkbox"/>
Healing goals (positive statements)	<input type="checkbox"/>	<input type="checkbox"/>

***13. Did you have training in the following Mind-Body techniques prior to surgery?**

	Yes	No
Breath work	<input type="checkbox"/>	<input type="checkbox"/>
Centering and Grounding	<input type="checkbox"/>	<input type="checkbox"/>
Guided Imagery	<input type="checkbox"/>	<input type="checkbox"/>
Biofeedback	<input type="checkbox"/>	<input type="checkbox"/>
Healing goals (positive statements)	<input type="checkbox"/>	<input type="checkbox"/>

***14. Did you use any of the following techniques before surgery or in the first 7 days after your surgery? Choose all that apply.**

	Yes	No
Breath work	<input type="checkbox"/>	<input type="checkbox"/>
Centering and Grounding	<input type="checkbox"/>	<input type="checkbox"/>
Guided Imagery	<input type="checkbox"/>	<input type="checkbox"/>
Biofeedback	<input type="checkbox"/>	<input type="checkbox"/>
Healing goals (positive statements)	<input type="checkbox"/>	<input type="checkbox"/>

Evaluation of Website

The purpose of the following questions is to obtain your thoughts about the website. Please answer each question.

***15. Ease of finding specific information.**

1 Very unsatisfied 2 3 4 5 6 7 Very satisfied

***16. Ease of reading the information given.**

1 Very unsatisfied 2 3 4 5 6 7 Very satisfied

***17. Ease of listening to audio-information.**

1 Very unsatisfied 2 3 4 5 6 7 Very satisfied

***18. Overall appearance of the site.**

1 Very unsatisfied 2 3 4 5 6 7 Very satisfied

***19. Overall quality of graphics.**

1 Very unsatisfied 2 3 4 5 6 7 Very satisfied

***20. Quality of video information.**

1 Very unsatisfied 2 3 4 5 6 7 Very satisfied

***21. I found the use of the Web site easy to learn.**

1 Strongly disagree 2 3 4 5 6 7 Strongly agree

***22. Finding information on the Web site requires a lot of mental effort.**

1 Strongly disagree 2 3 4 5 6 7 Strongly agree

***23. Overall, I find this Web site easy to use.**

1 Strongly disagree	2	3	4	5	6	7 Strongly agree
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

***24. Using this Web site will help me understand specific health problem.**

1 Strongly disagree	2	3	4	5	6	7 Strongly agree
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

***25. Using this Web site will help me improve my knowledge about health.**

1 Strongly disagree	2	3	4	5	6	7 Strongly agree
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

***26. Using this Web site will help me maintain better health habits.**

1 Strongly disagree	2	3	4	5	6	7 Strongly agree
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Appropriate

***27. This Web site is appropriate for women facing breast cancer surgery.**

1 Strongly disagree	2	3	4	5	6	7 Strongly agree
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Practical

***28. It is practical to use this Web site in the time period from breast biopsy to breast cancer surgery.**

1 Strongly disagree	2	3	4	5	6	7 Strongly agree
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Recommend

***29. I would recommend this Web site to someone who is facing breast cancer surgery.**

1 Strongly disagree	2	3	4	5	6	7 Strongly agree
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

***30. If you recommend the preparingforyoursurgery.com website, when is the best time to introduce women to the website?**

- From the surgery team at the appointment planning surgery (after biopsy results are obtained).
- From the medical oncology team at first appointment.
- From the radiation oncology team at first appointment.
- From the plastic surgery team at first appointment.
- From pre-op testing department.

Other (please specify)

Usefulness

Please type in your thoughts about the website.

31. What is most useful on this Web site?

32. What is not useful on this Web site?



Time, Audio, Video

***33. How much time did you spend on each page of the website?**

	Number of Minutes
Introduction	<input type="text"/>
...Benefits	<input type="text"/>
...How it works	<input type="text"/>
Before surgery	<input type="text"/>
...Introduction	<input type="text"/>
...Self-Assessment	<input type="text"/>
...Learn Relaxation	<input type="text"/>
Techniques	<input type="text"/>
...Breath work	<input type="text"/>
...Centering and Grounding	<input type="text"/>
...Guided Imagery	<input type="text"/>
...Biofeedback	<input type="text"/>
...Healing Goals	<input type="text"/>
After Surgery	<input type="text"/>
...Introduction	<input type="text"/>
...7-Day schedule	<input type="text"/>
Healing Results	<input type="text"/>
Relaxation Resources	<input type="text"/>

***34. Did you use the audio button on the website pages?**

	Yes	No
Introduction	<input type="radio"/>	<input type="radio"/>
...Benefits	<input type="radio"/>	<input type="radio"/>
...How it works	<input type="radio"/>	<input type="radio"/>
Before surgery	<input type="radio"/>	<input type="radio"/>
...Introduction	<input type="radio"/>	<input type="radio"/>
...Self-Assessment	<input type="radio"/>	<input type="radio"/>
...Learn Relaxation	<input type="radio"/>	<input type="radio"/>
Techniques	<input type="radio"/>	<input type="radio"/>
...Breath work	<input type="radio"/>	<input type="radio"/>
...Centering and Grounding	<input type="radio"/>	<input type="radio"/>
...Guided Imagery	<input type="radio"/>	<input type="radio"/>
...Biofeedback	<input type="radio"/>	<input type="radio"/>
...Healing Goals	<input type="radio"/>	<input type="radio"/>
After Surgery	<input type="radio"/>	<input type="radio"/>
...Introduction	<input type="radio"/>	<input type="radio"/>
...7-Day schedule	<input type="radio"/>	<input type="radio"/>
Healing Results	<input type="radio"/>	<input type="radio"/>
Relaxation Resources	<input type="radio"/>	<input type="radio"/>

***35. What are your thoughts about the video teaching breathing techniques?**

- Video was very helpful.
- Video did not add to the text information.
- Video was not helpful.
- I did not view video
- Other (please specify)

36. Where there pages of the website that you did not evaluate? If not why?



37. Any comments on the Web site you would like to share?



You have completed the study.

Thank you for participating in this study! Your time and thoughts are appreciated and will benefit others.

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